

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 Stoltz, '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) *EMBO 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 entities, 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 executors 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 patents⁴⁶ 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 encompass 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 science⁶⁴ 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 nature's 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 provision 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 Keller 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.⁸⁵ 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

⁸⁵ 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 – I19149 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 depository 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 Sorghum Line R07007' US Patent No 8,420,906 B2 (16 April 2013).

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.