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What Does It Mean to Invent Nature?

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In recent years, there has been a proliferation in the number of superior court decisions concerned with patentable subject matter. Despite this, there is still a great deal of confusion about the types of things that are eligible for patent protection. Building on the idea that the subject-matter inquiry in patent law is effectively a taxonomic process of classification, this Article explores the different techniques that have been used to categorize patentable subject matter. Focusing on recent litigation in the United States and Australia involving Myriad Genetics' patents for the BRCA1 and BRCA2 genes, this Article argues that while some of the uncertainty that accompanies the subject-matter inquiry is inevitable, many of the problems associated with subject matter eligibility arise because there is no real clarity about the criteria to be used when categorizing subject matter in patent law. Thus, it will be argued that patent law in the United States and Australia is ill equipped for the task of determining subject matter eligibility, at least in a way that does not seem to be arbitrary and capricious.

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INTRODUCTION

Over the last few years, there has been a lot written about Myriad Genetics' controversial patents that grew out of the discovery of the human BRCA1 and BRCA2 genes and the fact that there was a close relationship between mutations in those genes and the development of breast and ovarian cancer. Given the subject matter of these patents¹ and the way that they were implemented, it is not surprising that the patents were met with considerable resistance. It was also not surprising that the patents were challenged in a number of courts around the world. In this Article I wish to focus on two legs of that global litigation—namely, the decisions in the United States that culminated in the 2013 U.S. Supreme Court decision of *Association for Molecular Pathology v. Myriad Genetics, Inc.*² and the ongoing litigation in Australia: the latest instalment being the unanimous 2014 decision by the Full Federal Court in *D'Arny v. Myriad Genetics, Inc.*³

While the secondary literature devoted to Myriad's patents covers a range of topics from a variety of different perspectives, it is united by the fact that most of the commentary has been very partisan in nature: it has either been written in support of, or against, Myriad's patents and/or the relevant decision pronouncing on the fate of those patents. While there are some notable exceptions, most of the literature reads as if it was written as either an amicus curiae brief or a policy submission to some fictitious inquiry. On the one side, supporters of the patents have highlighted the important role that patents play in stimulating investment, while downplaying the negative consequences of such protection. In commenting on the U.S. Supreme Court decision, supporters of the patents also raised concerns about the chilling impact the decision might have on research in molecular diagnostics and in cognizant fields of study. On the other hand, critics of the patents have been united in their concern about the negative impact of the patents, particularly upon women's health. As with many other biological innovations, there is also a sensitivity about the commodification of nature, which is exacerbated by the gravity of the illness, the business model used to exploit the invention, and the way this was perceived outside of the United States as a Trojan horse that was being used to undermine national approaches to health care.

While the relative merit of Myriad's patents is an important issue, in this Article I wish to change tact to focus on a separate issue which has linked both sides of the debate, namely, the criticisms that have been made about the reasoning of the courts

1. A number of different types of subject matter were at issue in the litigation including raw genomic or native DNA (gDNA), isolated DNA, synthetic DNA created in a laboratory from mRNA (complementary DNA or cDNA), and related methods claims.

2. See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013) (holding that while raw DNA and isolated gene sequences were not patent eligible, synthetic cDNA sequences were).

3. See *D'Arny v. Myriad Genetics, Inc.* [2014] FCAFC 115, ¶ 218 (Austl.) (finding that the isolated DNA and the synthetic DNA were both patent eligible and upholding the single Federal Court decision in *Cancer Voices Austl. v. Myriad Genetics, Inc.* [2013] FCA 65, ¶ 136 (Austl.)). An application for leave to appeal to the High Court is pending.

when attempting to pass judgement over the patents. The feelings of many commentators are captured in the remark that the Supreme Court decision in *Myriad* will “only serve to increase the ambiguity and uncertainty plaguing the U.S. patent system.”⁴ They are also reflected in the comment that while the decision is useful insofar as it confirms that there is a distinct product-of-nature doctrine in the United States, “it leaves the substance of that doctrine, as well as its boundaries and application more uncertain than ever.”⁵ Criticisms of this ilk have been repeated again and again in the commentary on the decisions, which have consistently been described as uncertain, confused, puzzling, and contradictory. These criticisms about the reasoning in the *Myriad* litigation form part of a wider chorus of complaints that have accompanied other recent U.S. Supreme Court decisions where patentable subject matter was at issue.

The aim of this Article is to stand back from the debates about the relative merits of *Myriad*'s patents to consider why it is that subject matter has created so many problems in both the United States and Australia. In a sense, the question that underpins this Article is: Why is it that patent law has experienced so many problems in dealing with the type of invention that is at stake in the *Myriad* litigation? In effect, it asks: What is at stake in asking the question, “what does it mean to invent nature?” This is not intended as an apology for the decisions, nor as a commentary on the patents at issue in those decisions. Instead, this Article attempts to situate the American and Australian litigation as part of a broader discussion about subject matter jurisprudence and the challenges currently facing patent law in both jurisdictions. Placing the *Myriad* decision in a broader context will not only help us to identify some of the problems with the subject-matter inquiry, it will also provide us with some possible ways of responding to these problems.

Before attempting to answer these questions, it is important to note that the problems that have arisen in the *Myriad* litigation are neither endemic to genetic materials specifically nor to biological innovations more generally. Rather, as I will argue, the problems are a consequence of the way subject matter is addressed in American and Australian patent law. While with plant patents and plant variety rights protection there might inevitably be issues at the boundaries, for the most part the question of what qualifies as eligible subject matter in those contexts is relatively straightforward: questions of subject matter simply do not arise. The situation is similar in European patent law. Although questions about the scope and nature of biological inventions do arise—something that I will return to later—for the most part, European patent law is not concerned, at least in relation to biological innovations, with preliminary questions about the types of things that are to count

4. Christopher M. Holman, *Editorial: In Myriad the Supreme Court Has, Once Again, Increased the Uncertainty of U.S. Patent Law*, 32 BIOTECHNOLOGY L. REP. 289 (2013). This is particularly true in relation to the “patent eligibility status of a synthetic molecule that shares a common, or highly similar, structure with a naturally occurring biomolecule.” *Id.*

5. Dan L. Burk, *Editorial, Are Human Genes Patentable?*, 44 INT'L REV. INTEL. PROP. & COMPETITION L. 747, 749 (2013).

as appropriate subject matter. The reason for this is that, as with plant patents and plant variety rights protection, decisions about the types of things that should be protected have already been decided in advance.⁶ The situation is markedly different however with (utility) patents in the United States and Australia where the question of whether it is possible to patent biological inventions is largely left to the judiciary and the patent offices to decide.

It is also important to note that the problems associated with subject matter that have proliferated in recent years are a consequence of recent attempts by the courts to impose more stringent limits on patentable subject matter. Over the last few years, subject matter has become a key issue both in the United States and, to a lesser extent, in Australia. While questions occasionally arose prior to this, subject matter did not generate anywhere near the same types of problems that we have witnessed recently. In one sense, the reason for this change is straightforward: when the courts adopt a liberal approach to patentable subject matter, in a world where “anything under the sun that is made by man” is potentially patentable,⁷ there is no need to determine where and how the limits are to be set. In the world prior to *Myriad*, *Alice Corp. v. CLS Bank Int’l*, *Mayo Collaborative Services v. Prometheus Labs, Inc.*, and *Bilski v. Kappos*, questions about where and how limits are to be drawn did not arise, or at least not as frequently as they have recently. The situation changed, however, when the courts attempted to impose some sort of (meaningful) limitation on the types of subject matter that can be patented. As a result, the courts found themselves in the position whereby they had to be able to explain why certain things were excluded, while others were included. It is the inability of patent law to respond to these demands that is at the heart of many of the complaints that have recently been made about patent jurisprudence.

I. THE LEGAL ORDER OF THINGS

The last five or so years have seen a dramatic increase in the number of decisions both in the United States and Australia, particularly superior court decisions, concerned with patentable subject matter. While there are important variations, these decisions have typically followed an almost formulaic approach that begins, unsurprisingly, with the relevant legislative considerations.⁸ Thus in the United States, judgments usually begin by reciting the language of § 101 that

6. This was primarily the result of the EU Biotechnology Directive. The situation has been very different, however, in relation to computer programs and computer-generated inventions, where questions of subject matter have frequently arisen. On this, see L. BENTLY & B. SHERMAN, INTELLECTUAL PROPERTY LAW 475–96 (4th ed. 2014).

7. See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. Rep. No. 1979, at 5 (1952); H.R. Rep. No. 1923, at 6 (1952)).

8. As the Supreme Court said in *Chakrabarty*, “we begin, of course, with the language of the statute.” *Id.* at 308. The formulaic nature of the inquiry is reflected in the revised USPTO guidelines, which treat the subject matter inquiry like an algorithm to be applied and followed. See Memorandum from Andrew H. Hirshfeld, Deputy Comm’r for Patent Examination Policy, to the Patent Examining Corps (Mar. 4, 2014), http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf [http://perma.cc/74ND-NDQX].

provides that an inventor may obtain a patent for a “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”⁹ This is then followed by the rider that an invention that falls *prima facie* within § 101 may still be ineligible for patent protection if it falls within one of the categories of excluded subject matter, namely, laws of nature, natural phenomena, and abstract ideas.¹⁰ In contrast to the situation in Europe where the excluded categories have largely been provided by the legislature,¹¹ the excluded categories in the United States have been developed piecemeal by the courts:¹² they are said to be implicit in the relevant legislative provisions. While there are many unanswered questions about the scope and nature of the categories of excluded subject matter, not least how they relate to each other,¹³ in recent years they have been treated as givens by the courts. With “laws of nature,” “natural phenomena,” and “abstract ideas” effectively acting as *de facto* statutory exceptions, the task for U.S. courts is to categorize and classify subject matter. In the *Myriad* litigation, for example, the question for consideration was whether the subject matter was to be classified as a nonpatentable product of nature or as a patent eligible invention.¹⁴

In Australia, the starting point for the subject-matter inquiry is also with the relevant statutory provisions, which provide that an invention is *prima facie* a patentable invention if it is a “manner of manufacture” within the meaning of section 6 of the 1623 *Statute of Monopolies*.¹⁵ Typically, this is followed by a reminder that the Jacobean words of the legislation should not be read literally. Instead, subject matter eligibility is meant to be determined on the basis of principles and concepts the courts have developed in applying section 6.¹⁶ Although the courts have not been as clear as they might have been in distilling the scope of these principles, they are often reduced to the positive requirement that to be patent eligible, there must be some sort of human interaction with preexisting materials

9. See 35 U.S.C. § 101 (2012).

10. See, e.g., *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012); *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010); *Chakrabarty*, 447 U.S. at 307–10; *Gottschalk v. Benson*, 409 U.S. 63, 67–68 (1972); *O'Reilly v. Morse*, 56 U.S. (1 How.) 62 (1853).

11. See Convention on the Grant of European Patents, art. 53, Oct. 5, 1973 [hereinafter *European Patent Convention*].

12. See Christopher Beauchamp, *Patenting Nature: A Problem of History*, 16 STAN. TECH. L. REV. 257, 264 (2013). In *Bilski*, it was suggested that the exceptions go back 150 years. *Bilski*, 130 S. Ct. at 3225.

13. One of the advantages of the *Alice Corp. v. CLS Bank Int'l* and *Mayo* decisions is that they focus attention on the categories more directly. See *Alice Corp. Pty., Ltd. v. CLS Bank, Int'l*, 134 S. Ct. 2347, 2354 (2014); *Mayo*, 132 S. Ct. at 1293.

14. See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013); see also *D'Arcy v. Myriad Genetics, Inc* [2014] FCAFC 115, ¶ 1 (Austl.).

15. Patents Act 1990 (Cth) s 18(1) (Austl.).

16. See, e.g., *Myriad* [2014] FCAFC 3, ¶ 113 (citing *Nat'l Research Dev. Corp. v. Comm'r of Patents* [1959] 102 CLR 252 (Austl.)).

that creates something artificial.¹⁷ While Australian courts have been at pains to distance themselves from the approach adopted in the United States—notably in the suggestion that the product-of-nature doctrine does not exist in Australian patent law¹⁸—the approach in Australia is nonetheless conceptually very similar (if not identical) to the approach that has been employed in the United States. While the categories may be labelled differently and the courts may emphasise different aspects of the inquiry,¹⁹ the process of determining whether subject matter is patent eligible is the same in the United States and Australia: it is essentially a taxonomic exercise of labelling, classifying, and categorizing.²⁰

Over time, a number of different approaches have been used to decide how patentable subject matter is to be classified. While the approaches often overlap and are sometimes used inconsistently and with little analysis, it is still possible to distill a number of distinct techniques that have been used to categorize subject matter as either patent eligible or patent ineligible. Unlike much of the secondary literature, which has tended to focus on the consequences of granting or not granting protection, the approaches that have been adopted by the courts when classifying subject matter are, for the most part, essentially conceptual in nature:²¹ they stand or fall on the way that concepts are construed, applied, and interpreted. In the following Section, I will explain some of the key characteristics of the different approaches used to categorize subject matter.

A. *Natural Kinds*

One of the oldest and perhaps the most problematic ways of categorizing subject matter is one that does so on the basis that the subject matter is by its very nature the type or kind of thing that belongs in a particular category. Where this approach is applied, patent law effectively operates as if there were natural kinds that correspond to a preordained grouping or ordering that determines how things are to be classified.²² In these situations, courts assess the subject matter and classify it on the basis of whether it shares or exhibits certain (usually unstated)

17. There must be a human intervention “to produce from, or by means of, a naturally occurring product or the laws of nature, something artificial or of an artificial effect . . .” *Id.* ¶ 168.

18. *Id.* ¶ 114.

19. In both cases, the choice is whether to categorize subject matter as either patent eligible or as patent ineligible. The key difference is the focus of attention. While American case law tends to focus on patent ineligibility (the excluded categories), Australian patent law focuses on patent eligibility (artificial effect).

20. The “central question” is whether the subject matter “falls within the category of inventions to which, by definition, the application of the Act is confined.” *Myriad* [2014] FCAFC ¶ 115.

21. While the elaboration of these conceptual questions involves policy choices, such matters are nearly always implicit to the conceptual inquiries that underpinned. In this sense, the doctrinal questions embody policy arguments, but without the need for any empirical support.

22. See, e.g., *Blumenthal v. Burrell*, 53 F. 105, 107 (2d Cir. 1892). *Blumenthal* held that claims to a purified form of chymosin (an enzyme found in the stomach of pigs which was used to curdle milk in cheese production) were patentable because the enzyme was “not merely an improved, but an absolutely new, article, having its own distinctive nature . . .” *Id.*

characteristics or traits that warrant or demand that it be classified in a particular way.

In product-of-nature cases, the idea that some things are by their “nature” of a particular type or kind has occasionally been used to categorize things as ineligible products of nature. It has not, however, been used so much to classify things as patent eligible. In many cases, a decision that something is of the type or kind that warrants (or demands) it be classified as an unpatentable product of nature is not contentious. Thus, it has been readily and widely accepted that the discovery of a new mineral or a new plant found in the wild, or a human kidney removed from the body, would be products of nature and as such should be “free to all men and reserved exclusively to none.”²³ In the context of the *Myriad* litigation, the idea that subject matter could be classified according to its essential traits was used to categorize human genes in situ. This was reflected in the fact that it was widely accepted that genomic DNA—“as a portion of a larger native strand within a cell, which in turn is located within the human body”²⁴—was a product of nature and, as such, was not eligible for patent protection.²⁵ The Solicitor General captured the views of many when he said that in their preisolated form—“as a portion of a larger native gene within a cell—the BRCA sequences clearly are products of nature.”²⁶

In the *Myriad* litigation, the idea that certain things were in essence products of nature was, with the exception of the raw gDNA, very contentious. While critics of the patents argued that human genes were “quintessential products of nature,”²⁷ supporters of the patents took an opposing view and argued that they were “true inventions.”²⁸ Although the U.S. Supreme Court and the Australian Federal Court, like many of the lower courts, accepted that raw gDNA in the human body was by its very nature the kind of thing that ought to be classified as a nonpatentable product of nature,²⁹ beyond this the courts did not use essentialist arguments to reach any substantive conclusions.

There are a number of problems with such essentialist arguments: one of the most important is that there is rarely if ever any explanation given as to why subject matter is classified in the way that it is. Instead, we are simply presented with bald

23. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). For an interesting discussion of the role and place of kinds in patent law (primarily in relation to patent claims), see Andrew Chin, *The Ontological Function of the Patent Document*, 74 U. PITT. L. REV. 263 (2012).

24. Brief for the United States as Amicus Curiae in Support of Neither Party at 10, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (No. 12-398).

25. *Id.*

26. *Id.* at 20. In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 19 F. Supp. 3d 938, 948 (N.D. Cal. 2013), it was assumed that the presence of cffDNA in maternal plasma or serum was a natural phenomenon.

27. Brief of James D. Watson, Ph.D. as Amicus Curiae in Support of Neither Party at 12, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (No. 12-398).

28. Reply Brief for Petitioners at 13, *Myriad*, 133 S. Ct. 2107 (No. 12-398) (“[New genetic technologies] deserve patent protection . . . because they represent true inventions and not because resources were poured into their development.”).

29. See *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119 (2013); see also *D’Arcy v Myriad Genetics, Inc* [2014] FCAFC ¶¶ 115, 162–63, 171 (Austl.).

statements that build upon a belief that the subject matter is the type of thing that by its very nature belongs in a particular category. Thus, in the course of the litigation, Myriad argued that isolated DNA was patent eligible as a purified natural substance.³⁰ This was based on lower court decisions that held that natural compounds that had been “so refined and purified through human intervention . . . [had] become a substance different ‘in kind’ from the natural product.”³¹ While such statements are understandable and are to be expected from the parties and in the amici curiae briefs supporting one or other of the litigants, there is less justification for the courts to resort to this mode of reasoning. I will return to the problems with this below.

B. *A Change of Name as an Indication of Patent Eligibility*

In some situations, a change of name has been taken as being indicative of a change of kind and thus that the matter in question is patent eligible.³² In these cases, the fact that something was given a new name was taken to mean that the newly named thing was sufficiently different to other things in that class such that it qualified as patentable subject matter. For example one of the factors (supposedly) taken into account by the Supreme Court in *Diamond v. Chakrabarty* in deciding that the disputed genetically engineered bacterium was patent eligible was that it has been christened with a new name: *pseudomonas putida*.³³ As the Court said, the claim was “not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use.’”³⁴ In other situations, the fact that subject matter has *not* been given a new name has been taken to suggest that the subject matter is not patent worthy. Thus, in the 1931 decision of *American Fruit Growers v. Brodrex*,³⁵ the Supreme Court reversed the finding of the lower

30. Brief for Respondents at 36–40, *Myriad*, 133 S. Ct. 2107 (No. 12-398).

31. Brief for the United States as Amicus Curiae in Support of Neither Party, *supra* note 24, at 25 (citing *Kuehmsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701 (7th Cir. 1910); *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911); *In re Merz*, 97 F.2d 599 (C.C.P.A. 1938)). In these cited cases, the key question was: what were the traits that gave rise to a new thing?

32. For example, in *Intervet Inc. v. Merial Ltd.*, it was held that DNA constructs encoding a type of porcine circovirus as a new type of virus “comports with the way that viruses are typically classified in the relevant art.” *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1288 (Fed. Cir. 2010).

33. *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

34. *Id.* at 309–10 (citing *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

35. *American Fruit Growers v. Brodrex Co.*, 283 U.S. 1 (1931) (overturning the District Court of Delaware and the Court of Appeals for the Third Circuit). For earlier decisions construing “manufacture,” see *Hartranft*, 121 U.S. at 609–11. In *Hartranft*, the Supreme Court determined that shells cleaned by acid and then ground on an emery wheel were not manufactured shells and thus were exempt from duty: “There is no difference in name and use between the shells ground on the emery wheel and those not ground.” *Id.*; see also *Anheuser-Busch Brewing Ass’n v. United States*, 207 U.S. 556 (1908) (assessing whether corks had been “manufactured” in the United States and thus able to receive a rebate). “Manufacture implies a change, but every change is not manufacture, and yet every change . . . is the result of treatment, labor, and manipulation. But something more is necessary . . .” *Anheuser-Busch Brewing Ass’n*, 207 U.S. at 562 (citing *Hartranft*, 121 U.S. at 609). “There must be a transformation; a new and different article must emerge, ‘having a distinctive name, character, or use.’” *Id.*

court and held that an orange dipped in a solution of borax to render the skin mold resistant was not a manufactured article and thus not patentable.³⁶ One of the reasons for this was that there was “no change in the name, appearance, or general character of the fruit. It remains a fresh orange, fit only for the same beneficial uses as theretofore.”³⁷

The role that naming plays in the patent process is evident in the practices of American industrial microbiologists in the 1940s and 1950s. While plant breeders in the early part of the twentieth century decided that they needed to develop a stabilized and accepted set of naming practices before they were in a position to seek intellectual property protection for new plants (which they achieved when the *Plant Patent Act* was passed in 1930³⁸), the situation was not the same in relation to industrial microbiology, where patenting occurred before taxonomic and nomenclatural practices had been stabilized.³⁹ One of the interesting things about the discussions concerning microbiological taxonomy that occurred in the scientific literature in the 1950s were the complaints made about the way that patent lawyers were abusing the naming process to their own ends.⁴⁰ In particular, faced with a growing number of microbiological inventions, would-be patentees increasingly found it difficult to show that their inventions were novel. One of the tactics used to avoid this problem was to rename the microbiological inventions in question. While this may have annoyed taxonomists (since it added to the already high levels of nomenclatural confusion), it allowed patentees to pretend that their inventions were novel (which was difficult to disprove). Similar tactics were also used when someone wanted to use a patented microbiological invention but did not want to pay for that use. By giving a patented microbe used in an industrial process a new name, competitors were able to argue that they were not infringing the patent: a new name was indicative of a new thing.

Given that the subject-matter inquiry is effectively a process of (legal) classification or taxonomy, it is not surprising that patent law has drawn upon a change of name when deciding whether subject matter is patent eligible. This is

36. *American Fruit Growers*, 283 U.S. at 12.

37. *Id.* at 11–12; see also *In re Ewald*, 129 F.2d 340, 342 (C.C.P.A. 1942) (holding that a cored pear was not a manufacture because it did not possess a new name, character, or use); Robert C. Cook, *The First Plant Patent*, 22 J. HEREDITY 313, 317–18 (1931); Donald W. Strickland, *Recent Decisions*, 47 GEO. WASH. L. REV. 242, 245–46 (1978).

38. 35 U.S.C. § 161 (2012).

39. See Elio Baldacci, *The Classification of Actinomycetes in Relation to Their Antibiotic Activity*, 3 ADVANCES IN APPLIED MICROBIOLOGY 257, 276 (Wayne W. Umbreit ed., 1961) (showing that inventors abandoned the traditional practice of first publishing in a scientific publication in order to give a new species a new name and to avoid patent infringement); Selman A. Waksman, *Species Concept Among the Actinomycetes with Special Reference to the Genus Streptomyces*, 21 BACTERIOLOGICAL REV. 1, 13 (1957). Waksman illustrates the use of naming as a legal strategy in cases where “Company A . . . presents claims that to produce the same antibiotic or vitamin it is using a different species than that claimed in the patent granted to Company B. This is done, of course, to avoid patent infringements.” *Waksman, supra*. On this, see ALAIN POTTAGE & BRAD SHERMAN, *FIGURES OF INVENTION: A HISTORY OF MODERN PATENT LAW* 183–206 (2010).

40. See Baldacci, *supra* note 39, at 257.

reinforced by the important role that taxonomic practices play in other areas of patent law.⁴¹ While taxonomic practices play and continue to play a pivotal role in patent law in describing biological innovations and in ensuring that patented biological inventions are enabled (disclosed),⁴² they do not offer any real assistance in deciding whether something qualifies as patentable subject matter.

One of the problems with using a change of name as an indicator of a change of kind or type relevant to the subject-matter inquiry is that it defers the decision about patentability to another forum that is not necessarily any better equipped to decide these issues. One of the lessons to draw from the way that names of microbiological inventions were manipulated in the 1950s is that a change of name is not necessarily indicative of a change of kind. As such, it is not something that can always be relied upon. Relying upon change of name is also problematic because the process of giving something a new name usually tells us very little about the thing itself. To the extent that it does, this is not relevant to the subject-matter inquiry, because while the process of naming a new plant, animal, microorganism, or gene does require judgment (particularly in terms of how the new thing is similar to and different from other objects in the class to which it is attached), this is not a process that adds much to the subject-matter inquiry. The reason for this is that the taxonomic process is one that is not equipped or designed to pass judgment, at least in a way that is of any assistance in the subject-matter inquiry.

While taxonomy is a process that depends on difference, it is not a process that passes judgment over that difference.⁴³ Instead, once difference is established, taxonomy moves on: the primary focus is on fixing the name, the type specimen, and the description of the named object. Here, the primary goal is to enable objects and people to circulate, and for things to be recognized at a distance. This is not the case with the subject-matter inquiry in patent law, which depends on some type of (unspecified) qualitative change.⁴⁴

C. *Is There an Invention?*

While courts occasionally make decisions about how subject matter is to be classified on the basis that it exhibits the essential characteristics associated with the category in question or on the basis that the subject matter has been christened with a new name, these are, at best, marginal considerations. Instead, courts have tended to rely upon three different approaches when deciding whether something is patent

41. See Brad Sherman, *Taxonomic Property*, 67 CAMBRIDGE L.J. 560, 574 (2008).

42. It also potentially plays a role in determining the novelty of inventions.

43. All that the naming of a new plant variety tells us is that the new plant simultaneously shares certain defining characteristics with plants in that species and, at the same time, that it has at least one characteristic that distinguishes it from other plants in that species.

44. The problems that arise in using a change of name as an indication of a patent-worthy change of kind are more problematic when we move beyond biological inventions. While most of the would-be inventions that potentially fall within the product of nature exclusion would be governed by the sophisticated rules of taxonomy and nomenclature that have developed over the last century, this is not the case with many other inventions.

eligible. The first approach used to classify subject matter does so on the basis of the labor used to create the invention. A second approach focuses on whether or not there is an inventive concept somehow associated with the subject matter in question. A third approach used to classify subject matter operates on the basis that a nature-based invention will only be patent eligible if the invention is “markedly different”⁴⁵ (or in Australian terms “different”⁴⁶) from the raw material on which it is based.

While there are differences between the three approaches, they are all underpinned by the same question, namely, is there an invention?⁴⁷ More specifically, each of the approaches used to determine subject matter eligibility implicitly builds upon an image of how inventions come into being—an image, in effect, of the process of invention. It is important to note that the image of how inventions are generated that is employed in patent law is a legal one. Patent law does not attempt to reproduce laboratory life in a legal setting or to mirror or recreate scientific practice. Instead, the model of invention is one that marries a conception of scientific and technical creation with particular policy ends.

In essence, the process of invention that underpins the subject-matter inquiry is relatively straightforward. In the context of nature-based inventions, this is one in which the invention is a product of a process in which a human agent (or inventor) exercises their inventive skills to build on, modify, or adapt preexisting natural materials. In this context the “raw materials” act as the foundation or building blocks for the inventive process. A similar image of the inventive process is used in relation to laws of nature and abstract ideas. As the Supreme Court said in *Mayo*, “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.”⁴⁸ Given the pivotal role that these raw materials and ideas play in the inventive process—“they are the basic tools of scientific and technological work”⁴⁹—it is not surprising that the courts are constantly vigilant to ensure that they are protected, preserved, and maintained and not subject to patent protection. It is here that the excluded categories come into their own: they operate to protect the *a priori* domain. In the context of the *Myriad* litigation, this was reflected in the belief that people should not be restricted in their ability to study, use, or research native gDNA. To allow patents to be granted over the raw materials of the inventive process would, as the Solicitor General said, unduly compromise the public’s ability to study and use nature⁵⁰ and in so doing

45. See *Ass’n for Molecular Pathology v. USPTO*, 702 F. Supp. 2d 181, 222 (S.D.N.Y. 2010).

46. See *D’Arcy v Myriad Genetics Inc* [2014] FCAFC 115, ¶ 211 (Austl.).

47. As William Robinson said, has there been a human-made invention? 1 WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* 114, 115 (1890).

48. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012).

49. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013) (citing *Mayo*, 132 S. Ct. at 1292). Protecting these basic tools would be “at odds with the very point of patents, which exist to promote creation.” *Id.*

50. Brief for the United States as Amicus Curiae in Support of Neither Party, *supra* note 24, at 9.

“unduly restrict the public’s study and productive use of resources found in the natural world.”⁵¹

The second stage of the inventive process sees the human inventor, as an agent of change, interact with the preexisting natural materials to produce something new. Here, the inventor is tasked with the job of using “inventive” skills to change, mold, or rearrange a transcendent, preexisting nature into something new, something that is “markedly different” from what has preceded it. In Australia, this is reflected in the idea that for subject matter to be patent eligible, it must be the product of “human intervention that creates an artificial state of affairs.”⁵² Importantly, to be patentable the inventor must act in such a way so as to “individualize” nature.⁵³ While an inventor may not impose their personality on the resulting invention in the way the Romantic author is presumed to mark the texts that they write, they do shape or mold the invention. In this sense, the notion of individualization gives rise to the suggestion that the patented subject matter is somehow “unique,” whether in terms of its “originality” or its novelty. It is this (relative) uniqueness that allows the logic of the patent doctrine to suggest that patents, by their very nature, do not preempt.

By stipulating that patents are only ever granted for inventions that “individualize” nature, patent law can proceed on the basis that patents will not preempt subsequent uses of the underlying raw materials. Under this logic, a patented invention does not monopolize nature because an invention is defined as something that builds upon, expands, or modifies the underlying raw natural material. As a result of the intervention and action of the human inventor, the resulting invention is necessarily different from the natural materials that it is based on. Under this logic, it is then easy to conclude that patented inventions do not monopolize laws or products of nature.⁵⁴ In this sense, the image of invention that underpins the tests used to determine subject matter eligibility ensures that the grant of a patent based on raw materials does not preempt or preclude others from using those raw materials. Demanding that patents are only issued on raw materials that have been individualized creates, in the words of the Solicitor General, “no risk of preempting other uses of the raw materials from which cDNA is created.”⁵⁵ The same logic applies to laws of nature and to abstract ideas.

Armed with this (fictitious) image of the process of invention, we are now in a position to revisit the different approaches used to categorize subject matter. In

51. *Id.* at 11.

52. *D’Arcy v Myriad Genetics Inc* [2014] FCAFC 115, ¶ 11 (Austl.).

53. On this, see *D’Arcy v Myriad Genetics Inc* [2015] HCA 35, ¶ 116 (Austl.); BRAD SHERMAN & LIONEL BENTLY, *THE MAKING OF MODERN INTELLECTUAL PROPERTY LAW: THE BRITISH EXPERIENCE 1760–1911*, at 46 (1999); and Brad Sherman, *Before the High Court—D’Arcy v Myriad Genetics Inc: Patenting Genes in Australia*, 37 SYDNEY L. REV. 135, 138 (2015).

54. It is this logic that allowed the Solicitor General to argue that human made inventions do not monopolize laws or products of nature. Brief for the United States as Amicus Curiae in Support of Neither Party, *supra* note 24, at 13.

55. *Id.* at 10.

effect, what happens where questions about subject matter arise is that one or more aspects of the inventive process are called into question. Given that all elements of the process of invention must be present for there to be a (legal) invention, if one element is missing, the subject matter is deemed to be patent ineligible.

Each of the different approaches used to determine subject matter eligibility corresponds to a specific feature of the inventive process. In effect what each of the approaches does is to ask whether the element in question is present in a way that is (or is meant to be) appropriate to the matter in hand. For example, in the case of the test of marked difference, the focus is on the end product and its relationship to the materials that it is based on. Here the inventor silently operates in the background as the agent of change. In the case of a labor-centered approach, the focus is on the work of the inventor and whether or not they have exercised the requisite skill to individualize nature. The test for the existence of an inventive concept is similar to the labor-centered approach, except that it does not focus specifically on the effort of the inventor. Instead it looks for evidence of the existence of an inventive concept either in the subject matter or in the process by which the subject matter was generated.

In reflecting upon the different tests, it is important to note that while the process of categorization may be an all or nothing exercise,⁵⁶ the tests used to classify subject matter are not. One of the consequences of accepting that “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas”⁵⁷ is that it ensures that the subject-matter inquiry is always a question of degree. Indeed, as the Solicitor General said (in relation to the inquiry into marked difference) “patent-eligibility depends on the degree to which the purported invention differs from its naturally occurring antecedent.”⁵⁸ Similar comments apply where the labor of the inventor or the existence of an inventive concept is used to classify subject matter.

In the fictitious model of invention described above, the role of the inventor is to individualize the raw materials. While they may not impose their personality on the resulting product, the notion of individualization gives rise to the suggestion that the patented subject matter is somehow “unique,” whether in terms of its originality or its novelty. It is this uniqueness that allows the logic of the patent doctrine to suggest that patents, by their very nature, do not preempt.⁵⁹ The problem with this, however, is that this is clearly not the case. Indeed, one of the

56. Dan L. Burk, *Edifying Thoughts of a Patent Watcher: The Nature of DNA*, 60 UCLA L. REV. DISCOURSE 92, 101 (2013).

57. *Mayo Collaborative Serv. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012).

58. Brief for the United States as Amicus Curiae in Support of Neither Party, *supra* note 24, at 32.

59. As one amicus argued, cDNA molecules do not occur naturally (other than in rare cases), but must be synthesized in the laboratory. Because of this, there is no risk that patenting will tie up other uses of the natural raw materials involved in the creation of the cDNA. Brief for the Pharmaceutical Research and Manufacturers of America as Amicus Curiae Supporting Respondents at 16, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (No. 12-398).

fundamental features of patents is that they can be used to stop people from doing certain things. If, as the Supreme Court has repeatedly said, “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,”⁶⁰ then it must be the case that all patents, to some extent, potentially preempt. At the very least, they must potentially prevent others from using (or individualizing) nature in the way that is disclosed in the patent. As such, the concern is not really about preemption per se. Rather, the complaint is about the extent of preemption. With a patent over raw materials, it is extremely broad. While a patent over an invention that modifies raw material should not (in theory) restrict use of the raw materials generally, it does restrict (or preempt) access and use of the modified raw materials, if only in terms of the particular way that the materials have been deployed in the patented invention. The situation is similar with a patent that draws upon an abstract idea or a law of nature. The question in all these cases is: What degree of preemption is acceptable? With these general points in mind, I now turn to look in more detail at the different tests that have been used to categorize subject matter.

1. *Labor*

Over the course of the eighteenth and nineteenth centuries, one of the key factors that shaped the emergence of intellectual property law generally and patent law specifically was the labor involved in the generation of intellectual assets and how that labor was perceived.⁶¹ While labor may no longer be as important as it once was, it is still sometimes used to categorize subject matter in patent law. A labor-centered approach is one in which the courts focus on the role that the inventor plays in the production of the subject matter to decide how that subject matter should be categorized. The application of this approach can be seen, for example, in *J.E.M. Ag Supply Inc. v. Pioneer Hi-Bred International, Inc.* where the Supreme Court said that the dividing line between an unpatentable product of nature and a patent eligible invention was human ingenuity: the distinction was “not ‘between living and inanimate things, but between products of nature, whether living or not, and human-made inventions.’”⁶² In part, the decision to use labor as a guide to categorize subject matter draws upon the fact that something that is “naturally occurring” is, almost by definition, “unaltered by the hand of man.”⁶³ Thus while unaltered naturally occurring organisms are not patentable (as in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*), altered nonnaturally occurring organisms are (as in *Chakrabarty*).⁶⁴

60. *Mayo*, 132 S. Ct. at 1293.

61. See generally SHERMAN & BENTLY, *supra* note 53, at 1760–1911.

62. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 130 (2001) (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980)).

63. *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333, 1336 (Fed. Cir. 2014).

64. See *id.* In *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948), the “patent that claimed a mixture of naturally occurring strains of bacteria that helped leguminous plants extract nitrogen from the air and fix it in soil” was held not to be patent eligible “because the patentee did not

Over the last decade, courts have frequently looked at the labor exercised in the development of subject matter when deciding whether that subject matter is patent eligible. In defending their patents, Myriad took a similar approach when they suggested that it would be “judicious to determine patent-eligibility based on the presence of human ingenuity.”⁶⁵ In line with this, proponents of Myriad’s patents highlighted the effort that went into the creation of the subject matter protected by the patents. As one amicus argued, “[e]xtensive human intervention is required to isolate specific DNA molecules” from the host organism.⁶⁶

There are currently two different approaches taken by the courts when using labor as a means to judge subject matter eligibility. Under one approach, the courts seem reluctant to impose qualitative limits on the type of labor that is able to confer patent eligibility on subject matter.⁶⁷ While this does not mean that there are no limits on the type of labor that is able to confer eligibility on subject matter—there are many types of labor that would be dismissed out of hand as being inappropriate or irrelevant—there is a sense in which, within certain parameters, the mere exercise of labor, skill, and effort will be enough to render subject matter patent eligible. In this situation, the mere fact that a scientist, for example, has exerted labor and effort in the generation of the subject matter is enough for that subject matter to be deemed patent eligible. There are a number of advantages with this approach; not least that it is easy to apply and easy for third parties to predict outcomes. Depending on how the approach is applied, however, it may also lead to a lowering of standards and to an increase in what can be patented.

The second way in which labor has been used to decide how subject matter is classified is where the courts are more willing to impose qualitative limitations on the type of labor that transforms raw materials into something that is patent eligible. This approach is underpinned by the idea that the mere fact that someone has exerted labor to create something—that raw materials have been “altered by the hand of man”⁶⁸—is not necessarily enough for it to qualify as patentable subject matter. In turn, this is premised on the idea that not all types of labor are sufficient to confer patent eligible status on subject matter. Thus, even though it may take “significant effort and creativity” to “discover the natural law or substance and to

alter the bacteria in any way.” *In re Roslin*, 750 F.3d at 1336. “[T]here is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention. But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed.” *Id.* (quoting *Funk Bros.*, 333 U.S. 127 at 132).

65. Brief for Respondents, *supra* note 30, at 33.

66. Brief for the Pharmaceutical Research and Manufacturers of America as Amicus Curiae Supporting Respondents, *supra* note 59, at 2–3. As the Supreme Court said in *Myriad*, the central dispute at the Federal Circuit was “whether the act of *isolating* DNA . . . is an inventive act.” *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2114 (2013).

67. For a discussion on the role of labor in patent law, see SHERMAN & BENTLY, *supra* note 53.

68. For a discussion of this idea of “anything under the sun that is made by man,” see *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. Rep. No. 1979, 82d Cong., 2d Sess., at 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., at 6 (1952)).

appreciate its potential utility,”⁶⁹ this high level “creation” is not patentable. The situation is the same with the discovery of laws of nature and the development of abstract ideas. In these cases, no amount of skill or labor will allow someone to patent the fundamental raw materials that underpin the inventive process. It is also clear that the mere fact that someone has exerted labor and effort to modify and change raw materials will not necessarily be enough to guarantee that the resulting subject matter is patent worthy. This is because patent law only recognizes certain types of labor, often unhelpfully described as inventive labor, as giving rise to patentable subject matter.⁷⁰ This need to exercise a particular type of labor was reflected in the comments of the Solicitor General, which were adopted by the Supreme Court in *Myriad*, that “[s]ynthesized genetic materials such as cDNA are patent-eligible subject matter because they do not occur in nature but instead are the product of significant human creativity.”⁷¹ It was also reflected in the comment by the Supreme Court in relation to the isolated gDNA that “Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention”⁷²: labor, but not the right type of labor.

Once the decision was made that only certain types of labor exercised in certain ways is able to render subject matter patent eligible, it was not only necessary for decision makers to be able to distinguish between these different types of labor, they also had to be able to provide justifications for doing so. In this situation it was necessary for them to be able to explain why, for example, that a certain type of labor was deemed “creative” enough to produce something that was potentially patentable, while other labor was not. It may be possible to talk at an abstract level about classes of labor (such as the effort of a laboratory manager who plays an important but noninventive role in the generation of a new technology). Beyond this, however, it is much more difficult to use labor, skill, and effort as a means to categorize subject matter, at least in a way that does not appear to be arbitrary. As I demonstrate below, it is the inability of decision makers to do this that lies at the heart of many of the problems facing patent law in this context. The problems that arise when using labor to categorize subject matter are compounded by the fact that it is not clear what is being judged here. Is it the case, for example, that parties need to produce evidence of the skill and effort actually used to generate the subject matter (as with inventive step)—which seems to run counter to the idea that the

69. Brief for the United States as Amicus Curiae in Support of Neither Party, *supra* note 24, at 9–10.

70. See generally *Teets v. Chromalloy Gas Turbine Corp.*, 83 F.3d 403 (Fed. Cir. 1996).

71. Brief for the United States as Amicus Curiae in Support of Neither Party, *supra* note 24, at 9. “Nature does not create cDNA; only laboratory scientists do” (in contrast to mRNA and native DNA). Brief for University of Baltimore/Johns Hopkins University Center for Medicine & Law et al. as Amici Curiae Supporting Respondents at 11, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (No. 12-398). “The real problem lies in knowing . . . what degree of human intervention is necessary before it can be concluded that the requisite artificial state of affairs exists.” *Cancer Voices Austl. v Myriad Genetics, Inc.* [2013] FCA 65, ¶ 102 (Austl.).

72. *Myriad*, 133 S. Ct. at 2117.

subject-matter inquiry is a preliminary examination—or is it that the case that the decision is made on the basis of the indicative labor used to generate subject matter of the type in question?

Given the uncertainty about the type, degree, and amount of labor needed to render subject matter patent worthy, it is not surprising that where labor is used to categorize subject matter that the focus of attention often shifts to the product of that labor. In these instances, the labor of the inventor is treated as a proxy for change, which is reflected in the end product and the fact that is markedly different from the raw materials on which it is based. This can be seen in the now repealed 2001 USPTO *Utility Examination Guidelines* that stated that isolated and purified naturally occurring DNA was patent eligible.⁷³ While the shift away from a focus on the labor used to generate subject matter as an end in its own right toward the change that the labor has on the (more concrete) resulting product may have some advantages, it does not really solve the problem of how subject matter is to be classified so much as defer the question to another area of doctrine, which (as we will see below), has its own problems.

2. “Inventive Concept”

Another approach used to classify subject matter is one that does so on the basis of whether the subject matter incorporates an inventive concept. This is premised on the idea that to be patent eligible, subject matter that is based on a law of nature, natural phenomenon, or an abstract idea must include an “inventive concept.”⁷⁴ In *Alice Corp.*—which considered whether a patent for a computer-implemented invention designed to facilitate securities trading was excluded on the basis that it was for an abstract idea—the test for eligibility was presented as a two-stage process.⁷⁵ First, it is necessary to identify whether the claim in question was directed to an abstract idea.⁷⁶ It is then necessary to examine the claims to determine whether they contain an “inventive concept” sufficient to transform the abstract idea into something that is patent eligible.⁷⁷ A similar approach is sometimes used when deciding whether subject matter is excluded on the basis that it embodies natural phenomenon or a law of nature. In one sense, the use of the existence of an inventive concept as a means of categorizing subject matter is similar to the approach outlined above, whereby subject matter is categorized on the basis of the type or quality of labor used to generate the subject matter in question. In other senses, however, it is different. Specifically, while a labor-centered approach focuses on the role that the inventor plays in the production of the subject matter, this approach looks more holistically at the inventive process, at the individualization of

73. USPTO *Utility Examination Guidelines*, 66 Fed. Reg. 1092 (Jan. 5, 2001).

74. See *Alice Corp. Pty., Ltd. v. CLS Bank Int’l.*, 134 S. Ct. 2347, 2355 (2014) (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012)).

75. *Id.* at 2351–52, 2355.

76. *Id.* at 2355.

77. *Id.* at 2357.

nature, and asks whether there is something “inventive” in that process. The role that inventiveness is able to play in classifying nature-based subject matter can be seen in *Ariosa Diagnostics v. Sequenom, Inc.*, where Judge Illston of the Northern District of California said that a claim will not be patentable if the only innovation in the patent was the use of natural phenomenon.⁷⁸ On the facts, the court held that amplifying and detecting paternal cell-free foetal DNA (cffDNA) was not patentable because the techniques were conventional in the field.⁷⁹ Here the absence of an inventive concept was taken as an indicator of the ineligibility of the subject matter.

3. “Markedly Different”

Yet another approach used to categorize subject matter is one that does so on the basis of whether the matter in question is “markedly different” from the natural material on which it is based.⁸⁰ This approach, which played an important role in deciding the fate of Myriad’s patents, is captured in the comment that a patent may be issued for “a modified natural substance if the modified version is sufficiently different from its naturally occurring antecedent.”⁸¹ It is also reflected in the remark that “[t]he patent-eligibility of a modified natural substance depends on whether the modified substance is so ‘markedly’ different from its natural predecessor as to warrant the conclusion that the claimant has invented something new.”⁸² Although this approach has a long pedigree, many of the recent U.S. decisions that categorized subject matter on the basis of how the subject matter differs from the raw materials on which it is based cited *Chakrabarty*, where the Supreme Court held that the modified bacterium was eligible subject matter because it had “markedly different characteristics from any found in nature and one having the potential for significant utility.”⁸³ While the Australian Federal Court said that the test of “marked

78. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 19 F. Supp. 3d 938, 949–50 (N.D. Cal. 2013).

79. *Id.* On this, see Christopher M. Holman, *District Court’s Interpretation of Mayo in Ariosa Diagnostics Does Not Bode Well for Patent Eligibility of Diagnostics and Personalized Medicine*, 33 BIOTECHNOLOGY L. REP. 46, 47 (2014).

80. On this basis, discoveries that possess “markedly different characteristics from any found in nature” are eligible for patent protection. In contrast, any existing organism or newly discovered plant found in the wild is not patentable. *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333, 1336 (Fed. Cir. 2014); see also *In re Beineke*, 690 F.3d 1344, 1352 (Fed. Cir. 2012), *cert. denied*, 133 S. Ct. 1243 (2013) (holding that a newly discovered type of plant is not eligible for plant patent protection, in part, because such a plant was not “in any way the result of [the patent applicant’s] creative efforts or indeed anyone’s creative efforts.”).

81. Brief for the United States as Amicus Curiae in Support of Neither Party, *supra* note 24, at 10.

82. *Id.* at 14 (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980)); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1302 (2012).

83. *Chakrabarty*, 447 U.S. at 310. “The inventor had altered a naturally occurring bacterium by transferring to it several plasmids that altered the bacterium’s structure and imbued it with the ability to break down crude oil—a ‘property[] which [was] possessed by no naturally occurring bacteria.’” Brief for the United States as Amicus Curiae in Support of Neither Party, *supra* note 24, at 14–15 (quoting *Chakrabarty*, 447 U.S. at 305).

difference” had no place in Australian law, the decision that the isolated gDNA was patent eligible was made on the basis that the isolated DNA was different to the raw gDNA.⁸⁴

As with each of the different tests used to categorize subject matter, the test for marked difference focuses on a specific aspect of the inventive process, namely, the end product and its relationship to the materials on which it is based. In effect, the test asks: Has the composition of matter been sufficiently changed so that it is no longer a product of nature? By ensuring that patents are only granted for inventions that are markedly different from the underlying raw materials that they are based on, it is possible to argue that the grant of a patent does not take anything away from anyone. The gap between nature and invention that is guaranteed by the product-of-nature doctrine ensures that patents do not unduly prevent third parties from working with the underlying raw materials. This logic underpinned the argument made by the Solicitor General, which was effectively adopted by the Supreme Court, that cDNA should be patentable. The Solicitor General began by arguing that the cDNA was markedly different to the underlying material that it was derived from.⁸⁵ This was because the process of creating synthetic DNA “involves significant manipulation of the underlying natural substances to create a substance that is new and different.”⁸⁶ As a result, the cDNA molecule “has a different nucleotide sequence than DNA created naturally within the cell.”⁸⁷ Drawing on the fact that the cDNA was different from the underlying raw materials, the Solicitor General argued that “[e]xtending patent protection to cDNAs therefore poses no risk of ‘tying up’ other uses of the natural raw materials involved in the creation of cDNA.”⁸⁸ That is, a patent on a “particular cDNA molecule leaves others free to study and exploit the original native DNA, RNA, and mRNA molecule that were used to create the cDNA.”⁸⁹ As these substances can be removed from their cellular environment and studied without creating the cDNA, it was possible to argue that upholding the patent would not prevent others from working with the original naturally occurring microorganism.

The process of determining whether something is materially different from the natural raw materials on which it is based is a two- or possibly three-step process. First, it is necessary to determine what is being compared. Specifically, it is necessary to determine how the subject matter and the natural material on which it is based are to be characterized. Once this is done, it is then necessary to compare the subject matter and the raw materials as characterized. In some cases, a third step may be needed to determine whether any identified differences are in fact “marked.”

84. See *D’Arcy v Myriad Genetics, Inc* [2014] FCAFC 115, ¶¶ 114, 213–18 (Austl.).

85. Brief for the United States as Amicus Curiae in Support of Neither Party, *supra* note 24, at 12.

86. *Id.* at 18.

87. *Id.*

88. *Id.* (citing *Mayo*, 132 S. Ct. at 1294).

89. *Id.* at 12.

One of things that is clear from the cases that have used “marked difference” (or “difference”) as a means of categorizing subject matter is that the outcomes of the decisions often turn on the way that the raw material and the subject matter are characterized. One of the problems that underpinned the *Myriad* litigation, particularly in relation to the isolated gDNA, was that the inventions could legitimately be characterized in *both* chemical and genetic terms. In many ways, the *Myriad* litigation can be seen as a dispute over which of these different ways of characterizing DNA—which each carried different legal conclusions—should dominate. On the one hand, Myriad and their supporters highlighted the chemical nature of the inventions.⁹⁰ Given that both the isolated and synthetic DNA were chemically different from the naturally occurring gDNA, this enabled Myriad and their supporters to argue that the subject matter was markedly different from the raw material which it was based on and, as such, that it was patent eligible. This style of argument (which was accepted by the Australian Federal Court⁹¹ and by the U.S. Federal Circuit⁹²), was summed up in an amicus curiae brief that stated that “[c]laims to isolated DNA molecules are patent-eligible, just like the new microorganisms in *Chakrabarty*, because they are novel creations that are chemically different from naturally-occurring DNA.”⁹³ While a leaf snapped from a tree remained a leaf, “an isolated gene is, as a matter of chemistry, not the same as a gene in a natural context.”⁹⁴ A similar point was made by the Pharmaceutical Research and Manufactures of America who said that each “claimed isolated DNA molecule is a tangible, human-made chemical compound that differs in structure, function, utility, and informational content from its native counterpart. Therefore, none of the patent claims at issue in this case read on genes as they exist in the human body.”⁹⁵

While supporters of Myriad’s patents highlighted the chemical nature of the DNA, opponents of Myriad’s patents lobbied for a genetic reading of the DNA. Although the opponents may have been willing to recognize that the DNA could be described in chemical terms, they nonetheless argued that the defining and distinguishing characteristic of DNA was its ability to “be our instruction book on life.”⁹⁶ As such, the DNA should be viewed genetically. This was reflected in the Petitioner’s argument in *Myriad* that “[g]enes are chemicals, but they are unique because they are much more; they embody the information and instructions the

90. Brief for Federal Circuit Bar Association as Amicus Curiae in Support of Respondents at 14, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (No. 12-398).

91. *D’Arny v Myriad Genetics, Inc* [2014] FCAFC 115 (Austl.).

92. *Ass’n for Molecular Pathology v. USPTO*, 653 F.3d 1329 (Fed. Cir. 2011).

93. Brief for Federal Circuit Bar Association as Amicus Curiae in Support of Respondents, *supra* note 90, at 14.

94. *Id.*

95. Brief for the Pharmaceutical Research and Manufactures of America as Amicus Curiae Supporting Respondents, *supra* note 59, at 3.

96. Brief for James D. Watson, Ph.D. as Amicus Curiae in Support of Neither Party, *supra* note 27, at 12.

body uses to function.”⁹⁷ James Watson made a similar point when he described human DNA as “a chemical entity, but DNA’s importance flows from its ability to encode and transmit the instructions for creating a human being”⁹⁸ and that the “human genome’s ability to be our instruction book on life distinguishes human DNA from all other chemicals covered by the patent laws.”⁹⁹ Given that the nucleotides that make up the DNA—or DNA’s information content—remained the same in the isolated gene as they were in the gene in the human body, the opponents were able to argue (and the Supreme Court ultimately accepted¹⁰⁰) that when viewed in genetic terms, there was no difference between gDNA and isolated gDNA.¹⁰¹ From this perspective, the opponents were able to argue that even though the isolated gene may have been chemically different to the gene in its natural state (isolation changed the form and structure of the gene by breaking the bonds that linked the pieces of the chromosome), this did not matter given that the genes were to be viewed genetically rather than chemically. On the basis that the gene sequences were the same when they were in the body as when they were isolated,¹⁰² the opponents argued that the subject matter in issue (the isolated gDNA) was no different from the raw materials on which it was based (gDNA in the human body).¹⁰³ As such, it was not patent eligible.

One of the things that underpinned the *Myriad* litigation, particularly in relation to the isolated gDNA, was the question of how that material should be characterized. At each stage of the litigation, the fate of the isolated gDNA turned on whether it was construed chemically or genetically. This is because the outcome of this process directly influenced the isolated DNA’s relationship with the raw material (the native gDNA) and thus whether it was markedly different and patent eligible. The differing conclusions of the U.S. Supreme Court and the Australian Full Federal Court (and the difference between the Supreme Court and the Federal Circuit decisions) was directly linked to the way that the isolated gDNA was construed.

In many instances, it would be normal to expect that the answer to the question of how subject matter is to be characterized would be resolved on the basis of a straightforward reading of the language in the patent claims. One of the reasons

97. Brief for Petitioners at 5, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (No. 12-398).

98. “[N]o other molecule can store the information necessary to create and propagate human life the way human DNA does.” Brief for James D. Watson, Ph.D. as Amicus Curiae in Support of Neither Party, *supra* note 27, at 5.

99. *Id.* at 12.

100. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119 (2013).

101. This was a prerequisite for the functioning of Myriad’s diagnostic use of the gene. Brief for Petitioners, *supra* note 97, at 5.

102. *Id.* at 10.

103. The Solicitor General argued that structural changes that left the natural substance’s operative properties entirely untouched were not sufficient in themselves to support patent eligibility. Otherwise, the removal of a kidney from the body might render the extracted kidney patent eligible. Brief for the United States as Amicus Curiae in Support of Neither Party, *supra* note 24, at 22.

why there has been so much diversity of opinion about how the subject matter is to be interpreted, which has been a feature of much of the recent subject matter litigation, is that there was a sense of suspicion about the patent claims and whether they properly represented what was being protected,¹⁰⁴ a concern which is often magnified with product claims. Here the concern was that patent attorneys should not be allowed to dress up patent ineligible subject matter in such a way as to make it appear to be eligible.¹⁰⁵ As the Supreme Court said in *Mayo*, patentees must not be allowed through drafting efforts to “monopolize the law of nature itself.”¹⁰⁶ In this situation, the courts are forced to look beyond the traditional rules of claim interpretation to determine how the subject matter and the material on which it is based are to be construed and ultimately whether the two are markedly different. Over time, a number of different techniques and strategies have been used to provide guidance in these matters.

One way of determining whether a modified natural product is “markedly different” from the underlying natural substance on which it is based, which was suggested by the Supreme Court in *Mayo*, is on the basis of “whether a patent on the modified product would have the practical effect of preempting the public’s ability to use the underlying substance.”¹⁰⁷ While this was not presented as an exclusive test, there are still a number of problems with it, not least that it simply repeats the rationale in reverse: the test does nothing to answer the question of how difference is to be determined. It is also problematic in that the question of whether something preempts use of the underlying material depends on how the material is construed is the very problem that it is supposed to answer. Another problem in using preemption as a basis to determine whether something is markedly different arises because, despite suggestions to the contrary, preemption is always a matter of degree. Given that all nature-based inventions that are patented restrict access and use, at the very least in the specific and particular use that is disclosed in the patent, this gives rise to a further question, namely, what type and degree of preemption is permissible?¹⁰⁸ The test outlined in *Mayo* does little to help answer this question.

It has also been suggested that another factor that needs to be taken into account when considering whether subject matter is markedly different from the raw material on which it is based is the cause or source of that difference. If it is the

104. This fear was reinforced by the view that Myriad’s claims were drafted so as to be difficult to invent around; that they did not claim “the specific chemical composition of a particular molecule” but instead the information “encoded in the BRCA1 and BRCA2 genes.” *Myriad*, 133 S. Ct. at 2118.

105. This has also given rise to the suggestion that some of the problems created by the *Myriad* decision for patentees might be avoided in the future through more careful (and different) claiming practices. Charles Lawson, *Patenting DNA Sequences After the Myriad Decision: New Frontiers or Just More of the Same?*, 33 BIOTECHNOLOGY L. REP. 3, 15 (2014).

106. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297 (2012).

107. Brief for the United States as Amicus Curiae in Support of Neither Party, *supra* note 24, at 17.

108. Following *Mayo*, the Solicitor General said that at a minimum a patent should not be allowed if the patent would have the effect of preempting all uses of the underlying natural substance. *Id.* at 17.

case that the difference is an inevitable or automatic consequence of dealing with the raw material it will not, so the argument goes, be patent eligible. Presumably the position would be the same in other situations where the inventive difference is not a product of the inventor's efforts. In effect, this is the basis on which the Solicitor General argued that Myriad's isolated DNA should be not be patent eligible.¹⁰⁹ The Solicitor General accepted that the process of isolating "a particular DNA segment [did change] the molecule's physical structure to a degree (since the ends of the segment must be 'snipped' in order to remove it from the cell of which it is a part)."¹¹⁰ That is, he accepted that there was a "difference" between the natural and the isolated DNA. Nonetheless he did not accept that there was a marked enough of a difference to render the isolated DNA patent worthy. The reason for this was that the changes were "simply inherent consequences of removing the original substance from its natural environment."¹¹¹ That is, the differences between isolated DNA and native DNA were "merely the inherent and necessary results of removing the DNA from its natural environment."¹¹² Given that the removal of the DNA from its natural environment is a prerequisite to studying and using it, to allow someone to patent something that was an inevitable consequence of that removal would have been tantamount to allowing a patent on the natural product itself.¹¹³

Another factor that is sometimes relied upon as evidence that a particular subject matter is sufficiently different for it to be patent worthy is the fact that the modified product has a new use. In an argument that has parallels with the use of commercial success as an indicator of the obviousness of inventions, the utility of an invention is sometimes cited as one of the reasons for it being patent eligible.¹¹⁴ Rather than attempting to characterize difference from the nature of the subject matter itself, here, marked difference is distilled from external considerations, namely from the value attributed to the modified substance that was not present in its unmodified form. Thus, one of the factors that underpinned the decision in *Parke-Davis* that the purified substance was patent eligible was that unlike the case when it was in its raw unpurified form, the purified substance was a useful pharmaceutical product.¹¹⁵

109. Genomic DNA that has been isolated should not be patent eligible "because it has merely been 'isolated'—i.e., extracted from its cellular environment . . . rather than significantly altered by human intervention." *Id.* at 12.

110. The Solicitor General also said it increased the utility since isolation allows researchers to study and exploit it in a laboratory. *Id.* at 10.

111. *Id.*

112. *Id.* at 20. Since isolation is "a prerequisite to meaningful productive use of native DNA," treating changes that automatically occurred as a result of that isolation as sufficient to support patent eligibility would have "effectively preempt[ed] the public's use of the underlying product of nature." *Id.* at 10–11. "Because the removal process is a prerequisite to any exploitation of native DNA, respondents' isolated DNA claims are the practical equivalent of patents on the underlying naturally occurring BRCA genes themselves." *Id.* at 20.

113. *Id.* at 18.

114. An invention must be useful to be patent eligible. See 35 U.S.C. § 101 (2012).

115. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911).

A similar approach was adopted in *Chakrabarty*, where the Supreme Court decided that an influential factor in determining whether the modified bacterium was patent eligible was that, unlike in the case with the unmodified bacterium, there was “potential for significant utility.”¹¹⁶ The question of whether utility is a useful guide to determine whether something is markedly different depends on the reason why the subject matter is excluded in the first place. If the exclusion exists because there is something inherently wrong with granting patent status to a certain type of subject matter, then it would not matter if a new use was found for that substance: it would remain unpatentable. In Europe, this is the approach taken in relation to human embryonic stem cells.¹¹⁷ If, however, the rationale for excluding subject matter is that granting protection would restrict the ability for third parties to use the underlying material, then there is more scope for using utility as a guide for categorizing subject matter. The problem here, however, is that there is no clear rationale given as to why products of nature are excluded.

Yet another approach used to determine whether a biological innovation is markedly different from the natural material on which it is based (and thus patent eligible) focuses on changes that occur at the genomic level; that is, biological subject matter is construed genetically. Specifically, the focus is on whether, through the action of the inventor, there have been changes that are able to be passed on from one generation to the next.¹¹⁸ This can be seen, for example, in the comments by the Supreme Court in relation to the isolated DNA that Myriad did not “create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes,”¹¹⁹ nor did they “create or alter the genetic structure of DNA.”¹²⁰ As the Court said, Myriad’s claims are “concerned primarily with the information contained in the genetic *sequence*, not with the specific chemical composition of a particular molecule.”¹²¹ The decision to construe biological material genetically can also be seen in the Federal Circuit decision of *In re Roslin Institute*,¹²² which concerned the patentability of cloned animals (cattle, sheep, pigs, and goats).¹²³ In the course of the proceedings, Roslin found themselves in the (ironic) situation where to establish

116. *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980); *see also* *Merck & Co. v. Olin Mathieson Chem. Corp.* 253 F.2d 156, 164 (1958) (contrasting vitamin B12 found in nature, which was only available in minute quantities and, as such, had no utility, therapeutically or commercially, with the synthetic vitamin B12 was both useful and commercially valuable).

117. European Patent Convention, *supra* note 11, art. 53(a), rule 28(b).

118. As the District Court in *Association for Molecular Pathology v. U.S. Patent & Trademark Office* said, the “information encoded by DNA reflects its primary biological function: directing the synthesis of *other* molecules in the body.” *Ass’n for Molecular Pathology v. USPTO*, 702 F. Supp. 2d. 181, 228 (S.D.N.Y. 2010) (emphasis added).

119. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013).

120. *Id.*

121. *Id.* at 2118. “Myriad’s claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes.” *Id.*

122. *In re Roslin Institute* (Edinburgh), 750 F.3d 1333 (2014).

123. *Id.* at 1334.

that they were subject matter eligible they had to argue that the cloned animals were markedly different to the donor animals used to create them. To this end, Roslin argued that the cloned animals were different to the donor animals as a result of the environment in which the respective animals lived.¹²⁴ Specifically, Roslin argued that environmental factors lead to phenotypic differences that distinguished the clones from their donor mammals (that is, the animal's external shape, size, or color that arose from the interaction of the organism's genotype with its environment).¹²⁵ While this issue was not considered in any detail by the Federal Circuit, primarily because the phenotypic differences were not claimed,¹²⁶ the court did say that they would have dismissed the argument anyway because the phenotypic differences were the work of nature (the environment), not the applicant.¹²⁷ Roslin also argued that the clones were patent eligible because they were time-delayed versions of their donor mammals and therefore were different.¹²⁸ This was rejected because the "difficulty with the time-delayed characteristic is that it is true of any copy of an original."¹²⁹

Roslin further argued that the clones were distinguishable from the original donor mammals because of differences in their mitochondrial DNA.¹³⁰ This was a consequence of the cloning process whereby the cloned animal's mitochondrial DNA comes from the oocyte used to create it and not from the donor's mammary cell.¹³¹ The problem for Roslin, however, was that the difference in the mitochondrial DNA between the donor and cloned animals was unclaimed. Instead, the clones were defined in terms of their nuclear DNA. Although the court was willing to accept that having the same nuclear DNA as the donor mammal may not necessarily result in patent ineligibility in every case, the problem here was that the claims did not describe clones with markedly different characteristics from the donor animals of which they were copies.¹³² On the basis that the cloned animal was "an exact genetic replica of the adult mammal from which the somatic cell nucleus was taken,"¹³³ the Federal Circuit "concluded that the claimed subject matter was ineligible for patent protection under § 101 because it constituted a natural phenomenon that did not possess 'markedly different characteristics than any found in nature.'"¹³⁴ In this sense, what the court found was that cloned animals were "natural" (or at least not different from a natural animal) and thus not patentable subject matter.

124. *Id.* at 1338.

125. *Id.*

126. *Id.*

127. *Id.*

128. *Id.* at 1339.

129. *Id.*

130. *Id.* at 1338.

131. *Id.*

132. *Id.* at 1339.

133. *Id.* at 1334.

134. *Id.* at 1335.

In assessing difference, the court in *Roslin* focused on whether the clones were genetically distinct to the raw materials that they were derived from.¹³⁵ That is, the biological subject matter was viewed through a genetic lens. This is reflected in the comments by the Federal Circuit when comparing the cloned animals with the isolated naturally occurring DNA strands in *Myriad* that were held not to be patent eligible.¹³⁶ As the Federal Circuit said:

Here, as in *Myriad*, Roslin “did not create or alter any of the genetic information” of its claimed clones, “[n]or did [Roslin] create or alter the genetic structure of [the] DNA” used to make its clones. Instead, Roslin’s chief innovation was the preservation of the donor DNA such that the clone is an exact copy of the mammal from which the somatic cell was taken. Such a copy is not eligible for patent protection.¹³⁷

In this sense the Federal Circuit stressed that the subject matter needed to be looked at genetically. This was also reflected in the court’s critique of the fact that Roslin’s patent application did not identify how differences in mitochondrial DNA influenced or could influence the characteristics of the cloned animals.¹³⁸ That is, they did not establish that there was a genetic difference.

It is interesting to note that a similar approach to interpreting biological subject matter was recently adopted by the Enlarged Board of Appeal at the European Patent Office in the *State of Israel/Tomatoes*¹³⁹ and *Plant Bioscience/Broccoli*¹⁴⁰ decisions. This occurred when, as part of the litigation, the Enlarged Board was called upon to consider the scope of one of the categories of subject matter expressly excluded from patent protection in European patent law, namely, “essentially biological processes for the production of plants or animals”¹⁴¹ In considering what is

135. The fact that the clones were genetic copies of their donor parents rendered the clones unpatentable. *Id.* at 1337.

136. *Id.*

137. *Id.* (citation omitted).

138. *Id.* at 1338.

139. Tomatoes/State of Israel, Decision of the European Patent Office, Enlarged Board of Appeal, Case G1/08 (Dec. 9, 2010), O.J. E.P.O. 206 (2012); *see also* Tomatoes II/State of Israel, Decision of the European Patent Office, Technical Board of Appeal, Case T1242/06 (May 31, 2012), O.J. E.P.O. 42 (2013); Decision of the European Patent Office, Enlarged Board of Appeal, Case G2/12 (March 25, 2015).

140. Broccoli/Plant Bioscience, Decision of the European Patent Office, Enlarged Board of Appeal, Case G2/07 (Dec. 9, 2010), O.J. E.P.O. 130 (2012); *see also* Broccoli/Plant Bioscience, Decision of the European Patent Office, Technical Board of Appeal, Case T83/05 (July 8, 2013), O.J. E.P.O. A39 (2014); Decision of the European Patent Office, Enlarged Board of Appeal, Case G2/13 (March 25, 2015).

141. EPC 2000, article 53(b) provides that European patents shall not be granted in respect of “plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof” European Patent Convention, *supra* note 11, at art. 53(b). On this, *see* BENTLY & SHERMAN, *supra* note 6, at 507–13. *See also* Law No. 9.279, art. 18, May 14, 1996 (Braz.), which provides for the possibility of patenting genetically modified microorganisms, which through direct human intervention, possess a trait normally not achievable by the species under natural conditions, except for all plants or animals or parts thereof, and which are not a mere discovery.

meant by “essentially biological,” the Enlarged Board looked at the legislative history of the exclusion, which showed that the legislator’s intention was to exclude from patentability the kind of plant breeding processes conventionally used at that time (namely, crossing and selection).¹⁴² Although classical breeding methods frequently use technical devices such as pruning shears, grafting tools, and greenhouses, the Enlarged Board said, “while such technical devices may perfectly well be patented themselves the biological process in which they are used may not.”¹⁴³ The Board also said that the mere fact that a breeding process includes a technical process did not necessarily mean that the process was not essentially biological. The willingness to accept that a process could still be essentially biological when it included technical steps gave rise to the question: How do we distinguish a process that includes a technical step that is still an essentially biological process from a process that includes a technical step that takes the process outside the scope of the exclusion?

In essence, the way that this question was answered was to focus on whether the process in question genetically changed the plant or animal. Like the Supreme Court in *Myriad* and the Federal Circuit in *Roslin*, the Enlarged Board looked at the subject matter in terms of its genetic identity. As the Board said: if a technical step modifies or introduces a trait into the genome of a plant or animal, the process will not be essentially biological. This would be the case, for example, where genetic engineering techniques are used to insert or modify one or more genes into a plant or animal. In contrast, where the modification to the genome of the plant or animal was a product of natural processes—that is, where the technical steps merely serve to enable or assist the performance of that process—the process as a whole will be essentially biological. This is also the case where the technical step includes the use of special greenhouses to grow plants, the use of specific tools to help with grafting or pollination, or the use of molecular markers to facilitate selection for the desired properties. While technical means are used in these situations to assist with the breeding process, they are nonetheless “characterised by the fact that the traits of the plants resulting from the crossing were *determined by* the underlying natural phenomenon of meiosis.”¹⁴⁴ That is, the traits of the plants (or animals) are primarily the result of natural forces.

As the European Patent Office Guidelines explain, a method of crossing, inter-breeding, or selectively breeding “say, horses involving merely selecting for breeding and bringing together those animals (or their gametes) having certain characteristics would be essentially biological and therefore unpatentable.”¹⁴⁵ The situation would remain unchanged even if the process contained an additional

142. Tomatoes/State of Israel, O.J. E.P.O. 206.

143. *Id.* at 64.

144. *Id.* at 66 (emphasis added).

145. EUROPEAN PATENT OFFICE, GUIDELINES FOR EXAMINATION § 5.4.2 ESSENTIALLY BIOLOGICAL PROCESSES FOR THE PRODUCTION OF PLANTS OR ANIMALS, http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_4_2.htm [<http://perma.cc/KP4N-JJ55>] (last updated Jan. 10, 2015).

feature of a technical nature such as the use of genetic molecular markers to select either parent or progeny. In all these instances, the resulting plant or animal is essentially the result of natural forces. The situation would change, however, in the case of a process where a gene or trait was inserted into a plant by genetic engineering that would be potentially patentable. In positive terms, this means that to fall outside the process exclusion, there has to be “an additional step of a technical nature which *by itself* introduced or modified a trait in the genome.”¹⁴⁶

One of the points of contention in *Myriad* was whether the isolated DNA should be seen in chemical or genetic terms. While a decision to evaluate change to biological subject matter at the genomic level would overcome this problem (but certainly not appease *Myriad* and their supporters), it gives rise to a number of additional concerns. In particular, if the innovation really is a chemical one, why shouldn't a patentee be able to describe their invention in chemical terms? In part, the problems arise here because while an applicant may highlight one aspect or dimension of the subject matter in order to present it in such a way that it is patent eligible (here, its chemical traits), once protected as a product patent, the patentee are able to claim other uses (here, genetic). Another thing to keep in mind here is that a decision to look at biological matter in terms of inheritable change does not necessarily mean that questions of how to interpret the genetic identity of that biological object will not arise. For example, while the Court in *Roslin* suggested that had the claims been drafted differently, the existence of mitochondrial DNA might have been sufficient to establish a difference, it is not clear how the presence of “foreign” mitochondrial DNA in a cloned animal would be construed. As Frieze has shown in a study of the way that different scientists view cloned animals, scientists do not agree what the existence of different mitochondrial DNA in a cloned animal means for the way cloned animals are classified—that is, whether the cloned animals are seen to be different to, or the same as, the donor animals they are derived from.¹⁴⁷ The use of heredity as a means to categorize biological subject matter would also run into problems where something that has the potential for life is modified to prevent it from developing. What would be the case, for example, in relation to human parthenotes (which are asexually reproduced cells) that cannot develop to term because of the absence of parental DNA,¹⁴⁸ or where a plant incorporates some form of genetic use restriction technology that prevents it from reproducing?

We can also see some of the problems that arise in construing biological subject matter genetically if we look at the way the synthetic cDNA (which was held

146. Tomatoes II/State of Israel, Decision of the European Patent Office, Technical Board of Appeal, Case T1242/06 (May 31, 2012), O.J. E.P.O. 42 (2013) (emphasis added).

147. CARRIE FRIESE, CLONING WILD LIFE: ZOOS, CAPTIVITY, AND THE FUTURE OF ENDANGERED ANIMALS 32–40 (2013).

148. See *Int'l Stem Cell Corp. v. Comptroller Gen. of Patents*, [2013] EWHC (Ch) 807, [21], [23], [36] (Eng.) (concerning “[p]arthenogenetic activation of oocytes for the production of human embryonic stem cells” and “non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis”).

to be patent eligible¹⁴⁹) was dealt with in *Myriad*. In arguing that the cDNA should not be patentable, the petitioners highlighted the fact that the cDNA contained the same protein-coding information (exon sequences) as DNA in the body.¹⁵⁰ That is, the petitioners effectively argued that when viewed genetically, there was no difference between gDNA and cDNA. It is interesting that neither the Solicitor General nor the U.S. Supreme Court was able to provide a convincing response to this argument. For example, in responding to this argument the Solicitor General noted that “the properties of any product originally derived from nature . . . can be traced to the operation of natural principles”¹⁵¹ (which doesn’t really address the issue). The Solicitor General downplayed the similarity and argued that the properties of the cDNA molecules exons operated within a molecule that does not exist in nature. Shifting focus again, they added that the “fact that a cDNA incorporates nucleotide sequences whose significance is derived from nature . . . does not mean that the molecule as a whole is a product of nature.”¹⁵² The response by the Supreme Court was even more elusive. While the Supreme Court accepted the Petitioner’s argument that the “nucleotide sequence of cDNA is dictated by nature, not by the lab technician,” nonetheless the Court went on to say “[t]hat may be so, but the lab technician unquestionably creates something new when cDNA is made.”¹⁵³ That is, while the cDNA may have been genetically the same as the raw gDNA, this was trumped by the fact that the lab technician had created something new.

While evaluating change to biological material at the genomic level provides some clarity, it does not provide a litmus-like test that enables us to readily determine whether biological subject matter is markedly different to the natural material that it is derived from. In many ways, the problems here are symptomatic of broader issues that are applicable to all of the techniques used to categorize subject matter. Having reviewed some of the methods used to categorize subject matter in patent law, we are now in a position to return to the question posed at the outset of the Article: Why is it that patent law has experienced so many problems in attempting to categorize subject matter?

II. LEGAL TAXONOMY

One of the reasons why botanical, zoological, and microbiological taxonomy have been so successful in what they do—which is to categorize subject matter, to provide certainty to third parties about this process, and thus to allow named objects to circulate—is that while the taxonomic exercise is one that involves judgement, it is a process in which the number of points at which judgment needs to be exercised

149. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013).

150. Brief for the United States as Amicus Curiae in Support of Neither Party, *supra* note 24, at 20–26.

151. *Id.* at 19.

152. *Id.*

153. *Myriad*, 133 S. Ct. at 2119.

have been minimized. It is also a process that forces those passing judgment to explain why they have reached a particular decision. While these factors have played an important role in ensuring the success of the modern taxonomic exercise, perhaps the most important reason for their success is that through a combination of factors, most notably the adoption of the type specimen (which has the “paradoxical status as a concrete abstraction”¹⁵⁴), scientific taxonomists created a new way of representing the many by the one. Through what has been described as an act of applied metaphysics, taxonomists created an artificial objectivity that allows them to classify and categorize things with a high degree of certainty and predictability.

Although patent law has made good use of these developments, scientific taxonomy is of little or no assistance in helping patent law to decide how subject matter is to be classified. At best, all scientific taxonomy has to offer patent law here are general insights into some of the problems that occur when classifying things and how those problems might be overcome. While science may play an important role in informing this process, ultimately the decision about how subject matter is to be classified is a legal question.¹⁵⁵ In this situation, patent law has to rely on its own resources to decide how subject matter is to be classified. The chorus of complaints that have accompanied recent decisions in the United States and Australia suggests that patent law has not been very successful in this task.

One of the criticisms made of the recent subject matter decisions is that it is not possible to identify a consistent or clear approach to the way that subject matter is classified: different tests are used at different times, often interchangeably and without explanation. There is not only diversity between different judgments; there is sometimes even diversity within a single judgment. Thus while most of the discussion about the isolated DNA in *Myriad* focused on whether—and, if so, how—the isolated DNA differed from its natural counterpart, the discussion about cDNA tended to focus on the labor that went into the creation of the synthesized materials.¹⁵⁶

The fact that when classifying subject matter the courts shift almost seamlessly between different tests, even within the same judgment, creates problems for treatise writers, academics, and lawyers. Nonetheless, the fluid, shifting, and interchangeable way in which the tests are employed is not necessarily indicative of some sort of fundamental problem with the law itself. Indeed, the situation would probably be even worse if the courts did not adapt the test to the particular problem at hand. While this does make the task of describing and explaining the law more

154. Lorraine Daston, *Type Specimens and Scientific Memory*, 31 CRITICAL INQUIRY 153, 158 (2004).

155. See Burk, *supra* note 56, at 95.

156. Thus, the Solicitor General argued that artificial DNA molecules such as cDNA were patent eligible inventions because “[c]reating cDNA requires significant manipulation and alteration of naturally occurring genetic materials,” and that “[i]ssuing patents on cDNA creates no risk of preempting other uses of the raw materials from which cDNA is created.” Brief for the United States as Amicus Curiae in Support of Neither Party, *supra* note 24, at 10.

problematic, this fluidity should not be seen as an inherent weakness. Rather, it is an inevitable consequence of the nature of the subject-matter inquiry, of the diversity of the subject matter under scrutiny, and the different ways in which that subject matter is presented to the law for examination. It is also a consequence of courts selecting the most appropriate test for the facts at hand. This is because, as we noted above, the different tests used to classify subject matter correspond to different aspects of the (fictitious) model of invention. In reflection of this, the courts select the test that is most suitable to the subject matter in question. This can explain why the U.S. Supreme Court asked different questions when deciding the fate of the isolated gDNA (marked difference) and the synthetic cDNA (creative labor). One of the consequences of this is there is not, nor can there be, a single universal test that can be used to determine how subject matter is to be categorized: the test needs to change depending on the situation. The complexity that this creates is compounded by the fact that as the different tests effectively look at the same thing from different perspectives, they are often used conjointly. These problems are made worse by the fact that the questions asked will often differ depending on the facts that are presented for adjudication and how the cases are argued.

Given that the tests commonly used to classify subject matter are based on a shared image of the process of creation, differing only in terms of the perspective they take on that process, it might be reasonable to expect that there is not only a synergy between the different tests but also that the tests can be used interchangeably without impacting on the outcomes of the classification process. It seems, however, that this may not necessarily always be the case. We can see this, for example, in the *Roslin* decision where, as we noted above, the court held that the cloned animals were not patentable because as genetic replicas of the donor animals they were not “markedly different” from the raw material that they were derived from.¹⁵⁷ One of the notable things about this decision was that it was made despite the fact that the cloned animals were clearly the product of human ingenuity. It was also made despite the fact that human ingenuity had clearly altered the donor animal. The celebration and horror that accompanied the creation of Dolly (the cloned sheep) is a testament to this. Rather, it was held that according to the criteria used to judge difference, namely genetic identity, that the cloned animals were identical to their donor animals.¹⁵⁸

While in most situations an examination that focused on the labor that goes into the development of a new invention would be coextensive with an examination that looked at the difference between a would-be invention and the things on which it is based, that was not the case here. Rather, the inquiry into whether the invention was markedly different from nature not only trumped an inquiry that focused on the labor and effort of the inventor, it also led to what would have probably been a

157. *In re Roslin Institute* (Edinburgh), 750 F.3d 1333, 1336 (2014) (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)).

158. *Id.* at 1339.

different result.¹⁵⁹ While this may not occur in many situations, the mere fact that it is a possibility compounds the uncertainty that surrounds the subject-matter inquiry. It also leads us to question the relative applicability of the different tests. Is it really the case, for example, that the tests can be used interchangeably without changing the outcome? Are they equally applicable to different types of inventions—to different factual scenarios? These questions are particularly relevant in relation to biological inventions (or at least to certain types of biological inventions). This is because while the fictitious model of invention that underpins the different tests used to categorize subject matter fits with mechanical inventions as the archetypical originating inventions, this is not the case with (some) biological inventions. The reason for this relates to the inventive process and the role that the human agent plays in that process. More specifically, it arises because a key feature of biological (inductive or empirical) inventions is that the role of the originating material and human agent are reversed.¹⁶⁰ Although with originating inventions the human inventor uses their special skills to modify the underlying materials and to reduce the abstract to the specific in order to produce a new invention, this is not the case with biological inventions. Here, it is nature that does the creating while the role of the human agent is relegated to identifying and documenting that innovation (which is a highly skilled art).

While in some cases humans may intentionally or accidentally stimulate a change in nature, they usually cannot pretend that the invention was the result of an originating design that shaped the final creation (other than to say, “we were looking for a better plant”). This manifests itself in the fact that the “inventor” is unable to reduce the invention to a written form that third parties can use to re-create the invention. The inability to reduce biological inventions to a recipe that allows them to be replicated by others posed a serious problem to the potential patentability of biological inventions in the early part of the twentieth century: a problem that was resolved when the law accepted deposit of a physical manifestation of the invention or the biological starting material for the invention as a way of satisfying the requirement of enabling disclosure.¹⁶¹ The fact that the process of invention changes depending on the subject matter in question also calls into question the applicability of the different tests used to determine subject matter eligibility. While it is possible to compare biological subject matter with the material on which it is based and to ask whether the latter is markedly different from the former, it is much more difficult to use either the labor of the inventor or the existence of an inventive concept as a way of categorizing certain types of biological subject matter. In these cases, at best there is an awkward fit; at worst, the tests are simply inapplicable.

159. It is possible that had the ingenuity approach been followed the court could have concluded that the subject matter was patent ineligible because it was created by the wrong type of labor.

160. For a discussion, see POTTAGE & SHERMAN, *supra* note 39, at 186–89.

161. Deposit of Biological Materials for Patent Purposes, 54 Fed. Reg. 34864 (Aug. 29, 1989) (to be codified at 37 C.F.R. pt. 1).

While some of the uncertainty associated with the subject-matter inquiry is attributable to the fact that courts apply different tests depending on the facts at hand, this is only part of the story. In order to understand the reason for the confusion, we need to look more closely at the way subject matter is classified. As was explained above, in order for courts to determine how subject matter is categorized, they need to make a number of preliminary decisions. How is the subject matter to be characterized? How is nature to be construed? How much and what type of labor is needed to transform nature into invention? And so on. It is clear that the fate of subject matter often depends on how these preliminary issues are resolved. It was clear, for example, that the fate of the isolated DNA in the *Myriad* litigation depended on how it was construed.¹⁶² So too in *Mayo*, where the fate of the subject matter in issue depended on the way abstraction was defined. In nearly all situations, the answer to the question of how subject matter is to be classified has already been decided before the courts asks, for example, “is the subject matter markedly different from the raw materials on which it is based?”

One of the problems here is that there is typically little or no explanation given as to why the subject matter was characterized in a particular way. Instead, we tend to get bald statements that effectively determine how the subject matter is to be classified. Thus, in the Australian Full Federal Court decision there was no explanation offered as to why the isolated gDNA was exclusively viewed as a chemical (which almost inevitably led to the conclusion that the isolated DNA was patent eligible): it was simply presented as a given.¹⁶³ As a result, we have little guidance as to why particular decisions were reached.¹⁶⁴ In situations where there are valid competing interpretations, we need to know why one interpretation was chosen over another. Why aren’t genes chemicals? The fact that the reasons for the decisions are often, at best, opaque, does little to help us understand how subject matter is categorized.¹⁶⁵

Another important reason for the uncertainty that surrounds the subject-matter inquiry is that there is no real clarity about many of the underlying concepts. If we take the case of something as fundamental as “nature,” for example, we can see that one of the reasons why the product-of-nature doctrine has been so elusive is because there is no clear sense of what is meant by “nature” in patent law. Robert Cook captured the essence of this problem when, in speaking about patent

162. The different conclusions reached by the Supreme Court and the Australian Full Federal Court in relation to the isolated gDNA can be explained by the way that the subject matter was construed (either chemically or genetically).

163. *D’Arcy v Myriad Genetics Inc* [2014] FCAFC 115 (Austl.).

164. It is not clear how we are to undertake the important task of characterizing subject matter and the material on which it is based. These problems are magnified in situations where a court becomes suspicious about the language of a patent because it believes that a patentee is attempting to dress up nonpatentable subject matter as if it was patentable.

165. Given that the process of determining how subject matter is to be classified is often a matter of degree, we also need to have some idea about where and how the limits are to be set. What does it mean, for example, for something to be *markedly* different?

protection for plants, he said, “[u]nquestionably the genetic elements which go to make up a new form of plant are ‘natural.’ Into which category of ‘naturalness’ the courts will conclude that these phenomena of plants should be placed in [sic] an extremely interesting problem.”¹⁶⁶ Given that “nature” is the very thing that the product-of-nature exclusion sets out to protect, it would be reasonable to presume that there would be some sense of understanding about what nature was. This, however, is not the case. Instead we are presented with a situation where there are not only a number of different “natures” at work in patent law,¹⁶⁷ the term is also used with little clarity and consistency.

While patent law has been willing to accept that biological inventions necessarily embody and build on natural elements, there has been less consideration given to the converse issue, namely whether and to what extent “nature” involves human intervention.¹⁶⁸ In some situations, nature is presented almost like a timeless ahistorical concept that is prelaw. This is the nature that the product-of-nature doctrine sets out to protect. While this nature includes human genes, the work of humans in changing nature is usually excluded from that definition. The problem with this, however, is that patent law rarely (if ever) has to deal with a nature untouched by human hands. It may work hard to protect and preserve a natural domain, but this nature is different from the nature that is presented to the law for evaluation and judgment. Thus, the bacteria in *Funk Brothers* (which were excluded as nonpatentable products of nature¹⁶⁹) were subject to an array of tests and interventions as they were transplanted from their natural environment to the laboratory.¹⁷⁰ Although patent doctrine often proceeds on the basis that it was dealing with nature in the Garden of Eden, there is usually some degree of human involvement with even the purest of natures that are presented to the law for scrutiny. The problems that this creates are compounded by the fact that like varieties and species, “genes” do not really exist in nature. Instead, they are a human construct; they are a product of our penchant and need to classify things, to name and order (a topic which is at the heart of patentable subject matter).¹⁷¹ This does not directly impact the subject-matter inquiry in the United States and Australia (in

166. Cook, *supra* note 37, at 318. “It is a little hard to distinguish the natural property of tungsten that renders it ductile under certain conditions from the natural properties of carbon and hydrogen and oxygen that permit them to combine in various ways to form a vast array of patentable chemical compounds.” *Id.* For an example of this, see the discussions about the changes needed to a crayfish for it to qualify as a manufacture in *Ex parte Grayson*, 51 U.S.P.Q. 413 (Bd. App. 1941), where it found that a shrimp with the head and digestive tract removed was not a manufacture.

167. In patent law’s version of the raw and the cooked, these include raw or pure nature, isolated raw nature, and modified nature.

168. While the issue has not been addressed in the United States and Australia, it has been discussed in Europe in the context of the exclusion of essential biological processes. See European Patent Convention, *supra* note 11, art. 53(a), rule 28(b).

169. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948).

170. See *id.* at 129–37.

171. See STAFFAN MÜLLER-WILLE & HANS-JÖRG RHEINBERGER, A CULTURAL HISTORY OF HEREDITY 5 (2012); Burk, *supra* note 56, at 95. This leads Burk to argue, “science informs—but cannot answer—the legal question as to whether a gene is a product of nature.” Burk, *supra* note 56, at 95.

the way that it does in Europe), but it does remind us that the concept of the gene, like nature more generally, is not something that is fixed and prehuman. This should also serve to remind us that the law's perception of what counts as "nature" has changed over time, and that nature has a history. It also serves to remind us that the *Myriad* litigation was not only concerned with the patentability of genes, but also with what we mean by "nature," and whether—and, if so, how—that concept has been changed by recent advances in biotechnology. While it may take some time before we are in a position to determine the impact that decisions like *Myriad* have on the way nature is construed in patent law, it only serves to introduce yet another variable into the subject-matter inquiry.

CONCLUSION

Over the last few centuries, patent law has undergone many changes that have allowed it to respond to new technologies and policy demands, shifts in geo-political considerations, and changes to where and how research and innovation are organized and funded. Unfortunately, however, this has not been the case in relation to the subject-matter inquiry in the United States and Australia, which largely remain locked in a premodern framework. The confusion that surrounds the recent subject matter decisions is testament to this. Although there have been some developments, it is as if patent law is effectively operating in the equivalent of a pre-Linnaean world. In contrast to scientific taxonomy, which has been successful in minimizing the number of places where decisions are made that affect how things are categorized, the fate of subject matter in patent law is potentially decided in a range of different places. The uncertainty that this generates is compounded by the fact that the boundaries of the excluded categories are either unclear or changing, or both. These problems are exacerbated by the uncertainty that accompanies the concepts underpinning the tests used to decide how things are to be classified. In many ways these problems are symptomatic of a broader problem with the subject-matter inquiry—namely, there is no clear guidance about the criteria to be used to categorize subject matter. In part this is a consequence of what patent law expects of the subject-matter inquiry. Courts in the United States and Australia not only have to establish the parameters of the categories, the demand for some type of *qualitative* taxonomy also means that the courts are also required to pass judgement over the things being categorized.¹⁷² One of the reasons why the subject-matter inquiry is so uncertain and problematic is that patent law has yet to develop a consistent and reliable means to navigate these issues.

The problems that this confusion creates are very real. They not only complicate the task of treatise writers, commentators, and lawyers attempting to

172. As with the decision to define essential derivation in plant breeders rights law in terms of "importance," so too the decision to require that patent eligible biological inventions are markedly different from the natural form on which they are based, or they build upon inventive concepts requires the courts to pass judgement. On this, see Jay Sanderson, *Essential Derivation, Law and the Limits of Science*, in *PATENT LAW AND BIOLOGICAL INVENTIONS* 34, 46–50 (Matthew Rimmer ed., 2006).

make sense of the law, they also potentially undermine the patent system itself, given that the value of patents depends on the extent to which they can be trusted. For critics of gene patenting, it is possible that the uncertainty generated by the lack of guidance about subject matter eligibility may be as effective a result in the long run as the Supreme Court decision in *Myriad* itself. In the meantime, the pressing question in this context is whether there is anything that can be done to rectify these problems. One potential solution is for the legislature to intervene, whether through the introduction of specific subject matter exclusions or by regulating how the rights are exploited.¹⁷³ Given the current political climate in the United States and Australia, it seems unlikely that any of these options will be taken up, at least in the near future. It is also possible, as has happened previously in patent law (notably in relation to patent claims¹⁷⁴ and the deposit system¹⁷⁵), that the solution to the problems confronting patent law will be provided by patent lawyers. One factor that militates against this is that where professional solutions have been adopted in the past, they have been developed in a consensual environment where there is widespread agreement. This is not the case in relation to the subject-matter inquiry, where there is a divergence of opinion. While this does not preclude a profession-driven solution, it does make it less likely.

It is also possible that the judiciary might intervene to resolve the problems confronting patent law in dealing with patentable subject matter. One possibility would be for the courts to follow the lead offered by American plant patent law over the course of the twentieth century. Faced with questions about how the relationship between breeder (*qua* inventor) and the resulting plant law was to be configured, plant patent law jettisoned the old settlement divide that underpinned traditional patent jurisprudence and redefined the notion of the nature and invention.¹⁷⁶ Another option would be for the courts to follow the lead of the European Patent Office, which has radically changed the way it approaches subject matter eligibility over the last decade. Frustrated by the uncertainty and confusion that accompanied the various efforts to navigate patentable subject matter, primarily in relation to computer related inventions, the European Patent Office effectively jettisoned the subject-matter inquiry (or at least reduced it to very broad brushstrokes: is the subject matter technological?), when it adopted the so-called any-hardware approach to patentable subject matter, whereby the existence of *any* type of technology is sufficient for something to be deemed patent eligible.¹⁷⁷ Under

173. Rai described patent validity doctrines as “a very blunt mechanism” for promoting access and autonomy. Arti K. Rai, *Biomedical Patents at the Supreme Court: A Path Forward*, 66 STAN. L. REV. ONLINE 111, 111–12 (2013).

174. See David J. Brennan, *The Evolution of English Patent Claims as Property Definers*, 4 INTELL. PROP. Q., 361, 398 (2005).

175. See POTTAGE & SHERMAN, *supra* note 39, at 186–91.

176. See Alain Pottage & Brad Sherman, *Organisms and Manufactures: On the History of Plant Inventions*, 31 MELB. U. L. REV. 539, (2007).

177. It is important to contrast situations where the existence (or otherwise) of an inventive concept is used to categorize subject matter (as in *Alice*), with the attempt to shift the inquiry away from

the new approach, the mere presence of a technological artifact or process, no matter how old or lacking in originality (such as a cup, a nail, or a personal computer), is sufficient for something to pass the subject matter threshold. Although the adoption of the any-hardware approach at the European Patent Office may have made it much easier for applicants to satisfy the subject matter threshold, this has not meant that there has been an overall lowering of standards and a corresponding increase in the number of patents. Instead, what has happened is that debates about validity have shifted from subject matter to inventive step.¹⁷⁸ As well as confronting the fact that the shift to inventive step has been rejected in the United States, one of the problems with the suggestion that we can shift the focus of attention from subject matter to inventive step is that it presumes that there is a type of symmetry between these different areas of law. While this may be the case when we are dealing with computer-based inventions, where it is generally accepted that computer hardware is a form of technology, in many cases this is the very thing that is being disputed in relation to biological inventions. One of the consequences of this is that it calls into question the possibility of transferring the focus of attention from subject matter to inventive step, at least in relation to biological inventions. It also serves to remind us that despite the flurry of judicial activity in recent years, patent law in the United States and Australia is still not in a position whereby it can sensibly answer the question, “what does it mean to invent nature?” nor is it any closer to developing an effective way of categorizing patentable subject matter than it was before.

one about subject matter to a more case-specific and fact based inquiry into the obviousness or inventiveness of the disputed claims. On the latter, see BENTLY & SHERMAN, *supra* note 6, at 465–71.

178. For a discussion, see BENTLY & SHERMAN, *supra* note 6, at 455–71.

