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Intangible Intangibles

Patent Law's Engagement with Dematerialised Subject Matter

Brad Sherman

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INTANGIBLE INTANGIBLES

This book takes as its starting point recent debates over the dematerialisation of subject matter which have arisen because of changes in information technology, molecular biology, and related fields that produced a subject matter with no obvious material form or trace. Arguing against the idea that dematerialisation is a uniquely twenty-first century problem, this book looks at three situations where US patent law has already dealt with a dematerialised subject matter: nineteenth century chemical inventions, computer-related inventions in the 1970s, and biological subject matter across the twentieth century. In looking at what we can learn from these historical accounts about how the law responded to a dematerialised subject matter and the role that science and technology played in that process, this book provides a history of patentable subject matter in the United States. This title is available as Open Access on Cambridge Core.

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Intangible Intangibles

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1

Introduction

Questions about the nature of the intangible have never been far from the surface in intellectual property law. Whether when deciding how something that you cannot touch, hear, or see is to be identified, demarcated, and bounded, or how these incorporeal immaterial things are to be traced as they move between formats, languages, and objects, the law has constantly struggled to give property status to intangibles. While these questions have often proved to be problematic, in some ways they are inescapable. This is because the intangible is the fiction that allows intellectual property law to do what it does: which is to juridically link creators with their outputs as they circulate beyond their physical or contractual control and, in so doing, allows them to manage how those outputs are used by third parties at a distance.

Over time, the questions that have been asked about the nature of the intangible have consistently been reframed as intellectual property law has been called upon to accommodate new types of cultural, technical, and scientific outputs, along with new ways of creating, consuming, and disseminating those outputs.[1] Despite this, there are a number of things that have remained constant: one of which is the central role that the tangible material form of the intangible has played in giving shape to the intangible. Indeed, one of the things that the history of intellectual property law shows is that many of the problems created by the intangible have been resolved by resorting to a tangible physical manifestation of the intangible. Whether it is the manuscript, the machine, or the chemical compound, the law has constantly turned to the physical expression of the intangible as a means of managing the intangible's incorporeal ephemeral form.

Over the last two decades or so, there has been a subtle but important change in the questions that have been asked about the intangible in intellectual property law. In large part, this is a result of developments in information technology, molecular biology, and related fields which have fundamentally changed how research

[1] See Hyo Yoon Kang, 'Law's Materiality: Between Concrete Matters and Abstract Forms, or How Matter Becomes Material' in (ed) Andreas Philippopoulos-Mihalopoulos, *Routledge Handbook of Law and Theory* (London: Routledge, 2018), 453.

is conducted and consequently the types of things that are presented to the law for scrutiny. For example, while life scientists in the past had mainly worked with physical biological material, they are now increasingly working with immaterial digital representations of that physical material; with the strings of A's, T's, C's, and G's that spell out the genetic code of biological subject matter. This is part of a broader change in biological work in which the structures and representations used by information technologies have increasingly come to stand in for the objects themselves.[2] While scientists may not yet be able to email a plant (although this is sometimes spoken of as a future possibility), they can recreate living viruses from sequence data.[3] They are also able to introduce genetic diversity that is captured in digital sequence information into organisms without physically accessing the organism.[4] In the biological sciences, the uncoupling of subject matter from its physical form has been facilitated by improved and cheaper sequencing technologies, which have led to a rapid increase in the availability of DNA sequence data and by advances in whole genome sequencing. These changes have placed scientists working in the life sciences on a similar footing to engineers where they are able to work with intangible subject matter independently of its physical material form.

Patents for messenger ribonucleic acid or mRNA vaccines, which introduce chemical molecules (mRNA) into the body that instruct cells how to build the proteins that produce the desired immune response, such as Moderna and Pfizer's Covid-19 vaccines, are another information-based invention. Modern medical diagnostic techniques that operate on the 'basis of a recursive patterning of signals' from the body 'rather than a linear transformation of inputs into outputs'[5] are another. Inventions of this nature, which mark a 'shift from an industrial or manufacturing paradigm to a bioinformational paradigm', represent 'the expressions of a new and different logic of invention, one that construes "nature" not in industrial terms (as an input for the production of pharmaceutical products) but in cybernetic terms (as diagnostic information that is used to fine tune therapeutic procedures)'.[6]

Similar changes have also occurred with computer-related subject matter where successive innovations extended the concept of invention beyond its physical roots to embrace a new type of (immaterial) information-based invention.[7] While physicality might have made sense for inventions from 'the brick and mortar world' of the

2 Hallam Stevens, *Life out of Sequence: A Data Driven History of Bioinformatics* (Chicago: Chicago University Press, 2013), 5.

3 Building International Capacity in Synthetic Biology Assessment and Governance Project. *Sequence Information: A Key Topic for the Biodiversity Convention* (2018), 2.

4 Claudia Seitz, 'Digital Sequence Information for Patent, Copyright, Trade Secret Protection and Sharing of Genomic Sequencing Data' (2020) *IOP Conference Series: Earth and Environmental Science* 482, 012002, 1.

5 Mario Biagioli and Alain Pottage, 'Patent Personalized Medicine: Molecules, Information, and the Body' (2021) 36 *OSIRIS* 221.

6 Ibid., 233.

7 See Mario Biagioli, 'Between Knowledge and Technology: Patenting Methods, Rethinking Materiality' (2012) 22 *Anthropological Forum* 285.

Industrial Age and been effective when applied to the special-purpose programmed computers of the 1960s and 1970s which were 'grounded in a physical or other tangible form',[8] many of the advances in computer technology that have taken place since then have been in relation to electronic signals and electronically manipulated data,[9] to 'improvements that, by their very nature, may not be defined by particular physical features but rather by logical structures and processes'.[10] The process of dematerialisation has been accelerated by applicants who have claimed inventions based on linear programming, data compression, the manipulation of digital signals, and a range of other information-based inventions.[11]

One of the defining features of these new types of subject matter is that unlike earlier information-based inventions, where 'information could still be attached to a machine (a telegraph, a computer, etc.)', these inventions do not have an obvious material form, connection, or trace. Medical diagnostic inventions, for example, are not 'deployed to produce material effects … but to yield diagnostic information'.[12] As with other types of information-based inventions, these inventions 'do not claim a new material innovation – a new drug or a device – but only methods to produce new information based on a novel combination of often previously known facts, discoveries and innovations'.[13]

The decoupling of the subject matter from its physical form that characterises the process of dematerialisation is widely seen as one of the major challenges facing contemporary intellectual property law.[14] There is a concern, for example, that the 'new but still embryonic notion of invention based on the elusive figure of "information"'[15] does not fit comfortably with 'a legal episteme that is still rooted in the figure of the machine, the technological exemplar of the industrial revolution'.[16] In line with this, it is also said that information-based inventions not only rupture 'the bond between the tangible and the intangible'[17] and 'destabilize the machine based

8 *Bilski* v. *Kappos* 130 S.Ct. 3218, 3227 (2010). See also *In re Bilski* 545 F.3d 943, 1015 (Fed. Cir. 2008).

9 *In re Bilski* 545 F.3d 943, 962 (Fed. Cir. 2008).

10 *Enfish* v. *Microsoft* 822 F.3d 1327, 1339 (Fed. Cir. 2016).

11 *Bilski* v. *Kappos* 130 S.Ct. 3218, 3227 (2010). See also Brief for Business Software Alliance as Amicus Curia in Support of Affirmance, *Bilski* v. *Kappos*, Supreme Court of the US, No. 08-964 (Aug 2009), 24–25; Brief for Biotechnology Industry Organization et al. in Support of Neither Party, *Bilski* v. *Kappos*, Supreme Court of the US, No. 08-964 (Aug 2009), 14–27.

12 Mario Biagioli and Alain Pottage, 'Patent Personalized Medicine: Molecules, Information, and the Body' (2021) 36 *OSIRIS* 221, 234.

13 Ibid., 221.

14 Stuart J. Smyth et al., 'Implications of Biological Information Digitization: Access and Benefit Sharing of Plant Genetic Resources' (2020) *Journal of World Intellectual Property* 267, 268.

15 Mario Biagioli and Alain Pottage, 'Patent Personalized Medicine: Molecules, Information, and the Body' (2021) 36 *OSIRIS* 221, 222.

16 Ibid. There is an inherent tension between new information-based technologies such as business methods, software, and information-based diagnostic methods and the traditional historical figure of invention as 'machine'.

17 Stuart J. Smyth et al., 'Implications of Biological Information Digitization: Access and Benefit Sharing of Plant Genetic Resources' (2020) *Journal of World Intellectual Property* 267, 268.

logic of patent law', they also 'stretch the figure of the machine' that is said to underpin patent law 'to the point at which it ceases to be effective'.[18] Or, as the Supreme Court said in *Bilski*, there is a concern about how a patent law designed for inventions of the 'Industrial Age' is going to accommodate and deal with inventions from the 'Information Age'.[19] In part this is because information-based inventions are thought to undermine and challenge fundamental patent law concepts such as the distinction drawn between invention and discovery, as well as 'traditional categories of patentable subject matter like machine, process, and composition of matter.[20] In so doing, the patenting of information-based inventions is said to 'provoke a set of fundamental questions about the episteme of patent law'.[21]

Dematerialisation not only undermines existing rules and procedures, it is also said to call into question the relevancy of intellectual property law in the twenty-first century. Because the inventions of the Information Age have been 'unmoored from the machines that embedded and delimited them' they 'run the risk of expanding like a genie out of a lamp, creating very large monopolies – not just economic monopolies, but monopolies of knowledge that may constrain the development of future inventions'.[22] As a result, information-based inventions are said to create a series of 'remarkable political and policy challenges'.[23] In this context, there is a sense in which the dematerialisation of subject matter has given rise to conceptual questions that the law is not equipped to deal with.[24] In dealing with a subject matter that is itself intangible or immaterial, there is also a sense in which the law is in unchartered territory, that it is encountering problems that are unprecedented, and that in dealing with intangible intangibles the law has been caught out once again by scientific and technological change.[25]

[18] Mario Biagioli and Alain Pottage, 'Patent Personalized Medicine: Molecules, Information, and the Body' (2021) 36 *OSIRIS* 221, 222.

[19] *Bilski* v. *Kappos* 130 S.Ct. 3218, 3235 (2010).

[20] Mario Biagioli and Alain Pottage, 'Patent Personalized Medicine: Molecules, Information, and the Body' (2021) 36 *OSIRIS* 221, 222.

[21] Ibid., 221.

[22] Ibid., 234.

[23] Ibid.

[24] Stuart J. Smyth et al., 'Implications of Biological Information Digitization: Access and Benefit Sharing of Plant Genetic Resources' (2020) *Journal of World Intellectual Property* 267, 268. The dematerialisation of genetic resources is also said to undermine international and national agreements (the *Convention on Biological Diversity*, the *Nagoya Protocol*, and the *International Treaty on Plant Genetic Resources*) and, as a result, risk 'rendering these agreements obsolete'. Alimata Traoré, 'The De-Materialization of Plant Genetic Resources: A Peasant's Perspective' in (ed) The Global Network for the Right to Food and Nutrition, *When Food Becomes Immaterial: Confronting the Digital Age* (Berlin: FIAN, Oct 2018), 15. The International Civil Society Working Group on Synthetic Biology, *Synthetic Biology and the CBD: Five Key Decisions for COP 13 & COP-MOP 8*, 5.

[25] 'The fundamental and radical transformation from material to data is unique in history'. C. Seitz, 'Digital Sequence Information for Patent, Copyright, Trade Secret Protection and Sharing of Genomic Sequencing Data' (2020) *IOP Conference Series: Earth and Environmental Science* 482, 012002, 1.

Although discussions about how intellectual property law will deal with a dematerialised information-based subject matter cover a variety of issues and concerns, they are underpinned by a shared question: namely, *what does it mean to grant patent protection over a subject matter that is itself intangible or dematerialised*? It is this question that I wish to pursue in this book. In order to do this – and arguing against the idea that the dematerialisation of subject matter is a uniquely twenty-first century problem – I look at three situations where American patent law has already embraced a subject matter that is essentially, or at least ostensibly, immaterial. In particular, I look at the process of dematerialisation that occurred with chemical inventions in the later part of the nineteenth century with the shift to formula-based inventions; with computer-related inventions that began in the early 1970s as a result of the unbundling or separation of software and hardware; and finally with the changes that took place in the later part of the twentieth century because of the shift to a (sequence-based) informational view of biological subject matter.

I also use the examination of the ways that patent law engaged with and responded to these different types of dematerialised subject matter to explore the general question of how law, science, and technology interact. While law, science, and technology have a long and complicated history, they are typically seen as being in a relationship in which the law is condemned to continually try to close the gap between an outdated law, an innovative science, and a disruptive technology.[26] From this perspective, the relationship is very much a one-sided asymmetrical one in which the law continually struggles to keep pace with advances in science and technology. The dematerialisation of subject matter being the latest in a long line where the law has been caught out by scientific and technological change.

One of the aims of this book is to challenge this way of thinking. This is based on the belief that patent law's relationship with science and technology is much more complex, nuanced, and interconnected than is often thought. When not bemoaning the gap between law and techno-science, there is a tendency when thinking about how law, science, and technology intersect to focus on the role that scientists as experts play in mediating scientific concepts in different legal settings. While this is important, I wish to shift the focus of attention away from scientific expertise to look at the role science plays in helping patent law to accommodate different types of subject matter, particularly when that subject matter is dematerialised or uncoupled from its physical form. As we will see, science and technology have not only consistently provided the law with potential new candidates for protection, they have also played an important role in helping the law deal with and accommodate that new subject matter. While the problems that changes in science and technology create for the law are well-known, what is less well-known is how the law has consistently looked to science and technology to resolve these problems. Although science and technology have not provided answers to the normative question of

[26] See Allison Fish, *Laying Claim to Yoga* (Cambridge: Cambridge University Press, forthcoming).

whether new subject should be protected and if so to what extent, patent law has repeatedly looked to science and technology to provide the means to allow the law to describe, demarcate, and identify new types of subject matter. While these techniques, practices, and norms – which range from taxonomic and nomenclatural rules and chemical formula to type specimens, engineering standards, and technological platforms – are mediated by the legal framework in which they operate, they have consistently played a pivotal role in allowing the law to deal with and accommodate different types of novel subject matter.

As well as looking at the impact of science and technology on the law, I am also interested in exploring the impact that the law has on science and technology. In doing so, I wish to move beyond a concern with whether or not intellectual property protection stimulates or hinders scientific and technological innovation to look at some of the other ways in which the law has impacted science and technology, including acting as an impetus for taxonomic and nomenclatural clarity within science or ensuring that the scientific public domain is legible to a legal audience.

When thinking about subject matter in patent law, it is important to distinguish between situations where *specific inventions* are presented to the law for consideration and situations where the question is whether a *general class of subject matter* is or should be protectable (which is the focus of this book). In patent law, subject matter eligibility for specific inventions operates as a threshold question that precedes other doctrinal considerations such as novelty, obviousness, and sufficiency of disclosure. The process of determining whether a specific invention complies with the subject matter requirement is a multi-step process. While there is no fixed pattern, it can be usefully divided into two stages. In the first instance, it is necessary to characterise the subject matter under consideration. Once the subject matter has been characterised, it is then necessary for it to be classified either as patent eligible or patent ineligible. In some legal regimes, such as in Europe, the legislature provides an exhaustive list of the classes of subject matter that are deemed to be non-patentable.[27] In the United States, the task of determining what the classes of patentable subject matter are and how they are to be treated is left to the courts, patent officials, and others to decide. As a result, there is now a long list of things that are widely accepted to be patent-worthy and a smaller more problematic group of things that are deemed to be ineligible subject matter (currently products of nature, natural phenomena, and abstract ideas).

In contrast to its dealings with specific inventions, there is no particular process or format that the law follows in accommodating new classes of subject matter; as different types of subject matter give rise to different considerations, they are consequently treated differently. There is also no particular forum where the fate of classes of subject matter is decided. Thus, while Congress directly grappled with

[27] For an overview, see Lionel Bently, Brad Sherman, Dev Ganjee, and Phillip Johnson, *Intellectual Property Law* (6th edn, Oxford: Oxford University Press, 2022), 466 ff.

the status of plant inventions (with some success), the status of chemical inventions and computer-related inventions was left to the courts and patent officials to decide. Typically, questions about the nature and standing of a particular type of subject matter arise when the law first interacts with or encounters a new class of would-be subject matter. In some cases, however, subject matter may come under scrutiny when for one reason or another the subject matter changes. While this does not usually happen with the incremental changes that inevitably take place in subject matter, occasionally the changes are more fundamental. In these cases, the changes may reopen questions about the nature and legal standing of a subject matter, and how the rules of patent law apply. This was the case with organic chemistry in the nineteenth century and with gene-based innovations at the beginning of the twenty-first century. As we will see, in both instances, the (apparent) dematerialisation of the subject matter served to reopen questions about the nature of the subject matter.

One of the things that you would expect to occur prior to a potential new class of subject matter being presented to the law for consideration is that there is agreement about the nature of the subject matter under consideration – some sort of consensus about what the archetypal invention is and what its defining characteristics are. While it is tempting to think of this as a prerequisite to protection, which it logically is, the historical record shows that this is not necessarily the case (this was especially so with computer-related subject matter). While some of the older classes of subject matter such as kaleidoscopes, steam engines, and dyes may now seem odd or quaint, it is relatively easy to compile a list of the different types of subject matter that have been presented to the law for evaluation over the years: recent examples include synthetic biology, AI-generated inventions, nanotechnology, and gene-based inventions. Although it may be relatively easy with hindsight to identify the subject matter under consideration at a particular point of time, when new forms of subject matter are first presented to the law for scrutiny, there is often confusion about what the subject matter should be called, what its defining features are, and how it compares to other types of subject matter. Given that would-be classes of potential subject matter are almost by definition novel, this is not surprising. What is more surprising, however, is how difficult the law found it in some situations to agree on what the subject matter was and how it should be characterised.

At the same time as decisions are made about the nature of a class of novel subject matter, it is also necessary to decide on the type of intellectual property protection, if any, that is best suited to protect that new subject matter. The process of deciding on the most appropriate form of protection is often a fluid process that unfolds hand-in-hand with the process of deciding on the nature of the subject matter under consideration. This is reflected in the fact that when new candidates for inclusion are first discussed, it is often not clear which area of intellectual property law, if any, offers the most appropriate form of protection. For example, when the question of whether intellectual property law should be used to protect botanical novelties first arose, it was not clear whether trademark, patent, or some combination thereof was most appropriate. So too with computer-related technologies, where copyright, patent, and new sui generis modes of protection were all mooted as possible options.

Where it has been accepted that patent protection for the new subject matter is a possibility, it is then necessary to determine whether the subject matter exhibits the qualities that are expected of it. Typically, the starting point for thinking about whether a class of subject matter (or a changed subject matter) is patent-worthy in the United States is to consider whether the subject matter complies with the language of the intellectual property clause in the Constitution or, in some cases, whether the subject matter falls within the 'technological arts'.[28] Since the 1980s or thereabouts, the focus has been on whether the subject matter falls within one of the judicially created categories of things that have been deemed to be patent ineligible: namely, laws of nature, natural phenomena, and abstract ideas. While these negative categories tend to be treated like juridically sanctioned boundary objects that determine the things that are protected by patent law, one of the lessons that a history of patentable subject matter shows is that historically these categories had relatively little impact on the standing of would-be subject matter. Instead, the fate of new classes of subject matter was dependent on whether that new subject matter could meet the things that were expected or demanded of it: demands that flowed from the nature of the patent system and what it sets out to do.

Typically, discussions about whether the law should accept a new class of subject matter presume that the process of inclusion is a logical and ordered process that begins with the threshold question of subject matter eligibility and once this is satisfied then proceed to other doctrinal considerations such as novelty, inventive step, and sufficiency of disclosure. In contrast to the way that the process is (for good reason) usually outlined in textbooks, the historical record shows that the process of accommodating new classes of subject matter was neither logical, neat, nor consistent, and that when new classes of would-be subject matter were first presented for discussion, these issues often merge and overlap.

While understanding the demands that are made of would-be subject matter is key to understanding how patent law interacts with new types of subject matter, it is important that we do not think of these demands as timeless criteria that unfold in a predetermined manner. Nor should we think of them as static and unchanging; indeed, as will become clear, not only were these demands applied differently to different types of subject matter, they (and with it the law) were also modified in the process of accommodating new subject matter. The interesting question is how far the law was willing to change in order to accommodate new subject matter and, in turn, how that assimilation changed the law. And while the doctrinal rules of patent law are important, we should not conflate the demands that the law makes of subject matter with legal rules such as novelty, inventive step, and sufficiency. Rather, the demands made by the law of patentable subject matter are the things that allow the

[28] See, for example, *In re Musgrave* 431 F.2d 882, 888–93 (CCPA 1970).

rules to be applied in the first place; they are the things that ensure that the subject matter is in a form that allows it to be examined, processed, and, where appropriate, patented.

In order for a new class of potential subject matter to qualify for protection, it must either exhibit the traits or characteristics that the law expects of it or be able to be modified to do so. In some rare instances, the law has shown itself willing to modify the things its demands of would-be subject matter in order to ensure that the subject matter is protected. While the things that are demanded or expected of would-be subject matter vary both between types of subject matter and over time, at minimum it could be said that to be in a position where subject matter can qualify for protection, it needs to be *repeatable*, *identifiable*, and *traceable*; importantly, this must occur beyond the physical, social, and contractual reach of the inventor. The subject matter also needs to be *bounded* and *delimited*.

One of the things that is expected of patentable subject matter is that it should be able to be reduced to a format that allows third parties with appropriate skill, expertise, and knowledge to replicate the invention at a distance. At the same time, it is also important that the subject matter is able to be identified, particularly for the purposes of examination, exploitation, and infringement. This means that there needs to be a common language to describe and identify the subject matter, along with some means of tracking the intangible property as it moves between objects and forms. There also needs to be a way of connecting the invention as described in the written patent documentation with the invention in its material form. The historical decision to base American patent law on a first-to-invent rather than a first-to-file system, as was the case in many other jurisdictions and is now the case in the United States, also meant that it was necessary to be able to identify who the creator of the subject matter was, as well as when their invention came into being. As we will see, this was particularly problematic with chemical and biological subject matter. To evaluate the novelty of inventions, there is an expectation that there is an historical prior art that is legible, accessible, and searchable. Importantly, there is also an expectation that the subject matter should be able to be reduced to a format whereby it can circulate beyond the laboratory, workshop, or greenhouse. That is, there is an expectation that patents should operate as immutable mobiles that allow inventions to circulate beyond the reach of the inventor.[29] The expectation that the subject matter should be bounded and closed was also reinforced by the fact that it is very difficult to pass judgement over something that is open-ended or unbounded, at least in a way that does not appear arbitrary or capricious. To the extent that subject matter is taken seriously, it is often treated as if it consists of a series of inert stable objects that come preformed and ready for evaluation. Viewing subject matter in this way overlooks an important part of the way that the law deals with would-be subject matter. As a result, it reduces our ability to fully appreciate the way that the

[29] See John Law, 'Objects and Spaces' (2002) 19(5/6) *Theory, Culture & Society* 91.

law reacted to a dematerialised subject matter and in so doing our understanding of how law, science, and technology were implicated in that process. To avoid this problem, when thinking about the way patent law dealt with a dematerialised subject matter I approach subject matter in a particular way.

The starting point for which is that instead of seeing scientific and technological outputs as things that are inherently inert, stable, and closed and that come preformed and ready for evaluation, I see subject matter as something that is potentially uncertain, open-ended, fluid, and heterogeneous. This is particularly the case when the law first begins to grapple with a new class of potential subject matter or where this has already occurred and the subject matter has changed substantially.

While patents operate as closed immutable mobiles that allow inventions to circulate beyond the reach of the inventor, this does not mean that there is no place for uncertainty in patent law. Indeed, there is a large body of law dealing with the type of uncertainty that is acceptable in a patent. While patent claims are often read down for being overly vague or unclear, there has never been an expectation that patentees need to provide precise details of every aspect of an invention; it is acceptable to leave certain things for third parties to work out for themselves when they are replicating the invention from the written form. The main limitation is that in doing so they should not be required to exercise anything approaching 'inventive' effort. Patent law has also never required patentees to know everything about their inventions: so long as an invention does what it is meant to do and is able to be identified and repeated, the law is content.

While applicants may not be required to disclose all the details of their inventions or to explain the reasons why the invention does what it does, they are under an obligation to ensure that the patent is able to operate as an immutable mobile: they must ensure that third parties are able to repeat the invention at a distance and that the invention is able to be identified and its boundaries demarcated. While this may be fine and well with mechanical inventions, it is less so when dealing with subject matter that is less certain and clear cut, as was the case with early chemical and biological subject matter. Given this, rather than being content merely to criticise the law for failing to keep up with scientific change or attempting to define the subject matter in a way that rids the law of uncertainty, it is better to shift the focus of attention to ask: what are the techniques used within law to accommodate scientific uncertainty? Or, what is it that allows an uncertain subject matter to be translated into an immutable legal object? The upshot of this is that to appreciate how patent law responded to a dematerialised subject matter and how science and technology are implicated in that process, we need to understand how patent law deals with an uncertain subject matter. As we will see, this was particularly important with chemical and biological subject matter.

As well as understanding how patent law deals with scientific uncertainty, it is also important to recognise that the subject matter patent law deals with is potentially much more open-ended, fluid, and heterogeneous than is often thought.

Recognising the open and fluid nature of scientific and technological objects means, for example, that rather than seeing software, which has been described as a quintessential heterogeneous technology, as a pre-packaged consumer product that contains the instructions or code that controls computers, it is better seen as being 'inextricably linked to a larger social-technical system that includes machines (computers and their associated peripherals), people (users, designers, and developers), and processes (the corporate payroll system, for example)'.[30]

While an appreciation of the fact that scientific and technical outputs are inherently fluid and open-ended is important, this is only part of the story. The reason for this is patent law does not have the luxury of dealing with an open-ended and fluid subject matter.[31] Instead, when determining the standing of a class of subject matter, patent law needs to reduce the open and fluid subject matter into something that is both closed, demarcated, and predictable and, at the same time, flexible enough to accommodate variations across the class of subject matter, as well as changes to the subject matter that occur over time. (The latter is particularly important where changes take place which mean that the subject matter is dematerialised).

The upshot of this is that to appreciate how patent law responded to a dematerialised subject matter and how science and technology are implicated in that process, we need to understand how and where the fluid and open subject matter is shut down and rendered inert.[32] In some situations, as with chemical and biological inventions, these issues have largely been resolved before the subject matter is presented to the law for scrutiny. In other situations, as was the case with software-related inventions, the task of setting the boundaries of the subject matter was left to the law to resolve. Whether it is called cutting the network, purification, or drawing boundaries,[33] the result is the same: to understand subject matter in patent law, we need to understand the process by which heterogeneous subject matter is rendered manageable. This means that instead of merely celebrating the heterogeneous nature of techno-scientific outputs, we need to understand how it is that the law produces a freeze frame of those iterations: 'an image excerpted from a much longer, much more dynamic flow, like a well-placed photograph of unfolding events'.[34] While in

[30] Nathan Ensmenger, 'Software as History Embodied' (Jan–March 2009) 31(1) *IEEE Annals of the History of Computing* 88.

[31] For similar argument with legal interpretation or legal hermeneutics, see Hans-Georg Gadamer, *Truth and Method* (London: Sheed and Ward, 1975).

[32] Kyle McGee, *Bruno Latour: The Normativity of Networks* (Abingdon: Routledge, 2014), 192. The disclosure requirement, which requires the invention to be reduced to 'a stable written form, is one mechanism by which patents are "cut" from their socio-material milieu'. Michael S. Carolan, 'The Mutability of Biotechnology Patents: From Unwieldy Products of Nature to Independent Objects' (2010) 27(1) *Theory, Culture & Society* 110, 113.

[33] On purification, see Bruno Latour, *We Have Never Been Modern* (New York: Harvester Wheatsheaf Publisher, 1993). On cutting the network, see Marilyn Strathern, 'Cutting the Network' (1996) 2(3) *The Journal of the Royal Anthropological Institute* 517.

[34] Kyle McGee, *Bruno Latour: The Normativity of Networks* (Abingdon: Routledge, 2014), 9.

some cases (such as with chemical subject matter), this was a relatively straightforward almost invisible process, in other cases, such as with software-related subject matter, it was particularly problematic.

While it is important that we are aware of the processes that are used to render a heterogeneous and uncertain subject matter manageable, it is a mistake to see the results of these processes as closed, isolated, and insular. To see subject matter in this way misses two important characteristics of patentable subject matter: The first is that it overlooks the fact that at the same time as patent law cuts networks to render heterogonous subject matter manageable, it is also careful to ensure that the closed (previously heterogeneous) subject matter is placed into new alliances and networks. The difference being that these new networks and alliances have been sanctioned (or demanded) by the law. Indeed, one of the reasons why heterogonous subject matter is shut down is to solidify the object's legal autonomy and in so doing ensure that the patented subject matter can circulate as a form of currency in new techno-scientific and commercial networks.[35] In this sense, we can see the process of dealing with heterogeneous subject matter as one in which certain technical and scientific networks and alliances were sacrificed to ensure that the (closed) subject matter was able to enter new juridically sanctioned networks. As we will see, the trade-off between the scientific and the technical on the one hand and the commercial on the other creates tensions that patent law has long struggled with.

At the same time, there is also an expectation that the (closed) subject matter has a specific history both in terms of its genesis and its relationship with other types of subject matter (which translate into the doctrinal requirements of non-obviousness and novelty and the need for an ordered and searchable public domain). Unlike the case with an open-ended heterogeneous subject matter that creates problems for the law, these (new) juridical alliances and networks are integral to what the law does; they enable doctrinal rules to be applied and policy goals enacted. The presence of these networks is sufficiently important that when they did not exist for a potential new class of subject matter, patent law refused to deal with that subject matter until the necessary networks were both in place and legible, particularly to patent examiners: this was the case with chemical, software, and biological subject matter.

As well as taking account of the juridically sanctioned networks and the impact they have on patentable subject matter, we also need to be mindful of the fact that no matter how successful the law may be in bounding scientific and technical objects that the subject matter patent law engages with is never really closed, discrete, and inert. To see subject matter in this way misses an important part of the way that patent law deals with classes of would-be subject matter that, in turn, reduces our ability to appreciate how patent law deals with a dematerialised subject matter and also

[35] On the roles that patent law played in the emergence of dye production in late nineteenth century, see Andrew Pickering, 'Decentering Sociology: Synthetic Dyes and Social Theory' (2005) 13(3) *Perspectives on Science* 352, 366. On the history of the chemical industry and its relationship to chemistry, see Ernst Homburg, 'Chemistry and Industry: A Tale of Two Moving Targets' (2018) 109 *Isis* 565.

how science and technology are implicated in that process. To avoid this, instead of seeing the objects that patent law deals with as inert and insular, I see chemical substances, computer-related inventions, plants, genes, and other types of subject matter as 'informed materials'. In part this builds on Whitehead's idea that instead of seeing material entities as closed bounded objects, material entities should be seen as simultaneously extending into other entities (which creates a heterogonous subject matter), while folding elements of other entities inside them.[36] This is based on the idea that entities, both material and immaterial, are shaped by the specific environments in which they are generated. Importantly these environments should not be considered to be external to the subject matter. Instead, the environment should be seen as entering into the very constitution of the objects themselves.[37] The result is a subject matter that is informed or 'rich in information'. This means that even when the law successfully draws boundaries around a heterogeneous subject matter, the resulting (closed) subject matter still contains elements of the entities, alliances, and networks that were folded into it.[38] From this perspective, there is no such thing as a material or immaterial object per se. Instead, objects such as chemical substances, software-related inventions, plants, and genes are always informed. This means that rather than seeing the subject matter of chemistry, for example, as merely consisting of bare molecules – 'structures of carbon, hydrogen, oxygen and other elements – isolated from their environments', the subject matter is better seen as consisting of 'a multitude of informed molecules, including multiple informational and material forms of the same molecule'.[39] The situation is similar with computer-related and biological subject matter.

While subject matter's interconnectedness is usually perceived as a problem that the law deals with by cutting alliances and redrawing boundaries, patent law has come to rely upon the informed nature of subject matter as a way of ensuring that the expectations that the law has of would-be subject matter are met and that it is able to deal with different types of subject matter. That is, patent law relies upon the information that is embodied in the subject matter as a way of ensuring that the subject matter is bounded, identifiable, repeatable, and traceable. This is made possible because as informed objects carry their context with them they are able to be removed from the environment where they were created to circulate without losing the benefits that that context provides in giving meaning to and shaping those objects.

[36] Alfred North Whitehead, *Process and Reality* (New York: Free Press, 1978), 80; Andrew Barry, 'Pharmaceutical Matters: The Invention of Informed Materials' (2016) 22(1) *Theory, Culture & Society* 51, 57.

[37] Andrew Barry, 'Pharmaceutical Matters: The Invention of Informed Materials' (2016) 22(1) *Theory, Culture & Society* 51, 59.

[38] Alfred North Whitehead, *Process and Reality* (New York: Free Press, 1978), 80.

[39] Andrew Barry, 'Pharmaceutical Matters: The Invention of Informed Materials' (2016) 22(1) *Theory, Culture & Society* 51, 59.

The upshot of this is that when thinking about how the law deals with a (potentially) dematerialised subject matter and how science and technology are implicated in this process, we need to pay attention to the processes that are used to render uncertain or heterogeneous subject matter manageable, to the networks that are associated with different types of subject matter, and to the informed nature of that subject matter. That is, we must recognise that the subject matter that the law deals with is both closed *and* informed (or as Luhmann would say, open but closed). This is important because these are the places where we can see the consequences of dematerialisation most clearly. These are also the places where science and technology are consistently enlisted by the law to ensure that the subject matter is fit for purpose. In the following chapters, I use this way of thinking about patentable subject matter to frame the discussions about how patent law in the United States interacted with chemical, software-related, and biological innovations, the changes that occurred when that subject matter was dematerialised, and the role that science and technology played in helping the law to accommodate those changes.

2

An Impure Law

INTRODUCTION

Like a square peg in a round hole, chemical inventions are often portrayed as having been shoe-horned into a patent law that was built upon a mechanistic and mechanical view of innovation: a view that has led to the law of chemical patents being labelled an impure law that was the 'child' or 'orphan' of 'mechanical patent law'.[1] This way of thinking about chemical subject matter is part of a wider narrative that developed and took hold over the twentieth century, which sees patent law's engagement with chemical subject matter as an inherently problematic one, primarily because of the ineffectual attempts to modify patent law to accommodate the nuances of chemical subject matter.[2] It is also a product of seeing chemical subject matter through the lens of medical and pharmaceutical patents, which, at least until the later part of the nineteenth century or thereabouts, were thought to belong outside the remit of patent protection.[3]

One of the things that the history of chemical inventions reveals is how inaccurate this way of thinking about chemical subject matter is. Specifically, it shows that while chemical inventions are often presented as having been subsumed into a patent law initially designed to deal with mechanical inventions, chemical inventions have always been a part of American patent law. Indeed, a 1911 handbook on chemical patents went so far as to claim that the first patent ever granted in the United States – to Samuel Hopkins for making pot ash and pearl ash – brought 'the first

[1] This was similar to the pejorative view of chemistry as an impure science in the sense that chemists were unable to arrive at first principles or elaborate general laws (in the way that exact sciences of physics and maths do). Bernadette Bensaude-Vincent and Jonathan Simon, *Chemistry: The Impure Science* (2nd edn, London: Imperial College Press, 2012), 63.

[2] See, for example, Paul Eggert, 'Uses, New Uses and Chemical Patents: A Proposal' (1969) *Journal of the Patent Office Society* 768, 783; William D. Noonan, 'Patenting Medical Technology' (1990) 11 *Journal of Legal Medicine* 263; Jackie Hutter, 'A Definite and Permanent Idea? Invention in the Pharmaceutical and Chemical Sciences and the Determination of Conception in Patent Law' (1995) 28 *The John Marshall Law Review* 687, 689.

[3] See Joseph M. Gabriel, *Medical Monopoly: Intellectual Property Rights and the Origins of the Modern Pharmaceutical Industry* (Chicago: University of Chicago Press, 2014).

United States patent into the realm of chemical patents'.[4] While we need to be cautious about overstating the historical impact of chemical patents on the law more generally, and we should not underestimate the impact of the mechanical-origins narrative, it is clear that patents relating to industrial chemistry were 'one of, if not the oldest in the realm of patents'.[5]

While patent law's engagement with chemical inventions is often presented as having been problematic and troubled – primarily because of the need to retrofit chemical subject matter into a law designed for mechanical inventions and because of the ethical issues relating to the use of patents within medicine – one of the things that the history shows is how relatively seamless and straightforward the process has been.[6] Unlike other countries that limited the protection available for chemical inventions (notably Germany, which excluded patents for chemical products but allowed patents over chemical processes[7]), there have never been specific limitations placed on chemical inventions in the United States. So long as chemical products or processes satisfied the general criteria for patentability (such as subject matter, novelty, obviousness, and utility) they were eligible for protection. The decision not to exclude chemical product patents avoided the problem of having to determine what a chemical product or process was, at least one that would have stood up to legal scrutiny. As a US patent attorney wrote, 'I do not even know … whether dissolving sugar in water is a "chemical process."'[8] Any 'attempt to sort out the chemical goats

4 Hugo Mock, *Handbook of Chemical Patents: How Procured, Requisites of, and Other Information Concerning Chemical Patents in the United States and Abroad* (Washington, DC: Mason, Fenwick, and Lawrence, 1911), 8. Mock was referring to Samuel Hopkins, US Patent Number X001, 'The Making of Pot Ash and Pearl Ash' (31 July 1790). It was also said that between 1554 and 1598 about 'forty-eight licenses or monopolies were granted in England, of which one half were truly chemical patents'. A. J. Nydick, 'Book Review of Edward Thomas: The Law of Chemical Patents' (1938) 87(1) *University of Pennsylvania Law Review* 135, 136.

5 Seabury Mastick, 'Chemical Patents I' (1915) *The Journal of Industrial and Engineering Chemistry* 789. A report from 1792 noted a range of patent chemical industries in the United States including candle and soap, chemicals (such as Glauber salts and saltpeter), distillery products, drugs, fermentation products, and plaster; metals, naval stores (turpentine, tar, rosin, etc.); oils, fats, and waxes; paint and varnish; paper, potash; salt; sugar, molasses, etc.; and various miscellaneous products such as glue and lampblack. C. A. Browne, 'Early Chemical Industries in America' (1922) 14 *The Journal of Industrial and Engineering Chemistry* 1066.

6 At times the assimilation of chemical subject matter into patent law was so effective that it blended into the background. As the author of a 1917 treatise on chemical patents complained, it was difficult to write about chemical decisions because chemical 'facts frequently do not appear on the face of the decision'. Edward Thomas, *Chemical Patent and Allied Patent Problems* (Washington, DC: John Byrne & Co, 1917), 8. This treatment seems to have ended by 1945. See John Boyle and Henry Parker, 'Patents for New Chemical Compounds' (1945) 27 *Journal of Patent Office Society* 831, 836 (it is 'extremely difficult to obtain from the Patent Office adequate protection for inventions and discoveries in the chemical field' predicting that 'the patenting of new chemical compounds will prove to be the exception rather than the rule').

7 For some of the issues see the *Hearings before the Committee on Patents United States Senate on S. 2718 Sixty-Fifth Congress: First Session* (4 June 1917) discussing a Bill to suspend a German patent on salvarsan, which was used in the treatment of syphilis.

8 K. P. McElroy, 'Product Patents' (1939) *Journal of the Patent Office Society* 550, 553.

from the physical sheep in the composition of matter class would prove like the task of hunting polar bears in purgatory – "apt to be arduous in detail and disappointing in result". There are too many hybrids, goatish sheep and sheepish goats.'[9]

The ease by which patent law embraced chemical subject matter was also reflected in the fact that in contrast to computer-related inventions and biological subject matter, which attracted and continue to attract attention, there was comparatively little critical discussion about chemicals as patentable subject matter. As a commentator noted in 1939, the question of the standing of patents for new chemical compounds was a 'question to which little thought has been given'.[10] There were two notable exceptions where the standing of chemical patents was called into question in the United States.

The first occasion where chemical patents were questioned was in relation to their use in the medical and health fields, which were thought to be beyond the reach of patents. The main reason for this was that physicians were 'supposed to be practising from a higher motive than the despised tradesman'.[11] While the belief that patents over pharmaceuticals and medicines would have a negative impact on healthcare did impact on patenting practices across the nineteenth century, once the ethical objections to the patenting of medical innovations were overcome, pharmaceutical-based chemical inventions were readily accepted within patent law.

The second occasion where chemical patents were called into question was in the early part of the twentieth century when concerns about the dominance of the German chemical industry in the United States led to calls for patent protection for chemical inventions to be curtailed. This was prompted by concerns that the American public was being exploited by the German chemical industry who had been systematically taking out product patents in the United States with the goal not of working the invention but of stopping the growth of the American organic chemical industry and thus making the United States dependent on Germany for chemicals.[12] The move to eliminate chemical patents reached a highpoint in 1916 when Charles Paige introduced a Bill into Congress that proposed to exclude chemical product patents and in so doing limit the protection available for chemical inventions to process patents. Specifically, the Bill provided that 'no patent shall be

9 Ibid., 553–54.

10 There was 'very little sentiment for restricting the field of patentable subject matter for chemicals in the United States'. P. J. Federico, 'Patents for New Chemical Compounds' (1939) 21 *Journal of the Patent Office Society* 544, 546–47.

11 Charles Woodruff, 'Should Patent Law Discriminate against Chemical and Medical Discoveries' (1917) *Journal of the American Pharmaceutical Association* 475, 468. For the post-war period see Kathryn Steen, 'Patents, Patriotism, and "Skilled in the Art": USA v. The Chemical Foundation, Inc., 1923–1926' (2001) 92 *Isis* 91.

12 Charles Woodruff, 'Should Patent Law Discriminate against Chemical and Medical Discoveries' (1917) *Journal of the American Pharmaceutical Association* 475, 468. 'German houses have exploited America during the last twenty-five or thirty years'. Ibid., 478–79.

granted … upon any drug, medicine, medicinal chemical, coal-tar dyes or colors, or dyes contained from alizarin, anthracene, carbazol, and indigo, except insofar as the same relates to a definite process for the preparation'.[13] Despite growing support for the Bill, Congress instead passed laws that allowed for the compulsory acquisition of German patents. When the war ended in 1919 and the American Drug Manufactures came out in support of product patents, the push to eliminate chemical patents quickly lost momentum and all but disappeared from public discussion.[14]

While it is often suggested that patent law is unable to keep up with the pace of scientific and technical change, patent law was easily able to embrace the myriad of changes that occurred in chemistry across the nineteenth century and beyond. As we will see, judges, patent officials, and treatise writers were consistently willing to accommodate the idiosyncrasies of chemical subject matter. Indeed, rather than being hostile or indifferent to the particularities of chemical inventions, courts in the United States (along with the US Patent Office) were said to have shown 'special sympathy'[15] and 'unusual respect for chemical inventions'.[16] For example, in identifying and demarcating chemical subject matter, patent law readily accepted changes in the way boiling and melting points were measured and in the way chemical substances were analysed and described. As well as accommodating changes in the way chemical subject matter was identified, traced, and demarcated, patent law was also willing to accommodate more fundamental changes in the nature of the subject matter, often with little or no fanfare or debate. This was particularly the case with the adoption of structural formula in the later part of the nineteenth century. While this transformation had important consequences, there was surprisingly little discussion about the move from a material chemical substance to a more dematerialised formula-based subject matter: the changes were simply presented to and subsequently accepted by patent officials, judges, and legal commentators.

Although the process of extending patent protection to chemical substances may have been relatively straightforward and uncontroversial, this should not be taken to mean that patent law did not have to change to accommodate the specific characteristics of chemical subject matter. Far from it. This is because although the process of assimilating organic chemistry into nineteenth-century patent law was a seamless, straightforward process that attracted little discussion or scrutiny, nonetheless a number of changes were needed in order to accommodate the idiosyncrasies of the science.

13 64th Cong, 1st Sess HR No. 11967 21 February 1916. The Paige Bill HB 11967 (to amend sections 4886 and 4887 of Revised statutes relating to patents).

14 The Bill lapsed and by 1919 the American Drug Manufactures Association said the reasons for its introduction no longer existed. L. E. Sayre, 'Patent Laws in Regard to the Protection of Chemical Industry' (1919–1921) 30 *Transactions of the Kansas Academy of Science* 39, 43.

15 Horatio Ballantyne, *Lecture on Chemists and the Patent Laws, The Institute of Chemistry of Great Britain and Ireland* (Cambridge: Heffer & Sons, 1922), 14.

16 Howard Forman, *Law of Chemical, Metallurgical and Pharmaceutical Patents* (New York: Central Book Co, 1967), 247.

The aim of this and the following two chapters is to look at the way that patent law dealt with the idiosyncrasies of chemical subject matter across the nineteenth and early part of the twentieth centuries and how science and technology were implicated in that process. Specifically, the focus is on organic chemical patents in the United States from the 1840s to the 1940s or thereabouts. The 1840s being the time when organic chemistry – the branch of chemistry concerned with organic carbon-based compounds and materials – emerged as a discrete area of science. The 1940s being the time when the impact of the shift within patent law away from a reliance on physical criteria to a more dematerialised subject matter became clear.[17]

THE IDIOSYNCRASIES OF CHEMICAL SUBJECT MATTER

At the beginning of the nineteenth century, plant and animal chemistry was an experimental practice concerned with the extraction and description of organic substances.[18] In contrast to inorganic chemistry, where substances were classified and identified 'on the basis of experimentally obtained knowledge about their constitution and binary constitution', organic substances such as gums, sugars, oils, gelatines, blood, milk, and saliva were classified on the basis of their natural origins (plant or animal), their properties (sweetness, smell, etc.), and the techniques by which they were extracted. At the time, it was thought that compounds obtained from living organisms were endowed with a 'vital force' that distinguished them from inorganic materials. This also contributed to the belief that compounds obtained from living organisms were too complex to be created synthetically which, in turn, led to the bodies of living creatures being viewed as the laboratories in which the synthesis of organic compounds occurred.[19]

Over the course of the early part of the nineteenth century, plant and animal chemistry was gradually replaced by the 'new, experimental culture of organic carbon chemistry'.[20] The organic chemistry that emerged in the 1830s – which is the focus of this book – brought about a fundamental transformation in scientific culture: it changed what countered as a scientific object, the way experiments were conducted, and the objects that were studied and produced in laboratories.[21] The new organic chemistry was an industrial, applied, and empirical discipline that was

[17] Joachim Schummer, 'The Impact of Instrumentation on Chemical Species Identity from Chemical Substances to Molecular Species' in (ed) Peter J. Morris, *From Classical to Modern Chemistry: The Instrumental Revolution* (London: Royal Society of Chemistry, 2002), 188, 190.

[18] Ibid.

[19] Ursula Klein, 'Paper Tools in Experimental Cultures' (2001) 32 *Studies in History and Philosophy of Science* 265, 268.

[20] Ursula Klein, 'Technoscience avant la lettre' (2005) (13:2) *Perspectives on Science* 226, 249; Alan J. Rocke, 'Origins and Spread of the "Giessen Model" in University Science' 50(1) (2003) *Ambix* 90.

[21] Joachim Schummer, 'The Impact of Instrumentation on Chemical Species Identity from Chemical Substances to Molecular Species' in (ed) Peter J. Morris, *From Classical to Modern Chemistry: The Instrumental Revolution* (London: Royal Society of Chemistry, 2002), 188, 190.

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concerned with material substances, the chemical transformations of substances, and the development of novel synthetic substances.[22] It was also a discipline that showed a growing interest in the constitution and structure of organic compounds and the experimental study of chemical reactions.

One of the defining features of organic chemistry was that it was an inherently empirical science.[23] The reason for this was that chemists did not have access to what went on below the surface of chemical compounds, nor could they explain why things happened in the way that they did.[24] While chemists and other natural philosophers had been 'pondering the invisible microworld for centuries',[25] chemical reactions remained invisible processes that lay beyond the direct reach of the chemist; they were processes that could not be seen, touched, or otherwise observed (at least directly).[26] While chemical reactions were accompanied by visible effects – such as changes of colour, smell, or temperature, or the creation of a new chemical compound – the reasons why and the manner in which these changes occurred could not be observed. Because chemists could neither access the chemical microworld nor see what was happening below the surface, they had to work backwards from the experimentally produced traces to try and identify what they had invented. That is, they had to work backwards from the results of a chemical reaction in an attempt to discern what had happened and, in turn, what had been produced.

The starting point for the study of the hidden microworld of chemical reactions was the creation of substances that revealed the traces or signs of the invisible objects of inquiry. This was done by letting a substance interact with another substance and in so doing change into a new substance. The material substances produced by this interaction were then separated from each other and processed into pure substances 'that were "readable" as meaningful signs'.[27] In this sense the substances created in the laboratory were of interest in so far as they offered experimental marks, traces, or signals of the invisible reactions that occurred when chemical substances were

[22] Ursula Klein, 'Objects of Inquiry in Classical Chemistry: Material Substances' (2012) 14 *Foundation Chemistry* 7, 8; Ursula Klein and Wolfgang Lefèvre, *Materials in Eighteenth-Century Science: A Historical Ontology* (Cambridge, MA: MIT Press, 2007), 1.

[23] Rather than working from first principles, chemistry worked from the contingent. Chemistry is a science 'which points to a new form of empiricism. It produces substances, the properties of which cannot be derived from general laws'. Andrew Barry, 'Pharmaceutical Matters: The Invention of Informed Materials' (2016) 22(1) *Theory, Culture & Society* 51, 53.

[24] Alan J. Rocke, 'Vinegar and Oil: Materials and Representations in Organic Chemistry' in (ed) Ursula Klein and Carstein Reinhardt, *Objects of Chemical Inquiry* (Sagamore Beach, MA: Watson Publishing, 2014), 47, 56.

[25] Alan J. Rocke, 'Preface' in (ed) Alan J. Rocke, *Images and Reality* (Chicago: University of Chicago Press, 2010), xiii.

[26] Ursula Klein, 'Paper Tools in Experimental Cultures' (2001) 32 *Studies in History and Philosophy of Science* 265, 273. These problems were compounded by the fact that there was no agreement or consensus about what lay below the surface of a chemical substance. Alan J. Rocke, 'Vinegar and Oil: Materials and Representations in Organic Chemistry' in (ed) Ursula Klein and Carstein Reinhardt, *Objects of Chemical Inquiry* (Sagamore Beach, MA: Watson Publishing, 2014), 47, 56.

[27] Ursula Klein, 'Technoscience avant la lettre' (2005) 13(2) *Perspectives on Science* 226, 254.

combined. Once the elements of a compound were separated and purified, these 'experimental signals were then transformed step by step firstly into analytic data and then into chemical formula'.[28]

One of the consequences of this was that it was often difficult or impossible to predict in advance what the outcomes of an untried chemical experiment would be. This lack of 'prevision' meant that chemists could not know what the consequences of mixing substances A and B would be, whether the results of that process would change if the substances were mixed at a higher or lower temperature, or what the consequences of changing the relative concentration of the substances might be: not at least until they had tried it. The only reliable way of answering these questions was by experiment: it was only by mixing the substances, altering the concentrations, or changing the temperature – and then isolating and identifying the end products – that a chemist could know what the outcome of an experiment would be.

While it was possible to work out what a machine would do a priori, 'a discovery of a new substance by means of chemical combinations of known materials' was 'empirical and discovered by experiment'.[29] As a chemical patent examiner explained to a meeting at the Patent Office in 1916, 'No prophesy is possible in chemical discoveries such as is frequently possible in purely mechanical inventions.' While from 'an inspection of the drawings and a perusal of the specification in the majority of applications for purely mechanical inventions, it is often safe to say that the invention is operative. On the contrary, it is never possible to foretell with certainty, that any untried chemical process is operative.'[30] As it was frequently difficult or impossible to predict in advance what the outcomes of an untried chemical experiment would be, it was not safe to draw inferences from past experience or analogies from known substances: instead, 'an actual trial or demonstration would be necessary to prove the inference'.[31] As we will see, the 'impossibility of predicting what will happen in hitherto-unknown situations'[32] had important consequences for patent law. Indeed, in his 1940 treatise on chemical patents, Edward Thomas went so far to suggest that the 'greater part of … chemical patent law' was said to stem from the lack of prevision.[33]

Another important characteristic of organic chemistry was that it was very much a lab-based science. Indeed, chemistry has been described as the archetypal laboratory science.[34] The fact that chemical compounds were things that needed to

28 Ibid., 253.

29 *Tyler* v. *Boston* 7 Wall 327, 330; 74 U.S. 327 (1868).

30 George S. Ely, *Chemical Inventions and Discoveries: A Paper Read November 23, 1916 before the Examining Corps of the United States Patent Office* (Washington, DC: The Law Reporter Printing Company, 1916), 4–5.

31 Ibid. Benton A. Bull, 'Prevision in the Law of Chemical Patents' (1943) 25 *Journal of the Patent Office Society* 473, 474–75.

32 Edward Thomas, *Handbook for Chemical Patents* (New York: Chemical Publishing Company, 1940), 11.

33 Ibid.

34 Melvyn C. Usselman, C. Reinhart, K. Foulser and A. Rocke, 'Restaging Liebig: A Study in the Replication of Experiments' (2005) 62 *Annals of Science* 1, 45 (the very word laboratory developed from a chymical context in the early modern period).

be tested and witnessed meant that as a 'theatre of proof' the laboratory was pivotal to the success of organic chemistry: it 'did much more than merely *house* a complicated array of rooms devoted to the specific activities which produced scientific knowledge: the laboratory was *instrumental* in producing that knowledge'.[35] Chemical laboratories not only produced new entities, they also provided the space within which those new entitles 'could reliably be witnessed'.[36] The chemical laboratory, which allowed organic chemists to 'amass the huge experimental material upon which organic synthesis was built'[37] was 'essential to the material production as well as the validation of new knowledge'.[38]

Another feature of organic chemistry that had important consequences for the way that it interacted with patent law was its reliance on chemical formula. While the nature and role of chemical formula changed over the course of the nineteenth century, for my purposes here two types of formula standout: empirical and rational formula (I look at a third type of formula – structural formula – in the next chapter). The first type of formula that were important in patent law were *empirical formula*. These were the formula that set out the elements in a compound. At the beginning of the nineteenth century, chemists assumed that the identity of a substance was determined by the composition of its elements. Typically, the proportion (or ratio) of elements in a substance was determined using a Kaliapparat, an apparatus consisting of five glass bulbs that had been invented in 1831 and quickly taken up by chemists around the world. While organic elemental analysis had been practiced since the early part of the century, the Kaliapparat marked a new era in analysis in so far as it provided a fast, easy, and accurate way of analysing organic substances, which allowed chemists to identify the elements in compounds.[39]

Drawing on the law of equivalent proportions, which provides that 'all chemical reactions take place in proportions by weight represented by elemental "equivalent weights"',[40] the information about the elements in a composition provided by the Kaliapparat was used to develop the empirical formula of the compound, which was a simple way of expressing the results of the chemical analysis. Typically, the

35 Catherine M. Jackson, 'Chemistry as the Defining Science: Discipline and Training in Nineteenth-Century Chemical Laboratories' (2011) 35(2–3) *Endeavour* 55, 60.

36 Isabelle Stengers, *Power and Invention: Situating Science* (Minneapolis: Minnesota University Press, 1997), 95.

37 Catherine M. Jackson, 'Chemistry as the Defining Science: Discipline and Training in Nineteenth-Century Chemical Laboratories' (2011) 35(2–3) *Endeavour* 55, 60.

38 Ibid., 61.

39 See Alan J. Rocke, 'Origins and Spread of the "Giessen Model" in University Science' 50(1) (2003) *Ambix* 90; Melvyn C. Usselman, C. Reinhart, K. Foulser and A. Rocke, 'Restaging Liebig: A Study in the Replication of Experiments' (2005) 62 *Annals of Science* 1, 2.

40 Alan J. Rocke, 'Chemical Atomism and the Evolution of Chemical Theory in the Nineteenth Century' in (ed) Ursula Klein, *Tools and Modes of Representation in the Laboratory Sciences* (Dordrecht: Kluwer Academic Publishers, 2001), 1, 10. On Berzelius's symbols, see Helen Cooke, 'A Historical Study of Structures for Communication of Organic Chemistry Information Prior to 1950' (2004) 2 *Organic and Biomolecular Chemistry* 3179, 3180.

summary of the empirical elemental analysis was written up using the system of abbreviations that was developed in the early part of the century (which, in slightly modified form, is still used today). Under this system, for example, the formula H_2O represented the elemental composition of water: of two parts hydrogen (H) to one part oxygen (O).[41] In this sense, empirical formula were formal quantitative statements about the proportions of the components in a particular chemical substance. As we will see, empirical formula played an important role in allowing patentees to describe their novel chemical compounds and the Patent Office to classify and organise the chemical prior art.

The second type of chemical formula that were important for patent law were *rational formula*, which began to take shape in the 1840s. One of the notable things about rational formula is that the formula not only represented the elements in a compound (as empirical formula did), they also represented the internal structure or constitution of chemical compounds. In part, rational formula grew out of problems that had developed with empirical formula. Specifically, they grew out of the fact that empirical formula could not account for 'isomerism'; namely, that it was possible for different substances, often with very different properties, to share the same empirical formula.[42] While empirical formula had many benefits they could not explain, for example, why substances such as ethanol and dimethyl ether had the same empirical formula but very different properties.[43]

The realisation that different chemical compounds could have the same empirical formula eroded confidence in the assumption that the identity of substances could be determined solely by their elements. In attempt to explain isomerism and to better understand the relationship between starting materials and the products of chemical reactions more generally, chemists shifted their attention away from a concern with the composition of compounds to focus on the constitution or inner organisation of compounds: that is, with the way that the elements were organised rather than merely on the number and kind of elements that were in a compound.[44]

The discovery of isomers served to highlight a shortcoming of empirical formula, namely that while they provided information about the elements in a compound, empirical formula said nothing about the way those elements were arranged or structured. These problems were compounded by the fact that, at the same time as organic chemists were grappling with isomers, they also began to embrace the idea that organic substances consisted of two parts (one of which was a compound radical that was as stable as an element). While the idea of the binary constitution

[41] Alan J. Rocke, 'Origins and Spread of the "Giessen Model" in University Science' 50(1) (2003) *Ambix* 90, 96.

[42] Bernadette Bensaude-Vincent and Jonathan Simon, *Chemistry: The Impure Science* (2nd edn, London: Imperial College Press, 2012), 206.

[43] Alan J. Rocke, 'Origins and Spread of the "Giessen Model" in University Science' (2003) 50(1) *Ambix* 90, 93.

[44] Ibid.

of organic compounds was short-lived,[45] it served to highlight a further shortcoming with empirical formula; namely, that it was not possible to identify the building blocks of a compound and thus its constitution based on quantitative analysis alone.

It was here that rational formula came into their own. While empirical formula listed the elements in a compound, rational formula translated that information into a binary format that represented the constitution of the compound.[46] Thus the empirical formula for oil of bitter almonds – $C_{14}H_{12}O_2$ – was translated into $(C_{14}+H_{10}+O_2) + H_2$, which designated the compounds constitution of a 'benzoyl radical' and hydrogen. In selecting the rational formula for a particular compound, chemists were often faced with a series of choices. This is because it was often possible to translate empirical formula into a number of different mathematically valid rational formula. For example, the empirical formulas for alcohol – C_2H_6O – could be represented by $(C_2H_4)+(H_2O)$, $(C_2H_6)+(O)$, $(C_2H_5O)+(H)$, or $(C_2H_5)+(OH)$.[47] The only rule that chemists had to follow was that the rational formula and the empirical formula had to contain the same number of elements. In an iterative process, chemists would attempt to fit what was known about chemical reactions and compounds with a possible rational formula for the compound in question. For instance, in the case of alcohol, the formula $(C_2H_4)+(H_2O)$ was supported by the fact that it was possible to dehydrate alcohol.[48] In this way, organic chemists were able to gradually transform 'fuzzy inscriptions … into sharp ones'.[49] Once selected the proposed formula would then be tested and refined by additional experimental investigations of the chemical reaction of the compound'.[50] Once finalised, a rational formula operated as a blueprint of an organic species that denoted the binary composition of the compound and distinguished it from other organic compounds.[51]

What we see in this process is an important transformation in the role that chemical formula played in organic chemistry. This is because rather than merely functioning to indicate the elements and their ratio in a particular compound, rational

45 Alan J. Rocke, 'The Theory of Chemical Structure and Its Applications' in (ed) M. Nye, *The Cambridge History of Science* (Cambridge: Cambridge University Press, 2002), 255, 256.

46 Ursula Klein, 'Paper Tools in Experimental Cultures' (2001) 32 *Studies in History and Philosophy of Science* 265.

47 Alan J. Rocke, 'Chemical Atomism and the Evolution of Chemical Theory in the Nineteenth Century' in (ed) Ursula Klein, *Tools and Modes of Representation in the Laboratory Sciences* (Dordrecht: Kluwer Academic Publishers, 2001), 1.

48 Alan J. Rocke, 'The Theory of Chemical Structure and its Applications' in (ed) M. Nye, *The Cambridge History of Science* (Cambridge: Cambridge University Press, 2002), 255, 257. Based on chemical formula, it was possible to draw conclusions about the regroupings taking place in the reaction by comparing the composition of the initial substance with the composition of the reaction products. Ursula Klein, 'Technoscience avant la lettre' (2005) 13(2) *Perspectives on Science* 226, 253.

49 Ursula Klein, 'Paper Tools in Experimental Cultures' (2001) 32 *Studies in History and Philosophy of Science* 265, 275.

50 Ibid.

51 Ibid.

formula were now also being used, in Klein's words, as paper tools that were used to produce new representations of what was happening below the surface of the compound.[52] That is, chemists applied rational formulas not merely as a way of expressing and illustrating existing knowledge about the make-up of a compound, they also used them as paper tools for developing chemical models and classificatory systems in organic chemistry: of rendering the invisible visible.[53] In this sense, rational formulas functioned like laboratory instruments for producing new representations of invisible objects and processes.[54] The ability to manipulate formulas provided organic chemists with an 'extraordinary productive theoretical tool, a means to create endless ideas for investigation, and endless new substances to try to create'.[55] This marked a major transition in the culture of organic chemistry from what had predominately been a science that 'exhibited a natural-historical character' (in which experimental investigations of chemical reactions were extremely rare) to a science characterised by 'a highly experimental approach, with the preparation of new artificial substances placed in the foreground'.[56]

Rational formulas proved to be particularly popular with organic chemists. There were a number of reasons for this, not least because they provided an effective and relatively easy way of building models of the chemical constitution of compounds. Another reason why rational formulas were popular was because they helped chemists to navigate the 'unseen sub-microscopic chemical world'.[57] That is, rational formulas helped chemists to understand what went on beneath the surface of chemical compounds. At the beginning of the nineteenth century, when chemists were unable to access the inner workings of chemical compounds, there were a number of different ways of thinking about the invisible microworld of chemical substances. These ranged from ontological realists (such as Dalton who thought that the symbols in chemical formula actually 'signified a very small but very real billiard ball') through to those who saw chemical formula as a mere 'aid to memory in representing the empirical facts of chemical analysis and having no real referent in the microworld at all'.[58]

One of the reasons why rational formulas were so successful is because they allowed chemists to work with and think about chemical reactions and compounds without having to commit to any particular way of thinking about what went on below the surface. The reason for this was that rational formulas were based on Berzelius's theory of chemical proportions. In contrast to other ways of thinking about atoms that existed at

[52] Ibid., 265.
[53] Manuel DeLanda, *Philosophical Chemistry: Genealogy of a Scientific Field* (Bloomsbury: London, 2015), 84.
[54] Ursula Klein, 'Paper Tools in Experimental Cultures' (2001) 32 *Studies in History and Philosophy of Science* 265.
[55] Alan J. Rocke, 'Origins and Spread of the "Giessen Model" in University Science' 50(1) (2003) *Ambix* 90, 97.
[56] Alan J. Rocke, *Images and Reality* (Chicago: University of Chicago Press, 2010), 6–7.
[57] Ibid., 7.
[58] Ibid., 6.

the time, the 'theory of proportions' did not make any statements 'about the mechanical properties, orientation in space, or scale of the hypothesised invisible entities.[59] Instead, Berzelius' theory of chemical proportions assumed that chemical elements and compounds were made up of discontinuous bits or portions, which were defined by their invariable and characteristic combining weight. A Berzelian chemical (as opposed to physical) atom was simply a packet of elemental matter of a certain relative weight;[60] it made no commitment about what this matter was or whether it really existed. In line with this, each of Berzelius's letters, which symbolised an invisible chemical entity – 'a proportion, portion, equivalent, atom, or whatever' – stood for a recombining unit of a specific chemical element or an 'elemental building block'. Thus, the three entities in Berzelius's 'preferred water formula H_2O referred to a quantity of matter', the 'real micro-characteristics of which were deliberately elided'.[61]

As rational formulas were metaphysically non-committal, they could be used by both pro- and anti-atomists.[62] Importantly, this made it possible for chemists to develop a building block image of chemical portions without having to invest in (physical) atomic theory.[63] The idea of chemical portions allowed chemists to move back and forth between the external macroscopic and internal microscopic worlds as needed. Importantly, as the agnostic nature of the rational formula allowed chemists to take for granted that the formulas were true representations of the composition of the substances being investigated, they also allowed chemists to 'go on with their experiments and identification of material substances without having to answer many theoretical problems … their mode of comprehending chemistry was independent of an explanation of chemical combination at a deeper level'.[64] In this way rational formulas were used to identify and demarcate the distinct building blocks of the substances that combined in the reaction.

Rational formulas played a number of important roles in patent law. As well as providing information about the composition and make-up of compounds, as paper tools rational formulas helped chemists generate the novel organic chemical compounds that patent law was called upon to protect. Patent law also drew upon rational formula – or more specifically the agnosticism that allowed chemists to treat rational formula as if they were accurate representations of reality – to accommodate some of the idiosyncrasies of these novel compounds, particularly the lack of prevision that characterised organic chemistry.

59 Ibid., 276.
60 Ibid., 6–7.
61 Ibid., 6.
62 See Emily Grosholz, *Representation and Productive Ambiguity in Mathematics and the Sciences* (Oxford: Oxford University Press, 1991).
63 Ursula Klein, *Experimental, Models, Paper Tools: Cultures of Organic Chemistry in the Nineteenth Century* (Stanford: Stanford University Press, 2003), 35.
64 Ursula Klein, 'Objects of Inquiry in Classical Chemistry: Material Substances' (2012) 14 *Foundation Chemistry* 7, 10.

Another important characteristic of nineteenth-century organic chemistry was that the substances that were presented to the law for scrutiny were very fickle: a slight change in ingredients or in the experimental conditions in which a substance was created could 'profoundly and critically alter the result'.[65] With some compositions, changing quantitates, proportions, purity, or conditions (solid, liquid, gaseous) of the materials could dramatically change the resulting compound. Likewise, changes to the conditions under which experiments were conducted, including altering temperature, pressure, or time could have a profound effect on the resulting compounds. The fickleness of chemical compounds had important ramifications for patent law, particularly in terms of the exactness of the definitional detail that this necessitated in patents. The fact that even a slight change in the composition of the elements or how they were combined could fundamentally change the resulting compound also had an impact on the way the courts viewed the subject matter. This can be seen for example in the decision of *Mathieson Alkali Works*, which concerned the patentability of an invention for the bleaching of cellulose materials using a chlorite in an acid solution. In light of the fact that the prior art disclosed the use of a chlorite in an alkaline solution, it was argued that the substitution of a chlorite in an acid solution was an obvious and therefore unpatentable step. The court rejected this argument on the basis that it was substantially the same as arguing that 'hydrogen peroxide (H_2O_2) is an obvious substitute for drinking water (H_2O) or that carbon monoxide (CO), the deadly poison which is present in automobile exhaust gases, is an obvious substitute for dry ice, carbon dioxide (CO_2)'. As the court said, if 'the suggested substitution was obvious it would seem even more obvious to covert graphite into diamonds because their atomic contents are not merely similar but exactly the same [which no one has yet done] … Slight atomic changes or rearrangements in the constituents of chemical combinations produce profound changes in their properties and reactions'.[66]

Yet another characteristic of nineteenth-century organic chemistry that shaped the way it interacted with patent law was the rate and speed of change. Organic chemistry, which originated in Germany, France, and the United Kingdom, quickly spread to the United States across the nineteenth century.[67] (There is work needed on the role patents played in this process.) As well as spreading geographically, there was also a phenomenal increase in the size of the science, particularly in terms

65 George S. Ely, *Chemical Inventions and Discoveries: A Paper Read November 23, 1916 before the Examining Corps of the United States Patent Office* (Washington, DC: The Law Reporter Printing Company, 1916), 10.

66 *The Mathieson Alkali Works* v. *Coe* 99 F.2d 443 (1938) CD 105, 497 OG 768.

67 R. Dolby, 'The Transmission of Two New Scientific Disciplines from Europe to North America in the Law Nineteenth Century' (1977) 34 *Annals of Science* 287. For discussion of the early twentieth century see Peter. J. Hugill and Veit Bachmann, 'The Route to the Techno-Industrial World Economy and the Transfer of German Organic Chemistry to America before, during, and Immediately after World War I' (2005) 3(2) *Comparative Technology Transfer and Society* 159; Kathryn Steen, 'Confiscated Commerce: American Importers of German Synthetic Organic Chemicals, 1914–1929' (1995) 12 *History and Technology* 261.

of the number of organic chemical compounds in existence. As organic reactions often resulted in a cascade of different products, each of which potentially generated other products, the number of chemical compounds grew and continued to grow exponentially across the century. While it has been suggested that in 1820 only about 120 organic compounds had been described in the literature, by the 1860s there was talk of there being billions of compounds. The scale of the increase was captured by the French organic chemist Marcellin Berthelot who calculated in 1863 that the '1.4×10^5 possible esters of sorbitol would fill 14,000 libraries each containing a million books comprising a campus that would require an area the size of Paris'; this was just to list the names, not even a description of their properties.[68] While these figures were crude, nonetheless they capture the enormous growth that occurred in organic chemistry across the nineteenth century. The rapid and dramatic increase in the number of organic compounds created a number of problems for patent law. As well as contributing to the 'chemical identity crisis'[69] that plagued both science and the law across the nineteenth century, the number of organic compounds in existence also created problems when navigating the prior art for the purpose of determining whether a chemical compound was novel.

One of the reasons for the rapid growth of nineteenth-century organic chemistry was that the new experimental science allowed chemists to produce artificial substances in an unprecedented way. The creation of artificial material substances included both the development of products not found in nature such as acetylsalicylic acid (aspirin) and new dyes (such as mauveine), along with the artificial creation of pre-existing natural products such as urea, acetic acid (vinegar), and glucose. Many of these new compounds transformed existing industries or laid the foundation for new industries across the nineteenth century.[70] The creation of artificial substances, which became a defining feature of nineteenth-century chemistry and a key concern of patent law, was based on the insight that as the properties of substances were dependent on their molecular architecture, new synthetic substances could be created by changing the nature of that architecture. Specifically, it was based on the concept of substitution, where one portion of a compound was replaced with another portion to produce unexpected and novel compounds.[71] Organic chemists used a range of different experimental techniques to alter or transform the molecular architecture of substances in order to create novel synthetic substances. These included experimenting with the substances that were mixed together, the relative

68 Alan J. Rocke, 'Origins and Spread of the "Giessen Model" in University Science' (2003) 50(1) *Ambix* 90, 94.

69 Catherine M. Jackson, 'Chemical Identity Crisis: Glass and Glassblowing in the Identification of Organic Compounds' (2015) 72(2) *Annals of Science* 187.

70 Joachim Schummer, 'The Impact of Instrumentation on Chemical Species Identity from Chemical Substances to Molecular Species' in (ed) Peter J. Morris, *From Classical to Modern Chemistry: The Instrumental Revolution* (London: Royal Society of Chemistry, 2002), 188, 190.

71 Ursula Klein, 'Paper Tools in Experimental Cultures' (2001) 32 *Studies in History and Philosophy of Science* 265, 284.

concentration of substances, and the conditions under which the substances were mixed (by doing things such as changing temperature or pressure).[72]

As well as producing novel artificial compounds for use in industry, another important output of organic chemistry was the creation of compounds that were used as research tools to create other compounds. Here, novel chemical compounds, particularly those that were highly reactive, were used to generate new compounds rather than as ends in themselves.[73] Initially, organic substances were primarily derived from substances extracted from plants and animals. From around the 1850s, coal tar, which was a by-product of the coal gas and coke industries, became an increasingly important source of carbon compounds. Overtime, however, the majority of new substances were derived from artificially transformed synthetic organic compounds that emerged during the experimental study of organic chemical reactions.

Yet another output of organic chemistry was chemical knowledge. As well as producing knowledge about experimental techniques, the research process also produced knowledge about the synthetic pathways that led from starting materials to the final product and the characteristics of the resulting compounds, including information about their constitution, their melting and boiling points, along with how they looked, smelt, or tasted. While there was no attempt to protect this knowledge, it did play an important role in allowing patentees to identify and demarcate chemical inventions.

DEALING WITH A FICKLE, CHANGING, AND EMPIRICAL SUBJECT MATTER

In the introduction to his 1940 *Handbook for Chemical Patents*, Edward Thomas set out to explain why a separate book on chemical patents was warranted. For Thomas, the answer was straightforward: as chemical subject matter was fundamentally different from other types of patentable subject matter, it raised questions that did not arise with mechanical or electrical inventions. The key reason for this can be traced to the fact, as Thomas said, '[c]hemistry is essentially an experimental science, and chemical prevision is as impossible today, in spite of the accumulation of the great knowledge as it was in former times'.[74]

One of the notable things about nineteenth-century patent law was that judges, patent examiners, lawyers, and legal commentators all unquestionably accepted

72 Ibid., 290.

73 Ursula Klein, 'Technoscience avant la lettre' (2005) 13(2) *Perspectives on Science* 226, 253. 'Chemists cannot study the substances under investigation by means of chemical reactions without producing new substances'. Wolfgang Lefèvre, 'Viewing Chemistry through Its Ways of Classifying' (2012) 14 *Foundations of Chemistry* 25, 29.

74 Edward Thomas, 'An Outline of the Law of Chemical Patents' (1927) 19 *Industrial and Engineering Chemistry* 176, 177.

that chemical subject matter was the product of experiment: there was no doubt even amongst the harshest of critics that prevision was not possible and that organic chemistry was, at heart, an empirical science.[75] As Justice Grier wrote in 1868, 'a machine which consists of a combination of devices is the subject of invention, and its effects may be calculated *a priori*; while a discovery of a new substance by means of chemical combinations of known material is empirical, and discovered by experiment'.[76] Patent law mirrored the practice in chemistry of treating organic substances as 'experimentally defined objects throughout, from the bottom, that is their individuation and identification, up to their classification'.[77] With one notable exception (discussed below), there was also no question that the law should change to accommodate the experimental nature of the science.[78]

The willingness of judges, lawyers, legal commentators, and patent examiners to accept that chemistry operated 'by trial, not by reasoning' had a number of consequences for patent law, particularly in terms of how the subject matter was viewed.[79] While it is sometimes said that the experimental, empirical nature of organic chemistry disadvantaged chemical patentees, this was rarely the case.[80] This was particularly evident in relation to the doctrinal requirement that to be patentable an invention needed to be useful (or have utility). While meeting this requirement was not a problem for the small number of chemical inventions that had a direct industrial application (such as a new anti-fouling paint or dye) in the vast majority of cases, however, as chemical compounds had no direct industrial use, utility could have posed a problem. This was not the case however. Indeed, rather than being a problem, 'usefulness was assumed by the Patent Office for both chemical processes and compound inventions'.[81] The reason for this was that patent law latched onto

[75] The fact that 'chemistry is a mysterious science and that no one can tell exactly what will happen until he has tried it' meant that 'patents are sometimes granted for chemical inventions in instances where it would appear that the amount of ingenuity exercised on behalf of the chemists would have been called "mere mechanical skill" had he been working in a mechanical art'. Bruce K. Brown, 'The American Patent System Aids Chemical Industry' (1938) 31 *Industrial and Engineering Chemistry* 580, 584.

[76] *Tyler* v. *Boston* 74 U.S. 327, 330 (1868).

[77] Ursula Klein, 'Shifting Ontologies, Changing Classifications: Plant Materials from 1700 to 1830' (2005) 36 *Studies in History and Philosophy of Science* 261, 272.

[78] The courts had 'come to regard synthetical chemistry as compounds of the very essences of under determinability and unpredictability'. Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part II' (1941) *Temple University Law Quarterly* 321, 335.

[79] As a patent examiner noted, the 'courts have frequently recognized the futility of an attempt to prophesy or foretell in chemical procedure'. George S. Ely, *Chemical Inventions and Discoveries: A Paper Read November 23, 1916 before the Examining Corps of the United States Patent Office* (Washington, DC: The Law Reporter Printing Company, 1916), 5. The judicial willingness to accept the empirical nature of organic chemistry was reflected in the comment of the Supreme Court that with chemical research, there was 'no "of course" as to what nature can do, except as proved by observation and experimentation'. *Minerals Separation North America Corp.* v. *Magma Copper Co* 280 U.S. 400 (1930).

[80] A chemist was said to be in an 'unusually favourable position' in relation to subject matter and novelty, 'since he is less exposed to attack by analogy.' Harold E. Potts, *Patents and Chemical Research* (Liverpool: University Press of Liverpool, 1921), 141.

[81] Paul H. Eggert, 'Uses, New Uses and Chemical Patents: A Proposal' (1968) *Wisconsin Law Review* 901.

the fact that chemical compounds had the *potential* to act both as building blocks in the creation of other compounds and also as a means for establishing chemical knowledge to declare them useful enough to warrant protection.[82] In so far as compounds 'could be regarded as intermediates in the preparation of other compounds', utility was assumed.[83] The fact that these chemical inventions were 'baldly empirical'[84] did not matter so long as the compound was able to be identified.[85]

CHEMICAL SUBJECT MATTER AS THE PRODUCT OF INVENTIVE PROCESS

Dealing with a fickle, empirically based, and rapidly changing subject matter posed a number of challenges for patent law including how to give shape to the intangible chemical property, how to define the boundaries of what was being examined or protected, and once this was done, how that subject matter was to be identified. Overall, there was very little discussion about the changes that were needed to accommodate the idiosyncrasies of organic chemistry or about what the consequences of those changes might have been. One notable exception to this was Charles E. Ruby who in a series of articles written for both legal and scientific audiences from 1939 to 1941 mounted what was effectively a single-handed and unsuccessful campaign against chemical product patents. Following the publication of an article in *Science* that set out his basic argument that chemical compounds should not be entitled to patent protection because they were not inventions, Ruby, who was a Member of the Massachusetts and Federal Bars, wrote to the readers of the Journal of Chemical Education, alerting them to his article in *Science* with the aim of eliciting 'criticisms *pro* and/and or *con*' from the readers of the journal as he was preparing an 'exhaustive treatment of the thesis and [Ruby] want[ed] to 'incorporate all such criticism in this proposed longer paper'.[86]

This longer paper eventually emerged as a series of articles where Ruby argued that patents for chemical compounds such as US Patent Number 644,077 for

[82] *Potter* v. *Tone* 36 App DC 181 (DC Cir 1911) (a compound was regarded as possessing utility if it was 'useful to chemist as an educational device or as a research vehicle in the formation of other compounds)'. Paul H. Eggert, 'Uses, New Uses and Chemical Patents: A Proposal' (1968) *Wisconsin Law Review* 901, 905.

[83] A. M. Lewers, 'Composition of Matter' (1921–22) *Journal of the Patent Office Society* 530, 542.

[84] Edward Thomas, 'An Outline of the Law of Chemical Patents' (1927) 19 *Industrial and Engineering Chemistry* 176, 178.

[85] '[A]ll that the law requires is that the invention should not be frivolous or injurious to the well-being, good policy or sound morals or society … in contradistinction to mischievous or immoral'. *Lowell* v. *Lewis* 15 F Cas 1018, 1019 (CC Mass 1817). The application of this 'lower' standard continued until 1940. See John Boyle and Henry Parker, 'Patents for New Chemical Compounds' (1945) *Journal of the Patent Office Society* 831, 831–32, discussing the change adopted at the Patent Office that saw the introduction of a stronger utility requirement, which was challenged in *Application of Nelson* 280 F.2d 172 (CCPA 1960).

[86] Charles E. Ruby, 'Patents for Acts of Nature' Letter to the Editor (1939) *Journal of Chemical Education* 498.

acetylsalicylic acid (aspirin) and Patent Number 1,533,003 for mercurochrome[87] were an abuse of the patent system or, as he put it, 'the most preposterous patent monopoly that have ever been foisted upon the public with … the sanction of some of our courts'.[88] While Ruby accepted that chemical compounds were 'indubitably' compositions of matter, he felt that they constituted a very special kind of composition of matter that did not warrant or deserve to be protected.

There were a number of reasons why Ruby believed that product patent protection should not be available for chemical subject matter.[89] In an unconvincing form of originalism, Ruby argued that chemical product patents should be excluded from protection because when Congress introduced the term 'composition of matter' into the categories of patentable inventions in 1793, Congress could not have intended to include chemical compounds because the science was not yet in existence. Drawing on the fact that 'man is … largely ignorant'[90] of chemical compounds, Ruby also argued that chemists were not in a position to disclose their inventions in a way that met the requirements of patent law. As he said, the fact that the 'molecules of any true chemical compound defy conception … since they are unknown' meant that chemical compounds 'necessarily lack, and will always lack, the completeness demanded of conceptions of inventions in patent law'.[91] As 'no chemist can "know" the actual structure of any true chemical compound as the "inventor" of a machine … knows the structure of his "invention"' … 'no chemists can make a completely adequate disclosure of an alleged "invention" of any true chemical compound'.[92]

While these arguments were important, the main reason why Ruby objected to the patenting of chemical compounds was because they were 'not "inventions" as defined … in the patent law in the United States'.[93] Rather, he believed that chemical compounds were 'quintessentially discoveries'.[94] For Ruby, an invention was 'a specifically human affair' that evolved out of the inner consciousness of its creator who then embodied it in a tangible substance: the immaterial (conception) was created by the human inventor and then given shape in a material tangible form. As he said, an invention was 'necessarily a creating or contriving by man – some things or some actions or series of actions performable upon materials that man can, and does,

[87] 'In 1902 the US Circuit Court of Appeals for the Third Federal Circuit upheld US patent No. 444,086 for aceytlphenetidine (phenacetin) and, in 1910, the US Circuit Court of Appeals for the Seventh Federal Circuit sustained US patent No 644,077 for acetyltsalicylic acid (asprin)'. Charles E. Ruby, 'Patents for Acts of Nature' (28 April 1939) 89 (2313) *Science* 387, 388.

[88] Ibid.

[89] Ibid.

[90] Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part II' (1941) *Temple University Law Quarterly* 321, 336.

[91] Ibid., 330.

[92] Ibid., 333.

[93] Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part I' (1940) *Temple University Law Quarterly* 27, 31.

[94] Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part II' (1941) *Temple University Law Quarterly* 321, 335.

make or perform – in short, a purely human accomplishment; it is above all *not* something that nature, and only nature, can create'.[95] Here, Ruby drew upon the comment of the Supreme Court in *United States* v. *Dubilier Condesor Corp* that invention is the 'result of an inventive act; the birth of an idea and its reduction to practice; the product of original thought; a concept demonstrated to be true by practical application or embodiment in tangible form'.[96] Given that inventions were conceptions that 'evolved from the inner consciousness of "inventors" and embodied by them in a tangible substance', this meant that inventions were predeterminable and predictable. It also meant that conception necessarily preceded embodiment chronologically.[97]

For Ruby, for something to qualify as an invention, it was necessary to be able to show that a human agent had exercised 'substantial control' in the development of the invention,[98] without which there could be no 'true' reduction to practice of the alleged invention.[99] While 'the role of the discoverer is essentially a passive one, for the discovery itself is never the creation of the discoverer, who merely observed it in his act if discovery',[100] in contrast, the role of the inventor was 'essentially an active one, for the invention is the creation of the inventor, who truly contrived it and gave it its existence'.[101] As Ruby said:

> the inventor creates or contrives or contrives to create his invention according to a conception thereof evolved by him out of his inner consciousness. This doctrine implies that the inventor knows exactly what he is inventing, that he truly participates creatively in the act of inventing. He actually imparts to his invention its existence, he exercises choice, albeit limited in scope, in selecting the appropriate means, materials, operating conditions, *etc*, in order to effectuate his invention, and he exercises a substantial measure of control over all of the factors of the act of inventing and of his invention itself.[102]

While Ruby believed that mechanical and electrical innovations satisfied this definition of invention, he felt that this was not the case with chemical compounds. As he said, if 'there is one thing that man cannot "invent", it is a true chemical compound'.[103] Ruby's argument against protection largely turned on the way he saw chemical compounds. Drawing on the law of constant composition of chemical compounds that had been developed by the French chemist Joseph Proust in 1794, Ruby argued that chemical compounds were unchanging 'invariants' that

[95] Charles E. Ruby, 'Patents for Acts of Nature' (28 April 1939) 89(2313) *Science* 387, 388.
[96] *US* v. *Dubilier Condesor Corp* 289 U.S. 178, 53 Sup Crt 554 (1933).
[97] Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter': Part II' (1941) *Temple University Law Quarterly* 321, 335.
[98] Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part I' (1940) *Temple University Law Quarterly* 27, 50.
[99] Ibid.
[100] Ibid., 36.
[101] Ibid.
[102] Ibid., 37.
[103] Charles E. Ruby, 'Patents for Acts of Nature' (28 April 1939) 89 (2313) *Science* 387, 388.

were 'predetermined by violations of nature';[104] they were 'unique molecularly-homogenous substances of invariant composition and fixed properties, unalterable by man'.[105]

While a chemist could 'put together mutually reactive substances' (in a way that might constitute a patentable process), Ruby believed that the chemical compounds that were produced by those processes 'depend wholly on the violation of nature'. The reason for this was that 'Nature, and nature alone, fixes the structure, the composition and the inherent properties of every true chemical compound that is producible by processes devised by man, and neither you or I nor anyone else can alter any of them. Obviously no true chemical compound, as such, can be an "invention"'.[106]

Although the processes by which chemical compounds were 'first ushered into existence' were 'almost invariably … man contrived',[107] Ruby believed that chemical compounds always remained the product of the handiwork of nature. While a chemist could select the appropriate reactive materials and 'contrive suitable conditions of operation which yielded novel chemical compounds', chemical compounds were always expressions of the violations of nature rather than the work of the chemist.[108] This was because if 'properties of matter alter when substances are subjected to treatments in man-contrived processes, such alterations of properties of matter are not caused by man himself, but occur in obedience to the laws of nature'.[109] As Ruby said, the intense sweetness of saccharine did not evolve out of the inner consciousness of its 'inventor' Professor Ira Remsen in 1879 to be thereafter embodied in matter. Rather the 'unique ensemble of properties embodied in matter and known as saccharin' was 'qualitatively and quantitatively indissoluble'[110] … 'nature, and only nature, can create and embody in, or impart to, matter those properties intrinsic to matter itself'.[111] That is, it was nature not Remsen who had created saccharine. While a chemist could

[104] 'In the unions termed "compounds" nature imposes laws on herself and on us so that no chemist can make compounds in new proportion' … a 'compounds is a privileged product to which nature has assigned a fixed composition. Nature never produces a compound, even when through the agency of man, otherwise in hand, *pondere et mesura* … we must recognise the invisible hand which holds the balance in the formation of true chemical compounds … These ratios, always the same, these constant proportions which characterize the true chemical compounds of art or nature … are no more left to the power of chemists than is the law of election (i.e., affinity) which governs all of these combination … Between pole and pole, true chemical compounds are identical in their proportion'. As cited in Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part I' (1940) *Temple University Law Quarterly* 27, 34.

[105] Charles E. Ruby, 'Patents for Acts of Nature' (28 April 1939) 89 (2313) *Science* 387, 388.

[106] Ibid.

[107] Ibid.

[108] Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part II' (1941) *Temple University Law Quarterly* 321, 334.

[109] Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part I' (1940) *Temple University Law Quarterly* 27, 60.

[110] Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part II' (1941) *Temple University Law Quarterly* 321, 340.

[111] Ibid., 342.

'select chemical elements at his pleasure, but himself cannot actually place them in designs of any character whatsoever, either man-contrived or nature volitionated, and they will not arrange themselves into designs other than designs predetermined by violations of nature, and undeterminable by the will of the chemist'.[112]

The fact that chemical compounds were 'determined, not by the will of man (the chemist), but by the violation of nature' meant that they could not 'evolve out of the inner consciousness of the chemist'.[113] The invariant nature of chemical compounds also meant that '[n]o chemist can exercise even the most limited choice in determining the actual structure of any novel true chemical compound'.[114] Because chemical compounds were the 'handiwork of nature'[115] rather than the result of the work of a human agent, Ruby said it was 'fatuous' to speak of someone inventing a chemical compound.[116] The upshot of which was that chemical compounds were nothing more 'than an ensemble of unpatentable properties of matter, created and quantitatively embodied in tangible substances solely by nature'. As chemical compounds were 'inherently a principle of nature, or an ensemble of principles of nature' they were 'unpatentable subject matter'.[117] For Ruby, to accept chemists as inventors was to give them an attribute of the Deity.[118]

Overall, the response to Ruby's argument that chemical compounds did not qualify for patent protection because they were not inventions was muted.[119] To the

[112] Ibid.
[113] Ibid., 326.
[114] Ibid., 333.
[115] Ibid., 327.
[116] Ibid.
[117] Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part I' (1940) *Temple University Law Quarterly* 27, 39. In *Schering Corporation* v. *Gilbert* 153 F.2d 428, 432 (1946) the appellants argued that a claim for a synthetic chemical compound was invalid because 'it was a claim for a product which was nothing but a molecule that has resulted from inevitable chemical reactions governed by the laws of nature'. This meant that the molecule was the 'inevitable result of the action of the so-called laws of nature which are immutable by man and remain free for the use of all unrestricted by patent law'. The argument was dismissed: 'the opportunities for changes in the atomic structure of the molecule within is chemically represented by the so-called benzene ring are theoretically to be numbered in the millions and are practically legion'. *Schering Corporation* v. *Gilbert* 153 F.2d 428, 432 (1946).
[118] Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part I' (1940) *Temple University Law Quarterly* 27, 58. Chemical compounds 'can be neither created or contrived by man by a fashioning and fitting together of parts actually designed and created or contrived by man, in the manner that man fashions and fits together the man-designed and man-created or man-contrived parts of a man-contrived machine; nor can they be fashioned by man as man fashions a man contrived true manufacture; nor are they subject to even such limited control by man as are those compositions of matter whose compositions are susceptible of variations in a continuous manner by man, with resulting corresponding variation of the intrinsic properties of such compositions of matter. ' Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part II' (1941) *Temple University Law Quarterly* 321, 322–23.
[119] In 1939 the Journal of Patent Office Society reprinted an article on product patents by the Washington based Patent Attorney, first published in April 1918 in the Journal of Industrial and Engineering Chemistry (at the time when there was talk of amending the patent laws to exclude patents for chemical products).

extent that his arguments were addressed, they were dismissed; they certainly did not get any traction with patent examiners, judges, or policy makers.[120] While Ruby's arguments against product patent protection for chemical compounds were unsuccessful, nonetheless they were still important in so far as they highlighted an important question: namely, how was it that chemical compounds with all their specific and unique qualities were able to be perceived as inventions?

Unlike the case with plants and software-related inventions where there was considerable debate about the status of the new subject matter when they were first presented to the law for consideration, the standing of chemical compounds as inventions was largely ignored. Instead, commentators were able to rely on the inertia that arose from the fact that chemical compounds had been part of the patent system since its outset and that 'new compounds and results of chemical reactions had been continuously patented'[121] to simply assert that chemists were inventors.[122] In line with this, and in contrast to Ruby who saw the development of chemical compounds as discoveries that were inherently non-patentable, there was also a willingness to accept 'discoveries' as patentable subject matter.[123] This is reflected in the comment in *Badische Anilin and Soda Fabrik* v. *Kalle* that in chemistry, where 'prevision was not certain' and 'progress … was reached largely through experiment', patents were 'often upheld where the inventor stumbles upon a discovery'.[124] And, as a principal examiner at the Patent Office wrote in 1916, while it was generally the practice to speak of patent laws as having been designed to protect inventions, the Constitution refers to discoveries. 'If there be a discovery, there need be no inquiry as to how it was made or how much ingenuity was needed to embody the discovery' … 'quite a considerable portion of the work in the chemical divisions of [the US Patent] Office relates to discoveries rather than inventions'.[125]

[120] Federico said that Ruby's 'argument that all new compounds exist implicitly or potentially in nature, and hence cannot be "invented", but only discovered, has been presented in an endeavour to make the prohibition appear more logical'. P. J. Federico, 'Patents for New Chemical Compounds' (1939) 21 *Journal of the Patent Office Society* 544, 546.

[121] P. J. Federico, 'Patents for New Chemical Compounds' (1939) 21 *Journal of the Patent Office Society* 544, 547.

[122] '[A]lmost every research chemist is an inventor in the legal sense, in that he is making patentable improvements'. Harold E. Potts, *Patents and Chemical Research* (Liverpool: University Press of Liverpool, 1921), 141. George S. Ely, *Chemical Inventions and Discoveries: A Paper Read November 23, 1916 before the Examining Corps of the United States Patent Office* (Washington, DC: The Law Reporter Printing Company, 1916), 2. P. J. Federico, 'Patents for New Chemical Compounds' (1939) 21 *Journal of the Patent Office Society* 544, 546. Anon, 'The Mortality of Chemical Patents in Court' (1946) 34 *The Georgetown Law Journal* 504, 508.

[123] A 'chemical invention is what the patent statute refers to as a patentable discovery as distinguished from inventions which are mechanical in nature'. Edward Thomas, 'An Outline of the Law of Chemical Patents' (1927) 19 *Industrial and Engineering Chemistry* 176, 177.

[124] *Badische Analin & Soda Fabric* v. *Kalle & Co*. 104 F. 802, 803 (2d Cir. 1900) 94 Fed 163 (CCSD NY 1899). *Dow Chemical Company* v. *Coe* 545 OG 905, 55 USPQ 166 (1942).

[125] George S. Ely, *Chemical Inventions and Discoveries: A Paper Read November 23, 1916 before the Examining Corps of the United States Patent Office* (Washington, DC: The Law Reporter Printing Company, 1916), 2.

Another tactic that was used to enable chemical compounds to be treated as inventions was to shift the focus of attention away from the role that chemists played in the development of compounds, as Ruby had done, to focus on chemical compounds as ends in their own right.[126] The focus on the objects of chemistry echoes Bachelard's idea of chemistry as a science where the 'human mind deals no longer with nature but with its own creations … chemistry is a science dealing with artifacts, a science of the "factitious"'.[127] This was the approach used by the Professor of Physical Chemistry at the Pennsylvania State College, J. H. Simons, to challenge Ruby's argument that chemical compounds were not human creations but 'entirely acts of nature', saying that in this regard Ruby was 'entirely incorrect'. In a letter written to *Science*, Simons argued that although many chemical compounds were naturally occurring, 'the synthetic methods of chemistry enable many very useful pure substances to be produced that are not found in nature. The conception and eventual construction of new and useful chemical compounds are accomplished only and entirely through the application of human mental and physical activity. This most certainly constitutes invention'.[128] While Ruby had focused on the relationship between inventors and their outputs (requiring the invention to emanate from the inventor and the inventor to exercise control over the shape, function, or form of the resulting invention), Simons sidestepped the question of the role chemists played in creating a compound to focus on the novelty of the compound. Justice Joseph McKenna was even more explicit in the Supreme Court's *Diamond Rubber* decision when he said that a 'patentee may be baldly empirical seeing nothing beyond his experiments and his results; yet if he added a new and valuable article to the world's utility he is entitled to the rank and protection of an inventor'.[129] And, as Judge Coxe explained in *Badische Anilin and Soda Fabrik* v. *Kalle*, to be patentable a discovery had 'to have the attributes of an invention, but the mental operation is somewhat different in one who invents a machine and one who discovers a process' … 'He may not understand the law upon which the process operates and may be unable to explain the cause of certain phenomena, nonetheless if he is the first to give the world as a result his method a new and valuable article of manufacture he is entitled to protection'.[130] That is, it

[126] *Bender* v. *Hoffman* 85 OG 1737 (the focus was not on the action of the agent/inventor, but on the invention and whether it was new & technical). George S. Ely, *Chemical Inventions and Discoveries: A Paper Read November 23, 1916 before the Examining Corps of the United States Patent Office* (Washington, DC: The Law Reporter Printing Company, 1916), 9.

[127] Bernadette Bensaude-Vincent, 'Chemistry in the French Tradition of Philosophy of Science: Duhem, Meyerson, Metzger and Bachelard' (2005) 36 *Studies in History and Philosophy of Science* 627, 642. While experimental sciences like chemistry create its objects in the laboratory, observational sciences like natural history or astronomy simply observe their objects in nature.

[128] J. H. Simons, 'Patents for Chemical Compounds' (9 June 1939) *Science* 535.

[129] *Diamond Rubber Company* v. *Cons. Rubber Company* 220 U.S. 428 (1911).

[130] *Badische Anilin and Soda Fabrik* v. *Kalle* 104 F. 802 (2d Cir. 1900) 94 Fed 163, 173–74 (CCSD NY 1899).

did not matter that the chemical compound did not emanate from the 'inner consciousness of the chemist' so long as the resulting compound was new.[131]

The focus on chemical subject matter as an end in its own right, rather than on the labour that the chemist had expended in creating the compound, was evident in the way subject matter was evaluated when deciding whether it fell within one of the four types of subject matter recognised under US patent law, namely, compositions of matter, processes (or methods), machines, and articles of manufacture.[132] While chemical subject matter was sometimes categorised as articles of manufacture,[133] for the most part patentees presented their chemical compounds as 'compositions of matter'.

In patent law, a composition of matter arises when two or more substances are combined to form a new composite article, whether by way of chemical union (such as baking powder or Goodyear's vulcanised rubber) or mechanical mixture (such as alloys or Nobel's dynamite). In the case of chemical compounds, the ingredients were an essential part of the formation of the composition of matter. This was because the integrity of a chemical compound depended 'upon the preservation of the precise union and co-operation of those elemental forces which are furnished to it by its essential ingredients'. While the fickle nature of chemical substances meant that exact ingredients were essential to the formation of compositions, once a composition was formed, the role of the ingredients changed. The reason for this was that a chemical composition was something in which the ingredients necessarily 'lose their identity and individuality when combined as to be no longer capable of being distinguished in the combination'.[134] Unlike a machine or a manufacture, where the parts were usually identifiable after they had been combined together (they were discernible in their 'independent as well as in its combined condition'),[135] when ingredients were intermingled in a chemical composition, the individuality of the constituent elements were 'removed from human observation'.[136]

Importantly, in coming together in a chemical union the ingredients of a chemical compound formed a new thing. In this sense the whole was greater than and different to the parts: a 'whole that yielded 'effects beyond the sum of the effects producible by all the elements in their separated state'.[137] For example, nitroglycerine was said to be a patentable composition of matter because when the original ingredients were mixed together they 'reacted so as to form an entirely new compound

[131] *Bender* v. *Hoffman* 85 OG 1737 (1899).

[132] The categories of patentable subject matter, *viz.*, 'art, machine, manufacture, or composition of matter' etc. (which persisted unchanged since 1793 in the statutory patent law of the United States through the Patent Act of 1836, the Patent Act of 1870, and the Revised Statues of 1875).

[133] A. M. Lewers, 'Composition of Matter' (1921–22) *The Journal of the Patent Office* 530, 531.

[134] Ibid., 532.

[135] William C. Robinson, *The Law of Patents for Useful Inventions: Vol 1* (Boston: Little Brown and Co, 1890), 278.

[136] Ibid., 410.

[137] Ibid., 225.

having distinct properties of its own'.[138] In line with this, a chemical composition was treated as a discrete and separate entity or in Robinson's words as 'a unit' with 'new properties of its own'.[139]

To qualify as a composition of matter, it was necessary to show that the ingredients combined together to form a new composite article. Importantly this was done by focusing on the end-product and its relationship to its composite parts: there was no consideration given to the role that the chemist played in the formation or creation of the chemical compound. As Lewers said, the 'fact that in chemical compounds the component elements will combine only according to certain definite laws as to proportion, which is not true of non-chemical compositions, is no good reason for excluding them'.[140] They are 'certainly not simple substances and they meet the definition and tests of a composition as laid down by [treatise writers] and the courts'.[141] A similar approach was evident in *Schering Corporation* v. *Gilbert* where in response to the argument that since new molecules were the result of laws of nature, immutable by man, they should be free for the use of all unrestricted by patent, the court 'refused to be led astray by the law of nature argument'. Instead it reverted to the long-standing definition of composition of matter (as the mixture of two or more ingredients that develop different or additional properties or properties that the several ingredients individually do not possess in common) to find the invention patentable.[142]

Another reason why chemical compounds were able to be accommodated as inventions within patent law related to the way that the labour of the organic chemist was viewed. This is evident in the writings on chemical patents by the influential nineteenth-century treatise writer, William Robinson. For Robinson, inventions were 'a class of agencies employed by man for the production of physical effects'.[143] Like Ruby, Robinson believed that every 'invention has its origin in man. It is his addition to the agencies already existing in nature, and owes to him its generation, its birth, and its application to the purposes for which it was designed'.[144] While Robinson and Ruby both believed that invention was the product of the agency of the human inventor, they differed in terms of how that agency (and thus invention)

[138] Joseph Rossman, 'What the Chemist Should Know about Patents' (1932) 9(3) *Journal of Chemical Education* 486, 490.

[139] William C. Robinson, *The Law of Patents for Useful Inventions: Vol 1* (Boston: Little Brown and Co, 1890), 278. Harwood Huntington, *Some Notes on Chemical Jurisprudence: A Digest of Patent-Law Cases Involving Chemistry* (New York: Blanchard Press, 1898), 16.

[140] A. M. Lewers, 'Composition of Matter' (1921–22) *The Journal of Patent Office* 530, 531.

[141] Ibid.

[142] A 'precise claim for a new and useful compound which has been adequately described in the specification is no less valid because the compound happens to be a new molecule'. *Schering Corporation* v. *Gilbert* 1 53 F.2d 428, 68 USPQ 84, 88 (CCA 2d, 1946).

[143] William C. Robinson, *The Law of Patents for Useful Inventions: Vol 1* (Boston: Little Brown and Co, 1890), 115.

[144] Ibid.

was viewed.[145] In particular, while Ruby had a fixed view of agency that was modelled on mechanical invention (an approach Robinson called 'crude notions of physical agencies'), in contrast Robinson, who was writing some 40 or so years before Ruby, argued that the idea of agency and with it the invention had to change to accommodate new types of scientific and technical innovation.[146]

For Robinson, a chemical compound was 'a force applied' that depended on 'the union and co-operation of certain other forces which are manifested through the properties of the individual ingredients'.[147] While Ruby's belief in the invariant nature of chemical compounds meant that there was no room for chemists to exercise any creativity in the development of new compounds, Robinson argued that the work of the chemist could be creative. As he said, the 'inventive act by which the composition is created … consists in the discovery of the ability of these elemental forces to unite in the production of the new force, and the contrivance of such a method of commingling them as will develop the new forced desired'.[148] For Robinson, the 'invention lay in' … 'the creative act of bringing components together' to unleash 'some new or as yet unawakened energy'.[149] That is, Robinson was willing to accept that the chemists' art consisted of 'managing populations of molecules in order to bring about the desired reactions'.[150] At the same time, Robinson was also willing to accept that the chemist's art also consisted in being able to identify when a valuable new compound had been created. As he said: 'the patient labours of a lifetime, the unpremeditated flash of an original thought upon the mind, the revelation made to *an appreciative intellect* by some trivial accident all stand upon equal footing both in character and merit and are entitled to the same reward'.[151]

Much like the French chemist Antoine Lavoiser who saw elements as 'actors in chemical operations' that were 'defined by how they act and react in a network

[145] 'In asserting that chemical compounds cannot be inventions, Dr. Ruby proposes to narrow a meaning of the word "invention"'. P. J. Federico, 'Patents for New Chemical Compounds' (1939) 21 *Journal of the Patent Office Society* 544, 549, n 10. McElroy was critical of Ruby arguing that 'invention' was a non-nuclear noun: which had no nucleus of definite meaning accepted by everybody … it was 'a mere verbal peg on which patent people hang correlations of fact'; 'it was something on which to join issues and kick about'. K. P. McElroy, 'Invention' (1931) 13 *Journal of the Patent Office Society* 565. See also K. P. McElroy, 'Elements in Patent Law' (1929) *Industrial and Engineering Chemistry* 608.

[146] In dealing with new subject matter, patent law was forced 'to penetrate more and more deeply into the mysteries of nature' and the 'essential characteristics of inventions'. William C. Robinson, *The Law of Patents for Useful Inventions: Vol 1* (Boston: Little Brown and Co, 1890), 115.

[147] This is similar to Bachelard who said that in 'modern chemistry, synthesis is the very process of invention, a process of rational creativity in which the rational plan for making an unknown substance is posed from the beginning as the problem that leads to the project. We can say that synthesis represents a process of penetration for modern chemistry, progressively penetrating in the course of realizing the project'. G. Bachelard, (1953) quoted in Bernadette Bensaude-Vincent, 'Gaston Bachelard (1884–1962)' in (ed) D. M. Gabbay et al., *Philosophy of Chemistry* (United States: Elsevier, 2011), 141, 147.

[148] William C. Robinson, *The Law of Patents for Useful Inventions: Vol 1* (Boston: Little Brown and Co, 1890), 412.

[149] Ibid., 228.

[150] Ibid.

[151] Ibid., 127.

of relations with other chemical actors',[152] Robinson saw the process of inventing a chemical compound as a collaborative or joint effort between the chemist and nature (not unlike Roald Hoffmann's view of chemical synthesis as being like a game of chess played between the chemist and nature). The joint invention of chemical compounds (which Ruby recognised if only to ridicule)[153] occurred either when an inventor 'sets into operation certain forces acting on certain materials and so conditions the force in action that their resultant produces a new product in consequence of intra-molecular changes, he has made a patentable invention',[154] or when the inventor recognised those new products. By configuring invention as a process whereby the chemist could work alongside nature in the generation of chemical compounds, Robinson was able to justify the recognition of empirically based chemical compounds as patentable inventions.

Patent law's willingness to configure the invention so that it was able to accommodate the empirical nature of chemical subject matter revealed itself in a number of ways, the most notable being when determining when an invention came into existence. The need to determine when an invention was first created arose because US patent law (then) operated on the basis of a first-to-invent system of registration, which meant that it was often necessary to determine the priority of inventions among competing 'inventors'. In determining when an invention was first created, patent law traditionally distinguished between the initial conception of an invention and the subsequent reduction of that conception to practice, which was the point in time when, at least for mechanical inventions, the invention was considered to have come into existence.[155]

In discussing 'conception' and 'reduction to practice', Robinson noted that while in many cases the act of conception was clearly distinct in point of time from that of

[152] See B. Bensaude-Vincent and J. Simon, *Chemistry: The Impure Science* (London: Imperial College Press, 2008), 203. For Gaston Bachelard 'artificial products, including natural substances in a chemically purified form, are social productions in the evident sense of implicating the structured co-operation of humans in their elaboration'. Cited in Bernadette Bensaude-Vincent and Jonathan Simon, *Chemistry: The Impure Science* (2nd edn, London: Imperial College Press, 2012), 50.

[153] If 'man' could be 'a co-inventor with nature, of novel true chemical compounds, (certainly a most generous concession), then patents granted solely to, and in the name of, man, a "joint-inventor" with nature, would be void'. Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part II' (1941) *Temple University Law Quarterly* 321, 349. Ruby also spoke of nature as sole inventor: 'if chemical compounds are solely the handiwork of nature, and are not in the slightest measures, the products of man's inventive ability, then, by inexorable logic, we arrive at the faintly amusing conclusion that nature, or whatever entity directs the scheme of things is the sole inventor of each and every true chemical compound'. Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part II' (1941) *Temple University Law Quarterly* 321, 349.

[154] George S. Ely, *Chemical Inventions and Discoveries: A Paper Read November 23, 1916 before the Examining Corps of the United States Patent Office* (Washington, DC: The Law Reporter Printing Company, 1916), 18.

[155] Robinson saw the inventive act as a continuous process which 'begins with the conception of the idea of means; it ends with the embodiment of that idea in a practically operative art or instrument'. That is, 'conception of the idea was sometimes instantaneous, sometimes gradual; the reduction to practice being in one case easy and rapid, in another slow and difficult'. William C. Robinson, *The Law of Patents for Useful Inventions: Vol 2* (Boston: Little Brown and Co, 1890), 537–38.

reduction, in some cases it was not possible to separate conception from reduction to practice. In these cases no date could be fixed 'as that before the conception was complete and after which the reduction to practice was begun'. For Robinson, this often occurred with inventions that were the result of experiment, 'where the inventor, instead of evolving the entire art or instrument out of his own thought, conjectures that such an act of substance will subserve a given purpose, and having tried it, finds that it accomplishes the end'. While Ruby had dismissed this as non-inventive, Robinson said that the 'production of a new means by this method is, equally with the former, an inventive act, but at no instant before the experiment succeeds can it be said that the conception of the invention exists in the inventor's mind. Until that instant it is mere speculation, at most a probable deduction from facts already known; and the same act which reduces it to practice gives to the conception its definite and final form'. Hence the date of the conception 'in such cases is the date, not when the experiments begin, but when they end; and the first to bring the art or instrument into successful operation is the first conceiver of the entire invention'.[156]

Robinson's proposal that to accommodate empirical-based chemical compounds, invention had to be reconfigured was taken up by the Court of Custom Patent Appeals in the 1940 decision of *Smith v Bousquet*,[157] a dispute about the priority of an invention for the use of a chemical compound as an insecticide. Drawing on Robinson, the court said that in the 'experimental science of chemistry and biology' the 'element of unpredictability frequently prevents a conception separated from actual experiment and test. Here the work of conception and reduction to practice goes forward in such a way that no date can be fixed as subsequent to conception but prior to reduction to practice'.[158] This meant that the fact that someone had formed a hypothesis that a group of chemical compounds might exhibit insecticidal activity did not matter. This was because conception did not occur until the inventor successfully completed experiments showing the feasibility of the idea and, as a result, conception and reduction to practice were inseparable. In other words, it was not possible for a chemist to predict the effectiveness of the compounds unless they actually performed experiments. Prior to this, the idea remained 'mere speculation or possibly a probable deduction from facts already known' but not conceived for the purposes of patent law.[159]

[156] Ibid. Where an invention is reached by a series of experiments, the one who first succeeds, not the one who first begins, is the first inventor. *Taylor* v. *Archer* (1871) 8 Blatch 324, 4 Fisher 456; *National Filtering Co* v. *Artic Oil Co* (1871) 8 Blatch 416, Fisher 514.

[157] *Smith* v. *Bousquet* 111 F.2d 157 (CCPA 1940), 45 USPQ 347. Given that chemical inventions had long been patented, this reconfiguration was in response to the rise of the mechanistic model of invention that had taken hold by this time.

[158] Ibid. See also *Dunn* v. *Ragin* v. *Carlile* Final Hearing in the US Patent Office; Patent Interference No. 77,764 (6 December 1940).

[159] *Smith* v. *Bousquet* 111 F.2d 157, 159 (CCPA 1940). The need for different standards reflects 'the fundamental differences between invention in engineering-related disciplines and the empirical sciences, such as pharmaceuticals and biotechnology'; Jackie Hutter, 'A Definite and Permanent Idea? Invention in the Pharmaceutical and Chemical Sciences and the Determination of Conception in Patent Law' (1995) 28 *The John Marshall Law Review* 687, 688.

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Despite Ruby's best efforts, his attempts to undermine chemical patents on the basis that they were not inventions failed. With little or no fanfare, patent law was able to configure the invention in such a way that it was able to accommodate the empirical nature of chemical subject matter. In so doing, the law was able to accommodate an important feature of chemical subject matter. In Chapter 3, I look at the way patent law dealt with a fickle, empirical, and rapidly changing subject matter.

3

Informed Subject Matter

INTRODUCTION

One of the challenges that a fickle, empirically based, and rapidly changing subject matter posed for nineteenth-century patent law was working out how to define the boundaries of what was being examined or protected. While patent law employed a number of different strategies to delimit chemical subject matter, one stood out. This was the decision to treat intangible chemical property as if it was coextensive with the material chemical compound described in the patent, that is, with the compound itself. Unlike with mechanical inventions, where protection extended beyond the machine as described in the patent to include inventions that were considered to be legally equivalent to the patented invention, the intangible property in a patented chemical compound was not only treated as if it was coextensive with the material chemical compound, it was also treated as if it was a 'chemical individual'[1] or a 'singular point in the general field of matter'.[2]

The decision to deal with some of the idiosyncrasies of organic chemistry by treating the intangible chemical property as if it was coextensive with the individual chemical compound was evident in the way that chemical subject matter was interpreted for the purpose of determining whether it met the doctrinal requirements of novelty and non-obviousness. While in considering the novelty of other types of subject matter, the law was willing to analogise and extrapolate away from the prior art; this was not the case where the prior art consisted of chemical compounds, where the information was restricted to the material chemical compound. The reason for this was that while it was often possible with mechanical inventions to predict whether the operation of a novel material substituted in an old combination could achieve similar results, this

1 *Dickerson* v. *Mauer* 113 Fed 870, 874 (CCA 3d 1902). Henry Guerlac, 'Quantification in Chemistry' (1961) 52(2) *Isis* 194, 196.

2 Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part II' (1941) *Temple University Law Quarterly* 321, 336.

was not the case with chemical compounds where prediction could not occur without experiment.[3]

Similarly, as it was not possible to predict what chemical subject matter would be like without creating it first, the courts were cautious about assuming the obviousness of a step taken by a chemist, even when the prior art was very close.[4] This can be seen, for example, in the 1928 Supreme Court decision of *Corona Cord Tire Company* v. *Donovan Chemical Corporation*, which concerned a patent for a chemical compound (an 'accelerator') that improved the elasticity, tensile strength, and other desirable commercial qualities of finished rubber products. The patent in question was for the discovery of a new type of accelerator, called diphenylguanidine. As the patent noted, diphenylguanidine was closely related chemically to another type of guanidine – triphenylguanidine – which had already proven itself useful as an accelerant. Drawing on the fact that the chemical compositions resembled each other, the petitioner argued that the patent was invalid because the utility of diphenylguanidine as an accelerator was 'plainly indicated by general chemical knowledge'.[5] That is, a person skilled in the art could have discovered diphenylguanidine merely using knowledge which 'was fully and readably available to everybody in the art and without exercising any inventive faculty whatsoever'. Chief Justice Taft disagreed saying that 'the catalytic action of an accelerator cannot be forecast by its chemical composition, for such action is not understood and is not known except by actual tests'.[6]

The decision to treat the intangible chemical property as if it was coextensive with the material chemical compound was also evident in the way that chemical subject matter was construed when questions of infringement arose. In many areas of patent law, a desire to protect the equity of an invention – that is a desire to ensure that third parties were unable to avoid an accusation of infringement by making minor (non-inventive) changes to the invention – led to patents being read in a way that extended protection beyond a strict literal reading of the claims to include similar or equivalent inventions. Under the doctrine of equivalents, for example, protection extended to include situations where a would-be infringer replaced or substituted part of an invention with something that performed the same or equivalent function. As Robinson said, an equivalent meant the 'interchangeability of agencies which are known in the arts to be capable of serving the same purpose as integral parts of the invention. By identity is meant, not the identity of tangible embodiments, but identity of effect, function or means'.[7]

3 *Naylor* v. *Alsop Process* 8 Cir., 168 F. 911, 918 ('reasoning by analogy in a complex field like chemistry is very much more restricted that in a simple field like mechanics').

4 *Ex Part Hentrich* 38 USPQ 249 (1937).

5 *Corona Co.* v. *Dovan Corp.*, 276 U.S. 358, 368 (1928).

6 Ibid., 368–69. Anthony William Deller, 'Principles of Patent Law Involved in the Weiss Patent Litigation' (1928) *Industrial and Engineering Chemistry* 1361, 1362. In 'chemistry one cannot anticipate a result. A result may be obtained only be experiment'. *United Chromium* v. *International Silver* 53 F.2d 390. Ridsdale Ellis, *Patent Claims* (New York: Baker, Voorhis, 1949), 275.

7 William C. Robinson, *The Law of Patents for Useful Inventions: Vol 1*, (Boston: Little Brown and Co, 1890), 336.

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What occurs in these situations is that the scope of the subject matter is shaped by legal considerations such as fairness to the patentee or a desire to protect the equity in the patent. Whatever term is used, the result is the same: the scope of the subject matter extends beyond a literal scientific or technical understanding to include things which are deemed to be legally equivalent.

While the doctrine of equivalents was widely applied in patent law, the idiosyncratic nature of organic chemistry meant that it was not extended to chemical compounds.[8] Specifically, the lack of prevision that was a characteristic of organic chemistry meant that it was not possible to abstract away from the invention as specified in the claim to include equivalent inventions. This was because while it was possible to 'predict with confidence in mechanics, in chemistry you almost entirely fail … as you can not anticipate the result'.[9] As one commentator noted, with mechanical inventions it was generally possible to state with certainty whether a mechanical element was equivalent to another element. It was possible to 'substitute a gear by a pulley, or a cam by a crank and obtain exactly the same result'. However, 'in chemistry no one element or reagent is universally equivalent to another, and in most cases it is not possible to predict that they are absolutely equivalent except by actual experiment'.[10] This was because '[y]ou cannot, because sulphuric acid will succeed, tell at all that nitric acid will succeed, or that any other acid will succeed, until you have tried. You cannot anticipate the result: it is a mere question of result upon experiment'.[11] Or, as Ruby put it, the fact that a chemical compound was 'an embodied utterly unique indissoluble ensemble of properties' meant that there were 'no equivalents of a chemical compound': the only equivalent of a chemical compound was the compound itself.[12] This meant that unlike the case with mechanical inventions, where protection extended beyond the machine as described in the patent to include inventions that were considered to be legally equivalent to the patented invention, the intangible property in a patented chemical compound was treated as if it was coextensive with the material chemical compound.

The decision to treat chemical subject matter as if it was a closed, singular, and bounded object that was coextensive with the material chemical compound reached its highpoint in the procedural requirement that as part of the application process patentees were required to deposit specimens of their chemical inventions

[8] *Stevens* v. *Keating* (1847) 2 *Webster* 181. 'I do not go along with doctrine of equivalents in chemistry. While you could predict with confidence in mechanics … in chemistry you almost always fail … you cannot anticipate the result'. For a rare case where chemical equivalents were recognised see *Treibacher-Chemische Werke* v. *Roessler & Hasslacher Chemical Co* 219 Fed. Rep. 210 (magnesium held to be equivalent of iron, which led to a finding of infringement).

[9] *Stevens* v. *Keating* (1847) 2 *Webster* 18.

[10] Joseph Rossman, *The Law of Patents for Chemists* (Washington, DC: The Inventors Publishing Company, 1932), 59.

[11] *In re Martin's Patent* (1848) 2 *Webster* 172.

[12] Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part II' (1941) *Temple University Law Quarterly* 321, 351.

FIGURE 3.1 Ferrous carbonate patent specimen
Josiah Lilly, 'Composition for the Production of Ferrous Carbonate' US Patent No. 876,366 (14 Jan 1908). Courtesy of the Division of Medicine and Science, National Museum of American History, Smithsonian Institution.

with their written descriptions at the Patent Office (see Figures 3.1–3.3). This long-standing requirement, which exists in a modified form today, was first introduced into US patent law by the 1793 *Act to Promote the Progress of Useful Arts*.[13] The 1793 law provided that where the invention was of a composition of matter, every inventor was required to submit 'specimens of the ingredients, and of the composition of matter; sufficient in quantity for the purpose of experimentation'.[14] Patent Office practice of exhibiting models and specimens was formalised in the 1836 Patent Act, which provided that 'models and specimens of compositions … patented and unpatented deposited in the Patent Office, should be arranged in suitable galleries and kept open for the inspection of the public'.[15] The rules in relation to specimens

[13] As Judge Rich said in 1980, the Commissioner's ability to require the applicant of a composition of matter to furnish specimens or ingredients for the purpose of inspection or experiment under section 114 of the 35 USC 112 was 'a continuation of the ancient authority vested in the Commissioner to require a model, specimen, or ingredient'. *In re Application of Breslow* (1980 Cust and Pat App) 616 F.2d, 205 USPQ 221, 227.

[14] Where the invention was of a composition of matter, Section 3 of the 1793, *An Act to promote the progress of Useful Arts; and to repeal the act heretofore made for that purpose* (21 February 1793) required every inventor to submit 'specimens of the ingredients, and of the composition of matter; sufficient in quantity for the purpose of experimentation'. See William C. Robinson, *The Law of Patents for Useful Inventions: Vol 1* (Boston: Little Brown and Co, 1890), 88. The 1790 Act spoke of model and drawings.

[15] Patent Act of 1836 (An Act to promote the progress of useful arts, and to repeal all acts and parts heretofore made for that purpose (4 July 1836)). Section 6: 'where the invention or discovery is of a composition of matter' applicants had to 'provide specimens of ingredients, and of the composition of matter, sufficient in quantity for the purpose of experiment'. Section 20 provided that 'models and specimens of compositions … patented and unpatented deposited in the Patent Office, should be arranged in suitable galleries and kept open for the inspection of the public'.

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FIGURE 3.2 Explosive compound patent specimen
Harry D. Van Campen, 'Explosive Compound' US Patent No. 288,516 (13 Nov 1883).
Courtesy of Hagley Museum and Library.

remained unchanged until the 1870s when because of a growing concern about the cost of storing and exhibiting models and specimens, the law was changed so that applicants were only required to 'furnish specimens of the composition, and of its ingredients, sufficient in quantity for the purpose of experiment, if required by the Commissioner'.[16] Despite this change, the Patent Office rules retained the proviso that where an article was not perishable, 'a specimen in the composition claimed, put up in proper form to be preserved by the office must be furnished'.[17]

Initially, the public were alerted to the existence of specimens by patentees in their patents, usually in the description but sometimes in the claims. For example, Robert Bartholow's 1865 patent for an improved oil for paint stated: 'I do hereby declare that the following is a full and exact description … being had to

[16] 1870 Congress abolished the legal requirement of models, but the Patent Office kept its requirement until 1880. Act of 1870, ss 28 and 29, RS 4890, 4891 (1874).

[17] *Rules of Practice in the United States Patent Office* (Revised 1 February 1883), Rule 61. When an invention or discovery is a composition of matter, the applicant, if required by the commissioner, shall furnish specimens of the composition, and of its ingredients, sufficient in quantity for the purpose of experiment. In all cases where the article is not perishable, a specimen in the composition claimed, put up in proper form to be preserved by the office must be furnished'. It was for the patent office to determine 'whether the nature of the case admitted of specimens'. *Badische Anilin & Soda Fabrik* v. *Cochrane* 2 Fed. Case 339, Case 718 (CC, 15 April 1879). See also 1920 Rule 61: Under the Patent Act, if required by the Commissioner, applicants were required to provide specimens of compositions of matter and their ingredients, sufficient in quantity for the purpose of experiment. 'In all cases, where the article is not perishable, a specimen of the composition claimed … must be furnished' E. J. Stoddard, *Annotated Rules of Practice on the United States Patent Office* (Detroit: Fred S. Drake, 1920), 216 (re Rule 62) (also rules 56, 60, and 61); Rev Stat. sec 4890.

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FIGURE 3.3 Detergent compound patent specimen
Edward Henderson, 'Detergent Compound' US Patent No. 259,389 (13 June 1882). Courtesy of Hagley Museum and Library.

the accompanying specimen'.[18] Similarly, the 1845 patent for a new and improved dye made from spent madder called 'carasene' stated that: 'A specimen of the spent madder from which the carasene is made accompanies the specification in a packet marked "spent madder", and of the dye-stuff, after it is prepared, in another packet marked "carasene"'.[19] From 1880, notification that a specimen had been lodged as part of a patent application shifted from the body of the patent to the header material, where it accompanied information about the patent, including the name of inventor and assignee, the name of the invention, when the application was filed, and the date when the patent was granted (see Figure 3.4). From 1880 to 1905, the Patent Office also included information about whether a specimen had been deposited with a patent – 'specimen' or 'no specimen' – in the monthly summary of patented inventions that was published in the Patent Office's *Official Gazette* (see Figure 3.5).[20]

[18] Robert Bartholow, 'Improved Oil for Paint' US Patent No. 47,083 (4 April 1865).
[19] Frederick Pfanner, 'Improvement in Preparation of Dye-Stuff from Spent Madder' US Patent No. 4,192 (13 September 1845).
[20] The practice of indicating whether a specimen had been deposited in conjunction with compound inventions in the Official Gazette by either 'Specimen' or 'No Specimen' ended in 1905. As Commissioner Allen said: 'Hereafter the words. "No Specimens" will be omitted from the specifications and drawings of patents when … specimens have been admitted as part of the applications, under Rule 56. The word … "Specimen" will be prefixed to the specification and inscribed upon the drawing when a … specimen has been so admitted'. F. I. Allen, 'Models and Specimens' (Order No.

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UNITED STATES PATENT OFFICE.

JOSIAH K. LILLY, OF INDIANAPOLIS, INDIANA, ASSIGNOR TO ELI LILLY & COMPANY, OF INDIANAPOLIS, INDIANA, A CORPORATION OF INDIANA.

COMPOSITION FOR THE PRODUCTION OF FERROUS CARBONATE.

No. 876,366. **Specification of Letters Patent.** **Patented Jan. 14, 1908.**

Application filed September 1, 1906. Serial No. 333,026. (Specimens.)

To all whom it may concern:

Be it known that I, Josiah K. Lilly, a citizen of the United States, residing at Indianapolis, in the county of Marion and State of Indiana, have invented certain new and useful Improvements in Composition for the Production of Ferrous Carbonate, of which the following is a specification.

The object of my invention is to produce in liquid form a mixture or solution which will remain practically permanently in condition to readily produce ferrous carbonate for introduction into the human system. Attempts have heretofore been made to this end but difficulty has been experienced in preventing the oxidation of the ferrous iron.

I have discovered that by suspending or dissolving a ferrous salt, as for instance ferrous sulfate, in a liquid carrier which will protect it from oxidation and by associating with this mixture or solution a carbonate, or substance capable of furnishing the CO_3 group at the moment of use, a solution or mixture may be obtained which may be kept for a considerable period with only slight oxidation of the ferrous iron. It is preferable that the liquid carrier be soluble in water, to facilitate introduction into the system, and I deem it advisable to use a carrier of this kind which is practically inert therapeutically, such a substance for instance as glycerin.

In producing the compound I find the following method advisable. A ferrous salt, such for instance as ferrous sulfate, is dissolved in glycerin; to this mixture is added a carbonate, preferably sodium carbonate, or potassium carbonate, being careful not to introduce an excess of the carbonate. If desired the carbonate may first be dissolved in glycerin and this mixture added to the glycerin solution of the ferrous salt. If desired a hydroxid, such for instance as sodium or potassium hydroxid, may be used instead of the carbonate and the mixture then carbonated with carbon dioxid.

In practice I have found that, for producing the medicine in commercial quantities, the following formula has been satisfactory. 1. In 11 gallons pure glycerin, dissolve by aid of gentle heat, 3 pounds, 4 ounces, 292 grains pure ferrous sulfate. 2. In 4 gallons pure glycerin, dissolve by aid of gentle heat, 1 pound, 10 ounces, 90 grains pure potassium carbonate. 3. When cool, place solution (1) in an earthenware vessel of sufficient capacity and add slowly, with stirring, solution (2). When thoroughly mixed, pour sufficient pure mineral oil to cover the surface in order to protect from oxygen and moisture in air. It is now ready to be drawn off below into bottles. This produces about 15 gallons.

If desired, mannite may be substituted for glycerin as it possesses substantially the same qualities, with respect to ferrous salts and any desirable carbonate, as gylcerin although it is a soft solid at ordinary temperatures and, if a liquid mixture is desired, it will be advisable to mix a small proportion of glycerin with the mannite.

I claim as my invention.

1. A composition consisting of a stable solution of a ferrous salt and an alkaline carbonate in a neutral liquid miscible with water and forming a protection against oxidation of the ferrous salt, substantially as described.

2. A composition consisting of a stable solution of ferrous sulfate and potassium carbonate in a neutral liquid miscible with water and forming a protection against oxidation of the ferrous sulfate, substantially as described.

3. A liquid composition consisting of a stable solution of a ferrous salt and an alkaline carbonate in glycerin.

4. A liquid composition consisting of a stable solution of a ferrous salt and potassium carbonate in glycerin.

5. A liquid composition consisting of a stable solution of ferrous sulfate and an alkaline carbonate in glycerin.

6. A liquid composition consisting of a stable solution of ferrous sulfate and potassium carbonate in glycerin.

In witness whereof, I, have hereunto set my hand and seal at Indianapolis, Indiana, this 30th day of August, A. D. one thousand nine hundred and six.

JOSIAH K. LILLY. [L. S.]

Witnesses:
Arthur M. Hood,
Thomas W. McMeans.

FIGURE 3.4 Lilly Patent
Josiah Lilly, 'Composition for the Production of Ferrous Carbonate' US Patent No. 876,366 (14 Jan 1908). Courtesy of the United States Patent and Trademark Office.

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dies while the sheet is interposed between said dies, said means being adapted to buckle the sheet to conform approximately with the dies before said sheet is compressed by the dies.

2. In a device of the class described, the combination of a pair of opposed embossing dies, one of the same being movable toward and away from the other, means for imparting a reciprocating movement to said movable die, feed mechanism controlled by said means and adapted to feed a sheet of material into position between said dies when the same are separated, and means adapted to operate in advance of the dies for buckling a sheet to approximately conform to the shape of the dies before said sheet is compressed thereby.

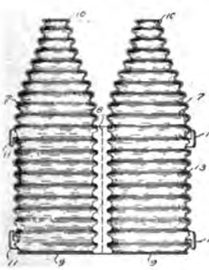
3. In a device of the class described, the combination of a pair of opposed dies, one of said dies being movable toward and away from the other and said dies being adapted to co-act with each other for embossing a sheet of material, and a part mounted on one die extending in advance thereof for buckling the paper to approximately conform to the shape of the dies, said part being adapted to yield to permit the remainder of the die to engage the sheet for pressing the same to form.

4. In a device of the class described the combination of a pair of opposed dies, one of said dies being movable toward and away from the other and said dies being adapted to co-act with each other for embossing a sheet of material, a part mounted on the movable die, being normally extended in advance thereof for buckling the paper to approximately conform to the shape of the dies and being adapted to yield to permit the remainder of the die to engage the sheet for embossing the same, and means for causing said part to recede with said movable die for a certain distance and then to assume its advanced position for discharging the sheet.

5. In a device of the class described, the combination of a pair of opposed dies, one of said dies being movable toward and away from the other and said dies being adapted to co-act with each other for embossing a sheet of material, a part mounted on the movable die and having a limited sliding movement longitudinally of the path of the movement thereof, and a stop adapted to engage said part when said die is moving away from the other die and cause said part to shift on the die for discharging a sheet therefrom.

[Claims 6 to 10 not printed in the Gazette.]

876,365. BOTTLE-WRAPPER. WILLIAM D. LEGGE and LOUIS N. WEIL, Chicago, Ill., assignors to Universal Bottle Wrapper Company, Chicago, Ill., a Corporation of South Dakota. Filed July 30, 1906. Serial No. 328,358.



A bottle wrapper, comprising two similar parts, having corrugated side-walls formed to surround a bottle, said walls being provided with integral flanges extending inwardly at one end of the wrapper to protect the corresponding end of the bottle, each of said parts being provided upon one edge with a pair of oppositely directed hook-like ears adapted to be interlocked for holding together the parts of the wrapper at one side, said parts being joined together at the opposite side.

876,366. COMPOSITION FOR THE PRODUCTION OF FERROUS CARBONATE. JOSIAH K. LILLY, Indianapolis, Ind., assignor to Eli Lilly & Company, Indianapolis, Ind., a Corporation of Indiana. Filed Sept. 1, 1906. Serial No. 333,026. (Specimens.)

1. A composition consisting of a stable solution of a ferrous salt and an alkaline carbonate in a neutral liquid miscible with water and forming a protection against oxidation of the ferrous salt, substantially as described.

2. A composition consisting of a stable solution of ferrous sulfate and potassium carbonate in a neutral liquid miscible with water and forming a protection against oxidation of the ferrous sulfate, substantially as described.

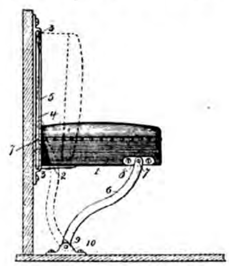
3. A liquid composition consisting of a stable solution of a ferrous salt and an alkaline carbonate in glycerin.

4. A liquid composition consisting of a stable solution of a ferrous salt and potassium carbonate in glycerin.

5. A liquid composition consisting of a stable solution of ferrous sulfate and an alkaline carbonate in glycerin.

[Claim 6 not printed in the Gazette.]

876,367. FOLDING SEAT. EDWARD LINDOW, Toledo, Ohio. Filed June 29, 1906. Serial No. 323,979.



1. In a folding device of the character described, a seat, a pair of legs pivoted at their upper ends to the lower part of the seat near its forward edge, floor-brackets, pivotal connections between the floor-brackets and the lower end of the legs, upright guides at the rear of and above the horizontal plane of the seat, said pivotal connections being disposed in advance of the plane of said upright guides and means upon the seat for slidably engaging said guides.

2. In a folding device of the described character, a seat, a pair of legs disposed at opposite sides of the seat, pivotal connections between the upper ends of the legs and the seat near its forward edge, a pair of floor-brackets adapted to be rigidly secured to a floor, a pair of slotted guide-plates adapted to be secured to a wall at opposite sides of and to the rear of and above the horizontal plane of the seat, said floor-brackets and slotted guide plates being disposed in different vertical planes, and laterally projecting pins at the rear of the seat engaged with and adapted to slide in the slots of said plates.

3. In a folding device of the described character, a series of seats disposed side by side, a pair of legs for each seat, pivotal connections between the upper end of the legs and the forward part of the seat, pivotal connections between the lower end of the legs and the floor, an upright guide-plate having guides for each neighboring pair of seats, said guide-plate being disposed above the horizontal plane of the seat and in a vertical plane back of said floor pivots, and means upon the seats at their rear for slidably engaging said guides.

FIGURE 3.5 USPTO Official Gazette summary of Lilly patent
US Patent Office, Josiah Lilly, 'Composition for the Production of Ferrous Carbonate' US Patent No. 876,366 (14 Jan 1908), patents granted January 14, 1908 (1908) 132 *Official Gazette of the United States Patent Office* 255. Courtesy of the United States Patent and Trademark Office.

Historically, there has been very little consideration given to chemical specimens and the role they play in patent law. To the extent that they have been discussed, it was usually as an afterthought when patent models were being considered. As with chemical patents generally, chemical specimens were overshadowed by mechanical inventions and their models. While it is unclear how frequently specimens were used and what role they played in the examination process, there is evidence to suggest that in the later part of the nineteenth century, specimens were commonly used when chemical compounds were patented (even when the use of patent models declined). As Walker said in his 1883 patent law treatise, the Commissioner 'does at least call for at least a specimen of the composition, put up in proper form to be preserved, unless that composition is in its nature perishable'.[21] Specimens were also important enough in 1880 for the Patent Office to include information about whether a specimen had been deposited in the header information of each chemical patent and in the Official Gazette.[22] While it is difficult to obtain exact figures, an examination of the chemical patents granted across the later part of the nineteenth century shows that specimens were widely used. It also seems that specimens continued to be used in the early part of the twentieth century. As Hugo Mock wrote in 1911: 'It is a somewhat curious feature of Patent Office practice that for some years the only department of the Patent Office requiring what may be termed models of inventions, is that relating to novel chemical products, as specimens of new chemical products are generally requested by the Patent Office examiners. It is many years since models have either been requested or accepted in other lines of invention.'[23]

Chemical specimens performed a number of different roles in patent law. Like patent models, specimens functioned as proof of the existence of the invention.[24] In the

1,616) Department of the Interior, United States Patent Office (6 December 1904) *Official Gazette of the United States Patent Office* 1421.

21 Albert H. Walker, *Text-Book on the Patent Laws of the United States of America* (New York: L. K. Strouse & Co, 1883), 83–84 (citing Revised Statutes, section 4890 and Patent Office Rule 61).

22 This coincided with the introduction of the new Rules of Practice in the United States Patent Office, Revised 1 December 1879 (in effect 1 January 1880).

23 Hugo Mock, *Handbook of Chemical Patents: How Procured, Requisites of, and Other Information Concerning Chemical Patents in the United States and Abroad* (Washington, DC: Mason, Fenwick and Lawrence, 1911), 16. By 1915, it was said that a specimen would only be required when the Examiner found it useful or necessary but that 'as a rule models or specimens are neither asked for nor desired'. Seabury Mastick, 'Chemical Patents II' (1915) *The Journal of Industrial and Engineering Chemistry* 874.

24 The utility of patents issued for making iron and steel directly from ore was determined from specimens which 'seem[ed] to possess considerable utility'. Annual Report of the Commissioner of Patents (1865), 17. Edward Thomas, *Handbook for Chemical Patents* (New York: Chemical Publishing Company, 1940), 183. The retention of chemical specimens was seen as an integral part of good laboratory practice. For example, an 1869 article in Scientific American extolling the virtues of both chemical inventions and their patenting, spoke of what was needed if someone was to invent an alloy that could substitute for brass. Following a life-work of systematic experiment, the chemist was advised to record 'the results of his experiments in tables, and preserving specimens of all alloys possessing any useful quality, and patenting such as prove applicable to special purposes, could not fail of success and fame'. Anon, 'Chemical Inventions' (20 February 1869) *Scientific American* 121, 121–22.

same way in which the Patent Office used the model requirement as a way of deterring applicants from applying for improbable inventions such as perpetual motion machines, the specimen requirement was also seen as a de facto workability requirement for chemical compositions.[25] For example, in an action relating to the patentability of artificial alizarine (a red dye originally obtained from the root of the madder plant) that was produced from the chemical compound anthracene (that was derived from coal tar), it was argued that the absence of a specimen showed that the claimed artificial alizarine was not a patentable composition of matter. While there was some indication that workability was one of the reasons why specimens were required in the United States, it was not a primary reason. This was in contrast to the position in the United Kingdom where from 1907 applicants for chemical patents were required to deposit samples of their invention at the UK Patent Office. This was to prevent foreign (German) patentees from lodging incomplete or faulty applications, or applications that did not properly disclose how to make the patented invention.[26]

Importantly, because the specimens deposited at the US Patent Office had the same proportions of elements as the chemical compound that had been made in the laboratory, the specimen not only functioned to define the invention: the specimen *was* the invention. By requiring applicants to place their chemical inventions in glass bottles, paper sachets, and metal cans, the chemical specimen helped to reinforce the mental or semiotic representation of the chemical substance as an individual bounded object. This also allowed chemical compositions to be seen as bounded 'wholes' (which helped to answer the question of what it means to speak of closed chemical subject matter given that chemical compounds as liquids, powders, amorphous solids, and gases have no inherent shape or form). In turn, by limiting protection to the specific substance contained in the specimen bottle, paper sachet, or metal can, the specimen requirement also reinforced the idea that protection was not available for abstract classes or groups of inventions. That is, it helped to individualise the subject matter.

[25] The Paige Bill, which proposed to add to section 4886 a 'compulsory working' provision, sought to make it necessary for foreign patentees to manufacture their products in the US within two years after a patent had been granted. See Bernhard C. Hesse, 'Compulsory Working of Patents in the United States. Germany and Great Britain' (1915) 7 *The Journal of Industrial and Engineering Chemistry* 304; Bernhard C. Hesse, 'Coal-Tar Dyes and the Paige Bill' (1915) 7 *The Journal of Industrial and Engineering Chemistry* 963.

[26] Sections 2(5) of the UK 1907 *Patent and Designs Act* (along with rule 36 of the 1908 *Patent Rules*). Specimens were required in many other jurisdictions. For example, the Hawaiian patent law of 1884 required applicants in relation to compositions of matter to furnish specimens of the ingredients and the final product 'sufficient in quantity for the purpose of experiment'. Act of 29 August 1884, to regulate the issuing of patents, section 4. In Switzerland (Law of 15 November 1888) patents were not granted for 'inventions which do not in themselves represent a visible and tangible marketable article'. As part of this process, applicants were required to deposit specimens of the invention. In Switzerland, prior to 1907, a requirement that all inventions needed to be able to be represented by a model meant that all chemical inventions (along with manufacturing processes) were excluded from protection. P. J. Federico, 'Patents for New Chemical Compounds' (1939) *Journal of the Patent Office Society* 544, 545.

Interestingly, the ability for chemical samples to individualise inventions was used by the German Patent Office in the 1880s to deal with a problem that had arisen in relation to chemical patents in Germany. While the German Patent Law of 1877 excluded chemical substances from the scope of patentability, it did allow chemical inventions to be patented insofar as they 'concerned "a particular process" (*ein beslimmles Verfahren*) for the manufacture of such substances'. While the law had been designed to exclude product patent protection for chemical compounds, nonetheless applicants attempted to use the fact that the law did not define what was meant by a particular process to circumvent the exclusion by indirectly claiming large classes of compounds.[27] This was particularly the case with azo dyes (which was a large class of synthetic organic dyes). The reason for this was that the dye industry used a specific process called a coupling reaction or Griess's method to produce new synthetic compounds that involved 'the pairwise combination of diazo compounds with aromatic amines or phenols to form azo compounds, i.e., compounds with a double nitrogen (azo) group uniting aromatic rings'.[28] The making of azo dyes was 'an endless combination game. The number of possible combinations was estimated at more than 100 million'.[29]

Building on the fact that the coupling reaction used by the dye industry could be construed as a *particular* process, patent applications for processes for the preparation of chemical substances frequently claimed the protection of groups or classes of compounds that had been produced by this process. To maximise protection, patents in the field of azo dyes also often claimed classes of analogues, homologues, and isomers of those compounds. As a result, patents for chemical inventions would often claim hundreds of individual substances. The practice of claiming classes or groups of compounds (rather than individual compounds) not only created administrative problems for the German Patent Office, who had to examine and classify the applications, by effectively allowing de facto product protection it also undermined German patent policy that had sought to exclude chemical products from the scope of patentability. In 1887 the German Patent Office responded to this problem by issuing a regulation that required patent applicants to provide samples of the substances for which they claimed protection.[30] As the new regulation stated:

> In view of the fact that patent applications for processes for the preparation of chemical substances frequently claim the protection of entire groups of bodies without convincingly demonstrating the technical utility of the individual members of

[27] Henk van den Belt and Arie Rip, 'The Nelson-Winter-Dosi Model and Synthetic Dye Chemistry' in (ed) Wiebe E. Bijker, Thomas P. Hughes, and Trevor Pinch, *The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology* (Cambridge, MA: The MIT Press, 2012), 129, 151.

[28] Ibid., 146.

[29] Ibid., 151.

[30] This was criticised because it put individual inventors at a disadvantage with respect to large scale industry. Ibid., 152–53. See also Andrew Pickering, 'Decentering Sociology: Synthetic Dyes and Social Theory' (2005) 13(3) *Perspectives on Science* 352, 395.

> these groups, samples of the substances presented will be kept in the Patent Office so that, for instance, if they are important pieces of evidence in the course of any controversy and for the appraisal of new patent applications, in accordance with the wishes of the industrialists involved.[31]

While an exception was made in the case of explosive substances, the new regulation provided that for 'those patent applications which relate to new methods of presentation of chemical substances, samples of these substances, as well as those intermediaries necessary for the production of substances which are still unknown, should be attached in two copies'. Specifically, applicants had to submit samples with a mass of approximately 8–10 grams in glass flasks of approximately 30 mm diameter and 80 mm height with glass stoppers, sealed with the seal of the patent examiner, and with a description matching the contents provided. By limiting protection to individual physical samples, the German Patent Office found a way of excluding applications for classes of chemical compounds. As in the United States, the intangible chemical property was treated as if it was coextensive with the chemical compound in the glass flask.[32]

The treatment of intangible chemical property in the United States as if it was coextensive with the material chemical compound was effectively a taxonomic-like decision that limited chemical subject matter to the level of species.[33] One of the consequences of this was that the intangible chemical property did not extend *upwards* to include more abstract classifications such as classes or families of chemical compounds, nor to what a more generous abstract (equity-based) legal reading might have provided. It also meant that the intangible property did not extend to equivalent or similar inventions, to abstractions of the invention, nor to other inventions in a species-genus like relationship. Rather, patented chemical compounds were treated as if they were interchangeable with the individual material chemical compound. In this sense, patent law mirrored nineteenth-century organic chemistry

[31] Der Präsident des Kaiserlichen Patentamt, 'Bekanntmachung: 19 March 1887' (1887) 12 *Patentblatt und auszüge aus den patentschriften* (Berlin 23 March 1887), 119.

[32] A similar process occurred in the UK in the beginning of the twentieth century. Sections 2(5) of the 1907 Patent and Designs Act (along with rule 36 of the 1908 Patent Rules) introduced a provision into British law that gave the Comptroller the power to demand the submission of samples in the case of chemical patents. This arose because 'in the past some patentees have framed their specifications in such a way as to secure proprietary rights in whole classes of imaginary chemical processes and not tried to make all the substances covered by the specification'. Anon, 'Patents for Chemical Inventions' (13 April 1907) *The Lancet* 1033.

[33] Claims were 'limited to the precise ingredients mentioned in each, no more and no less. They do not stand in the relation of genus and species to each other nor as combinations and sub-combinations'. A. M. Lewers, 'Composition of Matter' (1921–22) *Journal of the Patent Office* 530, 546. 'Species … are not equivalents and therefore comprehensive claims are needed to cover them. Species are distinct inventions and involve patentable differences. No range of equivalents can therefore overcome a patentable difference'. Joseph Rossman, *The Law of Patents for Chemists* (Washington, DC: The Inventors Publishing Company, 1932), 214; citing *Cheatham Electric Switching Device Co* v. *Brooklyn Rapid Transit Co* 238 Fed Rep 172 (1915).

where the 'most fundamental category of chemical practice – that is, of experimentation and classification – was that of a chemical substance'.[34]

The legal focus on specific compounds rather than on more abstract classes of subject matter helped US patent law to deal with the empirical nature of chemical subject matter. It also allowed the law to deal with the fickleness of chemical compounds, with the fact that slight changes in the ingredients in a compound or the conditions under which the ingredients were combined could fundamentally change the nature of the resulting compound. This was done by ensuring, for example, that if an inventor disclosed a new chemical compound (sulphanilyl cyanamide) that was made up of five elements: carbon (42.6%), hydrogen (3.5%), nitrogen (16.3%), sulphur, (16.3%), and oxygen (21.3%) with the empirical formula $C_7H_7N_3SO_2$, they would not be entitled to claim 'a compound consisting of carbon, hydrogen, nitrogen, sulphur and oxygen' because of the rule that 'an inventor is not entitled to claims broad enough to cover subsequent independent discoveries of others'.[35] While in this case the inventor may have discovered one compound consisting of these five elements, they 'would not be entitled to a patent covering every other compound which might therefore be discovered having those same elements in its make up'.[36] For similar reasons, an inventor was not entitled to claim a range of the various elements such as a 'compound consisting of carbon 15 to 45 %, hydrogen 2 to 6 %, nitrogen 10 to 25 %, sulphur 15 to 39 % and oxygen 10 to 40%',[37] the reason being that these proportions would extend to cover a number of different chemical compounds with very different structures and properties, including taurine ($H_2NCH_2CH_2SO_3H$), acetylthiourea ($CH_3CONHCSNH_2$), and nitrothioene ($NO_2C_4H_3S$).

The treatment of the intangible chemical property as if it was coextensive with the material chemical compound also meant that the intangible chemical property did not extend *downwards* (or internally) to the hidden microworld of the chemical compound. Rather protection was limited to the surface of the compound. In this sense, patent law followed the practice within science where the inability to explain what went on below the surface meant that when chemists interpreted or represented the results of their experiments or when they described and talked about what they had created, they 'were restricted to an operational level of macroscopic objects'.[38] To do this, patent law embraced the agnosticism that allowed chemists to work with and create new chemical compounds without having to commit to a

[34] Ursula Klein, 'The Creative Power of Paper Tools in Early Nineteenth-Century Chemistry' in (ed) Ursula Klein, *Tools and Modes of Representation in the Laboratory Sciences* (Dordrecht: Springer, 2001), 15.

[35] Ridsdale Ellis, *Patent Claims* (New York: Baker, Voorhis and Co, 1949), 584.

[36] Ibid.

[37] Ibid.

[38] Ursula Klein, 'Objects of Inquiry in Classical Chemistry: Material Substances' (2012) 14 *Foundations of Chemistry* 7, 10. See also Wolfgang Lefèvre, 'Viewing Chemistry through Its Ways of Classifying' (2012) 14 *Foundations of Chemistry* 25, 31.

particular way of thinking about what went on below the surface in chemical compounds.[39] In so doing it allowed patent law to deal with the fact that organic chemists were unable to explain the reasons why things had happened and why it was, for example, that mixing compound A with compound B produced compound X.

Based on the idea that the 'law requires no further certainty than science can afford',[40] patent law was indifferent to what happened below the surface of the compound, to the reasons why chemical change occurred, and to the workings that occurred when ingredients were combined. It did not matter, for example, that the 'method by which the ingredient perform[ed] its function in the combination' may have been 'entirely undiscernible',[41] nor that 'the inventor was … in total ignorance of the scientific nature of what he employed and what he did'.[42] Instead, all that mattered was that the patentee had created something that could be called a composition of matter, that they had ensured that the composition was in a format that allowed third parties to replicate the invention, and that they had met the other criteria for patentability.[43] For example, in response to an argument that a patent for a 'spirit varnish' that gave leather a bronze finish similar to a French metallic bronze finish was invalid because the specification did not explain why 'the articles are so compounded as to produce a chemical change', Justice Sheplex said it was 'not essential that the inventor should have been sufficiently understood or accurately stated the philosophy of a process which he had invented and reduced to practical use'.[44] So long as the specification allowed for the invention to be used, this was enough. It did not matter that the reasons why something occurred were unknown; what was important was that the end result was achieved by following the directions in the patent.[45]

39 In the same way in which the agnostic nature of the rational formula allowed chemists to take for granted that the formulas were true representations of the composition of the substances being investigated, they also allowed chemists to 'go on with their experiments and identification of material substances without having to answer many theoretical problems … their mode of comprehending chemistry was independent of an explanation of chemical combination at a deeper level'. Ursula Klein, 'Objects of Inquiry in Classical Chemistry: Material substances' (2012) 14 *Foundations of Chemistry* 7, 10.

40 William C. Robinson, *The Law of Patents for Useful Inventions: Vol 1* (Boston: Little Brown and Co, 1890), 411.

41 Ibid.

42 *Reed* v. *Street* 34 OG 339, 86 CD 65 (1885).

43 While in most cases, chemical reactions were simply black-boxed and ignored; one exception was William Robinson who explained 'the intermixture of ingredients results in the co-operation of their respective forces in such a manner as to produce a new force, which is distinct from the forces of the individual elements and from the sum of their collective forces, and is exhibited in the new qualities with which the composition is endowed'. William C. Robinson, *The Law of Patents for Useful Inventions: Vol 1* (Boston: Little Brown and Co, 1890), 279.

44 *Cahill* v. *Beckford* (April Term, 1871), Circuit Crt, D. Mass, Case No 2,290, 1003, 1005 (1871). St *Louis Stamping Co* v. *Quinby* 16 Official Gaz 135 (1880); *Andrews* v. *Cross* 8 Fed Rep 269 (1881). Anthony Deller, *Principles of Patent Law for the Chemical and Metallurgical Industries* (New York: The Chemical Catalog Company, 1931), 66.

45 *Cahill* v. *Beckford* (April Term, 1871), Circuit Crt, D. Mass, Case No 2,290, 1003, 1005.

While the law's response to the fact that chemists were unable to explain what was happening beneath the surface was typically framed as one of indifference, the law's pragmatic acceptance of the end products of the research process was not neutral. This was because although the law may have been indifferent to the reasons why chemical change occurred, this did not mean that the science that it accepted was. Like a Trojan horse, the veil of legal indifference not only allowed patent law to accommodate and protect organic chemical compounds, it also allowed certain types of scientific thinking to be inculcated within the law. Although science could not explain why and how chemical change occurred, it did embody theories (models, formulas, etc.) about what was going on, along with the language, rules, and techniques to identify and describe what was created. This was particularly the case in relation to the acceptance of chemical formula as a way of representing chemical compounds. This is because the writing of a chemical formula 'is not innocent. It is ideology laden. It carries, besides its face value, another message; in this case, the modern reunification of the theoretical and the experimental'.[46] As we will see, the adoption of structural formula in the later part of the nineteenth century profoundly changed the way that patent law interacted with chemical subject matter.

INFORMED SUBJECT MATTER

While the decision to treat intangible chemical property as a singular bounded object that was coextensive with the material chemical compound played an important role in allowing nineteenth-century American patent law to accommodate some of the idiosyncrasies of chemical subject matter, it only tells part of the story. The reason for this is that chemical subject matter was not merely coextensive with the physical chemical compound; it was also an 'informed material' that carried particular ways of thinking about the world with it. The idea of informed material is based on Whitehead's argument that material entities, including chemical compounds and molecules, are not bounded, discrete objects.[47] Rather, material entities extend into other entities while folding elements of other entities inside them. From this perspective, chemical compounds 'should not be seen as discrete objects, but as constituted in their relations to complex informational and material environments'.[48] Importantly, while chemical compounds exist in an informational and material environment, this environment is not simply external to the object. Rather, this environment enters into the constitution of the chemical compound itself.[49] From this

[46] Roald Hoffmann and Pierre Laszlo, 'Representation in Chemistry' 30(1) (1991) *Angewandte Chemie* 1, 3.

[47] Alfred North Whitehead, *Process and Reality* (New York: Free Press, 1978), 80; Andrew Barry, 'Pharmaceutical Matters: The Invention of Informed Materials' (2016) 22(1) *Theory, Culture & Society* 51.

[48] Andrew Barry, 'Pharmaceutical Matters: The Invention of Informed Materials' (2016) 22(1) *Theory, Culture & Society* 51, 52.

[49] Whitehead, who focused on the variability of the *association between* atoms and molecules (rather than the invariability of atoms and molecules, as Ruby had done), saw chemistry as a science of

perspective, the research process operates to build information into the chemical compound. In this sense, to say that a material entity such as a chemical compound is informed or 'rich in information' is to say that the material *embodies* information.

The result of this is that even when chemical substances were treated as closed, fixed objects, they still embodied information that connected compounds to other compounds, that told something of the compound's past (and whether it was novel and non-obvious) and, in some cases, its potential future (utility). Patent law relied upon the informed nature of chemical subject matter to accommodate the idiosyncrasies of nineteenth-century organic chemistry in a number of ways, perhaps the most important being in the identification of the subject matter (both during the application process and also after protection was granted). Specifically, patent law relied upon the fact that as informed chemical compounds carry their context with them, this meant (at least in theory) that compounds could be traced as they circulated beyond the reach and control of their creators.

The question of how the ephemeral and malleable intangible interest is to be described and identified has long troubled intellectual property law. These problems were amplified with chemical subject matter because chemical reactions (along with 'atoms' and molecular structures) were invisible processes that could not be seen, touched, or otherwise observed.[50] As Judge Lacombe said in the 1897 decision of *Matheson* v. *Campbell*, while the 'observation as the eye can give to the machine at rest and in action … will be ordinarily sufficient to determine its classification', it was 'far different … with a chemical compound'. The reason for this was that '[n]o mere observation by the eye, supplemented even by taste and touch, can go very far towards a solution of the problem. The same mysterious forces through whose action and reaction the compound was produced must be availed of to disintegrate and disrupt before there can be any assurance of what it is that we have before us'.[51] The problems that arose in 'defining something invisible',[52] which Edward Thomas saw as the root cause of many of the problems that arose with chemical subject matter, were compounded by fact that chemical subject matter had no inherent external shape or form.

As Robinson said, the particular nature of chemical compounds led 'to radical differences in the rules by which the identity of these' compounds is determined.[53]

associations. From this perspective he argued that a molecule or chemical compound should not be understood as a table or a rock, but rather as an event: 'a molecule is a historic route of actual occasions; and such as route is an "event"'. Alfred North Whitehead, *Process and Reality* (New York: Free Press, 1978), 80.

50 Ursula Klein, 'Paper Tools in Experimental Cultures' (2001) 32 *Studies in History and Philosophy of Science* 265, 273.

51 *Matheson* v. *Campbell* 78 Fed 910, 917 (CCA 2d, 1897).

52 Edward Thomas, *Handbook for Chemical Patents* (New York: Chemical Publishing Company, 1940), 11.

53 William C. Robinson, *The Law of Patents for Useful Inventions: Vol 1* (Boston: Little Brown and Co, 1890), 279.

To understand the reasons why these rules were so different, it is important to appreciate that the ingredients, along with the way they were combined, were critical to the nature of the resulting chemical compound; a slight change in proportions or the conditions in which the ingredients were combined could lead to a very different compound. In this sense the ingredients determined the nature and make-up of the compound. At the same time, however, chemical compounds differed from other combinations in that once they were united, the 'ingredients or elemental forces' 'often become individually undiscernible by human sense'.[54] This is because chemical compounds do 'not carry any characteristics peculiar to the process used in the manufacture by which the latter could be identified and by which infringement could be established directly'.[55] In other words, a chemical 'composition of matter is a complete and independent means, having an existence distinct from that of the substances of which it is composed, and the processes by which it is created'.[56] One of the consequences of this is that the 'character of a composition of matter cannot … be determined from an examination of its elements alone, nor of the method by which they have been combined. It must be judged also by its own intrinsic attributes'.[57] The upshot of this was that products had to be identified *independently* of the process by which they were made. As Lewers said, 'Every patent for a product or composition of matter must identify it, so that it can be recognised aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process'.[58]

The fact that a chemical compound was integrally connected to the ingredients and how they were combined and, at the same time, independent and distinct from those ingredients meant that description was a two-stage process (which was mirrored in the requirement that patentees needed to deposit specimens of both the ingredients and the resulting compound as part of the application process). This meant that it was necessary to describe the ingredients and how they were combined to create the compound in question. At the same time, it was also necessary for patentees to describe the resulting chemical compound so that it could be identified as an entity in its own right.

The first stage of the process of describing a chemical compound was to detail the ingredients and how they were combined to create the compound in question. The

54 Ibid.

55 B. Herstein, 'Patents and Chemical Industries in the United States' (1912) *The Journal of Industrial and Engineering Chemistry* 328.

56 A chemical composition of matter 'is a group of ingredients intermingled in a specific manner and producing a specific result which has new properties of its own'. William C. Robinson, *The Law of Patents for Useful Inventions: Vol 2* (Boston: Little Brown and Co, 1890), 101.

57 William C. Robinson, *The Law of Patents for Useful Inventions: Vol 1* (Boston: Little Brown and Co, 1890), 280.

58 *Holliday* v. *Pickhardt* (1887) 29 Fed 853 quoting *Cochrane* v. *Badsiche Anilin & Soda Fabrik* 111 US 293, 4 Sup Crt 455 (1884). Although chemical compounds needed to be evaluated independently of the ingredients, nonetheless the ingredients and the manner in which they were combined formed part of the tests of identification. A. M. Lewers, 'Composition of Matter' (1921–22) *Journal of the Patent Office* 530, 532 (the 'mode of operations to produce the composition is undiscernible').

fickle nature of chemical compounds meant that it was important that the ingredients that were used to create a composition were set out clearly and precisely.[59] This was because while replacing 'an iron bar in place of a wooden one and serving the same purpose' did 'not change the identity of the machine', with chemical inventions even a very small change either in the ingredients used or in the way that the ingredients were combined could lead to a very different compound.[60]

As Rossman explained in his 1932 treatise on chemical patent law, a 'patent for a composition of matter must name or describe and give the exact proportions of the ingredients used in addition to describing how the ingredients are mixed or combined to give the desired result. Inasmuch as the discovery of a new substance by means of chemical combination is empirical, and results from experiment, the law requires that the description in a patent for such a discovery should be specially clear and distinct'.[61] Unlike the case with mechanical compounds, where the law was willing to allow the patentee to leave the proportions to be determined at a later stage (so long as the elements and their characteristics were known), with chemical compounds, where the end result was often dependent on the precise proportions used, the law not only required the patentee to provide details about the ingredients and how they were to be combined, it also required patentees to provide details about the specific proportions needed to produce the compound.[62]

In order to describe ingredients with the requisite degree of precision, patentees tended to describe the ingredients in terms of proportions or ratios, rather than in terms of a fixed specific weight (such as 'rosin, three hundred pounds, Kentucky cement seventy-five pound' etc.[63]). As Ruby said, chemical compound were 'defined and claimed in terms of the chemical elements that are ultimately composed, by bloc- or graphic formula, parts-by-weight, or percentages compositions, and hence in terms of invariant ratios of the amounts of the chemical elements present in chemical combination in the true chemical compounds'.[64] In some cases (particularly in earlier patents), the proportions were simply listed in the patent, such as in US Patent Number

59 'Exactness of detail should be given in describing the invention'. George S. Ely, *Chemical Inventions and Discoveries: A Paper Read November 23, 1916, before the Examining Corps of the United States Patent Office* (Washington, DC: The Law Reporter Printing Company, 1916), 10.

60 *Hicks* v. *Kelsey* (1873) 18 Wall 670.

61 Joseph Rossman, *The Law of Patents for Chemists* (Washington, DC: The Inventors Publishing Company, 1932), 37.

62 *North American Chemical* v. *Dexter* 252 F. 147, 165 (1916) US Dist 908. *Tyler* v. *Boston* (1868) 7 Wallace 327.

63 For full list of ingredients see C. D. Smith, 'Improved Paint for Wood, Metal, and Woven Fabrics' US Patent No. 68,661 (10 September 1867). Occasionally patents would combine the two. For example, a 1845 patent for a new dye provided specific quantities (such five gallons of water, three pounds of washed madder, eight ounces of soda dissolved in warm water) and the advice that the specification was for three pounds of spent madder and that 'for a greater or less quantity a corresponding quantity of the other material must be used'. Frederick Pfanner, 'Improvements in Preparation of Dye-Stuff from Spent Madder' US Patent No. 4,192 (13 September 1845).

64 Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Unpatentable Subject Matter: Part I' (1940) *Temple University Law Quarterly* 27.

45,518 for 'Improved Composition for Crayons', which said that for ordinary school uses on a blackboard, the crayon should be made up using the 'formula': 'kaolin 48 parts, calclined plaster-of-paris (gypsum) 16 parts, water 35 parts, and white glue 1 part'.[65] More commonly, the proportions were captured in empirical or rational formula that specified the elements and their proportions in the patented compound. Thus, for example, US Patent Number 775,978 claimed a new product, 'a fragrant oil having the [empirical] formula $C_{15}H_{26}O$'.[66] Or, US Patent Number 719,720, which claimed a new indigo-reducing agent that had 'a chemical composition corresponding to the [rational] formula $Na_2S_2o_4 + 2H_2O$'.[67] Here, the chemical formula, which provided a succinct guide or blueprint to the elements in a compound, denoted its composition and helped to distinguish it from other compounds. The fact that the ingredients were listed in proportions or ratios rather than in fixed quantities reinforced the idea that a chemical compound was an individual that had no inherent size or (external) shape and whose parameters were determined by the proportion of its parts.

The fickle nature of chemical compounds also meant that it was important that the patentee provide clear and precise instructions as to how the ingredients were combined.[68] Typically, the descriptions of how the ingredients were to be blended read like cooking recipes. For example, an early patent for artificial alizarine (dye) began by stating: 'We take one part, by weight of anthracine, two and half parts, by weight, of biochromate of [potash], potassa, and ten or fifteen parts, by weight, of concentrated acetic acid, and we heat these substance together in a vessel either of glass or clay to about 100° centigrade to 120° centigrade, till nearly all of the bichromate of potash is dissolved and the liquid has acquired a deep green colour'.[69]

As well as describing the ingredients and how they were combined in order to create the compound, it was also necessary for patentees to describe the resulting chemical compound as an entity in its own right. Importantly, this had to be done in such a way that the compound could be identified independently of the ingredients that it was made up of. For the most part, patent law followed the practice within chemistry when it came to describing and identifying chemical compounds.[70]

[65] Isaac Peirce, 'Improved Composition for Crayons' US Patent No. 45,518 (20 December 1864).
[66] Max Kerchbaum, 'Process for Making Sesquiterpene Alcohol' US Patent No. 775,978 (29 November 1904).
[67] Max Bazlen, 'Hydrosulfite for Reducing Indigo' US Patent No. 719,720 (3 February 1903).
[68] Robinson advised against adding anything that was not part of the ingredients to stop people claiming they were not infringing. William C. Robinson, *The Law of Patents for Useful Inventions: Vol 2* (Boston: Little Brown and Co, 1890), 101.
[69] See *Cochrane* v. *Badische Anilin & Soda Fabrik* 111 U.S. 293, 295; 28 L ED 433, 434 (1884).
[70] Patentees were advised to follow the Journal of the American Chemical Society, which sets out the 'minimum and desirable standards of description of new compound'. Eugene Geniesse, 'Adequate Description' (1945) 27 *Journal of the Patent Office Society* 784, 785. The Journal of the American Chemical Society's notice to authors of papers (in a sheet inserted at the beginning of each new edition) specified the 'minimum and desirable standards of description of new compounds'. Geniesse suggested that these instructions should form the basis for a standard of adequate description in composition cases.

While the techniques used to describe chemical subject matter changed considerable across the nineteenth century,[71] one thing that remained constant was that the identification of chemical substances 'always took place on the macroscopic level of substances'.[72]

At the beginning of the century, plant and animal materials were identified and classified according to their natural origin, the mode of extraction or preparation, observable properties, and practical uses.[73] Using these criteria, early chemists were able to distinguish and characterise a substantial number of simple chemical substances such as sea salt, soda, magnesia, potash, along with certain elements (such as sulphur). 'These were set apart from each other by qualitative distinctions: texture, color, odor, taste, the source from which the material was obtained, or the use to which it was put.'[74] Early chemical patents followed this practice and described chemical subject matter using qualitative criteria.

As the century progressed, patentees increasingly relied on more quantitative 'chemical' criteria to describe their chemical compounds.[75] Thus, patentees began to describe their chemical substances in terms of physical constants and measurable chemical properties such as how the compound reacted when it was combined with other compounds (or reagents), along with the all-important melting and boiling points (which were 'the best tools available for the identification of substance').[76] For example, the traditional practice of describing sugars by their sweet taste and their ability to support fermentation was slowly supplemented by descriptions that

[71] The improvements that occurred in the chemist's ability to identify chemical compounds was the result of an array of factors including a better understanding of chemical reagents, improved chemical apparatus (notably glassware) that allowed chemists to control the reaction, purification, and characterisation of substances more accurately, improvements and standardisation of laboratory techniques (such as the depth thermometers should be submersed in a liquid), and laboratory training, which aimed to produce reliable results (such as how to use standard reagents, how to coax products to crystalize, how to measure reliable melting points, and how to perform accurate quantitative analyses). See Catherine M. Jackson, 'Emil Fischer and the "Art of Chemical Experimentation"' (2017) 55(1) *History of Science* 86, 93.

[72] Ursula Klein, 'Objects of Inquiry in Classical Chemistry: Material Substances' (2012) 14 *Foundation Chemistry* 7, 11.

[73] Ursula Klein and Wolfgang Lefèvre, *Materials in Eighteenth-Century Science: A Historical Ontology* (Cambridge, MA: MIT Press, 2007), 299; N. W. Fisher, 'Organic Classification before Kekulé' (1973) 20 *Ambix* 106, 107; Catherine M. Jackson, 'Chemical Identity Crisis: Glass and Glassblowing in the Identification of Organic Compounds' (2015) 72 *Annals of Science* 187, 202–3.

[74] Henry Guerlac, 'Quantification in Chemistry' (1961) 52(2) *Isis* 194, 196.

[75] These quantitative criteria were used to define compounds 'in concrete units of measurable physical or chemical quantities … a boiling point of 100° F, being a physical condition does not depend upon the imagination of the individual and is certainty is definite' Carroll F. Palmer, 'Patent Claim Construction and the Halliburton Oil Case' (1947) *Journal of the Patent Office Society* 515, 521.

[76] Catherine M. Jackson, 'Emil Fischer and the "Art of Chemical Experimentation"' (2017) 55(1) *History of Science* 86, 89. See also Catherine M. Jackson, 'Chemical Identity Crisis: Glass and Glassblowing in the Identification of Organic Compounds' (2015) 72 *Annals of Science* 187. The melting point is still one of the standard characterizing techniques employed. Joel Bernstein, 'Structural Chemistry, Fuzzy Logic, and the Law' (2017) *Israel Journal of Chemistry* 124, 126.

used empirical formula, melting points, and hydrazine tests (which examined how the compound reacted with phenylhydrazine).[77] While the Patent Office did not formally insist on a particular 'style or phraseology', patentees were advised 'to use the conventional chemical nomenclature wherever possible for the sake of definiteness and clarity'.[78] As we will see in Chapter 4, patentees followed this advice and adopted the naming practices developed by chemists to identify chemical compounds.[79]

The result of this was that as well as including the name and chemical formulae of the patented compound, it was also common for compounds to be described in terms of how they looked, smelt, or tasted, along with their melting and/or boiling point, and a description of what happened when particular chemical reagents were applied to the compound. To situate and contextualise the subject matter in relation to similar types of subject matter, patentees also often included a history of the invention, along with what amounted to a 'brief essay on the materials or the steps usable and a brief mention of the difficulties and failures of the prior art, and to include detailed examples of practising the invention'.[80] For example, US Patent Number 400,086, which was for a pharmaceutical product known commercially as 'phenacetine' and chemically as 'mono-acetyl-paramido-phenetol', stated:

> The product herein described, which has the following characteristics: it crystallizes in white leaves, melting at 135° centigrade; not colouring on addition of acids or alkalies; is little soluble in cold water, more or so in hot water; easy soluble in alcohol, ether, chloroform, or benzole; is without taste; and has the general composition $C_{10}H_{13}O_2N$.[81]

In a similar manner, Hoffman and Weinbergs's 1886 patent for 'a new coloring matter', which they called napthol-black, was described as producing 'on the fiber in an acidulated bath dark-blue shades' and as being 'very soluble in water, insoluble in spirit, dissolves in strong sulphuric acid with green color'.[82]

While patent law followed the practice within chemistry of describing chemical compounds in terms of how they smelt, looked, and tasted, the temperature that

77 Catherine M. Jackson, 'Emil Fischer and the "Art of Chemical Experimentation"' (2017) 55(1) *History of Science* 86, 107.

78 Joseph Rossman, *The Law of Patents for Chemists* (Washington, DC: The Inventors Publishing Company, 1932), 110. Patentees were advised not to use trade-names to describe chemical compositions, given that their meaning was often transient and their composition subject to change. Ibid.

79 Eugene Geniesse, 'Adequate Description' (1945) 27 *Journal of the Patent Office Society* 784, 785. If the law is to adopt a scientific term such as homology for a legal purpose, 'it has an obligation to employ that term in its scientific context'. Bruce M. Collins, 'The Forgotten Chemistry of the Hass-Henze Doctrine' (1962) *Journal of the Patent Office Society* 284, 285.

80 Edward Thomas, *Handbook for Chemical Patents* (New York: Chemical Publishing Company, 1940), 20–21.

81 Oskar Hinsberg, 'Phenacetine', US Patent No. 400,086 (26 March 1889) (Specimens); upheld in *Dickerson* v. *Mauer* 108 Fed 233 (CCED Pa 1901); affd 113 Fed 870 (CCA 3d 1902).

82 Meinhard Hoffman and Arthur Weinberg, 'Naphthol-Black Color Compound' US Patent No. 345,901 (20 July 1886).

they boiled or melted at, and how they responded or reacted when combined with other compounds, patent law added a subtle twist. This was because rather than merely providing a description of a compound's witnessable properties, the description of a compound in a chemical patent also included specific instructions that explained how the identity of the compound was to be determined.[83] That is, the descriptions included the experimental tests that were to be used to identify the patented compounds.[84] As Judge Lacombe said, these 'tests of identity' were 'devised by those skilled in the art and science of chemistry, which, in their opinion, as experts, will reveal the secrets of the composition to make the answer to the question positive enough to support the judgement of a court'.[85] In this sense, patentees included both the experiments and the results of those experiments in their patents as ways of identifying their patented chemical compounds.

Like many things in relation to chemical subject matter, the process of identification and description used in patent law was an inherently empirical process.[86] As in organic chemistry, the process of identifying and classifying chemical compounds in patent law was 'tied to processing and interpreting the experimental marks of the invisible object, and to the application of sign systems, culturally impregnated with meaning, in that endeavour'.[87] In the absence of any other way of identifying a chemical substance, the alleged infringing or anticipating compound was 'tried' to determine whether it met the experimental criteria set out in the patent: did it 'melt at 135° centigrade', was it 'easily soluble in alcohol, ether, chloroform, or benzole' and 'without taste'?[88] Patentees used the presence or absence of these identifying traces or 'marks of identification'[89] as litmus tests for determining whether a compound was the same as or different to the patented compound. If a claimant could show that the product 'answers all the tests of the patent, and other well-known test not therein named', this was taken as proof of similarity.[90] As the court said in

[83] Edward Thomas, *Handbook for Chemical Patents* (New York: Chemical Publishing Company, 1940), 17–18.

[84] *Pickhardt* v. *Packard* (1884) 22 Fed 530.

[85] *Matheson* v. *Campbell* (CCA, 13 January 1897), 78 Fed Reporter 910, 917.

[86] This is similar to the crimes of witchcraft, rape and poisoning in the early modern period which were seen as quintessentially hidden acts that depended on the evidence of things unseen. As in patent law, criminal law allowed indirect evidence – *indicia* –to stand as sufficient grounds of proof without recourse to torture (circumstantial evidence). This was in contrast to wounds which were seen as a classic legal exemplar of visible and physical violence. See Ian A. Burney, 'Testing Testimony: Toxicology and the Law of Evidence in Early Nineteenth-Century England' (2002) 33 *Studies in History and Philosophy of Science* 289.

[87] Ursula Klein, 'Introduction' in (ed) Ursula Klein, *Tools and Modes of Representation in the Laboratory Sciences* (Dordrecht: Springer, 2001), viii.

[88] *Badische Anilin & Soda Fabrik* v. *Cochrane* 2 Fed Case 339, 342 (CC, 15 April 1879).

[89] In *Maurer* v. *Dickerson* 113 F 870 (CCA, 1902), Judge Acheson said the 'patent in suit describes a new product with such clear marks of identification that it readily be recognised aside from the process of making it'. That is, the compound had sufficient 'distinguishing characteristics' for it to be patentable.

[90] In relation to process patents, once a plaintiff had shown using the tests of identity that products were the same, the onus shifted to the defendant to prove that the (same) product was made by a different

Matheson v. *Campbell*, (an action in relation to a patent for a black azo dye), the 'proofs show satisfactorily … that the defendants' colouring matter possesses the same peculiar characteristics of the patented article'.[91] This was sufficient 'to establish the chemical identity of the defendants colouring matter with the complainants by the evidence of the results produced by each in the experimental tests'.[92]

One of the consequences of the decision to use experimental tests to identify chemical compounds was that it increased the role that science played within the legal process. Another consequence of the decision to use experimental tests to identify chemical compounds was that it further embedded the chemist as expert within patent law.[93] This was because chemists not only devised the tests that were used to identify chemical compounds, they were also called on to undertake those tests and to interpret and explain the results to the courts.[94] While experts were commonly used in patent law to assist the courts in reaching decisions, the nature of chemical subject matter meant that the chemical expert or 'patent chemist'[95] took on a particular importance. While with a mechanical device like a drill or a typewriting machine, 'the deliverances of the experts are mere aids to the comprehension of the structure. If there be disputes among them as to how various parts are correlated and how they act, a judge must examine the device and decide for himself as to which is correct'. However, the situation was different with chemical patents. The reason for this was that there were 'things which the independent senses cannot appreciate, which cannot be seen or felt or heard … the reactions of bodies into some chemical union or disunion, are matters in which a court must perforce depend upon the assertions of someone who has made a profound study of the matter'.[96] As a result, when dealing with chemical patents, the court had to 'wait till someone skilled in

process; *Matheson* v. *Campbell* 77 Fed Reporter 280, 281 (Circuit Court, SD New York, 18 May 1896). When the body 'under investigation fails to responds to the specific test the patentee has himself selected, he cannot fairly insist that it is identical with his product'; *Matheson* v. *Campbell* (Circuit Court of Appeals, Second Circuit, 13 January 1897, 78 Fed Reporter 910, 917.

91 *Matheson* v. *Campbell* 77 Fed Reporter 280, 281 (Circuit Court, SD New York, 18 May 1896).

92 *Pickhardt* v. *Packard* (1884) 22 Fed 530.

93 The 'multiplication of … analytical instruments served to give chemists social authority in their role as experts in legal proceedings'. Bernadette Bensaude-Vincent and Jonathan Simon, *Chemistry: The Impure Science* (2nd edn, London: Imperial College Press: 2012), 67. For Klein, this was a consequence of the change in plant materials from 'ordinary, everyday materials and commodities in the eighteenth century to purified carbon compounds and organic substances familiar only to experts in the 1830s'. Ursula Klein, 'Shifting Ontologies, Changing Classifications: Plant Materials from 1700 to 1830' (2005) *Studies in the History and Philosophy of Science* 261.

94 For example, see Complainant's Record, *Read Holliday* v. *Paul Schulze-Berge* (Circuit Court of the United States: Southern District of New York), (New York: Evening Post Job Printing House, 1895) (detailed and lengthy transcript of the evidence of several chemical experts).

95 The label 'patent chemist' was suggested because it made the expert 'more nearly part and parcel of the working staff' of the legal system 'than does the designation "patent expert"'. Bernhard C. Hesse, 'The Patent Expert and Chemical Manufacturer' (1913) *The Journal of Industrial and Engineering Chemistry* 854, 855.

96 Edward Thomas, 'An Outline of the Law of Chemical Patents' (1927) 19 *Industrial and Engineering Chemistry* 176, 177.

the intricacies of that science and art appears to lead the way though its labyrinth of terms and symbols'.[97] Or, as the court said in *Matheson* v. *Campbell*, the determination of the issues raised in relation to the patentability of naphthol-black colour compound was made 'more difficult by reason of the mass of expert testimony concerning chemical characteristics and laboratory processes, which the court cannot verify by inspection or experiment'.[98]

The reliance on technical chemical information within the patent process led to calls for scientific experts to be embodied more formally within the legal process, rather than merely as witnesses (who largely operated as temporary visitors).[99] This included calls for the establishment of 'technical juries' consisting of experts engaged in the industry or science to which the action relates,[100] an unofficial and independent patent court which would be 'equipped to deal quickly, economically and wisely with patents, especially in the highly technical chemical field',[101] and the appointment of 'technical referees to assist the court to pass judgement' on technical chemical patents.[102]

The increased reliance on chemical information within the patent process also added impetus to the calls being made for a chemical laboratory to be established within the Patent Office to allow examiners to test the validity of applications.[103] The growing number of chemical applications was said to 'render it highly desirable, and indeed indispensable, that the examiners should have at hand the means of arriving at correct and definite decisions'.[104] As a research engineer said in 1918, a 'complete fireproof laboratory in the Patent Office Building for making physical, chemical, mechanical and electrical qualitative tests' was needed 'so that any questions arising in the course of the prosecutions as to the actual performance of processes and mechanism could be answered by authoritative tests'.[105] To this end, it was proposed to 'have room fitted up as a laboratory, and that the Commissioner be authorized to procure the requisite apparatus at an

97 Ibid. Specification of a chemical compound was 'not addressed to persons who are ignorant of chemistry'. *Allen* v. *Hunter* Case No 225, Circuit Court D. Ohio, 6 Mclean 303, (April Term, 1855); 1 Fed Case, 476.

98 *Matheson* v. *Campbell* (1895) 69 Federal Reporter 597, 600.

99 A large part of the cost of litigation was said to arise because of the way that chemical inventions were described. Horatio Ballantyne, 'Chemists and the Patent Laws' (June 1922) *The Journal of Industrial and Engineering Chemistry* 529.

100 F. W. Hay, 'Chemical Industry and Patent Law' (1918) *Journal of the Royal Society of Arts* 221, 222.

101 Anon, 'More on Patents' (April 1929) *Industrial and Engineering Chemistry* 299. Thomas W. Shelton, 'Why a Special Patent Court?' (13 May 1921) 92 *Central Law Journal* 333. For a critique see Ford W. Harris, 'Patents and Court Procedure' (June 1929) *Industrial and Engineering Chemistry* 609.

102 L. E. Sayre, 'Patent Laws in Regard to the Protection of Chemical Industry' (1919–1921) 30 *Transactions of the Kansas Academy of Science* 39, 41.

103 The 4500 German-owned patents, which were reputed to be faulty, was said 'to stand as a silent monument to the lack of such a [laboratory]'. See Abraham S. Greenberg, 'The Lessons of the German-Owned US Chemical Patents' (1926–27) 9 *Journal of the Patent Office Society* 19, 31.

104 *Report of the Commissioner of Patents for the Year of 1851* (1852) 32 Congress, Senate Doc No. 118, 18.

105 N. S. Amstutz, 'Needs of the Patent Office' (1918–19) 1 *Journal of the Patent Office Society* 453.

expense not exceeding $800'.[106] The provision of experimental facilities in the Patent Office, which was intended to provide a legal-space in which chemical compounds could be tested and witnessed,[107] would 'enable the examiner to verify or disprove alleged ingredients and results of applicants for patents for materials, processes and compounds':[108] particularly in relation to whether an application met the requirement of adequacy of disclosure.[109]

The repeated calls for the establishment of a chemical laboratory in the Patent Office were reinforced by the absence of a compulsory working requirement in US patent law which allowed foreign companies to take out product patents without requiring them to manufacture the products in the United States.[110] The lack of a working requirement was particularly problematic in relation to chemical compounds given that the only way of knowing whether a patent did what it claimed to do was to follow the instructions in the patent and to replicate the invention. The lack of a working requirement (which would have acted as de facto proof that the written patent properly disclosed how to make the patented compound) created the potential problem that patents could be granted for chemical compounds that did not meet the disclosure requirement. This became a concern in the early part of the twentieth century when complaints were made that many of the chemical patents that had been granted to German companies were 'faulty' in so far as the patented chemical compounds could not be made following the instructions in the patents. The fact that attempts to replicate inventions had been made by scientists of high standing led to the conclusion that the patents contained deliberate misrepresentations and that the 'literature on chemistry was clogged with such deceit'.[111] While it was possible for faulty patents to be invalidated after they had been granted, this was seen as a 'tedious process, necessitating a great amount of laboratory work and expense and loss of time in litigation'.[112]

Despite repeated calls by successive Commissioners of Patents for the establishment of a laboratory within the Patent Office, concerns about ventilation, explosion,

[106] *Report of the Commissioner of Patents for the Year of 1851* (1852) 32 Congress, Senate Doc No. 118, 18. For the UK see F. W. Hay, 'Chemical Industry and Patent law' (1918) *Journal of the Royal Society of Arts* 221 (calling for the establishment of Government laboratories to validate problematic and obscure chemical patents. Mere 'supply of samples' was 'deemed insufficient for this purpose').

[107] On the role of laboratories see Isabelle Stengers, *Power and Invention: Situating Science* (Minneapolis: University of Minnesota Press, 1997), 95.

[108] *Report of the Commissioner of Patents for the Year of 1851* (1852) 32 Congress, Senate Doc No. 118, 18.

[109] See Abraham S. Greenberg, 'The Lessons of the German-Owned US Chemical Patents' (1926–27) 9 *Journal of the Patent Office Society* 19, 26. The problem was made worse by the absence of a compulsory working clause (highlighted by *US* v. *Chemical Foundation* 272 U.S. 1 (1926) which 'revealed that the majority of German owned chemical patents were not of such sufficient and clear disclosure as to teach one skilled in the chemical art in the United States to commercially follow then'. Ibid., 23).

[110] Francis P. Garvan, 'Some Patent History and Its Lesson to American Chemistry' (March 1922) *Chemical Age* 127.

[111] Anon, 'A Patent Abuse' (March 1918) *The Journal of Industrial and Engineering Chemistry* 173.

[112] Ibid.

and fire (the latter being particularly important in light of the fires that had occurred at the Patent Office in 1836 and 1877 and the fact that the call for the establishment of a purpose-built laboratory in the Patent Office came at a time when the 'practice of chemistry had never been more dangerous'[113]), combined with concerns about the cost of building and maintaining a laboratory meant that an in-house laboratory was never built. Other suggestions, including that the Patent Office could make greater use of existing government laboratories such as the Bureau of Standards[114] or that the onus of proof be placed on the applicant to show the 'correctness of the specification'[115] were also rejected: the former because the Bureau was already overworked and the high cost, the later because it thought to be onerous on applicants of 'small means'.

DECOUPLING CHEMICAL SUBJECT MATTER FROM ITS MATERIAL FORM

While the ability of chemists to describe and identify chemical compounds improved greatly across the nineteenth century, many problems remained. In part this was because despite improvements in the accuracy of chemical analysis, there were still many problems including errors in collection, sampling, and measurement[116] caused by things such as inaccuracy in chemist's manipulations, accidental contaminations of samples, or parts of samples being lost when they were moved to new vessels or when they were weighed.[117] As a result, when experiments were repeated, they often yielded different results. Given that 'a relatively small error in the percentage composition could significantly affect the formula assigned to the compound',[118] these errors undermined the accuracy and thus the effectiveness of chemical formulae, which 'remained unstable for much longer than is usually recognised'.[119]

Given that the study of chemical compounds often produced ambiguous outcomes, this undermined the effectiveness and accuracy of the empirical formula

113 Catherine M. Jackson, 'The Laboratory' in (ed) Bernard Lightman, *A Companion to the History of Science* (Oxford: Wiley Blackwell, 2016), 296, 299.

114 Anon, 'A Patent Abuse' (1918) *The Journal of Industrial and Engineering Chemistry* 173–74. See Abraham S. Greenberg, 'The Lessons of the German-Owned US Chemical Patents' (1926–7) 9 *Journal of the Patent Office Society* 19, 31.

115 Anon, 'A Patent Abuse' (1918) *The Journal of Industrial and Engineering Chemistry* 173–74.

116 Melvyn C. Usselman, C. Reinhart, K. Foulser and A. Rocke, 'Restaging Liebig: A Study in the Replication of Experiments' (2005) 62 *Annals of Science* 1, 2.

117 Ursula Klein, 'Paper Tools in Experimental Cultures' (2001) 32 *Studies in History and Philosophy of Science* 265, 274.

118 Catherine M. Jackson, 'Visible Work: The Role of Students in the Creation of Liebig's Giessen Research School' (2008) 62 *Notes & Records of the Royal Society* 31, 46 n 37.

119 Catherine M. Jackson, 'The Curious Case of Coniine: Constructive Synthesis and Aromatic Structure Theory' in (ed) Ursula Klein and Carstein Reinhardt, *Objects of Chemical Inquiry: The Synergy of New Methods and Old Concepts in Modern Chemistry* (Sagamore Beach, MA: Science History Publications, 2014), 61, 70.

that were developed from this empirical information. These problems were compounded by the fact that while patentees used melting and boiling points to identify their compounds, nonetheless the 'problem of how to obtain reliable, comparable boiling points that would function as useful markers of identity and purity proved persistent' across much of the nineteenth century.[120]

Another related problem facing nineteenth century chemistry and by default patent law was that absolute chemical purity was an unobtained ideal: local samples of chemical species were rarely identical with other samples in every single aspect – there were 'varieties of indigo, potash, steel purchased from merchants; varieties of vitriolic acid, nitric air, spirit of wine prepared in the laboratory'[121] – samples often differed in colour, smell, taste, consistency and properties.[122] While the purity of chemical elements improved greatly across the century, this only served to create a new problem; namely, that chemical records were 'often difficult to interpret because the names of substances … remained constant while their purity has undergone changes of various magnitudes'.[123] This undermined the effectiveness of patents as a source of reliable technical information.

The ability for patent documentation to identify and recreate the patented compound was also undermined by the fact that in many cases important aspects of 'chemical knowledge did not reside in formula and structure, but rather in laboratory reasoning, the process by which chemists connected the minutiae of laboratory work with major advances in chemistry'.[124] This was particularly the case in relation to the creation of synthetic chemicals which was dependent 'on practical experience that was developed, learnt and taught in a very particular place: the institutional chemical laboratory'.[125]

These problems were compounded by the fact that in some ways organic chemistry was a victim of its own success. Improvements in chemical knowledge consistently forced chemists to 'differentiate between compounds that were previously considered to be identical, and to recognise as mixtures materials hitherto thought

[120] Catherine M. Jackson, 'Chemical Identity Crisis: Glass and Glassblowing in the Identification of Organic Compounds' (2015) 72 *Annals of Science* 187, 196.

[121] Eduard Farber, 'Errors in Chemical Identification: A Precautionary Note to the History of Chemistry' (1970) 61(3) *Isis* 379.

[122] See, for example, *Matheson* v. *Campbell* where the failure of the defendant's expert to recreate the patented invention from the written specification was explained away on the basis of impurities in the acids used in the experiments. *Matheson* v. *Campbell* (1897) 78 Federal Reporter 910, 914.

[123] Eduard Farber, 'Errors in Chemical Identification: A Precautionary Note to the History of Chemistry' (1970) 61(3) *Isis* 379.

[124] Catherine M. Jackson, 'Emil Fischer and "Art of Chemical Experimentation"' (2017) 55(1) *History of Science* 86, 90.

[125] Catherine M. Jackson, 'The Laboratory' in (ed) Bernard Lightman, *A Companion to the History of Science* (Oxford: Wiley Blackwell, 2016), 296, 304; Catherine M. Jackson, 'The Curious Case of Coniine: Constructive Synthesis and Aromatic Structure Theory' in (ed) Ursula Klein and Carstein Reinhardt, *Objects of Chemical Inquiry: The Synergy of New Methods and Old Concepts in Modern Chemistry* (Sagamore Beach, MA: Science History Publications, 2014), 61, 99.

of as pure'.[126] The constant revision had flow-on effects as it called into question and undermined existing practices which only served to complicate things further.

The ever-expanding number of chemical compounds also presented problems for patent law. Unlike the position with inorganic substances where the relatively small number of substances meant that 'a statement of a novel compound's constituent elements along with an identifying characteristic was enough to identify the compound',[127] the huge number of organic compounds meant that more complex modes of description were needed. The rapid increase in the number of organic compounds not only exacerbated and highlighted the taxonomic and nomenclatural uncertainty that existed, it also made it much more difficult to navigate the prior art (which was essential for determining whether a would-be patent was novel). These problems were reinforced by the fact that it often took some time for the scientific community to reach agreement about a compound's formula. Until this happened, a compound could be represented by a number of different formula. Water, for example, was represented at times as 2H+O, H_2O, and HO. In 1854, there were 11 different formula for acetic acid, which increased to 19 by 1861.[128]

While the ability to name, describe, and identify new compounds was essential to the ongoing success of organic chemistry, it took second place to the creation of new compounds. As a result, there was often a lag between scientific innovations leading to new compounds and the development of the taxonomic tools needed to describe these innovations. This can be seen, for example, in relation to Graebe and Liebermann's 1868 preparation of artificial alizarin (a red dye for cotton and a red pigment in painting) which is often seen as 'the first time a chemist had succeeded in producing a particular target molecule by synthesis'. Prior to this, (natural) alizarin had been sourced from plants and insects. While the creation of the artificial synthetic dye marked a major advance in organic chemistry, the same cannot be said for the way that the invention was described in the patent. This is reflected in the fact that because Graebe and Liebermann were unable to demonstrate either the purity or the chemical identity of their synthetic alizarin, which 'could be used in the same way as various madder compounds', they were limited to identifying their product by the 'yellow

[126] Ibid., 100. See also Catherine M. Jackson, 'Chemical Identity Crisis: Glass and Glassblowing in the Identification of Organic Compounds' (2015) 72 *Annals of Science* 187. 'Since there are indefinitely many characteristic properties in which chemical substances can differ, one has to determine and compare indefinitely many properties of two samples in order to prove their substance identity, which is impossible. Hence, all identity claims in chemistry based on an open set of characteristic properties are necessarily only provisional'.

[127] For example in *Potter* v. *Tone* CD 295, 36 App DC 181 (1911) a claim for a 'compound of silicon and oxygen, which when pure, has a soft brown color' was acceptable.

[128] Alan J. Rocke, 'Vinegar and Oil: Materials and Representations in Organic Chemistry' in (ed) Ursula Klein and Carstein Reinhardt, *Objects of Chemical Inquiry* (Sagamore Beach, MA: Science History Publications, 2014), 47, 50.

flocks of alizarin' that was produced in the compound when a particular process was followed.[129]

The upshot of this was that although there were many improvements in experimental practices across the nineteenth century, a number of problems undermined the accuracy and effectiveness of the way compounds were described and identified both within organic chemistry and by default in patent law. Here, the law was faced with a number of options. One possibility, which was not considered, would have been to deny chemical compounds patent protection on the basis that they did not meet the basic requirements of patentability. Another possibility, which was also not adopted, would have been simply to accept the best efforts of chemists to describe chemical subject matter, forcing examiners, patentees and interested third parties to make do with the descriptions that science could offer.[130] A third option, which was adopted, was to modify and adapt the nomenclatural and taxonomic practices used within chemistry to suit legal ends. As a result, the process of describing and identifying chemical subject matter in patent law became a scientific-legal hybrid. While this took many forms, I focus here on patent law's use of physical specimens as a means of identifying patented chemical compounds. I look at the efforts by the Patent Office to ensure that the scientific prior art was legible to a legal audience in the next chapter.

CHEMICAL SPECIMENS

While specimens did not have a direct bearing on the patentability of chemical compounds[131] nonetheless they played an important role in improving the accuracy and effectiveness of the way compounds were described and identified. In this sense it may appear that chemical specimens operated like patent models to evidence and showcase the invention. While chemical specimens were exhibited alongside patent models in the Patent Office Museum[132] and at industrial exhibitions,[133] they

[129] Charles Graebe and Charles Liebermann, 'Improvements in Dyes or Coloring-Matter Derived from Anthracene' US Patent No. 95,465 (5 October 1869); reissue No. 4,232 (4 April 1871).

[130] Another possibility would have been to reject chemical patents.

[131] *In re Application of Breslow* (1980 Cust and Pat App) 616 F.2d, 205 USPQ 221.

[132] As Keim's 1874 *Illustrated Guide to the Museum of Models at the Patent Office* explained, case 4 in gallery 1 of the Museum contained compounds including specimens of Goodyear's patented vulcanized rubber and samples of glue, soap, salt and candles. R. Keim, *Illustrated Guide to the Museum of Models at the Patent Office* (Washington, DC: Deb Randolph Keim, 1874), 13. In the 1823 classification of patent models, Class XIII was for chemical compositions (patent medicines, cements, dyes etc.): Class XIV was for fine arts included paints and varnishes. *An Authentic account of the fire of September 24, 1877 which destroyed the north and west halls of the United States Patent Office Building* (Washington, DC, 23 October 1877), 8.

[133] The South Gallery of the Great Exhibition of 1851 contained a number of chemical specimens, some of which were either patented or the product of a process that was patented. See *Official Catalogue of the Great Exhibition of the Works of Industry of All Nations* (Cambridge: Cambridge University Press, 1851), 22 ff.

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were very different. This was because while the 'materiality of the model' may have 'provided the basic medium in which inventions were revealed, scrutinized and compared',[134] the materiality of chemical specimens performed a different role. The reason for this was that while patent models (along with some biological specimens) could be evaluated on their face,[135] chemical specimens were mute. As Lloyd Van Doren explained in an article written in the Journal of Chemical Education that introduced chemical students to patent procedure, the key difference related to the fact that 'a mechanical patent has to do with something which is tangible, for example, a machine'. It was 'quite possible for a court to look at the drawings or perhaps even at a model of the machine and be able to satisfy itself that' the machine described in the patent would operate. 'In short, something tangible will be presented'. In contrast, in the case of a 'chemical patent which deals, for example, with a process for making anthraquinone, the court is not able from a drawing or even from a demonstration in the court room to visualise directly the operativeness of that process'.[136]

One of the notable things about chemical specimens was that there was little to see.[137] Other than the specimen number, the names of the patentee (or assignee) and the invention, and the date the compound was patented, a dark glass bottle or a sealed paper sachet revealed little about the intangible chemical property that was hidden inside (see Figures 3.1–3.3). As a clerk of the US Patent Office said when reporting back on his visit to the 1851 Great Exhibition in London, while the machinery displays presented the spectator with 'much to attract his observation and occupy his thoughts', the specimens of chemical and pharmaceutical products provided 'little that was interesting'.[138] The mute nature of chemical specimens meant that chemical proof was something that had to be mediated through the expertise of the chemist.

In so far as chemical samples were objects that either revealed or had the potential to reveal the 'traces of the invisible objects of inquiry', they were there to be

[134] Alain Pottage, 'Law Machines: Scale Models, Forensic Materiality and the Making of Patent Law' (2011) *Social Studies of Science* 621, 624.

[135] Whether it was in the courtroom, where models were required to 'exhibit every feature of the machine which forms the subject of invention' (E. J. Stoddard, *Annotated Rules of Practice on the United States Patent Office* (Detroit: Fred S. Drake, 1920)) or in the Patent Office Museum, where models, which were organised into classes and arranged chronologically, 'illustrated to the eye of the visitor' to the Patent Office Museum – patent models could be construed by non-experts on their face with little or no additional effort.

[136] Lloyd Van Doren, 'What the Chemistry Student Should Know about Patent Procedure III: Preparation of the Application' (May 1929) *Journal of Chemical Education* 966, 969.

[137] In determining whether an application for a process for purifying oil was novel, the Commissioner of Patents said that on examination of the 'specimen of powered copper matte which the appellant has submitted' it was found that 'no separation of the particles can be effected by a magnet'. *Ex parte Frasch* (1896) 77 OG 1427, Decisions of the Commissioner of Patents 77, 79.

[138] Edward Riddle, *Report on the World's Exposition*: Part 1 *Chemical and Pharmaceutical Products* in *Report of the Commissioner of Patents for the Year of 1851* (1852) 32 Congress, Senate Doc No. 118 347, 440.

tested (or at least potentially tested). This was reflected in the language of successive patent statutes which required applicants to provide specimens of ingredients and of the composition of matter 'sufficient in quantity for the purpose of experiment'.[139] While the patent legislation required applicants to deposit samples to allow the application to be tested, as successive Patent Commissioners complained, the absence of an in-house laboratory in the Patent Office meant that it was not possible to examine chemical applications properly. As the Commissioner of Patents Benton J. Hall said, the lack of laboratory facilities in the Patent Office meant that there was 'no means of testing such specimens that have been provided, although obviously within the meaning of the law'.[140] Despite this, specimens were still important.

The reason for this was that by linking the description of the patented invention to the physical chemical specimen, and by ensuring that sufficient materials were available 'to allow experiments to be undertaken that revealed the essential features of the invention',[141] specimens ensured that the accuracy of the written description could be tested during the application process if needed. In doing so, chemical specimens provided 'greater accuracy and completeness in the description of patented inventions'.[142] This was because once a patent had passed through the examination process and received the official imprimatur of the Patent Office, it could be presumed that the written description was accurate: either because the description was clear on its face, or because when the Commissioner asked for a specimen to be deposited, the written description corresponded with the material specimen (if it didn't, the patent would not have been granted). While applicants sometimes provided affidavits that attested to the qualities of the invention, the Patent Office was reluctant to rely upon this information because while the assertions may have appeared to be reliable, as the Commissioner of Patents said, 'in the absence of some means of testing the truth of the facts claimed, it is impossible for the Office to determine with what degree of certainty which should exist whether the invention is novel and useful and should be covered by a patent'.[143]

In this context it did not matter whether or not the patented compound had in fact been tested (the absence of an in-house laboratory within the Patent Office meant that this was rarely the case). It also did not matter if there were problems in the way

[139] Section 6 of the Act of 1836 provided that 'every applicant for a chemical patent shall accompany his application with specimens of ingredients and of the composition of matter, sufficient in quantity for the purpose of experiment'. *Report of the Commissioner of Patents for the Year of 1851* (1852) 32 Congress, Senate Doc No. 118, 18.

[140] *Annual Report of the Commissioner of Patents to Congress for the Year Ending December 31, 1887* (Washington: Government Printing Office, 1888), v.

[141] William C. Robinson, *The Law of Patents for Useful Inventions: Vol 2* (Boston: Little Brown and Co, 1890), 161. 'It is for the Patent Office to decide whether specimens of ingredients should be filed'. *Anilin* v. *Cochrane* (1879) 16 Blatch 155; 4 Bann & A 215; *Tarr v Folsom* (1874) Holmes 312; 5 OG 92; 1 Bann & A 24.

[142] William C. Robinson, *The Law of Patents for Useful Inventions: Vol 2* (Boston: Little Brown and Co, 1890), 156.

[143] *Annual Report of the Commissioner of Patents to Congress for the Year Ending December 31, 1887* (Washington, DC: Government Printing Office, 1888), v.

chemical compounds were described. This is because the legal fiction of the chemical specimen allowed the patent system to operate on the basis that the description was accurate. By ensuring that any potential problems there might have been in identifying or replicating a patented compound were 'resolved', chemical specimens allowed third parties to place trust in the written descriptions of the patented chemical compound.

At first blush it may seem that chemical specimens operated like biological specimens in so far as they provided an objective standard against which the written description could be evaluated. While in some ways they were similar, they differed in a number of ways. With biological subject matter the deposited specimen, the name, and the description all worked in tandem to define the invention.[144] In contrast, with chemical inventions, the specimen did not operate in conjunction with the written description (and the name) to define the invention: the specimen was the thing that was being described: it *was* the invention. This had important consequences for the way patent law interacted with chemical compounds. Because the written description and the chemical specimen were the same thing, and because it was possible to replicate the specimen from the written description, after a patent was granted the written description of the chemical invention could be uncoupled from its material form (unlike the type specimen in biology which is permanently tied to the name and the description). Thus, while during the grant process chemical specimens played an important role in building trust in the accuracy of the written description, after a patent was granted the specimens were no longer needed. Post-grant, the written description not only provided third parties with all that they needed to know about the patented chemical compound (both to identify the compound and to recreate it), they also did so in an easy-to-use and comparatively uncomplicated way. Uncoupling the tangible chemical specimen in this way allowed people interacting with chemical patents to focus on the written description in the patent documentation, rather than having to go through the timely and arduous process of testing the specimen. Post-grant, it was no longer necessary to refer back to the specimen at all. In so doing, it allowed chemical (paper) patents to circulate as immutable mobiles: as closed, fixed, and trustworthy scientific objects.

The shift away from the material specimen towards the written description that occurred after grant was reinforced by the fact that once a patent was granted, the findings of the Commissioner in relation to specimens could not be questioned or challenged. This can be seen, for example, in the 1874 decision of *Tarr v. Folsom*, which concerned a challenge to a reissued patent for an antifouling paint that was said to have 'launched the first industrial revolution in North America, that was commercial fishing'.[145] The patent was challenged on the basis that the reissued patent 'described substantially different inventions from any described and shown in the original

144 When 'biologists identify organisms', they focus on the 'type, side by side with its description, as the standard against which other specimens are measured'. Lorraine Daston, 'Type Specimens and Scientific Memory' (2004) 31(1) *Critical Inquiry* 153, 164.

145 Janie Franz, 'America's first copper paint' (August 2009) (Copper Development Association).

patent … or in the samples filed in the patent office in illustration thereof'.[146] The Circuit Court of New York rejected this argument and held that as the specification 'clearly describes the composition of matter and all the ingredients and proportions, in language perfectly intelligible to those skilled in the art, it would not be invalidated by the failure to deposit in the patent office a sample of one of the ingredients'.[147] Importantly, the court was not willing to reopen the question of the accuracy of the specimen and its relationship to the written description and the intangible chemical property. As Judge Shepley said, the requirement to deposit a specimen was obligatory before the granting of the patent, where it 'was for the commissioner to decide, before granting a patent, whether it is complied with. If he does so decide, and grants the letters-patent, that cannot be subsequently impeached by evidence tending to show a want of compliance with the law as to giving notice, or paying fees, or performing the other acts, or performing the other acts required before the patent is granted'.[148] That is, once the Commissioner had accepted that the written description corresponded to the deposited specimen, their decision could not be reopened or challenged.

By simultaneously black-boxing the chemical specimen and by decoupling the physical specimen from the written description, it was possible to focus on the paper form of the invention in the patent documentation. The focus on the written two-dimensional form of the invention was reinforced by the absence of a workability requirement which would have required patentees to show a material instantiation of the invention. The focus on paper-based inventions meant that in an infringement action or where the novelty of a patent was challenged, the written specification was treated as if it encapsulated the invention (or at least provided instructions for how the invention could be identified); it was the alleged infringing or anticipating compound, rather than the physical specimen, that was tested to see whether it complied with the descriptive tests set out in the patent documentation. In this sense, chemical specimens not only helped patent law to deal with any problems that might have arisen in the way chemical compounds were described, they also allowed the patent system to circumvent some of the problems that arose when dealing with empirical inventions more generally. In this sense, the legal fiction of the chemical specimen allowed the patent system to deal with chemical inventions in the much the same way as it interacted with mechanical inventions. While the process was not complete, it also played an important role in decoupling chemical subject matter from its material physical form.

[146] *Tarr* v. *Folsom* 1 Ban & A 24; 1 Holmes 312, 23 Fed Cas 704 (1874) Case 13,756. James Tarr and Augustus Wonson, 'Paint for Ship's Bottoms', Letter Patent No. 40,595 (3 November 1863). James Tarr and Augustus Wonson, 'Improvement in Paints for Ship's Bottoms' US Patent No. 40,595 (3 November 1863); reissue No 2,722, (6 August 1867), reissue No. 4,598 (17 October 1867).

[147] Ibid., 705.

[148] Ibid. The decision stands at the juncture of different ways of thinking about chemical compounds. The court had to consider the change in scientific nomenclature (old language of oxide of copper on the one side and sulphuric acid in another, compared to the new nomenclature 'as sulphuric acid in which two atoms of hydrogen have been replaced by copper'). See *Wonson* v. *Gilman* 30 F Case 420, 421 (1877) Case No. 17,933 (dealing with the patent in *Tarr* v. *Folsom*).

4

Speculative Property

INTRODUCTION

The later part of the nineteenth century was a period of consolidation in organic chemistry. Developments such as the publication of standardised melting and boiling points,[1] standardised reference materials,[2] and the increased use of standardised laboratory equipment (including glassware, thermometers, and scales) allowed chemists to exercise greater 'control over experimental spaces', which improved their ability to purify, characterise, and identify substances.[3] While patent law benefited from these changes, they did not really affect the way the two domains interacted. This is not the case, however, with a number of other changes that occurred in chemistry at the time; two of which stand out, namely, the development of structural theory and the standardization of naming practices. These changes, which were readily embraced by lawyers, patent attorneys, judges, and Patent Office officials, had a profound and lasting impact on the way that patent law interacted with chemistry. This is because it changed the way that patent law engaged with and thought about chemical subject matter.

As we saw earlier, in defining and demarcating the intangible property created by a chemical patent, nineteenth-century patent law relied on the tangible manifestations of the chemical invention. Whether directly, as with the use of chemical specimens, or more indirectly, as with the use of a compound's physical witnessable properties, the tangible material aspects of a chemical compound were pivotal to the way the law engaged with chemical subject matter. The attention given to the material tangible dimension of chemical inventions was reinforced by the fact that patent law only dealt with chemical inventions at the level of the species (or variety); that is, patent law treated chemical subject matter as if it was a closed, singular, and material entity that was co-extensive with the chemical compound. The situation changed, however, around the turn of the century as patent law embraced structural theory.

[1] See Thomas Carnelley, *Melting and Boiling Point Tables* (London: Harrison & Sons, 1885).

[2] A job taken over by the National Institute of Standards and Technology beginning in 1905 with production of standard samples of iron but quickly spreading to other standardized samples.

[3] Catherine M. Jackson, 'Chemical Identity Crisis: Glass and Glassblowing in the Identification of Organic Compounds' (2015) 72 *Annals of Science* 187, 204.

STRUCTURAL THEORY

As Alan Rocke said, the 'dominating story of chemistry in the 1860s, 1870s, and 1890s was neither the periodic law, nor the search for new elements, nor the early stages of the study of atoms and molecules as physical entities'. Rather, it was 'the maturation, and demonstration of extraordinary scientific and technological power of the "theory of chemical structure"'.[4] As with the rational formula that preceded them, structural theory grew out of the realisation that a simple understanding of the constitutive elements in a compound (provided by its empirical formula) was insufficient to account for the nature of chemical compounds.[5] In order to better understand chemical compounds, chemists realised that they needed to shift their focus of attention away from the composition of compounds to also include the compound's constitution or inner organisation, that is, with the way that elements were organised within a compound, rather than merely the proportion and kind of elements that were in the compound.[6]

Scientific understanding of the internal shape of compounds began to take shape in the 1860s when chemists drew together experimental findings of previous decades to formulate several principals – which became known as structural theory – that 'appeared to govern the internal architecture of organic chemical compounds in a way that accounted for different chemical phenomena and relationships'.[7] Loosely defined, structure theory was 'a collection of principles for understanding the behaviour and relationship of organic compounds in terms of a … model of their inner structure or "constitution"'.[8] That is, structure theory was a set of ideas that provided chemists with information about the way elements in a compound were joined (or bonded) together.[9]

In the early 1860s Alexander Brown developed 'a style of graphic notation' that translated this information into the now well-known structural formula (see for example Figure 4.1). These structural formula, which have been described as one of the trademarks of chemistry,[10] 'expressed the constitution of compounds in accordance with the principles of structure theory'.[11] Structural formula built upon and extended the empirical formula that had been developed in the 1830s which, through the arrangement of letters and numbers, visually showed how elements

4 Alan J. Rocke, *Image and Reality* (Chicago: University of Chicago Press, 2010), xx.

5 Bernadette Bensaude-Vincent and Jonathan Simon, *Chemistry: The Impure Science* (2nd edn, London: Imperial College Press, 2012), 206.

6 Alan J. Rocke, 'Origins and Spread of the "Giessen Model" in University Science' 50(1) (2003) *Ambix* 90, 93.

7 Helen Cooke, 'A Historical Study of Structures for Communication of Organic Chemistry Information Prior to 1950' (2004) 2 *Organic and Biomolecular Chemistry* 3179, 3181–82.

8 Evan Hepler-Smith, *Nominally Rational: Systematic Nomenclature and the Structure of Organic Chemistry, 1889–1940* (PhD Thesis, Princeton University, 2016), 12.

9 Alan J. Rocke, *Image and Reality* (Chicago: University of Chicago Press, 2010), xx.

10 Roald Hoffmann and Pierre Laszlo, 'Representation in Chemistry' (1991) 30(1) *Angewandte Chemie* 163, 164.

11 Evan Hepler-Smith, '"Just as the Structural Formula Does": Names, Diagrams, and the Structure of Organic Chemistry at the 1892 Geneva Nomenclature Congress' (2015) 62 *Ambix* 1, 8.

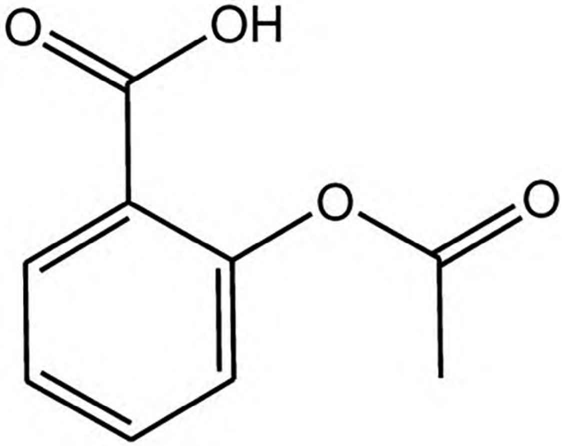

FIGURE 4.1 Modern structural formula for acetylsalicylic acid (Aspirin)

were combined with each other to display 'chemical and spatial arrangements in an even more pictorial form'.[12] In this sense, structural formula's diagrammatic representation of the internal structure of compounds marked a shift towards a more iconic mode of representation.[13] This is because while empirical formula only provided information about the nature and proportions of the components of a substance, structural formula also provided information about the way the elements in a compound were connected.

Structural formulas performed a number of different roles in organic chemistry. As well as providing information about the proportions of the elements in a compound, structural formulas also provided an 'important insight into the details of molecular architecture in an invisibly small realm of nature'. Structural formulas also provided 'heuristic guidance in the technological manipulation of those molecules, providing assistance in the creation of an important fine chemicals industry'.[14] In this sense, structural formulas were used as instruments of discovery to predict behaviour and to construct new compounds. That is they were used as tools that 'could be manipulated on paper to create representations of a hidden scientific object'. Typically, structural formulas would begin their lives as informed speculations about the structure of a compound. Building on the principle of chemical valence, which was the idea that different elements can only form certain numbers

[12] Ursula Klein, 'Not a Pure Science: Chemistry in the 18th and 19th Centuries' (5 November 2004) 306 *Science* 981, 982.

[13] See Ursula Klein, *Experimental Models, Paper Tools: Cultures of Organic Chemistry in the Nineteenth Century* (Stanford: Stanford University Press, 2003).

[14] Alan J. Rocke, 'The Theory of Chemical Structure and Its Applications' in (ed) M. J. Nye, *The Cambridge History of Science Vol. 5: Modern Physical and Mathematical Sciences* (Cambridge: Cambridge University Press, 2003), 255.

of bonds to other atoms – hydrogen (typically) to one; oxygen to two; nitrogen to three; and carbon to four – organic chemists worked backwards from chemical evidence to infer the way individual elements were linked to form molecules.[15]

In so far as structural theory established 'relations between chemical substances, between reaction partners and reaction products connected by chemical transformation',[16] it allowed chemists, more than ever, to draw inferences from existing compounds (or classes of compounds) to predict the existence of new compounds. On the basis that 'relations between substances corresponded to relations between chemical structures',[17] chemists could apply the rules of structural theory and systemic nomenclature to visualise or postulate the existence of undescribed or yet-to-be created compounds on an unprecedented scale.[18] Through the skilful interpretations of appropriate reactions based on structural theory, chemists were also able to discern patterns of atomic bonding which were then used to build a structural formula.[19] These initial speculations were then tested and retested until chemists were confident that the posited structural formula accurately reflected the inner makeup and shape of the compound in question.

Once a structural formula was firmed up and confirmed, its role changed. Once chemists were confident that a structural formula accurately represented the constitution of a compound, it could then be identified and classified.[20] Based on the idea that there was 'exactly one characteristic chemical structure for every chemical substance',[21] structural formula were used by chemists to identify, name, and single out the chemical compounds that the formula stood for. Structural formulas, 'which told a concise story to the chemical reader',[22] represented in two-dimensional form 'a three-dimensional object for the purpose of communicating its essence to some remote reader'.[23] On

15 Alan J. Rocke, *Image and Reality* (Chicago: University of Chicago Press, 2010), 67 ff.

16 J. Schummer, 'The Impact of Instrumentation on Chemical Substance Identity' in (ed) P. Morris, *From Classical to Modern Chemistry: The Instrumental Revolution* (Cambridge: The Royal Society of Chemistry, 2002), 188, 196.

17 Ibid., 196.

18 Eugene Geniesse, 'Adequate Description' (1945) 27 *Journal of the Patent Office Society* 784, 788. Structural theory allowed chemists to 'theoretically name all the members of a broadly defined chemical genus that encompassed a large number of species.' William D. Marsillo, 'How Chemical Nomenclature Confused the Courts' (1977) *Baltimore Intellectual Property Law Journal* 29, 30.

19 Chemists could 'explore the possibility of constructing molecules, in thought, following those valence rules. That is the essence of the theory of chemical structure'. Alan J. Rocke, *Image and Reality* (Chicago: University of Chicago Press, 2010), xiv.

20 Structural formula functioned as instruments of classification, 'as book-keeping devices for cataloguing chemical subunits'. Evan Hepler-Smith, '"Just as the Structural Formula Does": Names, Diagrams, and the Structure of Organic Chemistry at the 1892 Geneva Nomenclature Congress' (2015) 62 *Ambix* 1, 15.

21 J. Schummer, 'The Impact of Instrumentation on Chemical Substance Identity' in (ed) P. Morris, *From Classical to Modern Chemistry: The Instrumental Revolution* (Cambridge: The Royal Society of Chemistry, 2002), 188, 193.

22 Roald Hoffmann and Pierre Laszlo, 'Representation in Chemistry' 30(1) (1991) *Angewandte Chemie* 1, 13. Robin Findlay Hendry, 'Structure as Abstraction' (2016) 83(5) *Philosophy of Science* 1070.

23 Ibid., 6.

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the basis that there was a 'one-to-one correspondence between compound and formula',[24] structural formulas operated like models that stood in for the compounds they represented.[25]

One of the notable things about structural formulas and a key reason for their success was that they were treated as if they were an accurate representation of a molecular reality. While there may have been some early doubts about the reliability of structure theory[26] and many users of 'structural formulas insisted that the diagrams were not meant to represent the physical microstructure of compounds', nonetheless chemists often 'thought about chemical phenomena as if the structural formulas did'.[27] Irrespective of 'their particular commitments with regard to epistemology and chemical theory, the majority of nineteenth century chemists took on' a position 'that asserts that chemical formula resemble reality'.[28] In structural theory, 'molecular structure were hypothetical entitles whose ontological status each depended on the hypothesis of structure elucidation of the corresponding substance. The more this was supplemented by' experiment, the more chemists conceived 'of molecular structures as real entities. Thus, chemists no longer considered molecular structures simply as properties of chemical substances: instead, molecular species became ontologically on par with chemical substances'.[29]

Facilitated by improvements in printing technology that made it possible to include structural formulas in printed publications,[30] the development of conventions for the representation of structures,[31] and a growing realisation that structural

[24] Ibid., 11.

[25] Manuel DeLanda, *Philosophical Chemistry: Genealogy of a Scientific Field* (London: Bloomsbury, 2015), 88.

[26] Evan Hepler-Smith, '"Just as the Structural Formula Does": Names, Diagrams, and the Structure of Organic Chemistry at the 1892 Geneva Nomenclature Congress' (2015) 62 *Ambix* 1, 8. 'Neither the three-dimensional nor the two-dimensional structural formula could correspond to molecular reality because the formulas were static representations of what must really be a phenomenon of dynamics' Mary Jo Nye, *From Chemical Philosophy to Theoretical Chemistry: Dynamics of Matter and Dynamics of Disciplines 1800–1950* (Berkeley: University of California Press, 1994), 100–01.

[27] Evan Hepler-Smith, '"Just as the Structural Formula Does": Names, Diagrams, and the Structure of Organic Chemistry at the 1892 Geneva Nomenclature Congress' (2015) 62 *Ambix* 1, 8.

[28] Ibid., n 24.

[29] J. Schummer, 'The Impact of Instrumentation on Chemical Substance Identity' in (ed) P. Morris, *From Classical to Modern Chemistry: The Instrumental Revolution* (Cambridge: The Royal Society of Chemistry, 2002), 188, 207.

[30] At the end of the nineteenth century when structural representations 'were being developed, engraving was the main means of typesetting drawings. This was an expensive process and even more so for lines drawn at an angle, hence three-dimensional structures were drawn in two dimensions'. Helen Cooke, 'A Historical Study of Structures for Communication of Organic Chemistry Information Prior to 1950' (2004) 2 *Organic and Biomolecular Chemistry* 3179, 3182. In 1890s there were problems in printing 'quasi-three-dimensional drawings' – while there were no problems in doing so on a blackboard, 'the printing media was not up to it, at least not at the budgetary levels appropriate to mass dissemination of a scientific journal … engraving was the technique of choice for printing & it was expensive to set lines at an angle.' Roald Hoffmann and Pierre Laszlo, 'Representation in Chemistry' 30(1) (1991) *Angewandte Chemie* 1, 8.

[31] Helen Cooke, 'A Historical Study of Structures for Communication of Organic Chemistry Information Prior to 1950' (2004) 2 *Organic and Biomolecular Chemistry* 3179, 3189.

UNITED STATES PATENT OFFICE.

BRUNO RICHARD SEIFERT, OF RADEBEUL, NEAR DRESDEN, GERMANY, ASSIGNOR TO DR. F. VON HEYDEN, NACHFOLGER, OF SAME PLACE.

CARBONATE OF GUAIACOL AND CREOSOL.

SPECIFICATION forming part of Letters Patent No. 466,913, dated January 12, 1892.

Application filed December 17, 1890. Serial No. 374,981. (Specimens.)

To all whom it may concern:

Be it known that I, BRUNO RICHARD SEIFERT, chemist, of Radebeul, near Dresden, in the Kingdom of Saxony, German Empire, have invented a new and useful Improvement in Medical Compounds, of which the following is a specification, reference being had to the accompanying drawings.

I have found that from guaiacol and its homologues—for instance, creosol contained in beech-wood tar—medical compounds may be obtained which are preferable to guaiacol, inasmuch as they are colorless, tasteless, and without effect upon the mucous membrane. These compounds are intended to be mainly used internally against tuberculosis and the diseases of the stomach and externally against the diseases of the skin and as an antiseptic.

Figures 1, 2, and 3 represent central vertical sectional views of three different forms of apparatus which may be employed in the manufacture of my compounds.

My new medical compounds are obtained by the action of phosgene on guaiacol or the homologue creosol. The reaction takes place according to the following equation:

$$2C_6H_4\left\langle\begin{matrix}OH\\OCH_3\end{matrix}\right. + COCl_2 = CO(OC_6H_4OCH_3)_2 + 2HCl.$$

In carrying out the process I proceed as follows: Two hundred and fifty kilograms of guaiacol and one hundred kilograms of phosgene are heated in a closed vessel. A temperature of about 100° centigrade is sufficient. After several hours the vessel is opened to allow the hydrochloric vapors to escape. The residual product is washed with water, or, if necessary, with an alkaline solution, and thereafter crystallized from alcohol. For this process I preferably use the apparatus Fig. 1, in which *a* is a closed vessel surrounded by a steam-jacket *b*, with the steam admission and outlet pipes *c* and *d*.

e is an inlet-pipe for the phosgene, and *g* is an opening for the guaiacol to be put into the vessel *a*. This opening is provided with a suitable cover.

f is an outlet-pipe for the hydrochloric vapors to escape, and *h* is an outlet-pipe for the residual product to be drawn off.

Instead of guaiacol, a salt of it may be employed. In this case the reaction takes place, for instance, according to the following equation:

$$2C_6H_4\left\langle\begin{matrix}ONa\\OCH_3\end{matrix}\right. + COCl_2 = CO(OC_6H_4OCH_3)_2 + 2NaCl.$$

If a solid salt of guaiacol is employed, the apparatus Fig. 1 may be used; but I prefer to use an apparatus with an agitator. This apparatus is shown in Fig. 2, which is provided with or constituted of all the parts named in Fig. 1, and which are indicated in Fig. 2 by the same letters of reference; but this apparatus, Fig. 2, has, moreover, an agitator, which may be composed of an upright shaft *k*, with driving-gear *i* at top and with stirrers *l* within the vessel. If, however, a solution of guaiacol salt is employed, it is more simple and preferable to make use of an open vessel *a*—such, for instance, as Fig. 3—which is provided with agitator *i k l*, steam-jacket *b*, with pipes *c d*, phosgene-inlet pipe *e*, and draw-off pipe and cock *h*.

Of course the apparatus Fig. 3 may be used instead of Fig. 2, and the one shown in Fig. 2 instead of that in Fig. 3.

The mode of proceeding with salt of guaiacol is as follows: The vessel Fig. 2 or Fig. 3 is charged with solid or dissolved guaiacol salt, produced, for instance, from one hundred and twenty-five kilograms of guaiacol and forty and five-tenths kilograms of caustic soda. One hundred kilograms of phosgene are now admitted through pipe *e* until the contents of the vessel react neutral. This process is carried on at any desired temperature and pressure, all the while stirring by the agitator. The residual product is thereafter washed with water and crystallized from alcohol. The product resulting from such reaction consists of the carbonate of guaiacol. It is colorless, tasteless, and melts at about 85° centigrade. Its structural formula is

FIGURE 4.2 Early structural formula
Bruno Richard Seifert, 'Carbonate of Guaiacol and Creosol' US Patent No. 466,913 (12 Jan 1892). Courtesy of the National Archives at Kansas City.

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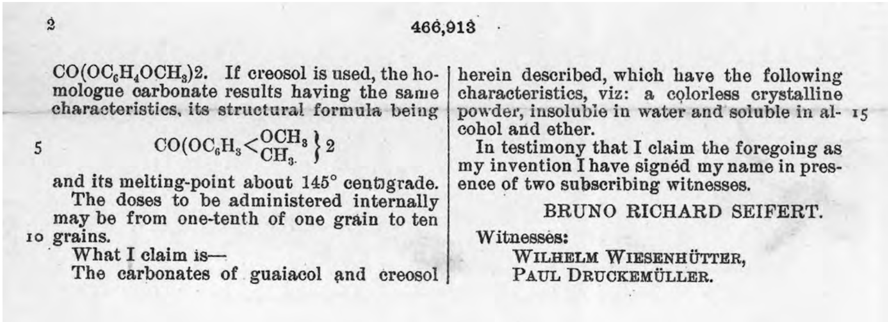

2 466,913

$CO(OC_6H_4OCH_3)2$. If creosol is used, the homologue carbonate results having the same characteristics, its structural formula being

$$CO(OC_6H_3<^{OCH_3}_{CH_3}\}2$$

and its melting-point about 145° centigrade.

The doses to be administered internally may be from one-tenth of one grain to ten grains.

What I claim is—

The carbonates of guaiacol and creosol herein described, which have the following characteristics, viz: a colorless crystalline powder, insoluble in water and soluble in alcohol and ether.

In testimony that I claim the foregoing as my invention I have signed my name in presence of two subscribing witnesses.

BRUNO RICHARD SEIFERT.

Witnesses:
WILHELM WIESENHÜTTER,
PAUL DRUCKEMÜLLER.

FIGURE 4.2 (cont.)

theory did what it promised, structural theory and the corresponding structural formulas were quickly adopted by organic chemists. By the end of the nineteenth century, structural formulas were 'by all measures the reigning doctrine of the science of chemistry, dominating investigations in both academic and industrial laboratories'.[32]

Structural formulas first began to appear in US patents in the 1890s.[33] As Helen Cooke has shown, there was little standardisation in the way chemical structures were represented in these early patents[34], a problem compounded by the fact that printing technology at the time made it difficult to reproduce structural formulas in printed patents. An early example of the use of structural formulas is the 1892 patent for a new medical compound that was used to prevent tuberculosis, which was described as a carbonate of guaiacol and creasol with the structural formula set out in Figure 4.2.[35] As a result of advances in printing, by the turn of the century patentees were able to include more familiar representations of structural formula in their patents, such as in Julius and Reubold's 1900 patent for a new black sulphur

32 Alan J. Rocke, 'The Theory of Chemical Structure and Its Applications' in (ed) M. J. Nye, *The Cambridge History of Science Vol. 5. Modern Physical and Mathematical Sciences* (Cambridge: Cambridge University Press, 2003), 255; Helen Cooke, 'A Historical Study of Structures for Communication of Organic Chemistry Information Prior to 1950' (2004) 2 *Organic and Biomolecular Chemistry* 3179, 3189. Thinking in terms of molecular structures soon became, and 'remains today, the heart blood of chemistry.' Alan J. Rocke, 'Ideas in Chemistry: The Pure and the Impure' (2018) 109 *Isis* 577, 582.

33 Although typographical errors were said to be 'commonplace in formula and structure in patents' in the 1890s, this changed by 1895. Helen Cooke, 'A Historical Study of Structures for Communication of Organic Chemistry Information Prior to 1950' (2004) 2 *Organic and Biomolecular Chemistry* 3179, 3188.

34 Ibid., 3188.

35 Bruno Richard Seifert, 'Carbonate of Guaiacol and Creasol' US Patent No. 466,913 (12 January 1892) (with specimen).

dye (Figure 4.3).[36] Given the advanced state of organic chemistry in Germany, it is not surprising that the structural formula first used in US patents were for German inventions, particularly in relation to dyes.[37] While structural formulas were used inconsistently across the 1890s and patentees were promiscuous in terms of the way they defined their chemical compounds (in the sense that they combined different modes of identification),[38] by the early twentieth century structural formulas were regularly being used by patentees, the Patent Office, patent attorneys, and the courts to identify, define, and demarcate chemical inventions. Indeed, on the basis that the chemical formula of a new product differentiated it from all other chemical products, Hugo Mock wrote in his 1911 *Handbook on Patents* that 'necessarily the most satisfactory definition of a new product is its [structural] chemical formula'.[39]

The Patent Office also recommended that patentees use structural formulas where they were known because they offered the clearest and best way of describing chemical compounds.[40] The Patent Office's adoption of structural formulas as the preferred way of identifying and describing chemical compounds was motivated by their efficiency and simplicity, by the fact that structural formulas offered, at least to a skilled reader, a quick and easy way of identifying and understanding the chemical compound in question. As the Commissioner of Patents said in 1923, 'If an applicant is claiming a structure and claiming it so that any one skilled in the art may make and use it and his claims are phrased in an allowable form … the Examiner should not waste Government time in compelling an applicant to draw fine distinctions with respect to the terminology of the materials used in his device, nor should be write a five-paper dissertation on the use of such expressions – particularly when he is about ten months behind with his work'.[41]

36 Paul Julius and Frederich Reubold, 'Black Sulphur Dye' US Patent No. 650,327 (22 May 1990).

37 Helen Cooke, 'A Historical Study of Structures for Communication of Organic Chemistry Information Prior to 1950' (2004) 2 *Organic and Biomolecular Chemistry* 3179, 3189.

38 While the courts accepted that a 'chemical formula may be the sole subject-matter of the claim', (Richard Wirth, 'The Framing and the Construction of US Patent Claims' (1923) *Journal of the Patent Office Society* 155, 180) nonetheless patentees continued to hedge their bets by using a range of techniques to describe their inventions, including the ingredients and how they were mixed, the chemical formula as well as the defining characteristics of the resulting compound (such as melting and boiling point). In part this was because 'the composition and formula of many simple organic substances remained unstable for much longer than is usually recognized'. Catherine M. Jackson, 'The Curious Case of Coniine: Constructive Synthesis and Aromatic Structure Theory' in (ed) Ursula Klein and Carstein Reinhardt, *Objects of Chemical Inquiry: The Synergy of New Methods and Old Concepts in Modern Chemistry* (Sagamore Beach, MA: Science History Publications, 2014), 61, 75.

39 Hugo Mock, *Handbook of Chemical Patents: How Procured, Requisites of, and Other Information Concerning Chemical Patents in the United States and abroad* (Washington, DC: Mason, Fenwick, and Lawrence, 1911), 18. By 1911, patentees were being advised to define chemical compounds 'in terms of its chemical formula or constitution, plus whatever chemical characteristics or properties may serve to identify the compound.' Chester H. Biesterfeld, *Patent Law for Chemists, Engineers, and Students* (New York: J. Wiley and Sons, 1943), 44.

40 *Report of the Executive Committee of the Patent Office Society* (1933) *Journal of the Patent Office Society* 842, 845 (recommendation 4:5).

41 *Ex Parte Christian* (1923) 308 OG 231 (cited in Richard Wirth, 'The Framing and the Construction of US Patent Claims' (1923–24) 6 *Journal of the Patent Office Society* 155, 158).

UNITED STATES PATENT OFFICE.

PAUL JULIUS AND FRIEDRICH REUBOLD, OF LUDWIGSHAFEN, GERMANY, ASSIGNORS TO THE BADISCHE ANILIN AND SODA FABRIK, OF SAME PLACE.

BLACK SULFUR DYE.

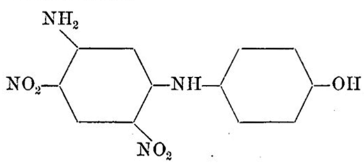
SPECIFICATION forming part of Letters Patent No. 650,327, dated May 22, 1900.

Application filed March 16, 1900. Serial No. 8,951. (No specimens.)

To all whom it may concern:

Be it known that we, PAUL JULIUS, doctor of philosophy, a subject of the Emperor of Austria-Hungary, and FRIEDRICH REUBOLD, doctor of philosophy, a subject of the King of Bavaria, both residing at Ludwigshafen-on-the-Rhine, in the Kingdom of Bavaria, Empire of Germany, have invented new and useful Improvements in Black Coloring-Matters, of which the following is a specification.

Our invention relates to the manufacture of a new deep-black coloring-matter which directly dyes unmordanted cotton. It can be obtained from a certain diphenylamin derivative by treating the same with sulfur and sodium sulfid. The said diphenylamin derivative results from the condensation of one molecular proportion of symmetrical dinitro-meta-dichlor-benzene with one molecular proportion of para-amido-phenol in the presence of a substance that will bind the hydrochloric acid formed during the reaction, such as sodium acetate, and heating the condensation product thus formed with ammonia under pressure, whereby dinitro-amido-para-hydroxy-diphenylamin is obtained, which, judging from the method of its formation, has the formula:



and this when treated with sulfur and sodium sulfid in the manner to be described yields the coloring-matter which we desire to claim.

The following example will serve to illustrate the manner in which our invention may be carried into practical effect and our new coloring-matter obtained. The parts are by weight.

Production of a new black coloring-matter from dinitro-amido-para-hydroxy-diphenylamin.—Prepare the required initial material by boiling in a reflux apparatus an alcoholic solution of one molecular proportion of dinitro-dichlor-benzene and one molecular proportion of para-amido-phenol, with sufficient sodium acetate to bind the hydrochloric acid formed during the reaction. Continue the heating until the dinitro-dichlor-benzene has practically disappeared. Isolate the dinitro-chlor-para-oxy-diphenylamin formed in any well-known manner. Heat seventy-five (75) parts thereof with one thousand (1000) parts of alcohol and five hundred (500) parts of an alcoholic solution of ammonia (containing about four and a half per cent. of NH_3) for three hours at a temperature of about 150° to 160° centigrade. Filter and precipitate the reaction product from the filtered solution by the addition of water when cold. Mix together thirty (30) parts of the dinitro-amido-para-oxy-diphenylamin obtained as above described, one hundred and eighty (180) parts of crystallized sodium sulfid, and fifty (50) parts of sulfur in an iron vessel provided with a stirring arrangement and heat slowly up to 140° to 150° centigrade. Maintain the melt at this temperature until it has become dry. The powdered melt can be directly used for dyeing.

Our new coloring-matter is easily soluble in water with a green-blue color and dyes unmordanted cotton deep-black shades which are not essentially altered in appearance on treatment with bichromate, copper sulfate, and also with sodium peroxid. The aqueous solution gives on addition of hydrochloric acid a yellow-brown precipitate.

Now what we claim is—

The new coloring-matter which can be obtained from dinitro-amido-para oxy-diphenylamin, sulfur, and sodium sulfid, which dissolves in water with a green-blue color, dyes unmordanted cotton deep-black shades which are not essentially altered in appearance on treatment with potassium bichromate and copper sulfate, and also not on treatment with sodium peroxid, and which in aqueous solution, on addition of hydrochloric acid, yields a yellow-brown precipitate substantially as described.

In testimony whereof we have hereunto set our hands in the presence of two subscribing witnesses.

PAUL JULIUS.
FRIEDRICH REUBOLD.

Witnesses:
ERNEST F. EHRHARDT,
JOHN L. HEINKE.

FIGURE 4.3 Structural formula for Black Sulfur Dye
Paul Julius and Friedrich Reubold, 'Black Sulfur Dye' US Patent No. 650,327 (22 May 1900). Courtesy of the United States Patent and Trademark Office.

THE STANDARDIZATION OF CHEMICAL NAMES

The 1890s not only saw changes in the type of chemical formula that were used to describe chemical compounds, it also witnessed the move towards a more standardised way of naming chemical compounds. Over the course of the nineteenth century a range of different, often inconsistent, techniques were used to name chemical compounds. These included names based on the origin of the substance,[42] on a property of the compound,[43] or the name of the inventor of the compound. Unsurprisingly, these disparate naming practices created confusion and uncertainty: they made it difficult for chemists to communicate with each other, to compare experimental data, and to organise and classify compounds. In some areas, chemical nomenclature 'was so dire that chemists could barely understand … their varying claims regarding chemical composition, structure and behaviour'.[44] By the 1880s these problems had become acute. Concerned about the detrimental impact that this confusion was having, a series of international conferences were held in the 1880s and 1890s where chemists set out to formulate universal rules for the naming of organic compounds:[45] these culminated in the Geneva Congress of 1892, which laid the foundation for the system of chemical nomenclature that we have inherited today.[46]

One of the things that was agreed on by organic chemists at the end of the nineteenth century was that 'every compound should bear a *systematic* name of such a character that it can at once be translated into the corresponding formula; and that, *vice versâ*, a name corresponding to any particular formula may be devised which we may count on finding in the *official* register, if the compound thought of have been described'.[47] It was also agreed that the way this was to be achieved was by breaking the structural formula down into parts that were each given individual names. Once this was done, the names of the parts were then reassembled to form the composite name of the chemical compound. While it was agreed that 'a chemical name should uniquely express the structure of a compound'[48] and that this was

42 Such as the use of the name 'formic acid' for the substance isolated from ants, *formica* being the Latin for 'ant'. Evan Hepler-Smith, '"Just as the Structural Formula Does": Names, Diagrams, and the Structure of Organic Chemistry at the 1892 Geneva Nomenclature Congress' (2015) 62 *Ambix* 1, 6.

43 Evan Hepler-Smith, *Nominally Rational: Systematic Nomenclature and the Structure of Organic Chemistry, 1889–1940* (PhD Thesis, Princeton University, 2016), 41.

44 Ibid., 39–40. Acetic acid had 18 different names in 1861. In 1859 Kekule identified 19 different formula for acetic acid (vinegar).

45 Evan Hepler-Smith, '"Just as the Structural Formula Does": Names, Diagrams, and the Structure of Organic Chemistry at the 1892 Geneva Nomenclature Congress' (2015) 62 *Ambix* 1, 14.

46 The Geneva Congress drew a distinction between a sphere of general usage (including trade names, trademarked names, well-established trivial names 'to be left to its own devices') and a 'realm of official nomenclature, where each name was a precise and unique transcription of a structural formula diagram.' Ibid.

47 See, Henry E. Armstrong, 'The International Conference on Chemical Nomenclature' (19 May 1892) *Nature* 56, 57.

48 Evan Hepler-Smith, *Nominally Rational: Systematic Nomenclature and the Structure of Organic Chemistry, 1889–1940* (PhD Thesis, Princeton University, 2016), 4. The rules fixed at Geneva Congress in 1892 demanded that the official name express the structure of the compound.

to be achieved by dissembling the compound into parts and reassembling them, the key issue was that chemists still needed to agree on how the disassembled parts were to be reassembled.

As Hepler-Smith has shown, in the lead up to the 1892 Geneva Congress, there were two competing views about the way structural formulas should be translated into words. One potential way of building the name of a new chemical compound, which did not prevail, was to organise the name of a compound around what it did and how it behaved. Under this approach, the functional groups in a compound are used as the starting point for determining the compound's name. The name of the compound was then built up around this functional core. For example, applying this approach the compound commonly known as *pinacone* was given the name *tetramethyl ethylglycol*. In this case, 'glycol' was selected as the root of the name 'to emphasise the compound's chemical function – a set of properties and characteristic chemical reactions that Friedel had established through painstaking experiment'.[49]

The alternate view, which eventually prevailed at the Geneva Congress, divorced the name of a compound from its function and properties to focus instead on the structure of the compound. Under this approach, compounds were 'divided … into substituent radicals and a core corresponding to a parent compound'.[50] In order to develop an official name, a chemist would start with 'a compound's structural formula, reduce it to a carbon skeleton, identify the longest chain in that skeleton', which would be the foundation for the name to be given to the chemical compound. The chemist would then apply a series of rules that generated 'consistent unique names through the application of a consistent, even algorithmic procedure'.[51] Using these rules, *pinacone* is known as *2,3-dimethyl-2,3-butanediol*[52] (rather than *tetramethyl ethylglycol*, which was what the compound is called when a functional approach is adopted).[53]

The process of naming chemical compounds that was adopted at the 1892 Geneva Congress, which was embraced by organic chemists around the world, did not link the chemical name to chemical function nor to the properties of the compound. Rather, it tied the name of the compound to regularities in the structural formula. The Geneva Congress established a set of rules that systematically disassembled a structural formula into parts. The Congress also established rules that determined how the names of these parts were reassembled to form the composite name of the compound. Importantly this was done in such a way that 'the process could be reversed to regenerate the diagram from its official name'.[54]

49 Evan Hepler-Smith, '"Just as the Structural Formula Does": Names, Diagrams, and the Structure of Organic Chemistry at the 1892 Geneva Nomenclature Congress' (2015) 62 *Ambix* 1, 19.

50 Ibid., 14.

51 Ibid., 19.

52 Evan Hepler-Smith, '"Just as the Structural Formula Does": Names, Diagrams, and the Structure of Organic Chemistry at the 1892 Geneva, Nomenclature Congress' (2015) 62 *Ambix* 1, 19.

53 Ibid.

54 Ibid., 22.

One of the consequences of applying this rule-bound approach to the formation of chemical names was that 'each name was a precise and unique transcription of a structural formula diagram'.[55] That is, the rules ensured that each chemical compound had a unique chemical name corresponding in a precise rule-bound fashion to a particular structural formula.[56] Another consequence of the application of this rule-bound approach was that the resulting names were often very cumbersome and ungainly. For example, the black sulphur dye patented by Julius and Reubold in 1900 was called *dinitro-amido-parahydroxy-diphenylamin* (for the corresponding structural formula see Figure 4.3). For organic chemists, the unwieldy names were seen as a 'necessary evil' that had to be put up with in order to 'identify and order chemical substances according to … structural formula'.[57] Specifically, it was an evil that had to be lived with to ensure that compounds could be placed in alphabetically ordered indexes in chemical dictionaries, handbooks, tables, journals, reference books, and Patent Office catalogues.[58]

As with structural formula, patent law readily adopted the newly standardised chemical nomenclature. While structural formula and chemical names were inextricably linked, patentees adopted the new naming practices before they adopted structural formula. Indeed it has been suggested that in the 1890s, when empirical formula rather than structural formula were still commonly used in patents, structural information was often 'conveyed through the … names of compounds rather than the formula themselves, with reliance placed on the readers ability to translate such names into structures'.[59] While there was no formal requirement that patentees had to follow the Geneva rules when naming new chemical compounds, they were advised to do so not least because it left 'less room for dispute than does the use of common words with their luscious accumulation of variant meanings'. The use of specialised technical terms was preferred by the Patent Office because it 'renders the description concise and often conveys a better idea of the matter referred to than any other description of reasonable length'.[60] In line with this, patentees were advised that when 'chemical substances are referred to the safest rule is to designate them by the correct chemical names … If thus defined or designated, or the formula stated no question can thereafter arise as to what is meant'.[61] Patentees were also

55 Ibid., 25.

56 While the basis of a name was the structural formula rather than the compound, as we will see, in patent law, at least, structural formula was treated as if they were coextensive with the compound.

57 Seabury Mastick, 'Chemical Patents II' (1915) *The Journal of Industrial and Engineering Chemistry* 874.

58 Evan Hepler-Smith, '"Just as the Structural Formula Does": Names, Diagrams, and the Structure of Organic Chemistry at the 1892 Geneva Nomenclature Congress' (2015) 62 *Ambix* 1.

59 Helen Cooke, 'A Historical Study of Structures for Communication of Organic Chemistry Information Prior to 1950' (2004) 2 *Organic and Biomolecular Chemistry* 3179, 3182.

60 Emerson Stringham, *Patent Claims: A Drafter's Manual (Vol II)* (Madison: Pacot Publication, 1941), 839.

61 A. M. Lewers, 'Composition of Matter' (1921–22) *Journal of the Patent Office* 530, 538. Seabury Mastick, 'Chemical Patents II' (1915) *The Journal of Industrial and Engineering Chemistry* 874.

advised in the Patent Office Style Guide to use the chemical spelling recommended by the American Chemical Society.[62]

THE IMPACT OF STRUCTURAL THEORY IN PATENT LAW

At the turn of the twentieth century, patent law was faced with two obvious choices when evaluating and dealing with chemical inventions. On the one hand, patent law could have focused on what a chemical compound did (its function). On the other hand, patent law could have ignored a compound's function and focused instead on the internal constitution or structure that was reflected in the compound's chemical name and formula. Unlike at the Geneva Congress where the delegates discussed the pros and cons of both approaches, patent law's decision to use structural formula and the newly standardised chemical nomenclature to identify and demarcate chemical compounds occurred with little fanfare or discussion. As was often the case with patent law's interaction with chemistry, the law simply passively accepted the changes that were presented to it, usually by patentees in their applications, which operated as syphers for the introduction of chemical innovations into the law.

Despite this, patent law's adoption of structural theory at the turn of the twentieth century fundamentally changed the way that the law dealt with chemical subject matter. This was particularly evident in the way that chemical compounds were identified. As we saw earlier, patent law relied on a mixture of factors to identify, demarcate, and distinguish chemical inventions prior to the uptake of structural formula. This included both the empirical formula of the compound (that listed the constituent elements) along with the compound's defining physical marks or traits such as how it smelt, what it looked like, and the temperature it boiled at. In many situations it also included the chemical specimens deposited with the application. One of the consequences of this was that the law treated chemical inventions as if they were tangible bounded individual entities. Because protection was limited to singular specific compounds, this meant that the law operated taxonomically at the level of the species rather than genus.

While patent law had previously relied on a mixture of factors to identify, demarcate, and distinguish chemical inventions (notably the empirical formula and the physical properties of the compound), this changed with the adoption of structural formula. This is because in the same way in which organic chemists came to visualize compounds in terms of their structural formula,[63] so too patent lawyers, judges,

[62] *Rules Governing the Printing of Specifications with a list of words and technical terms approved by the US Patent Office* (Washington: Government Printing Office, 1887), 28. The 1896 Patent Office style book *Rules Governing the Printing of Specifications* adopted the American Chemical Society's chemical spelling. K. P McKelroy, 'Patent Office Chemical Spelling' (1931) *Journal of the Patent Office Society* 183, 184–85.

[63] E. A. Ustinoav and O. V. Chelisheva, 'Are Markush Structures Matters of Chemistry and Law or Just Figments of the Imagination?' (1996) 18(1) *World Patent Information* 23, 24.

and Patent Office examiners also came to think about chemical compounds exclusively in terms of their structural formula and corresponding name.[64] Importantly, structural formulas and their associated names were not only treated as representational devices that stood in for the chemical compound, they also came to be treated as if they fully encapsulated the invention: a compound's function along with its physical features were no longer needed to identify a chemical compound. In this sense the 'description of a new compound by its formula or name in terms of standard nomenclature' was 'analogous to the description and drawing of a machine'.[65]

From the end of the nineteenth century, patent lawyers, examiners, and judges began to view chemical subject matter through the lens of structural formulas. Of particular importance was that chemical structures were used to identify and distinguish patented compounds.[66] For example, in the 1889 decision of *ex parte Latimer*, the Commissioner of Patents rejected an application for a patent for a fiber identified in the needles of the pine tree *Pinus australis*. This was on the basis that the 'pure fiber after it has been eliminated from the natural matrix of the leaf or stalk or wood is essentially the same thing and possesses the same construction. The chemical formula for this cellulose in all these variety of plants … is the same'.[67] The important role that chemical structure played in the way that patent law thought about chemical subject matter was also reflected in the idea that a chemical invention only came into existence when the chemist 'had a mental picture of the structure of the chemical compound'.[68] In line with this, chemical inventions were classified in the Patent Office on the basis of their chemical structure and their elements, rather than in terms of what the compound did or the industry in which they were used.[69]

64 While the decision of the Patent Office to refuse 'to issue a patent for a chemical compound if the chemical structure appeared anywhere in the published literature' was said to 'reflect the view of mechanical invention that if a drawing existed, an invention was unpatentable over the prior art' and was an 'illustration of the difficulty of attempting to fit chemical invention into the fixed confines of a body of law developed for mechanical invention', it is better seen as patent law following the lead of structural theory generally and the rules of chemical nomenclature established at the Geneva Congress more specifically. Jackie Hutter, 'A Definite and Permanent Idea - Invention in the Pharmaceutical and Chemical Sciences and the Determination of Conception in and Chemical Sciences and the Determination of Conception in Patent Law' (1995) *The John Marshall Law Review* 687, 720 n 232 (citing William D. Noonan, 'Patenting Medical Technology' (1990) *Journal of Legal Medicine* 263, 268–69 on the 'engineering bias in patent law').

65 Eugene Geniesse, 'Adequate Description' (1945) 27 *Journal of the Patent Office Society* 784, 787–88.

66 'A pure chemical compound such as nitroglycerine falls within the patentable class of "compositions of matter"'. 'In this case, the original ingredients have reacted so as to form an entirely new compound having distinct properties of its own. A composition of matter can thus be distinguished from others not only by its properties but also by its chemical structure'. Joseph Rossman, 'What the Chemist Should Know about Patents' (1932) 9(3) *Journal of Chemical Education* 486, 490.

67 *Ex parte Latimer* (12 March 1889) 46 OG 1638, *Decisions of the Commissioner of Patents and of the United States Courts in Patent* Cases (Washington: Government Printing Office, 1890), 123, 125.

68 *Amgen* v. *Chugai Pharma* (1991) 927 F.2d 1200, 1206 (treating the gene as a chemical compound).

69 US Patent Office, *The Classification of Patents* (Washington: Government Printing Office, 1915), 26. Ridsdale Ellis, *Patent Claims* (New York: Baker, Voorhis and Co, 1949), 321.

The decision to treat structural formulas as if they were a definitive representation of the patented chemical compound was also evident in the way the courts approached the obviousness of chemical compounds. When considering whether a chemical invention was obvious, the courts focused on the similarities between the structure of the claimed compound and the structure of the compound disclosed in the prior art.[70] If a compound shared the same structural core as an existing compound, it was likely to be obvious. With structural obviousness, the properties of the compound were irrelevant. Instead, the question of whether a compound was obvious was determined by comparing the structures of the compounds.[71]

Another example of the way in which structural formulas were treated as definitive representations of chemical compounds was when compounds were evaluated to determine whether they were new and therefore potentially patentable. In this context, the mere appearance of a name or formula of a chemical compound in a printed form was sufficient to anticipate a claim to a compound and thus to render it unpatentable.[72] It did not matter whether the prior art disclosed what the compound did (its function) or what its properties were: all that mattered was that the prior art disclosed the internal structure of the compound either through its official name or its structural formula. This was made clear in the decision of *Von Bramer*, which concerned an application by Harold Von Bramer to patent a new and improved type of motor fuel; the key feature of which was that it contained the compound known as N-(primary alkyl) aminophenol, in which the primary alkyl group contained at least five carbon atoms. The question that arose in this decision was whether a pre-existing patent that specifically named N-butyl aminophenol anticipated Von Bremer's application. Importantly the prior art reference only named the chemical: it made no mention of its potential use in improving the quality of motor fuel. After the Primary Examiner and the Board of Appeal rejected the application on the basis of the prior art, Von Bramer appealed to the Court of Customs and Patent Appeals where he argued that it was not enough for the prior art merely to name the compound in question to anticipate. Rather, Von Bramer argued that a prior art reference could only be anticipatory if the chemical compound was described in one of two ways: either (1) by reciting a sufficient number of chemical attributes such as 'melting point, boiling point, color, crystalline appearance, solubility' and the like; or (2) by reciting a process which unquestionably produced the substance.

70 William D. Marsillo, 'How Chemical Nomenclature Confused the Courts' (1997) *Baltimore Intellectual Property Law Journal* 29, 30.

71 *In re Papesch* 315 F.2d 381 (CCPA 1963) (a compound and its properties were inseparable).

72 Maurice W. Levy, 'Von Bramer: A Plea for Reorientation' (1951) *Journal of Patent Office Society* 401, 401–2. Emerson Stringham, *Patent Claims: A Drafter's Manual (Vol II)* (Madison: Pacot Publications, 1941), 853. A 'novel chemical compound was characterized by a unique feature: its structural formula.' E. A. Ustinoav and O. V. Chelisheva, 'Are Markush Structures Matters of Chemistry and Law or Just Figments of the Imagination?' (1996) 18(1) *World Patent Information* 23, 27.

The Court of Customs and Patent Appeals rejected Von Bramer's argument that a name without further description was insufficient to anticipate. This was because the N-butyl amino phenol mentioned in the prior art was 'more than a mere name of an individual substance, otherwise unrecognized'. Rather, as the Court said, it was 'a name according to a standard system of chemical nomenclature (Geneva system) whereby a chemical individual substance of definite chemical molecular structure is defined having generally predictable properties such as found for any similar N-alkyl amino phenol … The use of a name falling in the standard chemical system by the patents is no accident because all of the many compounds named in [the earlier prior art disclosure] are deliberately named from this standard chemical system'.[73] On this basis the Court concluded that 'the naming of the reagents by the citations even though they are complex organic compounds and disclosed no further than by the customary chemical nomenclature is sufficient anticipation'. This was because the system of chemical nomenclature established at the Geneva Congress was 'sufficient to disclose the structure of the compound in detail. It is not believed relevant or necessary to determine possibility of preparing these compounds or degree of difficult involved'.[74]

The Patent Office and the courts quickly extended the logic of *Von Bramer* beyond chemical names to include structural formulas. This meant that the novelty of a chemical compound could be defeated merely on the basis of the prior existence of either the name or the structural formula of the compound whether in a chemical journal, an earlier patent, or in a book such as the *Beilstein Handbook of Organic Chemistry*.[75] It did not matter where the name or formula of a compound appeared: so long as the publication was available to the public, it would anticipate and thus undermine the novelty of the compound. This was the case even when the pre-existing name or formula was the result of a typographical error, was factually inaccurate,[76] or 'the reference contains only an inoperative method for producing the compound, or no method at all'.[77] It also did not matter if a compound had actually ever been made, if the investigator had access to the required ingredients, if the compound was part of the structure of another compound,[78] or if the prior art made no mention of what the compound did or what its properties were; all that mattered

73 *In re Von Bramer* 127 F.2d 149, 152 (CCPA 1942).

74 Ibid., 151.

75 The appearance of the name and formula of a compound in a publication was sufficient to anticipate subsequent patent applications, notwithstanding the fact that the investigator did not have starting material required for the process, nor did they produce the product. *Ex Part Signaigo*, Patent File 2,436,233/Case No 221) as cited in Maurice W. Levy, 'Von Bramer: A Plea for Reorientation' (1951) *Journal of the Patent Office Society* 401, 402.

76 Maurice W. Levy, 'Von Bramer': A Plea for Reorientation' (1951) *Journal of the Patent Office Society* 401, 401–2.

77 *Application of Charles F. Baranauckas and Eerl T McBee* 228 F.2d 413 (CCPA 1956).

78 Maurice W. Levy, 'Von Bramer: A Plea for Reorientation' (1951) *Journal of the Patent Office Society* 401, 403.

was that the prior art disclosed a structure that was the same as the chemical compound being evaluated.[79]

TOWARDS A DEMATERIALISED CHEMICAL SUBJECT MATTER

Although patentees continued to use physical criteria to define their inventions, from the beginning of the twentieth century the Patent Office and the courts no longer used this information when interpreting chemical subject matter. Instead, they focused on the paper-based structural formula and name of the chemical compound. The willingness of the law to reduce a chemical compound to its structural formula and name meant that it was no longer necessary for patentees to deposit physical specimens of compounds as part of the application process. In line with this, the use of chemical specimens largely disappeared in the early part of the twentieth century. Indeed, by 1932 Rossman was able to write that it was rare that specimens of composition were required by the Patent Office during the prosecution of a patent.[80] The willingness to accept that a chemical compound could be identified solely on the basis of its structural formula and/or its associated name effectively decoupled chemical inventions from their physical material form. This had a profound and long-lasting effect on chemical subject matter.

As we saw above, prior to the adoption of structural theory it was common practice when describing their innovations for patentees to combine empirical formula that listed the proportion of elements in a compound, with the physical features of the resulting compound. The fact that the identity of a patented compound was inextricably tied to the compound's unique physical traits ensured that protection was limited to the specific compounds with those characteristics. The shift towards a paper-based subject matter that occurred at the turn of the twentieth century meant that the limitations that the physical features of a chemical compound imposed on the way the subject matter was construed no longer existed.[81] The fact that chemical patents were now decoupled (at least temporarily) from the physical compound meant that chemical inventions were no longer necessarily limited to individual

[79] This meant that to be valid, a patent had to define a difference in structure or composition: a mere statement of use was insufficient. P. W. Shepard and N. A. Asp, 'Claiming a New Use of an Old Substance' (1938) *Journal of the Patent Office Society* 912, 913. The idea that a chemical compound corresponded with (or was equivalent to) its chemical structure was also taken up in other areas of intellectual property. For example in an application in relation to register a trade mark for a medical compound, where questions about ownership arose, the Commissioner focused on the fact that the applicant was the 'owner or possessor of a formula for preparing a compound' as indicator of ownership of the compound *Richmond* v. *The Dr. S A Richmond Nervine Company* 52 OG 307 (21 June 1890), *Decisions of the Commissioner of Patents* 105. See also *Chadwick* v. *Covell* 51 OG 2087 (27 February 1890) (Supreme Judicial Court, State of Massachusetts) (Decisions of State Patent Courts).

[80] Joseph Rossman, *The Law of Patents for Chemists* (Washington, DC: The Inventors Publishing Company, 1932), 106.

[81] On the rise of 'paper-chemistry' see N. W. Fisher, 'Kekulé and Organic Classification' (1974) *Ambix* 29, 49.

(species-level) compounds that had a definite and verified physical form. In so doing, it created the possibility for change. And change it did. While patent law had previously only protected individualised chemical substances with a definitive and verified physical form, as a result of the acceptance of structural theory patent law now also protected families or classes of related compounds.

Across the nineteenth century, there was always a potential for class-based chemical patents. Thus, with recipe-based patents it was possible to claim, for example, 'strong acids' which covered the use of sulphuric acid or hydrochloric acids.[82] The situation was much the same when empirical and rational formula were used. Indeed, as we saw earlier, one of the problems with these formula was that it was possible for a single formula to apply to more than one compound (isomers). While there were exceptions, the potential for class-based claims did not eventuate. This was because it was common practice for patentees to combine chemical formulas with physical information about the compound such as melting and boiling points, how the compound looked, tasted, or smelt, and, in some cases, physical specimens. As a result, the potential that existed for broad class-based claims was ameliorated and protection was limited to single compounds.[83]

The situation began to change towards the end of the century. As Ruby complained when speaking of early twentieth-century chemical patents, while the composition of every true chemical compound was invariant, the composition 'rarely defines unambiguously a true chemical compound'.[84] In some situations, this was a consequence of a decline in the use of specimens. In other situations, it was a consequence of the fact that instead of using 'additional' information such as melting and boiling points in combination with the chemical formula to define a single compound, patentees used the additional information to describe a specific example of one of the members of the class of inventions covered by the formula.

This subtle but important change in patent practice can be seen in US Patent Number 1,649,670 for hexyl resorcinol (an organic compound with local anaesthetic and antiseptic properties). Specifically the patent claimed: 'New products as comprising hexyl resorcinols having the following formula: $C_6H3(OH)_2C_6H_{13}$'. While the patent only disclosed the production of one hexyl resorcinol of the given composition, 'the formula $C_6H_3(OH)_2C_6H_{13}$ represented two hundred and twenty two possible organic compounds'.[85] What made this class-based claim possible was

[82] Ridsdale Ellis, *Patent Claims* (New York: Baker, Voorhis and Co, 1949), 312–13.

[83] While it had been common practice for organic chemists to organise chemical compounds into classes or families of chemical compounds, for most of the nineteenth century 'the basic species of chemistry were chemical substances.' J. Schummer, 'The Impact of Instrumentation on Chemical Substance Identity' in (ed) P. Morris, *From Classical to Modern Chemistry: The Instrumental Revolution* (Cambridge: The Royal Society of Chemistry, 2002), 188, 207.

[84] Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Patentable Subject Matter: Part II?' (1941) *Temple University Law Quarterly* 321, 339–40.

[85] Ibid.

the fact that while the patent included additional information about how the new hexyl resorcinols were made and what their defining characteristics were, this was presented as a *specific example* of a class of compounds rather than the description of a singular patented compound.

While this change in patent drafting played an important role in shifting chemical patents towards class-based generic claims, the key reason for the move away from singular specific compounds was the rise of what were called '*general formula*': the key feature of which was that they applied to families or classes of compounds rather than to specific individual compounds.[86] Because general formula represent the composition of any member of an entire class of compounds, they were an effective and convenient way of representing very large classes of chemical compounds. Patentees first began to claim general formula claims in the early 1870s[87] and then more consistently from the 1890s.[88]

One of the notable things about general formula was that as well as using symbols that had an agreed chemical meaning such as O for oxygen or C for carbon, they also included non-chemical symbols that were only defined for the purpose of the particular formula where they were used: typically 'R',[89] but sometimes 'X', 'M', or 'H*'.[90] Thus, in US Patent Number 623,638 (1899), whose generic claim 3 was directed to certain aminoanthraquinones with the amino groups -NH–R-X and -NH–R-NO_2 – 'R' was defined as an 'aromatic radical of the series homologous and

[86] Genus class-based applications took different forms. In some cases, instead of claiming a specific compound as an object in its own right (which had been the norm prior to the compound being decoupled from its physical form), patentees presented the individual compound in the patent application as an example of one of the members of the class of inventions covered by the formula. This subtle change in patent practice can be seen in US Patent No. 1,649,670 for hexyl resorcinol, for 'New products as comprising hexyl resorcinols having the following formula: $C_6H_3(OH)2C_6H_{13}$'. While the patent only disclosed the production of one hexyl resorcinol of the given composition, 'the formula $C_6H_3(OH)2C_6H_{13}$ represented two hundred and twenty two possible organic compounds'. What made this class-based claim possible was the fact that while the patent included information about how the new hexyl resorcinol was made and what its defining physical characteristics were, the identified compound was presented as a member of a class of compounds, rather than the description of a singular patented compound. Charles E. Ruby, 'Are True Chemical Compounds, as Such, Inherently Patentable Subject Matter' (1941) *Temple University Law Quarterly* 321, 339–40.

[87] Adolph Ott, 'Improvement in Artificial Stones' US Patent No. 137,859 (27 March 1873) claimed a 'cement of the general formula: $10(SiO_2,R_2,O_3)22CaO$ in which the letter R represents the aggregate quantity of alumina and oxide of iron contained in the cement); 'Improvement in Processes of Manufacturing Ammonia' US Patent No. 161, 137 (10 March 1875) used the general formula $2(MR_3) + 2N + 3(H_2o) = M_2 + 6(RO) + 2(NH_3)$ 'where M represents the triad or pentad element and R the oxidizable element; N, nitrogen; H, hydrogen; and O, oxygen'.

[88] Karl B. Lutz, 'Evolution of the Claims of US Patents' (1938) 20 *Journal of Patent Office Society* 457, 462.

[89] While it has been suggested that nineteenth century German dyestuff chemists and German patent attorneys devised the 'R' group definition in the US at least the R symbol was used first for inventions made in the US and France. Harold C. Wegner, 'The Right to Generic Chemical Coverage' (1978) 6 *APLA Quarterly Journal* 257, 261.

[90] John E. Gordon and Joyce Brockwell, 'Formalisation of the Language of Organic Chemistry: Generic Structural Formulas' (1983) 23 *Journal of Chemical Information & Computer Science* 117, 118.

analogous to 'phenyl'.[91] The use of these free-floating symbols, which allowed for structural variation in compounds, allowed patentees to claim even larger classes of compounds.[92] The structural and general formula claims that began to appear in patents in the later part of the nineteenth century often encompassed extremely large numbers of compounds. For example in *Hercules*, the court said that the formula in the patent potentially covered up to 100,000,000 compounds.[93] Similar figures appeared repeatedly in the literature.

Another notable feature of class-based general formula was that they typically included a mixture of chemical compounds that had already been created and tested in the laboratory, along with a range of compounds that had not yet been made. While the empirical nature of organic chemistry meant that chemists had long speculated on the possible existence of yet-to-be verified chemical compounds, this took on a new life with structural theory. This was because as a patent examiner wrote, in the field of organic chemistry 'theoretical, generalized knowledge has outstripped actual exploration in many respects. The subject matter is systematized and generalized by investigation of the behaviour of each of the commonly occurring functional groups. It is assumed that the same functional groups will similarly combine in the absence of other interfering groups'.[94]

Courts in the United States first accepted generic claims for mechanical inventions in *Ex parte Eagle*,[95] an 1870 decision that concerned the patentability of a 'box' with a 'follower'. Drawing on the fact that the application listed four different embodiments of the box, the examiner held that each of the four constructions of the box should be placed in separate applications (the generic use of the term 'box' covered all four of these constructions).[96] Commissioner Fisher overturned the Examiner's objection arguing that 'the applicant describes a new genus, to wit, a box provided with a follower. He may fairly describe several species of this genus, and may make any claim that is generic in its character and includes them all'.[97] In doing so, the Commissioner opened the door to the possibility of generic class-based claims for mechanical inventions.

There was widespread support for extending the logic of *Ex part Eagle* to allow patentees to make generic claims for chemical inventions. As we have seen, the

[91] Harold C. Wegner, 'The Right to Generic Chemical Coverage' (1978) 6 *APLA Quarterly Journal* 257, 262. See M. Boniger, 'Yellow Azo Dye and Process of Making Same' US Patent No. 901,675 (20 October 1908) (where 'R' was used in a chemical formula as standing in for a methyl or carboxyl group).

[92] Helen Cooke, 'A Historical Study of Structures for Communication of Organic Chemistry Information Prior to 1950' (2004) 2 *Organic and Biomolecular Chemistry* 3179, 3182. 'X and M are fairly standard, nowadays R is frequently defined locally', Ibid.

[93] *Hercules Powder* v. *Rohm and Hass* 70 USPQ 297.

[94] Eugene Geniesse, 'Adequate Description' (1945) 27 *Journal of the Patent Office Society* 784.

[95] 1870 CD 137.

[96] This was made under Rule 41 'which limited applicants to one species claim'. Harold C. Wegner, 'The Right to Generic Chemical Coverage' (1978) 6 *APLA Quarterly Journal* 257.

[97] 1870 CD 137.

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Patent Office first allowed generic claims for chemical inventions from the early 1870s. Judicial support for generic class-based claims, which first appeared in the 1903 decision of *Ex part Dallas*,[98] was repeatedly reaffirmed, perhaps most famously in the Markush decision (which is often incorrectly seen as being the first decision to allow generic chemical inventions).[99]

While the process of extending patent law to allow for the possibility of generic class-based claims was relatively seamless, the idiosyncratic nature of chemical subject matter did create issues. Specifically, patent law had to deal with the fact that while patentees had begun to claim classes of chemical compounds that sometimes encompassed hundreds, thousands, or, in some cases, millions of individual compounds, patentees were not in a position where they could test all of the members of a class of compounds: primary because testing was prohibitively expensive, impractical, or overly time-consuming.[100] As one commentator noted, it was 'not possible in most cases to take the time and money to explore every possibility among the various compounds and groups to determine what is operative and what is not'.[101] As a result, patentees would frequently submit applications for very large classes of compounds even when they had only tested a small number of the compounds. Thus, for example, while the patent in *Matheson* v. *Campbell* for 'any sulpho acid of any radical' covered as many as 500 different sulpho acids, the applicant had only experimented with three or four compounds.[102]

In this situation, the law was faced with a choice. On the one hand, patent law could have limited protection to compounds that had actually been made and tested on the basis that the lack of chemical prevision meant that the only way of determining whether a given chemical was operative was to test it. If this had been followed it would have severely limited the protection available for patentees.[103]

[98] 106 OG 996 (CD 1903). On this see Harold C. Wegner, 'The Right to Generic Chemical Coverage' (1978) 6 *APLA Quarterly Journal* 257, 259.

[99] Harold Wegner spoke of the general myth that needed to be laid to rest that applicants were only permitted to claim generic chemical inventions since the decision of *Ex parte Markush* 1925 CD 126. Many '(if not the majority) of practitioners think of the Markush decision as being a decision of the Commissioner "permitting" structural formula type generic claims'. Instead he traces it back to *Eagle*. Harold C. Wegner, 'The Right to Generic Chemical Coverage' (1978) 6 *APLA Quarterly Journal* 257, 261. See also Robert I. Coulter, 'Markush" Claims' (1952) *Journal of the Patent Office Society* 901. Over time, Markush formulas became synonymous with generic formulas generally (despite the fact that the original Markush patent did not contain a generic formula in the claims), E. A. Ustinoav and O. V. Chelisheva, 'Are Markush Structures Matters of Chemistry and Law or Just Figments of the Imagination?' (1996) 18(1) *World Patent Information* 23.

[100] Herbert H. Goodman, 'The Invalidation of Generic Claims by the Inclusion of a Small number of Inoperative Species' (1958) *Journal of the Patent Office Society* 745.

[101] Chester H. Biesterfeld, *Patent Law for Chemists, Engineers, and Students* (New York: Wiley and Sons, 1943), 36–37.

[102] *Matheson* v. *Campbell* 78 Fed Rep 910, 915 (2nd Circ, CCA 13 January 1897).

[103] Not least because it would have 'become very difficult for the inventor in the chemical field to frame a claim that would adequately cover the invention without incurring the risk of invalidity because of exceptions.' Chester H. Biesterfeld, *Patent Law for Chemists, Engineers, and Students* (New York: Wiley and Sons, 1943), 38.

The alternative option would have been to allow patentees to claim large classes of chemical compounds, even though they had only tested a small number of those compounds. With the exception of Charles Ruby, there was overwhelming support from legal commentators, lawyers, judges, and Patent Office officials in favour of allowing patents for classes or families of chemical compounds irrespective of whether or not they had been tested.[104]

Little explanation was given as to why patentees were allowed to claim broad classes of untested compounds. At best we were told that 'in cases of doubt applicants should be permitted to claim the entire class. Only in that way can the inventor be made "secure" in his rights, as guaranteed by the US Constitution'.[105] In most cases, however, it was simply accepted that patentees should be able to patent their innovations. Thus we were told that as it was 'not always possible to devote sufficient time and money in a research laboratory to examine all compounds that could possibly come within the scope of the invention' that it was 'necessary to indulge in a bit of speculation within reasonable limits'.[106] Or, as a Primary Examiner in the Chemical Division of the US Patent Office and later member of the Board of Appeals, Eugene Geniesse, said: while 'it is desirable and customary … for an applicant to include such information as he may have regarding those compounds he has actually produced and studied … it is present practice to regard it as sufficient if a reaction product be described by its chemical constitution (i.e., name or formula) when it involves a definitive compound or class of compounds'.[107] Although the acceptance of class-based patents created exceptions to many of the doctrinal rules that had developed over the previous century, the changes went unacknowledged. Instead all Geniesse said was that he did know of any 'authority which denies protection when [an] applicant may not have actually produced the compounds he claims as his invention and hence is not provided with information as to their properties, but which he has visualized as the reaction product of known materials'.[108]

Once it was accepted that patent protection included untested compounds, the nature of the subject matter inquiry changed. This was because while it may not have been necessary for a patentee to test all the members of a class, it was necessary for them to test a sufficient number of examples to justify protection. As a result, the subject matter inquiry changed from one where patent law merely asked whether the patent disclosed a composition of matter to become one where it was asked: *how many* compounds did a patentee need to test to justify grant of the class-based

[104] To be valid there needed to be some shared quality running through the members of the family or class of substances. See *Incandescent lamp Patent Case* 159 U.S. 465 (1895).

[105] Ridsdale Ellis, *Patent Claims* (New York: Baker, Voorhis and Co, 1949), 278.

[106] Chester H. Biesterfeld, *Patent Law for Chemists, Engineers, and Students* (New York: Wiley and Sons, 1943), 36–37.

[107] Eugene Geniesse, 'Adequate Description' (1945) 27 *Journal of the Patent Office Society* 784, 787–88.

[108] Ibid.

patent?[109] Unsurprisingly, a range of different answers were given to this factual question that varied from vague platitudes (patentees were required to test 'sufficient numbers' to 'illustrate all ramifications of the class',[110] or to 'raise a presumption that the applicant number has really made a generic invention'[111]) through to equally unhelpful precise numbers.[112]

In part, the differing opinions about the number of compounds that an applicant had to test to justify protection for a class of compounds can be explained by the fact that the answer changed depending on the type of compound in question. In some cases the courts were more willing to allow claims for large classes of untested compounds on the basis of a small number of proven compounds. This was because as Wegner said, 'knowledge in some areas of chemistry has become so advanced that decisions have accepted the existence of a high degree of predictability as to how certain changes are likely to affect structure'.[113] This was particularly the case with homologous compounds and isomers, that is with compounds that shared a similar core structure (but differed in terms of their properties).[114] As the Supreme Court said in *Brenner* v. *Manson*, 'chemists knowing the properties of one member of a [homologous] series would in general know what to expect in adjacent members'.[115] The position was similar with isomers.[116] In other cases, however, the

[109] The converse question also arose: how many inoperative compounds were needed to invalidate a broad claim? Herbert H. Goodman, 'The Invalidation of Generic Claims by the Inclusion of a Small number of Inoperative Species' (1958) *Journal of the Patent Office Society* 745.

[110] Anon, 'The Mortality of Chemical Patents in Court' (1945–46) 34 *Georgetown Law Journal* 504, 510. For a more recent attempt to explain enablement see *Amgen* v. *Sanofi* 598 U.S. 594 (2023).

[111] Joseph Rossman, 'The Rejection of Broad Chemical Claims' (1932) *Journal of the Patent Office Society* 873, 874 (need for sufficient or reasonable number of species or members). Bert Russell, 'The Improvements of Our Patent System' (1933) *Journal of the Patent Office Society* 666, 672 ('a reasonable number of species of the genus').

[112] Bert Russell, 'The Improvements of Our Patent System' (1933) *Journal of the Patent Office Society* 666, 672.

[113] Helmuth A. Wegner, 'Prima Facie Obviousness of Chemical Compounds' (1978) 6 *American Patent Law Association Quarterly Journal* 271, 272.

[114] In 1944 courts were able to say that it was well understood by chemists that the 'members of a homologous series of chemical compounds possessed the same principal characteristics … and that knowledge of the properties and chemical behaviour of one of the members of the series suggest to the chemist the properties and chemical behaviour of the other members of the series.' *In re Hass* 141 Fed Rep, 2d Series 122, 125 (CCPA 1944). See also Bruce M. Collins, 'The Forgotten Chemistry of the Hass-Henze Doctrine' (1962) *Journal of the Patent Office Society* 284.

[115] The Supreme Court defined a homologous series as a family of chemically related compounds in *Brenner* v. *Manson* 383 U.S. 519, 148 USPQ 689 (US Sup Crt, 1966). See Irving Marcus, 'Chemical Product Patent Practice in the United States' (1970) 52 *Journal of the Patent Office Society* 543, 545. *In re Hass*, 141 F.2d 122, 127, 139 (CCPA 1940) (prima facie obviousness was shown when chemical compounds 'have similar structures that differ only in being adjacent homologs').

[116] The 'broad concept of homology between next-adjacent organic compounds is well known to every chemist. Making another novel compound which differs only by close homology, isomerism, replacing oxygen by Sulphur, or by double bond shift, is just an exercise in manipulative chemical procedures'. E. S. Simmons, 'Central Patents Index Chemical Code: A User's Viewpoint' (1984) 24 *Journal of Chemical Information and Computer Science* 10.

number of compounds a patentee was expected to test to prove the validity of a class of compounds increased. This was because 'unless there is structural similarity as to suggest to those skilled in the art that the result would be substantially the same',[117] it was well-established that 'in chemical cases not to assume that untried chemicals will have the same effect as other'.[118] While the nature of the compound influenced the number of representative samples that a patentee needed to test to facilitate the patenting of a class of compounds, at the end of the day, however, it was 'not easy to estimate with what degree of uniformity or certainty such rules as the foregoing may be applied; but it is easy to see that so elastic a tape can be stretched to conform to the whim of any authority having the last guess'.[119]

While the number of compounds that a patentee needed to test to prove the existence of a class of compounds may have been unclear, what was clear was that by allowing patentees to claim large numbers of untested compounds on the basis of a limited number of exemplary compounds that the nature of the subject matter inquiry changed. In particular, it become a quantitative, mathematical or, as one legal commentator preferred, an empirical exercise.[120] Allowing patentees to claim classes of untested compounds also impacted on chemical subject matter in other ways. This is because as Eugene Geniesse said, it allowed applicants to 'base a patent application wholly on speculation (visualize) without doing any actual work or producing an actual result. Lack of description of the result is excused by lack of knowledge or merely *visualized* results. In layman's language this means that a patent can be secured on mere supposition without having actually invented or discovered anything'.[121] That is, chemical subject matter became speculative.

While inventions are frequently never quite finished in the sense that there is often room for refinement and improvement, allowing patentees to make speculative claims for chemical compounds was different. This was because speculative paper-based patents, which protected 'compounds claimed in specifications which have never been made or characterised which are being treated as real',[122] allowed a patentee to make assumptions about the existence of things not yet tested or confirmed. And, unlike the case with the theoretical presumptions made about the

117 *Ex parte Morris S. Kharasch* (1938) 19 USPQ 185, 186.

118 Ibid.

119 Bert Russell, 'The Improvements of Our Patent System' (1933) *Journal of the Patent Office Society* 666, 672. Faced with a patent which claimed 'an enormous number of as yet non-existent compounds' … 'to support a generic claim to a class of organic compounds' a specification 'should disclose specifically, a substantial fraction of the compounds in that class sufficiently diversified to illustrate all ramifications of the class'. Anon, 'The Mortality of Chemical Patents in Court' (1945–6) 34 *Georgetown Law Journal* 504, 510.

120 Ridsdale Ellis, *Patent Claims* (New York: Baker, Voorhis and Co, 1949), 284.

121 Eugene Geniesse, 'Adequate Description' (1945) 27 *Journal of the Patent Office Society* 784, 788.

122 E. A. Ustinoav and O. V. Chelisheva, 'Are Markush Structures Matters of Chemistry and Law or Just Figments of the Imagination?' (1996) 18(1) *World Patent Information* 23, 24. Paper chemistry 'degrades science and discredits the patent system' (ibid).

hidden chemical microworld that was beyond the reach of scientists, speculative claims were allowed not because it was not possible to visualise what happened beneath the surface of a compound; rather, they were allowed because it was not feasible to test them.[123]

Although it had no real impact on the way chemical patents were treated, class-based chemical inventions based on structural formulas did not fit comfortably with the distinction traditionally drawn in patent law between practical patentable results and non-patentable theoretical knowledge (or discovery). This was because, as one critic complained, 'a description of what may be "visualized" is not a description of an invention nor discovery'.[124] As a result, class-based chemical patents occupied 'a gray zone', which made them 'difficult to categorize'.[125] A key reason why chemical patents were so hard to categorise (at least according to traditional accounts) was because they represented the 'modern reunification of the theoretical and the experimental'.[126] That is, chemical subject matter brought together things that were, at least from a mechanistic understanding of patent law, meant to be kept apart. While in other contexts, this may have been problematic, this was not the case with chemical patent law, which was able to accommodate a hybrid subject matter.

The adoption of structural formula in patent law fundamentally changed chemical subject matter. Previously, patent law had identified and dealt with chemical subject matter in terms of the elements that were combined to form the compound (typically expressed by way of empirical formula), along with the defining physical traits of the resulting composition that had been tested and verified in the laboratory. Here, the intangible interest was not only inextricably linked to but also treated as if it was coextensive with the physical form (exemplified most clearly in the deposited specimen). As a result, chemical subject matter, which was limited to single individual compounds, operated at the level of the species. This is in marked contrast to subject matter post-structural formula. This is because by reducing the chemical subject matter to the structural formula and the corresponding name, the paper-based subject matter was detached from its physical form. This dematerialisation of the subject matter not only changed the way that the doctrinal rules were applied, it also paved the way for class-based claims. As a result, chemical subject matter moved from the level of species to that of genus: a process that also saw chemical subject matter become both quantitative and speculative.

While chemical subject matter changed considerably over the nineteenth and early twentieth centuries, one thing that remained consistent was patent law's reliance on chemistry in dealing with that subject matter. Organic chemistry not only

[123] It was possible to test the presumptions made about the existence of yet-to-be made compounds, but this had not occurred and, for various reasons, patent law was comfortable with this.

[124] Eugene Geniesse, 'Adequate Description' (1945) 27 *Journal of the Patent Office Society* 784, 789.

[125] Stanley H. Cohen and Charles H. Schwartz, 'Do Chemical Intermediates Have Patentable Utility?' (1961) *Journal of the Patent Office Society* 479.

[126] Roald Hoffmann and Pierre Laszlo, 'Representation in Chemistry' (1991) 30(1) *Angewandte Chemie* 1, 3.

consistently produced new objects for legal scrutiny, it also provided patent law with the means to deal with that subject matter. Patent law's willingness to use science when dealing with chemical subject matter was wholehearted, unreserved, and, for the most part, consistent. Not only was legal doctrine tailored to take account of the idiosyncrasies of organic chemistry, patent law and practice also relied on chemistry to identify, evaluate, and distinguish chemical subject matter. In some cases, the influence was indirect, such as with the standardisation of laboratory equipment. In other cases, however, the influence was more direct, such as with the use of structural formula to identify chemical compounds.

While a chemical understanding of the subject matter always had to be filtered through a legal lens, chemistry consistently provided answers to the legal questions being asked of the subject matter. In this sense, it is not a stretch to say that many legal questions were decided scientifically.[127] Indeed, one of the things that a history of patent law reveals is that the laws and procedures that were developed to deal with chemical innovations were a hybrid mixture of legal demands and chemical solutions. Whether in determining whether and if so when a compound had come into existence, or considering whether a compound was new, obvious, or useful, or in deciding if two compounds were the same or different, patent law consistently looked to chemistry for answers. This is not so much a case of the law looking outside of itself to external experts to provide answers to legal questions (which is one of the things that scholars of law, science, and technology have tended to focus on), so much as the products of that expertise becoming embodied or internalised within the law. Whether in patent documents, doctrinal rules, or Patent Office practice and procedure, chemistry was integrated into and became a part of patent law.

While the resulting 'judicial chemistry',[128] which was highly technical and specialised, allowed patent law to protect the outputs of organic chemistry, at the same time it also ostracised many academics, lawyers, and judges who found it difficult to comprehend chemical subject matter, which was 'at once both part of the patent-legal and scientific literature'.[129] Indeed, when called upon to decide the patentability of a patent for purified adrenalin in *Parke-Davis* v. *Mulford*, Judge Learned Hand complained about the 'extraordinary condition of the law which makes it possible for a man without any knowledge of even the rudiments of chemistry to pass upon such questions as these', because 'only a trained chemist is really capable of passing upon such facts, e.g., in this case the chemical character of Non Furth's so-called zinc compound or the presence of inactive organic substances'.[130] As a result, judges were left blundering and 'blindly groping among testimony upon matters wholly out of their ken'.

[127] At best, and comparatively rarely, the law was called upon to adjudicate on different scientific interpretations of scientific matters.

[128] R. Frankel, 'Chemists Should Read Patents' (1942) *Journal of the Patent Office Society* 565, 567.

[129] Edward H. Valence, 'Understanding the Markush Claims in Chemical Patents' (1961) 1 *Journal of Chemical Documentation* 87.

[130] *Parke-Davis* v. *Mulford* 189 F 95, 115 (CCSNY 1911).

TOWARDS A MORE LEGAL SUBJECT MATTER?

As we have seen, patent law consistently relied on science to identify, demarcate, and classify chemical subject matter. Whether it was a mix of empirical formula and a compound's physical properties identified in a laboratory or, at the end of the nineteenth century, a compound's structural formula and/or its associated name (or a combination thereof), patent law routinely followed the scientific understanding of chemical subject matter. In these contexts, what the compound did – its function – was simply not relevant. The fact that utility was effectively guaranteed (because of the potential for compounds to be used to develop other compounds) meant that patent law focused almost exclusively on either the physical properties or the structure of the compound.

While patent law routinely internalised and followed the scientific rendering of chemical subject matter it was not all one-sided. The first crack in the unquestioned acceptance of a chemical understanding of the subject matter in patent law appeared in a series of cases at the turn of the nineteenth century where the courts adopted a more functional understanding of chemical compounds.[131] This can be seen, for example, in the 1896 decision of *Matheson* v. *Campbell*, which concerned a patent for a dye made from coal tar known as azo-black. The problem facing the patentee was that as azo-black dye had previously been imported into the United States, questions were raised about the patent's novelty and thus its validity. Because the patentee claimed azo-black as a product (rather than a process), it did not matter that the patented azo-black was made using mono-sulpho acid, while the imported azo-black had been made from di-sulphic acid. Instead, all that mattered was whether or not the imported dye was the same as the patented dye. In deciding whether the compounds were the same, the majority focused on a series of chemical tests that the patentee had included in the patent to identify the compound (including the fact that the resulting solution was very soluble in water, insoluble in spirit, dissolved in strong sulphuric acid with green colour, and so on). As the court said, the product 'answers all the tests of the patent, and other well-known tests not therein named, and that the azo-black is therefore the equivalent of napthol-black and therefore anticipates it'.[132] On the basis that the products were chemically identical, the majority found the patent invalid for lack of novelty.

While the majority in *Matheson* v. *Campbell* relied upon the scientific tests of the subject matter set out in the patent, Judge Townsend (in dissent), ignored the scientific reading of the subject matter in considering whether the imported and patented dyes were the same. Instead, he compared the compounds in terms of

[131] It also occurred with the shift towards the quantitative evaluation of the subject matter that took place when determining the number of exemplary compounds that needed to be tested to prove the existence of a class of compounds. While chemistry may have provided some assistance, ultimately this was a legal question that required a legal solution.

[132] *Matheson* v. *Campbell* 7 Fed Reporter 280, 281 (Circuit Court, SD New York, 18 May 1896).

their effectiveness as dyes. As he said, 'whatever may be the similarity or equivalency chemically, I do not understand that the azo-black was commercially or practically the same thing as the black of the patent in suit'.[133] The reason for this was that the imported dye was inferior to the patented dye (it rubbed off and was more expensive). For Judge Townsend, the 'fact that the prior azo-black was sold in small quantities, at a high price to the public, whereas the complainant's invention, a superior article is produced at a lower price, and is a marked commercial success, entirely replacing the original article in the market, is of much greater importance in the determination of the question of equivalency than are any mere chemical test, as to the sufficiency and effect of which experts differ and the court is in doubt'.[134] While chemical experts may have declared the patented azo-black and the imported azo-black to be chemically identical, the key factor for Judge Townsend was that they were not *practically* identical.[135]

One of the notable things about *Matheson* v. *Campbell* was that the imported dye had been described and named incorrectly. As the court noted, the imported dye was 'now known to be in fact a naphthol-black' rather than an azo-black dye.[136] While Judge Townsend was aware of this error, he did not challenge the accuracy of the scientific interpretation of the subject matter in reaching his decision. Instead, he simply shifted away from a scientific understanding of whether or not the two compounds were the same (the answer being yes) to focus on how the compounds functioned (the answer being differently).

The 1910 decision of *Kuehmsted* v. *Farbenfabriken*, which concerned the validity of Felix Hoffmann's patent for acetyl salicylic acid (aspirin),[137] is another situation where the courts were willing to ignore a scientific understanding of chemical subject matter. In his patent Hoffmann claimed acetyl salicylic acid as a new article of manufacture. After outlining the chemical formula, Hoffmann then described the physical traits of his invention including that when it was in a crystallized form it was easily soluble in benzene, alcohol, and glacial acetic acid, it was split by hot water into acetic acid and salicylic acid, and that it melted at about 135° centigrade. One of the notable things about the compound that Hoffmann had invented was that unlike previous products that were undesirable and unsafe, Hoffmann's aspirin was both effective and safe.

The problem Hoffmann faced when he lodged his application in August 1898 was that in the 1859 edition of the leading journal of organic chemistry, *Annalen der Chemie und Pharmacie*, the German chemist Karl Kraut had not only disclosed a process for making acetyl salicylic acid, he also named and provided the structural formula for 'acetyl salicylic acid'. As the compound disclosed in Kraut's 1859

133 Ibid., 282.
134 Ibid., 284.
135 Ibid.
136 Ibid., 281.
137 Felix Hoffmann, 'Acetyl Salicylic Acid' US Patent No. 644,077 (27 February 1900).

publication and the compound disclosed in the patent were chemically identical, it potentially undermined the novelty and thus the validity of Hoffmann's patent. Aware of this, Hoffmann challenged the pre-existing disclosure arguing that Kraut had not in fact made the 'real' acetyl salicylic acid. As he said, 'the compound described by Kraut cannot be the real acetyl salicylic acid, but is another compound'. To prove this, Hoffmann included in the patent the results of a series of chemical tests he had conducted on the two compounds that showed that the compounds were different.[138] Specifically, Hoffmann distinguished his 'real' acetyl salicylic acid from Kraut's 'fake' acetyl salicylic acid in terms of (i) what happened to them when they were boiled with water (with Kraut's compound no acetyl salicylic acid was produced, whereas acetyl salicylic acid was produced with Hoffmann's), (ii) what happened when a watery solution of the compound was mixed with ferric chloride (Kraut's solution turned a violet colour whereas Hoffmann's did not) and (iii) if a melted solution of the compound was allowed to cool, the temperature at which it solidified (Kraut's compound solidified at 118° to 118.5° centigrade whereas Hoffmann's solidified at 'about 70° centigrade'). On the basis of these tests, Hoffmann said that the two compounds were 'absolutely different' and that 'the body obtained by means of my new process if undoubtedly the real acetyl salicylic acid [formula].[139] Therefore, the compound described by Kraut cannot be the real acetyl salicylic acid, but is another compound'.[140]

While the court ultimately agreed with Hoffmann that his patented compound was different to Kraut's, it used different reasoning to reach the same conclusion. While Hoffmann had taken the scientific route of testing the compounds in a laboratory to show that they were not the same, the court began by casting doubts over the accuracy of chemical formula generally, something that Hoffmann would have strongly disagreed with. As the court said, the 'fact that the formulae are identical cuts little figure. A chemical formula is simply the symbolic expression of the composition or constitution of a substance; as the formula for water is H_2O'. The court continued in its attempt to undermine the accuracy of chemical formula arguing that '[c]ustomarily, chemists who intend to produce a combination of two substance write the formula of the product in advance of making it'. They continued in this vein saying that '[w]ithout doubt, processes have been described in chemical publications which give products differing somewhat in their chemical structure and name from which the writer supposed would be produced' or obtains a product that is not correctly represented by the structural formula or name given'.[141] In a statement that both mispresents the nature of chemical formula and also confuses chemical compounds (such as H_2O) with mixtures of

[138] Ibid.
[139] Ibid.
[140] Ibid. The 'responses to tests seems to be a fair method of determining the lack of identity of the product in suit.' *Kuehmsted* v. *Farbenfabriken* 179 Fed 701, 707 (7th CCA 1910).
[141] Ibid., 703.

chemical compounds (such as sea water, which is made up of water (H_2O) and other compounds including chloride, sodium, magnesium, and sulfate), the court went on to say that 'assuming that the formula actually expresses the constitution of the substance chemically, the substance physically, and in consequences therapeutically, may be widely different, as, for instance, the water of the seas, differs, in its physical body from the water of certain springs, though the chemical formula for "water", whether sea or spring, is H_2O. That is to say the two substances, having the same chemical formula, may differ widely, as to impurities upon quantitative analysis'.[142]

After downplaying the usefulness of chemical formula as a way of identifying compounds, the court felt free to shift its attention to focus on what the compound did: its function. Ignoring the fact that the compounds had the same chemical name and formula (and were thus chemically the same), the court held that Hoffmann's compound (which passed through the stomach to dissolve harmlessly in the intestine) was therapeutically different from Kraut's compound (which broke down in the stomach causing harm to users). In so far as Hoffmann had produced a compound that was effective and safe compared to previous compounds that were 'undesirable and unsafe', the court held that Hoffmann had produced 'a medicine indisputably beneficial to mankind – something new in a useful art, such as our patent policy was intended to promote'.[143] In the words of the lower court, Hoffmann took a comparatively worthless substance and changed it into something valuable.[144]

Unlike disputes over the patentability of aniline red dye in France in the early 1860s, where the push to look at dyes in terms of their functional properties rather than their structure was a consequence of scientific uncertainty ('because "science" was far from reaching a definitive answer … "practice" should have a much larger voice in the formation of judicial decision' on patentability'),[145] the decision to focus on a compound's function in *Kuehmsted* was not so much the result of scientific uncertainty, so much as that the science was wrong. While it was rare for the courts to be confronted with such an obvious scientific mistake, these decisions were harbingers of an approach to chemical subject matter that was to reappear, albeit inconsistently and sporadically, in the future where the courts would ignore a chemical understanding of the subject matter that identified a compound by its chemical structure (sometimes referred to as 'pure chemistry')[146]

[142] Ibid., 703–4.
[143] Ibid., 705.
[144] *Kuehmsted* v. *Farbenfabriken* 171 Fed. 887, 890 (1909).
[145] Henk van den Belt, 'Action at a Distance: A.W. Hofmann and the French Patent Disputes about Aniline Red (1860–1863), or How a Scientist May Influence Legal Decisions without Appearing in Court' in (ed) R. Smith and B. Wynne, *Expert Evidence: Interpreting Science in the Law* (London: Routledge, 1989), 184.
[146] Anon, 'The Mortality of Chemical Patents in Court' (1945–46) 354 *Georgetown Law Journal* 504, 509 n 29 (neither court permitted the dust of the prior art relating to pure chemistry to obscure the issue).

to look instead at what the compound did or, as in *Park Davis*, what its therapeutic properties were.[147]

While these decisions were atypical in the sense that they remained exceptions to the general rule that patent law consistently looked to and followed a scientific understanding of the subject matter,[148] nonetheless they are still important in so far as they highlight an issue that the law has long struggled with: namely, faced with a hybrid subject matter that can be construed in different and sometimes inconsistent ways, how and why is one reading favoured over another? A recent example of this can be seen in the *Myriad* litigation (involving the patentability of gene patents) where the subject matter (isolated genes) was able to be construed either chemically (which led to a finding of patentable subject matter) or genetically (which led to a finding of non-patentable subject matter). This is an important issue that I will return to later.

MARKUSH CLAIMS AS SCIENTIFIC-LEGAL HYBRIDS

Another situation where patent law did not follow scientific practice was in situations where chemical nomenclature failed to provide the tools needed to adequately describe chemical inventions in a legal context. This was particularly evident in relation to Markush claims, which were approved by the courts in the 1924 decision of *Ex Parte Markush*.[149]

In 1923, Eugene Markush, the founder and President of the New Jersey Pharma Chemical Corporation that specialised in synthetic dyes, filed an application in which he made a series of alternative claims, namely for 'a diazotized solution of aniline *or* its homologues *or* halogen substitutes'. While claims of this nature had been accepted previously, Markush's claims were rejected in the words of the sub-committee on chemical practice of the Michigan Patent Law Association by an 'overzealous' examiner.[150] In response, Markush replaced his original alternate claims with the generic term 'mono-amine'. The revised application was also rejected; this time on the basis that because it embraced material that was known to be inoperative, it was too broad.

The problem that Markush faced, which was increasingly common at the time, was that by claiming a very large classes of compounds there was a risk that the

[147] While *Parke-Davis* is usually seen as having laid the foundation for the product of nature doctrine, I prefer to look at it as an exception to the longstanding practice whereby legal questions about chemical substances were resolved using scientific criteria. For a history of the decision see Christopher Beauchamp, 'Patenting Nature: A Problem of History' (2013) 16 *Stanford Technology Law Review* 257.

[148] See also *Schering Corporation* v. *Gilbert* 153 F.2d 428, 435 (1946) (claim dismissed on the basis that it was 'nothing but a chemical formula'). Or, as Judge Rich said, 'a chemical compound and all of its properties are inseparable from the standpoint of patent law. The thing patented in a chemical compound is not the formula, which merely gives an identification, but the compound identified by it. What is critical is not the similarity of the formula to that of formulas of the prior art, but the similarity of the compounds and of all of their properties'. *In re Papesch* 315 F.2d, 137 USPQ 43 (CCPA 1963).

[149] *Ex parte Markush* 1925 CD 126 (Comm'r Pat. 1924).

[150] Sub-Committee on Chemical Practice, Michigan Patent Law Association, 'Markush Claims' (1955) *Journal of the Patent Office Society* 164, 166.

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patent might inadvertently include individual compounds or groups of compounds that were inoperative (and invalid). While with mechanical inventions this was not an issue, it was with chemical inventions because the existence of even a small number of inoperative compounds could potentially defeat a generic claim.[151] The problems Markush faced were compounded by the fact that there was no readily available scientific term that he could use to describe his invention in a way that simultaneously captured both the breadth of the class of inventions and, at the same time, also excluded those individual compounds that were legally invalid. As a result, by 1925 'it was becoming extremely difficult for applicants to define their inventions adequately in terms of available, recognized generic expressions'.[152] The reason for this was that the 'existing nomenclature failed to supply a term commensurate in scope with the field which the applicant was entitled to cover'.[153] In this sense, science was not up to the demands that the patent system was making of it.

Markush responded to this dilemma by amending the scientific nomenclature to suit his legal needs. He did this by adding the expression 'material selected from the group consisting of aniline, homologues of aniline and halogen substitution products of aniline' to his generic scientific claim. After the revised hybrid claim was rejected by the examiner, Markush appealed to the Commissioner of Patents who allowed the revised claim saying: 'if there is no known sub-generic term' there was no reason why an applicant should not be able to be 'employ a generic term limited by explanatory terms in the absence of anticipating art'. So long as the modified claims did not do violence to the accepted principles of scientific classification, they were acceptable.[154] While these types of claims had been used for some time, *Ex Parte Markush* was the first decision to rule on such a claim. The hybrid claim, which became known as a Markush claim, were readily accepted by the Patent Office, the courts, and patentees.[155]

In essence, a Markush claim allows a patentee to claim material selected from a general class of compounds in an abbreviated way. The claims operate in situations

[151] The Markush claim was designed for 'emergency situations' such as where 'the genus is of vast extent and comprises substances of rare occurrence or not easily obtainable for experimentation'. The problem here was that there was a 'possibility that there may exist some little known substance within the genus which is inoperative in the applicants process (or composition) and which would consequently defeat a generic claim. It only seems fair to permit the use of a claim of the Markush type under such conditions Such a 'Markush' claim must be restricted to the members of the generic class which applicants has shown in his application to be operative for this purpose'. *Ex parte Mayne* (PO Bd App) 59 USPQ 342. *Ex parte Dahlen* 21 USPQ 397, 1934 CD 9.

[152] Sub-Committee on Chemical Practice, Michigan Patent Law Association, 'Markush Claims' (1955) *Journal of the Patent Office Society* 164, 166.

[153] There was a 'lack of a suitable term or terms which will properly define the true scope of an applicant's invention'. *Ex parte Clark and Malm* 11 USPQ 52, 53.

[154] *Ex parte Dahlen* 1934 CD 9; 21 USPQ 397 (Comm December 1934) (cannot be so dissimilar that the grouping would be 'repugnant to accepted principles of scientific classification to associate them together as a generic if sub-generic group', Ibid., 399).

[155] Manuel Rosa, 'Outline of Practice Relative to "Markush" Claims' (1952) *Journal of the Patent Office Society* 324.

where scientific nomenclature fails to provide an adequate term to describe the invention; they are used in place of the ordinary generic claim when no generic language is available to describe one of the features of the invention together with its stated equivalents.[156] As the Commissioner of Patents said, 'the paucity of the language may necessitate a waiver of the technical rules of this Office to the end that the applicant may properly protect his real invention.'[157]

In providing a solution to the problem created by the peculiarities of class-based generic chemical formula, the Markush claim is an interesting blend of the scientific and the legal. This was because the sub-group that was excluded from the generic class of compounds simultaneously shared scientific things in common with other members of the overarching class of compounds while, at the same time, it differed legally from the class as a whole. In this sense, the Markush claim offers an example of a situation where the law modified chemical practice to its own ends. Because, chemically speaking, the sub-class was grouped arbitrarily (which had to be taken from a 'natural genus'),[158] the Markush claim was recognized as an artificial genus that was designed to separate operative and inoperative compounds.[159] It was a novel legal-scientific taxonomic hybrid that was devised to afford patent protection for chemical inventions where the existing scientific nomenclature 'failed to supply a term commensurate in scope with the field in which the applicant was entitled to cover'.[160]

While the hybrid nature of the Markush claim, which merged scientific and legal nomenclature, successfully allowed patent law to accommodate class-based chemical inventions, it was criticised by both legal and scientific purists. In part this was because like so many things in chemical patent law, Markush claims required some familiarity with the science. While patent office examiners were comfortable in dealing with chemical nomenclature, the courts were often less so. This can be seen in the complaint made by the court in *In re Thompson* that 'there has never been any explanation by the Patent Office tribunals how it is determined that the substances in a Markush type claim possess or do not possess' the requisite qualities needed for them to be valid.[161] The legal nature of the Markush claim also occasionally attracted the ire of chemists who found them difficult to understand, 'baffling', and an 'seemingly absurd idiom', which was a product of the fact that the claims appear to be scientific but are not. At heart the complaint here was that the legal system was exceeding its authority not least because 'chemistry can only be described adequately by chemists'.[162]

156 Robert F. Davis, 'Interpreting the Markush Decision' (1933) *Journal of the Patent Office Society* 187.
157 *Ex parte Markush* 1925 CD 126 (Comm'r Pat. 1924).
158 V. Richard, 'Infringement of a Markush Claim' (1941) *Journal of the Patent Office Society* 529, 531.
159 Harold C. Wegner, 'The Right to Generic Chemical Coverage' (1978) 6 *APLA Quarterly Journal* 257, 261.
160 *Ex part Mayne* (PO Bd App) 59 USPQ 342.
161 *In re Thompson* 61 USPQ 498 (1944).
162 E. A. Ustinoav and O. V. Chelisheva, 'Are Markush Structures Matters of Chemistry and Law or Just Figments of the Imagination?' (1996) 18(1) *World Patent Information* 23, 24.

LEGAL INFLUENCES ON CHEMICAL INFORMATION

Another situation where patent law's relationship with science was less one-sided was in terms of the way chemical information was organised and the role that patent law played in this process. (It seems that patent law also played a role in standardising drawing practices for chemical publications).[163] Chemical information, which was pivotal to the success of organic chemistry, took many forms including journal articles, patents, reference works, and textbooks.[164] One of the challenges that organic chemistry continually faced was ensuring that this ever-expanding corpus of information was able to be used.[165] Over time, a range of different methods were used to organise chemical literature to make it more accessible. These included the development of abstract journals, digests, and specialist bulletins such as the National Research Council's *Bibliography of Bibliographies in Chemistry and Chemical Technology* (1900–1924) and Marion E. Spark's *Chemical Literature and Its Use* (1921).[166] While these are important, I wish to focus here on the efforts of Edwin A. Hill, who after working as a lawyer and civil engineer for various railway companies 'switched gears' to undertake a PhD in chemistry at George Washington University where he subsequently become a professor of chemistry and his attempts to organise and catalogue chemical substances for use by the Patent Office.

One of the requirements for a patent to be valid is that the invention must be novel or new: that is, the invention must not have been available in the public domain previously. When examining a patent application, patent examiners search the prior art to determine whether the invention is in fact new. In many ways, the effectiveness of the examiner's search is largely dependent on the way that the prior art is organised and classified and whether it is legible to patent examiners. One of the challenges that the Patent Office faced when examining applications for chemical patents was the sheer size of the chemical prior art and the fact that much of it was chaotic and disorganised. As a result 'anything like a complete search' was 'rendered practically impossible'.[167] One of the

[163] Patent Office rules that specified how chemical inventions were to be represented in patents were used as part of the platform to standardise drawing practices for chemical publications. N. Edward and M. Hoshall, 'Chemical Drawing' (1934) *Journal of Chemical Education* 21, 27.

[164] Anon, 'Utilization of Chemical Literature' (15 March 1941) *Nature* 310. Patents were particularly useful source of chemical information in so far as they were up to date and also because they often were the only source of information for some compounds.

[165] In order to 'avoid priority struggles and parallel research one needs a powerful classification system, based on established criteria of species identity and able to incorporate indefinitely many new species.' J. Schummer, 'The Impact of Instrumentation on Chemical Substance Identity' in (ed) P. Morris, *From Classical to Modern Chemistry: The Instrumental Revolution* (Cambridge: The Royal Society of Chemistry, 2002), 188, 195.

[166] See Ivan P. Tashof, 'Prior Art Investigations' (1925–26) 8 *Journal of the Patent Office Society* 432.

[167] Edwin A. Hill, 'Chemical Patent Searches and the Chemical Card Index' (1923–24) *Journal of the Patent Office Society* 506, 508.

consequences of this was that 'the validity of chemical patents was more or less in doubt' because 'a five-line paragraph in the files of some little known chemical journal … would be sufficient if cited in court to invalidate the granted patent'.[168] To address this problem, in 1899 the US Patent Office commenced work under the guidance of Edwin A. Hill to develop a bibliographical card index of chemical substances for use in its official work. As Hill said, the Patent Office needed the index for the same purpose as the scientific or practical chemist; to 'obtain references to the literature concerning definitive chemical bodies, where either the name or the chemical composition or both is given'.[169]

As we have seen, one of the notable things about chemical substances is that they can be represented in a number of different ways, notably in terms of their official scientific names, as well as their empirical and structural formula. In putting his index together, Hill was faced with a decision as to which of these modes of representation he was going to use to organise chemical substances. For Hill, chemical names were not an option, not least because they were often unclear and changing. This was because as Hill said in an address to the Washington section of the American Chemical Society in 1900, 'most bodies known to chemists have more than one name, many have several, and the names approved in prior decades are generally not the names on highest repute to-day; nor is it likely that the names now in use will in all or even in most cases, remain in future years'.[170] One of the consequences of this was that it made a dictionary approach to the ordering the chemical prior art, which arranged chemical compounds alphabetically by name problematic. These problems were compounded by the fact that many chemical bodies were unnamed, which made a dictionary-style approach even more problematic.

Hill also rejected the use of structural formula to organise the card index. This was because he was guided by the principal that a 'reference index or digest should in no way depend upon any theory subject to future changes with advancing knowledge.'[171] The reason why he wanted to avoid theory-based representations of compounds (such as structural formulas) was because there was always a chance that if the theory changed, the structural formula would also change. The decision to avoid using any theoretical information in organising chemical compounds meant that Hill could not use structural formulas in developing his alphabetical list. As Hill

[168] *Report of the Taft Commission on Classification of Patents and Printed Publications*, as cited in J. Harold Byers, 'A Chemical Patent Index' (1934) *Journal of the Patent Office Society* 36.

[169] Ever 'since chemists started to represent chemical substances by means of names, formulae, and symbols, there was the need to find information about specific compounds, and this was primarily through the use of indexes where names would have to be searched for in the same way as other topics'. Helen Cooke, 'A Historical Study of Structures for Communication of Organic Chemistry Information Prior to 1950' (2004) 2 *Organic and Biomolecular Chemistry* 3179, 3189.

[170] Edwin A. Hill, 'On a System of Indexing Chemical Literature: Adopted by the Classification Division of the US Patent Office' (1900) *Journal of the American Chemical Society* 478, 479.

[171] Ibid.

said, the 'indexing, and conversely, the finding of the body in the index' should be rendered 'absolutely independent of any theories of constitution [or structure] whatsoever.' This meant that the index needed to be 'independent of any changes in the formula consequent upon future changes of view with reference to constitutional [structural] formulas and other matters of theory'.[172]

Instead of using scientific names or structural formulas to organise the *Card Index to Chemical Literature*, Hill decided to use empirical formula as the basis for indexing and digesting chemical literature. This was because while names and structural formula may change, one thing that did not change – 'the one unchangeable mark of identification of the substance' – were the elements in a compound, which were represented by its empirical chemical formula.[173] As Hill said, the 'kind and number of the component atoms of a chemical compound' which are set out in an empirical formula' are its most unvarying characteristic, and are subject only to errors of chemical analysis'.[174] By focusing on the empirical formula of a compound, Hill could say that 'the use of the digest is as far as possible independent of all theory, and founded only on unchanging facts.'[175]

With this decided, the next question that arose was how the empirical formula should be translated into an alphabetical list. As Hill said, the 'simplest, most certain and most direct system would be to recast the empirical formulas of the compounds, writing the atoms in the alphabetical order of their chemical symbols and them to arrange the formula on an alphabetical basis.'[176] The problem with this, however, was that as most organic compounds contain 'C' and 'H', if a straightforward application of the alphabetical organisation was used, it would have created problems in so far as it would have separated compounds that should have been grouped together. To avoid this, Hill proposed that the alphabetical approach should be modified so that the number of C atoms should be written first, the number of H atoms should be written second, and the remaining elements should be arranged alphabetically by their symbols.[177] The revised and rewritten formula were then arranged alphabetically. As Hill said, the rewritten formula was an 'arbitrary arrangement' that 'unerringly indicates one, and one only, definite and specific place in the index where we are to look for all references with a certainty that no other character, name or tile of the body can afford'.[178]

From three to six workers supervised by Hill worked continuously on the card index from 1900 to around 1920 (when it was suspended due to cost). The index

[172] Ibid., 483.
[173] Edwin A. Hill, 'Chemical Patent Searches and the Chemical Card Index' (1923–24) *Journal of the Patent Office Society* 506, 509.
[174] Edwin A. Hill, 'On a System of Indexing Chemical Literature: Adopted by the Classification Division of the US Patent Office' (1900) *Journal of the American Chemical Society* 478, 479.
[175] Ibid., 488.
[176] Ibid., 479–80.
[177] Ibid., 480.
[178] Ibid., 492.

ONE FORMULA CARD:

$C_{12}O_{18}Fe_2O_{12}$ or $(CH_3.CO_2)_6Fe_2$.

Ferric Acetate; Acetate of Iron; Klaproth's Iron Tincture; Tinctura Ferri Acetatis; Iron Tincture, Klaproth's.

See A Treatise on Chemistry. By H. E. Roscoe and C. Schorlemmer, Vol. 3, Organic Chemistry, Part I, Page 505.

ONE POLYMER OR MULTIPLE FORMULA CARD:

$C_6H_9FeO_6$ Polymer Class 2.

See $C_{12}H_{18}Fe_2O_{12}$ or $(C_6H_9FeO_6)_2$
Ferric Acetate.

TWO CLASSIFICATION CARDS:

Acetates

Ferric.
See $C_{12}H_{18}Fe_2O_{12}$ or $(CH_3.CO_2)_6Fe_2$.

Iron

Acetate of.
See $C_{12}H_{18}Fe_2O_{12}$ or $(CH_3.CO_2)_6Fe_2$.

FOUR SUBJECT-MATTER OR TITLE CARDS:

Ferric Acetate

See $C_{12}H_{18}Fe_2O_{12}$.

Klaproth's Iron Tincture

See $C_{12}H_{18}Fe_2O_{12}$.

Iron, Klaproth's Tincture of

See $C_{12}H_{18}Fe_2O_{12}$.

Tinctura Ferri Acetatis

See $C_{12}H_{18}Fe_2O_{12}$.

FIGURE 4.4 Library Bureau Card for Ferric Acetate
United States Patent and Trademark Office, Chemical Index.

was prepared and placed on a 7½ by 12½ cm Library Bureau card (see Figure 4.4). The rearranged formula of the compound was placed at the top of the card above a ruled blue line. Below the line, all of the given names of the compound were listed along with reference to any works indexed. By 1907, the card index included nearly

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500,000 cards.[179] By 1923 the card index had increased to over one million cards in 1040 drawers.[180]

The completed card index, which was described as a 'national monument to chemical literature',[181] was placed in the Patent Office Library where it was made available for use by patent examiners, patent lawyers, chemists, and scientific workers (all free of charge). While the card index was used 'enthusiastically' during the war by the Chemical Warfare Service[182] and was popular with members of the public, Hill complained that the index was not used much by patent examiners primarily because it was located 'far away from the examining divisions' in 'cramped, narrow and ill lighted quarters'.[183] Despite repeated recommendations from a range of quarters that the indexing work should be continued, a lack of funding meant that by 1934 Hill's card index at the Patent Office was obsolete.[184]

While Hill's card index may have run its course at the Patent Office by the 1930s, nonetheless it had an important and long-lasting impact on the way chemical information was organised outside of the legal system. This was particularly the case in relation to the efforts undertaken by the American Chemical Society to shape chemical literature. 'Faced by the unwieldy chaotic mess of rapidly accumulating chemical facts and chemical theories' the American Chemical Society established the magazine *Chemical Abstracts* in 1907 to 'collect, condense and then publish it in an abstract of every worthwhile article on chemicals and chemistry appearing in the current scientific magazines in every language.'[185] By 1921, abstracts were taken of articles from over 738 periodicals and from US and select foreign patents.[186]

To improve access to information on compounds, in 1920 *Chemical Abstracts* decided to publish a formula index. While there were various scientifically driven indexes that could have been used, the index system adopted by the American Chemical Society in *Chemical Abstracts* was the system that Hill had developed for use at the Patent Office.[187] Hill's system of organisation was chosen in preference to

[179] Edwin A. Hill, 'The Chemical Card Index of the Patent Office' (1907) 29 *Journal of the American Chemical Society* 936.
[180] Edwin A. Hill, 'Chemical Patent Searches and the Chemical Card Index' (1923–4) *Journal of the Patent Office Society* 506, 508. There were 1,200,000 cards by 1912: Edwin A. Hill, 'The Card Index to Chemical Literature of the United States Patent Office' (1912) 34 *Journal of the American Chemical Society* 416.
[181] L. H. Baekeland, 'The Index to Chemical Literature' (1913) *The Journal of Industrial and Engineering Chemistry* 534.
[182] Edwin A. Hill, 'Chemical Patent Searches and the Chemical Card Index' (1923–24) *Journal of the Patent Office Society* 506, 510.
[183] J. Harold Byers, 'A Chemical Patent Index' (1934) *Journal of the Patent Office Society* 36.
[184] Ibid.
[185] Edward Thomas, 'Computing Progress in Chemistry' (1936) *Journal of the Patent Office Society* 357.
[186] Frank E. Barrows, *Investigations of the Chemical Literature* (New York, 1921), 20.
[187] J. Harold Byers, 'A Chemical Patent Index' (1934) *Journal of the Patent Office Society* 36.

other chemical indexing systems such as Richter's Lexikon because of its simplicity and the speed and ease by which compounds could be located.[188]

As well as informing the way that *Chemical Abstracts* were indexed and the related Chemical Abstract Services (CAS) Number – which is the permeant, unique and unambiguous numerical identifier given to every chemical substance that is widely used by scientists and patentees today to define and describe chemical substances[189] – were organised, the Hill system was widely adopted and used within chemistry. Indeed it has been said that it is now the most commonly used system to sort lists of compounds in chemical databases and printed indexes.[190] What we see here is that as well as forming part of the chemical prior art, patent law also helped to shape the way chemical information was organised and classified. While in other contexts, patent law willingly followed the lead of chemistry, the roles were reversed when it came to the chemical public domain.

[188] William A. Noyes, 'Presidential Address: Chemical Publications' (1920) *The Journal of the American Chemical Society* 2017. The editors of the Chemical Abstracts 'gratefully acknowledge their indebtedness to Dr Edwin A. Hill for the opportunity and privilege of using his admirable system of arrangement'. American Chemical Society (December 1920) 14 *Chemical Abstracts* 4559.

[189] Chemical Abstracts Service, *A National Historical Chemical Landmark* (Chemical Abstracts Service, 14 June 2007), 2.

[190] Gary Wiggins, *Chemical Information Sources* (New York: McGraw Hill, 1991), 120.

5

Intangible Machines

'Software is or may be viewed as a new kind of property as, in effect, intangible machinery'.[1]

INTRODUCTION

In August 1967 Morton Jacobs, who was patent counsel for the Princeton-based software company Applied Data Research, wrote a letter to the Vice President and General Counsel of IBM, Burke Marshall, complaining about the way IBM was distributing its computer programs. Specifically, Jacobs complained that in giving customers who leased or bought IBM 360 computers a free copy of their Flowcharter program (which automatically developed flowcharts that set out the logic of a computer program) that IBM was destroying Applied Data Research's market for its Autoflow program (which also automatically developed flowcharts).[2] Jacobs added that in violation of antitrust laws and the law of unfair competition, IBM's actions would destroy his 'client's market for its Autoflow systems and destroy the property value of his clients software system by setting a "free" price as its market value, and make it impossible for our client to compete with IBM in the sale of such systems, all to the great detriment and injury of our client'.[3]

The main concern for Applied Data Research was that IBM distributed its Flowcharter program 'in the same way it distributed other software' whereby the software was 'given away "free" to IBM customers and "tied-in" to the sale of IBM/360

[1] Lawrence I. Boonin, 'Future Developments' as cited in C. McOustra, 'Legal Protection for Computer Programs' (1966) 8(4) *The Computer Journal* 289, 294.

[2] *Applied Data Research* v. *International Business Machines Corporation* 69 Civ, 1682 (filed 22 April 1969). Robert W. Wild, 'Computer Program Protection: The Need to Legislate a Solution' (1969) 54(4) *Cornell Law Review* 586, 588. ADR settled its antitrust suit with IBM for $2 million. Martin A. Goetz, 'How ADR Got Itself into the Software Products Business and Found Itself Competing against IBM' (1998) Computer History Museum 2.

[3] Letter written by Morton C. Jacobs to Mr. B. Marshall (16 August 1967), Charles Babbage Institute, Applied Data Research, Software Products Division records, CBI 154, Box 3, Folder 6.

computers'. Following a response from Marshall denying liability and saying that IBM would need to wait for Applied Data Research's patent (then pending) to issue on Autoflow, Jacobs responded saying that there 'can be no question that IBM's tie-in of its Flowcharter program to sales of the IBM 360 machines has misled potential customers of Applied Data Research's Autoflow into thinking that the IBM Flowcharter program is free'. On the basis that this 'illegal and anticompetitive practice by IBM has seriously injured [Applied Data Research's] sales', Jacob warned that unless steps were taken to correct these actions in violation of the antitrust laws Applied Data Research would be compelled to seek appropriate legal and enforcement remedies'.[4]

Applied Data Research followed up on its threat in April 1969 when it brought an antitrust action against IBM arguing that in giving its Flowcharter programs away for free that IBM had uncompetitively impeded the independent development of software.[5] Along with similar antitrust actions by Programmatics (a subsidiary of Applied Data Research), Control Data Corporation, and Data Processing Financial General Corporation, the Department of Justice also filed an antitrust action against IBM in 1969 arguing that by giving away software services for free and by bundling software with related equipment hardware under a single pricing plan (without detailing the price of the elements), IBM had engaged in anticompetitive practices that restrained actual or potential competitors from entering the relevant markets.[6]

In June 1969, IBM announced that from January 1, 1970, it would unbundle its software and hardware and charge separate prices for programming services and software packages. That is, it would separately price and sell the software it had previously bundled with its computers and sold at a single price. True to its word, in 1970 IBM not only began to sell hardware and software separately, it also began to charge a monthly fee for the use of its software or as IBM preferred, its 'program products'.

IBM's unbundling of hardware and software was part of a wide ranging set of changes that occurred in the computing industry in the 1960s and 1970s.[7] As the President of Programming Sciences Corporation, Albert M. Loring, said at the time, IBM's announcement 'has, in effect, given birth to the software industry as an Industry'.[8] As we will see, these changes also triggered a wide-ranging debate about the applicability of patent protection for the products of this emerging new industry.

4 Letter written by Morton C. Jacobs to Burke Marshall (4 October 1967), Charles Babbage Institute, Applied Data Research, Software Products Division records, CBI 154, Box 3, Folder 6.

5 *Applied Data Research* v. *International Business Machines Corporation* 69 Civ 1682 (SDNY 1969).

6 *United States* v. *IBM* 69 Civ 200 (SDNY 1969). One of the complaints was that IBM had 'committed a fraud on the US Patent Office by applying for and obtaining patents for computer systems based on software but disguised as hardware'. Howard R. Popper, 'From Hardware to Software: An Adventure Having Some Surprises' in *Software Protection by Trade Secret, Contract, Patent: Law, Practice, and Forms* (Washington: Patent Resources Group, 1969), 120.

7 Watts S. Humphrey, 'Software Unbundling: A Personal Perspective' (January–March 2002) *IEEE Annals of the History of Computing* 59, 62.

8 Alan Drattel, 'Unbundling: The User Will Pay for the Works' (August 1969) *Business Automation* 36, 40.

At first blush, it may appear that IBM's decision to unbundle its (intangible) software from its (tangible) hardware represents a dematerialisation of patentable subject matter: a change from the situation where the subject matter consisted of a tangible machine that embodied intangible software to a situation where there were now two potential forms of subject matter – the tangible computer hardware and the intangible instructions used to control a computer (the program). Building upon the idea that the computer program represented a turning point in the 'long struggle for information to emancipate itself from the shackles of materiality',[9] there is a sense in which the unbundling of hardware and software marks yet another situation where patentable subject matter was dematerialised.

While IBM's decision to unbundle its software set in play a process that ultimately led to the dematerialisation of computer-related subject matter, this did not occur until the end of the twentieth century. This is because while in the 1970s software and hardware may have been unbundled from a commercial and marketing perspective, they remained technologically intertwined.[10] As we will see, following the decision to accept a technological reading of the subject matter, computer-related inventions in patent law retained a physical form. This remained the case for the remainder of the twentieth century.

To explore the role that materiality played in patent law's interaction with computer-related subject matter, how the law ultimately dealt with an unbundled dematerialised subject matter, and the role that computer science and the computer industry more generally played in these processes, this and the following two chapters explore patent law in the United States from the 1960s through to the early part of the twenty-first century. After looking at how software was created and consumed in the 1960s and as this changed how it gave rise to questions about the role intellectual property might play in the emerging software industry, I look at the contrasting ways that patentable subject matter was seen within the information technology industry more broadly. In Chapter 6, I turn to look at the problems patent law experienced in the 1960s and 1970s in attempting to reconcile the conflicting views within the industry about what the subject matter was and how it should be interpreted. In Chapter 7, I show how in the 1980s patent law came to view computer-related subject matter through the lens of 'abstractness' and the role that materiality played in determining the fate of that subject matter in this context. I also look at how as a result of changes in technology, patent law gradually shifted away from the materiality of the subject matter to look at its 'specificity' and how in so doing the subject matter was dematerialised.

9 Jean-Francois Blanchette, *Burdens of Proof: Cryptographic Culture and Evidence Law in the Age of Electronic Documents* (Cambridge, MA: MIT Press, 2012), 18.

10 One of the issues that patent law grappled with until the early 1980s was how to reconcile these contrasting ways of thinking about the subject matter: that is, how was patent law to reconcile the computer program as a commercially unbundled and independent object from the computer program which was technologically bound to the computer hardware (which mirrors the tension that arises because a patent is both a commercial and a technical document).

SOFTWARE IN THE 1960S

Today, software is typically thought of as a pre-packaged consumer product that contains the instructions or code that controls computers. As software historians have shown, this was not always the case. 'Historically speaking … software was not something that was purchased off-the-shelf, nor was it a single application or product. Rather it was a bundle of systems, services and support'.[11] Indeed, it was not until the late 1960s that software came to be treated as a product and 'even then software as code represented only a small component of a larger software system of services and support'.[12] While there were exceptions, in the 1960s there were no stand-alone companies specializing in the creation and sale of software products: there was no organized and discrete software industry to speak of, or at least as we understand it today.

In this environment, users tended to obtain their software in one of four ways. In some situations, corporate programming staff would write the software in-house. While manufacturers provided customer support and training, users often developed their own custom written programs. Another important source of software in the 1960s were the user groups that had been established to facilitate the sharing of programs, algorithms, and associated information. By 1960, around 20 different user groups exchanged programs for free.[13] Interestingly, the user groups were actively promoted and supported by the hardware manufacturers. For example, in order to alleviate the expense of programming that occurred when IBM replaced the 701 computer with the 704 model in 1954,[14] IBM formed SHARE (Society to Help Avoid Redundant Effort) to exchange programs amongst members (over 300 programs were shared) and to 'serve as a conduit between users and IBM's future development in hardware and programming'. The success of these early user groups encouraged the development of similar groups by IBM, other manufacturers, and industry bodies such as the American Bankers Association (who set up a 'Swap Room' at their annual conference to facilitate the exchange of computer programs).[15]

Another important source of software in the 1960s were the programming service (or custom programming) companies who produced custom written software for users on a fee basis. Typically, these software contractors wrote bespoke programs for corporate and government customers.[16] Often the programs were very expensive

[11] Nathan Ensmenger, *The Computer Boys Take Over: Computers, Programmers, and the Politics of Technical Expertise* (Cambridge, MA: MIT Press, 2010), 6.

[12] Ibid., 7.

[13] Robert F. Brothers and Alan M. Grimaldi, 'Prater and Patent Reform Proposals' (1969) 17 *Catholic University Law Review* 389, 392.

[14] Martin Campbell-Kelly, *From Airline Reservations to Sonic the Hedgehog: A History of the Software Industry* (Cambridge, MA: MIT Press, 2004), 33.

[15] Robert Head, 'The Travails of Software Resources' (January–March 2002) *IEEE Annals of the History of Computing* 82, 84–85.

[16] Martin Campbell-Kelly, *From Airline Reservations to Sonic the Hedgehog: A History of the Software Industry* (Cambridge, MA: MIT Press, 2004), 3–4.

($1 million not being uncommon[17]) and specifically written for particular organizations. As most of the sales occurred through personal contacts of staff or were in response to requests for custom software,[18] software contractors often had close working relationships with their customers.

The computer manufacturers who provided software free of charge to customers who bought hardware from them were another important source of software in the 1960s.[19] While the software packages were often costly to produce – figures spanned from a million dollars through to the $50 to $60 million IBM reportedly invested in its IBM/360 software – nonetheless, hardware manufacturers bundled the cost of the software into the cost of the hardware.[20] At the time, there was no thought of recovering the cost of developing software by selling or leasing it separately.[21] Instead, in an environment where programs were distributed freely as an inducement to purchase hardware, software development was often seen as a marketing cost. In other situations the marketing and sale of software were presented as the selling of services (which, it was hoped, would take any illegal tie-ins outside the scope of antitrust laws).[22] Either way, software was bundled with the hardware and given away for free as part of the overall package that was provided to customers.

The manner in which software was created, exchanged, and consumed during the 1960s had an impact on how software was valued.[23] It also had an impact on what was expected or demanded of the law. In relation to the software that was obtained for free from computer manufacturers or user groups, there was no need or interest in legal protection. To the extent that software was seen as a proprietary object, there was also little call for legal protection. This was because the close personal relationships that existed between software contractors and the companies they created software for minimized the need for legal or extra-legal means to control the reproduction or imitation of software. To the extent that there was a concern with

[17] Ibid.

[18] Ibid., 5.

[19] This was dominated by eight large companies: IBM, Honeywell Information Services, Univac, Burroughs Corporation, Control Data Corporation, National Cash Register Company, Digital Equipment Corporation, and Xerox.

[20] For example, under its single price or bundling procedures, IBM charged customers a single price based on the hardware supplied. Morton C. Jacobs, 'Computer Technology (Hardware and Software): Some Legal Implications for Antitrust, Copyright and Patents' (1970) 1 *Rutgers Journal of Computers and Law* 50, 62.

[21] Martin Campbell-Kelly, *From Airline Reservations to Sonic the Hedgehog: A History of the Software Industry* (Cambridge, MA: MIT Press, 2004), 98.

[22] Morton C. Jacobs, 'Computer Technology (Hardware and Software): Some Legal Implications for Antitrust, Copyright and Patents' (1970) *Rutgers Journal of Computers and Law* 50, 62. Anon, 'Software Gets a Hardsell Approach' (21 October 1967) *Business Week* 171.

[23] To the extent that software was obtained for free from computer manufacturers or through user groups, it helped to create the perception of software as 'objects without intrinsic value, or at best with value that there were no market mechanisms to realize'. Martin Campbell-Kelly, *From Airline Reservations to Sonic the Hedgehog: A History of the Software Industry* (Cambridge, MA: MIT Press, 2004), 96.

software and how it circulated, the focus was on the body of the programmer rather that the product of their labour (the software). At a time when the major assets of software service companies would 'go down in the elevator every night',[24] the primary concern was the pirating of programmers (or 'body snatching'[25]) by competing firms and customers[26] rather than the copying or piracy of software. This was reflected in the fact that a key legal concern of the information technology industry at the time was the role that the law could play in restricting the mobility of workers via employment contracts, restraint of trade, non-compete contract clauses, and confidentiality agreements. In reflection of this, most of the legal disputes at the time were a result of clients hiring staff from professional services companies in violation of non-hiring clauses.[27]

Over the course of the 1960s, a number of changes took place that gradually and haphazardly undermined this pre-modern regime. For my purpose, one of the most important developments was the gradual emergence of a new type of software artifact: the *software product*. Software products were standardised off-the-shelf programs that were sold separately, some in the hundreds, a few in the thousands, typically for between $5,000 and $100,000.[28] Software products were discrete commercial objects that could be used without modification by a large number of contractors with little or no customization.[29] While Applied Data Research's Autoflow (1965) and Informatics Mark IV (1967) are often considered the earliest and most influential software products, by 1967 the number of proprietary programs on the market had increased to over a 100, with sales of about $4 million.[30] From a small number of companies at the beginning of the 1960s, there were reported to be over 3,000 independent software and service companies by 1968.[31] As a result, by the end of the 1960s the term 'software-industry' had taken on its present day meaning 'signifying commercial organizations engaged in the production of programming artefacts'.[32]

There were a number of factors that prompted the emergence of the software products industry in the later part of the 1960s. One important factor was the proliferation and growing capabilities of computers. The rapid increase in the number

24 Dave Sturtevant, ADAPSO Reunion Workshop, 'Industry Image', recorded 4 May 2002, CHM Ref No. X4425.2008, Computer History Museum, 19.

25 Gene Bylinsky, 'Help Wanted: 50,000 Programmers' (March 1967) *Fortune* 141.

26 Philip Stork, 'Legal Protection for Computer Programs: A Practicing Attorney's Approach' (1970) 20 *Copyright Law Symposium* 112, 115.

27 ADAPSO Reunion Workshop, 'Contract Reference Directory', Computer History Museum (2002), CHM Ref No. X4410.2008, 14.

28 Martin Campbell-Kelly, *From Airline Reservations to Sonic the Hedgehog: A History of the Software Industry* (Cambridge, MA: MIT Press, 2004), 3–4.

29 Ibid.

30 Anon, 'Software Gets a Hardsell Approach' (21 October 1967) Business Week 171. Donald H. Sundeen, 'General Purpose Software' (January 1968) *Datamation* 22.

31 Martin Campbell-Kelly, *From Airline Reservations to Sonic the Hedgehog: A History of the Software Industry* (Cambridge, MA: MIT Press, 2004), 50.

32 Ibid., 57.

of computers in the United States – estimated at 4,000 in 1960, 21,600 in 1965, and 48,500 in 1970[33] – created a number of software-related problems. One of which was that the software contractors who wrote bespoke programs for corporate and government customers were unable to keep up with the growing demand for custom-built software: simply put, computers were growing faster than programmers. This led to a concern about the shortage of software applications and programmers. These problems were compounded by the fact that the sharing organizations who supplied free software were criticized for being too hardware focused and because they did not share important and costly programs.[34] There was also a concern about the quality of the programs being created. Another problem was that many computer users lacked the in-house expertise to develop or customise software. And for those organizations that had the expertise to write software themselves, there were concerns about the cost of in-house production: it was often difficult to predict in advance how long it would take and how much it would cost to develop software. Pre-packaged software that was sold off the shelf at a fixed price helped to satisfy many of these concerns.

Another important factor that facilitated the emergence of the software products industry in the 1960s was the development of the common technical standards that interoperable pre-packaged objects require. One of the factors that had prevented the development of pre-packaged software in the early 1960s was the diversity of different standards then in use. For example, in 1960 IBM had at least seven different software incompatible computer architectures, each of which required unique operating systems and utilities. The situation changed in the mid-1960s, however, when IBM introduced the 360 family of computers. One of the features of the new 360 system, which consisted of fourteen different computers, many of which sold in large numbers, was that all of the computers used the same architecture. In so doing, IBM created a base-standard and a technical platform for the industry as a whole. As one independent software producer said, the establishment of 'a single architectural standard' facilitated by the 360 family of computers 'gave us a great customer base to sell to'.[35]

Yet another factor that played a role in the development of the software products market was the antitrust actions that were brought against IBM by the US Department of Justice and Applied Data Research. While there may be questions about the reasons for the unbundling, there is little doubt that it had a substantial impact on the nascent computing industry. One of the consequences of the unbundling that took place in the early 1970s was that software was marketed and sold separately from hardware. By helping to 'condition customers to pay for software' and by challenging the idea that software was a free good, the decision by IBM and

33 Ibid., 50.

34 Robert F. Brothers and Alan M. Grimaldi, 'Prater and Patent Reform Proposals' (1969) 17 *Catholic University Law Review* 389, 392; Editors Readout, (June 1966) *Datamation* 21.

35 Lee Keet, ADAPSO Reunion Workshop, 'Intellectual Property' (2002) Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 20.

other hardware companies to stop giving software away for free helped to create 'a vibrant market for software products, which previously had been merely embryonic. It was a turning point for the industry'.[36] As well as benefiting existing computer service and software firms such as Applied Data Research and Informatics, who saw a dramatic increase in sales after IBM announced that it would market and sell hardware and programs separately,[37] the unbundling of software also acted as a catalyst for new organisations to enter into the software products market. In this sense, unbundling was a 'crucial inflection point' in the development of the software products industry.[38]

The emergence of the software product industry not only saw a change in the way software was created, distributed, and used, it also changed the way people thought about software. For my purposes, the most important consequence of the development of the software product industry was that it changed what was expected or demanded of the law. While there had previously been little or no need for intellectual property protection, suddenly intellectual property was potentially relevant. Indeed, one of the consequences of the growth in the software product market was that it triggered a debate about the potential role that intellectual property might play in relation to software-related subject matter.

INTELLECTUAL PROPERTY PROTECTION FOR THE SOFTWARE PRODUCTS INDUSTRY

Early interest in the potential application of intellectual property to protect software was driven by two groups. The first were the financial institutions who loaned money to software companies. One of the concerns that banks and other financial institutions had when loaning money to software product companies was that many of the new start-up companies had very few assets other than the software that they were creating. The problem here was that the banks were uncomfortable loaning money purely on the basis of intangible assets. One of the strategies that the banks adopted to deal with this problem was to demand that software companies take out intellectual property protection over their software. This allowed the banks to point to the copyright or patent registration as if it was a tangible manifestation of the ephemeral software. The problems banks had with software's intangibility and the way that they dealt with this is captured in the comments of an industry representative about his experience in obtaining a loan from a bank at the time. As he said, the bank was 'alarmed that the principal software of the company had not been registered in the Copyright Office'. To remedy this, as a condition of the loan the bank

36 Martin Campbell-Kelly, *From Airline Reservations to Sonic the Hedgehog: A History of the Software Industry* (Cambridge, MA: MIT Press, 2004), 89.

37 Ibid., 115.

38 J. Yates, 'Application Software for Insurance in the 1960s and Early 1970s' (1995) 24(1) *Business and Economic History* 123.

insisted that the 'company file all of those pieces of software in the Copyright Office so that they would have a lien on a registered copyright'.[39]

The second group agitating for protection were lawyers. For some lawyers, ensuring that software products were protected was an integral part of what it meant to be a lawyer. As Irving Kayton said when opening a software law conference at George Washington University in 1968: 'lawyers must protect their client's property rights or they will not have clients or, indeed, practice law'.[40] For other lawyers, legal protection was an integral part of what it meant for something to be a product. As one legal commentator noted, the 'one essential ingredient of the package concept [or software product] is a means of protecting the program: for without such protection, it ceases to be a commodity'.[41] For most lawyers, however, the primary reason why legal protection was needed was to prevent software from being pirated. Here, lawyers either worked on first principals – arguing that no one would invest in software unless it was protected[42] – or cited other lawyers about the manifest need for protection. Whatever the justification, the message was clear: without protection, software was vulnerable; 'the degree of competition and inevitably the quality of the end product, will be diminished'.[43]

One of the things that underpinned the various pleas for legal protection for software was a belief that software piracy was a problem that needed to be solved. In a sense it was presumed that the development of software products as discrete commercial objects necessarily created a need for intellectual property protection. While the separation of intellectual outputs from the people who generate them often creates a need for intellectual property protection, this is not necessarily the case (as lawyers at the time seemed to presume). Ultimately, the question of whether intellectual property protection is needed in a given situation depends on a range of factors from how easy it is to reproduce or copy the creative output in question and whether copying is seen as a problem, to whether other means are available

[39] Oscar H. Schachter, ADAPSO Reunion Workshop, 'Intellectual Property' (2002) Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 13.

[40] Irving Kayton, 'Foreword' in *Software Protection by Trade Secret, Contract, Patent: Law, Practice, and Forms* (Washington: Patent Resources Group, 1969), 8.

[41] David Bender, 'Trade Secret Protection of Software' in *Software Protection by Trade Secret, Contract, Patent: Law, Practice, and Forms* (Washington: Patent Resources Group, 1969), 3. One question that needs consideration is the role lawyers played in creating an expectation that software needed to be protected. Martin Goetz attended a session chaired by Mort Jacobs at a 1964 Spring Joint Computer Conference in Washington on 'Patents and other legal problems relating to Electronic Computers'. Martin Goetz, 'Memoirs of a Software Pioneer' (January–March 2002) *IEEE Annals of the History of Computing* 43, 50.

[42] As Whitlow Computer Systems, a company engaged exclusively in the development, production and sale of computer programs said, many potential investors had refused to invest in Whitlow 'simply because it could not give assurance that its computer programs will be held to be patentable subject matter. Brief Amicus Curiae for Whitlow Computer Systems, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71–485 (Oct. Term, 1971), 2 n 2.

[43] David Bender, 'Trade Secret Protection of Software' in *Software Protection by Trade Secret, Contract, Patent: Law, Practice, and Forms* (Washington: Patent Resources Group, 1969), 6.

to prevent unwanted copying or imitation. It was the later point that is relevant here. This is because while the emergence of software products did shift the focus of attention away from programmers towards the products of their labour, it did not (immediately) affect the relationships that existed between creators/producers and users/consumers of software. As had been the case with software contractors who had built strong relationships with their customers, software product firms also managed to establish close relationships with the users of their software. These relationships were reinforced by the pre-and after-sale support (including product customization, user training, and regular updates) that software products firms regularly provided to customers.[44] This was particularly the case with application software companies, who were more service companies than packaged goods companies and therefore worked closely with customers.[45] One of the consequences of this was that the use/misuse of software was largely controlled through personal ties and business-to-business relationships. As a software industry representative explained, the data processing managers who the software companies dealt with were 'not going to cheat because he could end up losing his job. So there was very little thievery'.[46]

The upshot of this is that despite the suggestions by lawyers at the time, there was little need for legal protection (at least to prevent piracy). Indeed, one of the things that software industry representatives looking back on the 1960s have stressed is that, in spite of what the lawyers may have suggested, piracy or as it was known at the time, thievery was not a problem. These sentiments were captured in the comment by the former president of the software products group at Dun & Bradstreet, Leo Keet, when he said:

> It was just a bizzarre time. The word I would use is paranoia. We, as an industry … were paranoid about things that didn't happen. We thought that there was going to be a lot of thievery. We wanted to anticipate it because we put so much of our money and intellectual energy and effort into building these things, and we didn't want them stolen.
>
> It wasn't until the PC industry came along [in the 1980s] that it actually turned into a huge problem. I can't emphasise that enough. I don't think you'll find anybody from the era of the 1960s and 1970s that will tell you that they had a big problem with thievery.[47]

44 Martin Campbell-Kelly, *From Airline Reservations to Sonic the Hedgehog: A History of the Software Industry* (Cambridge, MA: MIT Press, 2004), 6.

45 Lee Keet, ADAPSO Reunion Workshop, 'Intellectual Property' (2002) Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 14.

46 Martin Goetz, ADAPSO Reunion Workshop, 'Intellectual Property' (2002) Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 16.

47 Lee Keet, ADAPSO Reunion Workshop, 'Intellectual Property' (2002) Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 14. 'The big concern we initially had was … unauthorised copying of software. But for us, it turned out, that rarely proved to be a problem … Piracy was not an issue for us. Remember this was not PC software where theft is a significant issue. This was all mainframe and mid-range stuff'. Dick Thatcher, ADAPSO Reunion Workshop, 'Contract Reference Directory' (2002) Computer History Museum CHM Ref No. X4410.2008, 14

While there may have been very little unauthorized use of programs by corporations[48] and even less by consumers,[49] this does not mean that intellectual property protection was not needed. One of the areas where this was the case was to protect software product firms from the predatory behaviour of the large hardware firms, particularly IBM. Rather than needing to prevent end-user piracy of software, software product firms needed legal protection to enable them to compete against hardware manufacturers and thus to get a share of the rapidly expanding market. The concern here was that without protection, software product firms were 'unable to compete with machine manufacturers who would be able to copy the programs with impunity and distribute them "free" with their machines'.[50]

One of the most vocal proponents of intellectual property protection for software was Martin Goetz, president and founder of Applied Data Research.[51] As we saw earlier, one of the earliest and most successful software products was Applied Data Research's Autoflow software program, which was designed to produce program flowcharts automatically. Applied Data Research, who had invested over US$4 million in software systems,[52] believed that one of the reasons for the low sales of its Autoflow software was because IBM had begun to offer for free a program called Flowcharter that also generated flowcharts automatically. As Goetz complained, the 'IBM Flowcharter became the major reason for a delayed or lost Autoflow sale. Our prospects went to IBM and asked for improvements to free IBM programs and it was widely believed IBM would develop a similar type of program and provide it to their customers for free'.[53] In response Goetz not only brought an antitrust action against IBM, he also joined with many others to argue that the only way that smaller software firms could protect themselves against the predatory behaviour of large hardware manufacturers was to ensure that software was given some type of legal protection.

Irrespective of whatever doubts there might be about whether legal protection was needed at the time, there is no doubt that there was a growing interest across the

[48] Martin Goetz, ADAPSO Reunion Workshop, 'Intellectual Property' (2002) Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 12. 'ADR was never aware of any company that was using [their] software without being authorized to use it'. Ibid., 16.

[49] 'I never had a customer steal from me'. Leo Keet, ADAPSO Reunion Workshop, 'Intellectual Property' (2002) Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 11.

[50] Morton C. Jacobs, 'Commissions Report (re: Computer Programs)' (1967) *Journal of the Patent Office Society* 372, 376.

[51] As Goetz said, 'I got indoctrinated very early by Mort Jacobs, my patent attorney, who had previously worked at the Patent Office and then worked at RCA and then he was in private practice'. Martin Goetz, ADAPSO Reunion Workshop, 'Intellectual Property' (2002) Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 10.

[52] Martin A. Goetz, 'Protecting Computer Program Concepts and Copies' (1970) 14 *Idea* 7.

[53] Martin A. Goetz, 'How ADR Got Itself into the Software Products Business and Found Itself Competing against IBM', Computer History Museum (1998), 2. See also Martin Goetz, 'Memoirs of a Software Pioneer', (January–March 2002) *IEEE Annals of the History of Computing* 43, 50–53. Potential customers 'questioned why they should pay for an outside product when they could acquire software for "free" through IBM or an industry trade group'. Robert Head, 'The Travails of Software Resources' (January–March 2002) 82 *IEEE Annals of the History of Computing* 84.

1960s in the potential role that intellectual property might play in protecting software, an interest that was heightened by changes in labour law that made it increasingly difficult to control the movement of employees.[54] While the first copyright registration for software was granted in 1964,[55] there was little industry interest in using copyright to protect software-related innovations.[56] (There was even less interest in trade secret protection, which was thought to provide ineffective protection).[57] While the hardware manufacturer's interest in using copyright increased over time, independent software companies consistently showed little interest in using copyright to protect software. There were a number of reasons for this, including uncertainty about whether the registration of software would be upheld by the courts, the limited protection that was available if software was in fact protectable (given that it only protected the expression of programs), and uncertainty about how software should be represented for the purposes of registration. These problems were compounded by the fact that the Copyright Office (initially) did not accept object code for the purposes of registration. Instead, applicants had to submit source code and provide the full scope of the program (this was later changed so that applicants were only required to file 'pieces of the program'[58]).

Unsatisfied with the protection offered by copyright and trade secrecy, it was believed that patents offered the only viable mode of protection for software. In arguing for patent protection, a number of familiar arguments were rehearsed. In particular, it was argued that patent protection would stimulate investment in innovation, promote the continued creation and circulation of software, overcome the growing shortage of programmers, and help to counter the culture of secrecy that the business environment encouraged. In response to the argument that protection

54 Employee's 'non-compete agreements were gradually being obviated by the courts, especially on the West Coast. California eventually made them useless.' Lee Keet, ADAPSO Reunion Workshop, 'Intellectual Property' (2002) Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 16.

55 The first copyright registration, was granted to John Banzhaff III under the 'rule of doubt' that favoured protection in 1964. John F. Banzhaf III 'Copyright Protection for Computer Programs' (1964) 14 *Copyright Law Symposium* 118; 'Copyright Registration for Computer Programs' (1963) 11 *Bulletin of the Copyright Society of the USA* 361. The Register of Copyrights accepted computer programs for registration provided that they contained sufficient original authorship, they had been published, and that the copies submitted for registration were in machine readable form.

56 IBM was slow to support copyright because 'they were originally calling all their programs a service that they were giving away and putting in the public domain'. Leo Keet, ADAPSO Reunion Workshop, 'Intellectual Property' (2002) Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 12. However IBM eventually embraced copyright. From 1964 to January 1977, IBM and Burroughs were said to account for 971 of the 1,205 programs registered. *Final Report of the National Commission on New Technological Uses of Copyrighted Works: July 31, 1978* (Washington: Library of Congress, 1979), 34.

57 See, e.g., David Bender, 'Trade Secret Protection of Software' (1969–70) 38(5) *George Washington Law Review* 909.

58 Oscar H. Schachter, ADAPSO Reunion Workshop, 'Intellectual Property' (2002) Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 10.

was not needed and that software should continue to be given away for free, the proponents of patent protection cast doubts over the quality of the software that was shared at no cost. They also suggested that the free exchange programs only provided access to less important programs and that they did not include the valuable programs that might help competitors (such as multi-million-dollar airline reservation programs).[59]

Interestingly, the push for patent protection was also closely tied up with a desire to change how people thought about software which, in turn, was tied up with the professionalisation of the emerging industry. One of the problems at the time was that software was looked down on as a 'second-class citizen'; something that was attributed to the fact that software 'started out being a free service in the public domain'. Here, patenting was seen as a means 'for elevating the view of what software was. It shouldn't be free, it should be patentable'.[60] As Goetz explained, 'really … what we were trying to do' in seeking to patent software 'was to get stature' …. 'Every other industry seemed to have patent protection but here was an industry where you couldn't get patent protection.'[61] Patenting was also seen as a means of enhancing the reputation of the firms that produced software. It was suggested, for example, that Bell Laboratories' support for software patent protection was motivated by a desire for more public recognition in the programming area. The rational here was that if Bell's 'patents appears on programs that find wide use, [Bell] would become known as a source of programming excellence'.[62]

The push for patent protection for software was met with a hostile response from a range of parties. Somewhat surprisingly this included the Patent Office (who we would now expect to champion patent protection) and IBM (who for many years were reported to have 'the most patents of any company in the US, or in the world', but were against the patenting of software[63]). A number of arguments were made against patent protection for software. These ranged from general complaints that patent protection would stifle innovation and be counterproductive to the industry's growth and development to more specific concerns about the ability of the Patent Office to cope administratively with software patenting. In reflection of the close connection that existed between software and hardware, it was also suggested that

59 Morton C. Jacobs, 'Commissions Report (re: Computer Programs)' (1967) *Journal of the Patent Office Society* 372, 376.

60 ADAPSO History Program: Interview with Martin Goetz (3 May 2002) (interviewed by Jeffery R. Yost), 8.

61 Martin Goetz, ADAPSO Reunion Workshop, 'Intellectual Property' (2002) Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 7. Patents were said to have a 'status' that copyright lacked. Calvin N. Mooers, 'Computer Software and Copyright' (March 1975) 7(1) *Computing Surveys* 45, 64. Martin Goetz, 'Memoirs of a Software Pioneer: Part 2' (October–December 2002) 14 *IEEE Annals of the History of Computing* 22.

62 James P. Titus, 'Pros and Cons of Patenting Computer Programs' (February 1967) 10(2) *Communications of the ACM* 126.

63 Martin Goetz, ADAPSO Reunion Workshop, 'Intellectual Property' (2002) Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 5.

if patents were granted over software, it would create problems for computer users who, given the intangible nature of software, would not know whether they were infringing someone else's patent.[64] In this sense, it was argued that patent protection on programs would restrict the ability of someone purchasing a computer from using the instructions built into it.[65] It was also argued, somewhat ironically, that patent protection was leading to more restrictive information handling practices by users and software companies. In particular, it was said that 'certain professional journals have now taken the position that they will no longer publish allegedly novel algorithms if the person who claims them claims patent protection'.[66] The opponents of patent protection also cautioned against changing something that they believed was already working well, indeed so well that it was 'difficult to conceive how the field could grow faster'.[67] Specifically it was said that as the rapid growth and innovation in software development that had taken place across the 1960s had occurred in an 'atmosphere of free and open exchange of computer program ideas' that protection was simply not needed.[68] In light of this it was suggested that the best strategy was to continue to give software away for free.[69]

For the most part, the arguments for and against the patenting of software in the 1960s and 1970s are familiar; they have been repeated in one form or another for a range of different types of subject matter over time. The situation is less familiar, however, when we shift to look at the contrasting ways software was perceived within the information technology industry and what this meant for the law.

THE 'CONTESTED ONTOLOGIES OF SOFTWARE'

While some of the older classes of patentable subject matter such as kaleidoscopes, steam engines, or dyes may now seem odd or quaint, it is relatively easy to compile a list of the different types of subject matter that have been presented to the law for evaluation over the years: recent examples include synthetic biology, AI-generated

[64] It was argued that if patents were patentable, each user of a computer would have to 'proceed at peril' in using a computer, since they never be able to know whether the algorithm used in the program was covered by an existing patent … leading to nuisance infringement actions. Brief Amicus Curiae on behalf of the Business Equipment Manufacturers Association, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71–485 (Oct. Term, 1971), 14.

[65] Memorandum of IBM before the Patent Office on the Guidelines, 15; cited in Morton C. Jacobs, 'Commissions Report (re: Computer Programs)' (1967) *Journal of the Patent Office Society* 372, 378.

[66] Brief Amicus Curiae on behalf of the Business Equipment Manufacturers Association, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71–485 (Oct. Term, 1971), 12.

[67] Letter from Donald Turner (Ass. Attorney General, Antitrust Division), to Edward J. Brenner (Commissioner of Patents) (21 October 1966) (cautioning against patent protection), as cited in Brief Amicus Curiae on behalf of the Business Equipment Manufacturers Association, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71–485 (Oct. Term, 1971), 11.

[68] For discussion see Brief Amicus Curiae for the American Patent Law Association, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71–485 (Oct. Term, 1971), 20.

[69] Brief Amicus Curiae on behalf of the Business Equipment Manufacturers Association, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71–485 (Oct. Term, 1971), 10–11.

inventions, nanotechnology, and genes. Although with hindsight it may be relatively easy to identify the subject matter that was under consideration at a particular point of time, when new forms of subject matter are first presented to the law for scrutiny, there is often confusion about what the subject matter should be called, what its defining features are, and how it compares to other types of subject matter. Given that would-be classes of potential subject matter are almost by definition novel, this is not surprising. What is more surprising, however, is that in some situations the law has found it difficult to determine what the subject matter in question is. This was and remains the case with software-related inventions.

One of the reasons why there were so many problems associated with the patenting of software is because as Nathan Ensmenger said, software is quintessentially a heterogeneous technology: meaning that software is 'inextricably linked to a larger social-technical system that includes machines (computers and their associated peripherals), people (users, designers and developers), and processes (the corporate payroll system, for example)'.[70] As would-be subject matter, software's heterogeneity presented problems for the law. The reason for this is that when determining the standing of a class of potential subject matter, patent law cannot and does not embrace an open-ended view of techno-scientific objects. Instead, when determining the standing of a class of subject matter, patent law needs to reduce the open-ended, fluid, and heterogeneous technology into something that is both closed, demarcated, and predictable and, at the same time, flexible enough to accommodate variations across the class of subject matter as well as changes that occur in the subject matter over time.

There were a number of reasons why patent law found software-related subject matter problematic. One reason for this was that software was defined negatively as those computer-related things that were not hardware. Indeed, in the 1959 article where the term was first used, John Turkey referred to software as those elements of a typical computer installation that were not 'tubes, transistors, wires, tapes and the like'.[71] The difficulty of defining something that was already defined in opposition to what it was not helped to contribute to software's 'widespread, ill-defined use'.[72] The difficulties that arose in ascertaining the contours of the subject matter were compounded by software's intangibility or immateriality[73] which meant, amongst other things, that there were no obvious traces or markers that could be relied upon to demarcate the boundaries of the subject matter.

While these factors were important, but often not in the way that we might first think, perhaps the most important reason why the law experienced so many

[70] Nathan Ensmenger, 'Software as History Embodied' (January–March 2009) 31(1) *IEE Annals of the History of Computing* 88.

[71] John Turkey, 'The Teaching of Concrete Mathematics' (1958) 65(1) *American Mathematical Monthly* 1, 9.

[72] Thomas Haigh, 'Software in the 1960s as Concept, Service, and Product' (January–March 2002) 24(1) *IEEE Annals of the History of Computing* 5.

[73] Unlike hardware which has visible boundaries to demarcate and define it.

problems in determining the ambit of software-related subject matter was because there was a fundamental disagreement within the nascent information technology industry about the way that the subject matter should be approached. This is important because as the history of patent law shows techno-scientific communities have not only consistently provided the law with potential new candidates for protection, they have also provided the means to allow the law to describe, demarcate, and identify that new subject matter. The presentation of new types of subject matter for legal scrutiny, whether organic chemicals, new plants, or mechanical innovations, has typically been accompanied by a shared understanding of what the subject matter is amongst the scientific and technical communities that generated it. What is so interesting about patent law's engagement with software-related subject matter is that this was not the case.

While there was an expectation (or hope) that the information technology community would help the law in dealing with the nascent subject matter, this did not occur. In part, this was because there were two contrasting ways of thinking about software-related subject matter that coexisted at the time: what Gerardo Con Diaz called the 'contested ontologies of software'.[74] While there was agreement that the fate of software turned on 'technological facts',[75] the parties were largely talking at cross purposes. This is because hardware manufacturers and software product companies did not agree on what the subject matter should be, let alone how it should be construed: they had very different understandings both about what the subject matter was and also about how it was to be interpreted. In particular, while hardware manufactures and their supporters argued that the debate should be about the patenting of computer programs, software companies argued that the debate should be about the patenting of programmed or special purpose computers as machines.

For hardware manufacturers, who were largely happy with the legal status quo, software-related subject matter was presented in such a way that it would not be patentable.[76] This was done by arguing that discussions about patentable subject matter should be limited to discussions about whether *computer programs* were patent eligible. In this context, programs were presented as 'nothing more than a set of instructions to a computer as to how it should manipulate information and data'.[77] Specifically, programs were presented as flat, inert, two dimensional descriptions of a process that 'specifies, in greater or lesser detail, the manner in which something

74 Gerardo Con Diaz, 'Contested Ontologies of Software' (2016) 38(1) *IEEE Annals of the History of Computing* 23.

75 Morton C. Jacobs, 'Patents for Software Inventions: The Supreme Court's Decision' (January 1973) 55 *Journal of the Patent Office Society* 59.

76 Steven W. Usselman, 'Unbundling IBM: Antitrust and the Incentives to Innovation in American Computing' in (ed) Sally H. Clarke, Naomi R. Lamoreaux, and Steven W. Usselman, *The Challenge of Remaining Innovative: Insights from Twentieth-Century American Business* (Stanford, CA: Stanford University Press, 2009), 261.

77 Brief Amicus Curiae on behalf of the Business Equipment Manufacturers Association, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71–485 (Oct. Term, 1971), 6.

may be implemented.[78] In this sense, it was argued that computer programs were essentially immaterial creations that had a 'certain ephemeral … non-physical or non-machine character'.[79] Importantly, the descriptive character of computer programs remained 'the same whether the language used is binary, mnemonic assembly language or even higher level languages. It also remains the same regardless of the recording media, whether it be paper, punched cards, magnetic tape or even the internal magnetic cores of a computer memory. In all of these cases, the program continues to be explicative, that is, descriptive'.[80]

By limiting the subject matter to computer programs and by presenting computer programs as inert two-dimensional descriptions of processes, hardware manufacturers were able to argue that computer programs were non-patentable mental processes. Specifically, it allowed them to suggest that a program, like a punched paper piano roll, was 'nothing more than a set of instructions for the machine (i.e., computer or piano) automatically to implement the mental processes or steps contained in the algorithm or musical composition. Such creativity as exists lies solely in the development of the algorithm or musical composition and any patent issuing thereon would necessarily be grounded on the ideas or mental steps involved'.[81] By limiting the subject matter to static two-dimensional programs that merely specified the manner in which something could be implemented, hardware manufacturers were able to argue that a program was 'no more the subject matter of patent application than is the schematic diagram of an electrical circuit'.[82] While the subject matter here had a technical dimension, it primarily reflected the idea of the program as a commercial commodity. It was also an object protected by copyright but not by patents.[83]

While hardware companies argued that the question to be asked was whether computer programs were patentable subject matter, software companies such as Applied Data Research argued that discussions about patentable subject matter should focus on computer-related subject matter as machines. As Morton Jacob

[78] 'A Case History: Benson and Talbot: Appellant's Position: Computer Programs in General', Appendix C, appended to Robert O. Nimtz, 'Computer Application and Claim Drafting under Current Law' in *Software Protection by Trade Secret, Contract, Patent: Law, Practice, and Forms* (Washington: Patent Resources Group, 1969), 261. IBM argued that a 'computer program is simply a mode of expressing ideas'. Brief for Amicus Curiae International Business Machines, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71–485 (Oct. Term, 1971), 3.

[79] Morton C. Jacobs, 'Patentable Machines: Systems Embodiable in Hardware or Software (The Myth of the Non-Machine)' in (ed) Irving Kayton, *The Law of Software* (George Washington University, 1968) B-77, B-85, 1.

[80] Robert O. Nimtz, 'The Data Processing Revolution' in *Software Protection by Trade Secret, Contract, Patent: Law, Practice, and Forms* (Washington: Patent Resources Group, 1969), 128.

[81] Brief Amicus Curiae on behalf of the Business Equipment Manufacturers Association, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71–485 (Oct. Term, 1971), 8.

[82] Ibid.

[83] *United States* v. *IBM* 69 Civ. 200 (SDNY 1969); *Applied Data Research* v. *International Business Machines Corporation* 69 Civ. 1682, (filed 22 April 1969).

said, a 'computing machine is clearly a "machine" within the statutory classes of 35 USC 101'.[84] 'Computer programs are parts of such machines, in fact, they are control mechanisms for the computer: as such, they are "machine" devices or an article of manufacture within the terms of 35 USC 101.' On this basis Jacob said: 'Once we recognize that the subject matter of these computer-program inventions is that of machines, we appreciate that the classical principles apply, and the issue of patentable subject matter under the Constitution or under the patent statutes is not really involved at all.'[85]

Unlike hardware companies who presented intangible computer programs and tangible hardware as discrete and separate objects, software producers argued that the subject matter only made sense when the program and the machine were combined.[86] While a programmable machine such as a general-purpose computer had potential, on their own these protean machines were 'merely a "warehouse" of unrelated parts'.[87] It was only when the program and hardware were combined to form a special purpose machine that the potential was able to be fulfilled.[88] That is, it was only when the computer was combined with the program that these 'moronic machines' were 'capable of accomplishing such varied jobs as corporate payrolls and Apollo moon shots.'[89] When loaded with a specific program that 'transfers the latent power of the theoretically general-purpose machine into a specific tool for solving real-world problems',[90] a computer becomes a special purpose machine; for example, 'an inventory control machine, a tax-return machine, a machine for automatically controlling a factory such as an oil refinery, a medical diagnosis machine, an engineering design machine for performing various calculations and for designing other machines etc etc'.[91]

84 Morton C. Jacobs, 'Patentable Machines: Systems Embodiable in Hardware or Software (The Myth of the Non-Machine)' in Irving Kayton (ed), *The Law of Software* (George Washington University, 1968) B-77, B-85. 1.

85 Ibid.

86 Ibid. Morton C. Jacobs, 'Computer Technology (Hardware and Software): Some Legal Implications for Antitrust, Copyright and Patents' (1970) *Rutgers Journal of Computers and Law* 50, 52. While these arguments drew upon patent law's longstanding recognition of the patentability of combination claims to claim the combination which the union of the program and the computer creates, there was very little reference to this jurisprudence. One notable exception is Max W. J. Graham Jr, 'Process Patents for Computer Programs' (1968) *California Law Review* 466, 472–480 (arguing that the protection was ineffective).

87 Edward J. Brenner, 'Guidelines to Examination of Programs' (9 August 1966) 829(2) *Official Gazette of the United States Patent Office* 442.

88 General purpose computers 'can do anything for which we can provide suitable instruction … that is the source of its power'. However, 'precisely because it can do anything, it can do nothing in and of itself. It does things only when we provide the programs that cause the universal machine to emulate particular machines of our design'. Michael S. Mahoney, 'What Makes the History of Software Hard' (July–September 2008) *IEEE Annals of the History of Computing* 8, 10.

89 William D. Smith, 'Fighter for Computer-Program Patents' (29 December 1968) The *New York Times* 19.

90 Nathan Ensmenger, *The Computer Boys Take Over: Computers: Programmers, and the Politics of Technical Expertise* (Cambridge, MA: MIT Press, 2010), 5.

91 Morton C. Jacobs, 'Computer Technology (Hardware and Software): Some Legal Implications for Antitrust, Copyright and Patents' (1970) *Rutgers Journal of Computers and Law* 50, 51.

For software producers, what made the modern electronic digital computers unique and the reason why they differed from piano players and jacquard looms was their 'ability to be reconfigured via software into a seemingly infinite number of devices … it is the ability to be programmed via software that … encapsulates the essence of modern computing'.[92] While a piano roll would never change a player piano into anything but what it is, computers were universal machines that could 'be programmed to perform an almost infinite range of operations from a musical synthesizer and a payroll system through to an airline reservation system, as a classically designed machine'.[93]

When viewed functionally, the addition of a software program to control a general-purpose computer was said to 'be just as much a machine addition to it as the additional hardware programming'. In both cases, the addition of programming results in a machine that is different from the original. One reason for this was that a programmed computer was said to be '*structurally* different from the same machine without the program since its memory elements are differently arranged'.[94] In this sense, software producers argued that by 'programming a computer, the user creates a new machine'.[95] As Robert Nimtz explained, '[d]uring the actual execution of a program, a logical process is taking place or a new logical machine is taking form … During such execution, a new logical machine is formed and new logical processes are carried out on that new machine. Generally speaking, it is these new extant machines and extant processes that are the subject matter of patent claims'.[96] This way of viewing the subject matter enabled software producers to argue that the programmed computer acquired a new function recognizable by patent law. Importantly, this meant that the subject matter was potentially patentable.

While software companies argued that placing a different program into a computer fundamentally changed the nature of that computer, hardware companies consistently argued that a computer remained the same machine irrespective of the program that was used to operate it. As IBM said, the programming of a computer 'does not vary the actual nature of the computer so as to constitute a patentable invention'.[97] The idea that a computer remained the same whether or not it

[92] Nathan Ensmenger, *The Computer Boys Take Over: Computers: Programmers, and the Politics of Technical Expertise* (Cambridge, MA: MIT Press, 2010), 5.

[93] Paul E. Ceruzzi, *Computing: A Concise History* (Cambridge, MA: MIT Press, 2012), 56.

[94] George A. Heitczman, 'Computer Programs Are patentable' (1970) 113(1) *Seton Hall Law Review* 113, 127.

[95] Brief for Amicus Curiae Institutional Networks Corporation, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71–485 (Oct Term, 1971), 4. The programmed computer was 'structurally different from the same machine without the program since its memory elements are differently arranged'. George A. Heitczman, 'Computer Programs Are Patentable' (1970) 113(1) *Seton Hall Law Review* 113, 127. See George V. Elgroth, 'Software and Patent Law' (1966) *Patent Law Annual* 1.

[96] Robert O. Nimtz, 'The Data Processing Revolution' in *Software Protection by Trade Secret, Contract, Patent: Law, Practice, and Forms* (Washington: Patent Resources Group, 1969), 129.

[97] Brief Amicus Curiae on behalf of the Business Equipment Manufacturers Association, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71–485 (Oct. Term, 1971), 3.

was programmed was highlighted in the oral argument before the Supreme Court in *Gottschalk* v. *Benson* where in response to Justice White's question 'When the computer is programmed … it is not the same machine as it is when it isn't programmed?', the Government Attorney replied: 'It is precisely the same machine, Mr Justice White. It is precisely the same machine'.[98] As the Government Attorney noted, 'That is precisely the heart of our case'. The digital computer is 'really no more than an extension of an adding machine or calculator'. He added:

> Well, Mr Justice White, the analogy which we use in our brief – and I think that this is the appropriate analogy – is an old piano player which carries out – which plays songs when piano rolls are inserted into it. We do not believe that the computer acquires a new function every time it carries out new calculations that it is inherently built to perform, any more than a player piano carries out a new use every time a new piano roll is inserted into it.[99]

By arguing that a computer was the same machine irrespective of whether it contained a new and different program, hardware manufacturers were able to argue that the 'computer does not acquire a new function, in any sense recognizable by the patent law, every time it is programmed to perform a different set of arithmetical calculations, any more than a piano played acquires a new function each time it plays a new song'.[100] In this sense hardware manufacturers were able to argue that the programming of a computer was no more than a conventional and unpatentable use of a known machine, similar to placing a new piano roll in a player piano. In both cases, the end result was patent ineligible. As IBM said, the programming of a computer 'does not vary the actual nature of the computer so as to constitute a patentable invention'.[101] This, in turn, allowed the hardware manufacturers to assert that 'computer-program inventions relate to things other than machines and therefore are non-patentable'.[102]

Over the course of the 1960s and 1970s, hardware and software companies repeated their strategic and self-serving arguments about the nature of software-related subject matter in a range of venues including conferences, academic journals, trade magazine, policy reviews, newspapers, and amicus curia briefs (to both the Court

98 Cited in Morton C. Jacobs, 'Patents for Software Inventions: The Supreme Court's Decision' (January 1973) 55 *Journal of the Patent Office Society* 59, 60 (transcript of oral arguments, 19).

99 Ibid.

100 Reply Brief for the Petitioners, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71–485 (Oct. Term, 1971), 5. As the Petitioners in *Gottschalk* v. *Benson* argued (including the US Solicitor General and the USPTO), a program in a computer was no different to a conventional use of a known machine, 'comparable to the insertion of a new piano roll in an old piano player'. Brief for Petitioners, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71–485 (Oct. Term, 1971), 17.

101 Brief for Amicus Curiae International Business Machines, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71–485 (Oct. Term, 1971), 3.

102 Morton C. Jacobs, 'Patentable Machines: Systems Embodiable in Hardware or Software (The Myth of the Non-Machine)' in (ed) Irving Kayton, *The Law of Software* (George Washington University, 1968) B-77, B-85, 1.

of Customs and Patent Appeals and the Supreme Court). In so doing they not only highlighted how important the task of deciding what the subject matter was, they also highlighted how entrenched and divided the industry's response was to this question. In a sense, the issue that underpinned these debates was whether or not the subject matter had been dematerialised. As we will see in Chapter 6, this had important ramifications for the way that patent law interacted with computer-related subject matter.

6

A Hybrid Subject Matter

'Computer-related inventions are a subject matter with "two or more faces"'.[1]

INTRODUCTION

In some ways, the situation with software-related subject matter in the 1960s and 1970s was similar to the position in relation to microbiological inventions in the 1940s and 1950s – where the lack of an agreed taxonomic framework made defining and identifying patented microbiological inventions problematic – and with isolated genetic sequences in the early years of the twenty-first century – where the law was called upon to decide whether isolated genes should be seen in chemical or genetic terms (the outcome of which determined subject matter eligibility). While software shared things in common with both microbiological inventions and isolated genetic material, it differed in one important respect. This was because while with microbiological inventions and isolated genes, the problem that the law faced in dealing with the new subject matter was how it was to be characterised, with software-related subject matter the problem was more fundamental: there was no clear idea of what the subject matter was, let alone how it should be interpreted. As a patent examiner wrote in 1969, the most prevalent problem in the debate over the patentability of computer programs was the 'lack of effective communication between the parties involved'. This was primarily because there was no 'concrete, workable definition set forth by the computer or software industry for even the most basic of terms'.[2]

One of the consequences of the fact that the computing industry was divided about patentable subject matter was that in contrast to organic chemistry where the question of what the subject matter was and once this was decided how it was to be characterised, defined, and described was largely resolved by the relevant scientific communities and then adopted in the law, with software-related subject matter

[1] Morton C. Jacobs, 'Computer Technology (Hardware and Software): Some Legal Implications for Antitrust, Copyright and Patents' (1970) 1 *Rutgers Journal of Computers and Law* 50, 69.

[2] T. Buckman, 'Protection of Proprietary Interest in Computer Programs' (1969) *Journal of the Patent Office Society* 135, 138.

these questions were aired in legal fora. That is, instead of the industry or scientific community agreeing on what the subject matter was and how it was to be characterised, with software the industry attempted to work out its ontological issues *through* the law. As a result, the task of determining the nature and characteristics of software-related subject matter was treated as a *legal* problem to be resolved using *legal* terms. As a patent examiner wrote in 1969, 'any system that interfaces law and technology, such as the patent system, must necessarily use the sometimes burdensome language of the law. The computer industry should be no exception!'.[3]

The legal response to the question of how to approach computer-related subject matter can be broken down into two periods. The first, which spans the 1960s and 1970s and which is the subject of this chapter, saw patent law attempting to reconcile the conflicting views about what the subject matter was and how it should be interpreted. The situation changed in the early 1980s, however, as patent law took a more active role in thinking about computer-related subject matter. More specifically, the 1980s saw patent law come to view computer-related subject matter through the lens of 'abstractness'. As we will see in Chapter 7, it was here that we see the influence of materiality and its absence most clearly.

EARLY LEGAL RESPONSES TO SOFTWARE PATENTING

In 1961, two Mobil Oil Corporation engineers, Charles D. Prater and James Wei, lodged a patent application for 'improvement in the art of mass spectography'. The application, which was based on their discovery of 'a new way to analyze the output that is produced when a mass spectrograph measures a sample containing an unknown mixture of gases',[4] was examined and 'allowed' by the Patent Office on 22 September 1961. Before paying the final fee that would have triggered the grant of the patent Prater and Wei's patent attorney discovered a number of minor typographical errors in the application. To correct these mistakes and to add additional data, a continuation-in-part application (which is effectively a revised application) was filed. While the revised application was only 'imperceptibly' different from the original application, nonetheless it was rejected by the Patent Office.[5] In effect what had happened was that between the time when the initial application was filed in August 1960 and when the revised application was filed in November 1961, the approach of the Patent Office had changed. By the time the revised application was examined, the 'Patent Office had become concerned about the new technology of computer programming, especially if such applications were about to descend upon the Office in great numbers'.[6]

3 Ibid.
4 *In re Prater* (Prater I) 415 F.2d 1378 (CCPA 1968). See also *Application of Prater and Wei* (Prater II) 415 F.2d 1393 (CCPA 1969).
5 Howard R. Popper, 'Prater II' (1970) 19 *The American University Law Review* 25.
6 Ibid., 26.

The approach taken by the Patent Office to Prater and Wei's revised application was indicative of a trend that would continue across the 1960s and beyond.[7] While there had been what was described as 'encouraging dictum' at the Patent Office Board of Appeals for those seeking patent protection for computer programs,[8] the Patent Office consistently rejected software-related applications. As the lawyer who represented Applied Data Research, Morton Jacobs, said in 1965, when an application was seen to claim a computer program, the Patent Office examining staff tended to classify the application as non-statutory on the 'basis that they were for a system of knowledge (like mathematics), rather than an industrial process'.[9]

While the approach of the Patent Office towards software patents in the early half of the 1960s was (fairly) consistent, there was still some confusion. In order to clarify the standing of software in patent law, Patent Office Examination Guidelines were drafted in 1966, which distinguished between software as a process and software as a device.[10] According to the draft Guidelines, as a process, computer programs 'are written in terms of algorithms rather computer component changes and, therefore, are not statutory subject matter'.[11] Building on the idea that algorithms 'are conclusions based upon a precise or mathematical premise and line of reasoning'[12] and the uncontroversial proposition that mathematical process, discoveries, and mathematical formula were not patentable, the Guidelines proposed that as a process computer programs were not patentable because they were mere mathematical or mental steps. While these processes may have been useful and important, nonetheless they were non-patentable on the basis that they were 'merely expressions of an algorithm'.

In contrast, the draft Guidelines proposed that programs that (i) controlled the changes in state of components of the computer itself and (ii) transformed a specific machine from a general-purpose to a specific-purpose device should be potentially patentable. That is, as a device for controlling the operation of a general purpose computer that dealt with 'tangible things and substances' (the later were called patentable 'utility processes'), programs were patent eligible.[13] In explaining the Guidelines the Commissioner of Patents, Edward J. Brenner, said that while 'program' had been defined loosely by the parties, the Office did not think it was necessary to define program (or computer) since these were merely 'adaptions of the concept of inventions of "automatic control", which

[7] *In re Prater* 415 F.2d 1378, 1390 (CCPA 1969). Rich J. dissenting from grant of rehearing noted in relation to patentability of software that 'the Patents Office's policy of refusing to follow what this reviewing court has now declared the law to be and to have been, at least since 1952'.

[8] Michael I. Rackman, 'The Patentability of Computer Programs' (1963) *New York University Law Review* 891, 893–94.

[9] Morton C. Jacobs, 'Patent Protection for Computer Programs' (1965) 47 *Journal of the Patent Office Society* 6, 10.

[10] 'Guidelines to Examination of Programs' (9 August 1966) 829(2) *Official Gazette of the United States Patent Office* 441.

[11] Ibid., 441–42.

[12] Ibid., 441.

[13] Ibid., 442.

the patent office already considered as patentable subject matter';[14] these included the Jacquard looms (class 139 Weaving, subclass 59) which have 'presented for many years the concept of processes and apparatus that include a program'. Subtly shifting the focus of attention from the program to the programmed computer, Brenner said that a machine that includes a 'program device' that causes a machine as a whole to function falls within the patent statute the same as any other special purpose machine. The fact that portions of the completed machine take the form of a replaceable program is of no moment'.[15] It did not matter 'whether a "program device" is termed a Jacquard card belt, a player piano roll, a plug-board or a magnetic tape and the corresponding "program" is termed a weaving design a musical composition, a switching scheme or a document listing a series of instructions which a machine will execute'.[16] In all cases, the special purpose machine was patent eligible subject matter.

The draft Guidelines were discussed by over a hundred people at a public hearing held at the Patent Office in October 1966 to ascertain the 'present law on patenting of programming'. All of the speakers at the hearing 'opposed adoption of the proposed Guidelines'. In reflection of the different approaches taken towards the patenting of software they were divided, however, 'on whether the Guidelines would or should authorise the issuance of patents on computer programs'.[17] While the Guidelines had been written to clarify the state of the law, it was said that the only effect of the guidelines, which had 'raised a small storm of protest in Washington', was that they 'succeeded in riling both the proponents and the proponents to the patenting computer programs'.[18] While 'Bell Laboratories felt the proposed guidelines were too restrictive … IBM felt the proposed guidelines were too broad'.[19] Given that no one supported the Guidelines,[20] it is not surprising that they never came into force.[21]

At the same time as the Patent Office was attempting to develop Guidelines for the examination of programs, the standing of computer programs was also being

[14] Ibid., 441.
[15] Ibid., 442.
[16] Ibid., 441.
[17] Anon, 'Patent Office Holds Hearing on Computer Programming Patents' (November 1966) 6(2) *The New York Patent Law Association Bulletin* 6.
[18] Elmer W. Galbi, 'Software and Patents: A Status Report' (1971) *Communications of the ACM* 274.
[19] Ibid. For some, the draft Guidelines provided a limited form of protection for programs. Statement of Richard C. Jones, President, Data Research, Patent Law Revision, Subcommittee on patents, trademarks, and copyrights of the Committee on the Judiciary United States Senate (Nineteenth Congress, First Session Pursuant to S Res 37 on S. 2, S. 1042, S. 1377, S. 1691, Part 2 (1–2 January, 1 February 1968), 751).
[20] Morton C. Jacobs, 'Commissions Report (re: Computer Programs)' (1967) *Journal of the Patent Office Society* 372.
[21] Elmer W. Galbi, 'Software and Patents: A Status Report' (1971) *Communications of the ACM* 274. Congressman Brooks (from Texas), who sat on the Judiciary Committee which was planning to holding hearings in 1967 to revamp patent law and who was reportedly 'alarmed at the prospect of patents on computer programs' convinced the Department of Commerce to set aside the draft Guidelines (pending the more wide-ranging review). James P. Titus, 'Pros and Cons of Patenting Computer Programs' (February 1967) 10(2) *Communications of the ACM* 126.

looked at by the *President's Commission on the Patent System*, which had been established by President Lyndon Johnson in July 1965 to undertake a wide-ranging review of patent law in the United States. The report of the Presidential Commission on the Patent System was released in December 1966. One of the findings of the Commission was that patents should *not* be granted for computer programs (which were defined as a 'series of instructions which control or condition the operation of a data processing machine').[22] A number of reasons were given for the decision, including the administrative difficulties that the Patent Office would have experienced if protection was allowed. Specifically, it was thought that as patent review searches would neither be feasible nor economical given the amount of prior art and that the 'current classificatory techniques and search files were inadequate' that the patent examination process would be put under great stress if protection was allowed. The Commission also noted that programs had grown satisfactorily in the past without protection and that, in any case, copyright protection was available.[23]

In reviewing the existing law, the Commission noted that attempts to patent programs per se had been rejected on the ground that they were not statutory subject matter. They also noted that '[i]ndirect attempts to obtain patents … by drafting the claims as a process, or a machine or components thereof programmed in a given manner rather than as a program itself, have confused the issue further and should not be permitted'.[24] To avoid this confusion, the Commission said that programs should not be patentable whether claimed as an article, a process described in terms of the operation performed by a machine pursuant to a program, or one of more machine configurations established by a program.[25]

The recommendation of the Presidential Commission in relation to software found its way into the *Patent Reform Bill* of 1967, which expressly excluded computer programs from patentable subject matter. Specifically, section 106 of the Bill provided that a 'plan of action or set of operating instructions, in whatever form presented, to cause controllable data processor or computer to perform selected operations shall not be patentable'. While discussions of software patenting at the President's Commission had been dominated by hardware manufacturers,[26] the draft

[22] *Report of the President's Commission on the Patent System* (1967), 20.

[23] Ibid. The Justice Department, saw program patent as being inherently anticompetitive, argued against protection. They also reminded the Patent Office that monopolies were the exclusive business of the Justice's Antitrust Division. James P. Titus, 'Pros and Cons of Patenting Computer Programs' (February 1967) 10(2) *Communications of the ACM* 126.

[24] *Report of the President's Commission on the Patent System* (1967), 21.

[25] Ibid., 20. Harold L. Davis, 'Computer Programs and Subject Matter Patentability' (1977–78) 6 *Rutgers Journal of Computers and Law* 1, 9 n 46.

[26] While the hardware manufacturers were represented on the committee by James Birkenstock (IBM, Vice President, Commercial Development) and by Bernard Oliver (Hewlett-Packard, Research and Development), the software industry was not represented. Software manufacturers also did not make submissions to the President's Commission. Brief Amicus Curiae for the Association of Data Processing Service Organisations, Software Products and Service Section, *Gottschalk* v. *Benson*, Supreme Court of the US, Oct Term, 1971, No 71–485, 19.

Act attracted the interest of the proponents of patent protection who argued against the proposed changes.[27] Section 106 was opposed by a number of software firms, the American Patent Law Association, the Electric Industries Association, the American Chemical Society, and the National Small Business Association.[28] It also seems that the administration had a change of heart, which was reflected in the fact that neither the President's Science Advisor nor the Assistant Attorney General testified in support of the proposed new law.[29] Interestingly, although the Patent Office had helped to prepare the legislation[30] and section 106 was said to have codified Patent Office practice,[31] nonetheless the Commissioner of Patents, Edward J. Brenner, also argued against section 106. While he noted that computer programs 'were not patentable under the present law, and we shall continue to deny applications for patents on computer programs per se', the Patent Office felt that there were 'substantial difficulties in finding an adequate definition for computer programs'. On this basis, Brenner said that it was 'premature to enact legislation at the present time'.[32] Similar complaints about the breadth of section 106 and the difficulties of defining computer program were made by a range of other parties. Following this hostile reaction, section 106 was removed from the Patent Reform Bill of 1967.[33]

Despite the concerns that had been raised about the decision to classify software as patent ineligible subject matter, the Patent Office reconfirmed its earlier anti-software approach in October 1968 when it issued new Examination Guidelines that said 'computer programming per se, whether defined in the form of process or

27 Discussed as part of the wide-ranging review of patents that took place by the Patent Law Revision, Subcommittee on patents, trademarks, and copyrights of the Committee on the Judiciary United States Senate (Ninetieth Congress, First Session Pursuant to S Res 37 on S. 2, S. 1042, S. 1377, S. 1691, Part 1 (17, 18 May 1967), Part 2).

28 William D. Smith, 'Fighter for Computer-Program Patents' (29 December 1968) *The New York Times* 19.

29 Morton C. Jacobs, 'Computer Technology (Hardware and Software): Some Legal Implications for Antitrust, Copyright and Patents' (1970) 1 *Rutgers Journal of Computers and Law* 50, 58.

30 Ibid., 57.

31 Edward J. Brenner, (Commissioner of Patents), *Subcommittee on patents, trademarks, and copyrights of the Committee on the Judiciary, United States Senate* (Ninetieth Congress, First Session Pursuant to S Res 37 on S. 2, S. 1042, S. 1377, S. 1691, Part 1 (17, 18 May 1967), 137).

32 Edward J. Brenner (Commissioner of Patents), *Patent Law Revision, Subcommittee on patents, trademarks, and copyrights of the Committee on the Judiciary United States Senate* (Ninetieth Congress, First Session Pursuant to S Res 37 on S. 2, S. 1042, S. 1377, S. 1691, Part 2 (1–2 January, 1 February 1968), 394). Brenner asked that it be recorded that the 'omission was not intended to pass judgement on the question of the patentability of computer programs' (ibid). The Electric Industries Association also counselled against the adoption of a legislative because the definition 'posed extreme uncertainty' (ibid., 516). While the American Chemical Society 'took no position on the question of the patentability of inventions with computer programs', they suggested that the definition used in the section 'would appear to prohibit patents on any chemical process which is ordinarily carried out with automated equipment'. Robert W. Cairns, President American Chemical Society, ibid., 533–3.

33 This, in turn, gave rise to further debate about whether the removal of section 106 was an indication of positive support for patent protection or that it was simply too early to make normative judgements about the fate of software.

apparatus, shall not be patentable'.[34] (Embarrassingly, Goetz's patent for Autoflow, which was heralded at the time as the first software patent, was granted shortly after).[35] Two related arguments were used by the Patent Office to reject software-related claims.[36] First, programs were denied protection on the basis that they could not satisfy the 'change of state' doctrine, which specified that to be patentable processes needed to operate physically on substances.[37] Programs – which were seen as a series of mental, mathematical steps – were also refused protection on the basis of the mental steps doctrine, which denied patents to processes that could be performed by or required the use of human intellect.[38]

While the reason given by the Patent Office for excluding software was that it lacked the requisite physical indicia and that it was a non-patentable mental process, the anti-software approach of the Office was also motivated by another concern: namely, a concern that if patent protection for software was allowed it would have increased the workload of the Patent Office at a time when the Office was facing a public backlash because of the time it was taking to process patents. As a patent examiner said, it was feared that software patenting would have 'imposed a tremendous burden at a time when [the Patent Office was] 'desperately trying to decrease its backlog'.[39] Interestingly, the backlog at the Office also played a role in determining the basis on which software would be denied protection (namely, subject matter ineligibility). As a patent examiner explained in 1968, the 'need for a more summary treatment of software (program) claims arose with the advent of the computer, since

[34] 'Guidelines to the Examination of Programs' 855 Official Gazette of the United States Patent Office 829–30, 33 Fed Reg 15609, 15610 (1968) (22 October 1968). See William D. Smith, 'Fighter for Computer-Program Patents' (29 December 1968) *The New York Times* 19.

[35] Robert F. Brothers and Alan M. Grimaldi, 'Prater and Patent Reform Proposals' (1969) 17 *Catholic University Law Review* 389.

[36] Elmer W. Galbi, 'Software and Patents: A Status Report' (1971) *Communications of the ACM* 274, 275.

[37] Howard R. Popper, 'Prater II' (1970) 19 *The American University Law Review* 25, 28. This was based upon the Supreme Court in *Cochrane* v. *Deener* that a 'process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject matter to be transformed and reduced to a different state or thing'. 94 U.S. 780, 788 (1876).

[38] T. Buckman, 'Protection of Proprietary Interests in Computer Programs' (1969) *Journal of the Patent Office Society* 135, 144 (Buckman was a Patent Office examiner). On the role of mental steps in relation to software, see Samuel J. Sutton Jr, 'The "Mental Steps" Doctrine: A Critical Analysis in the Light of Prater and Wei' (1969–70) 13 *Patent, Trademark and Copyright Journal of Research and Education* 458; Virgil E. Woodcock, 'Mental Steps and Computer Programs' (1970) 52 *Journal of the Patent Office Society* 275.

[39] Robert W. Wild, 'Computer Program Protection: The Need to Legislate a Solution' (1969) 54(4) *Cornell Law Review* 586, 604. On the backlog see Robert A. Choate, 'Backlog' (1966) 48 *Journal of the Patent Office Society* 274; *Official Gazette Patent Office* 668 (1968), 187; W. Scott Railton, 'The Examination System and the Backlog Problem' (1965–66) 9 *Idea* 487. The backlog had risen to 216,00 applications in July 1964, and had been going backwards at around 10,000 applications annually (at 493). By 1967, the delay had been reduced from 'about 3.5 years down to about 2.5 years'. Edward J. Brenner, (Commissioner of Patents), *Subcommittee on patents, trademarks, and copyrights of the Committee on the Judiciary, United States Senate* (Ninetieth Congress, First Session Pursuant to S Res 37 on S. 2, S. 1042, S. 1377, S. 1691, Part 1 (17, 18 May 1967), 128).

rejection for lack of novelty became entirely too involved'. In contrast, 'non-statutory holding was concluded to be an applicable basis for summary, no-examination treatment (along the lines of methods of doing business, printed matter, mathematics, etc) … There was always a lack of capacity (personnel shortage, lack of training, lack of prior art files) to perform the conscientious, meaningful examination'.[40]

For the most part, courts across 1960s accepted the Patent Office's argument that software should not be patentable. In a series of decision at the end of the decade, however, the Court of Customs and Patent Appeals overturned the approach that had been adopted at the Patent Office towards the patenting of software. The judicial change in approach was heralded by the 1968 decision of *Prater and Wei*, which concerned the application by the Mobil Oil Corporation engineers, Prater and Wei, for an 'improvement in the art of mass spectography'. As we saw above, while the initial application was allowed, the revised application was denied. After the Patent Office Board of Appeals affirmed the Patent Office decision to reject the application (on the basis that as the applicant's claims could be performed mentally they were not patentable subject matter), an appeal was made to the Court of Customs and Patent Appeals. In what was heralded as a landmark decision written by Judge Arthur M. Smith, the court reversed the decision of the Board of Appeals and upheld the validity of the patent.[41] While the decision was hailed by software companies as a 'magna carta'[42] that allowed them to compete with hardware manufacturers, the Patent Office feared that it would lead to the 'demise of an effective patent system'.[43] In order to end the 'path of destruction' that had been started by *Prater*,[44] the Patent Office petitioned for a rehearing, which was granted.[45] The matter was reheard and the case was decided anew (*Prater* II).[46] To the annoyance of hardware manufacturers, the court in *Prater* II followed the court in *Prater* I and upheld the validity of the apparatus claim (using a style of drafting that I look at in Chapter 7). The court also said that the mere fact that a process could be carried out by mental steps or performed in the mind was not a bar to patentability.[47]

40 L. Smilow, 'Comments on Computer-in-Law Institute's First Annual Conference' (November 1968) 50 *Journal of the Patent Office Society* 779, 780–81 (Smilow was a primary examiner at the Patent Office).

41 *In re Prater* (Prater I) 415 F.2d 1378 (CCPA 1968). Judge Smith died the day after the opinion was handed down.

42 Stacy Jones, 'Computer Programs Are Held Patentable: An Appellate Court Decides Case Concerning Software' (16 August 1969) *The New York Times* 35.

43 T. Buckman, 'Protection of Proprietary Interests in Computer Programs' (1969) *Journal of the Patent Office Society* 135.

44 Ibid.

45 160 USPQ 230, 415 F.2d 1390 (CCPA 1969).

46 *Application of Prater and Wei* (Prater II) 415 F.2d 1393 (CCPA 1969).

47 *In re Prater* (Prater I) 415 F 2d 1378, 1389 (CCPA 1968). Described as an anthropomorphic view of the new equipment and processes. James B. Gambrell and Irving Kayton, 'Patent Law in Perspective 1967' (1967) *The George Washington Law Review* 545, 551. See also Brief Amicus Curiae for Applied Data Research, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71-485 (Oct. Term, 1971), 11 n 13. ('Technical jargon in the computer field, which is quite often anthropomorphic in suggesting human

One of the notable things about *Prater* I and II is that they removed much of the 'semantic thicket surrounding the "mental process" and non-statutory subject matter lines of rejection'[48] by holding that the mental step and change of state cases were not bars to the patentability of software. Specifically it was said that to be patentable a process did not need to physically operate upon substances.[49] The rejection of the change of state and mental step cases as potential grounds of objection paved the way for a more positive approach to software patenting. This was reflected in the comment by the court in *Prater* II that '[n]o reason is now apparent to us why, based on the Constitution, statute, or case law, apparatus *and* process claims broad enough to encompass the operation of a programmed general-purpose digital computer are necessarily unpatentable'.[50] The court went on to say '[i]n one sense, a general purpose digital computer may be regarded as but a storeroom of parts and/or electrical components'. However, 'once a program has been introduced, the general-purpose digital computer becomes a special-purpose digital computer (i.e., a specific electrical circuit with or without electro-mechanical components) which, along with the process by which it operates, may be patented subject, of course, to the requirements of novelty, utility and non-obviousness'.[51]

Following *Prater II*, in October 1969 the Patent Office begrudgingly withdrew the Examination Guidelines that provided that computer programming was not patentable.[52] While the Commissioner announced that the Patent Office would henceforth look at applications for computer programs on a case-by-case basis,[53] the Office continued to reject applications for process claims (either on the basis of the mental steps doctrine[54] or in a shift away from subject matter on the basis that the invention was not adequately disclosed in the patent).[55]

Frustrated with the ongoing rebuffs by the Court of Customs and Patent Appeals and a belief that the Court was inappropriately attempting to legislate

characteristics where none exist draws upon the only available terminology we have … The hardware manufacturers arguments about "mental processes" are largely and speciously based on this anthropomorphic terminology').

48 Howard R. Popper, 'Prater II' (1970) 19 *The American University Law Review* 25, 27.

49 *In re Prater* (Prater I) 415 F.2d 1378, 1388 (CCPA 1968). T. Buckman, 'Protection of Proprietary Interests in Computer Programs' (1969) *Journal of the Patent Office Society* 135, 146.

50 *Application of Prater and Wei* (Prater II) 415 F.2d 1393; 162 USPQ 541, 549, n 29 (CCPA 1969).

51 Ibid. The Court of Customs and Patent Appeals went one step further shortly after in *re Bernhart and Fetter*: 'If a machine is programmed in a certain new and unobvious way, it is physically different from the machine without that program, its memory elements are differently arranged. The fact that these physical changes are invisible to the eye should not tempt us to conclude that the machine has not changed'. 163 USPQ 611 (CCPA 1969).

52 34 Fed Reg 15724 (1969) (Commissioner William E. Schulyer).

53 Ibid.

54 Pauline Wittenberg, 'Computer Software: Beyond the Limits of Existing Proprietary Protection' (1973) *Brooklyn Law Review* 116, 131 n 118.

55 Howard R. Popper, 'Prater II' (1970) 19 *The American University Law Review* 25, 27.

the patentability of computer programs,[56] the Patent Office decided to appeal the question of software patenting to the Supreme Court. The decision that the Patent Office selected for appeal was Benson and Talbot's 1963 application for a process where a general purpose digital computer was programmed with an algorithm that converted binary coded decimals to pure binary numbers. Given that the process could be performed manually using pen and paper, the Patent Office and the Patent Office Board of Appeals rejected the application on the basis that it was a mere mental process. Following the approach in *Prater*, the Court of Customs and Patent Appeals reversed the finding of the Board of Appeals, holding that while the process could be performed mentally, as no mental steps were required in the proposed method it was patentable. In an attempt to overturn the pro-patent stance that had been adopted at the Court of Customs and Patent Appeals, the Patent Office appealed the decision to the Supreme Court. As with *Prater* II, the appeal attracted a lot of industry interest (including 14 amicus curie briefs).[57]

While it had been hoped that the Supreme Court would have provided much-needed clarity about whether or not, and if so in what circumstances software might be patentable, when the 1972 decision of *Gottschalk* v. *Benson* was handed down, it readily became apparent that the decision only served to reinforce the existing confusion.[58] In part, this is because the court sidestepped the question of whether software was patentable and focused instead on the specific facts of the case – on the question of whether a process claim directed to a numerical algorithm was patentable. In relation to this point, the court found that 'the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself'. In response to the request that had been made by the hardware manufacturers in their amicus curia for the court to declare that 'the decision precludes a patent for any program servicing a computer', the court responded: 'we do not so hold'. In so doing the court left open the general question of whether software was patentable.

While it is sometime suggested that *Gottschalk* v. *Benson* decided that software did not qualify as patentable subject matter,[59] at the time the decision was handed down it was not clear what the outcome of the decision was. Indeed, one of the

[56] T. Buckman, 'Protection of Proprietary Interests in Computer Programs' (1969) *Journal of the Patent Office Society* 135, 147.

[57] It was said that *Benson* was an experiment in the limits of patent drafting to test whether embodied software was necessary (patent did not disclose a machine – program was designed only to manipulate numbers). See Robert D. Nimtz, 'Computer Applications and Claim Drafting under Current Law' in (ed) Irving Kayton, *Software Protection* (Washington: Patent Resources Group, 1969), 242, 252. For discussion see Gerardo Con Diaz, 'Embodied Software: Patents and the History of Software Development' (July–September 2015) *IEEE Annals of the History of Computing* 8, 16.

[58] See Kenneth Nichols, *Inventing Software: The Rise of Computer-Related Patents* (Westport, CT: Quorum Books, 1998), 16.

[59] See G. A. Stobbs, *Software Patents* (New Jersey: Wiley Law Publications, 1995); Robert P. Bigelow, 'Infosystems, the Law and Patents' (1973) *Jurimetrics* 129.

things that is apparent from contemporaneous accounts of the decision is that there were very different understandings of what was decided. While some interpreted the decision as 'effectively deny[ing] patent protection to all software claims',[60] others suggested that all that the Supreme Court had decided was that the particular algorithm in question could not be patented as a process.[61] The different ways in which the decision could be read was highlighted by articles in successive editions of the trade magazine *Computerworld*, which said that *Benson* precluded[62] and allowed[63] patent protection for computer software. In a decision that seemed to have something for everyone, it was suggested that there was text in *Benson* to support both of these incompatible views.[64] The confusing nature of the decision was reiterated in a comment by Justice Rich who said that he was 'probably as much – if not more – confused by the wording of the *Benson* opinion as many others … I have no idea what was in the collective mind of the … Court'.[65]

The Supreme Court decision set the tone for the way patent law approached computer-related subject matter for the remainder of the decade. As in the past, the law's response to the computer-related subject matter remained inconsistent, unclear, and unsettled. At times, such as in the *Presidential Commission on the Patent System*, the 1967 *Patent Reform Bill*, and the 1968 *Patent Office Examination Guidelines*, patent law embraced aspects of the hardware manufacturer's way of construing the subject matter. At other times, there was support for the approach favoured by software companies. For example, in several cases, including *Prater*, the Court of Custom and Patent Appeals sided with software companies and accepted the equivalence of a programmed general-purpose computer with a unique single purpose machine. While there was scattered support for both approaches, there was no overall agreement either about what the subject matter was nor about how it should be interpreted. As is often the case when the law first grapples with a new subject matter, the language used to describe computer-related subject matter was fluid and changing. The confusion was exacerbated by the widespread use of 'software' as a catch-all term for computer-related subject matter, even when talking about very different things. One of the consequences of this was that people often talked at cross-purposes[66] and 'read and understood patents and judgements

[60] Mary Jane Gaskin, 'In re Johnston: New Output by the CCPA on the Patentability of Computer Software' (1975) 36 *University of Pittsburgh Law Review* 739.

[61] See, e.g., Robert P. Bigelow, 'Infosystems, the Law and Patents' (1973) *Jurimetrics* 129, 130.

[62] *Computerworld* (29 November 1972), 1, col 3.

[63] *Computerworld* (13 December 1972), 37.

[64] Robert M. Milgrim, 'Software, Carfare and Benson' (1973) *Jurimetrics* 240.

[65] *In re Johnston* 502 F.2d 765, 773–4 (CCPA 1974). The reasoning is 'monstrously bad'. Donald S. Chisum, 'The Patentability of Algorithms' (1986) *University of Pittsburgh Law Review* 959, 977–78.

[66] In response to the 1967 testimony by Commissioner of Patents, Edward J. Brenner, to the House Judiciary Committee that the 'Patent Office has taken the view that computer programs are not patentable under present law, and no patent has been issued on a computer program per se', it was said that since it was not clear what was meant by 'computer' and 'program' that the claim was 'highly

differently'.[67] These problems were exacerbated by the fact that, at least from software producer's perspective, the patents that made their way to the courts for review in the 1960s and 1970s were the wrong type of subject matter. As Martin Goetz complained, the cases before the Court of Customs and Patent Appeals in the 1960s 'were not representative because they were industrial companies that had filed for patents and as part of the patent there was a computer. But they were not software companies that were filing for patents. These patents were usually controlling the machine, using an industrialized process … that included a computer program'. The patents had 'nothing to do with the software business, except one of the claims … involved software'.[68] The upshot of this was that patent law was unable to reach agreement about what the subject matter was, let alone how it should be dealt with.

Given this confusion, it is not surprising that commentators began to look elsewhere to regulate computer-related innovations. While a number of options were mooted, the most prominent and important change that occurred at the time was that the 'computer program *per se*' came to take on a special role in intellectual property law. The growing attention given to the computer program in patent law was primarily a consequence of changes in copyright law. In part this was a result of the fact that US, foreign, and international copyright practice adopted the computer program as the archetypical subject matter.[69] At the same time, there was also a growing expectation that the computer program would operate as a boundary object that regulated the divide between copyright and patents. In part this built upon the fact that it was accepted that computer programs, as descriptions of sets of machine instructions, were not and should not be patentable subject matter. Instead, they belonged if anywhere within copyright law. In effect what occurred was that the computer program was separated out, almost fetishized, and given pride of place as a discrete and distinct object amongst the myriad of things that fell within the field of computer technology. While the shift was never complete – software companies, in particular, consistently spoke about programmed machines and commentators still talk today about patenting software – the computer program came to occupy a

speculative'. Robert O. Nimtz, 'Computers, Programs and the Patent Laws' (1966–67) *Idea* 199, 207. Brenner testified that 'the Patent Office has not issued patents for computer programs per se'. Subcommittee on patents, trademarks, and copyrights of the Committee on the Judiciary, United States Senate (Ninetieth Congress, First Session Pursuant to S Res 37 on S. 2, S. 1042, S. 1377, S. 1691, Part 1 (17, 18 May 1967), 137).

67 Brief Amicus Curiae for Mobil Corporation, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71-485 (Oct. Term, 1971), 19.

68 ADAPSO History Program, Interview with Martin Goetz (3 May 2002) (interviewed by Jeffery R. Yost), 14–15.

69 In 1964 the Copyright Office defined a computer program as 'either a set of operating instructions for a computer or a compilation of reference information to be drawn upon by the computer in solving problem'. Copyright Office Announcement SML-47, May 1964; Copyright Office Circular 31D (January 1965).

special place within discussions about computer-related subject matter. As discussions were re-orientated to focus on the computer program, the computer program became the lens through which discussions about computer-related subject matter were framed (at least for a time).

Within patent law, the pride of place given to computer programs was reflected in the way that the Patent Office spoke about computer-related subject matter, in official inquires (such as the *Presidential Commission on the Patent System* and the 1967 *Patent Reform Bill*), and in the way many doctrinal accounts of the field were organized. In these accounts, the computer program (or the algorithm that was thought to underpin it) typically came to be seen as the 'intellectual heart of computer operation'.[70] The computer program also became the lens through which patents were viewed. As Martin Goetz, who is often credited with being granted the first patent on a computer program said, there was 'a lot of confusion because people thought of it as getting a patent for a program, which was not the case, because my patent … was for a sorting process'.[71] At times, the focus on the computer program became so dominant that software-related patents that did not expressly claim a computer program were criticized for obfuscating and disguising the 'true nature of their contribution by garbing the patent claims with recitations that appear to be directed to hardware components of digital computers and digital computer operations'.[72] The preoccupation with the computer program also came to shape the way that the history of software patenting has been viewed. To the extent that these histories move beyond the personal computer they tend to reach back to 1968, the year in which the 'first' software patent was granted to Martin Goetz. While this reading has been challenged on two fronts – first, by Goetz himself who (at least in some situations) has questioned whether his patent was for a computer program and more recently by Gerardo Con Diaz – nonetheless the history still centers on computer programs and software.[73]

While subject matter eligibility in US patent law was and remains a creature of jurisprudence, over the 1960s and 1970s the computer program took on a life of its own as it was entrenched in a network of formal and informal legal settings; a process that reinforced the expectation that the computer program would operate (at least ostensibly) as a boundary object to police the limits of software-related subject matter. This occurred as a result of a series of institutional, bureaucratic, and juridical changes in the United States, in other countries (notably in Europe), and at the international

70 Gabriel P. Katoma, 'Legal Protection of Computer Programs' (1965) 47 *Journal of the Patent Office Society* 955, 956.

71 Martin Goetz, ADAPSO Reunion Workshop, 'Intellectual Property' Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 5.

72 Brief Amicus Curiae for Burroughs Corporation, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71-485 (Oct. Term, 1971), 4.

73 From here program-focused histories often reach back to the Jacquard loom as providing the earliest antecedents. For example see Gerardo Con Diaz, 'Embodied Software: Patents and the History of Software development, 1946–1970' (July–September 2015) *IEEE Annals of the History of Computing* 8.

level: changes which gradually enmeshed the place of the computer program within intellectual property law. These included the 1970 *Patent Cooperation Treaty* (which allowed Member States to exclude computer programs from the examination process),[74] the 1973 *European Patent Convention* (which specifically excluded 'computer programs per se' from the scope of patentable subject matter), and a range of other efforts (such as the joint initiative of the National Bureau of Standards, the American Patent Law Association, and the Association of Computer Machinery Patent to classify computer programs to help with prior art searches).[75]

While this can be seen as a victory of sorts for hardware manufacturers, they were only partially successful. This was because while the computer program did operate (relatively) successfully as a boundary object to police the overlap between copyright and patents, it was much less successful in regulating patentable subject matter.[76] The reason for this, which is also a reason why patent law experienced so many problems in the 1960s and 1970s in dealing with computer-related subject matter, was that from a technological perspective the computer program and the programmed computer were inextricably connected and intertwined. While hardware and software companies had presented the choice of subject matter as a choice between non-patentable computer programs and patentable programmed machines, the fact that they were technologically intertwined meant that it was not easy to separate and distinguish them in this way.[77]

One of the consequences of this was that it was difficult to define a computer program in a way that did not bleed into and exclude other technologies that were considered to be patent eligible. (As we will see in Chapter 7, this is something that patentees exploited in drafting their patents to secure protection for their computer-related innovations.) These definitional problems led to the suggestion that any attempt to exclude computer programs from patentability was 'doomed to failure'. This was because any 'attempt to define software for the purposes of excluding it', such as in the *Patent Reform Act* of 1967, 'led to a definition that necessarily excluded other control devices or systems which, as machines or parts thereof, have always

[74] Rule 39(1), *Patent Cooperation Treaty*. For background see *Draft records of the Washington Diplomatic Conference in the Patent Cooperation Treaty: 1970 Conference Documents*, PCT/DC/3, (11 July 1969), item 32.

[75] G. Knight Jr, *Hierarchical Descriptor Classification System for Documents Related to Computer Software: With Scope Notes* (1970) (prepared for the Administrator, Office of Systems and Search Documentation, US Patent Office). Michael Duggan, 'Patents and Programs: The ACM's Position' (April 1971) 14(4) *Communications of the ACM* 278, 279. (Duggan was chairman of the ACM Committee on Copyrights, Patent and Trademarks).

[76] Thomas Haigh, 'Software in the 1960s as Concept, Service, and Product' (January–March 2002) *IEEE Annals of the History of Computing* 5.

[77] This ambiguity was captured in an article arguing for patent protection for algorithms which qualifies a statement that mathematical algorithms as such do not constitute patentable subject matter 'in theory' with a footnote that says that 'in fact a large number of patents are currently being obtained on what are essentially computer programming concepts'. Donald S. Chisum, 'The Patentability of Algorithms' (1986) *University of Pittsburgh Law Review* 959, 960–61, n 3.

been patentable',[78] such as 'built-in programs in special propose computers'[79] and 'programmable devices, such as an automatic dishwasher having certain predetermined cycles'.[80] The problem here was that while it may have been possible to demarcate and differentiate a computer program as an object of commerce, it was much more difficult to differentiate a program when the subject matter was seen from a more functional (or engineering) perspective.[81] In many ways these definitional concerns built upon the fact that using a computer program to run (or softwire) a computer was the engineering equivalent of hardwiring a computer. While there were physical differences, from an engineering or technological perspective the hardware and software forms of programming were functionally the same.[82]

One of the challenges that patent law faced when discussing patentable subject matter was that it had to deal with the fact that numerous patents had been granted for hardwired-programmed computers since the late 1940s.[83] The reason why this was important was because hardwiring was one of two ways by which special-purpose computers, that is computers programmed to perform specific tasks, could be constructed. Hardwiring was a permanent or semi-permanent solution that involved

[78] Morton C. Jacobs, 'Computer Technology (Hardware and Software): Some Legal Implications for Antitrust, Copyright and Patents' (1970) *Rutgers Journal of Computers and Law* 50, 58.

[79] B. M. Oliver, 'Major Recommendations of the US Presidents Patent Commission' (February 1967) *IEEE Spectrum* 57, 60.

[80] Statement by Philadelphia Patent Law Association, *Patent Law Revision: Subcommittee on patents, trademarks, and copyrights of the Committee on the Judiciary, United States Senate* (Ninetieth Congress, First Session Pursuant to S Res 37 on S. 2, S. 1042, S. 1377, S. 1691, Part 1 (17, 18 May 1967), 259).

[81] Morton C. Jacobs, 'Computer Technology (Hardware and Software): Some Legal Implications for Antitrust, Copyright and Patents' (1970) *Rutgers Journal of Computers and Law* 50, 52. '[M]any, many patents issue which disclose the hardware embodiment by which contain claims broad enough to cover the software equivalent'. Richard E. Kurtz, 'Examples of Inventions Embodying Software, Types of Disclosure and Claims' in *Software Protection by Trade Secret, Contract, Patent: Law, Practice, and Forms* (Washington, DC: Patent Resources Group, 1969), 188.

[82] Brief Amicus Curiae for Applied Data Research, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71-485 (Oct. Term, 1971), 4. A machine containing a programmed control system is the same in all features as that containing special purpose hardware controls'. Statement of Richard C. Jones, President, Applied Data Research, *Patent Law Revision, Subcommittee on patents, trademarks, and copyrights of the Committee on the Judiciary United States Senate* (Ninetieth Congress, First Session Pursuant to S Res 37 on S. 2, S. 1042, S. 1377, S. 1691, Part 2 (1–2 January, 1 February 1968), 751–52). If a patent application is filed disclosing only the claimed sequence of steps (in a flow chart for example), there is no conceivable way in which the Patent Office, or anyone else, can ascertain with certainty whether the applicant had in mind a computer program or a wired circuit. It is not surprising therefore that the Patent Office and certain patentees disagree as to whether or not a "computer program" has been patented'. 'A Case History: Benson and Talbot: Appellant's Position: Computer Programs in General', Appendix C, appended to Robert O. Nimtz, 'Computer Application and Claim Drafting under Current Law' in *Software Protection by Trade Secret, Contract, Patent: Law, Practice, and Forms* (Washington, DC: Patent Resources Group, 1969), 261.

[83] In *Ex Parte King and Barton* 146 USPQ 590 (1964) 'the Examiner took note of the engineering equivalence of hardware implemented inventions and those implemented by software and general-purpose hardware'. See Brief Amicus Curiae for the Association of Data Processing Service Organisations, Software Products and Service Section, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71-485 (Oct. Term, 1971), 16 n 38.

modifying the hardware of a computer to perform certain specified tasks. (A modern example would be a TV remote control.) The second way of developing a special-purpose computer, which was the technology that was under discussion in the 1960s and 1970s, was to use special (external) programs to control one of the standard general-purpose computers that were sold or leased by hardware manufacturers such as IBM.[84] Rather than adopting a different set of hardware connections each time a new purpose was desired, a computer engineer could use 'special software to achieve an equivalent softwire change in the connections and the general purpose hardware'.[85] That is, they could use different (soft-wired) programs to allow the computer to perform different tasks. In 'the place of the "hard-wire" of special purpose hardware, the software uses the "soft-wire" of recorded electrical signals which have the physical effect when placed in the general-purpose computer of setting thousands (or even millions) of electronic switches in unique combinations'.[86] 'Soft-wiring' was the term used by 'engineers in the industry to indicate that the recorded signal combinations of software achieve the same effects as actual "hard-wire", but the advantages of modifications and replacement without rewiring are also achieved'.[87]

The fact that a special-purpose computer could be created either by hardwiring or softwiring a general-purpose computer, combined with the fact that hardware manufacturers had been patenting hardwired computers since the 1940s, influenced the way hardware and software companies portrayed the subject matter in the 1960s and 1970s. On the one hand, hardware companies presented the 'new' technology in such a way that it allowed for the continued patenting of hardwired computers but, at the same time, excluded softwired computers operated by computer programs. In contrast, software companies presented the technology in such a way that allowed them to argue that softwired computers should be given the same type of protection as had been bestowed on hardwired computers. Specifically software companies argued that given that the decision to either hardwire or softwire a computer was based on economic and practical rather than engineering considerations that 'consequently there should be no legal difference since the two forms of the invention are engineering equivalents'.[88] To hold otherwise would have meant

84 Morton C. Jacobs, 'Patents for Software Inventions: The Supreme Court's Decision' (1973) *Journal of the Patent Office Society* 59.

85 Ibid., 60.

86 See Brief Amicus Curiae for the Association of Data Processing Service Organisations, Software Products and Service Section, *Gottschalk* v. *Benson*, Supreme Court of the US, No. 71-485 (Oct. Term, 1971), 10.

87 Ibid., 10 n 27. Computer engineers who recognize the equivalence of software and hardware, 'speak of the software techniques for the building of special-purpose computers as "softwiring."' Morton C. Jacobs, 'Patents for Software Inventions: The Supreme Court's Decision' (1973) *Journal of the Patent Office Society* 59.

88 Statement of Richard C. Jones, President, Applied Data Research, *Patent Law Revision, Subcommittee on patents, trademarks, and copyrights of the Committee on the Judiciary United States Senate* (Ninetieth Congress, First Session Pursuant to S Res 37 on S. 2, S. 1042, S. 1377, S. 1691, Part 2 (1–2 January, 1 February 1968), 751–2).

discriminating against 'inventors who chose a program as the preferred embodiment in favour of a hardware embodiment for the same inventive concept'.[89] If this was allowed it would, so the argument went, have created an unfair situation that arbitrarily favoured one segment of the computer industry over another.[90]

The upshot of this was that any attempt to exclude computer programs would have also excluded other 'control mechanisms; such as the 'circuitry embodiment of a machine invention' which was 'an engineering equivalent of the program embodiment'.[91] These problems were reinforced by the fact that despite the claims of the hardware companies, no one was really interested in patenting computer programs (algorithms, or mathematical methods) per se. As Martin Goetz said in 1970, '[a]t no time did' any of the software producers 'or any other advocate of "software patents" ever ask to protect computer programs. Rather, our goal is not to have the patentability of an "inventive machine process" denied solely because the inventor arbitrarily chose to embody that machine process in software (usually because of the prohibitive costs of embodying the same invention in hardware)'.[92] Robert Nimtz made a similar point when he said, the 'overall issue has never been the patentability of computer programs, as such. On the contrary, the issue has always centered around the patentability of processes carried out in response to programmed instructions in a computer, and to the patentability of apparatus configurations resulting from the execution of programmed instructions in a computer'.[93] Nimtz summed up these arguments when he said the 'program, as writing, has never been the subject matter of a patent claim, at least as far as this author is aware'.[94]

Since there was no real interest in patenting computer programs as ends in themselves and it was very difficult to define computer programs for the purpose of excluding them from protection in a way that did not also exclude subject matter

89 Anon, 'Computer Programs: Are They Patentable?' (29 December 1968) *The New York Times* 1.

90 'Those who manufacture the programs but not the machines should have the same rights to patent protection as those who manufacture the machine'. Computer engineers who recognize the equivalence of software and hardware, 'speak of the software techniques for the building of special-purpose computers as "softwiring."' Morton C. Jacobs, 'Commissions Report (re: Computer Programs)' (1967) *Journal of the Patent Office Society* 372, 376.

91 Ibid. The overlap was recognized in the comment, in relation to the suggestion that one of the reasons why computer programs should not be patentable was because of the problems facing the Patent Office that 'even if some defined area of computer programming technology were to be made "non-statutory", the Patent Office would still have the burden of classifying and searching the computer programming literature because of the close interplay between the software and hardware technologies'. George Metcalf, (US Chamber of Commerce), *Patent Law Revision, Subcommittee on patents, trademarks, and copyrights of the Committee on the Judiciary United States Senate* (Ninetieth Congress, First Session Pursuant to S Res 37 on S. 2, S. 1042, S. 1377, S. 1691, Part 2 (1–2 January, 1 February 1968), 454).

92 Martin Goetz, 'A Different Viewpoint on the Benson Talbot Decision' (May 1973) 16 *Communications of the ACM* 334.

93 Robert O. Nimtz, 'The Patentability of Computer Programs' (1970) 1 *Rutgers Journal of Computers and Law* 38.

94 Ibid., 38 n 4.

considered to be patent-worthy, it became clear that the computer program could not operate as an effective way of policing computer-related subject matter. While the decision in Europe to use the 'computer program per se' as a way of regulating patentable subject matter meant that European patent law was forced to work out a way of distinguishing computer programs per se from computer-related inventions, patent law in the United States went in a different direction. As we will see in Chapter 7, after struggling to reconcile the 'contested ontologies of software' for over two decades, in the 1980s US patent law shifted its focus of attention to develop a more legal approach to computer-related subject matter.

7

Fabian Patents

INTRODUCTION

Intellectual property law has been interacting with software-related inventions in one way or another for over 60 years. Despite the number of judicial decisions, legislative interventions, public inquiries, policy reports, articles, and books that have been devoted to the subject over this time, there are many unanswered questions concerning intellectual property law and its relationship to software-related subject matter. The confusion and uncertainty that characterises this area of law is particularly evident in patent law. As Dennis Crouch wrote in 2012, it 'is simply ridiculous that after 40 years of debate, we still do not have an answer to the simple question of whether (or when) software is patentable'.[1] The uncertainty about whether or not software is patentable subject matter was compounded by the 2014 decision of *Alice* v. *CLS Bank* where the US Supreme Court was asked, again, whether software was patent eligible. The uncertainty created by the *Alice* decision was captured in Robert Merges' comment that to 'say we did not get an answer' from the Supreme Court to the question of whether software was patentable 'is to miss the depth of the non-answer we did get'.[2] As a 2022 Patent Office report on subject matter eligibility shows, the situation since then has only got worse.[3]

While a number of explanations have been given for this confusion, three stand out. The first suggests that the confusion arises because of the peculiar nature of software. More specifically, the confusion is said to arise because as software is neither art nor science but a hybrid thereof, it does not fit neatly into intellectual property law, which distinguishes between artistic creative outputs (copyright) and

[1] Dennis Crouch, 'Ongoing Debate: Is Software Patentable?' (27 July 2012) *Patently-O*.

[2] Robert Merges, 'Symposium: Go Ask Alice – What Can You Patent after *Alice* v. *CLS Bank*?', SCOTUSblog (20 June 2014). www.scotusblog.com/2014/06/symposium-go-ask-alice-what-can-you-patent-after-alice-v-cls-bank/

[3] USPTO, 'Patent Eligible Subject Matter: Public Views on the Current Jurisprudence in the United States. A Report to Congress' (June 2022).

techno-scientific creations (patents).[4] At the same time, it is also suggested that while intellectual outputs have typically been protected by one form of intellectual property, this is not the case with software, which is afforded both copyright and patent protection, 'making it a unique phenomenon in the law of intellectual property'.[5]

A second explanation attributes the confusion and uncertainty to the ephemeral, non-physical nature of software, to its intangibility. While the incorporeal nature of intellectual property has long created problems for the law, there is thought to be something particularly disturbing about 'the unphysical nature of computer programming'[6] that makes it 'very different from any property we have every known'.[7] In particular it has been suggested that the confusion associated with software arises because it 'is neither tangible or intangible, but something else'.[8] This is because software 'has both tangible or intangible aspects. Indeed, it seems to have a chameleon nature, undergoing a transition from a tangible to an intangible and back to a tangible object depending upon how it is used or how it is being viewed'.[9]

A third explanation attributes the uncertainty to the law's inability to keep up with the speed of change associated with information technology and of the inevitable gap that this creates between the law and the technology it is meant to regulate.[10] In this sense, it is seen as yet another example of the dilemma that is created when the 'law does not keep pace with the advance of science and industry'[11] and of the problems that arise when the law attempts to make sense of complex new technologies.[12]

While these factors are important, the primary reason why patent law's relationship with software-related subject matter has been so fraught is because of the way the subject matter has been construed. Martin Goetz, from Applied Data Research, summed up these problems when in speaking about information technology in the 1960s and

[4] See Robert W. Wild, 'Computer Program Protection: The Need to Legislate a Solution' (1969) 54(4) *Cornell Law Review* 586, 589: programs were 'part science, part art'. In the 1970s IBM proposed the introduction of a hybrid registration system (copyright and patents) for software. See Elmer Galbi, 'Proposal for New Legislation to Protect Computer Programming' (1970) 17 *Bulletin of Copyright Society* 280. (Galbi was senior patent attorney for IBM).

[5] Kenneth Nichols, *Inventing Software: The Rise of Computer-Related Patents* (Westport, CT: Quorum Books, 1998), 3.

[6] Harold L. Davis, 'Computer Programs and Subject Matter Patentability' (1977–78) *Rutgers Journal of Computers and Law* 1, 22. Martin Campbell-Kelly, *From Airline Reservations to Sonic the Hedgehog: A History of the Software Industry* (Cambridge, MA: MIT Press, 2004), 3.

[7] Milton R. Wessel, 'Some Implications of the Software Decision' (1973) *Jurimetrics* 110, 111.

[8] Duncan M. Davidson, 'Common Law, Uncommon Software' (1986) *University of Pittsburgh Law Review* 1037, 1065.

[9] Ibid., 1064.

[10] Michael A. Duggan, 'Patents and Programs: The ACM's Position' (1971) 14(4) *Communications of the ACM*, 278. Harold L. Davis, 'Computer Programs and Subject Matter Patentability' (1977–78) *Rutgers Journal of Computers and Law* 1, 4 n 14.

[11] Philip Stork, 'Legal Protection for Computer Programs: A Practicing Attorney's Approach' (1970) 20 *Copyright Law Symposium* 112, 138.

[12] For a critical account of this way of thinking about law and technology see Allison Fish, *Laying Claim to Yoga* (New York: Cambridge University Press, forthcoming).

1970s he said: 'It was a very unclear era. There were questions of whether software was tangible or intangible and what was software. Of course IBM was giving it all away for free, and then suddenly they're selling it. What were they selling and how do you protect it. There was a question of: is software taxable, is it tangible? There was a great deal of confusion all wrapped up in the intellectual property issues.'[13]

While contemporary accounts of patentable subject matter tend to focus on excluded subject matter (laws of nature, natural phenomena, and abstract ideas), what is clear from patent law's engagement with software is that while these categories of non-patentable subject matter played a role, this was nowhere near as important as the way that the subject matter was construed. In the same way in which the fate of gene patents in the early part of the twenty-first century turned on whether the isolated genes were characterised in chemical or genetic terms, so too the fate of software-related subject matter across the second half of the twentieth century turned on how it was characterised. The problem for patent law at the time, and a key reason for the ongoing confusion about patent law's relationship to software, was that it was unable to find a suitable way of answering this question.

While the early discussions were framed in terms of the question – *is software patentable?* – the flexibility inherent in the term 'software' masked the fact that strictly speaking the debates were not about the patenting of software as such. Rather, what was at stake in these debates was the preliminary question: *what is the subject matter*? That is, the debates were not about how the class of subject matter should be characterized, so much as about what the class of subject matter was or should be.[14] As Leo Keet, former President of the software products group at Dun & Bradstreet said, 'during the early years of the software industry, we debated a seemingly simple question: What is software? The answer, once we could agree, would help determine our approach to intellectual property, taxation, contracting, and public policy issues'.[15]

As we have seen, the primary reason why patent law's relationship with software has been so troubled was because the computer industry could not agree on what

[13] ADAPSO Reunion Workshop, 'Intellectual Property' Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 23. For example, it was unclear whether software was a 'good' which fell under Article 2 of the Uniform Commercial Code, or whether it was some sort of 'service' that fell outside the scope of the code. The industry was said to have been whipsawed by the government on the nature and taxability of software. On the one hand, 'the Federal Government took the position that software was intangible and, therefore, did not qualify for things like accelerated depreciation the investment tax credit and other favourable federal tax treatment'. On the other hand, however, the States took the view that 'software was tangible and, therefore, its transfer or sale was subject to sales and use taxation.' Ron Palenskim, ADAPSO Reunion Workshop, 'Intellectual Property', Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 15.

[14] As a software industry representative reflecting on the 1960s said, 'during the early years of the software industry, we debated a seemingly simple question: What is software? The answer, once we could agree, would help determine our approach to intellectual property, taxation, contracting, and public policy issues'. Ernest E. Keet, 'A Personal Recollection of Software's Early Days (1960–1979): Part 2' (October–December 2005) *IEEE Annals of the History of Computing* 31.

[15] Ibid.

the subject matter was. This was important because patent law usually relies upon science and technology to accommodate new types of subject matter. As a Patent Office examiner wrote in 1969, what was needed to accommodate the new subject matter was a 'concerted, unemotional effort by the software industry to define its terminology and specific desires'.[16] While in most situations, technical and scientific communities have provided the law with the tools to understand and define the subject matter being considered, this was not the case with software-related subject matter.[17] Indeed, rather than providing an answer to the question of what the subject matter was or the means to allow that subject matter to be assimilated in the law, the industry sought to resolve its own disputes *through* the law. Unlike the case with organic chemicals and biological inventions, the inherently divided nature of the nascent information technology industry meant that the law was forced to develop its own way of dealing with the would-be subject matter. And while there was no particular reason why the legal response to this question should have been so confused, it was and remains so.

One of the challenges that patent law faced when confronted with software-related subject matter in the 1960s and 1970s was that it was not in a position to evaluate or judge the novelty and obviousness of patent applications. A key reason for this was that patent law 'had no history to look to'.[18] As the US President's 1966 Commission on the Patent System Inquiry found:

> The Patent Office now cannot examine applications for programs because of the lack of a classification technique and the requisite search files. Even if these were available, reliable searches would not be feasible or economic because of the tremendous volume of prior art being generated. Without this search, the patenting of programs would be tantamount to mere registration and the presumption of validity would be all but nonexistent.[19]

In response to this problem, members of the patent profession joined with information technical experts to tame the unruly and disorganized public domain. Notably, the National Bureau of Standards, the American Patent Law Association, and the Association of Computer Machinery Patent Committee joined forces in the late 1960s to classify computer software.[20] While this initiative was relatively short-lived,

[16] T. Buckman, 'Protection of Proprietary Interests in Computer Programs' (1969) *Journal of the Patent Office Society* 135, 151.

[17] Software was 'not yet a science, but an art that lacks standards, definitions, agreements on theories and approaches.' Gene Bylinsky, 'Help Wanted: 50,000 Programmers' (March 1967) *Fortune* 141.

[18] Leo Keet, ADAPSO Reunion Workshop, 'Intellectual Property', Computer History Museum, CHM Ref No. X4589.2008 (Recorded 4 May 2002), 9.

[19] *Report of the President's Commission on the Patent System* (Washington, DC, 1966), 13.

[20] Michael Duggan, 'Patents and Programs: The ACM's Position' (1971) 14(4) *Communications of the ACM* 278, 279. The Patent Office was said to be 'enthusiastic' about the work of the Committee. Letter from Gunter A. Haupton (IBM), (Chair) to members of the PLA Subcommittee on the Classification of Computer Programs (24 October 1969).

by 1970 approximately 700 subject areas had been established and defined for classifying an estimated 20,000 prior art publications relating to software.[21] As with the attempt to develop a test to allow would-be subject matter to be evaluated to determine if it was patent eligible, the attempt to classify computer-related prior art was hampered by the uncertainty as to what was meant by software.[22]

Another challenge the law faced in dealing with computer-related subject matter was working out when the subject matter was patentable. With Congress unable or unwilling to assist, there was (and remains) a hope and expectation that the Supreme Court would intervene to resolve this seemingly intractable problem.[23] As commentators have noted, however, the Supreme Court's pronouncements on software-related subject matter have created more problems than they have solved.[24] One reason for this is that despite repeated calls for the Supreme Court 'to rule on the broad question of whether "machine processes" that utilize a general purpose computer for their implementation constitute patentable subject matter', the Supreme Court has consistently refused to provide an answer.[25] Instead, the Court has tended to limit its findings to the specific facts of the case at hand, leaving it to others to fight over what the decisions meant for software patentability more generally. As Justice Rich said in criticising the approach of the Supreme Court to software patents, this was 'like taking the problem of school segregation to court on a case-by-case basis, one school at a time'.[26] And when the Supreme Court eventually did attempt to make a more general ruling (in *Mayo* and *Alice*), it merely restated the problem as a two-step process.

One of the factors that shaped the way the Supreme Court approached software-related subject matter was that it felt uncomfortable dealing with what the Court of

[21] G. Knight Jr, *Hierarchical Descriptor Classification System for Documents Related to Computer Software: With Scope Notes* (1970) (prepared for the Administrator, Office of Systems and Search Documentation, US Patent Office). This was said to be 10% of prior art documents.

[22] The attempt by the joint study by the Patent Office, National Bureau of Standards, and the ACM to classify extant computer literature dealing with programs was said to be 'intractable'. Michael A. Duggan, 'Patents on Programs? The Supreme Court Says No' (1973) *Jurimetrics* 135, 136.

[23] The Supreme Court in Benson concluded that the problems relating to software patentability could only be solved by Congress. *Gottschalk* v. *Benson* 409 U.S. 63, 73 (1972).

[24] See John F. Duffy, 'Rules and Standards on the Forefront of Patentability' (2009) 51 *William and Mary Law Review* 609; Dan Burk and Mark Lemley, *The Patent Crisis and How the Courts Can Solve It* (Chicago: Chicago University Press, 2009), 157. At times this led to calls for patent matters to be taken away from the jurisdiction of the Supreme Court. A questionnaire sent out to the members of the APLA Committee on Computer Program Protection to work out the impact of the Flook decision asked whether 'Issues of patentability of inventions under the statute should be removed from the jurisdiction of the US Supreme Court'. 'Questionnaire re Impact of Flook', sent out by Reed C. Lawlor (Attorney) to members of the APLA Committee on Computer Program Protection (11 August 1978). Charles Babbage Institute, Applied Data Research, Software Products Division records, CBI 154, File: Box 15, folder 7.

[25] Martin A. Goetz, 'The Flook Patent Opinion Signals that Inventive Software Processes Are Patentable Subject Matter' (n.d.) Charles Babbage Institute, Applied Data Research, Software Products Division records, CBI 154, Box 15, folder 7.

[26] *In the Matter of the Application of Glen F. Chatfield* 545 F.2d 152, 162 (CCPA 1976).

Customs and Patent Appeals in *Prater* II described as 'one of the most technical-legal matters ever appealed to this court'[27] (which led to calls, which have been repeated recently, that technological matters should be removed from the jurisdiction of the Supreme Court).[28] While it had been hoped that when the Supreme Court was asked in *Benson* to consider the patentability of a general-purpose digital computer programmed with an algorithm that converted binary coded decimals to pure binary numbers that the Court would have provided clarity about how software-related subject matter should be interpreted, this was not to be. While the parties recognized that the outcome of the decision turned on how the technology was construed, the Supreme Court felt that it was 'not competent to resolve' … 'the vast technological questions' that had been raised in the fourteen amici curiae briefs.[29] That is, the Court felt it was not in a position to decide either what the software-related subject matter was or how it should be interpreted.[30]

While the Supreme Court may not have offered much assistance in determining when computer-related subject matter might qualify as patentable subject matter, it has played an important role in framing the way this question was asked. The first way it did this was in terms of the way composite inventions should be approached, something that was particularly important with machine-based subject matter. While often overlooked, this is perhaps the most important and enduring contribution made by the Supreme Court to subject matter eligibility.

When the courts first began to consider software-related subject matter, there were two competing ways of approaching inventions that were made up of parts or elements. One approach, often confusingly called the 'point of novelty test', requires composite inventions to be separated into parts. Specifically, it requires courts to exorcise and then ignore those parts of the claimed invention that either lack novelty or are deemed to be excluded subject matter (such as a computer program). Motivated by a desire 'to discourage clever attorneys from using their skill to hide software claims among a sea of irrelevant non-novel limitations',[31] the courts

[27] *Application of Prater and Wei* 415 F.2d 1378, 1390 (CCPA 1969). Anon, 'Computer Patent Backed by Court' (23 November 1968) *The New York Times* 71

[28] In its brief amicus curiae in *Diamond* v. *Diehr*, Applied Data Research argued that the writ should be dismissed because the Supreme Court was not equipped to resolve what the Commissioner of Patents had presented as the key issues in the case, which would require the court to 'undertake a thorough inquiry into the complex technological facts of the construction of computerized machines'. The problem was that none of the eight computer program cases … has contained a factual record of the nature of this technology and the 'Supreme Court was not the appropriated forum for initial fact finding'. 'Brief Amicus Curiae for Applied Data Research and Whitlow Computer System' in *Diamond* v. *Bradley and Diamond* v. *Diehr* Nos 79–855 and 79–112, 7.

[29] Harold L. Davis, 'Computer Programs and Subject Matter Patentability' (1977–78) 6 *Rutgers Journal of Computers and Law* 1, 13–14 n 13.

[30] *Gottschalk* v. *Benson* 409 U.S. 63, 73 (1972). The court felt that the technological problems raised in the briefs could only be answered by committees of Congress: which was not forthcoming.

[31] Keith E. Witek, 'Developing a Comprehensive Software Claim Drafting Strategy for US Software Patents' (1996) *Berkeley Technology Law Journal* 363, 375.

were then expected to determine whether what was left of the invention fell within one of the classes of statutory subject matter. When applied to computer-related subject matter, the point of novelty approach meant that the court would ignore the computer program, mathematical method, algorithm, etc. and only consider the parts that remained (the computer).[32] Given that this would have excluded many computer-related inventions, it is not surprising that the point of novelty approach was supported by hardware manufacturers. The second more straightforward test, which was sometimes known as the 'whole contents approach', requires the courts to evaluate the invention as a composite entity without breaking it down into parts. That is, the courts were expected to consider whether the invention as a whole was statutory subject matter.

While the Supreme Court briefly flirted with the point of novelty test in *Parker* v. *Flook*, it changed course in *Diamond* v. *Diehr* and came out in favour of the whole contents approach: a position which it has consistently adhered to subsequently.[33] As the court said in *Diehr*, a claim was not unpatentable merely because it included a step(s) or elements(s) directed to a law of nature, mathematical algorithm, formula, or computer program so long as 'the claim as a whole is drawn to subject matter otherwise statutory'.[34] In doing so, the Supreme Court reinstated the long-held view that the 'practice of dissecting a machine and rejecting it piecemeal is without sanction of either reason or law'.[35]

A second change instigated by the Supreme Court that helped to frame the way computer-related subject matter was evaluated concerned the way the excluded subject matter was categorised. While contemporary accounts of patentable subject matter tend to treat laws of nature, natural phenomena, and abstract idea as timeless, ahistorical categories, they have a much more recent history. Until the 1980s or thereabouts, the language used to describe excluded subject matter was fluid,

[32] Although the appellant in *Noll* had couched his invention as an apparatus claim and argued that the invention should be scrutinised as a whole, this was rejected by the Patent and Trademark Office Board of Appels. The reason for this was that the applicant perceived his invention to lie in the computer program. Paraphrasing Gertrude Stein, they added 'a program is a program is a program' and to have allowed protection would have allowed protection over programs per se. *In re Noll* (18 November 1976) as cited in *In re Noll* 545 F2d 141, 148 (CCPA 1976) who rejected the approach by Board of Appeals holding that it was necessary to focus on the claimed subject matter as a whole.

[33] *Diamond* v. *Diehr* 450 U.S. 175, 188 (1981) ('It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the [35 U.S.C. § 101] analysis').

[34] George H. Knight, *Patent-Office Manual: Including the Law and Practice of Cases in the United States Patent Office and the Courts Holding a Revisory Relation Thereto, also, an Appendix of Copyright Decisions* (Boston: Little Brown, 1894), 135.

[35] Anon, 'Timely Hints for Patent Office Examiners' (25 May 1872) 26(22) *Scientific American*, 353. 'A machine may be either a single organism or a combination or organisms so related to each other as to co-operate, successively or simultaneously, in the production of the required result. When it is composed of parts, none of which without all the others constitute a machine, or when certain of its parts form a complete machine but the other portions, whether taken singly or together, are incapable of organic action the machine is a single organism.' William C. Robinson, *The Law of Patents for Useful Inventions: Vol 1* (Boston: Little Brown, 1890), 262.

inconsistent, and changing. This was particularly the case with computer-related inventions, where a number of different overlapping terms were used to describe the excluded subject matter including software, computer programs, algorithms, mathematical formula, mental methods, and a range of variations thereof.

Over the course of the 1980s, the way excluded subject matter was categorised began to change. We can get a sense of some of the reasons for and the nature of these changes from the letter that the patent attorney, Reed C. Lawlor, sent to the American Patent Law Association's Committee on Computer Program Protection in 1978 complaining about the impact of the Supreme Court decision of *Parker* v. *Flook*. As Reed said, the 'Flook case arose because the patent profession as a whole has neglected the computer program allegedly "because it involves special interests"'. To remedy this, Reed said it was 'time … to re-examine the fundamental principles of patent law concerning scientific principles, laws of nature, and mathematical formulas and algorithms, remembering that computer programming as merely one example, so that we can avoid another Flook'.[36] While the process may have been unscripted, sentiments such as these, combined with a string of decisions dealing with subject matter eligibility and a consequential growing academic interest in subject matter, had an impact on the way excluded subject matter was categorised.

Motivated by the legal impulse to codify, there were various attempts across the 1980s to synthesise the unwieldy and inconsistent list of subject matter that had been excluded by the courts over the last 150 or so years into a smaller number of more coherent categories. While there was some success, many issues were left unsettled. This was particularly the case with computer-related subject matter. In the early 1980s, there were many in the patent community who believed, for example, that in addition to the (now familiar) categories of 'laws of nature, natural phenomena, and abstract ideas' that *Benson*, *Flook*, and *Diehr* had created a fourth category of unpatentable subject matter, namely a general mathematical-algorithm exception.[37] This argument was considered and rejected by the Court of Appeals in *Alappat* where the court said, a 'close analysis of *Diehr*, *Flook*, and *Benson* reveals that the Supreme Court never intended to create an overly broad, fourth category of subject matter excluded from § 101'.[38] As the Court of Appeals explained, the reason for this was that 'at the core of the [Supreme] Court's analysis in each of these cases lies an attempt by the Court to explain a rather straightforward concept, namely, that certain types of mathematical subject matter, standing alone, represent nothing more than *abstract ideas* until reduced to some type of practical application, and thus that subject matter is not, in and of itself, entitled to patent protection'.[39]

[36] Letter sent by Reed C. Lawlor (Attorney at Law) to the members of the APLA Committee on Computer Programming Protection, 11 August 1978, 2.

[37] Charles A. Damschen, 'Patentable Subject Matter: Do the 2005 USPTO Interim Guidelines Intersect State Street at a Roundabout?' (2008) 93 *Iowa Law Review* 1889, 1901.

[38] *In re Alappat* 33 F.3d 1526, 1543 (Fed Cir 1994).

[39] Ibid.

As well as providing a useful review of the Supreme Court decisions in the 1980s dealing with computer-related subject matter, the *Alappat* decision also highlights some of the changes that occurred in the way excluded subject matter was categorised at the time. The most obvious was that the different types of excluded subject matter were now subsumed within three general categories: laws of nature, natural phenomena, and abstract ideas.[40] Importantly, as part of this process the excluded subject matter that had previously been associated with computer-related inventions – software, computer programs, algorithms, mathematical formula, and mental methods – were now subsumed within the newly anointed overarching category of excluded subject matter labelled 'abstract ideas'. As a result, instead of asking whether a computer-related application was really for a computer program or a mathematical formula, the courts now asked whether it was for an abstract idea. This brought about a change in the way excluded subject matter was interrogated, from the situation previously where excluded subject matter was described in technical or quasi-technical terms[41] to a situation where excluded subject matter was defined in terms of the thing that was presumed to unite the different types of excluded subject matter, namely, as the Court of Appeals said in *Alappat*, that they 'represent nothing more than *abstract ideas*'. And while this was certainly not the first time when a pre-emption argument was made – this is the argument that protection should correspond to what was invented – pre-emption took on a new prominence at the time as a means of justifying the shift to the more general principal-based categories. As the Federal Circuit said in *In re Bilski*, the question 'before us then is whether Applicants' claim recites a fundamental principle and, if so, whether it would pre-empt substantially all uses of that fundamental principle if allowed'.[42] Or as the Supreme Court said in *Alice*, 'while pre-emption is not the test for determining patent-eligibility' it is certainly the 'concern that undergirds our § 101 jurisprudence' dealing with subject matter eligibility.[43]

The adoption of the technologically neutral 'abstract ideas' category brought about a number of subtle but important changes in the way excluded subject matter was thought about. As we saw earlier, during the 1960s and 1970s patent professionals were aware that when thinking about subject matter eligibility, it was important to decide what the technology was and how it was to be interpreted. With the shift to a principle-based mode of categorisation, subject matter eligibility was decoupled from its technological origins to be replaced by debates about the meaning of abstract ideas, a process which accelerated following the 2014 Supreme Court

[40] 'The subject matter courts have found to be outside of, or exceptions to, the four statutory categories of invention is limited to abstract ideas, laws of nature and natural phenomena'. USPTO, *Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility*, Official Gazette of the United States Patent Office Notices (22 November 2005), 6.

[41] With the exception of mental steps.

[42] *In re Bilski* 545 F.3d 943, 954 (Fed Cir 2008).

[43] *Alice Corp*. v. *CLS Bank International* 134 S. Ct. 2347, 2358 (2014).

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decision of *Alice* v. *CLS Bank*. This not only further distanced patent law from the information technology industry (and with it the possibility that the industry would help the law to deal with computer-related subject matter), it also shifted attention away from the way the subject matter as technology was interpreted and, in turn, the role this played in deciding the fate of many types of subject matter. The shift away from a subject matter that was described technically to one based on more general criteria (abstract ideas) also undermined the role computer programs played as boundary objects in patent law. While the computer program continued to operate as a boundary object in copyright law and in patent law in other countries, patent law in the United States moved in a different direction.

The decision to subsume the excluded subject matter associated with computer-related inventions within 'abstract ideas' also had an impact on the way computer-related subject matter was evaluated. While many issues were unsettled in the 1960s and 1970s, when thinking about subject matter eligibility patent law tended to focus on whether the (unpatentable) two-dimensional computer program had been transformed into novel three-dimensional machine. As Morton Jacobs said at the time, the key issue for patentability was whether a 'machine invention has been made, or merely a discovery in mathematics, a mental process or the like'.[44] There were two notable features of this short-lived approach. The first was that it tended to see subject matter through a technical lens. The second was that the fate of computer-related subject matter depended on an applicant being able to show that they had brought about a change of kind, created a new kind of thing, or as the Commissioner of Patents said in 1966 transformed a general-purpose computer into a new type of specific-purpose machine.[45]

The decision to subsume excluded subject matter within the rubric of 'abstract ideas' changed the mode of questioning that was used to interrogate computer-related subject matter. At the heart of the new approach that took shape in the 1980s was the simple idea that a claim drawn to a fundamental principle such as an abstract idea was unpatentable because it risked 'disproportionately tying up the use of the underlying ideas'.[46] The problem with this however was, as the Supreme Court recognised, that because 'all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas',[47] to exclude an invention simply because it touched on an abstract idea would have run the risk that it would 'eviscerate patent law'.[48] To ensure that this did not happen, the Supreme Court was forced to qualify the idea that an abstract idea was unpatentable because

[44] Morton C. Jacobs, 'Commissions Report (re: Computer Programs)' (1967) *Journal of the Patent Office Society* 372, 374–75.

[45] Edward J. Brenner, 'Guidelines to Examination of Programs' (9 August 1966) Vol 829(2) *Official Gazette of the United States Patent Office* 441, 442.

[46] *Alice Corp.* v. *CLS Bank International* 134 S. Ct. 2347, 2354 (2014).

[47] *Mayo Collaborative Servs.* v. *Prometheus Labs*. 566 U.S. 66, 71 (2012).

[48] Ibid., 71.

it risked disproportionately limiting use of the underlying ideas. As the Supreme Court said in *Alice* and *Mayo*, 'an invention is not rendered ineligible for patent simply because it involves an abstract concept'.[49]

To ensure that the subject matter exclusion did not eviscerate patent law, it was necessary to work out some way of distinguishing legitimate and illegitimate uses of abstract ideas within patents. Patent law's response to this problem was to fall back onto the idea of invention as a transformative process to draw a distinction between applications that claimed the 'building blocks' of human ingenuity and those that integrated the building blocks into 'something more'. While the former disproportionately tied up use of the underlying ideas and were therefore ineligible for patent protection, the latter posed no comparable risk of pre-emption and therefore remained eligible for patent protection.[50] As the Supreme Court said, while a claim drawn to an abstract idea was unpatentable, the *application* of abstract ideas 'to a new and useful end' remained eligible for patent protection.[51]

The structure of the questions used to interrogate computer-related subject matter in the 1960s and 1970s was similar to the questions asked from the 1980s: both distinguished between subject matter that was ineligible (whether computer programs, algorithms, etc. or abstract ideas) and inventions that applied or used that ineligible subject matter to create something new. Where they differed, however, was in the way ineligible and eligible subject matter were distinguished. As we saw earlier, for an applicant to satisfy the subject matter eligibility requirement in the 1960s and 1970s, they had to show that they had brought about a change of kind – that they had created a new kind of thing. With computer-related subject matter this meant that they had to convince the Patent Office and the courts that they had created a specific-purpose machine, rather than a mere computer program.

With the shift in the 1980s away from an excluded subject matter described technically to a principle-based excluded subject matter, this approach was no longer possible. The reason for this was that once it was accepted that all computer-based inventions embody, use, reflect, rest upon, or apply abstract ideas (or that all patents pre-empt to some degree), this meant that the existence of an abstract idea in an application could not be used as a litmus test for deciding eligibility (without running the risk of eviscerating patent law). Unlike the situation previously, where machine-like status signalled patent eligible subject matter, there was no obvious end (or kind) that could be used to distinguish a legitimate (patentable) use of an

49 *Alice Corp.* v. *CLS Bank International* 134 S. Ct. 2347, 2354 (2014). *Mayo Collaborative Servs.* v. *Prometheus Labs.* 566 U.S. 66, 71 (2012). *Diamond* v. *Diehr* 450 U.S. 175, 187 (1981).

50 *Mayo Collaborative Servs.* v. *Prometheus Labs.* 566 U.S. 66, 81 (2012).

51 *Gottschalk* v. *Benson* 409 U.S. 63, 67 (1972); *Diamond* v. *Diehr* 450 U.S. 175, 187 (1981); *Mayo Collaborative Servs.* v. *Prometheus Labs.* 566 U.S. 66, 72 (2012).

abstract idea from an illegitimate unpatentable use. As a result, patent law was forced to find a different way of evaluating computer-related subject matter.[52]

Patent law's response to this task was shaped by the fact that while some degree of pre-emption or limitation on use was seen to be inevitable and thus permissible, too much was not. In light of this, instead of asking whether the subject matter was of the type that could and should be protected, patent law found itself in a situation where it had to decide what limitations on the use of an idea it was willing to accept, or how broadly the exclusionary principle should be applied. As a result, while subject matter eligibility for computer-related subject matter in the 1960s and 1970s had been a question of kind, it changed in the 1980s to become one of degree. The problem with this, however, as the courts repeatedly said, is that deciding where and how the law is to be drawn between legitimate and illegitimate use of an abstract idea is a challenging task.[53] As the court said in *Bilski*, the inquiry into 'whether Applicants' claim recites a fundamental principle and, if so, whether it would preempt substantially all uses of that fundamental principle if allowed' … 'is hardly straightforward. How does one determine whether a given claim would pre-empt all uses of a fundamental principle?'[54] Rather than helping to resolve the question of how the eligibility of computer-related subject matter was to be decided, the approach developed by the courts in the 1980s only served to compound the problems patent law faced when dealing with computer-related subject matter. This is because instead of helping to determine subject matter eligibility, it merely added a new question and an extra layer of complexity to the subject matter inquiry: namely, *where and how was the line to be drawn between a (non-patentable) abstract idea and an application of an idea that produces eligible subject matter?*

The upshot of this was while the Supreme Court may have set out the parameters that framed the way questions about the eligibility of computer-related subject matter were asked, it failed to provide any real guidance about how this question was answered. As Justice Stevens said in his dissent in *Diamond* v. *Diehr*, the cases considering the patentability of program-related inventions had not established 'rules that enable a conscientious patent lawyer to determine with a fair degree of accuracy which, if any, program-related inventions will be patentable'.[55] Instead,

[52] The underlying legal question that had to be decided was: 'what test or set of criteria governs the determination by the Patent and Trademark Office … or courts as to whether a claim to a process is patentable under § 101 or, conversely, is drawn to unpatentable subject matter because it claims only a fundamental principle.' *In re Bilski* 545 F.3d 943, 952 (Fed. Cir. 2008).

[53] 'The subject matter courts have found to be outside of, or exceptions to, the four statutory categories of invention is limited to abstract ideas, laws of nature and natural phenomena. While this is easily stated, determining whether an applicant is seeking to patent an abstract idea, a law of nature or a natural phenomenon has proven to be challenging'. USPTO, *Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility*, Official Gazette Notices (22 November 2005), 6.

[54] *In re Bilski* 545 F.3d 943, 954 (Fed. Cir. 2008).

[55] *Diamond* v. *Diehr* 450 U.S. 175, 219 (1981).

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as often happens in patent law, this was left to others to do. As we will see, the response to the question of how patent law should deal with computer-related subject matter emerged out of an iterative process that moved between patentees, the Patent Office, patent examiners, and lower-level courts, both in response to each other, to technological innovations, and to pronouncements by the Supreme Court. While all of these factors played a role, ultimately it was the way that patentees and their attorneys drafted their patent applications that drove the way that patent law responded to computer-related subject matter.

FABIAN DRAFTING STRATEGIES

The techniques used by patentees to describe computer-related subject matter changed constantly over the twentieth century. As well as responding to changes in technology and drafting in order to future-proof claims, patentees also had to work with a Patent Office that was at best finding its feet in terms of how it dealt with computer-related subject matter or at worst ambivalent or hostile to their inventions. Patentees also had to navigate case law and Patent Office practice regarding software patenting that was 'vague, largely form over function, constantly in flux and inconsistent'.[56] At the same time, patentees also had to deal with a judiciary that was inherently suspicious of them. In judging computer-related subject matter, the courts repeatedly warned that they needed to ensure that they were not being hoodwinked by patent attorneys who were using their nefarious drafting skills 'to evade the recognized limitations on the type of subject matter eligible for patent protection'.[57] As the court said in *In re Noll*, it was important to recognise that 'claims may be drafted in the *form* of one of the statutory classes but in *substance* be directed to non-statutory subject matter'.[58] Underpinning judicial warnings of this nature was a concern that patent attorneys were using their dark arts to obtain patent protection over computer programs. As the Supreme Court said in *Benson*: 'Direct attempts to patent programs have been rejected on the ground of nonstatutory subject matter. Indirect attempts to obtain patents and avoid the rejection by drafting claims as a process, or a machine or components thereof programmed in a given manner, rather than a program itself, have confused the issue further and should not be permitted.'[59]

56 Keith E. Witek, 'Developing a Comprehensive Software Claim Drafting Strategy for US Software Patents' (1996) *Berkeley Technology Law Journal* 363, 367.

57 *Diamond* v. *Diehr* 450 U.S. 175, 191 (1981).

58 *In re Noll* 545 F.2d 14 (CCPA 1976). The 'current status of the law requires patent practitioners to be particularly artful in drafting software patent applications, to engage in limited legal fiction in certain instances, and to inform their clients of the uncertainty that still exists in this area of patent law'. Lawrence Kass, 'Computer Software Patentability and the Role of Means-Plus-Function Format in Computer Software Claims' (1995) 15(3) *Pace Law Review* 787, 791–92.

59 *Gottschalk* v. *Benson* 409 US 63, 72 (1972).

While the courts and the Patent Office have periodically attempted to follow through on this threat to deny indirect protection to computer-related subject matter, applicants have consistently managed to find ways around the judicial hurdles that were imposed on them (which is reflected in the large number of computer-related inventions that have been patented since the 1980s).[60] A key reason for this was that in dealing with computer-related subject matter, the courts effectively backed themselves into a corner, which made it difficult for them to exclude indirect attempts to patent computer-related subject matter, a situation that patent attorneys skilfully exploited when drafting patents. As a result, the art of software patent drafting became 'an exercise in form over function mastery, for which software clients would pay their attorneys dearly.'[61]

While patent attorneys adopted a number of different drafting strategies in order to get around the judicial objections to computer-related subject matter that had been raised, they tended to coalesce around a shared goal, namely to 'disguise software innovations as hardware inventions by disclosing significant computer hardware details along with the software code within the patent specification.'[62] As a patent attorney explained, 'to fool the courts and the USPTO, practitioners needed to hand-craft and custom tailor the entire software patent application to look and feel like hardware'.[63]

Patent attorney adopted a number of different techniques to ensure that their patents looked, smelt, and felt like hardware.[64] One strategy that was adopted in the 1960s and 1970s was to avoid mentioning anything about 'algorithms' or 'software' in a patent.[65] Using what the Patent Office solicitor called the Fabian strategy 'of presenting the invention as though implemented by hardware programming not software'[66] patents were also drafted to 'show the software as a hardware system both textually and graphically.'[67] One way this was done was to draft applications in such a way that the software code appeared as part of the structure of a computer. As a result, software patent applications typically 'disclosed the computer hardware or electrical computer system which incorporated the software in a manner similar to

60 For an overview of the 'exponential growth' in software patents from 1971 to 1994 see Keith E. Witek, 'Developing a Comprehensive Software Claim Drafting Strategy for US Software Patents' (1996) *Berkeley Technology Law Journal* 363.

61 Ibid., 375–76.

62 Ibid., 371–72.

63 Ibid., 375

64 Ibid.

65 Ibid., 376.

66 'Actually [Applied Data Research's Autoflow patent] was the first one that *candidly* presented as implemented by software programming. Prior to that, hardware companies had obtained such patents by the stratagem (called Fabian Strategy by the Patent Office Solicitor) of presenting the invention as though implemented by hardware programming not software'. See Brief Amicus Curiae for Applied Data Research, *Gottschalk* v. *Benson*, No. 71–485 (Oct Term 1971), 2 n 2.

67 Keith E. Witek, 'Developing a Comprehensive Software Claim Drafting Strategy for US Software Patents' (1996) *Berkeley Technology Law Journal* 363, 375–76.

a typical electrical system patent'.[68] To do this, a practitioner would divide the program into different code segments, function calls, procedures, etc. Once this was done the practitioner would then draft the claim 'to make these software routines appear as hardware'.[69] In some cases, practitioners would illustrate the software to include other hardware components such as a printer, modem, keyboard, mouse, display screen, disk drive, register, sensors, motors, controllers, machinery, assembly line, or some other tangible object in order to properly process information, manufacture items, receive input, provide output, or execute software code. Claiming these 'tangible structural items via a structure software claim format rendered the mysterious and intangible software subject matter statutory as an apparatus'.[70]

The practice of drafting computer-related subject matter as hardware – whether as a machine, an apparatus, or a computer that included software as a component – was widely adopted by patentees at the time to enhance their chances of protection.[71] As Martin Jacobs said, Applied Data Research avoided the objections that were raised about their Autoflow and sorting system patents by defining software as a machine device.[72] As Martin Goetz wrote in his petition to the Patent Office to expediate the examination of Applied Data Research's application for an 'Automatic system for constructing and recording display charts' (which was a continuation in part of a 1965 application), the objections made to the initial application had been overcome by arguing that the application had 'disclosed a machine or apparatus.'[73] This meant that instead of claiming the algorithm that underpinned the invention, the patent claimed the material parts of the computer, the electronic components, and circuitry (see Figure 7.1).

Another technique used by patentees to ensure that computer-related subject matter met the subject matter requirements was to claim conventional computer technology with the software stored in the memory. Under this approach, a claim would 'recite the conventional and widely used structure of a computer which executes the novel software from memory locations'. As Witek said, the software patent practitioner of the 1970s illustrated and claimed the software with a central processing unit (CPU) to execute instructions; memory (either magnetic tape, a magnetic drum, magnetic disks, CDs, optical storage, RAM, ROM, EEPROM, EPROM,

[68] Ibid., 367.
[69] Ibid., 380.
[70] Ibid., 372.
[71] 'In the applications that arrived at the Patent Office' in the mid 1960s, 'software became tangible, and in the texts of patents such as Autoflows, it became hardware.' Gerardo Con Diaz, 'Embodied Software: Patents and the History of Software Development, 1946–1970' (July–September 2015) *IEEE Annals of the History of Computing* 8, 16.
[72] Brief Amicus Curiae for Applied Data Research, *Gottschalk* v. *Benson* No. 71–485 (Oct Terms 1971), 15, n 20.
[73] The patent office admitted as much when in responding to the suggestion that Goetz's 1968 Autoflow patent appeared to cover a computer program, the Office said the patent was not for a computer program: instead it 'involved a combination of equipment and program.' William D. Smith, 'Fighter for Computer-Program Patents' (29 December 1968) *The New York Times* 19.

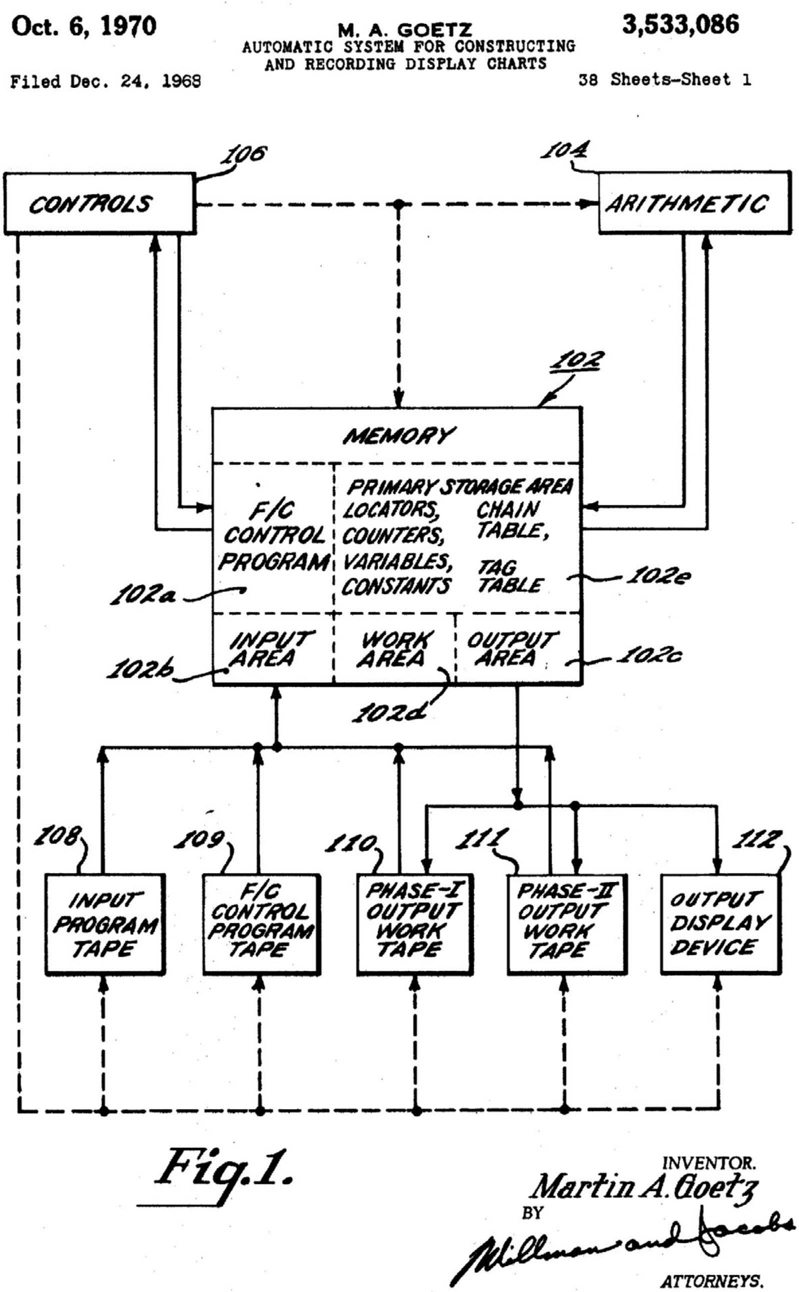

FIGURE 7.1 Schematic block diagram of a data processing system in accordance with the invention
Martin Goetz, 'Automatic System for Constructing and Recording Display Charts' US Patent No. 3,533,086 (6 Oct 1970). Courtesy of the United States Patent and Trademark Office.

flash memory, and/or like storage media) to store executable code and data. Where software was executed in a larger system containing more hardware than just central processing unit and memory, the software patent practitioner would claim the larger hardware system (see Figure 7.2). In these instances, the claim would 'recite a [central processing unit] or computer, memory, peripherals, and/or other computer or system technology, and then recite that the memory coupled in the computer system contains novel software that is executed within the computer system'.[74]

Another technique used to claim computer-related subject matter was to draft applications using the so-called 'means-plus-function claim', which allowed patentees to claim combined elements as 'a means for performing a specified function'.[75] Historically, the US Patent Office had viewed the means-plus-function claim as a permutation of a process claim. Accordingly, examiners would state that the claim recited an 'algorithm' and reject the means-plus-function claim outright. Following a series of decisions in the 1970s, which upheld the patentability of means-plus-function claims directed to physical apparatus, inventors began using 'means-plus-function claims to link software to generic computer hardware, making the claims appear to recite structure or machine'.[76] This increased the ability for software practitioners to hide algorithms and programs in a structure-like claim format.

One of the reasons why hardware claims were important for software producers was because although applications were evaluated by the Patent Office on the basis that they were hardware inventions, the protection that these patents provided extended to include software. This was because of the longstanding rule that patent protection for machines not only covered the machine's precise form but also extended to cover other forms that embodied the invention. Specifically, protection extended beyond the specific way the machine was described to include 'equivalent' machines. Under the doctrine of equivalents, two devices were equivalent if they did 'the same work in substantially the same way and accomplish substantially the same result, even though they differ in form, scope, and proportion.'[77] The purpose of the doctrine was to protect the patent by preventing competitors from making simple changes in the patented machines – for example using a cam instead of a lever or rearranging the constituent mechanisms – and thereby securing separate patents. Thus, 'to copy the principle or mode of operation embodied in an apparatus is an infringement, even though the copy is different in form or proportion.'[78] This principle was also applied where someone replaced a machine containing special purpose hardware controls with a machine containing software that performed the same function.

74 Keith E. Witek, 'Developing a Comprehensive Software Claim Drafting Strategy for US Software Patents' (1996) *Berkeley Technology Law Journal* 363, 382.

75 Max W. J. Graham, 'Process Patents for Computer Programs' (1968) 56(2) *California Law Review* 466, 477.

76 Keith E. Witek, 'Developing a Comprehensive Software Claim Drafting Strategy for US Software Patents' (1996) *Berkeley Technology Law Journal* 363, 390.

77 Max W. J. Graham, 'Patents for Computer Programs' (1968) 56(2) *California Law Review* 466, 476.

78 Ibid.

U.S. Patent **Oct. 24, 1995** **Sheet 1 of 2** **5,461,488**

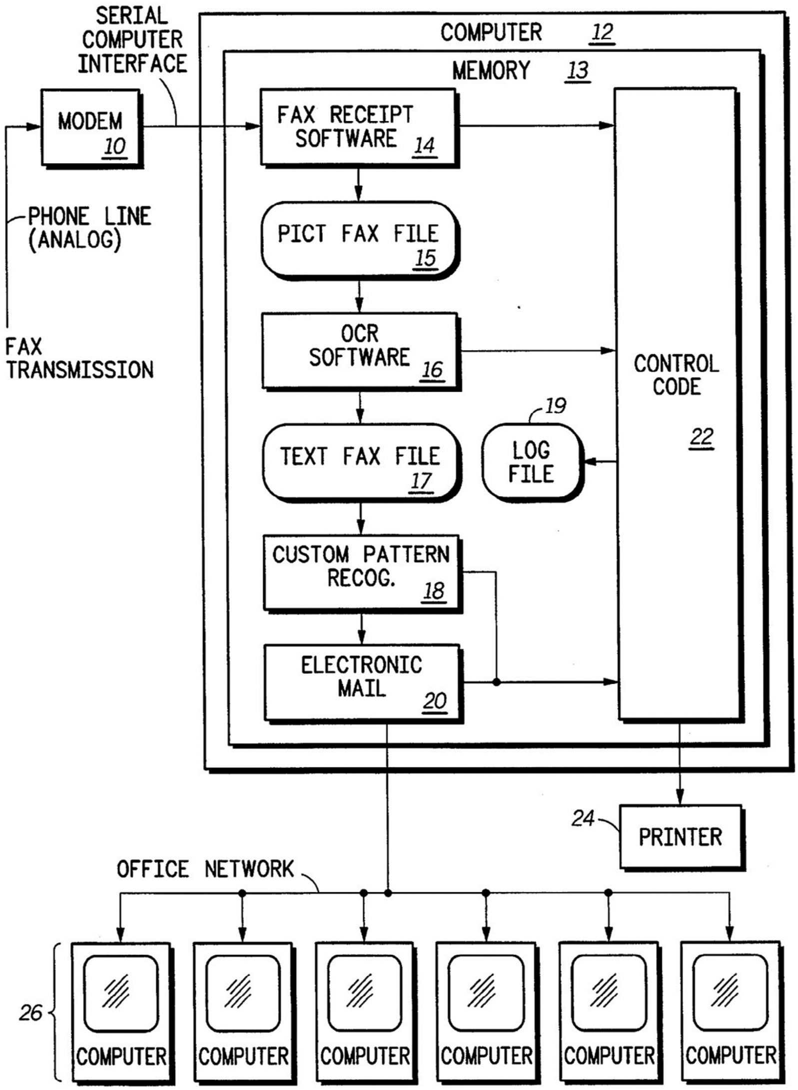

FIG.1

FIGURE 7.2 Block diagram of fax data processing system in accordance with the invention
Keith Witek, 'Computerised Facsimile (Fax) System and Method of Operation' US Patent No. 5,461,488 (24 Oct 1995). Courtesy of the United States Patent and Trademark Office.

We can get a sense of how the doctrine of equivalents operated to protect software-related subject matter from the advice given by a patent practitioner in 1968 about how to draft computer-related applications. In order to maximise the chances of registration, inventors were advised to design 'a fixed wire circuit that performs the same functions as would a computer operating according to this program'.[79] Once this was done, to avoid a patent application being rejected on the basis that it was for a computer program, inventors were advised to use hardware structural claims that described 'the operation both of the fixed wire system and the programmed computer'.[80] Importantly, to avoid being rejected on the basis that computer programs were not patentable, applicants were advised that the patent should only describe the fixed wire circuits. While the invention outlined in the patent would be limited to hardware (the fixed wire system), the doctrine of equivalents meant that patentees could 'argue that a computer, programmed to function in the same manner as his patented fixed wire circuit, is an equivalent device'. As a result, no one could 'use the program, which the patentee originally sought to protect, without infringing the patent on the fixed wire circuit. By using this scheme, then, the patentee is able to protect and monopolize the use of his computer program'.[81] That is, a patentee would indirectly protect a computer program by drafting a hardware claim disclosed in terms of a fixed wire system.

The strategy of representing computer-related subject matter as hardware proved to be an effective way of circumventing the objections that had been raised about software-related subject matter.[82] There were two reasons for this. The first was that by framing their inventions as hardware, software producers were able to connect their applications to the patents that had been granted since the 1940s for hardwired computers. More specifically, software producers relied upon the fact that to deny protection to claims with hardware limitations, the Patent Office and the courts would have set a precedent that would have invalidated 'every hardware/computer patent ever issued in U.S. history.'[83] If this happened, it 'would have invalidated tens of thousands of electrical systems, circuits, and like patents consistently issued by the USPTO for decades'.[84] As a commentator accurately predicted, it was 'unlikely that the USPTO or the [courts] would ever go that far.'[85] As a result, the courts and

79 Ibid., 477.
80 Ibid.
81 Ibid.
82 As patent examiners, attorneys and their clients became more comfortable with structural and means-end claims, patentees shifted their attention to look to claims that would maximise protection, rather than merely meet the subject matter threshold. While hardware structure claim remained the predominant claim format for U.S. software patenting, applicants began to experiment with other types of claims including method of manufacture claims and method claims. Stephen A. Becker, 'Drafting Patent Applications on Computer-Implemented Inventions' (1991) 4 *Harvard Journal of Law and Technology* 237, 255–56.
83 Keith E. Witek, 'Developing a Comprehensive Software Claim Drafting Strategy for US Software Patents' (1996) *Berkeley Technology Law Journal* 363, 406.
84 Ibid., 372.
85 Ibid., 406.

the Patent Office had little choice but to accept that when drafted as hardware that software-related subject matter was potentially patentable.

The second reason why hardware claims were successful was because they built upon a longstanding drafting practice that patentees used when machine-based inventions included intangible subject matter: namely, one in which the subject matter was tied to something material or physical. As we saw earlier, to qualify for protection in the 1960s and 1970s, applicants had to show that they had brought about a change of kind, that they had created a new kind of thing, or that they had created a specific-purpose machine rather than a mere computer program.[86] With the shift away from technologically specific excluded subject matter to the more general 'abstract ideas' category, subject matter eligibility for computer-related subject matter changed to become one of degree. As a result, patent law found itself asking: where and how was the line to be drawn between a (non-patentable) abstract idea and an application of an idea that produces eligible subject matter? By building on the idea that a 'machine is a concrete thing'[87] applicants offered patent law with a relatively straightforward way of answering this question that was subsequently endorsed by the Patent Office and the courts.

Prompted by the drafting strategies initiated by applicants and building on the idea that 'the opposite meaning of "tangible" is "abstract"',[88] subject matter eligibility was recast in terms of materiality. As part of this process, excluded subject matter was characterised in terms of its lack of physicality: it was intangible, ephemeral, and immaterial.[89] Albert Walker captured the long-standing view of the immaterial nature of excluded subject matter in his 1887 patent law treatise when in writing about laws of nature, scientific principles, and scientific facts he said 'by whatever name it is called', it is 'certain that the thing referred to is not a material substance. It is not to be apprehended by the sense of touch, but when discovered finds a lodgement in the mind as a mental conception only.'[90] In contrast to the ephemeral intangible excluded subject matter, eligible subject matter was characterised in terms of its physicality. As the Court of Customs and Patent Appeals said in the 1969 decision of *In re Bernhart*, a computer programmed with a new and unobvious program was physically different from the same computer without that program; the

86 For a discussion of natural kinds see Ian Hacking, 'A Tradition of Natural Kinds' (1991) 63 *Philosophical Studies* 109.

87 *Burr v. Duryee* 68 U.S. (1 Wall) 531, 570 (1863).

88 USPTO, *Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility*, OG Notices (22 November 2005), 9. 'Information as such is an intangible'. *Microsoft Corp. v. AT & T Corp.* 550 U.S. 437, 451 n 12 (2007). The Oxford Dictionary defines abstract as '[e]xisting in thought or as an idea but not having a physical or concrete existence'.

89 'The legal fiction of attributing physicality to software' allowed 'software developers to obtain patent protection where none was previously available'. Lawrence Kass, 'Computer Software Patentability and the Role of Means-Plus-Function Format in Computer Software Claims' (1995) 15(3) *Pace Law Review* 787, 850.

90 Albert Walker, *Text Book of the Patent Laws of the United States of America* (New York: L.K. Krouse & Co, 1887), 7.

programmed computer was a new machine, or at least a new improvement over the unprogrammed computer.[91]

With subject matter reframed in terms of its materiality, physicality now functioned as a litmus test for determining the eligibility of computer-related subject matter. This was reflected in the comment that '[w]ithout some stated relationship to something tangible, such as a computer on which the software can be run, software is merely an abstract idea, not useful itself, and thus not patentable.'[92] Conversely, 'where the process does not employ and affect physical elements, but is concerned solely with intangibles, it is not patentable.'[93] Or, as the Supreme Court explained in *Benson*, the difference between gravity, which was non-patentable subject matter, and a pendulum, which relies on gravity for proper operation, which was patentable subject matter, was that the former was math-like and intangible while the latter was a tangible apparatus.[94]

While the focus on physicality as a way of dealing with the eligibility of computer-related subject matter is often traced to the Supreme Court decisions of *Parker* v. *Flook* and *Diamond* v. *Diehr*, it has a much longer lineage.[95] An early example where physicality was used to indirectly protect excluded subject matter was in the patent reissued to Samuel Morse in 1848 for an 'Electromagnetic Telegraph' that was subject to the 1854 Supreme Court decision of *O'Reilly* v. *Morse*. As well as rejecting Morse's attempt to claim 'the use of the motive power of the electric or galvanic current' which he called 'electro-magnetism' and upholding what has been described as one of the earliest examples of software-like claims,[96] the Supreme Court also upheld Morse's claim to use machinery (a register, recording instrument) that embodied the excluded subject matter (See Figure 7.3). To use the language of the patent, Morse's patent laid out a physical 'apparatus for and system of transmitting intelligence between distant points by means of electro-magnetism'; that is, it laid out the material circuitry rather than the logic of a machine.[97]

[91] *In re Bernhart* 57 CCPA (Pat.) 737, 417 F.2d 1395 (1969).

[92] *In re Alappat* 33 F.3d 1526 (Fed. Cir. 1994).

[93] Max W. J. Graham, 'Patents for Computer Programs' (1968) 56(2) *California Law Review* 466, 482.

[94] *Gottschalk* v. *Benson* 409 U.S. 63, 71–73 (1972).

[95] Robinson defined a machine as 'an instrument composed of one or more of the mechanical powers and capable, when set in motion of producing by its own operation certain predetermined physical effects. It is an artificial rule of action, receiving crude mechanical force from the motive power and … transforming … it according to the mode established by that rule, William C. Robinson, *The Law of Patents for Useful Inventions: Vol 1* (Boston: Little Brown, 1890), 237. Physicality was used to decide the eligibility of other types of subject matter. For example, where some type of printed matter was at stake, it was held that only by showing a physical relationship between the printed matter and the material structure which effects a new and physical result does a claimant show patentability.' Max W. J. Graham, 'Patents for Computer Programs' (1968) 56(2) *California Law Review* 466, 474.

[96] Claim 5 of Morse's patent provides 'My system of characters consists of dots, spaces, and lines variously combined to form letters and other characters'. On this see Adam Mossoff, '*O'Reilly* v. *Morse*' *George Mason University: Antonia Scalia Law School Working Papers* (2014), 6.

[97] See Gerardo Con Diaz, *Software Rights: How Patent Law Transformed Software Development in America* (New Haven: Yale University Press, 2019), 19–20.

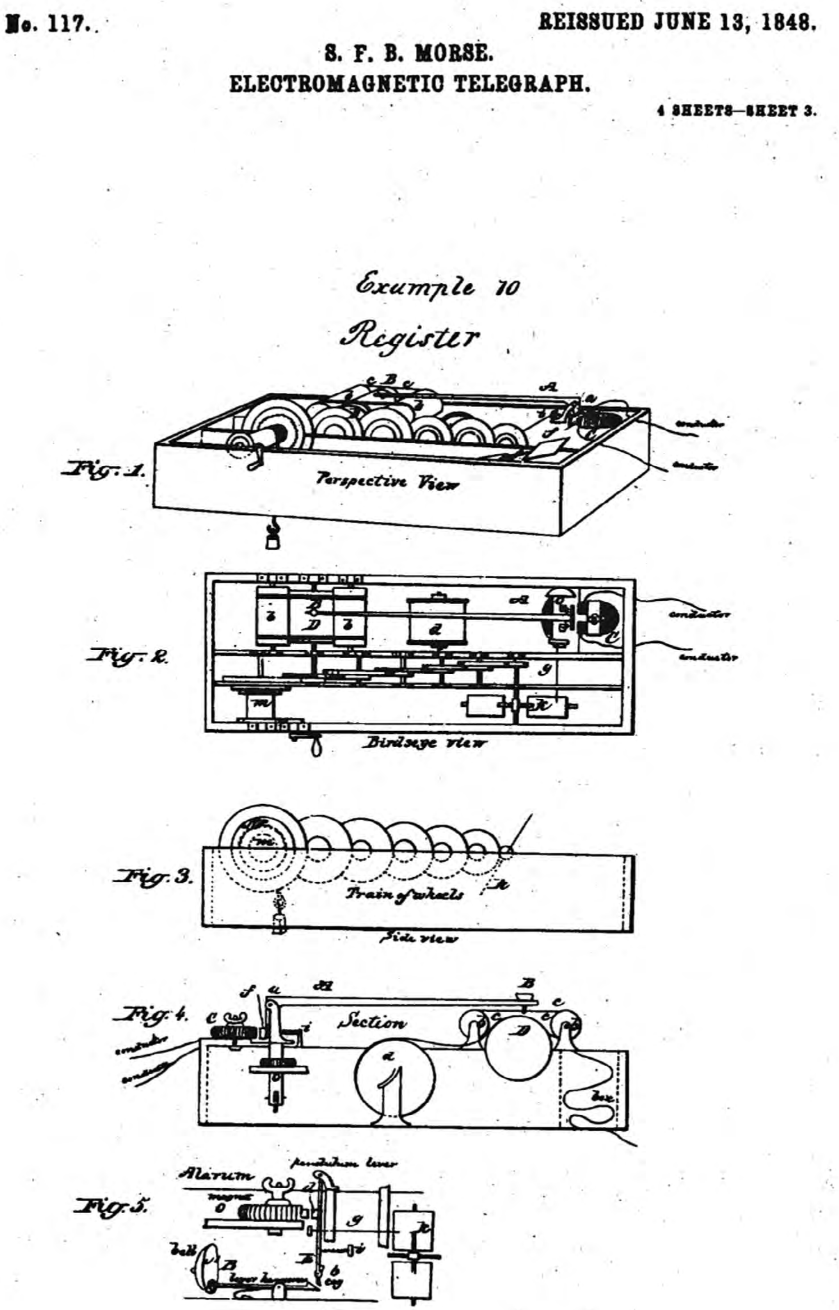

FIGURE 7.3 Register for telegraphic signs
Samuel Morse, 'Improvement in Electro-Magnetic Telegraphs' US Patent No. 1,647 (13 June 1848). Courtesy of the United States Patent and Trademark Office.

https://doi.org/10.1017/9781009479639 Published online by Cambridge University Press

The decision to use materiality as a touchstone for deciding the eligibility of computer-related subject matter was justified on the basis that it ensured that patents were only ever granted for practical inventions with 'real world' value.[98] Materiality also ensured that subject matter that was otherwise illusive, undefined, and difficult to delineate was confined within 'definite bounds'.[99] Physicality also aligned with a particular vision of property that had long held sway in intellectual property law. As Waite wrote in a 1917 article on the patentability of mental processes, the 'fact that possession has so correlated with the theory of property that it is difficult to disassociate ownership from the possibility of physical possession.'[100] The use of materiality as a litmus test for determining subject matter eligibility was also explained on the basis that it ensured that the claims did not reach beyond what was disclosed. The reason for this was that a 'claim that is tied to a particular machine or brings about a particular transformation of a particular article does not pre-empt all uses of a fundamental principle in any field but rather is limited to a particular use, a specific application. Therefore, it is not drawn to the principle in the abstract'.[101]

As well as being used as a guide for determining subject matter eligibility within patent law, materiality was also used to explain the way different types of intellectual property interacted with computer-related subject matter. In this sense, tangibility replaced the computer program as a boundary object within intellectual property law. This is reflected in the comment that while '[h]ardware, because tangible, receives its primary protection from the legal standards of patent law', '[s]oftware, because intangible, receives its primary protection from copyright law, although patent law provides some protection for software linked to physical manifestations. Algorithms, unless tied to a physical process, receive no protection at all'.[102] The explanation given for the 'different treatment of hardware, software, and algorithms lies in the Court's focus on the physical manifestations of property. Despite the inextricable bonds among them, hardware is tangible whereas software and algorithms are not'.[103]

While physicality was initially used as a touchstone to examine the eligibility of computer hardware and computer-related inventions that produced physical change outside the computer, it was versatile enough to accommodate many of the changes

98 USPTO, *Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility*, OG Notices (22 November 2005), 8.

99 T. Buckman, 'Protection of Proprietary Interests in Computer Programs' (1969) *Journal of the Patent Office Society* 135, 151. (Buckman was a Patent Office examiner). As Supreme Court said in *Benson:* '[T]he arts of tanning, dyeing, making waterproof cloth, vulcanizing India rubber, smelting ores … are instances, however, where the use of chemical substances or physical acts, such as temperature control, changes articles or materials. The chemical process or the physical acts which transform the raw material are, however, sufficiently definite to confine the patent monopoly within rather definite bounds'. *Gottschalk* v. *Benson* 409 U.S. 63, 69 (1972).

100 John Waite, 'The Patentability of a Mental Process' (1917) 15(2) *Michigan Law Review* 660.

101 *In re Bilski* 545 F.3d 943, 957 (Fed. Cir. 2008).

102 Note, 'Computer Intellectual Property and Conceptual Severance' (1990) 103 *Harvard Law Review* 1046, 1049.

103 Ibid.

that occurred in information technology across the later part of the twentieth century. This can be seen, for example, in the way that patent law responded to attempts to patent information embodied on a computer-readable medium (such as a floppy disc). In thinking about this new type of subject matter, patent law built upon the intangible/tangible dichotomy that underpins the physicality requirement to draw a distinction between non-functional and functional descriptive material. Because non-functional descriptive material such as music, literary works, and compilations of data recorded on a computer-readable medium was merely carried on rather than structurally and functionally interrelated to the medium, the subject matter was not a physical thing.[104] As such, non-functional descriptive material embodied on a computer-readable medium could not be protected. In contrast, functional descriptive material was deemed to be patent eligible.[105] The reason for this was that when functional descriptive material was recorded on a computer-readable medium it became structurally, functionally, and physically integrated into that medium.[106] Even as patent law extended its reach beyond programs embodied with a computer (as a machine) to recognise programs embodied on a computer-readable medium, it did so by focusing on the physicality of the subject matter.

While patent practitioners were largely successful in their efforts to draft patent applications for new types of computer-related subject matter in a way that highlighted their physicality and thus rendered them patent eligible, the physicality requirement did pose some problems. This can be seen, for example, in the decision of *In re Nuijten*, which concerned a technique for reducing the distortion caused when digital watermarks were introduced into signals. As well as claiming the process and apparatus for generating, receiving, processing, or storing signals, the applicants also attempted to patent the signals themselves. While the process and apparatus claims were allowed, the claims for the signals were not. The reason for this was that the signal claims 'were not limited by any specified physical medium, nor do the dependent claims add any physical limitations.'[107] As the Board said, the signal 'has no physical attributes and merely describes the abstract characteristics of the signal and, thus, it is considered an "abstract idea" unpatentable under *Diamond* v. *Diehr*'.

[104] USPTO, *Examination Guidelines for Computer-Related Inventions* (29 March 1996) 61 Fed. Reg. 7478, 5.

[105] Ibid.

[106] In response to the examiner and Board who had held that 'the provision of new signals to be stored by the computer does not make it a new machine, i.e., the computer is structurally the same, no matter how new, useful and unobvious the result, the court replied: 'To this question we say that if a machine is programmed in a certain new and unobvious way, it is physically different from the machine without that program; its memory elements are differently arranged'. Importantly, the court added that the fact that these physical changes were 'invisible to the eye should not tempt us to conclude that the machine has not been changed'. *In re Lowry* 32 F.3d 1579, 1583 (Fed. Cir. 1994) citing *Application of Bernhart* 417 F.2d 1395, 1400 (CCPA 1969).

[107] *In re Nuijten* 500 F.3d 1346, 1353 (Fed. Cir. 2007).

The Board and the Federal Circuit Court of Appeals also took the unusual step of framing subject eligibility in terms of the statutory categories of patentable subject matter (process, machine, manufacture, or composition of matter), rather than in terms of the judicially created excluded categories, which is usually the case with computer-related subject matter. Importantly in doing so the Board and the Federal Circuit drew upon the physicality requirement to find that the subject matter did not fall within the statutory categories of patentable subject matter. In particular, it was held that the signal claim did not qualify as a 'machine' (the possibility that they were processes or composition of matter were effectively dismissed out of hand) because it had 'no concrete tangible physical structure'. More specifically, it was held that a propagating electromagnetic signal was not a machine as that term is used in § 101 because while a transitory signal made of electrical or electromagnetic variances 'is physical and real, it does not possess concrete structure. No part of the signal – the crests or troughs of the electromagnetic wave, or perhaps the particles that make it up (modern physics teaches that both features are present simultaneously) is a mechanical device or part'.[108]

The Board and the Federal Circuit also looked to physicality when considering whether the signal was a 'manufacture'. In denying that it was the Board said that as the 'signal does not have any physical structure or substance' it 'does not fit the definition of a "manufacture" which requires a tangible object'. The Federal Circuit adopted a similar approach in denying that a signal was a manufacture. A key reason for this was that a signal, which was a transient electric or electromagnetic transmission, was neither a tangible article or a commodity. As the Federal Circuit said: 'While such a transmission is man-made and physical – it exists in the real world and has tangible causes and effects – it is a change in electric potential that, to be perceived, must be measured at a certain point in space and time by equipment capable of detecting and interpreting the signal. In essence, energy embodying the claimed signal is fleeting and is devoid of any semblance of permanence during transmission. Moreover, any tangibility arguably attributed to a signal is embodied in the principle that it is perceptible – e.g., changes in electrical potential can be measured. All signals within the scope of the claim do not themselves comprise some tangible article or commodity. This is particularly true when the signal is encoded on an electromagnetic carrier and transmitted through a vacuum – a medium that, by definition, is devoid of matter. Thus, we hold that Nuijten's signals, standing alone, are not "manufacture[s]" under the meaning of that term in § 101.'[109]

Whether it was the transformation of an article from one state or thing to another state or thing,[110] the existence of a physical step,[20] a 'useful, concrete and tangible result',[111] or a physical or tangible form,[112] the result was the same: subject matter

[108] Ibid., 1355–56.
[109] Ibid., 1356–57.
[110] *Parker* v. *Flook* 437 U.S. 584 (1978).
[111] *State Street Bank* v. *Signature Financial Group* 149 F.3d 1368 (Fed. Cir. 1998).
[112] *Digitech Image Techs* v. *Elecs. for Imaging* 758 F.3d 1344, 1348 (Fed. Cir. 2014).

eligibility of computer-related subject matter was dependent on the existence of a tangible material trace that the examiner or court could latch on to as proof of invention. That is, evidence of physical change (or some equivalent thereof) was treated as proof of the transformation of an abstract intangible computer program into a novel three-dimensional machine and thus of its patent-worthiness.[113] As a result, subject matter eligibility again became a question of kind, the difference now being that it now turned on the tangibility of the subject matter, rather than in terms of its machine-like status, which it had been previously. By calibrating subject matter eligibility in terms of materiality, patent law 'enunciated a definitive test to determine whether a … claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself.'[114]

Recognising patent laws ongoing reliance on physicality has a number of ramifications for how we think about patent law; one of the most important is that it forces us to question the suggestion I made earlier that the unbundling of hardware and software that took place in the early 1970s brought about a dematerialisation of computer-related subject matter. While from a commercial perspective, software products may have been separated from the hardware they interacted with, from a technical or engineering perspective they were still connected and intertwined (at least potentially) with material machines.[115] The situation was similar in patent law where the ongoing use of materiality as a touchstone for distinguishing ephemeral immaterial non-patentable subject matter from potentially patentable tangible computer-related inventions suggests, at least in this context, that the unbundling did not lead to the dematerialization of the subject matter. While the partisanal characterisation of the subject matter as an unbundled dematerialised computer program, on the one hand, and a bundled material computer-driven machine on the other, may have served the ends of software and hardware producers, it did not translate well into the subject matter inquiry in patent law. The reason for this was that the material and immaterial are not separate and distinct as these arguments presupposed. Rather, as the notion of informed materials reminds us, the material

[113] The 1996 Guidelines addressed the rationale for excluding claims to software alone from the realm of statutory subject matter as follows: '[C]omputer programs claimed as computer listings per se, i.e., the descriptions or expressions of the programs, are not physical "things," nor are they statutory processes.' See *Bilski* v. *Kappos* 561 U.S. 593 (2010).

[114] *In re Bilski* 545 F.3d 943, 954 (Fed. Cir. 2008). Even though part of the invention in *Diamond* v. *Diehr* was data transformation (process conditions data into rubber cure time data), 'an integral part of the invention was the physical transformation of uncured physical material or chemical compounds into cured rubber. It was this physical transformation that the Court found dispositive in rendering the process or method claims patentable. By focusing on the tangibility of inventions, the Court recognised a legal framework that provides protection for abstract inventions such as software and algorithms where they are linked to a physical process. Note, 'Computer Intellectual Property and Conceptual Severance' (1990) 103 *Harvard Law Review* 1046, 1051.

[115] One of the factors that Judge Rich relied upon in his dissent in *In re Johnson*, where he rejected the idea that a programmed computer was a unique machine, was that the invention was being sold as a computer program. *In re Johnson* 502 F.2d 765, 773 (CCPA 1974).

and the immaterial constantly blend into and inform each other; the immaterial (nearly) always has a material context.

FROM MATERIALITY TO SPECIFICITY

While physicality proved to be a versatile and resilient tool for deciding the eligibility of computer-related subject matter, it eventually ran up against a number of problems as the technology advanced. One reason for this was that while physicality may have provided courts, patent examiners, and lawyers with a relatively straightforward and easy-to-apply touchstone for determining the eligibility of the special-purpose machines of the 1970s where the change occurred outside of the computer, it was more difficult to apply when the changes occurred within the computer. As Judge Newman said in *Bilksi*, the physicality test was difficult to apply where the subject matter was for processes that dealt 'with data and information, whose only machinery is electrons, photons, or waves, or whose product is not a transformed physical substance'.[116] Problems also arose where applicants claimed advanced diagnostic medicine techniques and where inventions were based on linear programming, data compression, the manipulation of digital signals as well as other processes that handle data and information in novel ways.[117]

As the information technology industry progressed and the subject matter moved further away from the programmed computers of the 1970s, the courts and examiners increasingly found themselves struggling when applying the physicality test to answer difficult 'esoteric and metaphysical'[118] questions such as whether there were any limits on the type or amount of physical transformation that was needed to guarantee eligibility,[119] or whether a material trace was transitory, electronic, virtual, and so on. These problems were exacerbated by the fact that there was always some form of physical transformation whenever a computer functions (signals are transformed and the computers components are changed during execution of a computer program). As the Patent Office admitted, one of the consequences of this was that in these cases physicality could not be determinative of whether the computer-related subject matter was patentable.[120]

As technological developments moved subject matter even further away from the programmed machine, the physicality test became even more difficult to apply.

[116] *In re Bilski* 545 F.3d 943, 976, 985 (Fed. Cir. 2008).

[117] See Ibid., 964; *Bilski* v. *Kappos* 561 U.S. 593 (2010).

[118] *In re Nuijten* 500 F.3d 1346, 1353 (Fed. Cir. 2007).

[119] There was uncertainty about the type and extent of the functional relationship needed between software and a tangible object for the claimed invention to qualify. See Elizabeth A. Richardson, 'Toward a Direct Functional Relationship Requirement for Claims to Software Encoded on a Computer-Readable Storage Medium' (2006) 3 *Oklahoma Journal of Law and Technology* 30.

[120] Nancy J. Linck and Karen A. Buchanan, 'Patent Protection for Computer-Related Inventions' (1996) 18 *Hastings Communications and Entertainment Law Journal* 660, 669 (Linck and Buchanan were solicitors for the US Patent Office).

One of the consequences of this was as Justice Mayer said in *Bilski*, 'although [the Federal Court] has struggled for years to set out what constitutes sufficient physical transformation to render a process patentable, we have yet to provide a consistent or satisfactory resolution of this issue'.[121]

These problems were compounded by the fact that patent applicants rarely attempted 'to patent (let alone succeed in obtaining a patent for) an abstract idea per se. Instead, where a patent implicates the abstract idea exception' the claim 'typically involves some concrete or tangible implementation or application of that idea'. One of the consequences of this was that when deciding whether a claim was 'directed to an abstract idea', a court had to 'dissect the underlying abstract idea from the integrated claim, an inevitably subjective undertaking.'[122] As a result, deciding whether a particular claim was abstract was 'subjective and unsystematic, and the debate often trends toward the metaphysical, littered with unhelpful analogies and generalizations'.[123]

There were a number of different responses to the problems that arose in attempting to apply the physicality test to newer forms of computer-related subject matter. One response was to place limits on when physicality could be used to determine patent eligibility. While it was recognised that materiality (in the form of the machine-or-transformation test) was a 'useful and important clue' for determining patent eligibility,[124] technological change, which ensured that 'not all machine implementations [were] created equal', meant that the physicality test could no longer be applied automatically to all computer-related subject matter. As the Supreme Court said in *Mayo*, the reason for this was that 'not all transformations or machine implementations infuse an otherwise ineligible claim with an inventive concept'.[125] This qualification as to when physicality could be used to decide subject matter eligibility meant that simply using off-the-shelf technology for its intended purpose,[126] introducing generic computer limitations, or 'implementing a mathematical principle on a physical machine, namely a computer'[127] was not enough to ensure that the subject matter eligibility threshold was met. As Justice Chen said, the bare fact that a computer exists in the physical rather than purely conceptual realm was 'beside the point'.[128]

Another response to the problems that arose in using tangibility as a touchtone for eligibility was to expand what was meant by 'physicality'. This can be seen for example *in re Lowry* where the Federal Circuit was called on to evaluate the eligibility of an application for a data processing system that provided an efficient, flexible

[121] *In re Bilski* 545 F.3d 943, 1010 (Fed. Cir. 2008).
[122] See *CLS Bank Int'l* v. *Alice Corp*. 717 F.3d 1269, 1277 (Fed. Cir. 2013).
[123] Ibid.
[124] *Bilski* v. *Kappos* 130 S. Ct. 3218, 3227 (2010).
[125] *Mayo Collaborative Servs*. v. *Prometheus Labs*. 132 S.Ct. 1289, 130.
[126] *Chamberlain Group* v. *Techtronic Industries* 935 F.3d 1341 (Fed. Cir. 2019). See also *In re Marco Guldenaar Holding* 911 F.3d 1157, 1161 (Fed. Cir. 2018).
[127] *Gottschalk* v. *Benson* 409 U.S. 63, 64 (1972).
[128] *DDR Holdings* v. *Hotels.com* 773 F.3d 1245 (Fed. Cir. 2014).

method of organizing stored data in computer memory.[129] In upholding the patent, the Federal Circuit said that it did not matter that the stored data did not adopt a physical structure per se. The reason for this was that 'if a machine is programmed in a certain new and unobvious way, it is physically different from the machine without that program; its memory elements are differently arranged'. In a move which extended the meaning of physicality (and certainly moved it beyond Walker's idea that patentable subject matter was defined by its ability to be apprehended by the sense of touch) the court added that 'the fact that these physical changes are *invisible to the eye* should not tempt us to conclude that the machine has not been changed'.[130] The definition of physicality was expanded further *in re Abele* where the Federal Circuit said that physicality reached 'beyond physical objects or substances themselves to include *representations* of physical objects or substances.'[131] This meant that a claim providing for the electronic transformation of x-ray data or data 'clearly representing physical and tangible objects' into a particular visual depiction on a display was patentable.

While the decision to extend the meaning of physicality to encompass subject matter that brought about non-visible physical changes or produced representations of physical objects may have provided some relief to patentees, there were still situations where the 'focus on tangible physical inventions' meant that 'many abstract advances in computer technology remain[ed] unprotected'.[132] This led commentators to complain that physicality tied patent law to an outdated worldview that 'acted as a substantial obstacle to software inventors seeking patent protection',[133] or that in drawing 'an arbitrary distinction between the tangible and the abstract' it left 'abstract innovations either completely unprotected or distorted and "shoehorned" into some tangible expression', which resulted in 'high transaction costs and uncertain protection'.[134]

[129] *In re Lowry* 32 F.3d 1579, 1580 (Fed. Cir. 1994).

[130] Ibid., 1582–3 quoting *In re Bernhardt* 417 F.2d 1395, 1400 (CCPA 1969).

[131] *In re Abele* 684 F.2d 902, 908–9 (CCPA 1982) (emphasis added).

[132] Note, 'Computer Intellectual Property and Conceptual Severance' (1990) 103 *Harvard Law Review* 1046. With some technologies that the physicality test was 'too easily circumvented' that, for example, '[t]hrough clever draftsmanship, nearly every process claim can be rewritten to include a physical transformation' *In re Bilski* 545 F.3d 943, 1008–9 (Fed. Cir. 2008). 'The fact that a computer "necessarily exist[s] in the physical, rather than purely conceptual, realm," … is beside the point. There is no dispute that a computer is a tangible system (in §101 terms, a "machine"), or that many computer-implemented claims are formally addressed to patent-eligible subject matter. But if that were the end of the §101 inquiry, an applicant could claim any principle of the physical or social sciences by reciting a computer system configured to implement the relevant concept. Such a result would make the determination of patent eligibility "depend simply on the draftsman's art", thereby eviscerating the rule that "[l]aws of nature, natural phenomena, and abstract ideas are not patentable,"' *Alice Corp.* v. *CLS Bank International* 134 S. Ct. 2347, 2358–9 (2014).

[133] Lawrence Kass, 'Computer Software Patentability and the Role of Means-Plus-Function Format in Computer Software Claims' (1995) 15(3) *Pace Law Review* 787, 868–69.

[134] Note, 'Computer Intellectual Property and Conceptual Severance' (1990) 103 *Harvard Law Review* 1046, 1060.

While the physicality threshold might have worked for inventions from 'the brick and mortar world' of the Industrial Age and even been effective when applied to the special purpose programmed machines of the 1960s and 1970s, which were 'grounded in a physical or other tangible form',[135] it excluded many new information-age innovations such as electronic signals and electronically manipulated data.[136] The problem that patent law faced was that many of the advances in computer technology that had taken place since the 1970s consisted 'of improvements to software that, by their very nature, may not be defined by particular physical features but rather by logical structures and processes.'[137] Or, as Justice Radar wrote in 2008, '[t]oday's software transforms our lives without physical anchors.'[138] The situation was summed up by the comment in the amicus curiae brief for the United States in the *Alice* decision that the 'abstract-ideas exception should not encompass innovations in technology, science, or industry' … 'that improve computer function, including those "based on linear programming, data compression and the manipulation of digital signals"'.[139] Instead of being excluded it was argued that 'those invention should be patent-eligible because they disclose concrete technological applications and fall within patent law's traditional bailiwick of the scientific, technological, and industrial arts. That is so even if the advancement in computing technology is not grounded in "tangible form"'.[140] Building on the idea that it was not appropriate to freeze 'patents to old technologies, leaving no room for the revelations of the new, onrushing technology'[141] and that there was a need to make the subject matter eligibility test 'responsive to the needs of the modern world',[142] there was a growing sense in which the physicality test was antiquated and in need of change.

Patent law initially responded to this challenge by downplaying the role that physicality played in deciding subject matter eligibility. In rethinking how the eligibility of information-age subject matter was to be decided the courts said that while in some circumstances 'physical transformation' was a 'useful clue' for deciding subject matter eligibility,[143] they stressed that it was 'not an invariable requirement'. Instead, physicality was presented as an example of how excluded subject matter could bring about a useful application.[144] As a result, it was argued that physicality

[135] *Bilski* v. *Kappos* 561 U.S. 593, 605 (2010). See also *In re Bilski* 545 F.3d 943, 1015 (Fed. Cir. 2008) (Rader Circuit Judge, dissenting).
[136] *In re Bilski* 545 F.3d 943, 962 (Fed. Cir. 2008).
[137] *Enfish* v. *Microsoft Corp* 822 F.3d 1327, 1339 (Fed. Cir. 2016).
[138] *In re Bilski* 545 F.3d 943, 1015 (Fed. Cir. 2008).
[139] Brief for the United States as Amicus Curiae in Support of Respondents No 13–298 *Alice Corporation* v. *CLS Bank*, 16.
[140] Ibid.
[141] *Gottschalk* v. *Benson* 409 U.S. 63, 71 (1972).
[142] *ATT Corp* v. *Excel Communications* 172 F.3d 1352, 1356 (Fed. Cir. 1999).
[143] Brief for the United States as Amicus Curiae in Support of Respondents No 13–298 *Alice Corporation* v. *CLS Bank* 1.
[144] *ATT Corp* v. *Excel Communications* 172 F.3d 1352, 1358 (Fed. Cir. 1999).

should not be the sole criterion for determining the patentability of newer forms of computer-related subject matter.[145] At the same time the courts also began to distance themselves from the decisions of the 1970s and 1980s, which had promoted the use of materiality to prove eligibility. In light of changes in technology, these earlier decisions and with them the physicality test that they relied upon were now said to be 'of limited usefulness because the more challenging process claims of the twenty-first century are seldom so clearly limited in scope as the highly specific, plainly corporeal industrial manufacturing process of *Diehr*, nor are they typically as broadly claimed or purely abstract and mathematical as the algorithm *of Benson*.'[146]

Freed up from the ability or need to find physicality as a pre-condition for eligibility, the courts returned to focus (again) on the abstract nature of the excluded subject matter. As had been the case previously, the problem with abstract subject matter was that it provided too much protection (or at least too much protection in relation to what was being disclosed). As the Supreme Court said in *Mayo*, the concern underlying the exceptions to subject matter eligibility 'is not tangibility, but pre-emption.'[147] While some pre-emption was permissible, too much was not. As a result, the task that the law set for itself in dealing with computer-related subject matter was working out how to differentiate abstract ineligible subject matter which pre-empted too much from eligible subject matter, which did not.

Building on the idea that the 'preemption concern arises when the claims are not directed to a specific invention and instead improperly monopolize "the basic tools of scientific and technological work"',[148] subject matter eligibility was recast in terms of the *specificity* of the invention. Unlike the situation previously where abstractness was framed in terms of materiality, eligibility was now evaluated in terms of the specificity of the subject matter. With abstractness and specificity treated as opposites, the specificity of the subject matter came to be treated as a proxy for its eligibility. Conversely, the absence of specificity gave rise to a presumption that the subject matter was abstract and thus ineligible. Framed in terms of pre-emption this meant that while patenting a specific or particular invention 'would incentivize further innovation in the form of alternative methods for achieving the same result', allowing more abstract claims would 'inhibit … innovation by prohibiting other inventors from developing their own solutions to problem without first licensing the abstract idea'.[149]

[145] *Bilski* v. *Kappos* 561 U.S. 593, 604 (2010).

[146] *In re Bilski* 545 F.3d 943, 954 (Fed. Cir. 2008). *AT&T* 172 F.3d at 1358–59, 50 USPQ2d, 452 (physical transformation is only one example of a practical or useful application of an abstract idea).

[147] *Mayo Collaborative Servs.* v. *Prometheus Labs*. 132 S.Ct. 1289, 1301 (2012). On this see *McRo* v. *Bandai Namco Games Am.* 837 F.3d 1299, 1314 (Fed. Cir. 2016).

[148] *Gottschalk* v. *Benson* 409 U.S. 63, 67, 93 S.Ct. 253, 34; *Alice Corp.* v. *CLS Bank International* 134 S. Ct. 2347, 2354 (2014); *Association for Molecular Pathology* v. *Myriad Genetics* 133 S. Ct. 2107, 2116 (2013).

[149] *Electric Power Group* v. *Alstom* 830 F.3d 1350 (Fed. Cir. 2016).

The use of specificity as a guide for deciding the eligibility of computer-related subject matter can be seen in *DDR Holdings*,[150] a 2014 Federal Circuit decision, which concerned the eligibility of a system that allowed website owners who advertised third party goods and services to prevent visitors who wanted to purchase such goods and services from leaving their site. The invention did this by directing visitors who clicked on links to third-party vendors to a hybrid webpage that combined information for the third-party product with the look-and-feel of the host website. In finding the claims to be eligible, the court noted that the invention did 'not merely recite the performance of some business practice known from the pre-Internet world along with the requirement to perform it on the Internet', as was the case in many of the situations where software claims had been held to be ineligible. Instead, the invention was 'rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks.'[151] A key reason why the claims were allowed was because they specified how interactions with the Internet were manipulated to yield a desired result – a result that overrode the routine and conventional sequence of events ordinarily triggered by the click of a hyperlink.[152] As the court said, the claim was calculated to improve sales in a very specific manner. Importantly it did so without pre-empting all applications of the idea to increase sales by making two web pages look the same. Essentially, the abstract idea was narrowly tailored to increase sales in a specific application without broadly claiming ownership over a societal building block like the computer or the Internet.' Because the patent only claimed 'a specific way to automate the creation of a composite web page' the court felt it would only 'have a limited preemptive effect' and, as such, was eligible.

A similar approach was adopted in *Enfish*, a 2014 Federal Court decision that concerned the eligibility of claims for a 'method and system for reducing the time it takes for a trader to place a trade when electronically trading on an exchange, thus increasing the likelihood that the trader will have orders filled at desirable prices and quantities.'[153] To this end the patent claimed a data storage and retrieval system for computer memory, which allowed faster searching and more effective storage of data. To determine whether these claims were eligible, the court said it was necessary to 'look to whether the claims … focus on a specific means or method that improves the relevant technology or are instead directed to a result or effect that itself is the abstract idea and merely invoke generic processes and machinery.'[154] In applying this approach, the Federal Circuit held that the claims were not directed to an abstract idea. Rather, they were directed to a specific improvement in the way computers operated. The Court held that the 'challenged patents do not simply claim information displayed on a graphical user interface'. Nor did they merely

[150] *DDR Holdings* v. Hotels.com 773 F.3d 1245 (Fed. Cir. 2014).
[151] Ibid., 1257.
[152] Ibid., 1258–9.
[153] *Enfish* v. *Microsoft Corp* 822 F.3d 1327 (Fed. Cir. 2016).
[154] Ibid., 1336.

involve the routine or conventional use of computers or the Internet. Instead, the claims required 'a specific, structured graphical user interface paired with a prescribed functionality directly related to the graphical user interface's structure that is addressed to and resolves a specifically identified problem in the prior state of the art.)'[155] In doing so, the court distinguished between situations where 'general-purpose computer components were added post-hoc to a fundamental economic practice or mathematical equation (which were ineligible)' and situations where 'the claims were directed to a specific implementation of a solution to a problem in the software arts' (which were eligible).

Another example of the way specificity was used as a proxy for deciding subject matter eligibility was the 2016 Federal Court decision of *McRo*, which considered the validity of US Patent Number 6,611,278, which claimed a method for automatically animating lip movements and facial expressions for 3-D animated characters.[156] To do this, computer software applied a set of rules to control the lip movement and facial expressions of an animated character as it pronounced certain sounds. In evaluating the patent, the Federal Circuit applied *Enfish's* 'specific improvement' test to determine whether the claims were directed to abstract ideas.[157] In doing so, the court said: 'We look to whether the claims … focus on a specific means or method that improves the relevant technology or are instead directed to a result or effect that itself is the abstract idea and merely invoke generic processes and machinery'. While the District Court had said that the claims were ineligible because they were drawn to the abstract idea of automated rules, the Federal Circuit disagreed saying that the claims were 'limited to rules with specific characteristics'. In particular, the Federal Circuit said that the patent described a specific improvement to animation technology through its use of a specific set of rules governing how animated facial expressions should be synchronized with sounds. On this basis, the court concluded that the claimed invention was not drawn to an abstract idea, explaining that '[t]he claimed process uses a combined order of specific rules that renders information into a specific format that is then used and applied to create desired results: a sequence of synchronized, animated characters.'[158] Recognising the shift away from physicality, the court added that while 'the result may not be tangible, there is nothing that requires a method "be tied to a machine or transform an article" to be patentable'.[159]

While physicality remains an important touchstone for deciding the eligibility of some types of computer-related subject matter, when dealing with more immaterial inventions physicality has been replaced by a concern with the relative specificity

155 Ibid.

156 *McRo* v. *Bandai Namco Games* 837 F.3d 1299, 1314 (Fed. Cir. 2016).

157 Ibid.

158 The claim 'does not preempt approaches that use rules of a different structure or different techniques'. *McRo* v. *Bandai Namco Games* 837 F.3d 1299, 1316 (Fed. Cir. 2016).

159 *McRo Inc.* v. *Bandai Namco Games* 837 F.3d 1299, 1315 (Fed. Cir. 2016) citing *Bilski* v. *Kappos* 561 U.S. 593, 603 (2010).

of the subject matter. Whether it was the specific way sensors operate,[160] the 'specific method of filtering Internet content',[161] specific improvements in the way computers operate,[162] or a 'specific way of enabling a computer to monitor data from multiple sources across an electric power grid',[163] or some variation thereof, the fate of information-based computer-related subject matter in the early part of the twenty-first century turned on how precisely the subject matter had been claimed. As Mark Lemley said at a 2016 roundtable on subject matter eligibility organised by the US Patent Office, 'the Federal Circuit is beginning to define a "set of standards" to distinguish between an ineligible invention and one that is directed to a specific algorithm or improvement in computer technology'.[164]

While the decision to use the specificity of the subject matter as a proxy for eligibility was presented as a logical extension of the use of physicality to decide whether the subject matter threshold had been met and as a continuum of pre-existing practice, it did bring about a number of subtle but important changes in the way patent law interacted with computer-related subject matter. The first and most obvious was that it ensured that subject matter that would have otherwise been excluded because it lacked tangibility was now able to be protected. The decision to use specificity as a litmus test for deciding eligibility also changed the way subject matter was evaluated. Previously, eligibility had been treated as a question of kind: subject matter either had a physical dimension and was eligible or it didn't. With the shift to specificity, there was a sense in which subject matter eligibility was again a question of kind: subject matter was either classified as specific, non-abstract, and eligible, or it was abstract and ineligible. Working with these binary categories, there were no grey areas, no difficult questions of degree, and no problematic lines to be drawn: subject matter was either specific thus eligible, or abstract thus ineligible. As patent law confronted more and more information-based subject matter, however, this neat binary distinction began to break down.

Building on the realisation that it was possible to claim subject matter in a 'highly specific' way but nonetheless still 'manipulate abstract concepts', in their amicus brief for the United States in *Alice* the Solicitor General suggested that 'the term "abstract" [was] best understood to mean not the opposite of specific, but the opposite of concrete.'[165] While the advice of the Solicitor General was not followed

[160] *Thales Visionix* v. *United States* 850 F.3d 1343, 1344–5 (Fed. Cir. 2017).

[161] *Bascom Global Internet Servs.* v. *AT&T Mobility* 827 F.3d 1341 (Fed. Cir. 2016). ('A specific, discrete implementation of the abstract idea of filtering content').

[162] *Informatica Corp.* v. *Protegrity* CBM2015-00021 Patent Trial and Appeal Board (31 May 2016).

[163] *Electric Power Group* v. *Alstom* 830 F.3d 1350 (Fed. Cir. 2016). *Amdocs (Israel)* v. *Openet Telecom* 841 F.3d 1288 (Fed. Cir. 2016).

[164] USPTO, 'Patent Eligible Subject Matter: Report on Views and Recommendations from the Public' (July 2017), 39.

[165] Brief for the United States as Amicus Curiae in Support of Respondents No 13-298 (February 2014) *Alice Corporation* v. *CLS Bank*, 24. 'The opposite of "concrete" is unrepeatable or unpredictable'. USPTO, *Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility*, OG Notices (22 November 2005), 10.

(either in *Alice* or elsewhere), it is nonetheless still important in so far as it highlights the fact that specific subject matter is not the same as concrete subject matter and that specific subject matter is (potentially) broader and more abstract than concrete subject matter. It also highlights the fact that within the taxonomic framework being developed in patent law, specificity existed somewhere between concrete physical subject matter and abstract subject matter. Because specific subject matter potentially included abstract ideas, it was no longer possible to rely on it as a simple guide to determine eligibility. In doing so, it suggests that using the specificity of the subject matter to decide eligibility may not have been as straightforward as it may first have appeared.

In many ways this was confirmed by *McRo*; the decision of the Federal Circuit about the eligibility of a method for automatically animating lip movements and facial expressions for 3-D animated characters that was discussed above. As we saw, in finding the subject matter eligible the court recognised that the patent did not 'improperly purport to cover all rules'; nor did it pre-empt 'the field of rules-based animation' or 'all techniques for automating 3–D animation that rely on rules'. Rather, the court found that the claims were 'limited to rules with specific characteristics'. As such the patent could not be classified as abstract excluded subject matter. So far, so good. The ability to use specificity as a guide to subject matter eligibility was called into question, however, by the fact that while the specificity of the subject matter meant that it was not abstract, the court also found that the subject matter was not restricted to individual, concrete inventions. Rather, the claims were 'limited to rules with certain common characteristics, i.e., a genus'.[166] While it may have been 'self-evident that genus claims create a greater risk of preemption, thus implicating the primary concern driving § 101 jurisprudence' the court stressed that that 'this does not mean they are unpatentable'.[167] Drawing on *Diamond* v. *Chakrabarty* (which had recognised the patentability of a bacterium from the genus *Pseudomonas*), the Federal Circuit said that '[c]laims to the genus of an invention, rather than a particular species, have long been acknowledged as patentable.' And while patent law had 'evolved to place additional requirements on patentees seeking to claim a genus … these limits have not been in relation to the abstract idea exception to [subject matter eligibility in § 101]'. 'Rather they have principally been in terms of whether the patentee has satisfied the trade-off of broad disclosure for broad claim scope implicit' in the requirement of enabling disclosure (in section 112).[168]

Had patent law followed the advice of the Solicitor General in *Alice* and used concreteness as a proxy for subject matter eligibility, the eligibility test might have remained a question of kind. By accepting that specificity was potentially broader than a concrete individual invention (akin to a chemical sample) but something less than a patent that

[166] *McRo* v. *Bandai Namco Games* 837 F.3d 1299, 1313 (Fed. Cir. 2016).
[167] Ibid., 1314.
[168] Ibid., 1313–14.

claimed subject matter at the level of genus and even less than one that claimed abstract excluded subject matter, subject matter eligibility became a question of degree. It also confirms the remark in *Mayo* that 'all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas' which means that at a certain level of generality all inventions include ineligible subject matter, whether subject matter is judged in terms of physicality or specificity.

By recognising that specific subject matter potentially incorporates abstract ideas, patent law created a situation where it had to work out to what extent abstract ideas could be protected or, to use the language of the Federal Circuit in *McRo*, what degree of risk was the court willing to accept in the granting of a patent? In adopting specificity as a touchstone for deciding subject matter eligibility, rather than answering what the Supreme Court in *Alice* described as a key question in this context, namely, what is needed to 'transform the nature of the claim into a patent-eligible application'[169] patent law added a new question to the subject matter inquiry, namely where and how was the line to be drawn between a (non-patentable) abstract idea and an application of an idea that produces eligible subject matter?

While an appreciation of the problems that patent law created for itself in dealing with computer-related inventions that could not be made to look, feel, or smell like hardware is important for understanding some of the problems bedevilling patent law today, from my perspective, the most important change instigated by the decision to adopt specificity as a guide for deciding eligibility was that it uncoupled subject matter from its physical roots, that is, it dematerialised the subject matter. In this sense the decision to use specificity as a guide for eligibility allowed patent law to reconceptualise 'the notion of invention … not through the form of the machine or organism but through that of information and information processing'.[170] While this dematerislation changed the way that patent law interacted with computer-related subject matter, it was not as significant as the changes that occurred as a result of the shift to structural formula in chemical subject matter. As we will see in the next three chapters, it was also very different to the way that patent law responded to the dematerialisation of biological subject matter. The key difference being in terms of how the law interacted with science and technology. Unlike the case with organic chemicals and biological inventions where the law consistently looked to science and technology to help it deal with new types of subject matter, the inherently divided nature of the information technology industry meant that the law was forced to develop its own way of dealing with the would-be subject matter. It was this, much more than the process of dematerialisation, that shaped the way that patent law has interacted with computer-related subject matter since the 1960s.

[169] *Alice Corporation* v. *CLS Bank International* 134 S. Ct. 2347 2355 (2014) (this is the second part of the 2-part test).

[170] Mario Biagioli, 'Between Knowledge and Technology: Patenting Methods, Rethinking Materiality' (2012) 22(3) *Anthropological Forum* 285, 286.

8

Bio-legal Subject Matter

INTRODUCTION

The history of intellectual property and its interaction with biological subject matter is a subject waiting to be written. Much of the research into biological-based subject matter has, perhaps even more so than with chemical inventions, been overshadowed by a focus on mechanical inventions. It has also been distorted by the fact that biological subject matter has consistently been judged by its ability to fit within a mechanical framework. While there is no denying the influence that the mechanical narrative has had on the way intellectual property law has interacted with biological subject matter, it is important that the subject matter is understood on its own terms. The need to understand how intellectual property has engaged with biological innovations has been made all the more pressing as a result of the recent discussions about the dematerialisation of biological material, which are premised on the historical claim that what is happening with biological subject matter today is fundamentally different from what has occurred previously.[1]

Intellectual property law has been interacting with biological innovations for nearly a century and a half. The first type of biological subject matter that intellectual property law encountered were new types of plants. One of the notable things about the way that the law has responded to plant-based subject matter is that it has been graduated and staged. After initial attempts to protect the names of plants failed,[2] protection was granted to asexually reproduced plants (in the 1930 *Plant Patent Act*), then to sexually reproduced plants (in the 1970 *Plant Variety Protection Act*), and eventually extended to include utility patent protection in the 1980s.[3] The

[1] Mark Janis and Stephen Smith, 'Technological Change and the Design of Plant Variety Protection Regimes' (2007) *Chicago-Kent Law Review* 1557, 1570.

[2] While discussions about the form that this protection might take had begun by 1876, it was not until the end of the nineteenth century that organisations such as the American Association of Nurserymen began to formulate more concrete proposals. On the arguments made in 1876 by grape grower and Nurseryman Jacob Moore see Richard White, *A Century of Service: A History of the Nursery Industry of the United States* (Washington: The American Association of Nurserymen, 1975), 128.

[3] *JEM AG Supply* v. *Pioneer Hi-Bred International* 534 U.S. 124 (2001).

incremental change continued when the 2018 *Farm Act* extended plant variety protection to include asexually propagated plants.[4] As we will see, the type of protection granted and with it the nature of the intangible property was closely tied to the ability of breeders and scientists to satisfy the demands that intellectual property law made of the subject matter. As a result, there is a hierarchy of protection that reflects the idea that the nature and type of legal protection is commensurate with the level of scientific skill and expertise associated with the subject matter.[5]

If we leave aside the piecemeal and gradual way in which the subject matter was accommodated, the process of extending the reach of intellectual property to include plant-based subject matter has a familiar feel about it. As is often the case when a new type of subject matter is presented to the law for protection, one of the first questions that arose when intellectual property law was first confronted with plant-based subject matter was whether protection was desirable. In responding to this question, the proponents of intellectual property protection appealed to moral arguments (about how it was wrong for people to steal the fruits of the labour that breeders had used to develop new plants) and to economic arguments (about how intellectual property protection would stimulate investment in research and breeding).[6] In many ways these arguments were similar to the arguments that were made to justify extending protection to software-related subject matter (and to many other types of subject matter). The notable difference being that the argument that was first made in the 1930s and then repeated in the 1970s that intellectual property protection was needed to shift the responsibility for developing new plants from the public to the private sector. While these justificatory arguments played an important role in the passage of the 1930 *Plant Patent Act* and the 1970 *Plant Variety Protection Act*, by the 1980s (when plants were first protected by utility patents) the nature of the normative arguments had changed. Specifically, the justificatory arguments that had been so prominent over the last 50 or so years were supplemented by questions about whether intellectual property protection for plants had led to the loss of genetic material, encouraged the acquisition of seed companies by larger corporations, and increased the cost of seed.[7]

As well as asking whether the protection of plant-based subject matter was desirable, when intellectual property law was first confronted with this new type of

4 The 2018 Farm Act, extended plant variety protection to include asexually propagated plants. Deposit of asexually reproduced plant vanities was delayed until 6 January 2023.

5 Brief Amicus Curiae of American Crop Protection Association Cargill in support of affirmance, *JEM Ag Supply* v. *Pioneer Hi-Bred International* 2001 WL 674207 (US) No 99, 1996, 15 June 2001, 3.

6 Luther Burbank, the famous Californian plant breeder, appealed to a different type of moral argument when he said in 1911: 'No patent can be obtained on any improvement of plants, and for one I am glad that it is so. The reward is in the joy of having done good work, and the impotent envy and jealousy of those who know nothing of the labour and sacrifices necessary, and who are by nature and cultivation, kickers rather than lifters'. Luther Burbank, *How to Judge Novelties* (Santa Rosa, CA: Burbank's Experimental Farms, 1911), 2.

7 See *Hearings before the subcommittee on Agricultural Research and General Legislation of the Committee on Agriculture, Nutrition, and Forestry*: United States Senate, Ninety-Sixth Congress, Second Session on S 23. 17 and 18 June 1980, 1.

subject matter, questions were also raised about whether protection was possible. While the normative discussions about the desirability of extending intellectual property protection to plants were similar to those that had taken place in relation to software-related subject matter, the same cannot be said for the discussions that took place about the feasibility of granting protection, which largely turned on the peculiarities of plant-based subject matter.[8]

THE PECULIARITIES OF PLANT-BASED SUBJECT MATTER

One of the notable characteristics of plant-based subject matter was that no matter how much breeders and scientists tried, they were unable to explain why plant innovations had occurred. While breeders may have been able to stimulate change by crossing plants or subjecting plants to extreme conditions, they could not explain the reasons why the biological innovation had taken place. As David Burpee said of a new type of nasturtium, a super-double nasturtium, with very large double flowers that he discovered growing among several thousand experimental plants on one of his company farms, it was unclear whether the gene for super-doubleness was induced by exposure of the experimental plants to the places where they had been grown (including California, Miami, Porto Rio, Argentina, Chile, and Australia), or whether the gene was present in latent form in one of the parents used in the crosses. At best, all Burpee could say was that its expression was the result of experiments that were planned for the creation of new varieties of nasturtium. Although breeders may have 'assisted nature' in the development of new plants, for example by the cross-pollination of selected parent plants, the 'actual creation of the new plant, because of the almost infinite number of possible combinations between the genes and chromosomes, is not presently the subject to a controlled reproduction by act of man'. As Smith J. said in the 1960s, while those skilled 'in this art now understand the mechanics of plant reproductions and the general principles of plant heredity, they are not presently able to control the factors which govern the combinations of genes and chromosomes required to produce a new plant having certain predetermined properties'.[9] Despite the range of innovations and discoveries that have taken place over the last hundred or so years, the 'world of plants remains one that we cannot entirely access. The encounter with plants is an encounter with alterity and there are aspects of plant being that will always remain untranslatable to us'.[10]

While breeders worked on the basis that the external physical traits of plants were determined by their underlying units of inheritance (whatever they were called), breeders were unable to get access to this hidden domain; they could only observe

[8] The 'unique aspects of plants … have posed numerous problems to various tribunals'. *In re LeGrice* 310 F.2d 929 (CCPA 1962) 1127, 1129.

[9] *In re Le Grice* 310 F.2d 929, 939 (CCPA 1962) 1137 301 F.2d 929, 938 (CCPA 1962).

[10] Hannah Stark, 'Deleuze and Critical Plant Studies' in (ed) J. Roffe and H. Stark, *Deleuze and the Non/Human* (London: Palgrave Macmillan, 2015), 180.

and intervene in these 'genetic' elements through the medium of their external phenotypic expression. In this situation breeders were forced to distil what went on inside a plant from what occurred on the outside. As with other empirical sciences such as nineteenth-century organic chemistry, breeders, scientists, and farmers were forced to work backwards from the end-results in an attempt to explain what had happened inside the plant.[11]

The secretive nature of plant-based subject matter created a number of problems for law makers when they first began to think about extending intellectual property protection to this new type of subject matter. As had occurred with organic chemicals, questions arose as to whether in producing a new plant a breeder was an inventor. While questions of this nature had arisen previously, they came to a head in the lead up to the 1930 *Plant Patent Act*, which was the first occasion when intellectual property law grappled seriously with the possibility of extending protection to plant-based subject matter.

One of the most vocal critics of the proposed new plant patent law was the Commissioner of Patents who was 'very strongly of the opinion' that the plant patent scheme was unconstitutional, primarily because he did not think that breeders were inventors. The reason for this was that he 'doubted whether a valid patent can be granted for a plant even if it is a new variety, when that plant is *reproduced by the operation of nature*, aided only by the act of the patentee in grafting it by the usual methods, and a very serious question arises as to whether the definition given to the words "invention" and "discovery" in the proviso in the [Plant Patent] Bill', namely that they shall be interpreted 'in the sense of finding a thing already existing and reproducing the same as well as in the sense of creating' does not go beyond the power which the Constitution grants to Congress'.[12] The problem, in short, was that the 'person has done nothing in any way toward creating that variety'.[13] That is, the Commissioner doubted whether a person who developed or produced a new plant was an inventor.

11 Smith J. said that after the plant breeder had completed cross-pollination of the parent stock they needed to recall the lines of Tennyson's 'Flower in the Crannied Wall':

> 'Flower in the crannied wall
> I pluck you out of the crannies
> I hold you here – but if I could understand
> What you are, root and all, and all in all.
> I should know what God and Man is'.

In re Le Grice 310 F.2d 929, 939; 1137 301 F.2d 929, 938 (CCPA 1962).

12 Thomas E. Robertson (Commissioner of Patents), 'Memorandum to Secretary R. P. Lamont (Secretary of Commerce)', 8 March 1930, *Hearings of the House Committee on Patents* (1930) 71st Congress, 2nd Session on HR 11372 (A Bill to Provide for Plant Patents). R. P. Lamont (Secretary of Commerce), 'Letter to Albert Vestal (Chair of the House Committee on Patents), 12 March 1930', *Hearings of the House Committee on Patents* (1930) 71st Congress, 2nd Session on HR 11372 (A Bill to Provide for Plant Patents).

13 Thomas E. Robertson, ibid., As Senator Dill said, 'I have some doubt about the constitutionality of patenting a new form of plant somebody may develop through the process of nature' (14 April 1930) 72 Congressional Record, Senate Proceedings, 71st Congress, 7017–18.

As well as raising concerns about the constitutional validity of plant-based intellectual property, the secretive nature of plants also made it difficult to apply a number of the doctrinal rules of intellectual property law. This was the case in interference actions where the law was called on to determine when an invention was created. One of the features of American patent law for much of the twentieth century was that it employed a first-to-invent system where priority was given to the first inventor rather than as under a first-to-file system where priority is given to the party who files their application first. One of the consequences of this was that in determining priority between claimants, it was necessary to fix the moment of invention.

In determining when an invention first came into existence, patent law typically built on a mechanical model of invention which saw invention as a two-stage process: a mental operation involving the conception of an idea (form) and a physical operation involving the reduction of the mental concept to practice (matter). To determine when an invention came into existence, it was necessary to work out when the idea behind the invention first took shape. While this was possible with mechanical inventions, it was not with plant-based subject matter. While there was little difficulty in determining when a plant-based invention was reduced to practice, this was not the case when it came to ascertaining when the concept that was meant to underpin the invention was first conceived.[14] The reason for this was that unlike mechanical inventions, plant inventions were not the product of a prior mental design that was subsequently reduced to a material form. Rather, the secretive nature of plants meant that the inventor was only ever able to deal with the results of the inventive process, with the plant's external, empirically verifiable, physical characteristics or traits.

Another problem created by the secretive nature of plant-based subject matter was that breeders were unable to satisfy the longstanding requirement of patent law that required them to describe the invention so that a third party could recreate the patented invention without further inventive effort.[15] While mechanical inventions that consist of an idea that is subsequently reduced to practice are able to be translated into and out of a written form, the secretive nature of plant innovation meant that this was not possible with plant-based inventions. The secretive nature of plant invention also meant that breeders and scientists were not in a position where they could reduce the design or inventive concept that lay behind an invention to a written form that could be repeated.[16] As the Supreme Court said in *Chakrabarty*, one

[14] *Dunn* v. *Ragin* v. *Carlile* (Orange Tree) Final Hearing in the US Patent Office; Patent Interference No. 77,764 (6 December 1940).

[15] See Hearing Before the Subcommittee on Departmental Operations of the Committee on Agriculture, 91st Cong., 2d Sess 7, see *Ex Parte Hibberd* 227 USPQ (BNA) 444.

[16] The fusion of form and matter (conception and reduction to practice) that occurred with chemical inventions was only a temporary aberration. Even if the concept needed to be modified in light of the experiment, once the experiment was successfully completed the invention was able to be reconfigured to take its traditional form: as an originating conception that was able to be reduced to practice.

of the reasons why plants were not protected by patents for so long was because they were not amenable to the written description requirements of patent law.[17]

The fact that it was not possible to recreate a plant from a written form had other ramifications for intellectual property law. This can be seen for example in *Le Grice*, a 1962 decision that arose when the English rose breeder Edward Burton Le Grice applied to patent two roses that he had bred: *Rosa Floribunda* Charming Maid (see Figure 8.1) and *Rosa Floribunda* Dusky Maiden (Figure 8.2). The problem that Le Grice faced was that information about the Charming Maid and Dusky Maiden roses had already been published when the applications were filed on 15 January 1958. For example, the 1949 National Rose Society Annual of England contained the following information:[18]

> Dusky Maiden (Hy. Poly) raised and exhibited by E.B. Le Grice, North Walsham – Glowing dark scarlet with dusky velvet sheen. Single blooms carried in large trusses. Size when open 3-in on diameter. Vet fragrant. Vigorous. Foliage dark green and abundant. Trial Ground Certificate 1945. Prune 34.[19]

In addition, a number of nursery catalogues also included colour photographs of the Dusky Maiden and Charming Maid roses.[20] The problem Le Grice faced was that these prior disclosures potentially triggered section 102(b) of the Plant Patent Act, which provided that a plant patent would not be granted where the invention had been described in printed publications more than one year prior to the filing date of the application.

After the Patent Office Examiner and the Patent Office Board of Appeal rejected the applications on the basis that they fell foul of section 102(b),[21] Le Grice appealed to the Court of Customs and Patent Appeals. As there was no dispute that the publications were of the plants in the applications and that publication had occurred outside the one-year grace period, the only question on appeal was whether the publications anticipated the plant patent, that is, whether the prior publications had 'put the public in possession of the invention'.[22]

[17] *Diamond* v. *Chakrabarty* 447 U.S. 311, 312 (1980). The other reason was that plants, even those artificially bred by man, were products of nature not subject to patent protection.

[18] Similar information and photographs relating to the Charming Maid rose had also been published more than a year before Le Grice had applied for plant patent protection.

[19] *1949 National Rose Society Annual of England* (1949), 155.

[20] 'In each case, the prior catalogues publications included a colour picture of the rose clear enough to establish identity in appearance between the rose illustrated and the applicants variety, and the catalogue publication with the picture establishes that the rose described and illustrated is the variety described and claimed in the application, and the rose so described and illustrated is, in fact, the variety so described and claimed in the application'. *In re Le Grice* 310 F.2d 929, 936 (CCPA 1962).

[21] Section 102(b) read: 'A person shall be entitled to a patent unless … (b) the invention … was described in a printed publication … more than one year prior to the date of the application for patent in the United State.' 35 USC 102(b).

[22] *In re Le Grice* 310 F.2d 929, 936 (CCPA 1962).

FIGURE 8.1 *Rosa Floribunda* Charming Maid
Edward Burton Le Grice, 'Rosa Floribunda Plant' US Plant Patent No. 2,210 (8 Jan 1963). Courtesy of the National Archives at Kansas City.

FIGURE 8.2 *Rosa Floribunda* Dusky Maiden
Edward Burton Le Grice, 'Rosa Floribunda Plant' US Plant Patent No. 2,209 (8 Jan 1963). Courtesy of the National Archives at Kansas City.

The Court of Customs and Patent Appeals rejected the findings of the Patent Office and accepted Le Grice's argument that the written publications and photographs did not invalidate his patent applications.[23] While the court accepted that mechanical and chemical inventions could be recreated from a written and/or pictorial description, they found that this was 'not true of living matter'. The reason for this was that the 'description of a plant patent or in a printed publication at best can only recite, as historical facts, that at one time a certain plant existed, was discovered in a certain manner, and was asexually reproduced'. While this information may have been interesting historically, it did not 'enable others to reproduce the plant'.[24] The only way that a plant-based invention could be placed in the hands of the public was by ensuring that the public had access to the physical plant itself.[25]

As well as being secretive, plant-based subject matter was also fluid, malleable, and unstable. One of the consequences of this was that plant-based subject matter could (and did) take different forms. While lobby groups may have known what they wanted to protect, modern intellectual property law's preference for more abstract categories of subject matter rather than the tailored subject-specific protection favoured by pre-modern intellectual property law meant that the law had to translate these specific demands (that changed over time) into more abstract classes of subject matter. In creating these categories and deciding the form that the plant-based subject matter should take, the law was faced with a number of options. For example, one possibility was to limit protection to the process by which the subject matter was created (such as a novel breeding method), rather than the end products of those processes (new plants). To the extent that the focus was on the material object, decisions had to be made about whether the law should focus on the physiological or functional dimensions of that subject matter (such as how the plant performed therapeutically or in different environmental conditions) or whether protection should be detached from what the plant did. It also had to be decided whether protection should extend to part of a plant: its fruit, flower, seed, and so on. It also had to be decided, when it became feasible, whether protection should extend to the hidden and invisible aspects of a plant. Another important issue that had to be considered was the level of protection that should be granted. That is, it had to be decided whether protection should be limited to something that equated to the physical plant (or a part thereof) or whether protection should extend to more abstract groupings such as a species or genus of plants.

Another problem created by the fluid and malleable nature of plant-based subject matter was that breeders could not describe plant inventions with the specificity and detail demanded by intellectual property law, making it difficult if not impossible

[23] Le Grice argued that unlike with manufactured articles, processes, and chemical compositions that a written description of a plant, whether in a patent application, a plant catalogue, or a Rose Society Annual was not enough to enable others to reproduce or recreate the plant. Ibid., 935.

[24] Ibid., 939.

[25] Ibid., 944.

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to apply the existing rules and procedures to plant-based inventions.[26] This was particularly the case where the novel characteristics of a plant lay in its odour, flavour, or taste.[27] As a critic of the 1930 *Plant Patent Act* noted, applicants were unable to provide 'the botanical finger prints by which the plant may be identified and distinguished from other varieties'.[28] These problems were compounded by the fact that while a lever was always a lever, a cam was always a cam, and even a complex chemical compound stays the same in molecular structure, this was not so with plants, which change depending on the environment where they are grown.[29]

The problems that arose in describing plants with the specificity demanded by intellectual property law were compounded by the fact that certain types of plants – namely those that reproduced sexually – were non-uniform and unstable, and therefore ineligible for protection. As Rossman said, a 'machine, once made, stays put: it cannot grow or change. But it is impossible to determine whether a Baldwin apple is like the original Baldwins that grew on the first tree of that variety when it was discovered in 1793'.[30] As Mendel's laws of heredity had shown, when a plant was reproduced sexually, for example by seed, many of the desirable characteristics found in the parents divided up among the offspring.[31] While the characteristics of an asexually reproduced plant, that is a plant that has been propagated clonally from buds or cuttings remained constant when they were reproduced, there was no guarantee that the characteristics of a sexually reproduced plant would remain the same from generation to generation:[32] making patent protection difficult, if not impossible.[33]

[26] Joseph Rossman, 'The Preparation and Prosecution of Plant Patent Applications' (1935) 17 *Journal of the Patent Office Society* 632, 635–38. Harry C. Robb, 'Plant Patents' (1933) *Journal of the Patent Office Society* 752, 753. Robert Starr Allyn, *The First Plant Patents: A Discussion on the New Law and Patent Office Practice* (New York: Educational Foundation, 1944), 18.

[27] Robert Starr Allyn, *The First Plant Patents: A Discussion on the New Law and Patent Office Practice* (New York: Educational Foundation, 1944), 46.

[28] Joseph Rossman, 'The Preparation and Prosecution of Plant Patent Applications' (1935) 17 *Journal of the Patent Office Society* 632, 640–41. This was because 'botanists have not been completely successful in evolving accurate verbal diagnosis of species differences. Since this botanical experiment in plant description has been going on with varying success since Linnaeus' time, it may be that a valid definition of varieties differing only in a few rather variable characters may be virtually impossible. Robert Cook, 'Editors Note' (1936) 27 *Journal of Heredity* 478 (written in response to Keith Barrons, 'A Defense of Basic Plant Patents: From the Plant Breeder's Point of View' (1936) 27 *Journal of Heredity* 475).

[29] Joseph Rossman, 'Plant Patents' (1931) 13 *Journal of the Patent Office Society* 7, 15.

[30] Ibid.

[31] Joseph Rossman, 'The Preparation and Prosecution of Plant Patent Applications' (1935) 17 *Journal of the Patent Office Society* 632, 633. Rossman said that another reason why protection did not extend to sexual reproduction was because the seed (grain) was an article of commerce. Joseph Rossman, 'Plant Patents' (1931) 13 *Journal of the Patent Office Society* 7, 16.

[32] Robert Cook, 'Patents for New Plants' (1932) 27 *The American Mercury* 66, 66–67. Thus 'a verbal patent description, and even accurate coloured illustrations are not likely to prove altogether satisfactory in describing new plants'. Ibid.

[33] See, for example, (US) H. Rep. 1129 71st Congress 2d. Sess. (1930), 4; (US) S. Rep. 315, 71st Congress 2d. Sess (1930), 3; Peter Forbes Langrock, 'Plant Patents: Biological Necessities in Infringement Suits' (1959) 41 *Journal of the Patent Office Society* 787, 788.

While some of the complaints that greeted plant-based subject at the beginning of the twentieth century disappeared over time, one concern that endured related to the instability of sexually reproduced plants. The persistence of these concerns can be seen in the arguments that the Secretary of Agriculture, Orville Freeman, made against a 1967 Bill that proposed to extend the *Plant Patent Act* to include sexually reproduced plants, primarily on the basis that the law would have been unenforceable. As Freeman said, protection was 'scientifically difficult or impossible because of the inherent variability of seed-propagated plants'.[34] The reason for this was that many varieties of crop plants exhibit a change in genetic composition from year to year, so that a variety, in a few years would no longer fit the description of the basis on which it was patented'.[35] The 'variability in sexually reproduced varieties and changes in type attributable to genetic shift would vitiate the intent of the patent system, which rests on the protection of unique and reproducible' discoveries.[36] Despite the concerted efforts of the American seed industry, these concerns created enough doubt in the minds of the Senate Agriculture Committee and the Patent Office for them to reject the proposal to extend plant patent protection to sexually reproduced plants.[37]

RESPONDING TO THE PECULIARITIES OF PLANT-BASED SUBJECT MATTER

Over time, a number of different strategies were used to allow intellectual property law to accommodate the peculiarities of plant-based subject matter. Of these two stand out. As well as changing the way that the process of invention was configured in accommodating plant-based subject matter, intellectual property law makers also changed the way they viewed the intangible property that lies at the core of intellectual property protection.

[34] Patent Law Revision Hearings on S. 2, S. 1042, S. 1377, S. 1690, S. 2164 before the Subcommittee on Patents, Trademarks, and Copyrights, Committee of the Judiciary US Senate 90th Congress 2d See, Part 2, 30, 31, January 1968 at 715–19.

[35] Because of 'difficulty of proof of in infringement litigation as difficulty of enforcement of a patent in seed-producing plants' patenting would interfere with the free exchange of information. Patent Law Revision Hearings on S. 2, S. 1042, S. 1377, S. 1690, S. 2164 before the Subcommittee on Patents, Trademarks, and Copyrights, Committee of the Judiciary US Senate 90th Congress 2d See, Part 2, 30, 31 January 1968, 715–19.

[36] Patent Law Revision Hearings on S. 2, S. 1042, S. 1377, S. 1690, S. 2164 before the Subcommittee on Patents, Trademarks, and Copyrights, Committee of the Judiciary US Senate 90th Congress 2d See, Part 2, 30, 31 January 1968 at 788, 792.

[37] Faced with these doubts the Patent Office did not comment on the Bill not at least until supporters of the Bill could develop 'more convincing factual evidence that the Amendment is both feasible and necessary'. Patent Law Revision Hearings on S. 2, S. 1042, S. 1377, S. 1690, S. 2164 before the Subcommittee on Patents, Trademarks, and Copyrights, Committee of the Judiciary US Senate 90th Congress 2d See, Part 2, 30, 31 January 1968 at 715–19. (Letter from Edward J. Brenner, Commissioner of Patents, 31 May 1968). The 1968 Presidential Commission on the Patent System rejected the use of the patent system as the proper vehicle to protect the work done by plant and seed breeders – 1968 proposed amendment to plant patent act died in committee pending further study of appropriate means of protection.

The concerns that were raised in the 1930s about whether the creation of a new plant qualified as an act of invention and thus whether breeders were inventors were dealt with relatively easily and quickly. Despite the misgivings that had been raised when discussing the *Plant Patent Bill*, the House and Senate Committees on Patents Committees had no hesitation in reporting that they believed that breeding was a form of inventing and, as such, that the proposed law was constitutional. In explaining why they had reached this decision, the House and Senate Committees on Patents began by providing a history of the term 'inventor'. They started by noting that when the US Constitution was written, inventor meant both 'discoverer and finder' as well as someone who created something new.[38] This was reflected in the language of the Constitution, which provided Congress with the power 'to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries'. While there was little doubt that a person who discovered and reproduced a plant fell within the scope of the way that the patent clause was originally interpreted, by the 1930s the idea that someone who found or discovered something was an inventor was seen as an obsolete and archaic idea. In a sense the Committee had to deal with the fact that while the language of the Constitution linked inventions and discoveries, over the course of the nineteenth century the distinction between what is made and what is found, between invention and discovery, had come to be treated as a given.[39]

In light of this, the Committees turned to consider whether for the purposes of patent law breeding was a form of invention. The question of the status of breeders had attracted the attention of supporters of the *Plant Patent Bill* who in an attempt to ensure that breeders were cast as inventors emphasized the time, skill, and ingenuity that was needed in traditional breeding programs to develop a better flavoured fruit or a new flower with a pleasing perfume or graceful petals. By highlighting the fact that over 65,000 hybrid bushes had been grown and eliminated in the development of the white blackberry or that Burbank had selected his famous seedless plum from 300,000 artificially produced variations,[40] proponents of plant patents

[38] H Rep 1129 71st Congress 2d Sess (1930), 8–9; S Rep 315, 71st Congress 2d Sess (1930), 8.

[39] '[O]nly in the course of the eighteenth century did the distinction that matters so centrally to us eventually drive a wedge between "invention" and "discovery"'. Lorraine Daston, 'The Coming into Being of Scientific Objects' in (ed) Lorraine Daston, *Biographies of Scientific Objects* (Chicago: University of Chicago Press, 2000), 4. It was suggested that by 1841 US courts had decided that the word 'discoveries' in the Constitutional provision merely meant 'inventions' (which were a 'specifically human affair'). Charles E. Ruby, 'Patents for Acts of Nature' (1939) 21 *Journal of the Patent Office Society* 538, 539. A 'person who invents or discovers any new manufacture, merely discovers an art of practically applying some of the laws of nature on the manufacture or production of articles of commerce … An inventor … does not create, but only invents or finds something which had no prior existence, although unknown to the world, in precisely the same way as persons make discoveries in geography and astronomy'. W. M. Hindmarch, A *Treatise on the Law Relating to Patent Privileges* (London: V. R. Stevens, G. S. Norton & W. Benning, 1846), 227–28.

[40] Joseph Rossman, 'Plant Patents' (1931) *Journal of the Patent Office Society* 7, 10. It took Burbank 19 years to perfect the amaryllis and over 20 years to produce a new hybrid lily.

were also able to show that the development of a new plant required a considerable amount of experimentation and breeding.[41]

Supporters of plant patent protection also argued that as a result of scientific and technological developments largely facilitated by the rediscovery of Mendel's laws of heredity at the turn of the twentieth century, breeding was now a science and thus worthy of patent protection.[42] Luther Burbank summed up these changes when he said that 'plant breeding has developed into a practice, and as we learn more about the underlying principles of the art, we realize that it is beginning to be fixed as a science'.[43] The House and Senate Committees on Patents embraced the idea that breeding was a science when they drew an analogy between the efforts of a plant breeder and the work of a chemist in the development of new compositions of matter. More specifically, the Committees said that there 'is no apparent difference … between the part played by the plant originator in the development of new plants and the part played by the chemist in the development of new compositions of matter which are patentable under existing law. Obviously, these new compositions of matter do not come into being solely by act of man. The chemist who invents the composition of matter must avail himself of the physical and chemical qualities inherent in the materials and of the natural principles applicable to matter … He may simply find the resulting product and have the foresight and ability to see and appreciate its possibilities and to take steps to preserve its existence … The same considerations are true of the plant breeder. He avails himself of the natural principles of genetics and of seed and bud variation'.[44]

The House and Senate Committees on Patents went on to say that even if the contribution made by a plant breeder was less creative than that of a chemist (an assumption which the Committees did not believe), nonetheless they still felt that breeders were inventors and as such that the proposed law was within the constitutional power of Congress.[45] This was because there was 'a clear and logical distinction between the discovery of a new variety of plant and of certain inanimate things, such … as a new and useful natural mineral. The mineral is created wholly by nature unassisted by man and is likely to be discovered in various parts of the country'.[46] In contrast, the Committees said that a plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be 'produced by nature unaided by man, and such discoveries can only be made available to the

[41] R. France, 'Experiments with Animals and Plants: Studies in Artificial Mutation' (3 April 1909) 1735 *Scientific American Supplement* 216, 217.

[42] H Rep 1129 71st Congress 2d Sess (1930), 1; S Rep 315, 71st Congress 2d Sess (1930), 1. See also Cary Fowler, 'Protecting Farmer Innovation: the Convention on Biological Diversity and the Question of Origin' (2001) 41 *Jurimetrics Journal* 477.

[43] Luther Burbank, 'Prodigal Mother Nature' (June 1926) 134 *Scientific American* 366. Sere also Henry D. Hooker, 'Horticulture as a Science' (14 April 1922) 55 *Science, New Series* 384–5; Randall Howard, 'An Inventor of Roses' (2 June 1916) 25 *Illustrated World* 481.

[44] H Rep 1129 71st Congress 2d Sess (1930), 8; S Rep 315, 71st Congress 2d Sess (1930), 7–8.

[45] H Rep 1129 71st Congress 2d Sess (1930), 3; S Rep 315, 71st Congress 2d Sess (1930), 3

[46] H Rep 1129 71st Congress 2d Sess (1930), 7; S Rep 315, 71st Congress 2d Sess (1930), 6.

public by encouraging those who own the single specimen to reproduce it asexually and thus create an adequate supply'.[47] The Committees concluded that while nature originally creates plants, it could not be denied that breeders often control and direct the natural processes and produce a desired result.[48] From this perspective, the Committees concluded that plant originators were creators (or inventors) and as such that the proposed law was constitutional.

In reaching this conclusion, the House and Senate Committees on Patents not only paved the way for the passage of the *Plant Patent Act*, they also provided an insight into the way intellectual property law makers reconciled the peculiarities of plant-based subject matter with legal doctrine (or at least the mechanistic reading of doctrine which by this time had begun to dominate) across the twentieth century. Specifically, they provided an insight into how law makers reconciled the secretive nature of plant subject matter with a mechanistic understanding of invention, which presumes that the only entity able to exercise agency in the development of a novel invention is the human inventor. In line with this, it is also presumed that the inventor was not only the source of the 'concept' that was meant to lie behind invention, but that they could also reduce that concept to a written form that allowed third parties to repeat the invention at a distance.

Instead of using the asymmetrical relationship between nature and invention presupposed by a mechanical view of invention, plant-based subject matter forced the law to draw on a different conception of agency. The starting point for the reconfiguration of the process of invention was, as had occurred with organic chemicals, the recognition of the positive role that nature plays in the creation of plant inventions.[49] As well as altering the notion of agency that underpins the inventive process, plant patent law also reversed the roles played by the participants involved in the creation of the invention. While under the mechanical view of creation, nature provides the underlying material which the human inventor then shapes into the resulting invention, with plant intellectual property nature does the inventing and the breeder is relegated to the task of identifying and then reproducing nature's creations. As the Supreme Court said in *Chakrabarty*, in producing a new plant the breeder worked 'in aid of nature' to bring about the resulting invention.[50] In this sense, plant patent law developed a notion of agency that saw the breeder and nature working together as joint inventors in the development of plant inventions. Nature and breeder operated like Siamese twins in the creation of plant inventions; neither could operate independently of each other to develop a novel plant invention.[51] It

[47] H Rep 1129 71st Congress 2d Sess (1930), 7; S Rep 315, 71st Congress 2d Sess (1930), 6–7.
[48] H Rep 1129 71st Congress 2d Sess (1930), 8; S Rep 315, 71st Congress 2d Sess (1930), 7.
[49] Harry Robb, 'Plant Patents' (1933) 15 *Journal of the Patent Office Society* 752, 753.
[50] *Diamond* v. *Chakrabarty* 447 U.S. 311, 312 (1980).
[51] Burbank spoke of the breeder using his intelligence and skill in assisting Mother Nature. Luther Burbank, 'Prodigal Mother Nature' (June 1926) 134 *Scientific American* 365–66. 'Nature in such instances, unaided by man, does not reproduce the new variety true to type'. Joseph Rossman, 'Plant Patents' (1931) 13 *Journal of the Patent Office Society* 7, 18.

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was only when the skill and effort of the two were combined together that a plant invention's existence could be guaranteed. The fact that the plant invention would not have recurred in nature without the efforts of the breeder meant that the plant invention was simultaneously both natural *and* artificial. Importantly, the fact that the plant invention did not exist in a natural state meant, at least for patent law purposes, that it was not a product of nature and thus potentially patentable.

As well as being used to respond to the concerns raised about the constitutional standing of plant intellectual property law, the reconfigured invention was also used to modify the traditional rules of patent law so that they could be applied to plant-based subject matter. For example, in interference actions where it was necessary to determine when an invention first came into existence, patent law typically relied on a mechanical model of invention, which saw invention as a two-stage process: a mental operation involving the conception of an idea (form) and a physical operation involving the reduction to practice of the mental concept (matter). Confronted with the fact that the secretive nature of plant innovation meant that this model could not be applied to plant-based subject matter, intellectual property law abandoned the traditional approach where conception preceded reduction to practice when deciding priority disputes relating to plants. Instead, it adopted the approach pioneered in relation to chemical inventions whereby 'conception or discovery of the new variety' occurred '*concurrently* with the actual reduction to practice'.

Instead of drawing upon the image of an invention as an originating and creative act, as the conception or discovery of a new idea which was subsequently embodied or applied in a concrete physical form, plant-based intellectual property law came to focus upon the physical form of the protected intangible as an end in its own right. In this context, reduction to practice only occurred when the 'concept' was physically visible and empirically verifiable. Thus in a decision where the tribunal had to decide when a new type of sugar cane was invented, it was said that 'there could be no invention or discovery of new varieties of sugar cane prior to the time that the plants were grown and their characteristics determined'.[52] In a similar manner, in an interference action over a variety of seedless orange it was held that the invention was only reduced to practice when 'citrus trees would be established which bore fruits having all the attributes of the variety known as a pineapple orange with the exception of its habit of containing seeds'.[53] In what was to become a pattern that was repeated again and again, intellectual property law makers turned to the physical manifestation of the protected subject matter in order to accommodate the problems created by the peculiarities of the subject matter.

Accepting that breeders (qua scientists) were inventors helped to end the doubts that had arisen about whether the creation of a new plant qualified as a patentable

[52] *Bourne* v. *Jones* (1951, DC Fla) 114 F Supp 413, 98 USPQ 206.

[53] *Dunn* v. *Ragin* v. *Carlile* (Orange Tree) Final Hearing in the US Patent Office; Patent Interference No. 77,764 (6 December 1940).

act of invention. By reconfiguring legal doctrine to accommodate the peculiarities of plant-based subject matter (or at least those rules that drew upon a mechanistic image of invention), intellectual property law makers also ensured that the related doctrinal rules could be applied to plants. While there were exceptions, these changes were successful enough that the question of whether breeders were creative enough to qualify for intellectual property protection did not arise again. The same cannot be said, however, for the way that law makers dealt with the fluid, malleable, and unstable nature of plant-based subject matter, which created an ongoing and in some ways intractable set of problems that the law is still grappling with.

When horticulturists and their supporters appealed to Congress in the early part of the twentieth century to extend intellectual property to plant innovations, they were rebuked and told that protection was not possible – not at least until the way that plants were named was improved. This legal impetus for scientific change prompted the American Joint Committee on Horticultural Nomenclature to standardise the names given to cultivated plants – a process that ultimately resulted in the 1923 publication of *Standardized Plant Names: A Catalogue of Approved Scientific Names of Plants in American Commerce*.[54] While not complete, the list of officially sanctioned plant names was enough to overcome the nomenclatural stumbling block that had greeted breeders when they initially turned to the law for protection. With this problem resolved, intellectual property law makers began to take the possibility of extending protection to plant-based subject matter seriously.

Rather than merely seeing the fluidity of plant-based subject matter as a stumbling block that had to be overcome, intellectual property law makers used this malleability to accommodate the new subject matter. In many ways the law's response to the problems created by the fluidity and malleability of plant-based subject matter was directly tied to the way breeders, scientists, and agricultural agencies interacted with plants: specifically, it was tied to their ability to describe plants and to understand why plants performed in a particular way or why they took on certain characteristics or traits. It was also tied to the extent to which they were able to standardise unruly plants so that they could conform to the demands made by the law of the subject matter. One of the consequences of this was that the scope and ambit of plant-based subject matter was constantly reconfigured across the twentieth century in light of scientific, technical, and regulatory developments that either changed how plants were described and understood or the way they were stabilised and tamed.

Over time a range of different strategies were adopted to deal with the instability and fluidity of plant-based subject matter. In some ways, the simplest and most straightforward response was the decision to exclude sexually reproduced plants

[54] American Joint Committee on Horticultural Nomenclature, *Standardized Plant Names: A Catalogue of Approved Scientific Names of Plants in American Commerce* (Harrisburg: Mount Pleasant Press, 1923).

from the scope of the 1930 *Plant Patent Act*.[55] By limiting protection to unauthorised asexual reproductions of the patented plant, that is to vegetative propagations or clones of the patented plant,[56] the US Congress avoided the problems created by the fact that sexually reproduced plants changed from generation to generation, which made intellectual property protection difficult.[57] The decision to limit plant patent protection to asexually reproducing plants – which was reportedly taken on the advice of various agricultural scientists[58] – provided a 'guarantee that the variety's new characteristics had the genetic (rather than, say, environmental) causes and would prove genetically stable over time'.[59] By separating variations resulting from fluctuations in environmental conditions that were acceptable from variations in the plant that were not, the process of asexual reproduction helped to stabilise the new variety.[60] The fact that protection was limited to asexual clonal reproductions meant that plant inventions, like industrial artefacts, were near-perfect copies of each other.[61]

While in the 1930s sexually reproduced plants were thought to be too unstable to qualify for intellectual property protection, by the 1970s the situation had changed to such an extent that law makers felt comfortable enough to extend intellectual property protection to sexually reproduced plants, which took place when they passed the 1970 *Plant Variety Protection Act*.[62] The concerns that were raised in the 1920s and 1930s about granting intellectual property protection to sexually reproduced plants that were repeated until the 1970s were resolved by a host of interconnected factors. One of the most important was the gradual emergence of scientific breeding, notably the adoption of hybridisation, in-breeding, and pure line breeding.[63] Hand-in-hand with these shifts in breeding practices

[55] John Townsend Jr., 'The Importance of Plant Patents to Agriculture: A Statement by Senator John G. Townsend Jr' (April 1930) 38 *National Nurseryman: For Growers and Dealers in Nursery Stock* 5. Peter Forbes Langrock, 'Plant Patents': Biological Necessities in Infringement Suits' (1959) 41 *Journal of the Patent Office Society* 787.

[56] See *Imazio Nursery* v. *Dania Greenhouses* 69 F 3d 1560 (Fed. Cir. 1995) (plant patent infringement occurs only by actual taking of shoots from the protected plant; a mere showing of genetic similarity between protected and allegedly infringing plants is insufficient).

[57] H Rep 1129 71st Congress 2d Sess (1930), 4; S Rep 315, 71st Congress 2d Sess (1930), 3.

[58] Robert Cook, 'Patents for New Plants' (1932) 27 *The American Mercury* 66.

[59] *JEM AG Supply* v. *Pioneer Hi-Bred International* 534 U.S. 124, 150 (2001).

[60] 'Change the conditions and the plant changes. The Washington navel orange, which is the basis of the Californian orange industry, is practically worthless in Florida. The conditions are different and the plant is different'. Robert Cook, 'Patents for New Plants' (1932) 27 *The American Mercury* 66.

[61] Robert Starr Allyn, 'Patentable Yardsticks' (1943) 25 (11) *Journal of the Patent Office Society* 791, 816. This led commentators to remark that plants protected under the Plant Patent Act 'partake of the nature of manufacture'. John A. Dienner, 'Patents for Biological Specimens and Products' (1953) 35 *Journal of the Patent Office Society* 286, 289–90.

[62] Michael Carolan, 'The Mutability of Biotechnology Patents: From Unwieldy Products of Nature to Independent Object/s' (2010) 27(1) *Theory, Culture & Society* 110.

[63] In *Chakrabarty*, the Supreme Court said that the *Plant Variety Protection Act* was enacted to reflect advances in breeding techniques that made it possible to reproduce new varieties of plants, true-to-type, through seeds. For an overview of different breeding practices see Helen Curry, *Evolution Made*

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were a series of legal and regulatory changes that helped to standardize plant-based subject matter enough for it to qualify for protection. These laws, which form part of the unwritten history of intellectual property law, played an important role in helping to stabilise plant-based subject matter. These included State and Federal seed laws,[64] along with more crop-specific laws such as the Californian *One-Variety Cotton Act* (1925) or the *Fruit, Nut and Vegetable Standardisation Act* (1925). In their own way, these types of laws helped to reinforce and stabilise plant subject matter. The suite of legal schemes that stabilised plant-based subject matter were reinforced by other legal and regulatory schemes, including state quarantine laws (that operated like one-variety laws to control what was farmed in specific regions), the work of organisations such as the Committee of Varietal Standardization within the American Society of Agronomy,[65] the development of type books, improved methods of saving and storing seed, and changes in farming practices. While the requirements of distinctiveness, uniformity, and stability, which are often presented as a cornerstone of plant variety rights protection, played an important role in reinforcing the stability of plant-based subject matter, these legal criteria should not be mistaken for the reason or cause for the stability. Rather, these legal requirements were the beneficiaries of the scientific, agricultural, and (at least from a traditional perspective) non-intellectual property legal developments that took place over the course of the twentieth century that helped to stabilise plants and in so doing ensure that they were eligible for legal protection, 'just like any other modern technology'.[66]

RECONFIGURING INTANGIBLE PROPERTY

In accommodating plant-based subject matter, intellectual property law makers not only changed the way that they configured the process of invention, they also fundamentally changed how the intangible property that lies at the core of intellectual property was conceived. Intangible property plays a key conceptual role in intellectual property law. At its simplest, the intangible is the legal device that connects creators with their creations once they move beyond the sphere of their control (whether legal, physical, technological, economic, or social). Here, the intangible

to Order: Plant Breeding and Technological Innovation in Twentieth-Century America (Chicago: Chicago University Press, 2016).

[64] Seed certification involves the 'use of seed production and processing standards in combination with a system of record keeping, field inspections, and seed inspections to protect the genetic purity and maintain the genetic identity of crop varieties'. The 'Secretary may accept records of … any official seed certifying agency in this country as evidence of stability where applicable'. *Plant Variety Protection Act* 1970, s 52(3).

[65] See Walter A. Davidson and B. E. Clark, 'How We Try to Measure Trueness to Variety' (1961) *Yearbook of Agriculture* 448 (Washington, DC: US Government Printing Office, 1961).

[66] Brief Amicus Curiae of Cargill in support of the respondent, *JEM Ag Supply* v. *Pioneer Hi-Bred International* 2001 WL 674207 (US) No 99, 1996, (15 June 2001), 8.

is the invisible thread that allows the intellectual property owner to control how the protected subject matter is used at a distance. One of the key features of the intangible is that it is inherently flexible; it is able to change and move between different physical forms. Put differently, the intangible is the thing that links a novel to a screenplay, a poem in English to its Spanish translation, an architectural plan to a building, a flowchart to a computer program, or a blueprint of a machine to the machine. In line with this, the intangible is also able to expand to include material manifestations that are similar but not identical to the intangible when it is first materialised. Thus, in some cases intellectual property protection extends to near-copies, look-alikes, and to inventions that are equivalent of each other. As we saw with formula-based organic chemicals, it is also possible for intangible property protection to extend to classes or groups of inventions.

While under traditional accounts of intellectual property the tangible and intangible are inextricably linked, the intangible also has an existence independent from its material form. Thus, copyright will still exist in and continue to control reproductions of a painting that is destroyed by fire (subject to questions of proof). In this context, it does not matter if the physical form of the intangible disappears: the intangible property is able to exist independently from its material form. In patent law, this separation underpins the system of paper-based representation, which presupposes that the invention can be reduced to a written immaterial form and also that it can be recreated materially from that immaterial written form. While this story, or at least a version thereof, holds for many different types of subject matter, it does not work with plants or biological subject matter generally.

For the most part, the way that plant intangible property was construed remained fairly consistent over the twentieth century as protection moved from plant patents to plant variety certificates and eventually to utility patents. One of the most important and enduring characteristics of the intangible property recognised by the law was that it was coextensive with the *plant as a whole*, rather than specific parts of a plant such as fruit, flower, or seed. For example, based upon the practice developed for design patents, plant patent law limited applicants to a single claim that set out the distinguishing characteristics of the plant.[67] While the form of the claim varied, they followed a similar pattern where after linking the claim to 'the plant as described', applicants would highlight the distinct features of the invention. While protection may have indirectly covered the novel and commercially valuable parts of a plant (such as a new flower), the intangible interest was framed in such a way

[67] Each 'plant patent has a single claim directed to the disclosed plant. One cannot claim a genus or group of plants or any part of a plant' (generic protection is thus not available). A. Diepenbrock, C. Neagley and D. Jefferey, 'Section 101 Plant Patents: Panacea of Pitfall' (1983) 1(2) *Selected Legal Papers (American Intellectual Property Law Association)* A-1, A-10. Under the Design Act, the design had to be 'a *finished* and *completed* thing – must be one entire and integral thing'. Amos W. Hart, *Digests of Decisions of Law and Practice in the Patent Office and the United States and State Courts in Patents, Trade-Marks, Copyrights, and Labels* (Chicago: Callaghan and Company, 1898), 83.

that it covered all of the plant. As the law expanded to include sexually reproduced plants (with the passage of the 1970 *Plant Variety Protection Act*), the intangible interest continued to be treated as if it was coextensive with the whole plant.[68] This was also often the case when utility patent protection was extended to plant-based subject matter in the 1980s.[69]

Another characteristic of the plant intangible property recognised by intellectual property law, which was a consequence of the way that plants were understood scientifically, was that the intangible property was limited to the *external surface* of the protected plant.[70] In more technical terms, protection was limited to the phenotypical traits and characteristics rather than to the underlying reasons for or causes of these characteristics. While it was recognised that 'varietal characteristics were caused by the genetic complements of the cells', the secretive nature of plant-based subject matter meant that it 'was impossible to determine the genetic constitution by examination of the cells'. As a result, protection was limited to a plant's external traits and characteristics.

A third feature of the plant-based intangible property recognised by intellectual property law was that it was limited to *individual plants* rather than to more abstract groupings such as a genus or species of plants. Whether under plant patent law, where protection was limited to individual plants and their asexually reproduced progeny[71] or plant variety protection law, where protection was limited to specific varieties of plants, plant intellectual property only operated at the level of the individual plant. Interestingly, although people seeking utility patent protection for plant-based subject matter had the opportunity to decide for themselves the form that they wanted the intangible to take, plant-based utility patents were often framed in such a way that the intangible property was limited to individual plants (at least initially).

The upshot of this was that in accommodating the peculiarities of plant-based subject matter, the plant intangible property recognised by intellectual property law was configured so as to coincide with the external features of individual plants.[72] While the treatment of the plant intangible as if it coincided with the external surface of individual plants was accepted without question for most of the twentieth century, a notable exception was plant patent number 141 which was granted to David Burpee in 1935 for a new type of nasturtium with a mass of very large double flowers, a 'super-double nasturtium'[73] which David Burpee christened *Tropaeolum majus Burpeeii* (see Figure 8.3).

[68] While the 1970 *Plant Variety Protection Act* extended to 'plant groupings', this was a population of individuals.

[69] For discussion see *JEM AG Supply* v. *Pioneer Hi-Bred International* 534 U.S. 124 (2001).

[70] I discuss the shift below the surface to molecular level innovations in the next chapter.

[71] *Imazio Nursery* v. *Dania Greenhouses* 69 F.3d 1560, 1567 (1995).

[72] *Kim Bros.* v. *Hagler* 167 F. Supp 665, 120 USPQ 210 (SD Cal 1958).

[73] A double flower is a flower that has extra petals, sometimes described as a flower within a flower.

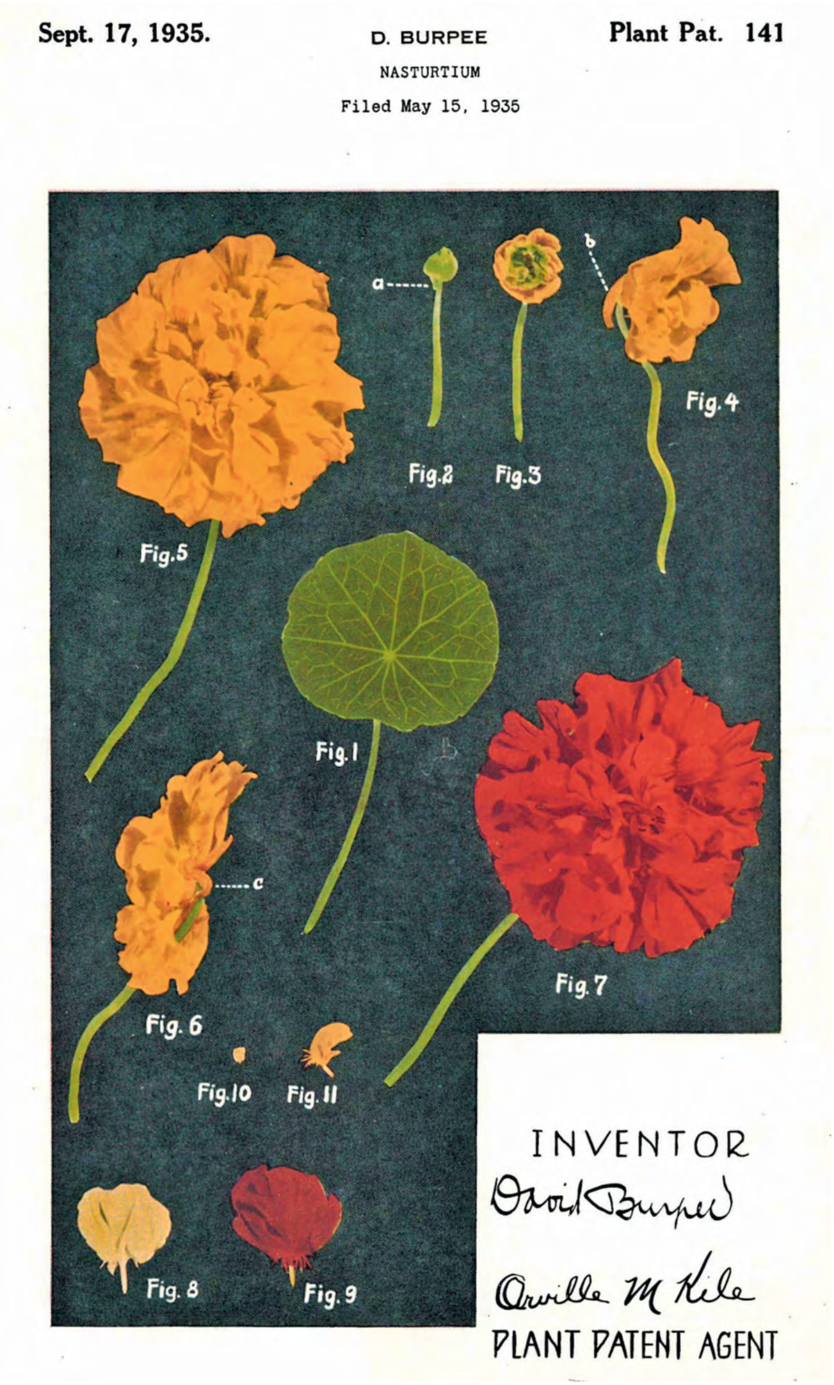

FIGURE 8.3 Super-double nasturtium
David Burpee, 'Nasturtium' US Plant Patent No. 141 (17 Sept 1935). Courtesy of the National Archives at Kansas City.

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The super-double nasturtium had been discovered in a greenhouse on a Burpee company farm in Pennsylvania growing among several thousand experimental double nasturtiums. Working with the new discovery, breeders at Burpee found that it was 'very simple by crosses and back-crosses with ordinary nasturtiums to produce numerous colours and other variations all possessing this peculiar type of flower'. As the common garden nasturtium had at least twelve distinct flower colours, three chlorophyll intensities, three leaf shapes, and four habits of growth, and that any combination of these elements could be combined with the super-double flower by making the proper crosses to make new super-double nasturtiums, it was found that 'no less than four hundred and thirty-two distinct clonal varieties' of the super-double nasturtium were 'within the realm of possibility'.[74] In this situation, Burpee was faced with the option of either taking out four hundred and thirty-two separate plant patents, or trying to obtain a single patent that covered all of the different variations. Given the cost of a patent application, Burpee opted for the latter option. He did this by drafting his application so that it claimed *any* nasturtium whose flower form was covered by the description regardless of colour, habit of growth, or other plant characteristics.[75] As the plant patent said, the claim was to the 'variety or genetic type of nasturtium (*Tropaeolum majus*) herein described and illustrated, characterised particularly by its vigorous stocky vegetative growth and the unusually large size and complete doubleness of its flowers'. While in the descriptive portion of the patent Burpee spoke of the different colours and forms that the super-double nasturtium could take, he did not refer to the colour of the flower in the claim. As a result, plant patent number 141, which Burpee called a 'basic patent', was broad enough to cover all of the different forms that the super-double nasturtium might have taken.[76]

While it had been suggested that the patent was commercially unimportant given that the super-double nasturtium was a 'mere oddity bound for the horticultural graveyard after a season or two of prominence as the result of extensive publicity', nonetheless it was legally important in so far as it raised the question of whether plant patents were limited to specific, singular clonal varieties (such as the Super-Double Scarlet Giant in Figure 8.4) or whether they extended to broad patent claims (as was allowed with mechanical inventions and chemical patents that used structural formula).[77] While David Burpee and one or two supporters favoured basic plant patents (primarily because it made commercial sense to allow applicants to take out one broad patent rather than a series of near identical patents), basic patents and with them plant patent number 141 came to treated as

74 Keith C. Barrons, 'A Defense of Basic Plant Patents' (1936) 27 *The Journal of Heredity* 475, 477. Barrons was employed as a plant breeder at Watlee Burpee until June 1936, where he worked on the double and super-double nasturtium. Ibid., 476 n.

75 Ibid.

76 M. J. Dorsey, Letter to Editor, 'What Is a "Basic Plant Patent"?' (1936) 27 *The Journal of Heredity* 213.

77 Keith C. Barrons, 'A Defense of Basic Plant Patents' (1936) 27 *The Journal of Heredity* 475, 477.

FIGURE 8.4 Advertisement for Burpee's patented super-double nasturtiums W. Atlee Burpee, *Burpee's Seeds Grow: Burpee's Annual Garden Book* (W. Atlee Burpee Co, 1935). Courtesy of Biodiversity Heritage Library.

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aberrations, as it quickly became clear that plant patent protection was limited to individual plants and their asexually reproduced progeny.[78] The chief reason for this was that unless plant patents were limited to specific clonal lines, the law would have been too difficult to enforce.

While plant patent number 141 was an aberration, it is nonetheless still important in so far as it highlighted the nature of the plant-based intangible recognised by intellectual property law. Specifically, it highlighted the fact that for much of the twentieth century the intangible property recognised by intellectual property law was treated like a legal hologram of the physical plant; it was treated, in effect, as if it was a virtual plant. As the editor of the *Journal of Heredity*, Robert Cook said, a plant patent was a bio-legal hybrid: 'a biological entity rather than a verbal abstraction outlined with doubtful completeness in the specification and almost defying exact definition'.[79]

Limiting protection to the external surface of individual plants played an important role in allowing intellectual property law to accommodate plant-based subject matter. By focusing on the plant as a whole, intellectual property law makers were not only able to answer the preliminary question of what the subject matter was and how it was to be construed, they also ensured that they did not need to make difficult decisions about how individual parts related to the whole or where parts started and ended. Instead, the law could simply focus on the plant as a whole and leave it up to others to dissect the plant into parts. In this sense, the focus on the plant as a whole helped to resolve some of the issues created by the fluid and uncertain nature of plant-based subject matter. The legal focus on the external phenotypical aspects of plants also helped the law to overcome some of the problems created by the secretive nature of plant innovation which meant that breeders, scientists, and farmers were unable to explain the reasons why biological change had taken place.

While thinking of the plant-based intangible recognised by the law as if it was a virtual plant is helpful, it only tells us part of the story. This is because it does not reveal one of key ways that the intangible was reconfigured in adapting the law to accommodate plant-based subject matter. Unlike with mechanical subject matter, where the intangible property is able to be separated from its material manifestation, with plant-based subject matter the intangible and tangible are unable to be separated or decoupled from each other; one cannot exist without the other. While copyright allows for photographs of a painting destroyed by fire to be controlled by the

[78] *Imazio Nursery* v. *Dania Greenhouses* 69 F.3d 1560, 1567 (1995). In relation to Burpee's invention, this meant that protection should have been limited to super-double nasturtiums of a specific colour, shape and form (and their clonal copies), rather than to some more abstract and less specific class of plants. Protection of a single plant meant that protection was 'not capable of being extended to cover an entire class of morphological types in a given species' such as all colours known to occur' in a species. Editor (Cook), 'What is a "Basic Plant Patent"?' (1936) *The Journal of Heredity* 213, 215. See William H. Eyster and David Burpee, 'Inheritance of Doubleness in the Flowers of the Nasturtium' (1936) *The Journal of Heredity* 51.

[79] Robert Cook, 'Plant Patent 110 Declared Invalid' (1936) *The Journal of Heredity* 475.

copyright in the (now non-existent) painting, the fused nature of plant-based subject matter means that if the material form of a plant disappears, the intangible does as well. The material nature of plant-based subject matter was expressed in the principle that the rights only persisted so long as the material objects survived or remained identifiable.[80] As Smith J. said in *Le Grice*, if a 'plant variety should become extinct one cannot deliberately produce a duplicate even though its ancestry and the techniques of cross-pollination are known'.[81]

In dealing with plant-based subject matter intellectual property law effectively wears its intangible heart on its sleeve: the 'intangible' property is always visible as the external surface of the protected plant. With plant-based subject matter, there is nothing below the surface to be found, nothing to be traced or interpreted; what you see is what you get. At the same time, the intangible was also unable to stretch to cover plants that were similar to the protected plant nor to more abstract groups or classes of plants: the plant intangible property was limited to and coextensive with the external characteristics of the protected material plant. In this sense, the plant-based intangible property was treated as if it was coextensive with its tangible instantiation or form. The ability of the tangible plant to function as an intangible was reinforced by the fact that the physical property has the intangible-like ability to reproduce itself and with it the intangible property that is carried with it.

Because the intangible effectively disappears or at least is always on show when the physical plant is present, it does not make sense to talk of an intangible being materialised or of an immaterial idea or concept taking a material form. In some ways, it does not make sense to talk of intangible property at all in relation to plant-based subject matter (or at least in the way it is ordinarily understood). Rather, it is better to talk about the plant in its material physical form as an end in its own right.

Intellectual property law's reliance on the physical plant as an end in its own right is evident in the way the law decided when a plant invention came into existence (for the purposes of deciding who was first to invent) and in the way infringement was determined (it was necessary to show that there had been a physical appropriation of the protected plant[82]). Another example of the role that the physical

[80] Alain Pottage, 'Literary Materiality' in (ed) Andreas Philippopoulos-Mihalopoulos, *Routledge Handbook of Law and Theory* (New York: Routledge, 2018), 409, 412.

[81] In contrast, however, '[m]anufactured articles, processes, and chemical compounds when disclosed are, however, susceptible to man-made duplication'. *In re LeGrice* 310 F.2d 929, 939 (CCPA 1962). 1132. *Imazio Nursery* v. *Dania Greenhouses* 69 F.3d 1560, 1569–70 (Fed. Cir. 1995). 'The court noted that there are inherent differences between plants and manufactured articles, observing … that should a plant variety become extinct, one cannot deliberately produce a duplicate even though its ancestry and the techniques of cross-pollination be known'. *Application of Le Grice* (1962) 49 CCPA 1124, 301 F.2d 929, 133 USPQ 365.

[82] Peter Forbes Langrock, 'Plant Patents: Biological Necessities in Infringement Suits' (1959) *Journal of Patent Office Society* 787, 788. The requirement of asexual reproduction was interpreted to mean that infringement was dependent on a plaintiff bringing evidence that the defendant's plant was derived from the patented plant. See, for example, *Yoder Bros.* v. *California-Florida Plant Corp* 537 F.2d 1347, 1380 (5th Cir 1976).

manifestation of the plant intangible played in intellectual property law can be seen in the 1970 *Plant Variety Protection Act*, which requires applicants to submit 2,500 viable seeds of the protected variety to the National Seed Storage Laboratory at Fort Collins, Colorado, as part of the application process.[83] In some cases, applicants are also required to submit physical specimens of their plants to allow examiners to test the claims made in their applications.[84] As well as being used to test the veracity and accuracy of the claims made in an application,[85] deposited samples also play a role in preserving the viability of the variety[86] and in ensuring, in the words of the American Seed Trade Association, that 'the variety will continue to be available to the public even when it is no longer protected and whether or not the former proprietor continues to produce it'.[87]

While users of the utility patent system have never had the same legal imperative to deposit a material specimen as is mandated under the plant variety protection regime, nonetheless since the first plant-based utility patents were issued in the 1980s, patentees have voluntarily deposited material samples of their plant inventions with approved public depositaries, such as the American Type Culture Collection (ATCC). For example, Pioneer Hi-Breds 1992 patent for an inbred corn line claimed 'Inbred corn seed designated PHP38 having ATCC accession No 75612'.[88] As well as being used to test the claims made in a patent, voluntary deposit in a public depositary, which were endorsed by the Patent Office, allowed patentees to satisfy the requirement of enabling disclosure; that is, the rule that in return for being granted protection over the patented subject matter, applicants were required to ensure that the invention was placed in the hands of the public. The problem patent applicants faced was that while mechanical inventions are able to be replicated

83 Applicants were under an obligation to replenish the seed sample if germination rate falls below 85%. Janice M. Strachan, 'Plant Variety Protection in the USA' in (ed) F. H. Erbisch and K. M. Maredia, *Intellectual Property Rights in Agricultural Biotechnology* (2nd edn, Cambridge, MA: CABI Publishing, 2004), 73, 80.

84 In other cases, applicants were required to 'furnish representative specimens of the variety or its flower, fruit or seeds, in a quantity and specified stage of growth, as may be necessary to verify the statements in the application'. It was also possible for applicants to ask examiners to inspect plants in the field so long as they paid all associated costs. Department of Agriculture, Agriculture Marketing Service, 'Plant Variety Protection: Notice of Proposed Rule Making' (18 April 1972) 37(75) *Federal Register* 7673 ('specimen requirements').

85 The Plant Variety Protection Office sometimes used seed samples to check for correct values about seed sizes and colours and 'we have found some mistakes by doing this'. Janice M. Strachan, 'Plant Variety Protection in the USA' in (ed) F. H. Erbisch and K. M. Maredia, *Intellectual Property Rights in Agricultural Biotechnology* (2nd edn, Cambridge, MA: CABI Publishing, 2004), 73, 80.

86 Plant Variety Protection Act Amendments; Hearings on HR 99 before the Subcomm on Department Investigations, Oversight and Research of the H Committee on Agriculture. 96th Congress 83 (1980) (statement of Bernard M. Leese, Commissioner Plant Variety Protection).

87 Hearings before the subcommittee om Agricultural Research and General Legislation of the Committee on Agriculture, Nutrition, and Forestry: United States Senate, Ninety-First Congress, Second Session on S 3070 11 June 1970, 58 (statement by Allenby L. White, Chairman, Breeders; Rights Study Committee, American Seed Trade Association).

88 Pioneer Hi-Bred, 'Inbred Corn Line PHP38', US Patent No. 5,506,367 (9 April 1996).

from a written form (the patent), the secretive nature of plant innovation meant that this was not possible with plant-based subject matter. Applicants responded to this problem by turning their attention to the physical plant as a material instantiation of the intangible. By depositing the res, the plant itself, in a publicly accessible collection and by listing the location of the depositary in the patent application, patentees ensured that the invention was publicly available and thus that they had made an enabling disclosure.[89]

As well ensuring that the public has access to the patented plant, deposited samples also functioned like a type specimen to set out and define the scope of the plant intangible. According to an examiner at the Plant Variety Protection Office, if a 'question ever arises about the characteristics of a variety that has [plant variety protection], we go to the voucher specimen and confirm the variety's characteristics through a grow-out trial or genetic fingerprinting'.[90] The reason for this was that 'the voucher seed sample is the most complete description of the variety'.[91] As a result, samples of biological material did not merely verify an application for protection: 'in a very meaningful sense, they affirmatively represent the plant breeder's disclosure of its invention'.[92]

While the written description of the plant in the intellectual property documentation is important, it is secondary to the deposited materials, which were treated as the primary, original, authentic, and permanent record of the intangible. In this sense it could be said that deposited physical samples created a particular way of representing the intangible. In a form of 'metaphysics in action', the deposited sample not only stood in for the intangible, it also created a platform that ensured that protected plants were able to be identified, defined, and demarcated. The fact that protection could not exceed the deposited materials also reinforced the correlation of the plant-based intangible to individual plants.[93]

This understanding of the role played by the deposit of physical material is premised on a series of socio-legal assumptions about what the law does and the impact it has on how plants and people behave. There are a number of reasons why we

89 USPTO, *Manual of Patent Examining Procedure* s 2404 (7th edn, July 1998).

90 This type of confirmation was 'needed in an infringement case, where the sample was supplied to a third party under court subpoena. It was also needed when a certificate holder 'wanted to change the varietal description and needed to demonstrate that the change was retroactively accurate'. Janice M. Strachan, 'Plant Variety Protection in the USA' in (ed) F. H. Erbisch and K. M. Maredia, *Intellectual Property Rights in Agricultural Biotechnology* (2nd edn, Cambridge, MA: CABI Publishing, 2004), 73, 81.

91 Janice M. Strachan, 'Plant Variety Protection in the USA' in (ed) F. H. Erbisch and K. M. Maredia, *Intellectual Property Rights in Agricultural Biotechnology* (2nd edn, Cambridge, MA: CABI Publishing, 2004), 73, 84.

92 Jim Chen, 'The Parable of the Seeds: Interpreting the Plant Variety Protection Act in Furtherance of Innovation Policy' (2005) 81 *Notre Dame Law Review* 105, 147.

93 '[V]ariety claims shall not be permitted to exceed the deposited materials. That is, while multiple varieties may be protected with a single application, a deposit will be required for each variety claimed'. William Lesser, 'The Impacts of Seed Patents' (1987) 9(1) *North Central Journal of Agricultural Economics* 37, 42.

should question this. While examiners use plant material during the examination process to test the accuracy of the claims, once protection has been granted deposited specimens are rarely used. With some exceptions, there is little evidence that the Plant Variety Office or the Patent Office make much use of deposited samples once an application has successfully made its way through the examination process. While the courts sometimes remind us that deposited samples allow patentees to make an enabling disclosure, there is little to suggest that they are used more generally. They certainly don't appear often (if at all) in litigation, at least to set the parameters of the intangible property. What then are we to make of the deposited sample beyond its limited role in the examination process?

One option is that rather than seeing the deposit of plant material as creating an objective standard that grounds and defines the intangible, it is perhaps better seen as a theoretical mechanism that helps to generate trust in the efficacy of the registration process specifically and the legal system more generally. It could be said that deposit of specimens creates trust by completing the logic of intellectual property law. As with nineteenth-century organic chemicals, it could be suggested that because examiners are able to interrogate the physical material, they have access to information that is not otherwise available from the written description. As a result, deposit of physical material allows examiners to evaluate plant-based subject matter properly. One of the consequences of this is that it increases public trust in the legitimacy of the intellectual property protection granted over plant-based subject matter.

While there is some strength in this argument, the idea that the deposit of plant material operates to complete the logic of the intellectual property system and thus generates public trust in its operation needs to be questioned. The reason for this is that it presumes that members of the public not only know about the deposit system but also understand where and how it fits within the intellectual property system. Given the lack of attention that experts in the field have given to the topic, it is safe to presume that public knowledge about the deposit of plant material is minimal.

Given this, what are we to make of the suggestion that deposited samples not only stood in for the intangible but that they also created a platform or standard by which protected plants were identified, defined, and demarcated? This way of thinking about deposit is underpinned by a temporal assumption about the deposited physical material and its relationship to the intangible. Specially, it presumes that the deposited tangible material is not only prior in time, but that it also acts as the foundation that grounds, demarcates, and defines the plant intangible. Given the doubts that exist about the extent to which deposited material is used post-grant, what does this mean for how plant-intangible property is construed?

While the idea that deposited material acts as the foundation of the intangible property may provide a sense of trust in the ability of the patent system to work for those few who know or care about it, it is possible that we are looking in the wrong direction. Rather than looking backwards to deposited plant materials for the a priori foundations of legal property, perhaps it is better to change direction and look forward to the plant that is marketed and sold under the imprimatur of legal protection. In this case, the marketed (named) plant becomes the reference point for determining the intangible property.[94] Whether connected by a scientific name, a trademark, an advertisement proclaiming that the plant is protected (see Figure 8.4), or the stamp of an official seed certifying agency, the end-result is the same; in a self-fulfilling act, the seed or plant purchased by the farmer, gardener, or breeder is the intangible. While there was always the potential for this to be challenged and the accuracy of the way a protected plant was described to be tested against the foundational deposit, this rarely, if ever, occurred. At best, it was simply presumed that the plant being sold was the same as the plant that had been deposited; at worst, there was no thought given whatsoever to the deposited material. It simply does not enter into consideration.[95]

INFORMED SUBJECT MATTER

One of the explanations often given for why plant-based subject matter was initially not protected by intellectual property was that breeders lacked the ability to describe their inventions in a way that would have allowed the intangible to be identified, demarcated, and distinguished. As the Supreme Court explained in *Chakrabarty*, one of the reasons why plants were thought to be unpatentable for so long was that they were not amenable to the written description requirement that demands that the patent 'contain a written description of the invention … [in] clear, concise, and exact terms'.[96] Underpinning this argument was a particular way of thinking both about plant breeding and also about the type of expertise needed to satisfy intellectual property law's written description requirement.

While by the 1930s breeders may have been recast as scientists for the purpose of deciding whether they were inventors and thus within the scope of patent law, it seems that this new-found scientific status did not extend to include their ability to describe their inventions in a way that satisfied the requirements of patent law. Instead, breeders were still largely seen as artisanal dabblers, as non-scientific amateurs who were not only unable to access the underlying cause or reason for the botanical innovation and as such were forced to work backwards from the end-results; they also lacked the skills to describe the end-product with the precision

94 Prior public use and sale of a plant are the avenues by which a plant enters the public domain'. *In re Le Grice* 310 F.2d 929, 939 (CCPA 1962).

95 The way that a plant patent advances the public purpose is 'by making it profitable for the developer to make as wide a distribution as possible of the res, the plant itself. If the variety is deserving, hundreds of specimens are likely to be widely distributed, thereby reducing the danger of their perishing in a common disaster. The likelihood of extinction of the res before an improved variety or worthy successor is developed is thus rendered remote. Publicity informs the public where specimens exist'. *In re Le Grice* 310 F.2d 929, 939 (CCPA 1962), 1133.

96 *Diamond* v. *Chakrabarty* 447 U.S. 303, 311 (1980).

demanded by intellectual property law. When discussing the then new 1930 *Plant Patent Act*, a commentator sarcastically asked: 'How do you describe in words what a violet smells like or a Jonathan apple tastes like?'[97] 'Pray tell me, what does an onion taste like? Please describe the odour of the rose[98] which you purchased on the 15th day of June 1932? … The possibilities of humour as to the "flowers that bloom in spring" are quite unlimited'.[99]

Accompanying these arguments was a belief that breeders would only really be in a position to describe their creations in a way that satisfied the requirements of intellectual property law when they were able to access the hidden interior of plant subject matter: the plant genome that contained the information that was needed to build and maintain that plant. In short, intellectual property protection would only be feasible when breeders were able to describe plants genetically. Until breeders were able to access the 'discrete, objective code within the plant itself',[100] any legal protection provided to plant-based subject matter would either be, as in the case of plant variety protection, inferior to the protection offered to other types of subject matter or, as in the case of plant patents, only possible because Congress was willing to lower its standards to create a special exception for plants (which occurred in 1930 when Congress relaxed patent law's written description requirement so that breeders only had to provide 'a description … as complete as is reasonably possible'.[101])

Faced with the prospect that plant breeders were unable to meet the demands of intellectual property law, judges sometimes fantasied about a time when science would intervene to allow plant-based subject matter to be treated on the same footing as manufactured articles. As Judge Smith wrote in 1962 decision of *Le Grice*, it was necessary to be 'mindful of the scientific efforts which are daily adding to the store of knowledge in the fields of plant heredity and plant eugenics which one skilled in this art will be presumed to possess'.[102] More specifically, Smith J. raised the possibility that '[c]urrent studies to "break the chromosome code" may also add to the knowledge of plant breeders so that they may someday secure possession of a plant invention by a description in a printed publication as is now possible in other fields of inventive effort'.[103] The image of the enthusiastic but amateurish breeder who was waiting to be saved by the wonders of modern genomics not only shaped the way that the future of plant-based intellectual property was imagined, it also

[97] Joseph Rossman, 'Plant Patents' (1931) *Journal of the Patent Office Society* 7, 15.

[98] Robert Starr Allyn, *The First Plant Patents: A Discussion on the New Law and Patent Office Practice* (Brooklyn, NY: Corsi Press, 1944), 46.

[99] Robert Starr Allyn, 'Plant Patent Queries' (1933) *Journal of the Patent Office Society* 180, 185.

[100] Brief Amicus Curiae of Cargill in support of the respondent, *JEM Ag Supply* v. *Pioneer Hi-Bred International* 2001 WL 674207 (US) No 99, 1996, (15 June 2001), 9.

[101] On this basis the Plant Patent Act was 'experimental' (Anon, 'Plant Patent Criticisms and Suggestions' (1934) *Journal of the Patent Office Society* 184) and 'embryonic' (D. H. Sweet, 'Disclosure in Plant Patents' (1934) *Journal of the Patent Office Society* 61).

[102] *Application of Le Grice* 301 F.2d 929, 939 (CCPA 1962).

[103] Ibid., 939 n 7.

shaped the way that the history of that interaction was told. As Monsanto said in its 1996 amicus curia submission to *JEM Ag Supply* v. *Pioneer*, 'plant inventors' were only able 'to describe and distinguish new varieties in a manner to satisfy the statutory requirements for utility patents' as result of 'scientific advances in new fields such as genetic mapping and gene fingerprinting'.[104]

While there is no doubt that the breeder's ability to describe their inventions improved over the course of the twentieth century and that advances in genomics played an important role in facilitating this, this way of thinking misses an important feature of plant-based subject matter that facilitated its eventual inclusion within intellectual property law, namely that across the twentieth century, plant breeders developed an increasingly sophisticated and effective range of techniques to describe and identify plants. This included the standardisation of naming practices, a growing agreement about how plants were classified and ordered, and the development and adoption of species-specific criteria to describe plant traits and characteristics (including the development of identification-aids such as colour charts to describe flower or leaf colour).[105]

Importantly, the various techniques and practices that breeders developed across the twentieth century to describe plants and the information that this generated was not something that was external to the plant subject matter. Rather, just as with chemical compounds, plant subject matter was an informed material that was constituted in relation to the informational and material environments in which it was generated. Importantly, this environment was not something that was external to the subject matter. Instead, the environment entered into the constitution of the plant: it was folded into and became part of the subject matter.[106] One of the consequences of seeing plant subject matter as informed material rather than as discrete material that is isolated from the environment in which it was created is that it reminds us that by the time that plant subject matter is presented to the law for registration, it will already have been subject to an array of tests and trials that generate a wealth of information; including how and where the plant grows, its shape and form, the length of its leaves, the colour of its flowers, the shape of its stamen, and so on.[107]

[104] Brief Amicus Curiae of Monsanto Company in support of the respondent, *JEM Ag Supply* v. *Pioneer Hi-Bred International* 2001 WL 674207 (US) No 99, 1996, (15 June 2001), 9.

[105] 'Colour differences should be reference with a standard such as the Munsell Book of Color or Royal Horticultural Society Colour Chart'. Janice M. Strachan, 'Plant Variety Protection in the USA' in (ed) F. H. Erbisch and K. M. Maredia, *Intellectual Property Rights in Agricultural Biotechnology* (2nd edn, Cambridge, MA: CABI Publishing, 2004), 73, 83.

[106] When the Plant Variety Protection Act was first passed, the Plant Variety Protection Office provided a list of around 500 descriptors for each class of plant. By 1979 the Office had computerised over 14,000 plant variety descriptions of 79 crops. House Committee on Agriculture, Subcommittee on Department Investigations, *Oversight and Research Hearings on the Plant Variety Protection Act Amendments* 96th Congress, 1st and 2nd Sess, 19 July 1972, 22 April 1980, 13.

[107] For example, where colour was claimed, it was necessary for the drawings to be as accurate and permanent as possible according to a recognised standard such as Ridgeway's Colour Chart, Maerz and Paul's Dictionary of Color, or Windsor & Newton's Specimen Tints of Artists Colours. Raymond

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The new plant will also have been classified, ordered, and given a taxonomic name that ties the named plant to its founding description and a type specimen that materially grounds the description. Drawing upon detailed rules, procedures, and guidelines that govern how the plant subject matter is described and named, the plant will not only be described in detail but also in a way that allows third parties to identify and differentiate it from similar plants at a distance.

While the format used to describe new plants differs depending on the type of legal protection used, plant patents, plant variety protection, and utility patents all tended to include similar information. As well as providing an historical account of the development of the new plant (including information on how the plant was bred, where the sport, bud, or mutation was found, or details of the parent plants), applicants also included information on how the plant differed from similar plants and detailed descriptive information about the characteristics of the plant.[108] Using a comparator variety (which was the variety most similar to the applicant variety) as the base line (and by default other taxonomically related varieties), applicants would simultaneously situate the applicant variety within the botanical order of things and, at the same time, evidence the novelty of the applicant variety by showing how the applicant plant differed from its closest comparator. For example, a 1974 plant variety certificate for a variety of onion known as 'Scanion' included a brief account of the genealogy and breeding history of the variety,[109] details of how the seed of Scanion differed from its closest comparator variety (Southport White Globe), and an objective description of the new variety that included information on growth times and the shape and size of the plant.[110]

The information embodied within the (informed) plant-based subject matter played an important role in allowing intellectual property law to accommodate some of the peculiarities of the subject matter. Specifically, in so far as the information that was folded into the subject matter allowed plant intangible property to be identified, demarcated, distinguished, and defined, it helped the law to deal with the fluid and malleable nature of plant-based subject matter. As well as explaining

Magnuson, 'A Short Discussion on Various Aspects of Plant Patents' (1948) 30(7) *Journal of the Patent Office Society* 493, 504. The colour charts were 'commercially manufactured sets of cards, much like paint-sample cards that breeders held against a plant to identify and match a name to its colours. Daniel Kevles, 'A History of Patenting Life in the United States with Comparative Attention to Europe and Canada' (12 January 2002) *Report to the European Group on Ethics in Science and New Technologies*, 11.

[108] Plant variety protection applicants were required to provide an 'Objective Description of the variety' using forms created by the Plant Variety Protection Office–to 'standardize a complete botanical description of the variety' and to determine differences between varieties. Janice M. Strachan, 'Plant Variety Protection in the USA' in (ed) F. H. Erbisch and K. M. Maredia, *Intellectual Property Rights in Agricultural Biotechnology* (2nd edn, Cambridge, MA: CABI Publishing, 2004), 73, 80.

[109] Section 52(2) Plant Variety Protection Act (1970). USPTO Section 160. *Patent Office Manual of Patent Examining Procedure* (9th Edition, Revision 10.2019).

[110] Keystone Seed Company, 'Onion Variety "Scanion"' PVP Certificate No. 7300001 (15 November 1972).

how the law dealt with some of the peculiarities of the subject matter, recognising the expertise and skill that breeders exercised in describing plants, along with the way this was folded into and became part of the subject matter, also helps to explain why there are comparatively few (formal) legal disputes about plant intellectual property. The reason being that many of the potential problems that might spill over into the legal arena (such as questions of the novelty of a plant or whether a plant is described in such a way that it can be demarcated and identified) are resolved scientifically in greenhouses, laboratories, and fields prior to the subject matter being presented to the law for scrutiny.

9

Molecular Subject Matter

TOWARDS A MOLECULARISED SUBJECT MATTER

The early twentieth century saw a number of changes in the way natural phenomena were investigated that had important ramifications for plant-based subject matter. Of particular importance was the emerging field of transmission studies, labelled genetics by Bateson in 1906,[1] which was concerned with the study of the 'units that were assumed to be strung together along the length of the chromosomes and that had the capacity to guide the formation of individual traits'.[2] At the heart of the new discipline was a new entity: the *gene* (a term first coined by Wilhelm Johannsen in 1909).[3] Over time the gene came to operate, like atoms in physics and molecules in chemistry, as the fundamental unit of biological explanation. As Rheinberger and Müller-Wille said, from the early twentieth century onwards the gene 'became central to all main branches of the life sciences and promoted unprecedented visions of controlling and directing life'.[4]

Despite the prominent role that the gene played in classical genetics, because the experimental systems were 'ill-suited for providing insights into the material molecular basis of genetic phenomena',[5] scientists had no real idea of what genes were nor what they did. As a result, the classical gene remained a largely theoretical concept that had to be inferred from external phenotypic variants, which were treated as

1 Hans-Jörg Rheinberger and Staffan Müller-Wille, *The Gene from Genetics to Postgenomics* (Chicago: University of Chicago Press, 2017), 12.

2 Hans-Jörg Rheinberger, 'Gene Concepts Fragments from the Perspective of Molecular Biology' in (ed) P. Beurton, R. Falk, and H. Rheinberger, *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2000), 219, 220–21.

3 The new discipline distinguished 'between genetic units and unit characters, taken in their entirety, between genotype and phenotype, respectively'. In 1909 Wilhelm Johannsen 'codified this distinction … by introducing the notions of *genotype* and *phenotype*, respectively, for these two spaces'. Ibid.

4 Hans-Jörg Rheinberger and Staffan Müller-Wille, *The Gene from Genetics to Postgenomics* (Chicago: University of Chicago Press, 2017), 1.

5 Ibid., 59.

indicators or windows into the genotype.[6] With no consensus as to whether genes were real or fictitious, genes were taken as abstract elements of an equally abstract space; they were hypothetical factors responsible for external phenotypic differences between organisms (such as the gene for white flowers in peas).

While classical genetics made many important discoveries,[7] it left many things unanswered including questions 'about the make-up of genes, the mechanism of gene replication, what genes do, and the way that genes bring about phenotypic differences'.[8] The situation began to change, however, with the molecularisation of genetics that began in the middle of the twentieth century.[9] A key feature of the new biology that took shape in the 1960s was that it was couched in terms of molecular level phenomena. The resulting molecularisation of biology fundamentally changed the way the gene and, with it, biology were seen. It also had an important impact on the way patent law interacted with biological subject matter.

There were two features of the molecular gene that distinguished it from the gene of classical genetics. The first related to the fact that by the middle of the twentieth century the gene was no longer seen as a quasi-mythical entity.[10] Instead, it had come to be recognised as a material chemical molecule made up of deoxyribonucleic acid (DNA).[11] That is, the gene was transformed from an abstract idea inferred from external phenotypic variants into a real physical chemical entity.[12] The second distinguishing feature of the molecular gene relates to its function. Unlike the gene of classical genetics, which was seen as a theoretical abstract entity that controlled an aspect of the phenotype, the molecular gene was reconceptualised as a carrier of

[6] Given that scientists in the first half of the twentieth century were unable to access the material nature of genes, the nature and existence of the classical gene had to be inferred from external phenotypic variants. Laurence Perbal, 'The Case of the Gene: Postgenomics between Modernity and Postmodernity' (2015) 16(7) *EMBO Reports* 777.

[7] Hans-Jörg Rheinberger and Staffan Müller-Wille, *The Gene from Genetics to Postgenomics* (Chicago: University of Chicago Press, 2017), 7.

[8] Hans-Jörg Rheinberger, 'Gene Concepts Fragments from the Perspective of Molecular Biology' in (ed) P. Beurton, R. Falk, and H. Rheinberger, *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2000), 219; citing Muller who said in 1951: '[T]he real core of gene theory still appears to lie in the deep unknown. That is, we have as yet no actual knowledge of the mechanism underlying that unique property which makes a gene a gene – its ability to cause the synthesis of another structure like itself … in which even the mutations of the original gene are copied … We do not know of such things yet in chemistry.'

[9] Hans-Jörg Rheinberger and Staffan Müller-Wille, *The Gene from Genetics to Postgenomics* (Chicago: University of Chicago Press, 2017), 7. See also Michel Morange, *The Black Box of Biology: A History of the Molecular Revolution* (Cambridge, MA: Harvard University Press, 2020).

[10] Hans-Jörg Rheinberger and Staffan Müller-Wille, *The Gene from Genetics to Postgenomics* (Chicago: University of Chicago Press, 2017), 7.

[11] Hans-Jörg Rheinberger, 'Gene Concepts Fragments from the Perspective of Molecular Biology' in (ed) P. Beurton, R. Falk, and H. Rheinberger, *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2000), 219, 226.

[12] Ibid., 221.

information for the precise specification of the structure of a protein that, in turn, was responsible for the characteristics of organisms.[13] Specifically, the molecular gene came to be seen as a fundamental entity that provided 'the information', 'the blueprint', or 'the program' for an organism that 'directed' the development and functioning of organisms by 'producing' the proteins that build and maintain living biological organisms.

For the molecular biologist, the gene was defined *structurally* as sequences of DNA (RNA in some viruses) that specify the amino acid sequences of a protein,[14] and *functionally* as a segment of DNA whose ordered sequence of bases stored the 'information' for the synthesis of a protein or other gene product.[15] Importantly the structural and functional dimensions of the gene were united by the notion of genetic information transfer, which explained how molecular order was transferred from one class of molecules to another. In 'one molecule, the DNA, the order was structurally perpetuated; in the other it was "expressed" … and became the basis of the biological function of either an RNA or a protein'.[16] With this, the structural (chemical/physical) and functional (biological/informational) conceptions of the gene converged on a single entity – the molecular gene.[17] As we will see, the merging of these approaches had an important impact on the way that patent law interacted with genes.

Based on the central dogma of molecular biology, which taught that a gene is a sequence of DNA that produces RNA, which, in turn, produces the proteins that are responsible for the characteristics of organisms,[18] the molecular gene was understood as a self-replicating molecule of DNA 'that not only holds the secrets of life but that it also executes its cryptic instructions – it was, in short, the "Master Molecule."'[19] Within this reductionist vision of life, genes, and genes alone, were thought to be responsible for biological traits and characteristics. The molecular gene was taken to be the guarantor of intergeneration stability, the factor responsible for individual

[13] Evelyn Fox Keller, 'The Postgenomic Genome' in (ed) Sarah S. Richardson and Hallam Stevens, *Postgenomics: Perspectives on Biology after the Genome* (Durham, NC: Duke University Press, 2015), 14.

[14] Karola C. Stoltz, Adam Bostanci, and Paul Griffiths, 'Tracking the Shift to "Postgenomics"' (2006) *Community Genetics* 190, 191.

[15] Hans-Jörg Rheinberger and Staffan Müller-Wille, *The Gene from Genetics to Postgenomics* (Chicago: University of Chicago Press, 2017), 64.

[16] Ibid.

[17] Hans-Jörg Rheinberger, 'Gene Concepts Fragments from the Perspective of Molecular Biology' in (ed) P. Beurton, R. Falk, and H. Rheinberger, *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2000), 219, 228.

[18] Evelyn Fox Keller, 'The Postgenomic Genome' in (ed) Sarah S. Richardson and Hallam Stevens, *Postgenomics: Perspectives on Biology after the Genome* (Durham, NC: Duke University Press, 2015), 14.

[19] Evelyn Fox Keller, *The Century of the Gene* (Cambridge, MA: Harvard University Press, 2000), 54. The 'central dogma' of molecular biology, namely, the idea that there was a direct correspondence between the sequence of nucleotides in a gene and the sequence of amino acids in a protein provided the slogan: DNA makes RNA, RNA makes protein, makes us'. See also Hans-Jörg Rheinberger, 'Beyond Nature and Culture: Modes of Reasoning in the Age of Molecular Biology and Medicine' (2005) *Science in Context* 249, 255.

traits, and, at the same time, the agent for directing an organism's development.[20] Genes were seen as inviolable messages passed between generations (save for occasional mutations) and as the ultimate causal factors lying behind development.[21] As a result, there was no longer any room for Divine providence, mysterious life forces, or external environmental influences.[22] Instead, the focus was now on the gene as the master molecule that underpinned all aspects of living matter. Given this vision of life, it is not surprising that the molecular gene came to operate as 'the organizing principle of twentieth-century biology'.[23] As we will see, it also came to play an important role in the way patent law interacted with biological subject matter.

The promise that was held out that molecular biology would eventually come to invent biological reality seemed to come to fruition in the 1970s with the advent of genetic engineering (or recombinant DNA technology).[24] As Rheinberger said, genetic engineering was a thoroughly constructive and synthetic process. This was because with 'DNA technology, molecular biology … turned, in less than twenty years, from a mode of discovery into a praxis of invention. Or, to be more exact, it has turned from the benign illusion of constituting a simple mode of discovery into a deliberate praxis of molecular writing, of bio-construction'.[25]

While molecular biology had previously approached the 'cell and its molecular elements from the outside in order to learn something about their physical and chemical properties',[26] genetic engineering offered a new way of doing biology, the key feature of which was that it made use of the organism's own molecules to copy, cut, and paste other molecules.[27] In doing so, gene editing provided researchers with a powerful new set of biological tools that allowed them to manipulate an organism's genome. With the help of these tools, researchers could copy and cut DNA, join different DNA segments together, and transfer DNA between organisms.[28] Researchers were now in a position where they could insert alien DNA into the genomes of plants and modify organisms to endow them with new characteristics and traits.

[20] Evelyn Fox Keller, *The Century of the Gene* (Cambridge, MA: Harvard University Press, 2000), 140–41.

[21] 'Introduction' in (ed) P. Beurton, R. Falk, and H. Rheinberger, *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2000), ix.

[22] Sakari Tamminen and Eric Deibel, *Recoding Life: Information and the Biopolitical* (London: Routledge, 2019), 1.

[23] Hans-Jörg Rheinberger and Staffan Müller-Wille, *The Gene from Genetics to Postgenomics* (Chicago: University of Chicago Press, 2017), 1. See also Hans-Jörg Rheinberger and Staffan Müller-Wille, 'Gene' in *Stanford Encyclopedia of Philosophy* (Revised 10 March 2009), 1.

[24] Hans-Jörg Rheinberger, 'Beyond Nature and Culture: Modes of Reasoning in the Age of Molecular Biology and Medicine' (2005) *Science in Context* 249, 256.

[25] Ibid.

[26] The 'basic genetic communication system of the organism itself … provided a "soft" technology for effectively interfering with the physiology of plant, animal, and human information processing'. Ibid., 256.

[27] Hans-Jörg Rheinberger, 'What Happened to Molecular Biology' (2008) 3 *BioSocieties* 303, 306.

[28] Hans-Jörg Rheinberger and Staffan Müller-Wille, *The Gene from Genetics to Postgenomics* (Chicago: University of Chicago Press, 2017), 76.

The results were creations such as insect resistant potatoes, glyphosate resistant soy plants, virus resistant papayas, and tomatoes that ripened slowly.

FROM PLANT TO BIOLOGICAL TO MOLECULAR SUBJECT MATTER

For much of the twentieth century, plant-based subject matter was largely limited to the external surface of individual plants (or parts thereof). Beginning in the 1970s, however, the type of plant-based subject matter that was presented to the law for scrutiny changed. Unsurprisingly, as research in biology progressed, so too did the landscape for biological patents. While this resulted in a diverse and wide-ranging subject matter (that still includes traditionally bred plants), in broad brush terms plant-based subject matter expanded in three new directions.

The first important change occurred when plant subject matter shifted below the surface to include the plant at the molecular and cellular level. As well as protecting the tools of molecular biology[29] – such as selectable markers, promoters, cloning vectors, bacteriophage DNA, and methods of gene introduction – patent protection was also gradually extended to include the things uncovered using those new tools. This included DNA sequences (complete or partial genes), promoters, enhancers, individual exons, plasmids, vectors, nucleic acid sequences (proteins), transit peptides, and isolated host cells transformed with expression vectors.[30]

Facilitated by the shift away from individual plants, patent protection also expanded to include groups or classes of taxonomically different plants. This included patents, for example, over transgenic fruit-bearing plants, glyphosate (round-up) resistant plants, or a patent for genetically modified plants selected from the group consisting of wheat, oat, barley, rice, maize, millet, rye, sorghum, triticale, buckwheat, quinoa, soybeans, beans, peas, alfalfa, potatoes, sweet potatoes, cassava, yam, tomatoes, peppers, tobacco, and cotton.[31]

From the 1970s, the ability for scientists to cut, paste, and edit genes not only underpinned the formation of a new industrial sector (biotechnology)[32] it also led to a third type of new subject matter being presented to the law for scrutiny, namely genetically modified plants. While similar to earlier patents in that protection was limited to specific plants, these differed in that they were the product of genetic

[29] Notably the Cohen–Boyer patent, 'Process for producing biologically functional chimeras', was a novel process to introduce genetic capability into microorganisms for the production of nucleic acids and proteins.

[30] For early protection of nucleotides see Charles Heidelberger et al., '5-Flourouracil' US Patent No. 2,802,005 (6 August 1957). See Jacob S. Sherkow and Henry T. Greely, 'The History of Patenting Genetic Material' (2015) *Annual Review of Genetics* 161, 164. For history of DNA patents (1971–1980) see Robert Cook-Deegan and Christopher Heaney, 'Patents in Genomics and Human Genetics' (2010) 11 *Annual Rev Genomics Human Genetics* 383, 391–92.

[31] See Carlos Correa, Juan Correa, and Bram De Jonge, 'The Status of Patenting Plants in the Global South' (2020) *Journal of World Intellectual Property* 121.

[32] N. Rasmussen, *Gene Jockeys: Life Science and the Rise of Biotech Enterprise* (Baltimore: John Hopkins University Press, 2014).

engineering rather than traditional breeding programs. Early examples include patents on tomato plants genetically engineered to produce fruit with an extended shelf-life[33] and patents for groups of plants (such as Patent Number 4,940,835, which covered soybean, cotton, alfalfa, canola, flax, tomato, sugar beet, sunflower, potato, tobacco, corn, wheat, rice, and lettuce that were genetically modified to be resistant to the herbicide glyphosate).[34]

The splintering of plant-based subject matter that began in the 1970s was also accompanied by subtle but important changes in the way that the subject matter was viewed. The process of change occurred in two stages. The first change that occurred was that plants became biological in the sense that they were grouped with and spoken about alongside other biological organisms as part of a new category of subject matter. While there were exceptions, for most of the twentieth-century plants were treated as a distinct sui generis type of subject matter; their unique nature demanded that they be treated as objects in their own right. The situation began to change in the 1970s, however, when plants were grouped with and spoken about alongside other biological organisms. After the asexually reproduced plants of plant patent law were linked to the sexually reproduced plants of plant variety protection, this new grouping was subsequently associated with the plants of utility patent law and eventually to bacteria, microorganisms, fungi, and other biological organisms.

Over time, the focus of attention also gradually shifted from specific individual organisms towards a more abstract legal grouping of living or biological subject matter. The process that began in the discussions surrounding the possible introduction of the *Plant Variety Act* in the 1960s crystallised in 1980 in *Chakrabarty* when the Supreme Court spoke of patents for living matter.[35] Adopting a form of 'organism agnosticism',[36] the law began to treat biological organisms (with the exception of humans) as a single unified category of subject matter. While this new legal category was relatively short-lived, nonetheless it was still important not least because in so far as plants were subsumed within biological (or living) matter, they effectively disappeared or were at least much less prominent than they had been previously.

Ironically, at the same time as plants were being subsumed within a broader class of biological (or living) subject matter, biological subject matter was also stripped of any vital force. As the Supreme Court said in *Chakrabarty*, 'the relevant distinction for purposes of [patentable subject matter] is not between living and inanimate things, but between products of nature, whether living or not, and human-made

33 William R. Hiatt, 'PG Gene and Its Use in Plants' US Patent No. 4,801,540 (31 January 1989). Marketed as the Flavr Savr tomato.

34 Dilip M. Shah et al., 'Glyphosate-Resistant Plants' US Patent No. 4,940,835 (10 July 1990). The patent included a deposit at the ATCC: 'Claim 59. Plasmid pMON546, ATCC accession number 53213'.

35 This took on a new form in the litigation which questioned the applicability of utility patent protection for plants. *JEM AG Supply* v. *Pioneer Hi-Bred International* 534 U.S. 124, 150 (2001).

36 Jane Calvert and Erika Szymanks, 'A Feeling for the (micro)Organism? Yeastiness Organism Agnosticism, and Whole Genome Synthesis' (2020) *New Genetics and Society* 1, 4.

inventions'.[37] While it would take some time for the process to be normalised, the rejection of vitalism marked the beginning of the second stage of the transformation of plant-based subject matter, as plant now biological subject matter was reconfigured as molecular subject matter.

As we have seen, intellectual property law's engagement with plant-based subject matter across much of the twentieth century was concerned with the external surface rather than the internal workings of plants. The situation changed in the 1980s as patents shifted below the surface of organisms to protect molecular-level innovations. Gradually, but with increasing frequency, the molecular gene not only made an appearance in intellectual property law, it also came to be treated as the common denominator that united all biological subject matter. While traditionally bred seeds and plants continued to be protected, they were largely sidelined. Moreover, while there were separate discussions about transgenic plants, these tended to be filtered through a (generic) molecular lens. While the transformation was never complete, biological living subject matter (that had previously subsumed plants) was effectively replaced by a molecularised subject matter. The biological subject matter was 'displaced, with the molecule overtaking or territorializing the organism'.[38] This was reflected in the way that the subject matter was spoken about, how it was classified, and consequently how it was dealt with by the law. The upshot of this was that within intellectual property law, to paraphrase Sarah Franklin, plant became biological became molecular subject matter.

The shift to a molecular subject matter and the way that it obfuscated the place of plants within patent law was illustrated by the problems that Rural Advancement Foundation International (RAFI) faced when it set out to review the utility patents that had been granted for plants in the United States between 1985 and 1995. While patents for gene-edited transgenic plants (which claim plants altered with foreign DNA) were readily identifiable, RAFI complained that it was difficult to get a complete picture of the transgenic plants that had been patented. The reason for this was that within the patent classificatory system, DNA sequences and the means of inserting foreign DNA were not considered transgenic plant patents 'even when the patent claims extend to plants that contain the patented gene or exhibit a patented trait'.[39] In short, the problem was that patents for plants were presented and classified as molecular inventions rather than as plant-based inventions.

There were a number of characteristics of molecular subject matter that were important for the way it interacted with patent law. Of these three stand out. The first notable characteristic of molecular subject matter related to the way the subject matter was represented. As we have seen, plant-based subject matter changed

37 *Diamond* v. *Chakrabarty* 447 U.S. 303, 313 (1980).

38 Richard Doyle, *On beyond Living: Rhetorical Transformation of the Life Sciences* (Stanford, CA: Stanford University Press, 1997), 1.

39 RAFI, 'Utility Plant Patents: A Review of US Experience (1985-July 1995)', *RAFI Communique*, (July/August 1995), 3.

considerably since the 1970s. At around the same time as utility patent protection was first allowed for traditionally bred plants, the subject moved inwards to include molecular-level innovations and outwards to include groups or classes of plants. It also expanded to include genetically modified transgenic plants. At the same time, the focus of attention shifted from plants to living (biological) subject matter and then below the surface to molecular subject matter. Within this biological milieu, gene patents were taken as the archetypical subject matter. The molecular gene or usually just simply the gene came to dominate discussions about plant-based subject matter. For all ostensible purposes, gene patents were treated as if they were a shorthand for molecular subject or genetic material matter more broadly.[40] In this sense, patent law mimicked the reductionist approach that had been adopted within molecular biology (albeit over a different time scale[41]) whereby biological systems were studied through their most elementary unit: the gene.

A second notable feature of molecular subject matter was that it saw the scope of the subject matter expand to include human genetic material. While when dealing with biological entitles at the level of organism, it had not been possible even to discuss extending patent protection to humans, this changed when patent law shifted below the surface and biological subject matter was molecularised. Reinforced by ongoing efforts to map the genome of different biological organisms, which revealed that biological organisms (including humans) share a high degree of genetic similarity,[42] there has been a tendency within patent law both doctrinally and in the accompanying commentary to treat all molecular level genetic material the same: questions about human DNA, for example, could be answered by discussions about the plant DNA, and vice versa. Thus, while the formal question the American Civil Liberties Union asked the Supreme Court in *Myriad Genetics* was whether human genes were patentable, the human dimension of the inquiry was quickly lost as the discussions broadened out to include discussions about leaves picked from plants in the Amazon, baseball bats carved from trees, animals, and genes generally.

A third characteristic of molecular subject matter that had an important bearing on how it was treated by patent law was in terms of the way the molecular gene was construed. In its early dealings with gene patents, patent law embraced a particular way of thinking about the molecular gene that continues to dominate today (albeit with some important changes). Building on a reductionist reading of genetic function, patent law presupposed that genes were solely responsible for the biological features of higher-level phenomena. Indeed as the Supreme Court's Justice Thomas

[40] See Patent & Trademark Office Society, 'Statement of the P.T.O.S. to the U.S.P.T.O. on Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, First Paragraph "Written Description" Requirement' (1999) 81 *Journal of Patent and Trademark Society* 140, 141–42.

[41] While biologists at the beginning of the twentieth century shifted their focus of attention below the surface to explore organisms at the molecular or cellular level, this did not occur in the legal realm until much later.

[42] Humans reportedly share 85% DNA with mice, 61% percent with the fruit fly, and around 50% with bananas.

said in the *Myriad Genetics* decision, 'Genes form the basis for hereditary traits in living organisms'.[43] Patent law also 'adopted a simplistic understanding of gene function',[44] which parallels the central dogma of molecular biology that DNA produces RNA, which produces the proteins that are responsible for the characteristics of organisms.[45] As Jane Calvert said, 'patenting fits nicely into this model because there is the assumption that if the function of the gene is discovered, then there will necessarily be a link to a protein, and that this protein will result in a trait. In this sense there is a parallel between the central dogma and the patenting requirements'.[46]

As many commentators have noted, the decision to extend patent protection to cover genes was a seamless and non-controversial process. Indeed, unlike the controversy that greeted Chakrabarty's patent over a living organism in the 1980s, the patenting of genes hardly attracted any attention at all.[47] A key reason for this was that genes were treated both epistemologically and ontologically as chemical compounds.[48] As the Federal Circuit said in *Amgen*, a 'gene is a chemical compound, albeit a complex one'.[49] The longevity of this way of thinking about the gene can been seen from the comment by the editor of the *Journal of Heredity* in 1936 when discussing David Burpee's attempt to patent the double nasturtium (that I discussed in the previous chapter) that a 'gene for doubleness might conceivably be granted a "chemical patent" under the old [utility] patent laws (assuming that a gene is a chemical catalyst)'.[50] Given that by 1970s, patent law had been protecting chemical inventions for over 150 years, it is not surprising that once the decision had been made that genes were chemical compounds that the courts and the USPTO 'hardly blinked at allowing patents on newly isolated genes'.[51] Indeed it wasn't until the 1990s, some 20

43 *Assoc. for Molecular Pathology* v. *Myriad Genetics* 133 S.Ct. 2107, 2111 (2013).

44 'It assumed in DNA patenting that a gene is analogous to a chemical compound, and has only one function'. Jane Calvert, 'Patenting Genomic Objects: Genes, Genomes, Function and Information' (2007) 16(2) *Science as Culture* 207, 208.

45 Ibid., 219. As we see below this 'does not reflect the more sophisticated understandings of gene function provided by developments in genomics'.

46 Ibid., 213. It is assumed that if the function of a gene is disclosed in patenting then there is an unproblematic link to a utility.

47 Rebecca Eisenberg, 'Why the Gene Patenting Controversy Persists' (December 2002) 77(12) *Academic Medicine* 1381. See Rebecca Eisenberg, 'Patenting the Human Genome' (1990) 39 *Emory Law Journal* 721; cf., Jeffrey S. Dillen, 'DNA Patentability: Anything but Obvious' (1997) *Wisconsin Law Review* 1024.

48 Jane Calvert and Pierre-Benoît Joly, 'How Did the Gene Become a Chemical Compound? The Ontology of the Gene and the Patenting of DNA' (2011) 50(2) *Social Science Information* 157, 174.

49 *Amgen* v. *Chugai Pharmaceuticals* 927 F.2d 1200, 1206 (Fed Cir 1991).

50 Robert Cook, 'What Is a "Basic Plant Patent?"' (1936) *The Journal of Heredity* 213, 215.

51 Rebecca Eisenberg, 'Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences' (2000) 49 *Emory Law Journal* 783, 784–85 (The advantage of assuming that a 'gene is a chemical compound, albeit a complex one' was that 'it provided a relatively clear point of departure for analyzing patent law issues presented by the first generation of biotechnology products produced through recombinant DNA technology'). Jane Calvert and Pierre-Benoît Joly, 'How Did the Gene Become a Chemical Compound? The Ontology of the Gene and the Patenting of DNA' (2011) 50(2) *Social Science Information* 157, 159. In 1988 the USPTO, the EPO, and the JPO issued a joint communique

or so years after the first gene patents had been granted, that there was anything like a public discussion about the validity and desirability of gene patents.[52]

The first public discussions about gene patents were triggered in the early 1990s when a team from the National Institutes of Health led by Craig Venter applied for patents that claimed thousands of partial cDNA sequences. The function of these partial sequences, called 'expressed sequence tags', was not known at the time, but it was assumed that they had a functional role to play in the organism that would be discovered with further research. Unlike the challenge to Myriad Genetics' breast cancer gene patents that took place in beginning of the twenty-first century, the debates over patents for expressed sequence tags were much more circumscribed. Indeed, while the debates and their subsequent resolution did see more onerous utility obligations imposed on gene patents,[53] they also confirmed that for patent law purposes genes were to be treated as chemical compounds and, as such, that there was nothing out-of-the-ordinary preventing them from being patented. With the utility-related hurdle overcome, patentees were able to return to their previous practice of patenting genes and related molecular material, a practice that remained unchallenged until the early part of the twenty-first century.

While the assimilation of genes within patent law as talisman for molecularised subject matter more generally may have been relatively straightforward, nonetheless the molecularisation of biological subject matter did bring about a number of changes. In particular, it changed the way that the law thought about the nature of the relationship between inventor and subject matter. Molecularisation also changed the way that the subject matter was described, as well as how it was judged and evaluated. I will look at each in turn.

MOLECULARISATION AND THE UNBUNDLING OF PLANT-BASED SUBJECT MATTER

As with other forms of biological subject matter, one of the problems that arose when people first thought about extending patent protection to plants was that it was not possible to reduce botanical innovations to first principles, at least in a form

explaining their position regarding the patentability of *Directive* technologies. The communique provides: 'Purified natural products are not regarded under any of the three laws as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes basis as other chemical compounds.'

[52] In comparing 'pure fibre when eliminated from the natural matric of the leaf or stalk or wood on which nature forms and develops' and its impure natural form, it was held that the 'chemical formula for this cellulose in all these variety of plants, I am advised, is the same'. *Ex parte Latimer* 46 OG 1638, 125, 126.

[53] The US Patent and Trademark Office (USPTO) adapted its requirement that a patent be useful in 2001 to say that rather than just demonstrating utility, a gene patent must demonstrate specific, substantial and credible utility. In practice this means that 'a patent applicant provide a specific function for a DNA gene sequence'. The US Court of Appeals for the Federal Circuit declared ESTs were not patentable except 'in the rare cases where the applicant showed a precise biological function sufficient to fulfil patent law's utility requirement'. *In re Fisher* 2005 421 F.3d 1365.

that allowed them to be recognised and repeated by third parties at a distance. As we saw earlier, patent law adopted a two-fold strategy to deal with this problem. On the one hand, patent law allowed patentees to deposit and third parties to access physical manifestations of the patented invention. While in relation to biological subject matter this first occurred in relation to microorganisms, it was soon extended to plants and other biological organisms.

The second tactic that was used to allow patent law to accommodate the idiosyncrasies of biological subject matter related to the way the inventive process was configured. As we saw in Chapter 8, for the idiosyncrasies of plant innovations to be accommodated within intellectual property law the process of invention was reimagined. The starting point for this was the recognition of the positive role that nature plays in the creation of biological inventions. That is, patent law recognised that 'nature had done the heavy lifting, creating products and phenomenon with awesome capabilities'.[54] At the same time, patent law also reversed the roles played by the inventor and nature in the creation of the invention. While under the mechanical view of creation, nature provides the underlying material, which the human inventor then shapes into the resulting invention, with biological subject matter nature does the inventing, while the human agent is relegated to the task of identifying and reproducing nature's creations. In this context, nature and inventor operated like Siamese twins in the co-invention of biological inventions; neither was able to operate independently of the other to develop a novel invention.[55] It was only when the skill and effort of the two were combined that a biological invention's continued existence could be guaranteed. One of the consequences of this was that the subject matter and the inventor were bundled together both conceptually in terms of how the process of invention was configured and literally in terms of the physical manifestation of the invention deposited as part of the application process to ensure that third parties had access to the patented invention.

One of the first changes that occurred as a result of the molecularisation of biological subject matter was that the role that the human agent played in the inventive process was recast. Specifically, molecularisation changed the way patent law thought about how the inventor and nature interacted and the role that each played in the generation of biological inventions. While the role of the inventor working with plants had previously been limited to recognising and preserving nature's innovations, this began to change in the 1970s or thereabouts. The 1980 Supreme Court decision of *Diamond* v. *Chakrabarty* captured the change that took place in the way the process of invention was figured at the time. The case arose when General Electric attempted to

[54] Rebecca Eisenberg, 'Biotech Patents: Looking Backwards while Moving Forwards' (2006) 24(3) *Nature Biotechnology* 317.

[55] Burbank spoke of the breeder using his intelligence and skill in assisting Mother Nature. Luther Burbank, 'Prodigal Mother Nature' (June 1926) 134 *Scientific American* 365–66. 'Nature in such instances, unaided by man, does not reproduce the new variety true to type'. Joseph Rossman, 'Plant Patents' (1931) 13 *Journal of the Patent Office Society* 7, 18.

file a patent for a genetically modified bacteria (*Pseudomonas putida*) made by one of its employees, Ananda Chakrabarty. While in working with the *Pseudomonas* bacteria Chakrabarty had clearly made use of nature, there was no doubt in the litigation that in modifying the bacteria so that they could break down crude oil that Chakrabarty had created the artificial organism. Instead of speaking about how Chakrabarty had worked with nature to co-invent the new artificial bacteria, the focus was on evaluating the changes that Chakrabarty – the genetic engineer – had made to nature.

What occurred here was a subtle but important change in the way the inventive process was configured. While previously nature and inventor had been inextricably intertwined, with molecularization the inventor was unbundled from the subject matter. In minimising the role of nature-as-inventor while elevating the role of the human inventor, patent law fundamentally changed the way that the process of invention was presented. As a result, there was no longer any discussion of co-invention or of nature and inventor working side-by-side to create biological inventions. Instead, the focus was now on the relationship between inventor and nature, and the extent and manner in which the inventor had changed nature: an issue I return to below. One of the consequences of this was that the process of biological invention was recast so that it was comparable to the figure of invention used for mechanical inventions. As a result, the role of the biological inventor was now comparable to the structural chemist or the mechanical engineer.

While the unbundling of computer-related subject matter that started in the 1970s was instigated by legal interventions, the unbundling of biological (now moleculaised) subject matter was a consequence of changes in the way biological innovations were seen. While for much of the twentieth century some forms of biological innovations, such as the development of new microbiological-based inventions, were characterised as scientific endeavours and treated as such, others, such as the breeding of new plants, were still seen as artisanal non-scientific practices. This began to change in the 1970s. In part this was because plant breeding was recast as a more-scientific activity. As one commentator noted, ‘Now that plant innovation has become so much a matter of biochemistry and molecular genetics – so high-tech one might say – its structure and development has come to resemble that of other high-tech industries.’ While many of the pejorative views about plant breeding persist, this has been masked by the shift to a molecular subject matter, which now stands in for plant subject matter. Whatever criticisms might be made of molecular biology, there is little doubt of its scientific credibility nor about the role that molecular biologists play in the generation of biological inventions.

While Chakrabarty had managed to modify nature to create something new and his status as creator had been elevated to something akin to a mechanical inventor, he was still unable to persuade nature to disclose its secrets; he was unable to reduce the design or principle of the invention to a written form so that third parties could recreate his discovery at a distance. To deal with this problem and to ensure that the invention satisfied the requirements of enabling disclosure, physical samples of the invention were placed in publicly accessible locations. As Chakrabarty's patent states: 'Microorganisms prepared by the genetic engineering processes described herein are exemplified by cultures now on deposit with the US Department of Agriculture.'[56] In this sense *Chakrabarty* and many of the decisions that applied its logic to other types of biological organisms spanned two worlds. It is a decision firmly rooted in the physical, empirical patent law of the past century while, at the same time, a decision that marks the beginning of the shift to a dematerialised subject matter. To better understand the nature of this change, we need to look at the impact that molecularization had on the way biological subject matter was represented.

REPRESENTING MOLECULAR SUBJECT MATTER

One of the challenges that often arise in accommodating new types of subject matter in patent law is working out how new inventions are to be represented so that they can meet the various demands that the law makes of them. This includes ensuring that inventions are distinct enough for them to be examined, judged, and evaluated, and that third parties are able to repeat the patented invention without undue effort. The techniques used to represent plant-based subject matter to achieve these ends changed considerably over the twentieth century. After using the written description and the drawing of the plant in the patent to build a virtual-legal plant, intellectual property law came to rely on the deposit of the physical manifestation of the protected plant. As the subject matter was molecularised and attention shifted from the surface of plants to the interior molecular world, the way subject matter was presented to the law for scrutiny also changed.

In early molecular patents, gene-based inventions were expressly presented as chemical compounds. For example in what has been described as 'likely the first gene patent',[57] which was granted to Jack J. Manis, a researcher at the Upjohn Company in Michigan, for a patent 'claiming a purified version of a naturally occurring plasmid found in *Streptomyces espinosus*' (and deposited at the NRRL), the invention was described in the patent as a 'novel chemical compound, essentially pure plasmid pUC6, which is obtainable from a biologically pure culture of the microorganism'.[58] While the chemical reading of the gene prevailed until the 2013 Supreme Court decision *Association for Molecular Pathology* v. *Myriad Genetics*, at least in terms of how genes were judged, molecular subject matter began to give way

[56] Ananda M. Chakrabarty, 'Microorganisms Having Multiple Compatible Degradative Energy-Generating Plasmids and Preparation Thereof' US Patent No. 4,259,444A (31 March 1981).

[57] Jacob S. Sherkow and Henry T. Greely, 'The History of Patenting Genetic Material' (2015) *Annual Review of Genetics* 161, 166.

[58] Jack J. Manis, 'Plasmid and Process of Isolating Same' US Patent No. 4,273,875 (16 June 1981), Abstract. See also H. Yanagawa et al., 'Molecule Assigning Genotype to Phenotype and Use Thereof' US Patent No. 72,087 A1 (13 June 2002), Figure 3 (chemically-modified portions of the 3'-terminal ends of nucleic acid portions).

to more biological modes of representation from the outset. As is often the case with innovations in patent law, the techniques developed to describe molecular subject matter were initiated by patentees and subsequently endorsed by the Patent Office and the courts. While patentees used a range of different techniques to describe the (non-chemical) biological gene, three stand out.

While early gene-based inventions were described by patentees (and accepted by the courts) as types of chemical compounds, during this transitional period they were not represented using chemical nomenclature or structural formula (as chemical patents were). Instead, patentees employed a range of experimental techniques to represent their gene-based inventions. These included gel electrophoresis diagrams (Figure 9.1),[59] schematic representations (Figure 9.2), and cleavage maps which represent the sites where restriction enzymes cleave a DNA molecule (Figure 9.3).[60]

A second technique that patentees used to ensure that molecular subject matter met the representational requirements of patentability was to deposit biological material at public depositaries such as the American Type Cultural Collection or the Northern Regional Research Laboratory of the US Department of Agriculture.[61] In some cases, patentees deposited biological source material such as bacteria, along with instructions for how the protected DNA (gene) could be extracted from that material using well-known techniques.[62] More often, however, patentees deposited plasmids containing genes typically frozen in liquid nitrogen to preserve them at public depositaries.[63]

The practice of depositing biological material to describe and enable molecular inventions was formally recognised by the US Patent Office in the late 1980s when in making changes to accommodate biotechnological inventions, the Patent Office introduced new rules dealing with the deposit of biological materials.[64] While the

[59] The poor quality of this image, which the USPTO says is the best that is available, raises interesting questions about the effectiveness of the patent in disclosing the invention.

[60] Jack J. Manis, 'Plasmid and Process of Isolating Same' US Patent No. 4,273,875 (16 June 1981), Abstract. See also H. Yanagawa et al., 'Molecule Assigning Genotype to Phenotype and Use Thereof' US Patent No. 72,087 A1 (13 June 2002).

[61] See USPTO, 'Deposit of Biological Material' 37 CFR 1.801–1.825 (Added, 54 FR 34880, 22 August 1989); USPTO, Manual of Patent Examining Procedure, 'The Deposit Rules', section 2402.

[62] Jack J. Manis, 'Plasmid and Process of Isolating Same' US Patent No. 4,273,875 (16 June 1981) (the microorganism used to produce the claimed plasmid was deposited at the Northern Regional Research Laboratory of the US Department of Agriculture as NRRL 11439). Corrina Herrnstadt et al., 'Cloning and Expression of *Bacillus thuringiensis* Toxin Gene Toxic to Beetles of the Order Coleoptera' US Patent No. 4,853,331A (1 August 1989).

[63] See *In re Lundak* 773 F.2d 1216 (Fed. Cir. 1985). Because of the uncertainties of reproducibility that inhere in such processes, at least in the present state of biotechnology, this invention is of the class covered by the deposit requirement'. Berge Hampar, 'Patenting Recombination DNA Technology: The Deposit Requirement' (1985) 67(11) *Journal of the Patent and Trademark Office Society* 569, 580.

[64] As the MPEP explained in introducing the 1990 Rules since most of the provisions of the rules reflect policy and practice existing prior to 1 January 1990, little change in practice or burden on applicants for patent and patent owners relying on the deposit of biological material has occurred. 2402 The Deposit Rules.

U.S. Patent Oct. 4, 1983 Sheet 3 of 3 **4,407,948**

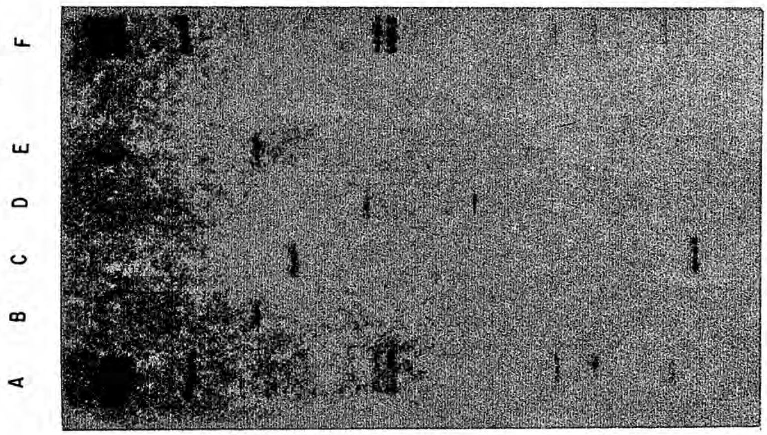

FIG. 5

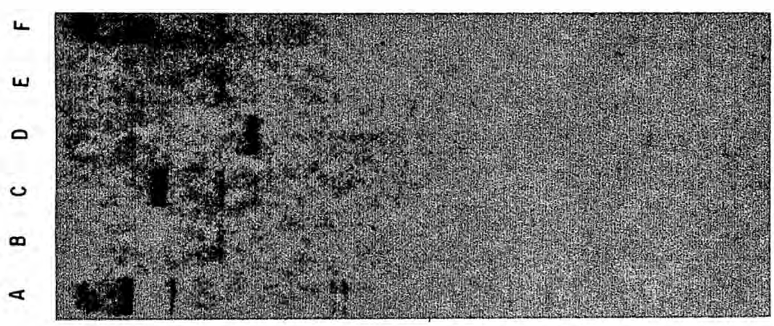

FIG. 4

FIGURE 9.1 Autoradiogram of gel electrophoresis results
Howard Goodman, John Shine and Peter Seeburg, 'Purification of Nucleotide Sequences Suitable for Expression in Bacteria' US Patent No. 4,407,948 (4 Oct 1983). Courtesy of the United States Patent and Trademark Office.

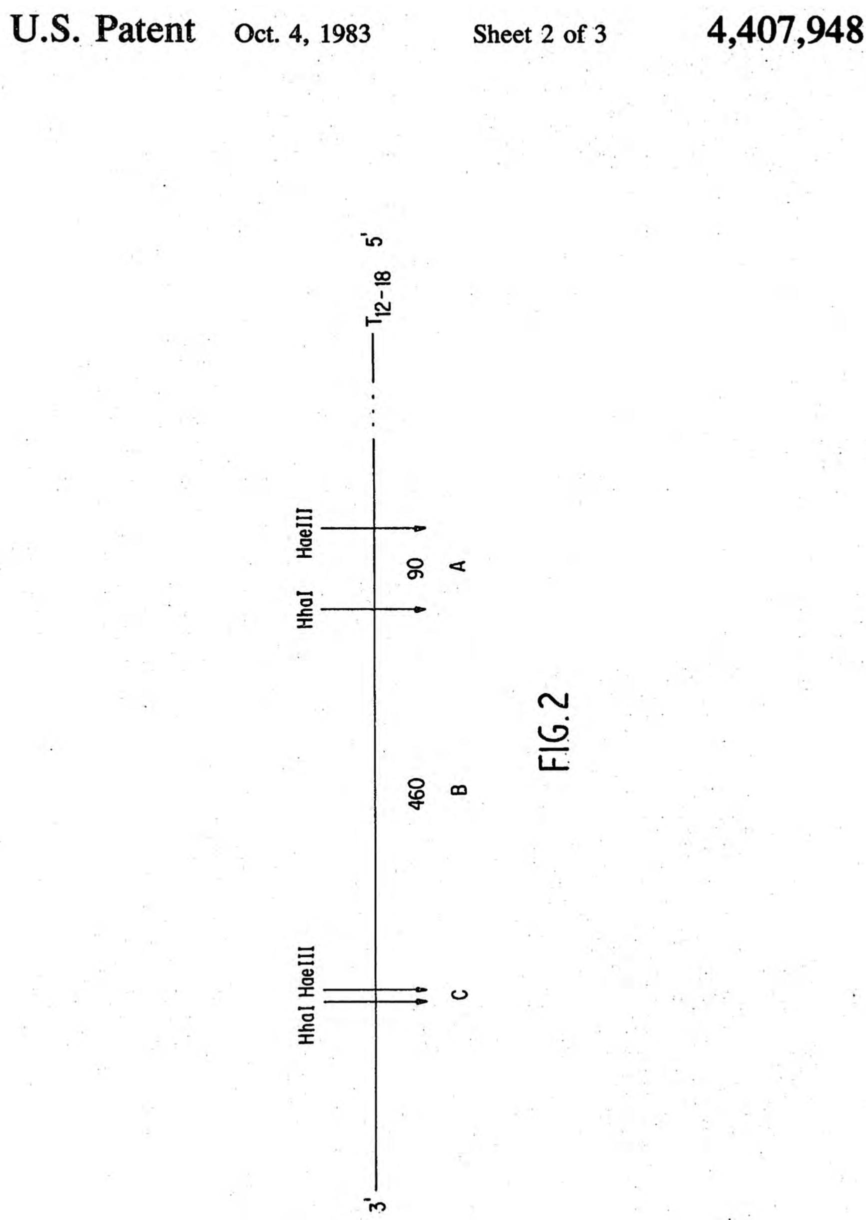

FIGURE 9.2 Schematic representation of the nucleotide sequence
Howard Goodman, John Shine and Peter Seeburg, 'Purification of Nucleotide Sequences Suitable for Expression in Bacteria' US Patent No. 4,407,948 (4 Oct 1983). Courtesy of the United States Patent and Trademark Office.

United States Patent [19] [11] **4,273,875**

Manis [45] **Jun. 16, 1981**

[54] **PLASMID AND PROCESS OF ISOLATING SAME**

[75] Inventor: **Jack J. Manis,** Portage, Mich.

[73] Assignee: **The Upjohn Company,** Kalamazoo, Mich.

[21] Appl. No.: **17,812**

[22] Filed: **Mar. 5, 1979**

[51] **Int. Cl.**[3] **C12N 1/20**
[52] **U.S. Cl.** **435/253;** 435/91; 435/317; 435/820; 435/886
[58] **Field of Search** 435/91, 317, 820, 253

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Primary Examiner—Alvin E. Tanenholtz
Attorney, Agent, or Firm—Roman Saliwanchik

[57] **ABSTRACT**

A novel chemical compound, essentially pure plasmid pUC6, which is obtainable from a biologically pure culture of the microorganism *Streptomyces espinosus* biotype 23724a, NRRL 11439. The pUC6 plasmid is useful as a cloning vehicle in recombinant DNA work. For example, using DNA methodology, a desired gene, for example, the insulin gene, can be inserted into pUC6 and the resulting plasmid can then be transformed into a suitable host microbe which, upon culturing, produces the desired insulin.

5 Claims, 1 Drawing Figure

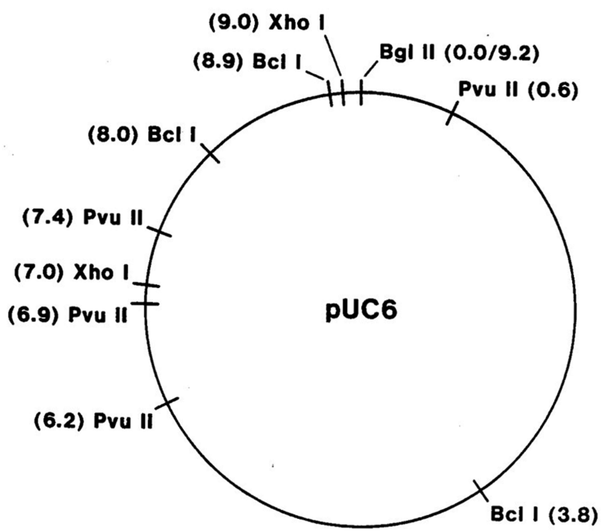

FIGURE 9.3 Circular plasmid diagram
Jack Manis, 'Plasmid and Process of Isolating Same' US Patent No. 4,273,875 (16 June 1981). Courtesy of the United States Patent and Trademark Office.

Patent Office rules had previously been limited to the deposit of microorganisms, this was changed in 1988 to encompass 'microorganisms and other biological material'.[65] This was followed in 1990 by the introduction of new rules for the 'deposit of biological materials for patent purposes'.[66] For the purpose of the new rules, 'biological material' was defined to include material that was capable of self-replication either directly or indirectly after insertion into a host. Representative examples include bacteria, fungi, yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens, and seeds.

Importantly, while plasmids – which are small, circular molecules of DNA that are able to replicate independently – were not included in the 1986 draft rules, they were added to the final rules promulgated in 1990. In making these changes, the US Patent Office formally recognised the deposit of plasmids as a way of ensuring that gene patents met the requirements of written description and enablement. In doing so, the patent office drew upon the scientific practice of using plasmids as tools (or vectors) to clone, transfer, and manipulate genes. This was made possible by the fact that researchers are able to insert DNA fragments or genes into a plasmid vector, creating a so-called recombinant plasmid. This plasmid can be introduced into a bacterium by way of the process called transformation. Then, because bacteria divide rapidly, they can be used as factories to copy DNA fragments in large quantities.

While the courts readily accepted that the deposit of a biological sample allowed third parties to repeat the patented invention (and thus ensured that that the disclosure was enabling), there were some lingering doubts about whether it ensured that patents satisfied the written description requirement.[67] In 2002, this question was addressed by the Federal Circuit in two decisions, *Enzo I* and *Enzo II*. The patent in dispute in these decisions was for nucleic acid (DNA) probes that were used to detect the bacteria that cause gonorrhoea, *Neisseria gonorrhoeae*. Rather than including either a structural description or the genetic sequences of the probes in the specification, the patent simply referred to the genetic material (the DNA probes) that Enzo had deposited at the American Type Culture Collection.[68] After being sued by Enzo for infringement, the defendants (Gen-Probe) argued that Enzo's patent did not meet the written description requirement and as such that it was invalid.

In a surprising decision, the District Court of Southern New York in *Enzo I* agreed with the defendants that while the deposit made at the American Type Culture

[65] USPTO, *Manual of Patent Examining Procedure*, 5th edition, rev 8 (May 1988), 608 (1)(p)(C).

[66] U.S. Department of Commerce, Patent and Trademark Office, 'Deposit of Biological Materials for Patent Purposes; Advance Notice of Proposed Rulemaking' (1987) 52(174) *Federal Register* 34080–93. Final rules for deposits of biological materials for patent purposes was published in the Federal Register, 54 Fed. Reg. 34864 (22 August 1989) and in the Official Gazette, 1106 OG 37 (12 September 1989).

[67] Dennis J. Harney and Timothy B. Mcbride, 'Deposit of Biological Materials in Support of a US Patent Application' in (ed) A. Krattiger et al., *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, Vol. 1 (Oxford: MIHR and Davis, CA: PIPRA, 2007), sect 10, ch 10.10, para 1.2.

[68] The patent also described the three probes in terms of function. Given that it was accepted that a description of genetic material by function alone was insufficient, the question for the court was whether in depositing the probes at the ATCC Enzo had met the written-description requirement.

Collection ensured that the patent met the requirement of enabling disclosure, it did not satisfy the written description requirement and as such that the patent was invalid.[69] The court in *Enzo I* said that even though an invention had been reduced to practice and embodied in a physical form, it was still possible that it might fail to meet the written description requirement if the invention was not described in sufficient detail in the patent specification. As the court said: 'What the deposit does, in addition to enabling the practice of the invention, is tell the public where a sample of the invention can be found so that the invention can be carried out when the patent expires or used in other ways that may not infringe the patent'.[70] The problem for the patentee, however, was that the court held that this was 'not describing the invention in the patent … the deposit here essentially contains the invention, and the invention must be described more than by stating that it exists in a depository'.[71]

Three and a half months later, in *Enzo II* the Federal Court readdressed the question of whether the written description requirement could be satisfied by the deposit of genetic material.[72] To the relief of the biotech industry, the court reversed its earlier ruling and held that the deposit of a biological sample in a public repository could fulfil the written description requirement. This was on the basis that while 'deposit in a public depository most often has pertained to satisfaction of the enablement requirement', the court 'concluded that reference in the specification to a deposit may also satisfy the written description requirement with respect to a claimed material'.[73] Specifically, the court agreed with Enzo that 'reference in the specification to deposits of nucleotide sequences describe those sequences sufficiently to the public for purposes of meeting the written description requirement'.[74] In doing so *Enzo II* affirmed the long-held belief that a biological deposit could be used to satisfy the written description requirement.

The practice of depositing biological material at public depositaries to satisfy the patentability requirements for molecular subject matter shares similarities with the deposit of chemical compounds discussed earlier. Despite this, there was no question in either *Enzo I* or *II* that the DNA probes deposited at the American Type Cultural Collection were biological materials.[75] While this may simply be a consequence of

[69] *Enzo Biochem Inc.* v. *Gen- Probe Inc.* 285 F.3d 1013 (Fed. Cir. 2002) (Enzo I) (2 April 2002).
[70] Ibid., 1023.
[71] Ibid.
[72] *Enzo Biochem Inc.* v. *Gen- Probe Inc.* 296 F.3d 1316 (Fed. Cir. 2002) (Enzo II) (15 July 2002).
[73] Ibid., 1326.
[74] Ibid.
[75] As Chief Justice Louries said in *Enzo II*, in 'light of the history of biological deposits for patent purposes, the goals of the patent law, and the practical difficulties of describing unique biological materials in a written description' a 'reference in the specification to a deposit in a public depository' of genetic material (purified chromosomal DNA) 'which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112'. That is, 'a deposit may be necessary, where 'the invention involves a biological material and words alone cannot sufficiently describe'. Ibid., 1325.

a lack of appreciation for the historical role that chemical specimens played in patent law, it also reflects a shift to a (non-chemical) biological understanding of genes. This was evident in the way the Patent Office approached the question of how genes were described. In explaining what were soon to become the rules for deposit of biological materials the Commissioner of Patents, Donald J. Quigg, said: 'Chemical compounds, no matter how important or defined their biological activity, are not regarded as biological material within the scope of these regulations.' As a result, 'materials such as proteins, enzymes, or other complex organic materials need not be deposited where the written description alone is adequate to enable those skilled in the art to make and use the claimed invention'.[76]

Although the deposit of biological material as a way of ensuring that gene patents met the requirements of written description and enablement is usually seen as a continuation of a practice that began with microorganisms in the 1930s and expanded over time to include other biological material, there are important differences. In particular, while biological materials such as microorganisms, seeds, and plant tissue were treated as if they were coextensive with (or were) the patented invention, molecular subject material was different. This was because unlike other types of biological deposits that were treated as if they were the invention, deposited plasmids housed the invention. As the court said in *Enzo I*, 'the deposit here essentially contains the invention'.[77] In this sense, it was not so much that the glass vials deposited at the American Type Cultural Collection contained frozen samples of the invention, so much as that the invention was located within the frozen physical material within the vials.

While the courts in *Enzo I* and *II* may have disagreed about what an applicant needed to do to satisfy the written description requirement,[78] they did agree on what and where the invention was; namely the way that the chemical compounds (nucleotides) expressed as the alphabetic symbols of As, Ts, Cs, and Gs were ordered within the deposited DNA substances. The difference between *Enzo I* and *II* was what the courts expected of the applicant in relation to the sequence information hidden within the frozen material in the glass vials. While the court in *Enzo II* was satisfied that because the deposited materials could, if someone wanted, be sequenced and the order of the chemical compound determined that the written description requirement was satisfied (that

[76] In 1988, PTO published proposed rules for deposit of biological materials for patent purposes U.S. Department of Commerce, Patent and Trademark Office, 'Deposit of Biological Materials for Patent Purposes; Notice of Proposed Rulemaking' (1988) 53(194) *Federal Register* 39420–32. 'Chemical compounds are capable of description at least through the identification of starting materials end explanation of appropriate procedures used in making the compounds. It must not require undue experimentation in order to make or use the chemical compound from the written description in the patent application'.

[77] *Enzo Biochem Inc.* v. *Gen- Probe Inc* 285 F.3d 1013, 1023 (Fed. Cir. 2002).

[78] The defendants also assert that the expert's opinion that the deposited genetic materials could actually have been sequenced did not cure the actual failure of the inventors to identify them by some distinguishing characteristic such as their structure.

is, that the disclosure inherently described the claimed nucleotide sequences), this was not enough for the court in *Enzo I* who expected the applicants to have actually sequenced the deposited materials and included the resulting sequence information in the patent.

In so far as the *Enzo* decisions saw the legal focus of attention shift from the material DNA substance towards the sequence information contained within that physical material, they mark a move towards a more dematerialised subject matter. Despite this, the subject matter in the Enzo decisions was still closely intertwined with the physical material deposited at the American Type Cultural Collection. (At the time, genes were also still seen ontologically as chemical compounds.) The process of dematerialisation took on a life of its own, however, with the third technique used by patentees to ensure that molecular subject matter met the representational requirements of patentability.

The third technique that patentees used to ensure that molecular subject matter satisfied the representational requirements of patentability was to describe the specific way that chemical molecules were organised within an organism: that is, they included the sequence information for the subject matter in the patent. Sequences took one of two forms depending on what was being described. In the case of claims for deoxynucleic acid (DNA), this information consists of the way the four chemical building blocks or nucleotides ('bases') that make up DNA were ordered ('nucleotide sequence information'). Specifically, it consists of the particular way that the four nucleotide building blocks of adenine, thymine, cytosine, and guanine (which are represented by the alphabetical letters A, T, C, and G) that make up a gene are ordered. In the case of proteins, the sequence information consists of the particular way that the twenty different amino acids (designated with either single or triple letter codes, such as the use of 'V' or 'val' to represent the amino acid valine) that are joined to form proteins are ordered ('amino acid sequence information'). In both cases, the use of sequence information to represent the molecular gene built on the discovery that the particular way nucleotides (within DNA) and amino acids (within protein) were ordered (their sequence) determined what the gene did.[79] Once they were identified, sequences were written out in a linear ticker-tape form as a series of As, Ts, Cs, and Gs in the case of DNA or in the case of amino acids as a series of single or triple letter codes (see Figure 9.4).[80]

While scientists and breeders have long been able to stimulate change within biological subject matter, until the mid-part of the twentieth century, they were not in a position where they could explain the reasons for those changes. Because they could not explain the internal workings of biological subject matter, patentees had to focus on the external (phenotypical) features of biological organisms or to rely upon the

[79] The order or sequence of these bases determines what biological instructions are contained in a strand of DNA.

[80] John Baxter et al., 'Adrenocorticotropin-Lipotropin Precursor Gene' US Patent No. 4,322,499 (30 March 1982).

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15301  gaatttaatcatttgtgtgacatgaaagtaaatccagtcctgccaatgagaagaaaaag
15361  acacagcaagttgcagcgtttatagtctgcttttacatctgaacctctgtttttgttatt
15421  taagGTGAAGCAGCATCTGGGTGTGAGAGTGAAACAAGCGTCTCTGAAGACTGCTCAGGG
15481  CTATCCTCTCAGAGTGACATTTTAACCACTCaggtaaaaagcgtgtgtgtgtgtgcacat
15541  gcgtgtgtgtggtgtcctttgcattcagtagtatgtatcccacattcttaggtttgctga
15601  catcatctctttgaattaatggcacaattgtttgtggttcattgtcvvvvvvvvvvvvvn
15661  gngaatgtaatcctaatatttcncnccnacttaaaagaataccactccaanggcatcnca
15721  atacatcaatcaattggggaattgggatttccctcnctaacatcantggaataatttca
15781  tggcattaattgcatgaatgtggttagattaaaaggtgttcatgctagaacttgtagttc
15841  catactaggtgatttcaattcctgtgctaaaattaatttgtatgatatattntcatttaa
15901  tggaaagcttctcaaagtatttcattttcttggtaccatttatcgtttttgaAGCAGAGG
15961  GATACCATGCAACATAACCTGATAAAGCTCCAGCAGGAAATGGCTGAACTAGAAGCTGTG
16021  TTAGAACAGCATGGGAGCCAGCCTTCTAACAGCTACCCTTCCATCATAAGTGACTCTTCT
16081  GCCCTTGAGGACCTGCGAAATCCAGAACAAAGCACATCAGAAAAAGgtgtgtattgttgg
16141  ccaaacactgatatcttaagcaaaattctttccttcccctttatctccttctgaagagta
16201  aggacctagctccaacattttatgatccttgctcagcacatgggtaattatggagccttg
16261  gttcttgtccctgctcacaactaatataccagtcagagggacccaaggcagtcattcatg
16321  ttgtcatctgagatacctacaacaagtagatgctatggggagcccatggvvvvvvvvvvv
16381  vvccattggtgctagcatctgtctgttgcattgcttgtgtttataaaattctgcctgata
16441  tacttgttaaaaaccaatttgtgtatcatagattgatgcttttgaaaaaaatcagtattc
16501  taacctgaattatcactatcagaacaaagcagtaaagtagatttgttttctcattccatt
16561  taaagCAGTATTAACTTCACAGAAAAGTAGTGAATACCCTATAAGCCAGAATCCAGAAGG
16621  CCTTTCTGCTGACAAGTTTGAGGTGTCTGCAGATAGTTCTACCAGTAAAAATAAAGAACC
16681  AGGAGTGGAAAGgtaagaaacatcaatgtaaagatgctgtggtatctgacatctttattt
16741  atattgaactctgattgttaatttttttcaccatactttctccagtttttttgcatacag
16801  gcatttatacactttattgctctaggatacttcttttgtttaatcctatataggvvvvv
16861  vvvvvvvvggataagntcaagagatatttgataggtgatgcagtgatnaattgngaaaa
16921  tttnctgcctgcttttaatcttccccgttctttcttcctncctccctcccttcctncct
16981  cccgtccttncctttcctttccctcccttccnccttctttccntctntctttcctttctt
17041  tcctgtctacctttctttccttcctcccttcctttttcttttctttctttcctttcctttt
17101  ctttcctttctttcctttcctttctttcttgacagagtcttgctctgtcactcaggctgg
17161  agtgcagtggcgtgatctcgnctcactgcaacctctgtctcccaggttcaagcaatttc
17221  ctgcctcagcctcccgagtagctgagattacaggcgccagccaccacacccagctactga
17281  cctgcttttvvvvvvvvvvvvvvaaacagctgggagatatggtgcctcagaccaacccat
17341  gttatatgtcaaccctgacatattggcaggcaacatgaatccagacttctaggctgtcat
17401  gcgggctctttttgccagtcatttctgatctctctgacatgagctgtttcatttatgct
17461  ttggctgcccagcaagtatgatttgtcctttcacaattggtggcgatggttttctccttc
17521  catttatctttctagGTCATCCCCTTCTAAATGCCCATCATTAGATGATAGGTGGTACAT
17581  GCACAGTTGCTCTGGGAGTCTTCAGAATAGAAACTACCCATCTCAAGAGGAGCTCATTAA
17641  GGTTGTTGATGTGGAGGAGCAACAGCTGGAAGAGTCTGGGCCACACGATTTGACGGAAAC
17701  ATCTTACTTGCCAAGGCAAGATCTAGgtaatatttcatctgctgtattggaacaaacact
17761  ytgattttactctgaatcctacataaagatattctggttaaccaacttttagatgtacta
17821  gtctatcatggacactttgttatacttaattaagcccactttagaaaaatagctcaagt
17881  gttaatcaaggtttacttgaaaattattgaaactgttaatccatctatattttaattaat
17941  ggtttaactaatgattttgaggatgwgggagtcktggtgtactctamatgtattatttca
18001  ggccaggcatagtggctcacgcctggtaatcccagtayycmrgagcccgaggcaggtgga
18061  gccagctgaggtcaggagttcaagacctgtcttggccaacatgggngaaaccctgtcttc
18121  ttcttaaaaaanacaaaaaaaattaactgggttgtgcttaggtgnatgccccgnatccta
18181  gttnttcttgngggttgagggaggagatcacnttggaccccggaggggngggtgggggng
18241  agcaggncaaaacacngacccagctggggtggaagggaagcccactcnaaaaaannttnv
18301  vvvvvvvvvvvvttttaggaaacaagctactttggatttccaccaacacctgtattcat
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FIG. 10F

FIGURE 9.4 Myriad patent sequence listing
Mark Skolnick et al., '17Q-Linked Breast and Ovarian Cancer Susceptibility Gene' US Patent No. 5,747,282 (5 May 1998). One page of the genomic sequence for BRCA1 used in the patent application. The lower-case letters denote intron sequence (non-coding) while the upper-case letters denote exon sequence (coding). Courtesy of the United States Patent and Trademark Office.

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deposit of (physical) samples of their inventions when they were describing their creations. The situation began to change as advances in molecular biology allowed scientists to unlock some of nature's secrets. As a result of a series of scientific and technical developments that began in the 1960s, there was a growing sense in which scientists had discovered the book of life: all that was left to be done was to find the relevant sequence information and everything else would follow. As John Toy said of the human genome project: 'We have discovered the human alphabet – what we now have to do is put the letters in the right order and make a sentence. Only when all of that is done shall we have the book of life to read'.[81]

One of the consequences of these changes was that prevision was no longer seen as a problem: there was a sense in which scientists were now in a position where they could explain why things had happened, why it was that a modified plant behaved in a particular way, why it fruited early, or why it was able to survive with less water. As the US Patent Office wrote in 1999, while 'the state of DNA inventions was once unpredictable, today the state of the art has advanced to the point where isolating nucleotide sequences is routine to persons skilled in the art, and therefore predictable'.[82] Importantly, scientists were also now in a position where they could reduce biological subject matter to a written form that ensured that the subject matter could be identified and that third parties could replicate the invention at a distance. As a result, it was now possible to trust the immaterial representation of biological subject matter; it was no longer necessary for patentees to resort to the physical manifestation of the intangible or to focus on the external features of an organism when representing their innovations.

While there may initially have been problems with the accuracy of the sequence data in some patents,[83] there was never any doubt cast over its efficacy in representing molecular inventions. Sequence information first appeared in patents in the early 1980s.[84] However, the cost and difficulty of sequencing meant that this was relatively rare. As trust in sequence information grew and sequencing became cheaper, faster, and more accurate, so too did confidence in the ability of sequence data to represent the molecular subject matter. Initially, risk adverse patentees would submit both a physical deposit of the DNA and sequence information.[85] By the 1980s, however, there was a growing acceptance that in relation to a 'less complex life-form, such as a DNA

81 John Toy, *Medical Director of the UK's Imperial Cancer Research Fund* (26 June 2000). As cited in Judith Root, *The Poetics of DNA* (Minneapolis: University of Minnesota Press, 2007), 84.

82 See Patent & Trademark Office Society, 'Statement of the P.T.O.S. to the U.S.P.T.O. on Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, First Paragraph "Written Description" Requirement' (1999) 81 *Journal of the Patent and Trademark Society* 140, 141–42.

83 For example see Myles Jackson, *The Genealogy of a Gene: Patents, HIV/AIDS, and Race* (Cambridge, MA: The MIT Press, 2015).

84 For early examples see John Baxter et al., 'Adrenocorticotropin-Lipotropin Precursor Gene' US Patent No. 4,322,499 (30 March 1982); Graeme Bell et al., 'DNA Transfer Vector and Transformed Microorganism Containing Human Proinsulin and Pre-proinsulin Genes' US Patent No. 4,431,740 (14 February 1984).

85 Berge Hampar, 'Patenting Recombination DNA Technology: The Deposit Requirement' (1985) 67(11) *Journal of the Patent and Trademark Office Society* 569, 608.

molecule (i.e., gene)' that 'a written description absent a deposit should suffice … so long as the specification includes the nucleotide sequence or a procedure for isolating the molecule from genomic DNA'.[86] It was also recognised that 'sequences claims may be enabled' … 'merely by stating the sequence, rather than by deposit of the host organism'.[87]

While applicants may not have been under a formal obligation to use sequence data to represent molecular subject matter,[88] nonetheless it quickly became a defacto standard that was widely used in gene patents.[89] The use of sequence information to represent molecular subject matter was also endorsed by the courts. As the Federal Circuit said in *Eli Lilly* in 1997, adequately describing a cDNA (synthetic DNA) in a patent specification 'requires the kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA'. As the Federal Circuit said in *Chiron Corp* v. *Abbott Laboratories*, 'every case in which it analysed the conception of an invention involving DNA encoding a human protein, the Federal Circuit has held that an inventor does not have knowledge of the specific chemical structure (and thus conception) until the inventor knows the nucleotide sequence of the relevant DNA and has a viable method for obtaining it'.[90]

Although patentees and the courts readily embraced the use of sequence information as a way of satisfying the representational requirements of patentability, the Patent Office experienced a number of problems. The reason for this was that while there might have been consensus by the 1980s that a gene patent that incorporated information about the way the nucleotides and amino acids were ordered satisfied the representational requirements of patentability, there was no agreement as to how that sequence information should be presented nor about the symbols that should be used to refer to the nucleotides and amino acids. This lack of uniformity created a number of problems for the Patent Office, which was concerned that undisciplined sequence data was slowing down the examination process (leading to a backlog of biotech patents at the end of the 1980s), increasing the cost, and undermining the effectiveness of the examination process. The lack of standardisation also made it difficult to compare what had been claimed in a patent application with what had been disclosed in the prior art, not least because it was impractical for an examiner searching a particularly lengthy sequence in a nonconforming format to accurately key the query necessary to search the sequence in a computerized

86 Ibid.

87 Iver Cooper, *Biotechnology and the Law* (July 2022 Update), § 5:67.

88 'Describing the complete chemical structure, i.e., the DNA sequence, of a claimed DNA is one method of satisfying the written description requirement, but it is not the only method … Therefore, there is no basis for a per se rule requiring disclosure of complete DNA sequences or limiting DNA claims to only the sequence disclosed'. USPTO, *Guidelines for Examination of Patent Applications under the 35 U.S.C. 112 Written Description Requirement* (2001), 41.

89 John M. Lucas, 'The Doctrine of Simultaneous Conception and Reduction to Practice in Biotechnology' (1998) 26(4) *AIPLA Quarterly Journal* 381, 481.

90 *Chiron Corp* v. *Abbott Laboratories* 902 F Supp 1103, 1120 (ND Cal 1995).

search. Faced with different formats, examiners had to convert the sequence data as it appeared in patent applications into formats that were consistent with those appearing in the prior art to evaluate the patentability of the inventions claimed in a patent application. These problems were compounded by the complexity and volume of the data that the Patent Office had to deal with. There were also concerns about the accuracy of the sequence data that appeared in the printed patent records. The reason for this was that patent printing procedures used at the time meant that the Patent Office could not simply cut and paste sequence information from an application into the official records. Instead, the sequence data had to be rekeyed from the material submitted by the applicant. Not surprisingly, this often resulted in the printing of erroneous sequences.

To address these problems, the Patent Office made a number of changes in the late 1980s. As well as changing the way biotechnological inventions were classified, the Patent Office also introduced a special biotechnology examining division (Group 180) equipped with a specialised computer system for searching sequences of amino acids and nucleotides.[91] In 1990, the Patent Office introduced rules for '*Patent Applications Containing Nucleotide Sequence and/ or Amino Acid Sequence Disclosures*'. The rules were part of an ongoing coordinated effort between the private sector and the European, Japanese, and US Patent Offices to standardise the use of symbols and the format for sequence information in order to facilitate the exchange and use of published data.[92] The rules set out a standardised format that had to be used when nucleotide and amino acid sequence data were submitted as a part of a patent application. The rules also specified the symbols that applicants had to use as shorthand for nucleotides and amino acids. The standardized format, which was mandatory, was needed to 'permit proper examination and processing of such applications and to improve quality and efficiency of the examination process, promote conformity with usage of the scientific community, and improve dissemination of sequence data in electronic form'.[93] While in drafting the sequence rules the Patent Office consulted with nucleotide and protein sequence data libraries generally, the rules were based on the data format and forms used at the GenBank Sequence Database (the open access collection of publicly available nucleotide sequences and their protein translations maintained by the National Center for Biotechnology Information). As the Patent Office said, the standardised format was as close to the GenBank format as the Office could come while accommodating the special requirements of patent applications.

[91] Patent and Trademark Office, Biotechnology Examining Group, 'Patent and Trademark Office Creates New Biotechnology Examining Group' (May–June 1988) 7(3) *Biotechnology Law Report* 203.

[92] 'Requirements for Patent Applications Containing Nucleotide Sequence and/ or Amino Acid Sequence Disclosures' (1 May 1990) 55(84) *Federal Register* 37 CFR Part 1, 18230.

[93] 'Requirements for Patent Applications Containing Nucleotide Sequence and/ or Amino Acid Sequence Disclosures' (Tuesday, 2 May 1989) 54(83) *Federal Register* Proposed Rules, 180671.

Applicants were also encouraged to use sequence identification numbers in the form SEQ ID NO: X as a shorthand way of claiming their inventions.[94] In addition to providing a paper-based version of the sequence information, applicants were also required to submit a copy of the sequence listing in computer readable form on floppy discs. The computer readable form was entered into the Patent Office's database for searching nucleotide and amino acid sequences. The electronic database enabled the US Patent Office to exchange patented sequence data in electronic form with the European and Japanese Patent Offices. To build a comprehensive database that allowed the Patent Office to properly assess the prior art, applicants had to provide sequence information for all sequences mentioned in an application, whether claimed or not. Sequence listings were also disclosed as part of the published patent application or issued patent. They were also provided to the National Center for Biotechnology Information for inclusion in their GenBank sequence database.[95]

While the 1990 sequence disclosure rules resolved many of the problems that had arisen with sequence information, a number of problems remained: mostly associated with the requirement that applicants had to submit sequence data in both paper and a computer readable form. The continued use of paper-based disclosure created a number of logistical problems for the Patent Office. One reason for this was that the number of sequence listings that were being lodged at the Patent Office increased by over 100% per year in the 1990s.[96] Moreover, while early sequence listings were sometimes only 40 or so base pairs long,[97] by 1995 individual sequence listings of over a million base pairs were being lodged. Paper-based sequence listings of this size were not only unable to be searched by the human eye, they were also heavy, cumbersome, and voluminous. For example, in 1990 the Patent Office received a submission containing twenty-two thousand sequence listings, which required eight boxes of paper to print. The size and weight of paper print-outs of sequence listings, which were often thousands of pages in length and over a foot thick, meant that the patent office needed specialised carts to carry the applications to examiners for processing. Storage was also a problem. As the Patent Office complained: 'Considering that the growth rate of sequence listings is such that they now approach one foot per application, this would require one thousand linear feet of shelf space. With each rack holding twenty-four linear feet, the PTO would need

94 'Response to and Analysis of Comments, Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures' (Tuesday, 1 May 1990) 55(84) *Federal Register* 37 CFR Part 1, 18230. The final rules were published in the Federal Register at SS FR 18230 (1 May 1990) and in the Official Gazette at 1114 OG 29 (15 May 1990) 18235. The sequence rules went into effect on 1 October 1990.

95 'Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures' (Monday, 22 April 2019) 84(77) *Federal Register* Notices, 16653.

96 By 2002, the USPTO was processing more than 21,000 sequence listings per year. Robert Wax and James Coburn, 'Sequence Rule Compliance' (2003) 22 *Biotechnology Law Report* 397, 400.

97 John Baxter et al., 'Adrenocorticotropin-Lipotropin Precursor Gene' US Patent No. 4,322,499 (30 March 1982).

forty-two … racks for the application resulting from that one application. Clearly, something needs to be done to address this onslaught of paper.'[98]

While the electronic version of the sequence listing was treated as an unofficial copy of the official paper version, this was largely a pretence given that in practice the electronic version served as the basis for examination, printing, and making copies. Because the Patent Office was not in a position where it could undertake the laborious and expensive task of ensuring that the electronic and paper-based versions of a sequence were the same (something that was usually only ever done in litigation),[99] the concurrence of the electronic and paper-based versions of the sequence was assumed on the basis of a statement to that effect by a registered attorney or agent. Given the difficulty of maintaining the two independent versions of the sequence listing and the 'irony that the official paper copy was effectively ignored while the unofficial electronic copy is the only that is used', in 1999 the Patent Office eliminated the paper copy in 'favour of the useful, handy and verifiable computer readable version'.[100]

The use of digital sequence information to describe genetic inventions, which has been treated as a defining feature of molecular gene patents, fundamentally changed the way molecular subject matter was represented. In this sense it was not merely as the Patent Office wrote in 1999 that there was an inverse relationship 'between the level of predictability in the art and the *amount* of disclosure necessary to satisfy the written description requirement', so much as the *nature* of the disclosure changed.[101] The reason for this was that in reducing biological subject matter to a string of digitized letters and symbols, sequence information represented the 'virtualisation' of biological labour and biological objects within patent law: organisms and genes become codes made up of zeros and ones.[102] In this sense, it could be said that patent law's acceptance of sequence information, which erased 'the boundaries between life in vivo and life in silico',[103] represented the informatisation or dematerialisation of biological subject matter.[104]

While the adoption of sequence information in lieu of either structural chemical formula or physical deposit marked an important change in the way molecular subject

98 USPTO, 'Permitting Electronic Submission of Voluminous Material' (5 January 1999) 1218 Official Gazette (37 CFR 1.96, 1.821), 193.

99 Ibid.

100 Rochelle K. Seide and Janet M. MacLeod, 'Drafting Claims for Biotechnology Inventions' in *Eight Annual Patent Prosecution Workshop: Advance Claim Drafting and Amendment Writing* (New York: Practising Law Institute, 1998), 337, 391.

101 USPTO, 'Revised Interim Guidelines for the Examination of Patent Applications under the 35 U.S.C. § 112(1) "Written Description" Requirement' (21 December 1999) 64 *Federal Register* 71427.

102 Hallam Stevens, *Life Out of Sequence: A Data Driven History of Bioinformatics* (Chicago: Chicago University Press, 2013), 5.

103 Hallam Stevens, 'On the Means of Bio-production: Bioinformatics and How to Make Knowledge in a High-Throughput Genomics Laboratory' 6(2) (2011) *BioSocieties* 217, 241.

104 Adrian Mackenzie, 'Bringing Sequences to Life: How Bioinformatics Corporealizes Sequence Data' (2003) 22(3) *New Genetics and Society* 315, 330.

matter was conceptualised, nonetheless it was only a partial process. This is because when it came to deciding the fate of genes as patentable subject matter, the subject matter was still grounded in the materiality of the gene as a chemical substance. Put differently, while epistemologically molecular subject matter had been reduced to a paper/digital form, ontologically molecular subject matter was still treated as a tangible physical chemical compound when deciding subject matter eligibility.[105]

JUDGING MOLECULAR SUBJECT MATTER

One of the techniques that patent law used to allow it to deal with an ungiving biological subject matter was to bundle nature and inventor together. The process of invention was also figured accordingly: nature was seen to provide the inventive contribution while the role of the human inventor was relegated to recognising and preserving nature's innovation. The resulting co-inventions were judged accordingly. With molecularisation, biological subject matter was unbundled and the role of the inventor was recast in more familiar terms. As a consequence, it was now possible to isolate and evaluate what the inventor had contributed to the resulting invention. That is, it was now possible to judge biological subject matter in a manner similar to the way mechanical inventions were evaluated.

In thinking about what an inventor working with biological material needed to do to ensure that the end-results were patentable, patent law not only recast the figure of the inventor in more familiar terms, it also saw 'nature' emerge for the first time as a discrete legal category. While nature had previously made an appearance in patent law, it was predominately as a source of innovation and change (mutation, sports) – as the agent of invention – rather than anything like the way it is thought about today. And, even in the rare instances where unmodified plants, microorganisms, and bacteria were treated as natural things that were beyond the reach of patent law (as is the case now), there was no sense in which they belonged to some overarching legal category. To the extent that there was any sustained focus on natural inventions – and, again, this was rare – this was usually part of a broader discussion about how to configure empirical inventions so that they complied with the doctrinal rules that were imposed on them.

The situation began to change with the emergence of a more molecularised subject matter in the 1970s. As is often the case when patent law grapples with the products of scientific and technical innovation, the process of change was neither straightforward nor logical. While the 1980 *Chakrabarty* decision did see a more abstract grouping of biological subject matter emerge within patent law, nonetheless 'nature' still did not yet exist, at least in the way that it understood today. By the first decade of the twenty first century, however, the situation had changed: the focus of attention had shifted from living biological subject matter to a more general and more familiar grouping

[105] 'Patent law is ill suited to protecting the informational value of these molecules'. Rebecca Eisenberg, 'Do EST Patents Matter?' (October 1998) 14(10) *Trends in Genetics* 379, 380.

that consistently encompassed both animate biological matter as well as inanimate natural matter such minerals, metals, and elements. While patent law may not have invented nature as a legal category (although it is tempting to say so), it is safe to say that over the last 40 or so years that nature has been elevated in status, given a name, and a body of law. As part of the process, nature was also given a history.

Recognising that 'nature' has only recently emerged within patent law as a meaningful albeit confused and problematic category of excluded subject matter helps to explain why it is that the various attempts to write the history of the product of nature doctrine have proved to be so problematic; why it is that the doctrine has such divergent origins; why it is that the case law on natural subject matter 'remains a kaleidoscope of doctrine';[106] and why it is that '[a]nyone looking for a historical "right" answer on the product of nature question will probably be disappointed'.[107] The simple reason for this being that people are trying to write the history of something that did not yet exist.

One of the characteristics of the abstract legal category that emerged alongside molecular subject matter is that it included a wide range of nature-based innovations that spanned from oranges dipped in borax and wire made from tungsten and uranium, through to fibre extracted from pine needles, products made up of different strains of bacteria, and novel chemical compounds such as adrenalin and aspirin. One of the consequences of this diversity was that the product of nature doctrine potentially reached back in a range of different directions within patent law. This meant, for example, that a decision about the patentability of a human gene was now connected to earlier decisions about microorganisms, minerals, plants, and synthetic chemicals.

Another consequence of this diverse history was that it offered a number of different ways of potentially evaluating and judging the unbundled subject matter. As a result, and to the annoyance of textbook writers and doctrinialists, there is no easy way of determining how nature-based subject matter might be judged: there is no simple question that can be asked or litmus test that can be applied to determine whether nature-based subject matter is patent-worthy. Instead, different tests are used at different times, often seemingly chosen to suit the facts at hand. At different times decisions have turned on the nature of the invention and how it was classified,[108] on the type of labour used to create the invention, on the ability of the

[106] Christopher Beauchamp, 'Patenting Nature: A Problem of History' (2013) 16 *Stanford Technology Law Review* 257, 310.

[107] Ibid.

[108] In many cases, a decision that something is of the type or kind that warrants (or demands) it be classified as an unpatentable product of nature is not contentious. Thus, it has been readily and widely accepted that the discovery of a new mineral or a new plant found in the wild, or a human kidney removed from the body, would be products of nature and as such should be 'free to all men and reserved exclusively to none'. *Diamond* v. *Chakrabarty* 447 U.S. 303, 309 (1980). For a discussion of the role and place of kinds in patent law (primarily in relation to patent claims) see Andrew Chin, 'The Ontological Function of the Patent Document' (2012) 74 *University of Pittsburgh Law Review* 263.

applicant to show that the invention in question was 'markedly different'[109] from the raw material on which it was based, or on the way the invention was named (with a change of name being taken as being indicative of a change of kind and thus that the matter in question is patent-eligible).[110]

The confusion this creates is compounded by the fact that judges often switch between questions or rely on different factors to decide subject matter eligibility. In a single judgement a court may simultaneously focus on the labour of the inventor (and whether it is 'inventive'), on the way the invention in question differs from the raw material on which it is based (is it markedly different?), and, at the same time, on the character of the invention (is it the right kind of invention?). Indeed, this is what happened in *Diamond* v. *Chakrabarty* where in finding that the disputed genetically engineered bacterium was patent-eligible, the Supreme Court not only highlighted the labour that Chakrabarty had used to create the modified bacteria and how 'markedly different' that genetically modified organism was from the starting material, the Court also took account of the fact that the bacteria had been christened with a new name: *Pseudomonas putida*.[111] As the Court said, the claim was 'not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter – a product of human ingenuity "having a distinctive name, character [and] use"'.[112]

A similar multi-pronged approach was also adopted by the Supreme Court in its 2013 decision of *Association for Molecular Pathology* v. *Myriad Genetics*. While the patents being challenged in this case covered a range of subject matter – including isolated DNA sequences (BRCA1 and BRCA2), methods to diagnose propensity to breast cancer by looking for mutated DNA sequences, and methods to identify drug candidates using isolated DNA sequences – in line with the reductionist spirit that characterises the way patent law engages with molecular subject matter, the case and associated commentary focused on the patentability of Myriad's claims over the BRCA1 and BRCA2 genes. Specifically, it focused on whether the isolated DNA segment was patentable.

While the Supreme Court in *Myriad* may not have been as promiscuous as it had been in *Chakrabarty* in terms of the factors that were used to determine patentability, nonetheless the Court did make use of a number of different factors in deciding that

[109] *See Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office* 702 F. Supp. 2d 181, 222 (SDNY 2010).

[110] For example, in *Intervet* v. *Merial*, it was held that DNA constructs encoding a type of porcine circovirus as a new type of virus 'comports with the way that viruses are typically classified in the relevant art'. 617 F.3d 1282, 1288 (Fed. Cir. 2010).

[111] *Diamond* v. *Chakrabarty* 447 U.S. 303, 310 (1980).

[112] Ibid., 309–10. In other situations, the fact that subject matter has *not* been given a new name has been taken to suggest that the subject matter is not patent-worthy. Thus, in *American Fruit Growers* v. *Brogdex*, the Supreme Court held that an orange dipped in a solution of borax to render the skin mould-resistant was not a manufactured article and thus not patentable. One of the reasons for this was that there was 'no change in the name, appearance, or general character of the fruit. It remains a fresh orange fit only for the same beneficial uses as theretofore'. *American Fruit Growers* v. *Brogdex* 283 U.S. 1, 11–12 (1931). See also *In re Ewald* 129 F.2d 340, 342 (CCPA 1942) (a cored pear was not a manufacture because it did not possess a new name, character, or use).

'naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated'. In explaining the reasons for this conclusion, Thomas J. compared the patentable invention in *Chakrabarty* with the non-patentable BRCA1 and BRCA2 genes saying that while due to the additional plasmids and resultant capacity for degrading oil, the Chakrabarty bacterium was new 'with markedly different characteristics from any found in nature', by contrast Myriad had not created anything.[113] Thomas J. also compared the BRCA1 and BRCA2 genes with the bacteria-based invention at stake in *Funk Brothers* noting that the composition in *Funk* was held to be ineligible for protection because the patent holder did not alter the bacteria in any way.[114]

As is clear from even a cursory look at the literature, the *Myriad* decision has been cut and spliced in many ways. For some, the decision is tied up with discussions about doctrinal purity and questions of whether subject matter inquiry should be distinct from novelty and obviousness. For others, the key question is understanding how the Supreme Court managed to distinguish non-patentable isolated sequences from patentable synthetic lab-made cDNA[115] (isolated sequences were functionally identical to those found in nature), whether the decision was policy masked as science,[116] or whether the science relied upon in the decision was accurate.[117] For others *Myriad* left open the question of what constitutes patent eligible cDNA and the extent to which cDNA needs to be altered for it to be patent eligible. While these are important questions, I wish to take a different tact. In particular, I want to shift the focus of attention away from the question of how the nature-based subject matter should be judged to focus on the way that the subject matter was construed and the impact this had on the ultimate decision. That is, I want to consider the relatively neglected question of the ontology of the gene in patent law.[118]

In contemplating the status of genes as patentable subject matter, intellectual property law makers were faced with competing interpretations of how the subject matter could be construed. This was a consequence of the gene's ambiguous status whereby it was simultaneously thought of as a material chemical entity *and* as a carrier of information.[119] As Sweet J. noted in the first instance decision in *Myriad*, genes are of

113 *Assoc. for Molecular Pathology* v. *Myriad Genetics* 569 U.S. 576, 577 (2013).

114 Ibid., 591.

115 Dan L. Burk, 'Are Human Genes Patentable' (2013) *IIC* 747; See also Charles Lawson, 'Patenting DNA Sequences after the Myriad Decision' (2014) 33 *Biotechnology Law Report* 3.

116 Shubha Ghosh, 'Myriad post-*Myriad*' (2020) 47(5) (October 2020) *Science and Public Policy*, 638. ('Deference to the Scientific Community Is Implicit in the Court's Exegesis of the Science of DNA').

117 Brief for Amicus Curia Eric S. Lander in Support of Neither Party, No 12–398, *The Association for Molecular Pathology* v. *Myriad Genetics*, 11–14. Mateo Aboy et al., 'After Myriad, What Makes a Gene Patents Claim 'Markedly Different' from Nature?' 35(9) (September 2017) *Nature Biotechnology* 820.

118 For a notable exception see Jane Calvert and Pierre-Benoît Joly, 'How Did the Gene Become a Chemical Compound? The Ontology of the Gene and the Patenting of DNA' (2011) 50(2) *Social Science Information* 157, 168.

119 See Hans-Jörg Rheinberger, 'Gene Concepts Fragments from the Perspective of Molecular Biology' in (ed) P. Beurton, R. Falk, and H. Rheinberger, *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2000), 219.

double nature. On the one hand they are chemical substances or molecules. On the other hand, they are also physical carriers of information 'where the actual function of this information is coding for proteins'. One of the consequences of this was that when deciding the fate of gene patents, the courts found themselves in a situation similar to the position they had been in with software-related inventions where they were presented with two very different ways of thinking about the subject matter. In this sense it was not only as Eric Lander said in his amicus brief in *Myriad* that the question before the Supreme Court was a scientific question about the subject matter, so much as that it was a choice between different scientific understandings of the subject matter.[120]

Unlike the case with software-related inventions, the law did not attempt to merge the two approaches when dealing with the patentability of genes. Rather, patent law approached subject matter eligibility as an either/or decision. The consequences of which were clear. If the gene was seen as a chemical molecule – as the Federal Circuit did – the result was that isolated genes were almost inevitably patentable subject matter. The reason for this is that because when DNA is removed from the body chemical bonds are severed and replaced with new bonds, the isolated compound is chemically different from its natural equivalent. Because the isolated DNA was 'markedly different' to the natural DNA in the body, it was patentable subject matter. In contrast, if the gene is seen as a carrier of biological information – as Sweet J. at first instance and the Supreme Court did – the outcome was different. Because the gene in the body and the isolated gene both act as carriers of information,[121] the isolated gene was not 'markedly different' from native DNA as it exists in nature. On this basis it was held that the isolated DNA was unpatentable subject matter.

Prior to the *Myriad* litigation, the status of the gene in patent law had been clear: a gene was treated as a chemical compound, which meant that when it was isolated from its natural state, it was markedly different from the raw material on which it was based and thus potentially patentable. Given that this view of the ontology of the gene had been unquestionably accepted in patent law for over 40 years, it is not surprising that Judge Sweet's first instance decision in *Myriad* that 'DNA represents the physical embodiment of biological information'[122] caught so many people by surprise. While this may have been seen by some as a temporary aberration that was corrected by the Federal Circuit (which reinstated the chemical view of the gene and consequently upheld the validity of the patents), the new view of the legal gene was confirmed by the Supreme Court in 2013 when in declaring the gene patents invalid the court stressed that Myriad's claim were 'concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular

[120] Brief for Amicus Curia Eric S. Lander in Support of Neither Party, No 12–398, *The Association for Molecular Pathology* v. *Myriad Genetics*, 2.

[121] Jane Calvert and Pierre-Benoît Joly, 'How Did the Gene Become a Chemical Compound? The Ontology of the Gene and the Patenting of DNA' (2011) 50(2) *Social Science Information* 157, 158.

[122] *Assoc. for Molecular Pathology* v. *USPTO* 702 F. Supp. 2d 181, 185 (SDNY 2010).

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molecule'.[123] As Justice Thomas said, Myriad's claims were not 'saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a non-naturally occurring molecule'. The reason for this was that Myriad's claims were 'simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes'.[124] By prioritising biological information over chemical structure, the Supreme Court decision represents a continuation of the process that has seen subject matter shift from the organism to molecules, then from molecules to information, and finally from information to 'prescriptive script'.[125]

When gene patents first appeared in patent law in the 1960's, genes were treated as chemical compounds both in terms of how they were described and how they were conceptualised and judged. That is, the gene was treated both epistemologically and ontologically as a chemical compound. While this remained unchanged when the inventor was unbundled from the subject matter, the situation began to unravel when patent law adopted sequence information as a way of describing, identifying, and enabling molecular subject matter. By accepting that it was now possible to repeat the invention from its paper/digital form, patent law also accepted that it was no longer necessary to deposit physical samples of the invention as part of the application process. While the adoption of sequence information in lieu of a physical deposit to describe and enable the gene marked an important change in the way molecular subject matter was conceptualised and a shift towards a more dematerialised subject matter, nonetheless when it came to deciding the fate of genes as patentable subject matter, the subject matter was still grounded in the materiality of the gene as a chemical substance.

The situation changed in 2013 with the Supreme Court decision in *Myriad*. By elevating biological information over chemical structure,[126] the Supreme Court completed the process that had begun in the 1980s of rendering molecular subject matter biological and informational.[127] The reason for this was that after *Myriad*, genes (DNA sequences) were no longer simply chemical molecules. Nor were they material chemical entities that carried information or instruction.[128] In the post-Myriad world, the utility of gene patents was based on the information

[123] *Assoc. for Molecular Pathology* v. *Myriad Genetics* 569 U.S. 576, 593 (2013).

[124] Ibid., 577.

[125] Sakari Tamminen and Niki Vermeulen, 'Bio-objects: New Conjugations on Living' 21(5) (2019) *Sociologias* 156, 162.

[126] Bernhard D. Saxe, 'Gene Patent Decision: A Chemist's View' (2013) 33(15) *Genetic Engineering and Biotechnology News* 8, 12.

[127] On the role of information in biology see Lilly E. Kay, *Who Wrote the Book of Life?* (Stanford: Stanford University Press, 2000), 226.

[128] 'DNA sequences are not simply molecules, they are also information. Patent claims to information – even useful information – represents a fundamental departure from the traditional patent bargain.' Rebecca Eisenburg, 'Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences' (2000) 49(3) *Emory Law Journal* 783, 786.

provided by the DNA sequence, rather than the material substance. In a subtle but important change, genes were now informational both in terms of the way they are represented and also in terms of how they are conceptualised and judged.[129] While 'information' may have started out as a metaphor or analogy, it came to be treated as a thing in itself within patent law – as an ontology. And, as Jane Calvert said, when 'something is taken as an ontology it becomes a potential object of patentability'.[130]

In adopting the life-as-information paradigm, the subject matter of patent law underwent a radical transformation from organic into virtual form, as the subject matter of patent law was 'displaced, with the molecule overtaking or territorializing the organism and getting plugged into the computer'.[131] As a result, the material chemical molecule (which had supplanted plant-based subject matter) gave 'way to molecules that contain the code for life and that information technologies have captured life's vitality and transformed it into bits'.[132] One of the consequences of this was that the legal gene, like its scientific equivalent, became 'curiously intangible'.[133] One of the distinctive features of the new informational subject matter is that it is separate and distinct from the material physical form of the invention. Unlike the pre-*Myriad* molecular gene, which was rooted in the material chemical compound, the molecular gene post-*Myriad* was decoupled from its physical form. It was, in short, dematerialised as the subject matter was reconceptualised through its immateriality.[134]

The shift from surface to subsurface, and then from chemical structure to genetic information, and then from gene as chemical compound to gene as carrier of information brought about a number of changes in biological subject matter. In the case of plants, for example, while patent protection had previously been limited to individual plants, this changed when the subject matter shifted below the surface and became informational. One of the consequences of this was that patentees were no longer tied to a claim that was taxonomically literate nor limited to individual

[129] In this sense the gene became informational both epistemologically in the sense of '*information about genes*', which refers to the particular way that genes are represented; and ontologically in the sense of '*information encoded in genes*.' Paul Griffiths, 'Genetic Information: A Metaphor in Search of a Theory' (2001) 68(3) *Philosophy of Science* 394, 409.

[130] Jane Calvert, 'Patenting Genomic Objects: Genes, Genomes, Function and Information' (2007) 16(2) *Science as Culture* 207, 217.

[131] Richard Doyle, *On Beyond Living: Rhetorical Transformation of the Life Sciences* (Stanford: Stanford University Press, 1997), 1.

[132] Sakari Tamminen and Niki Vermeulen, 'Bio-objects: New Conjugations on Living' 21(5) (2019) *Sociologias* 156, 163.

[133] 'Introduction' in (ed) P. Beurton, R. Falk, and H. Rheinberger, *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2000), x. 'The more molecular biologists learn about genes, the less sure they seem to become of what a gene really is. Knowledge about the structure and functioning of genes abounds, but also, the gene has become curiously intangible'.

[134] Sakari Tamminen and Niki Vermeulen 'Bio-objects: New Conjugations on Living' 21(5) (2019) *Sociologias* 156, 159.

organisms; patentees could and frequently did claim groups or classes of plants, or groups of plants that were united by the fact that they exhibited shared characteristics (such as being glyphosate resistant). While the validity of a patent for super-double nasturtiums had been questioned at a time when the focus of the law was on individual plants, the shift below the surface meant that it was now possible to patent a novel double flower gene in Verbena that produced flowers with additional petals.[135]

The nature of plant-based subject matter was changed further by the use of sequence information to claim genetic innovations. While physical samples deposited as part of the application process provided or at least were treated as if they provided boundaries around the invention, these markers disappeared when the subject matter was represented using sequence information.[136] One of the consequences of this is that decisions needed to be made about the limits of sequence-based inventions. One option was to limit protection to identical, facsimile copies of the claimed invention. With these 'picture claims', protection would have been limited to nucleotide sequences that were identical to the sequences that were depicted in the patent.[137] One of the arguments made in favour of this approach was that if the line was 'not drawn at 100% sequence identity, these claims become a slippery slope with boundaries that must be individually defined'. To accept anything less would have opened 'a Pandora's box that the patent law is unable to control'.[138] It was also argued that as genes vary so much between and within species, yet are so closely related, any alternative approach to patenting genes, other than disclosing exact nucleotide sequences would have risked granting overly broad patent rights to single inventors.[139]

Whatever advantages there might have been with this approach, it was not followed. One of the problems with limiting protection to 100% sequence identity was that it would have been relatively easy for would-be infringers to avoid a patent by making (non-functional) cosmetic change to the genetic structure of a biological organism which, in turn, would have changed the sequence information. To protect the equity of patented inventions, the courts decided that protection should extend beyond the literal sequence specified in the patent application to include related sequences.[140] As the Patent Office said, claims typically include the 'sequence and any sequence having a certain percentage identity or homology to the sequence or any sequences which hybridizes to the sequence'.[141] That is, it was very common for patentees to

[135] Mitchell Eugene Hanes and Staislaw Naleoa, 'Double Flower Gene of Verbena and the Method of Producing Same' US Patent No. 6,150,591 (21 November 2000).

[136] See *Ajinomoto Co.* v. *Archer-Daniels-Midland* 228 F.3d 1338 (Fed. Cir. 2000).

[137] Diana Sheiness, 'Patenting Gene Sequences' (1996) 78(2) *Journal of the Patent and Trademark Office Society* 121.

[138] Margaret Simpson, 'The Evolution of the Enablement and Written Description Requirement under 35 USC Sec 112 in the Area of Biotechnology' (2000) *Berkeley Technology and Law Journal* 1233, 1261.

[139] Ibid.

[140] Guillaume Dufresne and Manuel Duval, 'Genetic Sequences: How Are They Patented?' (2004) 22 *Nature Biotechnology* 231.

[141] Patent and Trademark Office, 'Notice of Hearing and Request for Comments on Issues Relating to Patent Protection for Nucleic Acid Sequences' (12 March 1996) 61(49) *Federal Register* 9980, 9981

claim sequences that have at least a threshold level of percentage with the specified sequence, for example, sequences that have at least 90% identity with the specified sequence.[142]

One of the consequences of limiting patent protection to 100% sequence identity would have been that protection was limited to the individual invention that was disclosed in the patent. By allowing patentees to claim homology of less than 100% similarity, patent law opened up the possibility of extending the scope of the invention to groups of inventions, which were sometimes very large. For example, in one decision it was noted that a patent claiming 'a recombinant yeast with a coding region at least 90% identity with SEQ ID No 11' potentially covered 3.4×10^{41} variants.[143] As was the case with the shift to formula-based chemical inventions, this created further questions about the number of inventions that patentees needed to disclose to enable their inventions. This was part of a more general change whereby the subject matter became mathematical to the extent that the courts, the Patent Office, and others reading the patent claims were called on to decide questions of similarity and difference in mathematical terms.[144] Instead of deciding infringement or patentability by looking at the external traits of an invention or what the invention did, similarity and difference was now decided by relative degree of similarity. As a result, the question became where and how the level of homology or sequence identity should be set. If 80% similarity was enough, what about 79%? And so on.[145] The upshot of this was although on first blush the use of sequence information to identify biological inventions represents a continuation of the longstanding practice whereby questions in patent law are answered using scientific criteria, on closer inspection, the process was ironically rendered more legal.[146]

142 Guillaume Dufresne and Manuel Duval, 'Genetic Sequences: How Are They Patented?' (2004) 22 *Nature Biotechnology* 231.

143 *Ex parte Porro (2008) BPAI* Appeal 2008–9814 (11 March 2008).

144 Guillaume Dufresne and Manuel Duval, 'Genetic Sequences: How Are They Patented?' (2004) 22 *Nature Biotechnology* 231.

145 The threshold value for percentage of identity varies with some claiming rights over sequences with as little as 70% homology. Osmat A. Jefferson et al., 'Gene Patent Practice across Plant and Human Genomes' (2015) 33 *Nature Biotechnology* 1034.

146 At least in the sense that the law could not rely upon science to provide an answer.

10

Postgenomic Subject Matter

'Scientists speak inarticulately about precise objects, lawyers speak in precise terms about vague objects.'[1]

INTRODUCTION

The legal image of the gene has changed considerably from the time when intellectual property law first encountered gene patents in the 1970s. Initially, genes were called chemical compounds and described using different chemical and biological experimental techniques (such as gel electrophoresis diagrams or cleavage maps). At the same time, genes were judged on the basis that they were chemical subject matter. This changed in the late 1970s when patentees began to describe their gene-based inventions in terms of the way the chemical molecules in the claimed DNA sequences (genes) were ordered (represented by strings of As, Ts, Cs, and Gs). As a result, genes and molecular subject matter more generally were no longer described chemically. Instead, they were now described, for want of a better word, informationally. Despite this important change, genes were still judged in patent law on the basis that they were chemical compounds. This situation remained unchanged until 2013 when the Supreme Court in *Myriad* decided that genes formed the basis for hereditary traits in living organisms and were to be judged accordingly.

While it is important when thinking about how patent law has engaged with molecular subject matter to appreciate how the legal image of the gene has changed over time, this is only part of the story. The problem with the account I have given so far is that while it recognises that the legal image of the gene has changed, it presumes that in other ways that the gene has remained stable. That is, it presumes that the vision of the molecular gene that emerged in the 1950s and 1960s is still relevant today. In so doing it fails to take account of the profound changes that have taken

[1] Bruno Latour, 'Scientific Objects and Legal Objectivity' in (ed) Alain Pottage and Martha Mundy, *Law, Anthropology, and the Constitution of the Social: Making Persons and Things* (Cambridge: Cambridge University Press, 2004), 81, 88.

place in molecular biology and related fields over the last 60 or so years. To appreciate the nature of these changes and what this means for patent law and its interaction with molecular subject matter, I will briefly look at how the classical molecular gene has fared within the life sciences since it emerged in the middle of the twentieth century. While historians of biology may disagree on how to respond to these changes, one thing that they do agree on is that the molecular gene has not fared very well.

As we saw earlier, the classical molecular gene was presumed to perform a number of different roles. Building on the idea of the gene as the master molecule, the molecular gene was assumed to be the guarantor of intergeneration stability, the factor responsible for individual traits and, at the same time, the agent for directing an organisms development.[2] As molecular biology matured the 'impracticality (perhaps even impossibility) of the gene being able to perform these different functions become apparent'. In particular, it became apparent that the 'secrets of life' were 'vastly more complex and more confusing than they seemed on the 1960s and 1970s'.[3] The more molecular biologists learnt about genes, the less sure they became about what a gene really was and what it did.[4] As research progressed and scientists learnt more about genes, the over-simplified assumptions of the molecular gene were modified, undermined, and refined.

The first cracks in the idea of the gene as master molecule appeared very soon after it was formulated in the 1960s when it was discovered that genes came in two classes, 'one structural, the other regulatory and that some chromosomal DNA did not code for polypeptides, but nevertheless were essential for the regulation of gene expression'.[5] The tenability of the gene concept was further called into question by subsequent research that revealed that the relationship between DNA and protein was much more indirect and mediated than first thought,[6] that phenotypic traits were often influenced by many genes, that genes were able to impact a number of different phenotypic traits,[7] and that the connection between a gene, a gene

[2] Evelyn Fox Keller, *The Century of the Gene* (Cambridge, MA: Harvard University Press, 2000), 140–41.

[3] Ibid., 55.

[4] 'Introduction' in (ed) P. Beurton, R. Falk, and H. Rheinberger, *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2000), x.

[5] Hans-Jörg Rheinberger, 'Gene Concepts Fragments from the Perspective of Molecular Biology' in (ed) P. Beurton, R. Falk, and H. Rheinberger, *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2000), 219, 229.

[6] Karola C. Stoltz, Adam Bostanci, and Paul Griffiths, 'Tracking the Shift to Postgenomics' (2006) *Community Genetics* 190, 192.

[7] What is interesting is how difficult it is to reduce genes (correlations with traits) to molecular genes (stretches of DNA) because it has been shown that there are usually many molecular genes which play a role in influencing one phenotypic trait, and also that one molecular gene has effects on many different phenotypic traits. Jane Calvert and Pierre-Benoît Joly, 'How Did the Gene Become a Chemical Compound? The Ontology of the Gene and the Patenting of DNA' (2011) 50(2) *Social Science Information* 157, 167.

product,[8] and a trait was very rarely straightforward'.[9] As Michael Morange's 1998 history of molecular biology showed, despite over 50 years of successful research in molecular biology little was known about the causal chains that link genes to the phenotypic traits of organisms.[10] Instead, by the end of the twentieth century, ongoing genetic research had revealed a 'complexity of developmental dynamics' that made it impossible to conceive of genes as distinct causal agents in development.[11] As a result, the idea of a single and universal definition of the gene was disappearing, along with the idea that one (or a few) genes were the ultimate determinants of phenotypic traits.[12]

The demise of the idea of the gene as master molecule was accelerated by the emergence of what has been called the era of 'postgenomics', which has been defined 'temporally as the period after the completion of the sequencing of the human genome' and technically in 'reference to the advent of whole-genome technologies as a shared platform for biological research across many fields and social arenas'.[13] While DNA sequencing methods were available from the 1970s, they were slow and laborious processes that were limited to simple organisms such as bacteria. The introduction of faster automated sequencing methods in the 1990s facilitated the sequencing of more complex organisms: initially yeast, then animal, plant, and ultimately human genomes.[14] While the Human Genome Project may not have made good on the promise that it would unlock the secrets of life, nonetheless it still brought about a conceptual change in our understanding of genes,

8 A 'gene product' is biochemical material, either RNA or protein, resulting from expression of a gene.

9 Jane Calvert and Pierre-Benoît Joly, 'How Did the Gene Become a Chemical Compound? The Ontology of the Gene and the Patenting of DNA' (2011) 50(2) *Social Science Information* 157, 167. Even 'if a scientist discovers what a gene transcribes he or she may be very far from knowing how it comes to influence the final phenotype, because there will inevitably be many further molecular interactions, cascades and feedback loops involved.'

10 Michel Morange, *A History of Molecular Biology* (Cambridge, MA: Harvard University Press, 2000).

11 See Evelyn Fox Keller, *The Century of the Gene* (Cambridge, MA: Harvard University Press, 2000).

12 Laurence Perbal, 'The Case of the Gene: Postgenomics between Modernity and Postmodernity' (2015) 16(7) *EMBO Reports* 777. Peter J. Beurton, 'A Unified View of the Gene, or How to Overcome Reductionism' in (ed) P. Beurton, R. Falk, and H.-J. Rheinberger, *The Concept of the Gene in Development and Evolution* (Cambridge: Cambridge University Press, 2000), 286. Paul E. Griffiths and Karola Stotz, 'Genes in the Postgenomic Era' (2006) 27 *Theoretical Medicine and Bioethics* 499, 515.

13 Sarah S. Richardson and Hallam Stevens, 'Beyond the Genome' in (ed) Sarah S. Richardson and Hallam Stevens, *Postgenomics: Perspectives on Biology after the Genome*, (Durham, NC: Duke University Press, 2015), 1, 2 ('postgenomic' are those areas of the biological sciences that now use genomic information or approaches as a foundational or standard element of their research practices). With 'the completion of the human genome sequence and the beginning of … postgenomics, genetics is again experiencing a time of conceptual change. The concept of the gene, emerging out of a century of genetic research, has been and continues to be … a concept in tension'. Hans-Jörg Rheinberger and Staffan Müller-Wille, 'Gene' in *Stanford Encyclopedia of Philosophy* (Revised 10 March 2009), 1.

14 These disciplines are driven by the availability of improved technologies that are producing new types of data that undermine the classical molecular concept. Karola C. Stoltz, Adam Bostanci, and Paul Griffiths, 'Tracking the Shift to Postgenomics' (2006) *Community Genetics* 190, 191.

genomes, and genetics. The reason for this was that it led to a number of surprising findings, including that the human genome contained far fewer genes than had been thought,[15] that only a small portion of the genome's structure was devoted to protein-coding sequences,[16] and that the practice of fabricating alternative gene products from one and the same sequence ('alternative splicing') was much more common than people had expected. While the Human Genome Project may not have laid 'bare the blueprint of human biology',[17] it did show that the gene was not the Rosetta Stone that many had claimed,[18] that 'sequence information alone would not tell us who we are', and that the 'sequence alone does not provide the complete set of genetic instructions of the human being'.[19]

The ability to sequence whole genomes led to important changes in the way genes and genomes were understood.[20] Genomics and high-throughput biology not only revealed the growing complexity and increasing ambiguity of the notion of the gene, it also 'undermined popular genetic determinism, and in that sense, albeit somewhat belatedly, joined and even underlined the importance of the deconstruction of the gene within molecular biology'.[21] One of the things that genomics studies revealed was that many traits – 'even traits that biologists might have supposed to be quite straightforward' – turned out to be associated with hundreds or even thousands of locations on the genome. 'One 2010 study', for example, 'associated 180 distinct locations with human height'.[22] In contrast to the simplistic, deterministic, and atomistic approach of early molecular genomics where genes were treated as master molecules, in the postgenomic era there is an emphasis on complexity, indeterminacy, and gene-environment interactions.[23]

While the 'reductionist method of dissecting biological systems into their parts and studying them in isolation' was successful in explaining the chemical basis of simple living processes in the early days of molecular biology,[24] it could not capture the complex architecture of more complicated biological organisms such

[15] The human chromosome consisted of just over 20,000 rather than 100,000 or so coding sequences.

[16] Evelyn Fox Keller, 'The Postgenomic Genome' in (ed) Sarah S. Richardson and Hallam Stevens, *Postgenomics: Perspectives on Biology after the Genome* (Durham, NC: Duke University Press, 2015), 17.

[17] Ibid., 9.

[18] Evelyn Fox Keller, *The Century of the Gene* (Cambridge, MA: Harvard University Press, 2000), 5.

[19] Evelyn Fox Keller, 'The Postgenomic Genome' in (ed) Sarah S. Richardson and Hallam Stevens, *Postgenomics: Perspectives on Biology after the Genome* (Durham, NC: Duke University Press, 2015), 9.

[20] Jane Calvert, 'Patenting Genomic Objects: Genes, Genomes, Function and Information' (2007) 16(2) *Science as Culture* 207, 213.

[21] Hans-Jörg Rheinberger and Staffan Müller-Wille, *The Gene from Genetics to Postgenomics* (Chicago: University of Chicago Press, 2017), 86.

[22] Ibid., 2.

[23] Sarah S. Richardson and Hallam Stevens, 'Beyond the Genome' in (ed) Sarah S. Richardson and Hallam Stevens, *Postgenomics: Perspectives on Biology after the Genome* (Durham, NC: Duke University Press, 2015), 1, 4.

[24] Marc H. Van Regenmortel, 'Reductionism and Complexity in Molecular Biology' (2004) 5(11) *EMBRO Report* 1016 (the classical gene concept of early molecular biology was based on research undertaken on a limited range of relatively simple organisms: prokaryotes and bacteriophages).

as plants, which have 'properties that cannot be explained or even predicted, by studying their individual parts'.[25] Molecular pathways, for example, never work alone but operate in highly structured and integrated biological networks. To understand complex biological activity, scientists turned away from the study of individual molecules and genes to focus on the way these 'components assemble and function together. Interactions between the parts, as well as influences from the environment, give rise to new features, such as network behaviour which are absent in the isolated components'.[26] Scientists also increasingly turned to computing and mathematical modelling to simulate complex systems and biological networks.[27]

The growing scepticism about the role genes played as unique carriers of heredity was exacerbated by the growing realisation that traits and characteristics were 'not simply expressions of genetic information'. Instead, the characteristics of biological organisms were now thought to 'emerge from "developmental systems" that encompasses many aspects of what would be traditionally regarded as the environment'.[28] Over time, this led to a growing interest in epigenetic (environmental) influences, or the study of mechanisms that regulate gene expression in response to environmental signals, which 'represents the new age of genomics in which nature and nurture are seen to interact in profound ways that overturn the old reductionism and determinisms of Watson and Crick's genetic code'.[29]

One of the consequences of the molecular biological research that has taken place since the 1960s is that it 'convoluted, even fragmented, what we understand genes to be, and their role and nature in living organisms'.[30] As the twentieth century progressed, science moved away from the vision of the gene as a simple and single bit of DNA carrying the information for a protein. It also moved away from the idea that the gene was the primary driver of the characteristics or

[25] Paul E. Griffiths and Karola Stotz, 'Genes in the Postgenomic Era' (2006) 27 *Theoretical Medicine and Bioethics* 499, 513.

[26] See M. Morange, 'A Successful Form of Reductionism' (2001) 23 *The Biochemist* 37.

[27] For example see C. Emmeche, 'Aspects of Complexity in Life and Science' (1997) 59 *Philosophica* 41; E. Alm and A. Arkin, 'Biological Networks' (2003) 13 *Current Opinion Structural Biology* 193.

[28] Paul E. Griffiths and Karola Stotz, 'Genes in the Postgenomic Era' (2006) 27 *Theoretical Medicine and Bioethics* 499, 515. Researchers have also pointed to the importance of epigenetic inheritance, which involves the activation or repression of various genes. Jane Calvert and Pierre-Benoît Joly, 'How Did the Gene Become a Chemical Compound? The Ontology of the Gene and the Patenting of DNA' (2011) 50(2) *Social Science Information* 157, 167. Sara Shostak and Margot Moinester, 'The Missing Piece of the Puzzle? Measuring the Environment in the Postgenomic Moment' in (ed) Sarah S. Richardson and Hallam Stevens, *Postgenomics: Perspectives on Biology after the Genome* (Durham, NC: Duke University Press, 2015), 192.

[29] Sarah S. Richardson and Hallam Stevens, 'Beyond the Genome' in (ed) Sarah S. Richardson and Hallam Stevens, *Postgenomics: Perspectives on Biology after the Genome* (Durham, NC: Duke University Press, 2015), 1, 4. Hans-Jörg Rheinberger and Staffan Müller-Wille, *The Gene from Genetics to Postgenomics* (Chicago: University of Chicago Press, 2017), 8.

[30] James W. E. Lowe and Ann Bruce, 'Genetics without Genes? The Centrality of Genetic Markers in Livestock Genetics and Genomics' (2019) 41(5) *History and Philosophy of the Life Sciences* 1.

traits of organisms. This was reinforced by the advent of postgenomics, which signalled 'an important break from the gene-centrism and genetic reductionism of the genomic age'.[31]

The conceptual advances that have taken place over the last 50 years or so have 'led to wholesale destruction of a view of genes that prevailed during the period of classical genetics and early molecular genetics'.[32] At the same time, these advances have shown that despite the enormous developments that have taken place in our understanding of living things that much is still unknown. Rather than settling debates, these developments 'muddied the waters; rather than answering older questions, [they have] raised new ones'.[33] There was also a growing realisation that 'complex objects of investigation such as organisms cannot be successfully understood by a single best account or description'.[34]

The early gene-centric vision of the life sciences, where genes were considered as singular causes for traits, has been replaced by a focus on networks, multiple genes, and by a growing concern with understanding organisms as complex self-organising systems.[35] In this sense, postgenomics 'radically undermined' the core driving concept of the gene.[36] In this new world, genes are no longer seen as 'straightforward, structurally defined entities, or even … mixed functional-structural entities'.[37] Nor are genes seen as a unique functional or molecular entitles, or as discrete entities with clear causal properties.[38] Instead, a postgenomic understanding suggests that genes are as much acted upon as actors. While the reductionist classical gene may have enabled molecular biologists to present a vision of biology as a non-empirical science akin to the mechanical arts, this has been undermined by subsequent

[31] Sarah S. Richardson and Hallam Stevens, 'Beyond the Genome' in (ed) Sarah S. Richardson and Hallam Stevens, *Postgenomics: Perspectives on Biology after the Genome* (Durham, NC: Duke University Press, 2015), 1, 4.

[32] Hans-Jörg Rheinberger and Staffan Müller-Wille, *The Gene from Genetics to Postgenomics* (Chicago: University of Chicago Press, 2017), 116–17.

[33] Sarah S. Richardson and Hallam Stevens, 'Beyond the Genome' in (ed) Sarah S. Richardson and Hallam Stevens, *Postgenomics: Perspectives on Biology after the Genome* (Durham, NC: Duke University Press, 2015), 1, 6.

[34] Hans-Jörg Rheinberger and Staffan Müller-Wille, *The Gene from Genetics to Postgenomics* (Chicago: University of Chicago Press, 2017), 118.

[35] Systems biology is based upon the idea that living organisms are self-organizing systems that involve countless interactions between proteins, nucleic acids, and metabolites within a complex structure, there has been a move to understand and model the interaction of many components in an effort to explain how genetic information translates into phenotypic traits.

[36] Evelyn Fox Keller, *The Century of the Gene* (Cambridge, MA: Harvard University Press, 2000), 5.

[37] Paul E. Griffiths and Karola Stotz, 'Genes in the Postgenomic Era' (2006) 27 *Theoretical Medicine and Bioethics* 499, 509.

[38] Despite the prominence given to the gene 'the science of genetics never provided one generally accepted definition of the gene. More than a hundred years of genetic research have rather resulted in the proliferation of a variety of gene concepts, which sometimes complement, sometimes contradict each other'. Hans-Jörg Rheinberger and Staffan Müller-Wille, 'Gene' in *Stanford Encyclopedia of Philosophy* (Revised 10 March 2009), 1.

research which has shown that prevision remains an issue in biology and in this sense that it remains an empirical science.[39]

LEGAL REACTIONS TO A FUZZY SUBJECT MATTER

What does it mean for our understanding of the law to accept that there is still much about biological subject matter that scientists do not know and cannot explain? What does it mean to accept that the gene may not be the master molecule nor the ultimate determinant of life that classical molecular biology presumed? As Jane Calvert asked, 'if our understanding of the object of investigation changes, what implications does this have for patenting?'[40]

One obvious response is that patent law's engagement with a postgenomic subject matter is simply the latest situation in a long line where the law has been outpaced by scientific and technical change. While there is something in this way of thinking about how law and science interact, it doesn't really help us to understand how patent law has dealt with postgenomic subject matter. A more fruitful response, which I pursue here, is suggested by Hans-Jörg Rheinberger and Staffan Müller-Wille in their historical account of the gene from genetics to postgenomics. One of the things they show in this history is how since the 1970s or thereabouts, 'conceptual advances in understanding organismic metabolism, development and evolution have led to wholesale destruction of a view of genes that prevailed during the period of classical genetics and early molecular genetics'.[41] At the same time, they also show that despite the fragmentation if not the dissolution of the early molecular gene concept, that in certain contexts, particularly in public debates and discussions – to which we can add patent law – that genes still appear as the ultimate determinants and executers of life. That is, they show that despite mounting evidence to the contrary 'that talk about genes "coding for this and that" have become so entrenched in public discourse, with no sign of abatement'; and that genetics is still understood 'in the constitutive reductionist vein that assumes an ability to account for the prediction of the phenotype on the basis of the genes'.[42]

For Rheinberger and Müller-Wille the reason for the continued public gene talk is because during the 1970s genes came to be seen as 'technical objects'. That is, in public discussions the 'gene became a technical product and a commodity, which

[39] For criticisms of gene-centrism see John Dupré, 'The Polygenomic Organism' in (ed) Sarah S. Richardson and Hallam Stevens, *Postgenomics: Perspectives on Biology after the Genome* (Durham, NC: Duke University Press, 2015), 58.

[40] Jane Calvert, 'Patenting Genomic Objects: Genes, Genomes, Function and Information' (2007) 16(2) *Science as Culture* 207.

[41] Hans-Jörg Rheinberger and Staffan Müller-Wille, *The Gene from Genetics to Postgenomics* (Chicago: University of Chicago Press, 2017), 116–17.

[42] Ibid. (Despite the progress made in the molecular understanding of genes, functionalist expressions– 'genes for'–have never stopped multiplying: the gene 'for' cancer, or schizophrenia, diabetes, intelligence, crime depression, and so on).

created the impression that it was a manageable and exchangeable "thing", rather than a fragile and context-sensitive molecular entity'.[43] A key reason for this was the rise of genetic engineering (biotechnology) in the 1970s, which 'worked against, and certainly masked, the deconstruction of the classical molecular gene concept in molecular biology itself, thus backing a public discourse that perpetuated a vision of the "molecular gene" that had been conserved from the 1950s and 1960s'.[44] As they explain, the 'fragmentation if not dissolution of the early molecular gene concept during the 1970s coincided with the upsurge of a kind of countercurrent associated with the rise of genetic engineering or gene technology: this was the rise of a reified concept of the gene as a manipulable and exchangeable "thing" – which became popular and increasingly influential in public debates about the potential application'.[45] The public image of the gene as a technical product and commodity, which was bolstered by the granting of gene patents[46] and the way biotech products were marketed,[47] 'reinforced a conception of genes that was heavily laden with associations to economic goods'.[48] Although 'the deconstruction of rigid gene conceptions progressed relentlessly in laboratories dedicated to molecular biological research', in public debates and discussions 'genes appeared to be things that could be appropriated, manipulated and alienated … And it appeared that the distinguishing feature of such genes was that each had a particular clearly defined function'.[49]

Even a cursory look at the literature on gene patents or the legal decisions that have dealt with gene-based inventions shows that genetic determinism is alive and well in patent law.[50] As Jane Calvert said, patent law 'adopted a simplistic understanding of gene function, which parallels the "central dogma" model, and does not reflect the more sophisticated understandings of gene function provided by developments in genomics'.[51] In many ways this is not surprising. In the same way in which scientists black box complex ideas or create models to allow them to focus on the questions that interest them or that they are able to answer, the law also simplifies scientific concepts and procedures to allow it to decide whatever question is at issue. The fact that something is simplified or black-boxed within patent law is not the

43 Ibid., 117.
44 Ibid., 85–86.
45 Ibid., 74.
46 See generally Kaushik Sunder Rajan, *Biocapital: The Constitution of Postgenomic Life* (Durham, NC: Duke University Press, 2006); Kaushik Sunder Rajan, *Lively Capital: Biotechnologies, Ethics, and Governance in Global Markets* (Durham, NC: Duke University Press, 2012).
47 Evelyn Fox Keller, *The Century of the Gene* (Cambridge, MA: Harvard University Press, 2000), 141.
48 Hans-Jörg Rheinberger and Staffan Müller-Wille, *The Gene from Genetics to Postgenomics* (Chicago: University of Chicago Press, 2017), 76.
49 Ibid.
50 'The term 'gene patent' itself is ambiguous, and this term has been used loosely in the media to encompasses a wide variety of patents related to genetics'. Allison W. Dobson and James P. Evan, 'Gene Patents in the US: Focusing on What Really Matters' (2012) 13 *Genome Biology* 161.
51 Jane Calvert, 'Patenting Genomic Objects: Genes, Genomes, Function and Information' (2007) 16(2) *Science as Culture* 207, 219.

issue. Rather, the important question is whether the simplification matters, which will depend on what is being assumed and whether this has a bearing on the way judgement is made or decisions are reached. This will always be a fact dependent question. In some cases, it may simply not be relevant, while in other cases, it may determine the fate of a legal dispute.[52]

While an appreciation of the reasons for and consequences of the continued gene talk in law may be relevant for understanding the academic, policy and judicial discussions about molecular subject matter, the situation is different when it comes to understanding the way that molecular subject matter has been dealt with by patentees. To understand the way that molecular subject matter has been incorporated within patents and the way that patentees and the Patent Office have dealt with the uncertainty of a postgenomic subject matter, we need to look at another situation where gene-centrism and genetic reductionism have continued in spite of the evidence to the contrary, namely within science itself.[53]

For Rheinberger and Müller-Wille, the reason why gene centrism has continued in science is not because, as with legal and public discourse about gene patents, the gene was treated as a technical product and a commodity. Nor is it because genes are the major determinants of the main processes in living beings. Rather, they suggest that the reason why the gene figured and continues to figure so prominently in science is tied to the role that the gene plays as a tool of research. Instead of seeing the gene as a commodity or as entity that explains things, Rheinberger and Müller-Wille suggest that the gene is better seen as an 'epistemic object or thing': that is, as an investigative, heuristic device that provides highly successful entry points into the investigation of living things. The reason why 'the classical molecular gene concept continues to function as something like a stereotype for biologists, despite the many cases in which that conception does not give a principled answer to the question of whether a particular sequence is a gene',[54] is because the gene operated as a 'productive resource that has allowed scientists to move from one interesting case to another'.[55] The success of gene-centrism, according to this view, is not ontologically but first and foremost epistemologically and pragmatically grounded.[56]

The thing that made the gene so successful as a research tool for such a long period of time was that it was a generic historical concept with fuzzy boundaries; it was loosely defined, hazy, uncertain, and subject to change and reinterpretation.[57] Rather than seeing this fuzziness as a shortcoming to be eliminated, Rheinberger

[52] John Dupré, 'Understanding Contemporary Genomics' (2004) 12(3) *Perspectives on Science* 320, 336–37.

[53] Hans-Jörg Rheinberger and Staffan Müller-Wille, *The Gene from Genetics to Postgenomics* (Chicago: University of Chicago Press, 2017), 117.

[54] Ibid.

[55] Ibid., 71.

[56] Ibid., 118.

[57] Ibid., 71.

sees this as the very thing that allowed genes to be treated as epistemic things, that is as objects subject to on-going research, in the first place.

There are a number of consequences of seeing the gene as a fuzzy, historically contingent object of scientific research. Because epistemic objects such as the gene 'are crafted, more than by any theory, by the practices and instruments of the particular experimental contexts in which they are invoked'[58] this means that the definition of a gene varies according to the discipline (and the experimental systems it employs) in which it was invoked.[59] We have already seen in the context of the *Myriad* litigation how for a biochemist a gene is defined by the chemical properties of a sequence of DNA, whereas in molecular genetics genes are informational elements positioned on chromosomes that can control functions or products. To this we can add the views of the biophysicist for whom the gene is characterised by the atomic coordinates of a macromolecule, a molecular evolutionary biologist who sees genes as complex products of processes (such as changes, duplications, rearrangements) that affect sections of DNA in a complex chromosomal environment, and developmental biologists who see genes as hierarchical sets of instructions that induce the differentiation and whose activation depends on their state of differentiation.[60]

As well as allowing the gene to operate as an ongoing object of research, the gene's fuzziness also allows it to perform other roles. In particular, it facilitates communication between people with different but related concerns. It also facilitates continuity between successive historical inquiries.[61] For Rheinberger, central scientific concepts like the gene function by remaining sufficiently vague so as to allow communication between the various groups that have an interest in talking about such things but very diverse accounts of what it is they are talking about.[62] The vagueness 'is necessary for the construction of bridges between different contexts, such bridges work to guide biologists in their exploration of phenomena that are, by definition, still poorly understood, ill-defined, and open-ended'.[63] Appreciating the important role that vagueness plays in allowing the gene to operate as a boundary object within science[64] helps to explain why the 'spectacular rise of molecular

[58] See also Hans-Jörg Rheinberger, 'Gene Concepts Fragments from the Perspective of Molecular Biology' in (ed) P. Beurton, R. Falk, and H. Rheinberger, *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2000), 219, 225.

[59] Jane Calvert and Pierre-Benoît Joly, 'How Did the Gene Become a Chemical Compound? The Ontology of the Gene and the Patenting of DNA' (2011) 50(2) *Social Science Information* 157, 166.

[60] Ibid.

[61] John Dupré, 'Understanding Contemporary Genomics' (2004) 12(3) *Perspectives on Science* 320, 336–37.

[62] Hans-Jörg Rheinberger, 'Gene Concepts Fragments from the Perspective of Molecular Biology' in (ed) P. Beurton, R. Falk, and H. Rheinberger, *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2000), 219.

[63] Evelyn Fox Keller, *The Century of the Gene* (Cambridge, MA: Harvard University Press, 2000), 140–41.

[64] Hans-Jörg Rheinberger, 'Gene Concepts Fragments from the Perspective of Molecular Biology' in (ed) P. Beurton, R. Falk, and H. Rheinberger, *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2000), 219, 225.

biology has come about without a comprehensive, exact, and rigid definition of what a gene is'.[65] It also explains why for 'years, scientists have lived with the coexistence of different definitions (ontologies) of the gene'.[66] It also helps us to appreciate why attempting to define a gene too precisely may be self-defeating for the research effort proper; namely, because it risks using language too closely tied to particular experimental practices, which 'would, by its very specificity, render communication across different experimental contexts effectively impossible'.[67]

What are the consequences of Rheinberger and Müller-Wille's account of the gene for our understanding of a postgenomic molecular subject matter in patent law? One potential lesson is that rather than merely criticizing the law for lagging behind scientific change or trying to create ever more precise and accurate legal definitions that capture those changes, there is a need to understand how and why fuzzy concepts work in the law.[68] To paraphrase Rheinberger, instead of trying to codify meaning, we need an 'epistemology of the vague'.[69] In thinking about what this might mean for how we understand patent law, it is important to keep in mind the distinction Rheinberger drew between '*epistemic things*' and '*technical things*'.[70] During the research process, when material scientific objects are being explored, they tend to be loosely defined, hazy, uncertain, and subject to change and reinterpretation: what Rheinberger calls 'epistemic things'. Over time, as scientific approaches towards epistemic things settle and stabilise, they often change into 'stable, technical objects that may define the boundary conditions of further epistemic objects'.[71] Once stable, technical things are able to operate as immutable mobiles or as 'inscriptions which circulate unchanged across different contexts'. While patent law occasionally shows an interest in the processes by which epistemic objects are transformed into immutable technical objects (primarily in terms of the doctrinal requirement that applicants need to show that the process that led to the invention was non-obvious), for the most part patent law is only concerned with research once it is stable and settled. That is, it is mainly concerned with research results rather than the research process itself.

While patents operate as closed immutable mobiles that allow legal-technoscientific objects to circulate beyond the reach of the inventor, this does not mean that there

[65] Ibid., 221.

[66] Jane Calvert and Pierre-Benoît Joly, 'How Did the Gene Become a Chemical Compound? The Ontology of the Gene and the Patenting of DNA' (2011) 50(2) *Social Science Information* 57, 166.

[67] Ibid.

[68] 'Introduction' in (ed) P. Beurton, R. Falk, and H. Rheinberger, *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2000), x.

[69] Hans-Jörg Rheinberger, 'Gene Concepts Fragments from the Perspective of Molecular Biology' in (ed) P. Beurton, R. Falk, and H. Rheinberger, *The Concept of the Gene in Development and Evolution: Historical and Epistemological Perspectives* (Cambridge: Cambridge University Press, 2000), 219, 223.

[70] Hans-Jörg Rheinberger, *Toward a History of Epistemic Things: Synthesizing Proteins in the Test Tube* (Stanford: Stanford University Press, 1997).

[71] Hans-Jörg Rheinberger, 'A Reply to David Bloor: Toward a Sociology of Epistemic Things' (2005) 13(3) *Perspectives on Science* 406, 407.

is no place for uncertainty in patent law. Indeed, there is a large body of law dealing with the type of uncertainty that is acceptable in a patent. While patent claims are often read down for being overly vague or unclear, there has never been an expectation that patentees need to provide precise details of every element of an invention; it is acceptable to leave certain things for third parties to work out for themselves when replicating the invention from the written form. The main limitation being that in doing so third parties should not be required to exercise anything approaching 'inventive' effort. Patent law has also never required patentees to know everything about their inventions: so long as an invention does what it is meant to do and is able to be identified and repeated from the patent documentation, the law is content.

While applicants may not be under an obligation to define all the details of their inventions nor to explain the reasons why the invention does what it does, they are under an obligation to ensure that the patent is able to operate as an immutable mobile: they must ensure that third parties are able to repeat the invention at a distance, that the invention is able to be identified, and that its boundaries are demarcated. While this may be fine and well with mechanical inventions, it is less so when dealing with subject matter that is less certain and clear cut; as is the case with postgenomic subject matter. Given this, rather than being content merely to criticise the law for failing to keep up with scientific change or attempting to provide a definition of molecular subject matter (or whatever term is chosen) that rids the law of uncertainty, it is better to shift the focus of attention to ask: what are the techniques that are used within the law to accommodate scientific uncertainty? Or, in this context, what is it that allows an uncertain postgenomic molecular subject matter to be translated into an immutable legal object?

As we have seen, the uncertainty associated with molecular subject matter was initially dealt with through the deposit of physical samples of the invention at public depositories. Over time, patentees came to rely on dematerialised digital sequence information to represent the patentable subject matter. Building on the reductionist molecular gene and a series of associated beliefs – including the idea that with the discovery of DNA that scientists had finally unlocked natures' secrets, that genes were solely responsible for biological traits and characteristics, and that prevision was no longer an issue that applicants had to contend with – there was (and remains) a view in law that scientists were now in a position where they could reduce biological subject matter to a written form that not only ensured that the subject matter could be identified but also that third parties could replicate the invention at a distance. As a result, there was a sense within the law that because of these scientific and technical innovations it was now possible to rely upon the immaterial representation of biological subject matter; it was no longer necessary for patentees to resort to the physical manifestation of the intangible or to focus on the external features of an organism when representing their innovations. Instead, patentees could rely on the dematerialised subject matter to satisfy the various demands that patent law made of them.

While the reductionist logic of classical molecular genetics may allow us to represent patent law's engagement with molecular subject matter as a relatively straightforward and complete process, this is called into doubt when we acknowledge the changes brought about by the shift to a more postgenomic subject matter. To return to the question I asked above: what does it mean for patent law's engagement with molecular subject matter when the reductive classical gene is questioned, when prevision is still a problem, and when much is still unknown about the subject matter? How is the uncertainty of postgenomic subject matter accommodated with an informational subject matter that is represented using dematerialised digital sequence information? This is an important issue that needs more research (particularly in light of the growth of patents for mRNA vaccines and other information-based inventions).

We can get a sense of the types of issues that patent law needs to address when dealing with a postgenomic molecular subject matter from the 2019 decision of *ex parte Christensen*.[72] The decision concerned the validity of Christensen's patent application for plants transformed with a novel gene to provide an increased level of cold tolerance. The problem for Christensen was that a 2006 article published by Michelle Churchman in *The Plant Cell* disclosed a plant transformed with the same gene. Importantly, however, the journal article made no mention of increased cold tolerance as one of the consequences of inserting the gene into plants: instead the article focused on different phenotypic traits caused by the gene. In rejecting the application for lack of novelty, the examiner said that it did not matter that the article in *The Plant Cell* did not mention cold tolerance as an outcome of inserting the gene into the plant. Building on the premise of classical molecular genetics that genes were responsible for biological traits and characteristics, the examiner assumed that plants transformed with the claimed gene would necessarily exhibit the increased level of cold tolerance. The mere fact that the prior publication disclosed a plant transformed with the gene was enough for the examiner to conclude that the Churchman article anticipated the claims in question.

The examiner's decision was overturned on appeal on the basis that increased cold tolerance was not necessarily present in plants in which the gene had been added. This was based on evidence that showed that only around 50% of the transformed plants were actually cold tolerant. As the applicant's expert explained, the disjuncture between gene and trait 'is often observed when creating transgenic plants'. Rejecting the idea of classical molecular genetics that there was a direct correspondence between genes and traits, the expert said that '[a]lthough plant transformation is often routine, the phenotypes of individual transformation events harboring identical transgenes are not uniform. For transgenes that impart a phenotype, it is typical to find that more than half of the successfully transformed plants actually exhibit phenotypes that are indistinguishable from controls'.[73] There were a number of reasons why a successfully transformed plant might not exhibit a particular trait or characteristic

[72] *Ex parte Cory Christensen and Bonnie Hund* Appeal 2019-002834 (PTAB, 24 October 2019).
[73] Ibid., 3.

including 'dosage effects, threshold mechanism, differential tissue expression, genetic background dependence, transgene silencing, disruption of endogenous genes by transgene insertion, and paramutation'.[74] Reconfirming the postgenomic vision of molecular subject matter, the expert said, 'Thus, any one or a combination of multiple mechanisms may explain why expression of a transgene by a transformation event is not accompanied by the phenotype, and, even if the transgene is expressed, there is no guarantee that the transformation event exhibits the phenotype'.[75]

Given that all the court had to decide in this case was whether the prior art disclosed a modified plant with increased cold tolerance, the lack of certainty readily translated into a finding that the prior art did not anticipate the claimed invention. While in this instance the uncertainty associated with postgenomic subject matter was relatively easy for the court to negotiate, in other situations the uncertainty has required more creative solutions.

A useful starting point for thinking about how postgenomic molecular subject matter is accommodated in patent law is with science itself. This is because while vagueness may be a virtue in some scientific contexts, there are many situations where imprecision is not tolerated.[76] Where this is the case, the requisite precision is provided by the experimental context in which terms and concepts are invoked. As Evan Fox Kellar said, while 'terms like *gene* may be subject to a variety of different meanings' … 'locally, misunderstandings is avoided by the availability of distinct markers directly and unambiguously tied to specific experimental practices. Within that practice, the marker has a clear and unambiguous reference'.[77] 'And', in a move that calls into question the dematerialisation of molecular subject matter, 'inevitably these markers will pick out somewhat different physical entities'.[78] These material makers are incorporated into patents either directly via the descriptions of the inventions in the patents or indirectly via the experimental knowledge that is attributed to the person skilled in the art that informs the way that the patent is interpreted.[79]

As well as relying upon experimental markers to delimit and identify genetic innovations, patentees have also adopted other tactics to deal with the uncertainty associated with a postgenomic subject matter.[80] To appreciate these tactics, it is necessary to

74 Ibid., 4.

75 Ibid.

76 'Precision is necessary (and absolutely so) in particular laboratory practices'. Evelyn Fox Keller, *The Century of the Gene* (Cambridge, MA: Harvard University Press, 2000), 140. See also John Dupré, 'Understanding Contemporary Genomics' (2004) 12(3) *Perspectives on Science* 320, 332.

77 Evelyn Fox Keller, *The Century of the Gene* (Cambridge, MA: Harvard University Press, 2000), 140.

78 Ibid.

79 This means that despite its fuzziness, within 'the context of a given and clearly understood set of experimental conditions, the term *gene* can still safely serve as an operational shorthand indicating (or pointing to) the markers of the immediate experimental significance'. Ibid.

80 For another tactic, where patentees used both sequence ID and deposit, see Myles W. Jackson, 'How Gene Patents Are Challenging Intellectual Property Law: The History of the CCR5 Gene Patent' (2015) 23(1) *Perspectives on Science* 80, 90 ff. See also Myles W. Jackson, *The Genealogy of a Gene: Patents, HIV/AIDS, and Race* (Cambridge, MA: MIT Press, 2015), ch 4.

shift the focus of attention away from the catch-all biological subject matter to focus, again, on plant-based subject matter. We also need to move away from an exclusive focus on sub-surface molecular subject matter to place the gene in its broader context. In doing so we see that in drafting patents for their plant-based molecular innovations, patentees have made use of the fact that plants are not only different to other biological organisms, they are different in ways that matter for the law.

For the most part, the particularity of plant-based molecular subject matter has been overlooked. Instead there has been a tendency since the 1980s to group plants, animals, microorganisms, and other organisms together under the rubric of biological subject matter. This categorisation was repeated when the law shifted its attention below the surface to focus on genetic innovations: the only change being that the grouping was now extended to include human genetic material. In line with this, there has been a tendency to presume that genes are interchangeable; that a question about a human gene can be answered, for example, by reference to a plant or animal gene, or that a decision on the patentability of a human gene can be decided by reference to decision involving a plant or a microorganism.

The problem with this assumption is that genes are not the same. When we move beyond a scientific understanding of the subject matter to place genes in their biological, social, cultural, and legal context, we see that whatever genomic similarities and overlaps there might be, plants are different to animals and humans. While research on humans and animals is routinely subject to ethical limitations, research on plants is not. Moreover, while human eugenics and slavery are widely viewed as abhorrent and antiquated practices that have no place in the modern world, they are alive and well in plant breeding. Plant breeders openly intervene in 'populations for which they can control the breeding and, therefore, construct families and make particular crosses; options not open to the human geneticist'.[81] In addition, while humans can no longer be owned, plants are widely treated as commodities to be bought and sold. As a result, we can add to what Marder called the ontological particularity of plants – namely, the specificity of plant growth (their rootedness in space), their structure, their experience of temporality, and their response to seasonal change – their ability to be manipulated and owned.[82] While the ability for plants to be manipulated is important for the generation of new plants, it is this ability for plants to be owned that patentees have relied upon when drafting their patents in order to deal with the particularities of plant-based subject matter. In a sense, patentees make use of the physical material to claim their molecular level innovations for the simple reason that they can.

[81] James W. E. Lowe and Ann Bruce, 'Genetics without Genes? The Centrality of Genetic Markers in Livestock Genetics and Genomics' (2019) 41(5) *History and Philosophy of the Life Sciences* 1, 4 (citing Staffan Müller-Wille, 'Making and Unmaking Populations' (2018) 48(5) *Historical Studies in the Natural Sciences* 604).

[82] Michael Marder, *Plant Thinking: A Philosophy of Vegetal Life* (New York: Columbia University Press, 2013), 93.

Patentees have adopted a number of different ways of drafting claims that help them to deal with the uncertainty of postgenomic molecular subject matter. Of these two stand out. The first is one that mixes dematerialised sequence information with physical material. While the specific form that these patents take is not uniform, one thing they share in common is that they are divided into two parts. Typically, patentees will use sequence information to claim the molecular level invention (the 'gene' or some related genetic innovation) and what it is meant to do. In the second part of the claims, the focus of attention shifts away from the molecular level innovations (represented by sequence information) to claim the physical material – the tissue, seed, or plant – that embodies the molecular invention. Importantly, while the molecular part of the application will specify what the genetic material does, the second part of the claims are carefully drafted to avoid any mention of function; there is no mention that the modified seed or plant is cold resistant, will flower earlier, or produce redder apples. Instead, all that is claimed is the physical material that has been modified to include the molecular innovation. For example, Patent Number 8,344,209 for 'Plant regulatory sequences' begins by claiming a 'regulatory nucleotide sequence comprising SEQ ID NO: 13 which mediates expression of an operably-linked protein encoding polynucleotide of interest, wherein the protein encoding polynucleotide is transcribed in leaf tissue and not in pollen'. The patent ends by claiming a transgenic plant that includes the regulatory sequence set out in claim 1 (without making any claims about what the modified plant can do). By separating 'gene' and 'trait' in this way, patentees can avoid making any claims about the role the gene plays in the development of the trait. In a sense this allows patentees to claim a gene without having to speak as if it causes the phenotype. At best, the link is suggestive; it is implied, but not claimed. In these instances, the modified physical material acts as a black box that allows the patentee to claim the molecular level invention and the impact it has on plant phenotype without the need to make a claim about the causal link between genes and traits or that the gene causes the trait.[83] By black-boxing this link – which was presumed by the classical molecular gene and problematised by postgenomics – patentees are able to avoid making causal claims about the relationship between the sequence information and the modified plant.

A second approach, which is used with inventions relating to hybrid and inbred plants, takes the physicality of the plant material as the core of the patent. As the descriptions of the inventions in the patents and the accompanying scientific publications make clear, these inventions are the product of highly innovative scientific breeding. They are underpinned by molecular level research, mathematical modelling, genomic insights, and a range of other highly technical and cutting edge scientific practices. Despite the role that these scientific insights play in the development

[83] Mikyong Lee et al., 'Plant Regulatory Sequences' US Patent No. 8,344,209 (1 January 2013). See also Terrence A. Walsh et al., 'Production of Dha and Other LC-PUFAs in Plants' US Patent No. 2018/0,310,512 (1 November 2018).

of these new plants, they are nowhere to be seen when the patent claims are drafted. Instead, these patentees continue with the practice that goes back to 1980s of claiming the plant as whole and using deposit of the physical material as a way of ensuring that the requirements of patentability are met.

This mode of claiming can be seen in the patent granted to Monsanto in 2009 for 'Plants and seeds of corn variety CV605722'.[84] As the patent states, the 'present invention relates generally to the field of corn breeding. In particular, the invention relates to corn seed and plants of the variety designated CV605722, and derivatives and tissue cultures thereof'. Corn variety CV605722 is an inbred plant derived from a cross between two other varieties of inbred corn – I119149 and 94INK1A (which are described in the patent as 'proprietary Monsanto Technology LLC inbreds').

As the description in the patent makes clear, the invention was clearly the product of molecular level innovations. Despite this, there was no mention of this in the way the invention was claimed. Instead the patent focuses on the physical material – the plant, seed, and parts of plants and seeds (pollen, an ovule, or a cell) – deposited at the American Type Culture Collection. This is reflected in the patent which claims:

> 1. A seed of corn variety CV605722, wherein a sample of seed of corn variety CV605722 has been deposited under ATCC Accession No. PTA-10865.
>
> 2. A plant of corn variety CV605722, wherein a sample of seed of corn variety CV605722 has been deposited under ATCC Accession No. PTA-10865.

Even when the patent claims a genetically modified version of corn variety CV605722, it does so without reference to the sequence information or the gene. Instead, the patent simply claims the method of producing genetically modified corn variety CV605722.

> 11. A method of producing a plant of corn variety CV605722 comprising an added desired trait, the method comprising introducing a transgene conferring the desired trait into a plant of corn variety CV605722, wherein a sample of seed of corn variety CV605722 has been deposited under ATCC Accession No. PTA-10865.
>
> 12. The method of claim 11, wherein the desired trait is selected from the group consisting of male sterility, herbicide tolerance, insect or pest resistance, disease resistance, modified fatty acid metabolism, and modified carbohydrate metabolism.

This pattern of claiming modified physical material and depositing just enough of that material at a public depositary to satisfy the patentability requirements has been repeated again and again,[85] particularly by large agricultural companies and

[84] John Popi, 'Plants and Seeds of Corn Variety CV605722' US Patent No. 7,872,183 B2 (18 January 2011).

[85] See, for example, Steven H. Schuetz, 'Inbred Corn Line BB202' US Patent No 9,518,269 B2 (13 December 2016); William L. Rooney, 'Inbred Ssorghum Line R07007' US Patent No 8,420,906 B2 (16 April 2013).

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universities. One of the reasons why this mode of claiming has been adopted is that patents are not only scientific and technical documents; they also have a strategic commercial dimension. The black-boxed deposited physical material allows patentees to overcome any uncertainty that may exist in relation to the invention and thus to satisfy the requirements of patentability. Because the parental lines used to breed the patented hybrids and inbreds are either not disclosed or treated as the property of the breeding company (as with the Monsanto patent above), by claiming plant-based innovations in this manner patentees also gain a strategic commercial advantage. This mode of claiming builds upon the fact that plants (as organisms) can be owned and the fact that so long as patentees satisfy the requirements of patentability there is no obligation on them to use the latest scientific methods to do so. This is the case even when they make use of the latest scientific and technical advancements to create their inventions.

As we saw with traditional (non-molecular) plant-based subject matter, the material deposited as part of the patent process defines the invention. In these cases, the invention is tied to and coextensive with the deposited material. The situation remains the same with hybrid and inbred plants produced by less-traditional scientific breeding when patentees take the physicality of the plant material as the core of their patents. The situation is much the same where the patent mixes dematerialised sequence information with physical material. In these situations, the deposited material *is* the invention: the fact that the invention is the product of genomic insights or genetic modification is irrelevant. The focus is on the plant that is the result of this science, rather than the science that helped to produce the plant.

An appreciation of the techniques that patentees have used to ensure that their patents are able to accommodate the particularities of postgenomic subject matter gives us cause to rethink some of the claims made about a dematerialised molecular subject matter.[86] While much of the literature on the dematerialisation of patentable subject matter suggests that digital sequence information negates or transcends the physical, experience with patent protection for plant-based molecular innovations suggests otherwise.[87] In addition, while the dematerialisation thesis may hold true for human-based molecular innovations (which cannot be owned or hybridised) it is not necessarily the case with the patenting of plant-based innovations, which retain a material physical dimension. In this sense it seems that when it comes to intangible intangibles, to a dematerialised subject matter, that the tangible is never far from the (sub)surface.

[86] 'Celebratory narratives of the de-materialization of biology seem to suggest that, once sequence information is on the internet, it negates or transcends the physical plane. While DNA's expressive capacities may continue to grow while the material capacities of physical samples become less central, it won't stop being both.' Molly R. Bond and Deborah Scott, 'Digital Biopiracy and the (Dis)assembling of the Nagoya Protocol' (2020) 117 *Geoforum* 24, 27–28.

[87] Soraya De Chadarevian, 'Things and Data in Recent Biology' (2018) 48(5) *Historical Studies in the Natural Sciences* 648, 656.

11

Conclusion

In his 1917 article on the patentability of mental methods, John Waite speculated about the possibility of patent protection being granted over immaterial subject matter: what I have called intangible intangibles. As he said, an 'idea of means' (which we would probably today call an inventive idea or concept), 'which is not capable of embodiment as an objective means has never … been the subject of an adjudicated patent. It is therefore an undecided question whether an invention which does not require tangible instrumentalities to effectuate the result desired is patentable.'[1] While a 'large number of patent law experts had expressed the belief that such an idea could not be the subject of a patent,' Waite said it 'is difficult, though not impossible, to conceive of an idea of means which does not involve the use of tangible instrumentalities.'[2] While it may have taken some time for this to come to fruition, patent law did eventually embrace non-physical inventions that used intangible instrumentalities. That is, patent law eventually did recognise intangible property rights in intangible subject matter or intangible intangibles.[3] As we saw earlier,

[1] John Waite, 'The Patentability of a Mental Process' (1917) 15(2) *Michigan Law Review* 660, 662.

[2] Ibid., 663.

[3] In thinking about the role of materiality in patent law, it is important to keep in mind the difference between patentable subject matter and the intangible legal rights that exist in relation to that subject matter. There is another important dimension, which has largely been lost in contemporary patent jurisprudence, which relates to force or principle employed in the invention. As Lee explained, the thing to be patented is not a 'mere elementary principle or intellectual discovery but a principle put in practice and applied to some art, machine, manufacture, or composition of matter.' Benjamin F. Lee, 'What constitutes patentable subject matter: An Address delivered before the Congress of Patents and Trade-Marks of the World's Columbian Exposition of 1893' (Congress of Patents and Trade Marks: Chicago, IL., 1893). 10. Or as Robinson said: a 'machine is an instrument composed of one or more of the mechanical powers, and capable, when set in motion, of producing, by its own operation, certain predetermined physical effects. It is an artificial organism, governed by artificial rule of action, receiving crude mechanical force from the motive power, and multiplying, or transforming, or transmitting it, according the mode established by that rule.' … 'The rule of action, imposed by the inventor on the material substances of which the machine consists, is what the courts have called the "principle of the machine"; a phrase synonymous with "*modus operandi*" and "structural law." It is, however, neither more nor less than the idea of means, which is embodied in the machine itself.' William C. Robinson, *The Law of Patents for Useful Inventions: Vol 1* (Boston: Little Brown, 1890), 257–58.

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the recent shift to a more information-based subject matter has created a sense of unease, a concern that the law is out of its depth, and that it is dealing with a novel and unique type of subject matter that it is not equipped to deal with.

Having looked at how as a result of changes in chemistry, information technology, and biology patent law dealt with dematerialised subject matter, I am now in a position to return to the question I posed at the outset: namely, what does it mean to grant patent protection over a subject matter that is itself intangible or dematerialised? In order to get a sense of what might be lost or is at stake when engaging with a dematerialised subject matter, it is necessary to understand the role that materiality plays in patent law. While as Waite said 'patent law has invariably acted on the assumption that patented property is intangible,'[4] one of the things that the history of patent law shows is that the intangible is 'more indebted to materiality than one might suspect.'[5] Whether it is the vials of chemical compounds or packets of seeds deposited as part of the application process, the physical change that indicates the eligibility of a computer-related invention, or the ways in which plant intangible property was crafted to replicate the external form of the physical subject matter, it is clear that materiality has played and continues to play an important role in patent law.

Given the longstanding role that materiality has played in patent law, it might be reasonable to assume that there might be something at stake in the shift to an information-based subject matter. How then should we respond? Instead of rushing to look for policy solutions to deal with the perceived problems created by a dematerialised subject matter or bemoaning how the law is being outpaced by science, it might be more helpful to pause and consider the role materiality plays in patent law and what its absence might mean. In doing this it is important that we look at subject matter on its own terms. It is particularly important that we resist the temptation to see all subject matter through the lens of a mechanical or machine-based jurisprudence or to presume that the conceptual form of the invention is the machine. That is, we should not assume that it is Watt's steam engine rather than Hofmann's formaldehyde or Burbank's Santa Rosa plum that is the quintessential patentable subject matter (or even that there is such a thing). In line with this we should not presume that the process of invention is always one in which a priori inventive ideas are transposed into a material form or to use more doctrinal language that the inventive concept is reduced to practice. That is, we should not presume as Charles Ruby did that invention is 'a specifically human affair' that evolves out of the inner consciousness of its creator who then embodies it in a tangible substance, nor that the immaterial (conception) is created by the human inventor and then given shape in a material tangible form.[6] The problem here is not so much that these accounts

[4] John Waite, 'The Patentability of a Mental Process' (1917) 15(2) *Michigan Law Review* 660, 663.

[5] Alain Pottage, 'Literary Materiality' in (ed) Andreas Philippopoulos-Mihalopoulos, *Routledge Handbook of Law and Theory* (London: Routledge, 2018) 409, 425.

[6] Charles E. Ruby, 'Patents for Acts of Nature' (28 April 1939) 89(2313) *Science* 387, 388.

build on a series of unhelpful binary oppositions such as tangible and intangible, form and matter, material and immaterial, so much as how they see the relationship between these extremes.

As well as leading us to overlook important aspects of patent law, this way of thinking also skews the way we think about the impact that information-based subject matter has on patent law. To view physical samples, for example, through the lens of the figure of the machine suggests that samples and specimens operate in a similar way to the originating ideas of mechanical jurisprudence and that they lay the foundation for the subsequent transposition of the invention into a material form. One of the lessons that the history of patent law shows is that this temporal logic does not apply to chemical and biological subject matter. As we saw in relation to the deposit of chemical compounds, it was the *possibility* of reviewing physical objects rather than the review itself that was important. So too with the deposit of biological samples, where there was a disjuncture between the deposited material and its impact. In both cases, the role that physical samples played did not follow the temporal logic that underpins a machine-based jurisprudence.

Rather than following the lead of Ruby when thinking about patentable subject matter, it might be better to follow the approach of the nineteenth-century treatise writer, William Robinson. While Robinson and Ruby both saw invention as the product of the agency of the human inventor, they differed in terms of how they saw agency and thus invention. In particular, while Ruby's view of agency was modelled on mechanical invention (an approach Robinson called 'crude notions of physical agencies'[7]) in contrast Robinson argued that the idea of agency and with it the invention should change to accommodate different types of subject matter. If we follow this lead and reject the temptation to see patent law through the mechanical lens of the 'crude notions of physical agencies' we are led in a different and more fruitful direction.

While patentable subject matter often coincides with the physical form of the invention, a useful starting point for thinking about the consequences of a shift to information-based subject matter is to remind ourselves that materiality does not necessarily 'connote physical attributes of substances, such as their mass, density, or spatial definition' so much as an 'agency that is afforded by, elicited from, or ascribed to them.'[8] One of the consequences of this is that when we are confronted with a dematerialised subject matter, rather than lamenting the loss of materiality, a better response is to ask: what roles does materiality play and can these roles be performed by some other means?

While materiality has performed a number of roles in patent law, two stand out. The first is that the use of physical samples allowed patent law to accommodate a

[7] William C. Robinson, *The Law of Patents for Useful Inventions: Vol 1* (Boston: Little Brown and Co, 1890), 115.

[8] Alain Pottage, 'The Materiality of What?' (2012) 39 *Journal of Law and Society* 167, 168.

mute, ungiving, and secretive subject matter. This was the case with nineteenth-century organic chemical compounds and with many biological inventions. In both cases, the inability of science to explain what went on below the surface when something happened meant that scientists were unable to reduce the invention to a paper format: they were unable to isolate, identify, and capture the inventive idea that was meant to motivate and shape the resulting invention, at least in a way that could be repeated from the patent documentation. Instead, they were forced to rely upon the results of those changes: the tangible objects that captured and embodied the inventive ideas.

A second role performed by materiality was that by individualising the subject matter, materiality helped to ground the intangible.[9] In doing so, materiality helped patent law to demarcate the boundaries of what was protected. Thus while the physicality of Morse's tangible telegraphic machines were patented, his untethered claim to electromagnetism was not. By individualising the subject matter, materiality also ensured that the subject matter could be identified, examined, and once patented, put into circulation. In this sense physicality ensured that the intangible was rendered visible to a legal, scientific, and commercial audience and that it was confined within acceptable limits.

While materiality played an important role in allowing patent law to embrace different types of subject matter, it is clear that patent law is able to accommodate a subject matter that lacks physical form. Whether it is speculative chemical inventions claimed using structural formula, post-*Myriad* gene patents, or information-based computer-related inventions, there is nothing inevitable about physicality in the way that patent law engages with its subject matter. Physicality is a tool that patent law uses to allow it to achieve certain ends that can in certain circumstances be performed without recourse to physical effect or trace.

While physicality may not be integral to the way patent law deals with patentable subject matter, this does not mean that a shift away from materiality will not have an impact on the scope, operation, and effect of the law. One of the things that the history of patent law shows is that the relative materiality or immateriality of the subject matter is not the issue. This is because it is not the act of dematerialisation that is important, so much as the way that the law responds to this lack of materiality and the changes this brings about; it is here that we see the influence of a shift to information-based subject matter most clearly.[10]

In thinking about the consequences of a shift to information-based subject matter, it is important to distinguish between the problems that arise because of the process of dematerialisation and the more fundamental, almost inescapable problems that

9 In this sense, deposited materials operated like type specimens in so far as they ensured that patent law operated taxonomically at the level of the species.

10 On the means of bioproduction see Hallam Stevens, 'Bioinformatics and How to Make Knowledge in a High-Throughput Genomics Laboratory' (2011) 6(2) *BioSocieties* 217.

lie at the heart of the subject matter eligibility inquiry, which arise with most types of subject matter.[11] One of the most notable and consistent changes brought about the dematerialisation of subject matter was in terms of the impact it had on the scope of what could be patented and how the subject matter was evaluated. While chemical samples and biological specimens may have been introduced to deal with one problem (namely, a lack of prevision), the deposit of physical samples served other functions. For example, although chemical and biological specimens may not have been introduced with the goal of individualising the protected inventions (as occurred in Germany with chemical compounds), this was an indirect consequence that patent law seized upon to help it deal with an otherwise unruly subject matter. In this context, the materiality of the physical samples functioned to demarcate and limit the intangible. Once it was accepted that prevision was no longer a problem and that patentees were able to rely on paper-based representations of their chemical and biological inventions, physical samples were no longer needed.

While structural formula and sequence information performed a similar role to deposited samples in helping patent law to capture the inventive concept, the shift away from the use of physical samples did have consequences. This was because in the absence of a patent tied to a physical specimen, there was no reason to limit the subject matter to individual inventions. In this sense, the shift from physical specimens to paper-based representations created the possibility for patents to be granted for classes of inventions. When tied to the decision that applicants for a class of inventions were able to disclose a select number of members rather than each individual member of a class, subject matter eligibility became a question of degree not kind. The situation was similar in the case of computer-related subject matter where the shift from physicality to specificity as the touchstone for subject matter eligibility opened up the possibility for patents for classes of specific inventions.

While physicality may not be integral to the way patent law engages with patentable subject matter, this is not the case in relation to the information that explains, defines, and characterises that subject matter. As we have seen, patent law consistently relied upon the informed nature of the subject matter in deciding eligibility.[12] The information that is generated in the experimental systems and practices that produce the subject matter is incorporated into patent law either directly via the descriptions of the inventions used in the patents or indirectly via the experimental

[11] In part this is because patent law is fundamentally concerned, to paraphrase Rheinberger, with things that we do not know yet but we wish to discover. At the same time, while lawyers, patent attorneys and the Patent Office deal with recent science, the courts, particularly appeal courts, are often deal with dated inventions. For example, the US Supreme Court decision of *Myriad* was concerned with an invention that made its way into the patent system some 27 or so years earlier. See Sean V. Tavtigian et al., 'Chromosome 13-Linked Breast Cancer Susceptibility Gene' US Patent No. 6,033,857 (7 March 2000), filed on 20 March 1998 but based on earlier abandoned applications from 1995.

[12] While for the most part patent law passively accepted the way that the subject matter was presented to the law for scrutiny, one area where the law constantly pushed back was in terms of the way that the scientific prior art or public domain was organised and accessed.

knowledge that is attributed to the person skilled in the art that informs the way that the patent is construed. As different types of information become part of Patent Office practice (which is a 'blend or mayonnaise of law with science and technology') and adopted by lawyers and judges when thinking about and interrogating patents (sometimes with the aid of experts), the information is eventually assimilated and normalised within the fabric of the law.[13]

To understand how patent law deals with techno-scientific subject matter, whether nineteenth-century organic chemical compounds, medical diagnostic inventions, or mRNA vaccines, we need to look to the information that is embodied within or attached to that subject matter. That is, to get a sense of how patent law deals with subject matter, whether dematerialised or not, we need to look to the information that allows that subject matter to be visualised, defined, and explained and in so doing ensures that it is rendered legible and manageable. It was here, perhaps more than anywhere else, that we see the influence of science and technology on patent law most clearly. In a relationship that is neither one of co-production nor one in which the law is destined to play catch-up with scientific change, science and technology not only play a role in providing new candidates for protection, they also provide the means which allow these new types of subject matter to be assimilated within the law. In this sense, patent law sees subject matter not as the thing in itself; rather it sees subject matter in the way that science allows it do so. While the problems associated with a shift to an information-based dematerialised subject matter may ultimately be resolved by mundane technical factors that are developed in the experimental systems and practices where the subject matter is generated or where that information is used, one of the unexpected outcomes of the debates about the dematerialisation of subject matter is that they might lead to a more nuanced understanding of patent law and its interaction with science and technology. And that would not be a bad thing.

[13] K. P. McElroy, 'Our Anomalous Patent Office' (May 1921) *The Journal of Industrial and Engineering Chemistry* 469.

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