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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

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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.



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



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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'. 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.

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'. '2 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'. '3

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. There is a concern, for example, that the 'new but still embryonic notion of invention based on the elusive figure of "information" 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'. In line with this, it is also said that information-based inventions not only rupture 'the bond between the tangible and the intangible' 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).
- 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.
- Mario Biagioli and Alain Pottage, 'Patent Personalized Medicine: Molecules, Information, and the Body' (2021) 36 OSIRIS 221, 234.
- ¹³ Ibid., 221.
- ⁴ 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.
- 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'.
- You 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.



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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

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

- ²¹ Ibid., 221.
- ²² Ibid., 234.
- 23 Ibid.

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.

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

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

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.



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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. 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).



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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

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.



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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



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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).



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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.



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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.