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12-1-2014

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### Recommended Citation

90 Notre Dame L. Rev. 505 (2014)

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# THE CURIOUS INCIDENT OF THE SUPREME COURT IN *MYRIAD GENETICS*

Dan L. Burk\*

## ABSTRACT

*Often what is not said is as significant as what is said. In its recent Myriad Genetics decision, the United States Supreme Court is curiously silent about the relationship between its holding in that case and the holding in its immediately previous patent subject matter case, Mayo v. Prometheus. This reticence is all the more puzzling given that the Court initially remanded Myriad to the lower courts for reconsideration in light of the Mayo holding. The Court's silence regarding Mayo leaves uncertain the relationship between the "products of nature" doctrine that serves as the basis for the Myriad decision, and the "laws of nature" doctrine that has been the basis of nearly all of its other subject matter cases. In this Article I assemble the clues in the laws of nature cases to suggest what the Court might have said or might still say regarding products of nature.*

## INTRODUCTION

This is an essay about something not said. In its recent gene patenting opinion in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the United States Supreme Court held that genomic DNA sequences (gDNA) that had been extracted and purified from human cells fell outside of patentable subject matter.<sup>1</sup> It further held that claims to another type of nucleotide sequence, complementary DNA (cDNA) that had been replicated in the laboratory, *did* fall within patentable subject matter.<sup>2</sup> And the Court squarely held that there exists a judicially created doctrine on products of nature that distinguishes between the two types of molecules.<sup>3</sup>

But what is *not* said is often as important as what *is* said. In Sir Arthur Conan Doyle's mystery story, *Silver Blaze*, Sherlock Holmes announces that

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1 133 S. Ct. 2107, 2117–18 (2013).

2 *Id.* at 2119.

3 *Id.* at 2116.

the critical clue to solving the mystery presented is the “curious incident of the dog in the night-time.”<sup>4</sup> When the ever-hapless Scotland Yard Inspector Gregory observes that the dog did nothing in the nighttime, Holmes responds, “[t]hat was the curious incident.”<sup>5</sup>

Despite all that it did say in its *Myriad* opinion, the Supreme Court said not a word explaining the relationship of the products of nature doctrine to the holding in its previous opinion in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, decided only a year before.<sup>6</sup> *Mayo* was also a case about patentable subject matter. In the *Mayo* opinion, the Court declared claims to a medical diagnostic test to be excluded from patentable subject matter, because they read on a law or principle of nature. *Mayo* concerned the disposition of natural processes; *Myriad* involved the disposition of natural substances.<sup>7</sup> The Court is prone to mention both in the same breath,<sup>8</sup> but their relationship remains unarticulated.

The Court’s deafening silence on this relationship is particularly odd given the procedural history of the *Myriad* decision. It began conventionally enough with a district court decision that was affirmed in part and reversed in part by the Court of Appeals for the Federal Circuit.<sup>9</sup> The parties petitioned the Supreme Court for certiorari. But while the *Myriad* petition was pending, the Supreme Court decided the *Mayo* case and remanded *Myriad* to the Federal Circuit for reconsideration in light of the *Mayo* opinion.<sup>10</sup>

One might think, given its earlier instruction to the intermediate court to reconsider *Myriad* in light of *Mayo*, that the Court might have expressed some view on the connection between the cases. Indeed, the *Myriad* opinion begins by citing *Mayo* regarding the patentability of natural law.<sup>11</sup> But it quickly moves on to discuss unpatentable *products* rather than unpatentable *principles* without a word about the relationship between the two.<sup>12</sup> The ultimate holding regarding *Myriad*’s claims to DNA molecules is as silent on the subject as Holmes’s dog in the nighttime.

A good deal has been written about *Mayo* and the Court’s laws of nature jurisprudence.<sup>13</sup> No doubt a good deal will be written about the implications

4 A. CONAN DOYLE, *Silver Blaze*, in MEMOIRS OF SHERLOCK HOLMES 1, 22 (New York, A.L. Burt Co. 1894).

5 *Id.*

6 132 S. Ct. 1289 (2012).

7 See Dan L. Burk, *Are Human Genes Patentable?*, 44 INT’L REV. INTELL. PROP. & COMPETITION L. 747, 749 (2013).

8 See *infra* text accompanying notes 49–61.

9 Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1358 (Fed. Cir. 2011).

10 Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012) (mem.) (order granting certiorari, vacating, and remanding).

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

12 See Burk, *supra* note 7, at 749.

13 See, e.g., Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 YALE L.J. ONLINE 341, 341–42 (2013) (discussing *Mayo* and noting the opportunity the Court had to “clarify the applicable rules” of patent eligibility in *Myr-*

of the Supreme Court's decision in *Myriad*.<sup>14</sup> But my brief here is to trace the connections between the two that the Court left unarticulated in the latter opinion. I begin by reviewing salient features of the *Myriad* decision itself and the somewhat dubious history of the "product of nature" doctrine. I then turn to the parallel line of cases regarding laws of nature, tracing the conceptual threads that culminate in the *Mayo* decision. I conclude by looking for some consonance or point of contact between the two lines of cases and by suggesting the work that remains to be done, probably by lower courts, to articulate the connections that the Supreme Court left unspoken.

## I. PATENT ELIGIBILITY OF DNA

Even without its strange silence regarding the *Mayo* decision and principles of nature, the *Myriad* opinion would be something of a puzzle. The case presented to the Supreme Court involved patents over two types of genetic molecules: genomic DNA, or "gDNA" that was extracted from human cells, and complementary DNA or "cDNA" that was synthesized in the laboratory using a process called reverse transcription, and which would generally not occur in the normal course of human cellular function.<sup>15</sup> In a unanimous opinion written by Justice Thomas, the Court found the gDNA not patent eligible, but the cDNA to fall within patentable subject matter.<sup>16</sup>

The principal opinion from the intermediate Court of Appeals for the Federal Circuit also held that the cDNA was the patent eligible product of human manipulation.<sup>17</sup> But it additionally held that the gDNA was patentable subject matter, because extraction from the cell separated the gene sequence from the larger chromosome in which it was embedded, changing the chemical structure of the molecule.<sup>18</sup> The Supreme Court rejected that logic, opining that because the sequence of nucleotides in the extracted molecule was the same as that found in the native chromosome, the extracted molecule was for subject matter purposes a product of nature.<sup>19</sup>

This reasoning is at best incoherent.<sup>20</sup> Thomas's opinion tells us that the *Myriad* genomic DNA is unpatentable, because it is for subject matter purposes identical to what is found in nature. How is it identical? The iden-

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*iad*); Katherine J. Strandburg, *Much Ado About Preemption*, 50 HOUS. L. REV. 563, 610–14 (2012) (discussing the holding in *Mayo*).

14 For early evaluations, see Burk, *supra* note 7; Arti K. Rai, *Biomedical Patents at the Supreme Court: A Path Forward*, 66 STAN. L. REV. ONLINE 111 (2013).

15 JAMES D. WATSON ET AL., *MOLECULAR BIOLOGY OF THE GENE* 601, 749 (6th ed. 2008).

16 *Myriad*, 133 S. Ct. at 2119–20.

17 *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1329 (Fed. Cir. 2012), *aff'd in part and rev'd in part*, 133 S. Ct. 2107 (2013).

18 *Id.* at 1328.

19 *Myriad*, 133 S. Ct. at 2118.

20 Justice Thomas has, alas, a history of authoring unfortunately reasoned patent opinions. See, e.g., DOUGLAS LAYCOCK, *MODERN AMERICAN REMEDIES* 339–41 (4th ed. 2012) (pointing out the clear doctrinal errors in Thomas's opinion in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006)); Dan L. Burk, *Legal Constraint of Genetic Use Restriction Technologies*, 6 MINN. J.L. SCI. & TECH. 335, 351–53 (2004) (pointing out the clear doctrinal errors

tity between the native molecule and the extracted gDNA, he tells us, is found in the coding information—never mind that the extracted molecule has a different chemical structure than what one finds in the human chromosome.<sup>21</sup> It is the nucleotide sequence that counts.

I have previously criticized the characterization that Thomas adopts here of DNA as “information,”<sup>22</sup> but, very well then, one would think—and the petitioners certainly argued<sup>23</sup>—if the Court is going to adopt this rationale, it should also preclude the Myriad patent claims drawn to the cDNA, since such molecules code for exactly the same gene product as the gDNA. Indeed, the cDNAs are reverse transcribed from mRNA molecules produced in the cell using the gDNA as a template. But no, Justice Thomas tells us, the Myriad cDNA *is* patent eligible because it is for subject matter purposes *distinct* from what is found in nature.<sup>24</sup> What is the distinction? The distinction between the native molecule and the cDNA is found in the structural difference between the reverse transcribed molecule and what one finds in the human chromosome.<sup>25</sup> Because it was produced by a process of reverse transcription, the cDNA lacks intervening nucleotide sequences or “introns” found in the native gene—never mind that it carries the same coding information.<sup>26</sup> It is the chemical structure that counts.

Reading Thomas’s opinion, one is therefore forced to conclude that molecules that differ structurally from a native molecule are both excluded from and included within patentable matter, while molecules with the same coding information as a native molecule are *also* both excluded from and included within patentable subject matter. It is, in short, quite impossible to logically determine from the opinion whether a given macromolecule meets the criterion for patent eligibility. The Patent Office initially adopted the most simplistic reading of the case, instructing its examiners that extracted genomic DNA is not patent eligible.<sup>27</sup> But this reading gives no guidance as

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in Thomas’s opinion in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124 (2001)).

21 *Myriad*, 133 S. Ct. at 2118. The Court’s reasoning here is that a molecule comprising an additional nucleotide residue beyond that claimed by Myriad would have a new structure, but would infringe the Myriad patent. *Id.* While the observation might be true, it is irrelevant to the question of subject matter. It is of course deeply disturbing that the Court apparently cannot tell the difference between the question of subject matter and the question of infringement.

22 See Dan L. Burk, *The Problem of Process in Biotechnology*, 43 Hous. L. Rev. 561, 588 (2006).

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

24 *Id.*

25 *Id.*

26 See *id.*

27 Memorandum from Andrew H. Hirshfeld, Deputy Comm’r for Patent Examination Policy, U.S. Patent & Trademark Office, to Patent Examining Corps (June 13, 2013), *available at* [http://www.uspto.gov/patents/law/exam/myriad\\_20130613.pdf](http://www.uspto.gov/patents/law/exam/myriad_20130613.pdf).

to the patent eligibility of a wide range of other molecules that may or may not be precluded from § 101<sup>28</sup> by the *Myriad* opinion's reasoning.<sup>29</sup>

The problem is perhaps most starkly illustrated by a molecule known as a peptide nucleic acid, or PNA.<sup>30</sup> The molecule's title is a bit of a misnomer, as it is not a nucleic acid at all; it is rather a synthetically created polymer in which the natural sugar-phosphate chain "backbone" of a nucleic acid is replaced by peptide backbone, but maintains the same nucleotide side structures as found in a nucleic acid—in other words, the PNA combines features of a protein and a nucleic acid.<sup>31</sup> It is, therefore, an entirely artificial molecule that would never occur in the wild, but which is capable of carrying the same sequence information as a nucleic acid.

Consider a PNA with the nucleotide sequence from a particular gene, such as BRCA1. What could one tell a client about the patentability of such a molecule? The molecule is entirely a synthetic creation and would never be synthesized by cells in the wild. Thus, under the structural rationale of the second half of the *Myriad* opinion, it seems to be patentable. Certainly it differs structurally from any naturally occurring molecule more than does a cDNA molecule. But at the same time, the PNA carries the same base sequence information as the native gDNA molecule. Thus, under the informational rationale of the first half of the *Myriad* opinion, it seems to fall outside patentable subject matter.

This logical discontinuity throws into doubt the patent eligibility of a wide range of macromolecules, not necessarily used in diagnostic testing, but in a range of industries from chemical manufacturing to agriculture. And the mischief done by the opinion does not, of course, stop with macromolecules. Pharmaceutical and other chemical developers routinely extract potentially useful organic molecules from a variety of native sources: plants, microorganisms, sea creatures. Antibiotics, cancer treatments, and other medicinal substances are routinely discovered in this fashion. Such small molecules of course have no coding sequence as macromolecules do, and they may or may not be structurally altered from what is found in the wild. Depending on whether one believes that structure or information is the determining criterion in *Myriad*, it is difficult, and perhaps impossible, to fathom how Justice Thomas's reasoning is to be applied to the patent eligibility of such novel chemicals.

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28 35 U.S.C. § 101 (2012).

29 At the time of this writing the PTO has issued a more recent guidance memorandum—currently undergoing a period of public comment—that adopts a complicated examination methodology and which would appear to apply a restrictive reading of *Myriad* to a much broader range of molecules. See Memorandum from Andrew H. Hirshfeld, Deputy Comm'r for Patent Examination Policy, U.S. Patent & Trademark Office, to Patent Examining Corps (March 4, 2014), available at [http://www.uspto.gov/patents/law/exam/myriad-mayo\\_guidance.pdf](http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf).

30 See Peter E. Nielsen et al., *Sequence-Selective Recognition of DNA by Strand Displacement with a Thymine-Substituted Polyamide*, 254 SCI. 1497 (1991); Pernilla Wittung et al., *DNA-like Double Helix Formed by Peptide Nucleic Acid*, 368 NATURE 561 (1994).

31 See Nielsen et al., *supra* note 30, at 1497.

Why then would the Court tender an opinion so entirely at odds with itself? Setting aside the very real possibility that the Court did not understand what it was doing,<sup>32</sup> the most plausible rationale is that the Court hesitated to cordon off such molecules from the incentive structure of the biotechnology industry. For thirty years prior to the *Myriad* decision, the Patent Office treated purified macromolecules the way they treated other purified chemicals, as the non-natural product of human ingenuity.<sup>33</sup> A robust American biotechnology industry grew up around this policy. Similar standards were adopted by the United States' trading partners.<sup>34</sup> The Supreme Court has, in the past, chided lower courts for adopting new rules that disrupt the settled expectations of patent holders.<sup>35</sup> Overturning three decades of consistent administrative practice would be fairly disruptive.

So it appears that the Supreme Court split the baby, giving something to the plaintiffs but also reserving the possibility of cDNA patents for the biotechnology industry. However, it is worth remembering that "splitting the baby" by no means implies a just or preferable outcome. In the classic biblical story from which the term is derived, King Solomon *threatened* to split the baby as an information-forcing strategy to resolve a dispute over parenthood.<sup>36</sup> Carrying out the threat was the last thing anyone wanted, and would have been detrimental to all the parties—most especially to the baby. It remains to be seen how detrimental the *Myriad* split will be to biotechnology and related industries.

## II. THE PRODUCTS OF NATURE DOCTRINE

The exclusion of gDNA from patentable subject matter has garnered much of the attention directed to the *Myriad* decision; the inclusion of cDNA less so.<sup>37</sup> But the major holding of the *Myriad* case is perhaps not so much that genomic DNA is probably, mostly, presumptively unpatentable, but rather that patent law in fact *has* a discrete and operating product of nature

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32 Notably, to the otherwise unanimous opinion, Justice Scalia addended a concurrence confessing that he neither understood the science involved in the case nor believed that his colleagues did either. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2120 (Scalia, J., concurring in part and concurring in the judgment).

33 *Id.* at 2118–19 (majority opinion).

34 *See, e.g.*, Council Directive 98/44/EC, art. 3(2), 1998 O.J. (L 213), 18 ("Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature."); European Patent Convention, Implementing Regulations to the Convention on the Grant of European Patents, Rule 27(a), Oct. 5, 1973, 1065 U.N.T.S. 199 (as amended Dec. 9, 2004), *available at* <http://www.epo.org/law-practice/legal-texts/html/epc/2013/e/r27.html>.

35 *See, e.g.*, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002).

36 1 *Kings* 3:16–28. I am grateful to Glynn Lunney for pointing this out.

37 *See* Dan L. Burk, *What Media Missed About Gene Patent Case*, CNN (June 14, 2013, 10:09 AM), <http://globalpublicsquare.blogs.cnn.com/2013/06/14/what-media-missed-ab-out-gene-patent-case/>.

doctrine. We had all suspected that this was the case, given the frequent repetition of Supreme Court dicta to this effect, but actual previous holdings were dubious or absent. Over the past thirty years, the Court's subject matter cases have all been cases about *laws* of nature rather than about *products* of nature. Nonetheless, these opinions have typically opened with a series of stock citations, including a passage from the landmark *Diamond v. Chakrabarty* opinion, stating that items such as a "new plant" or a "mineral discovered in the earth" lie outside patentable subject matter.<sup>38</sup>

However, not only were such stock quotations dicta in the context of the laws of nature opinions where they appeared, the original statement in *Chakrabarty* was itself essentially dicta. The *Chakrabarty* opinion concerned the patent eligibility of a genetically modified bacterium, which was controversial subject matter because it was alive.<sup>39</sup> Despite an examiner's initial, indefensible rejection of claims to the bacterium as impermissibly drawn to a product of nature,<sup>40</sup> by the time the case reached the Supreme Court no one seriously argued that *Chakrabarty*'s genetically altered bacterium was a product of nature—manifestly it had been altered by human manipulation.<sup>41</sup> Rather, the Court in that case used the oft-cited products of nature trope as a foil to elaborate its argument that the proper distinction in patentable subject matter is between naturally and non-naturally occurring entities, not between living and non-living entities.<sup>42</sup> This allowed it to reject as irrelevant the question of whether the patented invention was alive.

Similarly, the older cases that the Court relied upon in *Chakrabarty*, and then subsequently for product of nature citations, were not in fact subject matter cases, but rather, cases about invention—what would now be called obviousness cases, or in some instances, novelty cases.<sup>43</sup> For example, although an aphorism about phenomena of nature has become the most enduring legacy of *Funk Bros. Seed Co. v. Kalo Inoculant Co.*,<sup>44</sup> the case as decided was not about products of nature. *Funk Bros.* concerned a mixture of six nitrogen-fixing bacteria that could be beneficially used by farmers to populate the root nodules of certain agricultural crops such as legumes.<sup>45</sup> Prior

38 447 U.S. 303, 309 (1980).

39 See Dan L. Burk, *Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed*, 17 RUTGERS COMPUTER & TECH L.J. 1, 30 (1991).

40 *In re Chakrabarty*, 571 F.2d 40, 42 (C.C.P.A. 1978).

41 See *infra* text accompanying notes 124–31.

42 *Chakrabarty*, 447 U.S. at 313 ("Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."). Justice Brennan's dissent adopts the same logic in refuting the majority's argument on legislative intent. *Id.* at 320 (Brennan, J., dissenting).

43 See Dan Burk, *The "Runcible" Product of Nature Doctrine*, SCOTUSBLOG (Feb. 4, 2013, 3:50 PM), <http://www.scotusblog.com/2013/02/the-runcible-product-of-nature-doctrine/> ("Those [previous] cases addressed the judicially created concept of 'invention,' which we know today as distinct statutory requirements of novelty, utility, and non-obviousness.").

44 333 U.S. 127 (1948).

45 *Id.* at 128–29.



to the patentee's mixed inoculant product, the bacteria had been sold separately, and indeed it was believed that they must be used separately because they would inhibit one another.<sup>46</sup> The case was rather clearly a decision about invention, and whether the combination of the three bacterial strains in a single inoculum constituted an invention. It is clear from the opinion that the Court regarded the patentee's invention as a more convenient form of packaging, and that it did not consider better packaging to reach the required level of inventiveness.<sup>47</sup>

The question of invention, rather than nature, was similarly at issue in the oft-cited *American Fruit Growers, Inc. v. Brogdex Co.*<sup>48</sup> There the particular question was whether citrus fruit, having its rind impregnated with borax to prevent mold spoilage, constituted a "manufacture" under the subject matter clause of the then-current patent statute.<sup>49</sup> The Court reasoned that the treated fruit was insufficiently altered to constitute a "manufacture," and held forth at some length regarding the unchanged character of the fruit and of the borax, just as it would later in *Funk Bros.* regarding the unchanged nature of the nitrogen-fixing bacteria.<sup>50</sup> The fruit may indeed still have been fruit, and coating fruit with borax may be what we would now call obvious given the known characteristics of borax. But the holding was not one regarding products of nature—it seems clear that citrus fruit in its natural state is decidedly free of borax; there is no question that borax-treated fruit is a human-generated artifact.

At the same time, whatever such cases originally meant or perhaps now should mean, the Supreme Court has repeatedly relied upon them to justify and shore up the products of nature concept. Throughout its cases on subject matter, the Court has in particular "retconned"<sup>51</sup> *Funk Bros.* as the go-to citation for the *Chakrabarty* dicta on products of nature. In *Myriad*, Justice Thomas reviews *Funk Bros.* at some length, concluding that the treatment of the Funk bacterial inoculum serves as squarely analogous precedent for the treatment of *Myriad*'s genomic sequence.<sup>52</sup> Thus, notwithstanding its actual holding, the case seems to have undergone hindsight reconstruction as a decision about the patentability of natural products. Thomas uses this to provide a veneer of precedent for the Court's holding on gene patents.

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46 *Id.* at 129.

47 *Id.* at 131 ("But we think that that aggregation of species fell short of invention within the meaning of the patent statutes.").

48 283 U.S. 1 (1931).

49 *Id.* at 6.

50 *Id.* at 11–12.

51 See *Retcon*, [DICTIONARY.COM](http://dictionary.reference.com/browse/retcon?s=t), <http://dictionary.reference.com/browse/retcon?s=t> (last visited Nov. 15, 2014) ("[Abbreviation of] retroactive continuity. The common situation in fiction where a new story 'reveals' things about events in previous stories, usually leaving the 'facts' the same (thus preserving continuity) while completely changing their interpretation.").

52 *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2117 (2013).

### III. THE LAWS OF NATURE DOCTRINE

As *Myriad* constitutes the first Supreme Court case since the codification of the obviousness doctrine to squarely hold that a claimed material is unpatentable as a product of nature, much of the authority for the decision comes not from repurposed obviousness holdings, but from the subject matter line of cases dealing with laws of nature. The most recent of those opinions prior to *Myriad* is the *Mayo* opinion, and so reference to *Mayo* is not utterly absent from *Myriad*, at least not as citations go. The Court's analysis in *Myriad* in fact begins with a quotation from the *Mayo* opinion, that "[l]aws of nature, natural phenomena, and abstract ideas are not patentable."<sup>53</sup>

Later on in the same paragraph, Thomas quotes the usual dicta we have already described from *Diamond v. Chakrabarty* regarding the exclusion of natural products from patentable subject matter, moving in the space of a single paragraph, without explanation, from citation of authority excluding natural *principles* from patentable subject matter, to citation of authority excluding natural *products* from patentable subject matter.<sup>54</sup> The shift from excluded principles to excluded products takes place within the space of a few words and seems to elide any distinction between the two categories.

Thus, one very real but troubling explanation for the Supreme Court's silence on the relationship between laws of nature and products of nature is that the Justices perhaps cannot see any distinction between the two. In *Myriad*, Justice Thomas characterizes the bacterial inoculum from *Funk Bros.* as falling squarely within the "laws of nature"—and not "products of nature"—exception, as he says do the genetic claims in the *Myriad* patents.<sup>55</sup> But this conversion is not original to Justice Thomas. The full passage that he relies upon from *Chakrabarty* makes a similar categorical juxtaposition, jumping from principles to products and back again:

The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that  $E=mc^2$ ; nor could Newton have patented the law of gravity.<sup>56</sup>

One might attempt to cure the disjunction in this passage by assuming that "minerals" and "plants" constitute "physical phenomena," placing them alongside "laws of nature" and "abstract ideas" in the introductory sentence.<sup>57</sup> This reading would not cure the problematic confusion of products and processes, but it at least relates the sentences of the passage together. However, this usage would not be the usual meaning of the word phenome-

53 *Id.* at 2116 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012)).

54 *Id.*

55 *Id.* at 2117–18.

56 *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citations omitted).

57 Indeed, Professor Strandburg appears to have made precisely this assumption. See Strandburg, *supra* note 13, at 586–614.

non, which commonly refers to observable “fact[s], occurrence[s], or circumstance[s].”<sup>58</sup> The *occurrence* of a mineral in the earth may constitute a phenomenon of nature—it was not buried or formed there by human agency—but the mineral itself is an object or substance, not a phenomenon.

Neither would this reading be consistent with the Court’s prior usage of the term in similar discussions; for example in the decision regarding laws of nature in *Parker v. Flook*, where Justice Stevens treats “phenomena” as synonymous with “process”: “[t]he rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of ‘discoveries’ that the statute was enacted to protect.”<sup>59</sup> Thus plants and minerals may not be phenomena, but phenomena, ideas, laws, minerals, and plants are all seemingly treated by the Supreme Court as equivalent within the category of the “natural.” Natural products and natural laws are left undifferentiated. As if to cement this amalgamation, Thomas in *Myriad* goes on to discuss both categories as “naturally occurring things,”<sup>60</sup> reifying, or as the saying goes “thingifying,” natural principles into objects alongside natural products.<sup>61</sup>

Language from the earlier *Funk Bros.* opinion also lends itself to collapsing product into principle. Despite the Court’s acknowledgement in *Funk Bros.* that in the disputed inoculum patent “[w]e have here only product claims,”<sup>62</sup> the opinion by Justice Douglas then focuses entirely on the *qualities* or *traits* of the bacteria in the claimed mixture as manifestations of the laws of nature:

Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.<sup>63</sup>

Much the same logic is apparent in the other pre-1952 invention cases that the Court has relied upon in string citations to support the product of nature doctrine, such as *American Fruit Growers*. There the Court similarly reasoned that the product was patent ineligible because the borax protec-

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58 *Phenomenon*, DICTIONARY.COM, <http://dictionary.reference.com/browse/phenomenon?s=t> (last visited Nov. 15, 2014).

59 437 U.S. 584, 593 (1978).

60 *Myriad*, 133 S. Ct at 2116 (emphasis added).

61 See Felix S. Cohen, *Transcendental Nonsense and the Functional Approach*, 35 COLUM. L. REV. 809, 815 (1935) (discussing the “‘thingification’ of property”); Michael J. Madison, *Law as Design: Objects, Concepts, and Digital Things*, 56 CASE W. RES. L. REV. 381, 401 (2005) (discussing “thingification” of legal concepts).

62 *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

63 *Id.* (citation omitted).

tively coating the rinds of citrus fruit was simply exerting its natural characteristics.<sup>64</sup>

The logic of such assertions is more than a little puzzling if taken as a statement about the metric for recognizing products of nature. The Court in these cases considers the components of the claimed inventions piecemeal, rather than as a whole. When any human creation is considered as an amalgamation of its initial components, they will not surprisingly be found to exhibit merely their natural properties. At some level, such qualities or attributes may be said to constitute “laws” or “principles” or “phenomena” of nature—they are the recurring, observed characteristics of materials behaving in accordance with the observations of physics or chemistry.

But all materials incorporated into human artifacts exhibit such intrinsic characteristics—the silicon incorporated into window panes or semiconductor chips exhibits exactly the same qualities or attributes as that found in the wild; the steel incorporated into automobile chassis or cutlery behaves exactly like steel. Indeed it is the very qualities or attributes inherent in the material that make it useful in those applications. Neither on this logic is it possible for humans to alter a substance’s “natural” characteristics, since any alteration itself follows natural principles and is by definition a natural characteristic of the newly modified substance.

Nor does this logic seem to map onto the subject matter actually at issue in the patents considered in such cases. Product patents typically do not attempt to claim the qualities of a particular material; they rather claim a material that has particular qualities. The qualities may well be used to describe the material claimed, but this is not a claim to the qualities. Adopting Justice Stevens’s *Funk Bros.* example of “the qualities of metals,”<sup>65</sup> it would be peculiar to find a patent that claimed as its invention “conductivity of 4.23 siemens,” or “resistance of 2.45 ohms” or “ductility of 18% elongation.” The claims to a new metal might well use conductivity, resistance, and percentage elongation to *describe* a substance claimed, but this is not a claim to those qualities.<sup>66</sup>

Certainly the claims at issue in *Funk Bros.* or *American Fruit Growers* claimed no qualities, but rather physical materials, even though the qualities of the materials were the focus of the Court’s discussion. This seeming peculiarity of these cases, focusing on the characteristics or qualities of physical materials, seems largely an artifact of reconstructing the inventiveness cases after the fact as establishing a product of nature doctrine. The Court in cases such as *Funk Bros.* was assaying the claims for invention, and took the qualities of the material as a measure of obviousness or “inventive step” rather than as a measure of patent eligibility. Thus, in the analysis of those cases,

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64 *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11–12 (1931).

65 *Funk Bros.*, 333 U.S. at 130.

66 Such claims would also certainly and properly fail the abstract ideas criterion, not to mention they would be impossible to support in the specification. See *infra* note 209 and accompanying text.

deeming the *qualities* or *attributes* of the bacteria to be unchanged from their native state signals a lack of inventiveness.

This metric might make sense in the context of our current § 103,<sup>67</sup> but it makes far less sense in the context of our current § 101, and absolutely no sense in the case of the Myriad nucleotide sequences. As Judge Moore noted in her concurring opinion to the Federal Circuit decision, the qualities of the isolated nucleotide sequences are decidedly different from those found in the cell.<sup>68</sup> Judge Moore's metric for patent eligibility was the new uses to which the claimed Myriad molecules could be put—the isolated nucleotide structures could be used for genetic testing, or as primers or probes, while the native cellular structures could not be due to being embedded within the millions of bases of a human chromosome.<sup>69</sup>

What then is the quality or attribute that Justice Thomas appears to see, that like the “unchanged” qualities of the *Funk Bros.* bacteria is shared between the chromosomal nucleotide sequence and the extracted nucleotide sequence? It seems to be just that—the nucleotide sequence itself. He emphasizes that this attribute has not been added to or altered by Myriad in extracting their claimed molecules from the chromosome.<sup>70</sup> As Judge Lourie correctly pointed out in the Federal Circuit opinion below, this view of the claims ignores the differences between the native and isolated molecules to focus instead on a particular similarity.<sup>71</sup> What Thomas's opinion lacks—among other failings—is a coherent theory as to why the differences in certain molecular characteristics should be overlooked in favor of the similarities in other characteristics.

One might argue that gDNA merits different treatment on the theory that genetic sequences embody process information—that is, the coding sequence that Thomas relies upon in the first part of the *Myriad* opinion serves as a template or guide for the processes of transcription to mRNA and translation to proteins. In other words, as an “informational” molecule, a given gDNA embodies the process that leads to its gene product. This view shifts the emphasis from whether the problem with patenting nucleotide sequences stems from their occurrence in nature, like a “mineral in the earth,” to whether it might rather stem from their embodiment of a natural principle or phenomenon in the same vein as the metabolic correlation in *Mayo*.

This take on the opinion would certainly be consistent with how the trial court in *Myriad* viewed the question, although the trial court opinion is far more consistent on this point than the Supreme Court seems to have been. In the trial court opinion, Judge Sweet rejected Myriad's genomic DNA claims as drawn to unpatentable products of nature, however—inverting the

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67 35 U.S.C. § 103 (2012).

68 *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1341 (Fed. Cir. 2012) (Moore, J., concurring).

69 *Id.* at 1342.

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

71 *Ass'n for Molecular Pathology*, 689 F.3d at 1330.

logic ultimately adopted by Justice Thomas in the Supreme Court's opinion; he likewise rejected Myriad's cDNA claims as drawn to unpatentable subject matter, because they contained the same informational content as the native gDNA molecules.<sup>72</sup> Judge Sweet explicitly looked to *Funk Bros.*' reasoning that the coding information shared by both genomic and complementary DNA molecules is a natural principle or phenomenon.<sup>73</sup>

This approach in essence converts the product of nature issue into a law of nature issue, at least for DNA molecules. But this sort of argument proves too much, as all chemical entities embody information in the thermodynamic sense, and biological molecules in particular embody process information in their specific spatial configurations.<sup>74</sup> Thus even were the "informational molecule"<sup>75</sup> characterization correct, it would not supply a satisfactory general theory for other products of nature. Somehow cabining the rationale to only DNA or other macromolecules might exclude isolated small-molecule substances from the more pernicious practical effects of the *Myriad* rule, but would fail to explain the *Myriad* holding on cDNA.

#### A. *The Nature of Natural Law*

Implicit in this juxtaposition of natural principles and natural products is a rationale of physical immanence, an assumption that natural laws or phenomena are embedded in the fabric of the universe, waiting for human discovery, as would be a mineral or substance found in the earth. In the germinal subject matter decision *Gottschalk v. Benson*,<sup>76</sup> which launched the Supreme Court's patent eligibility odyssey,<sup>77</sup> the Court extended this rationale to mathematics.<sup>78</sup> Designating mathematics as an a priori component of reality constitutes a highly questionable assumption, as there is a very strong argument to be made that mathematics is not inherent in the universe, but is rather a human language created by humans to describe the universe.<sup>79</sup> But this caveat applies equally well to natural laws or principles that are typically expressed in mathematical form; far from existing outside

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72 *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 229 (S.D.N.Y. 2010).

73 *Id.*

74 *Burk*, *supra* note 22, at 585–88. Judge Sweet explicitly rejected this argument, offering the bizarrely teleological rationale that DNA uniquely informs the structure of other molecules. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 229. This kind of supposition is only possible by conceptually divorcing the molecule from the system in which it operates, *Burk*, *supra* note 22, at 583–84, which ironically parallels the physical basis for Myriad's claims to an isolated and purified nucleotide fragment removed from its cellular context.

75 *Burk*, *supra* note 22, at 587.

76 409 U.S. 63 (1972).

77 I note that Odysseus was said to have been lost for only ten years; the Supreme Court has been wandering for nearly thirty. See Bernard Knox, *Introduction to HOMER, THE ODYSSEY* 3, 3 (Robert Fagles trans., 1996) (stating that Odysseus wandered for ten years).

78 *Benson*, 409 U.S. at 72–73.

79 Dan L. Burk, *Patent Law's Problem Children: Software and Biotechnology in Transatlantic Context*, in *PATENT LAW IN GLOBAL PERSPECTIVE* 187, 197 (Ruth L. Okediji & Margo A. Bag-

of human experience, they might better be viewed as human expressions describing the causal order of materiality.

Thus, the Supreme Court is fond of saying that neither Einstein nor Newton could patent their famous formulations of physics because they constitute principles of nature.<sup>80</sup> But both formulations show every sign of being the product of human ingenuity. We know, for example, that Newton's formulae are in some sense wrong, or are at best incomplete. They are gross approximations of physical causality that work relatively well at the scale of everyday physical interactions, because the inaccuracies at that scale are small enough not to be readily measured or particularly inconvenient to macroscopic predictions. However, they break down at the atomic level and must be replaced by a different set of quantum mechanical formulae that are capable of predicting the behavior of matter at that scale.<sup>81</sup> Quantum calculations yield accurate and workable results at the macroscopic level, too, although at a level of precision not really necessary for everyday activity.<sup>82</sup> Probably we will find out some day that our quantum mechanical descriptions of matter are equally mistaken—we just have not discovered it yet. So far these quantum formulae seem fairly robust, but we must suppose that at some point in the future they may well yield to some better and more accurate mathematical description, just as Newton's did in the early twentieth century.

The history of science is littered with such models that were useful for a time but which were eventually superseded: Bohr's atom,<sup>83</sup> Kepler's solar system,<sup>84</sup> Euclid's geometry.<sup>85</sup> Each was peculiar to the inventive imagination of its author, although not entirely peculiar. Absent a descent into utter solipsism, we expect to find some extrinsic constraint on the vision articulated by the scientist. We may see through the glass of science darkly, but we assume there remains a causality to perceive. As Karen Barad puts it, "the world kicks back."<sup>86</sup> Matter still matters,<sup>87</sup> so that the scientific model is not

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ley eds., 2014); see also Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371, 406 (2005) (noting this assumption in the laws of nature doctrine).

80 See, e.g., *Diamond v. Chakrabarty*, 477 U.S. 303, 309 (1980).

81 See PETER ATKINS & JULIO DE PAULA, *ATKINS' PHYSICAL CHEMISTRY* 244–72 (8th ed. 2006).

82 See J. REX GOATES ET AL., *GENERAL CHEMISTRY* 377 (1981) (calculating the deBroglie wavelength of bullets and race horses as well as neutrons in a problem).

83 *Id.* at 374 (noting that Bohr's "solar system model" of the atom proved unworkable).

84 Kepler spent much of his life futilely attempting to get his model of the solar system to fit the musical scale or the geometry of regular solids. See J. BRONOWSKI, *SCIENCE AND HUMAN VALUES* 12 (rev. ed. 1965).

85 See MICHAEL GUILLEN, *BRIDGES TO INFINITY* 110 (1983).

86 Karen Barad, *Agential Realism: Feminist Interventions in Understanding Scientific Practices*, in *THE SCIENCE STUDIES READER* 1, 2 (Mario Biagioli ed., 1999).

87 See Karen Barad, *Posthumanist Performativity: Toward an Understanding of How Matter Comes to Matter*, 28 SIGNS 801, 803 (2003) (arguing that matter is still an "active participant in the world's becoming").

wholly the figment of the human imagination. But this realization puts the formulae of a Newton or Einstein into the same category as all other human inventions that the Supreme Court recognizes “at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.”<sup>88</sup> A Newton or an Einstein constructs a model that entails the qualities or characteristics of the universe but is not a quality or characteristic of the universe.

The fact that a model such as Newton’s very persistent and very useful formulations of physical law turn out to be incorrect is neither an indictment of Newton nor of science; it is simply an example of how science works and of how it is supposed to work. It may however constitute an indictment of patent doctrine, as Newton’s failures demonstrate the human inventiveness of such expressions of natural law. Newton’s laws are not discoveries of principles somehow embedded in physical reality; they are rather mistaken or incomplete *human descriptions* of observed phenomena, which work well enough for macroscopic human endeavor, but which are not in fact accurately descriptive of how matter is actually behaving.<sup>89</sup> Like a book, poem, or other expressive statement, Newton’s scientific concepts bear the imprint of the mind that formulated them and of the society that produced them; they are only wrong insofar as they are superseded by the formulation of a different author incorporating a different viewpoint.<sup>90</sup>

Since laws of nature are fairly obviously the product of human ingenuity, we are left with the question of exactly why we have such an exclusion from patent eligibility when the American patent statute has been held to encompass “anything under the sun that is made by man[kind].”<sup>91</sup> Certainly the exclusion is not required by the explicit terms of the statute. As the Court admits, the product of nature doctrine itself, let alone any justification for its existence, is entirely judicial gloss on what is otherwise a fairly straightforward statute.<sup>92</sup> And as Judge Giles Rich pointed out long ago, were one to follow the plain meaning of § 101, we could very quickly see whether the claimed invention constituted a process, machine, composition, or manufacture, and then move on.<sup>93</sup>

To the extent that there may be any statutory hook on which to hang the doctrine, it might be found in § 101’s requirement that the invention be “new”—products or principles drawn unaltered from nature might be considered new under some meanings of that term. But the Court long ago rejected that reading of the statute, stating that “newness” in § 101 means neither more nor less than “novelty” as encompassed in § 102,<sup>94</sup> and the for-

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

89 See ATKINS & DE PAULA, *supra* note 81, at 240.

90 See J. BRONOWSKI, *THE COMMON SENSE OF SCIENCE* 37–38 (1951).

91 *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 82-1979, at 5 (1952)) (internal quotation marks omitted).

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

93 *In re Bergy*, 596 F.2d 952, 960 (C.C.P.A. 1979).

94 35 U.S.C. § 102 (2012).



mer is merely a reference to the latter.<sup>95</sup> And even had the Court adopted a different stance, a “newness” criterion would not necessarily solve the problem under consideration here—since nothing is drawn from nature unaltered by humans, and is always “new” to humankind at its first discovery. There is, in short, no solace to be drawn from the statute; since the doctrine was wholly created by Court, its meaning must be supplied by Court.

Summing up to this point, the Court is insistent that there is a non-statutory products of nature exception to patentable subject matter, and that it is related to the more frequently articulated laws of nature doctrine—indeed, Justice Thomas seems to find the two indistinguishable. So it is there that we must look to understand how *Myriad* fits into the rationale the Supreme Court has built around § 101. But the laws of nature doctrine itself seems largely incoherent, having little to do with “nature,” and instead primarily addresses human concepts. Perhaps this should not be surprising, however. Somewhat ironically, prior to *Mayo*, the cases in which the Supreme Court has elaborated on “laws of nature” are almost entirely those reviewing the patent eligibility of what would seem to be the inarguably human artifact of computer software. And yet software provides the setting that takes us a step nearer to understanding how the *Myriad* case might be considered in light of the *Mayo* decision.

### B. *The Strangest Feeling of Déjà vu*

When it comes to patentable subject matter, the Supreme Court, much like Lewis Carroll’s Bellman, seems to express itself in threes.<sup>96</sup> In the 1970s the Court produced in rapid succession a trilogy of consecutive, though not entirely coherent, opinions on the patent eligibility of computer software, in which the Court attempted to define the parameters of patentable subject matter exclusions. In the earliest of these opinions, *Gottschalk v. Benson*,<sup>97</sup> the Court declared unpatentable a process for transforming one type of numerical notation into another.<sup>98</sup> The Court found the claims to read on a mathematical relationship that constituted a law or principle of nature, placing it outside patentable subject matter, and which the Court found unpatentably abstract to boot.<sup>99</sup> In the second opinion, *Parker v. Flook*,<sup>100</sup> the Court similarly invalidated claims to a method of calculating an “alarm limit,” which is to say a method of measuring and determining whether the state of an industrial chemical process was approaching a point of danger.<sup>101</sup>

95 See *Diamond v. Diehr*, 450 U.S. 175, 189 (1981) (“Section 101 . . . is a general statement of the type of subject matter that is eligible for patent protection. . . . Specific conditions for patentability follow and § 102 covers in detail the conditions relating to novelty.”).

96 LEWIS CARROLL, *THE HUNTING OF THE SNARK* at fit 1, stanza 2 (Chatto & Windus 1941) (1876) (“What I tell you three times is true.”).

97 409 U.S. 63 (1972).

98 *Id.* at 72–73.

99 *Id.* at 68.

100 437 U.S. 584 (1978).

101 *Id.* at 585, 594, 596.

In a third case, *Diamond v. Diehr*,<sup>102</sup> the Court seemingly reversed course, finding patent eligibility on facts surprisingly similar to those in *Flook*.<sup>103</sup> In *Diehr*, the Court held claims to a method for calculating an industrial process parameter, using a standard chemical formula, to be patentable.<sup>104</sup> The automated calculation was used to judge the completion of a curing process for synthetic rubber used to produce output such as automobile tires.<sup>105</sup> This seems to be the only appreciable difference between the cases: in *Flook*, as in *Benson*, the Supreme Court took the end product to be a number, whereas in *Diehr* it took the end product to be a tire. The opinion emphasizes the materiality and tangibility of the *Diehr* process as opposed to the immateriality and abstraction of the *Flook* process.<sup>106</sup>

In the early twenty-first century the Court now seems to have produced a companion trilogy on subject matter, returning first to the question of software patentability in *Bilski v. Kappos*,<sup>107</sup> then turning to laws of nature in *Mayo v. Prometheus*,<sup>108</sup> and finally back to computer programs with the recent decision in *Alice Corp. v. CLS Bank International*.<sup>109</sup> The decision in the first installment of this contemporary subject matter trilogy, *Bilski v. Kappos*, revisited the questions regarding software and mathematical processes addressed in the *Benson* opinion nearly forty years before.<sup>110</sup> The claims in the *Bilski* case concerned a “business method” for hedging financial investments, expressed as a particular mathematical formula.<sup>111</sup> Much as in *Benson*, the claims to the method might most usually be implemented in a computer, but were not explicitly limited to such implementation. Whereas a divided Federal Circuit had held the claims were not patent eligible because they were neither limited to embodiment in a machine, nor to a particular material transformation, the Supreme Court excluded the claims from patentable subject matter as an illegitimate attempt to claim an abstract idea.<sup>112</sup> In doing so, the Court held that characterizing the invention as a machine or transformation of matter may be a relevant consideration, but not the sole determinant of patent eligibility under § 101.<sup>113</sup>

Close on the heels of its *Bilski* opinion, in *Mayo v. Prometheus*, the Court took up the limits of patents directed to laws or principles of nature.<sup>114</sup> Much as in the earlier *Parker v. Flook*, which the *Mayo* opinion references with

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102 450 U.S. 175 (1981).

103 *Id.* at 177–81, 184.

104 *Id.* at 177–78, 192–93.

105 *Id.* at 177–78.

106 *Id.* at 186–87.

107 561 U.S. 593 (2010).

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

109 *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2013).

110 See Rochelle C. Dreyfuss & James P. Evans, *From Bilski Back to Benson: Preemption, Inventing Around, and the Case of Genetic Diagnostics*, 63 STAN. L. REV. 1349, 1351–52 (2011).

111 *Bilski*, 561 U.S. at 611–12.

112 *Id.*

113 *Id.* at 3227–28.

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

some regularity,<sup>115</sup> the Court rejected a set of diagnostic method claims as reading on unpatentable natural phenomena.<sup>116</sup> The *Mayo* claims were directed to a course of medical treatment: administering to a patient a particular pharmaceutical, determining the level of the pharmaceutical metabolites in the patient's blood, and then raising or lowering the dosage to an effective level.<sup>117</sup> In an opinion by Justice Breyer, the Court reversed the Federal Circuit's conclusion that this was a patent eligible application of natural principles, holding that the claims were directed to natural principles themselves.<sup>118</sup> While the Federal Circuit saw in the metabolism of the drug a tangible transformation of matter, the Supreme Court only saw the natural activity of the human liver, producing a characteristic level of metabolic products.<sup>119</sup> Measuring the level of such metabolites, and administering therapeutically effective dosages of the drug, was characterized as routine or conventional activity that was insufficient to transform an unpatentable natural correlation into a patentable invention.<sup>120</sup>

It is this holding that is so strangely disconnected from the succeeding products of nature holding in *AMP v. Myriad*.<sup>121</sup> Yet there is odd precedent for the Court's silence. During the run of software patent opinions thirty years ago, in which the Court formulated the laws of nature doctrine in its current incarnation, the Supreme Court also ventured for the first time into the biotechnology field. Much as the current Court has addressed *Myriad's* product of nature issue between *Mayo* and *Alice Corp.*, the Court thirty years ago generated a subject matter opinion on genetically engineered organisms—*Diamond v. Chakrabarty*—between its second and third process patent decisions.<sup>122</sup> In some senses *Chakrabarty* might be considered the fourth opinion in the Court's twentieth-century software trilogy.<sup>123</sup> The decision has become famous for its expansive view that all new technologies are presumptively patentable subject matter unless there is a clear signal from Congress to the contrary.<sup>124</sup> The case's oft-cited trope is that American patent law is intended to extend to “anything under the sun” made by a human.<sup>125</sup> But this also implies the contrapositive: that American patent law does *not*

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115 See *id.* at 1294, 1298, 1299, 1301, 1303 (referencing *Parker v. Flook*, 437 U.S. 584 (1978)).

116 *Id.* at 1294.

117 *Id.* at 1296–97.

118 *Id.* at 1299–1300.

119 *Id.* at 1296, 1298.

120 *Id.*

121 *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

122 See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

123 Cf. DOUGLAS ADAMS, *SO LONG, AND THANKS FOR ALL THE FISH* (1984) (the fourth book in *The Hitchhiker's Guide to the Galaxy* trilogy).

124 See Dan L. Burk, *Reflections in a Darkling Glass: A Comparative Contemplation of the Harvard College Decision*, 39 CAN. BUS. L.J. 219, 229 (2003) (“*Chakrabarty* assumes that the door is open and it is up to Congress to shut it . . .”).

125 *Chakrabarty*, 447 U.S. at 309 (quoting S. REP. NO. 82-1979, at 5 (1952)).

extend to things under the sun *not* made by humans,<sup>126</sup> which leads in turn to the subject matter inquiry as to what is and is not considered made by humans.

But that inquiry was not taken up in *Chakrabarty*. Instead, as I have already indicated, the *Chakrabarty* opinion dealt with the problem of suitability of patents for living organisms.<sup>127</sup> Although the patent examiner had initially rejected the *Chakrabarty* application, as well as the application in the companion case, *In re Bergy*,<sup>128</sup> as drawn to non-statutory products of nature, this position was rejected by the Patent Office's internal review board.<sup>129</sup> The Patent Office's alternate and preferred rationale for denying the claims shifted to a patent ineligibility rejection for being drawn to living subject matter.<sup>130</sup> This is the issue that was twice reviewed by the intermediate Court of Customs and Patent Appeals.<sup>131</sup> By the time the cases reached final review by the Supreme Court, the issue properly before the Court was the patent eligibility of living organisms, not of natural products.

Yet the Court at the time clearly viewed the *Chakrabarty* subject matter issue as closely related, perhaps identical, to the *laws* of nature question addressed in its contemporary software cases. Indeed, the procedural positioning of the *Chakrabarty* opinion eerily presaged that of the more recent *Myriad* opinion. After certiorari was granted in *Chakrabarty*, the case was remanded to the Federal Circuit's predecessor court of appeals for reconsideration in light of *Parker v. Flook*,<sup>132</sup> much in the same way that *Myriad* was later to be remanded for reconsideration in light of *Mayo v. Prometheus*.<sup>133</sup> Just as the current Supreme Court saw some doctrinal connection between *Myriad* and *Mayo*, the Court thirty years ago apparently saw some doctrinal connection between *Chakrabarty* and *Flook*.

And, much as the connection between the *Myriad* and *Mayo* seems to have evaporated after remand to the present-day Federal Circuit, the connection between *Chakrabarty* and *Flook* escaped the 1980s Court of Customs and Patent Appeals. Judge Rich, writing for the intermediate appellate court

126 See Dan L. Burk, *Edifying Thoughts of a Patent Watcher: The Nature of DNA*, 60 UCLA L. REV. DISCOURSE 92, 94 (2013).

127 See *supra* text accompanying notes 39–42.

128 *In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979).

129 *In re Bergy*, 563 F.2d 1031, 1032–34 (C.C.P.A. 1977).

130 Professor Swanson suggests that this was a very calculated political move on the part of the Patent Office in order to avoid the social controversy attending genetic engineering technology. See Kara W. Swanson, *Patents, Politics and Abortion*, in INTELLECTUAL PROPERTY LAW IN CONTEXT (William T. Gallagher & Debora J. Halbert eds., forthcoming), (manuscript at 20), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2337062](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2337062) (discussing the agency practice of “avoiding issuing patents to deeply contentious technologies” in order to avoid controversy).

131 See *In re Bergy*, 596 F.2d at 955 (discussing intervening events since the first decision).

132 437 U.S. 584 (1978).

133 *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012) (mem.) (order granting certiorari, vacating, and remanding).

panel, rather bluntly pronounced *Parker v. Flook* inapposite to the question of patenting living organisms.<sup>134</sup> He then proceeded to instruct the higher Court on the distinctions between patent eligible subject matter and the patentability requirements of novelty and obviousness, which in his view the Court had improperly muddled in *Flook*.<sup>135</sup> A majority of the Supreme Court appeared to take the criticism to heart, explicitly disavowing and limiting the reasoning of *Flook* in the later *Diehr* opinion.<sup>136</sup>

Thirty years later in the remand of *Myriad*, all of the Federal Circuit judges on remand gave at least lip service to the direction to reconsider *Myriad* in light of *Mayo*, with differing degrees of solicitude for the applicability of *Mayo*. Judge Lourie, while diplomatically conceding that *Mayo* “illuminate[s] broad . . . principles” regarding § 101,<sup>137</sup> flatly concluded, notwithstanding the instruction for reconsideration, that “a composition of matter is not a law of nature.”<sup>138</sup> Judge Moore gave a somewhat more sympathetic reading to the equation of products and principles, opining that *Mayo v. Prometheus*, while not controlling, was instructive because “the *Prometheus* discussion of laws of nature (process claims) clearly ought to apply equally to manifestations of nature (composition claims).”<sup>139</sup> And Judge Bryson in dissent, while conceding that *Mayo* “does not decide this case,” attempted a type of analogy between the issues raised in the two cases, suggesting that just as a patentable invention involving a principle of nature must do more than simply describe the principle, so a patentable invention involving a product of nature must do more than make incidental changes to the product.<sup>140</sup>

The differing opinions of the Federal Circuit judges offer a plausible spectrum of rationales for the otherwise unexplained remand of *Myriad*. Thirty years ago the remand of *Chakrabarty* produced only a flat intermediate appellate rejection of any connection to *Flook*, a position that the Supreme Court subsequently embraced.<sup>141</sup> That bit of history seems not to have repeated itself; the Court’s most recent software decision in *Alice Corp.*, the modern doppelgänger to *Diamond v. Diehr*, relies heavily on citations to the *Mayo* opinion and perhaps gives new legitimacy to *Flook*.<sup>142</sup> But *Alice Corp.*,

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134 *In re Bergy*, 596 F.2d at 964–65.

135 *Id.* at 959.

136 *Diamond v. Diehr*, 450 U.S. 175, 189 n.12 (1981).

137 *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 689 F.3d 1303, 1326 (Fed. Cir. 2012), *aff’d in part and rev’d in part*, 133 S. Ct. 2107 (2013).

138 *Id.* at 1331.

139 *Id.* at 1339–40 (Moore, J., concurring in part).

140 *Id.* at 1354 (Bryson, J., concurring in part and dissenting in part).

141 *See Diehr*, 450 U.S. at 189 n.12; *see also* Dan L. Burk, *Anticipating Patentable Subject Matter*, 65 STAN. L. REV. ONLINE 109, 112–13 (2013) (discussing the rejection of the *Flook* prior art analysis).

142 Both the *Mayo* and *Alice Corp.* opinions cite *Parker v. Flook* with some frequency, and with apparent approval. *See Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355, 2359, 2360 (2014) (citing *Parker v. Flook*, 437 U.S. 584, 594–95 (1978)); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1291, 1293, 1294, 1298, 1299, 1300, 1301, 1303 (2012) (citing *Flook*, 437 U.S. at 590).

while firmly tying its analysis to *Mayo*, says nothing substantive about *Myriad*, and nothing that would connect *Myriad* to its other contemporary subject matter cases. By saying nothing thus far about the *Mayo* connection, the Supreme Court has to some extent given the judges of the Federal Circuit the last word on the meaning of *Mayo* for the *Myriad* patents. Although the Supreme Court neither rejected nor adopted any of the three Federal Circuit views, they remain the likeliest set of possibilities as to what unarticulated connection was originally seen by the Justices considering *Chakrabarty* and *Myriad*.

#### IV. ABSTRACT IDEAS AND THE LIKE

The line of subject matter cases that begins with *Gottschalk v. Benson* encompasses not only the exclusion of natural laws from patentable subject matter, but a string of related exclusions for abstract ideas, mental steps, and symbolic indicia.<sup>143</sup> The mathematical transformations in *Benson* may have failed patent eligibility as principles of nature, but could just as well have been excluded because they were abstract ideas, or because the claims read on mental processes, or because they were expressed as written matter outside the purview of the patent system. The more recent claims in *Bilski*, *Mayo*, and *Alice Corp.* similarly implicate multiple subject matter exclusions. *Bilski* might be said to address business methods, *Mayo* to address natural laws, and *Alice Corp.* to address abstract ideas, but in fact it is impossible to cleanly sort the opinions by the type of exclusion; each of these opinions to a greater or lesser extent relies on the exclusions addressed in the others.

These doctrines of course travel as a pack: claims that are too abstract are likely to read so broadly as to encompass principles of nature; claims that encompass purely mental processes are likely too abstract; claims that encompass mental processes are likely to read on written matter. If it seems nearly impossible to tell in a case like *Benson* or *Bilski* exactly which of these doctrines the Court is relying upon to reject a patent, it is because only the slightest conceptual reframing is necessary to turn the opinion from an abstract ideas case to a mental steps or to a principle of nature case and back again. Thus, *Mayo* might be a case about a natural diagnostic correlation, or it might be a case about an invention that is too abstract. Or it may very well be a case about both.<sup>144</sup>

At the same time, although these doctrinal categories certainly overlap and seem to offer a tantalizing commonality of character, that commonality is in practice very difficult to discern. The European Patent Office (EPO), faced with a similar list of patentable subject matter exclusions in the European Patent Convention (EPC) that animates that Office, attempted to

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143 See Dan L. Burk, *Patenting Speech*, 79 TEX. L. REV. 99, 137–46 (2000).

144 Compare *Mayo*, 132 S. Ct. at 1296 (“Prometheus’ patents set forth laws of nature . . .”), with *id.* at 1297 (holding that the process step of administering was insufficient to overcome the “prohibition against patenting abstract ideas” (quoting *Bilski v. Kappos*, 561 U.S. 593, 610 (2010))).

divine some common principle among them. The EPC, paralleling American common law, specifically excludes from patentable subject matter discoveries, scientific theories and mathematical methods, aesthetic creations, rules and methods for performing mental acts, for playing games or for doing business, programs for computers, and presentations of information.<sup>145</sup> These specific exclusions seem hauntingly similar in some way, and determining their underlying logic would aid in applying them to borderline cases such as software.

Unfortunately, the conclusion reached by the EPO on doctrinal commonality probably obscured rather than clarified the range of permissible subject matter. The Office concluded that the common feature among these exclusions is that they are not “technical,”<sup>146</sup> a term which has caused no end of trouble in European patenting ever since, as the EPO and national courts expended enormous effort in an ongoing futile pursuit of content for that term.<sup>147</sup> The past thirty years of EPC subject matter jurisprudence have been characterized by a series of shifts in approach and emphasis, from searching for the invention’s “technical character” to searching for its “technical contribution,” to seemingly abandoning the entire enterprise.<sup>148</sup> The more recent EPC decisions on this topic seem to have concluded that recitation of any physical apparatus is sufficient to render claims technical,<sup>149</sup> and the work of weeding out the dubious ones can be left to other doctrines such as novelty or inventive step, which Americans would call non-obviousness.<sup>150</sup> That outcome is instructive, not only for the explicit list of exclusions in the EPC, but for the parallel doctrines inferred under the American § 101.

#### A. *Products and Processes*

While the EPO has developed its subject matter jurisprudence from categories explicit in the EPC, in the United States much of the distinction between the doctrinal exposition that culminates in *Mayo* and which begins in *Myriad* arises from distinctions that are only implicit in our patent statute. Section 101 of the U.S. patent statute defines patentable subject matter as new and useful processes, machines, compositions of matter, or articles of

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145 Convention on the Grant of European Patents (European Patent Convention), art. 52(2), Oct. 5, 1973, 1065 U.N.T.S. 199 (as amended Jan. 1, 2006), available at <http://www.epo.org/law-practice/legal-texts/html/epc/1973/e/ar52.html>.

146 See Estimating Sales Activity/Duns Licensing Assocs., Case T 154/04, 2/2008 O.J. E.P.O. 46, 61, 64 (Tech. Bd. App. 2006), available at [http://archive.epo.org/epo/pubs/oj08/02\\_08/02\\_0468.pdf](http://archive.epo.org/epo/pubs/oj08/02_08/02_0468.pdf) (“Article 52(2) EPC covers subjects whose common feature is a substantial lack of technical character.”).

147 See Rosa Maria Ballardini, *Software Patents in Europe: The Technical Requirement Dilemma*, 3 J. INTELL. PROP. L. & PRAC. 563, 567–68 (2008).

148 *Id.*; Erika Ellyne, *Patent Eligibility—the ‘Sick-Man’ of Patent Law*, in ACCESS TO INFORMATION AND KNOWLEDGE 139, 153–54 (Dana Beldiman ed., 2013).

149 See Ballardini, *supra* note 147, at 568.

150 See Burk, *supra* note 7, at 748.

manufacture.<sup>151</sup> One of these things, as children's television might musically advise us, is not like the others.<sup>152</sup> Machines, compositions, and manufactures, which as a group constitute the subject matter of product patents, are (usually) tangible and discrete entities. But the fourth category of statutory subject matter, which constitutes the separate class of *process* patents, is not made up of tangible entities, but is rather characterized by sets of relationships between tangible entities.

At the same time, § 112(a) of the patent statute requires a patent applicant to teach those of ordinary skill the manner of making and using the claimed invention.<sup>153</sup> This terminology runs throughout U.S. patent law; for example, § 271 grants patent holders the exclusive right to “make[ ], [and] use[ ]” the claimed invention;<sup>154</sup> and patentable novelty is defined in terms of making and use.<sup>155</sup> These terms apply in a fairly straightforward way to product inventions; we can sensibly speak of making and using machines, manufactures, and compositions. The terminology makes only half as much sense when it comes to processes, however; we can sensibly speak of using a process, but we typically do not speak of processes as being made—processes are perhaps implemented or arranged or catalyzed, but not made.

However, making and using are themselves terms that *imply* processes, and process patents are frequently divided into the categories of “methods of making” and “methods of using.”<sup>156</sup> Section 101 itself makes no mention of these distinctions, and does not explicitly limit the universe of patentable processes to these categories. But as a practical matter, it is fairly difficult to imagine a process that does not fall into one or the other of these two classifications, and it seems likely that any candidate for an alternative classification could be redefined so as to fit into the categories of making or using. Indeed, it is typical that a process falling into one of these categories can often be reconceived as falling into the other; processes of making necessarily use some type of input, and processes of using typically generate, or make, some type of output.<sup>157</sup>

This indicates an implicit but unavoidable relationship between the two broad types of subject matter found in § 101. Products, at least to the extent that they constitute objects, are inherent in the concept of process, including processes of making and using. Making and using entail some type of object; some *thing* is made, and some *thing* is used. In classic industrial settings, the substrates of the process were fairly apparent, and extant in what is now § 101; machines and materials visibly interacted as inputs generating outputs. As the Supreme Court long ago explained in *Cochrane v. Deener*:

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151 35 U.S.C. § 101 (2012).

152 See JOE RAPOSO & JEFFREY MOSS, *THE SESAME STREET SONGBOOK* 40 (1971).

153 35 U.S.C. § 112(a).

154 *Id.* § 271(a).

155 See Burk & Lemley, *supra* note 79, at 395 (noting the terminology threaded through provisions of the patent statute).

156 See Burk, *supra* note 22, at 564.

157 See Burk, *supra* note 39, at 43.



A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing. If new and useful, it is just as patentable as is a piece of machinery. . . . The machinery pointed out as suitable to perform the process may or may not be new or patentable; whilst the process itself may be altogether new, and produce an entirely new result. The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence.<sup>158</sup>

This passage, filtered through the decisions of the *Benson* trilogy, ultimately formed the basis for the bright-line “machine or transformation test” developed by the Federal Circuit, and held by the Supreme Court in *Bilski* to constitute a possible subject matter test, although not the sole determinant of process patent eligibility.<sup>159</sup> In particular, Justice Kennedy’s *Bilski* opinion explicitly declined to limit patent eligibility to machines or transformations of matter due to the probability of thereby excluding inventions in areas such as programming and diagnostics that might not fit this definition of materiality.<sup>160</sup>

And yet, however tempting it may be to believe that modern inventions such as software or diagnostic methods are somehow different than more “classical” processes, this view is deceptive.<sup>161</sup> There are no immaterial processes. The substrates of contemporary informational processes may seem invisible, or even absent, but they are surely there as circuits, storage devices, or other apparatus.<sup>162</sup> Even mental processes necessarily entail material interactions: neurons fire, ions diffuse, membranes polarize, neurotransmitters bind.

The materiality of any given process thus implicates the subject matter exclusions for laws of nature and related doctrines. The interactions among components in a process necessarily follow the causal order of the universe, which is to say that they follow the causal statements we call natural laws, which are themselves generalized statements about processes.<sup>163</sup> Such causal relationships can typically be described in the representative language of mathematics, which can of course describe objects, but which is very typically used to describe the relationships among objects. Mathematics is a step removed from phenomena of nature, although it may be integral to describe such phenomena.<sup>164</sup>

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158 *Cochrane v. Deener*, 94 U.S. 780, 788 (1877).

159 *Bilski v. Kappos*, 561 U.S. 593, 604–05 (2010). See generally Dreyfuss & Evans, *supra* note 110 (reviewing the *Bilski* holding).

160 *Bilski*, 561 U.S. at 605–06.

161 Margaret Jane Radin, *Information Tangibility*, in *ECONOMICS, LAW AND INTELLECTUAL PROPERTY* 395, 396–418 (Ove Granstrande ed., 2003) (arguing that software, DNA, and other information is physically instantiated).

162 Jean-Francois Blanchette, *A Material History of Bits*, 62 J. AM. SOC’Y INFO. SCI. & TECH. 1042, 1042 (2011).

163 See *supra* text accompanying notes 86–90.

164 See *supra* text accompanying notes 77–79.

And this is, of course, the reason that the Supreme Court has primarily addressed the laws of nature doctrine and its companion subject matter exclusions in the context of software, where they occur so often. Software is not mathematics, as the Court seems once to have supposed in *Benson*,<sup>165</sup> but both are expressive forms of logic. Neither constitutes natural law, but either may constitute an expression of causal material relationships, rendered symbolically rather than physically. Thus, as Phil Agre once observed, computers are able to model anything that can be described in text, as they are machines that are inscribed with text.<sup>166</sup>

Indeed we might say that software defines a set of physical relationships that may model other relationships. Software itself is in large measure a symbolic representation of a logical apparatus, albeit an executable representation capable of configuring a physical apparatus.<sup>167</sup> Although one could build hardwired machines that are the functional equivalent of software, we more typically write expressions that temporarily configure universal machines to particular tasks.<sup>168</sup> Thus software routinely collapses the usually comfortable distance between symbolic expression and physical instantiation, concomitantly collapsing the distance between laws of nature and their material substrates. And this mercurial character of software, seeming sometimes an apparatus, and sometimes the state of an apparatus, more than any other current technology reveals the untenable division between product and process in the patents that claim it.<sup>169</sup>

### B. *A Process by Any Other Name*

The Supreme Court's twentieth-century software cases and their twenty-first century counterparts have thus been the primary vehicle by which the Court has articulated the related set of subject matter exclusions denominated mental steps, abstract ideas, and laws of nature. But these same exclusions could be and on occasion have been formulated as disclosure problems that in the United States run afoul of the enablement and written description requirements of § 112. The American patent statute requires the patent applicant to provide a disclosure that enables one of ordinary skill to make and use the claimed invention; the applicant is also required to describe the invention in sufficient detail that one of ordinary skill would know she has possession of what is claimed.<sup>170</sup> Thus, the disclosure in the patent must be commensurate with the scope of the claims: a patentee who wants to claim

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165 *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972).

166 Philip E. Agre, *Internet Research: For and Against*, in 1 INTERNET RESEARCH ANNUAL: SELECTED PAPERS FROM THE ASSOCIATION OF INTERNET RESEARCHERS CONFERENCES 2000–2002, at 25, 27 (Mia Consalvo et al. eds., 2004).

167 See Pamela Samuelson et al., *A Manifesto Concerning the Legal Protection of Computer Programs*, 94 COLUM. L. REV. 2308, 2316 (1994).

168 *Id.* at 2320.

169 See Dan L. Burk, *Method and Madness in Copyright Law*, 2007 UTAH L. REV. 587, 609–10. As should be clear by now, biotechnology comes in a close second. See *id.*

170 35 U.S.C. § 112(a) (2012).

more must disclose more; patentees who disclose less are only entitled to claim less. Claims drawn to mental steps, abstract ideas, and natural principles are all difficult to enable, or to properly describe. How does one enable a particular thought, or all embodiments of a general principle?

The solution to this problem has often been to draft process claims as if they were product claims, in terms of the apparatus or physical substrates involved.<sup>171</sup> Such drafting lends a veneer of tangibility to claims that might otherwise seem abstract or conceptual. Indeed, this might seem to be the lesson of the *Benson/Flook/Diehr* trilogy: processes in the first two cases that produced a numerically represented output were held patent ineligible, whereas the process in the third case that produced a solid and palpable industrial product—such as a tire—passed patent muster.

Of course, as I have suggested in the discussion of software above, the disfavored numerical outputs in *Benson* and *Flook* were not in fact ephemeral, ideal objects: they were embedded in some solid and palpable substrate.<sup>172</sup> Binary representations—the 0s and 1s of machine-readable computer code—are visualized as numbers, which seem fairly conceptual or ephemeral. But in an actual digital processor, they are implemented as high and low voltages in a circuit. Patent claims can describe them in either formulation; if a numerical characterization seems overly abstract, the same invention can be claimed as the state of voltages hardware. Consequently, for many years after the Court's twentieth-century subject matter trilogy it became the norm in the United States to avoid claims with generalized expressions of numerical output, couching the claims instead in terms of their substrate.<sup>173</sup> Similarly, the two-step analysis in *Alice Corp.* seems to suggest that the second step becomes moot if the initial step has been sufficiently tied to a structural claim. And as I have already mentioned, in the EPO, too, claims that recite any type of apparatus are now considered patent eligible (although likely to be denied on other grounds such as obviousness).<sup>174</sup>

Lemley and Cohen refer to this dodge as “the doctrine of the magic words” whereby one description of an invention is disallowed while an alternative description of the same thing is permissible.<sup>175</sup> But this kind of exercise becomes tedious at some point, not to mention counterproductive. Even though clever drafting can describe an invention in either process terms or product terms, inventions typically lend themselves to one type of description or another.<sup>176</sup> Although it is possible to describe machines, manufactures, and compositions in terms of functional relationships, this tends to be awk-

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171 Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CALIF. L. REV. 1, 9 (2001).

172 See *supra* text accompanying notes 161–69.

173 See Dreyfuss & Evans, *supra* note 110, at 1357.

174 See *supra* text accompanying notes 145–50.

175 Cohen & Lemley, *supra* note 171, at 9.

176 Cf. *Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1537–38 (Fed. Cir. 1990) (attempting—albeit unsuccessfully—to characterize genetically modified cells as “‘non-traditional’ process claims”).

ward—indeed, one specialized form of claiming where this was regularized, by which inventions were claimed in terms of the process that made them, led to ongoing controversies about the claim scope that are still not entirely settled.<sup>177</sup> Instead of roundabout functional descriptions, the most straightforward description of product inventions will tend to be largely or wholly structural. And although process claims can be written in terms of the substrates that stand in a particular process relationship, the most natural and straightforward description of a process will tend to focus on the relationship rather than the structures—even though this type of description will tend to appear abstract, conceptual, or naturally phenomenological.

Even when not employed to avoid a laws of nature characterization, the commonality of process and product claims routinely engender interlocking claims of each type. The relationships between novel materials may themselves be patentably novel, just as patentably novel relationships may give rise to novel materials.<sup>178</sup> Thus a new technological development often gives rise to both process and product claims that following § 101 are considered related but separate inventions. This was, for example, the case for Myriad's DNA sequences; the company held patents claiming not simply the DNA sequences for certain cancer-inducing genes, but also patents claiming the process of using those sequences in a diagnostic test.

The initial suit against Myriad considered both the DNA product claims and the associated process claims; the plaintiffs who challenged the gene patents considered by the Supreme Court initially challenged the diagnostic patents as well. And although the *Mayo* opinion is conspicuously absent from the Supreme Court's reasoning in its *Myriad* opinion, and for that matter makes only brief cameo appearances in the Federal Circuit's reconsideration of *Myriad* on remand, it played a starring role in the diagnostic process reasoning of the lower courts. Neither the diagnostic claims nor the rationale for rejecting them ever reached the Supreme Court, which granted certiorari only on the question of patent eligibility for human genes.

Both the trial court and the Federal Circuit unanimously agreed that the process claims were not patent eligible.<sup>179</sup> Myriad's diagnostic process was to compare a patient's BRCA1 sequence to a set of reference sequences known to predispose carriers toward cancer, and to conclude from the comparison whether the patient was predisposed toward cancer.<sup>180</sup> All of the judges to examine the question agreed that Myriad had simply claimed a natural correlation between a particular nucleotide sequence and the propensity to can-

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177 *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1299 (Fed. Cir. 2009) (holding that infringement of product-by-process claims requires use of the defining process).

178 Sorting such patentability out has become known as the *Durden* problem, from the line of cases grappling with these issues. See Burk, *supra* note 39, at 50–53; Burk, *supra* note 22, at 572–75.

179 *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 683 F.3d 1329, 1355–57 (Fed. Cir. 2011); *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 233–37 (S.D.N.Y. 2010).

180 *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 237.

cer, paralleling the Supreme Court's reasoning in *Mayo v. Prometheus*. Just as in the case of software, this ineligible claim might be characterized in a variety of ways. Judge Lourie, writing for a unanimous Federal Circuit, reasoned that quite apart from the Supreme Court's natural law reasoning in *Mayo*, the *Myriad* "comparing" and "analyzing" process claims attempted to claim a correlation that constituted an "abstract" mental step.<sup>181</sup>

But this application of the *Mayo* logic is troubling, since on this logic all diagnostic procedures seem at risk of exclusion from the patent system. Diagnosis is by definition a process of deduction, which necessarily involves incidental correlation. Any diagnosis relies on natural relationships to define such correlations: the patient displays a symptom or characteristic associated with disease, or does not display a symptom or characteristic associated with disease; the observer concludes from the presence or absence of the particular indicator that the patient does or does not have the associated disease. If the presence of such natural correlations precludes patenting, then diagnostic methods seem generally unpatentable.

This outcome is all the more puzzling in light of the Supreme Court's endorsement at the end of its *Myriad* opinion of process claims to genetic testing that may incorporate unpatentable genomic DNA. Perhaps intending to reassure the U.S. biotechnology industry that has for the last three decades flourished around gene patents, the opinion disclaims certain implications of its analysis, hinting that these areas remain legitimate or at least undisturbed by its ruling.<sup>182</sup> The first of these encompasses what might otherwise be called methods of making and methods of use, although the Court does not employ such terminology, referring instead to "method[s] of manipulating genes" or to "*applications* of knowledge about" the DNA sequences.<sup>183</sup> These, the Court says, are not part of its holding, and might have been permissible subject matter for *Myriad* to have claimed.<sup>184</sup> And yet the unanimous holding of the lower courts seems inescapable: that the logic of *Mayo* precludes what the *Myriad* dictum on processes says should be permissible.

## V. PROCESSES AND PREEMPTION

The recurring theme of the laws of nature doctrine within cases that contemplate process claims is no accident. Of the categories enumerated in § 101, two categories imply human craftsmanship—machines are typically thought of as made by humans,<sup>185</sup> as are articles of manufacture. Composi-

181 *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 689 F.3d 1303, 1334 (Fed. Cir. 2012).

182 *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119–20 (2013).

183 *Id.*

184 *Id.*

185 One might debate whether there are naturally occurring "machines." For example, certain bacteria have a wheel and axle structure that drives their flagella. See STEVEN VOGEL, *COMPARATIVE BIOMECHANICS* 455 (2d ed. 2013). However, denominating such structures as "machines" seems more of an analogy than a proper ontology.

tions of matter might be human artifacts or they might be assembled without human intervention. While some processes might be arranged by humans, the vast majority of processes occur outside of human control or even human cognition. This raises the question of whether one can have an “unnatural” or “artificial” process. Even those processes practiced by humans follow or rely upon the causal order of the universe. Any process claim inherently entails a “natural” law, which is to say a causal relationship among its substrates that can be exploited by humans, but never created *de novo*.

Thus all processes are at some level “natural” and, if viewed as constituting no more than their underlying causal relationships, seem most likely to be disallowed as claiming laws of nature. Avoiding that characterization is inevitably a descriptive question. Processes most likely to avoid that label seem to be characterized by the status of the substrates of that process—relationships among machines and manufactures are most likely to appear “non-natural” if characterized in terms of the human artifacts on which the process depends. Processes related to compositions of matter, which may be human artifacts or not, present more of a problem.

The Supreme Court’s endorsement of process inventions at the end of the *Myriad* opinion suggests a similar tack. As we have seen, *Mayo* and its predecessor laws of nature cases are process cases. Following the “magic words” regime of abstract ideas in software, one might argue that the outcome in *Mayo* and in the intermediate *Myriad* decision stem not so much from claims that entail a natural correlation as they do from the presence of claims encompassing *all* of a class of methods that entail a natural correlation. Some commentators have dubbed this the “preemption” doctrine that bars patents on concepts that would “preempt” large swaths of future innovation.<sup>186</sup>

Justice Thomas went to some length to reaffirm this rationale in *Alice Corp.*: the Court there refers to the forbidden categories of abstract ideas, products of nature, and natural laws as “building blocks” that cannot be claimed lest they become unavailable to future innovators.<sup>187</sup> Justice Thomas formulates from this a two-part subject matter test, founded on the earlier *Mayo* decision, that requires a court to first ask if a claimed invention is a building block category, and then if it is, whether the claims entail an “inventive concept” that is more than a claim to the building block.<sup>188</sup> The implication seems to be that if the claims in such patents were narrower, confined to a particular instantiation or apparatus, then either they would become sufficiently concrete to avoid the abstraction label, or they would not “preempt” all the future applications of the principle.<sup>189</sup>

But this formulation of the Court’s preemption jurisprudence cannot be entirely correct. As Professor Strandburg points out, the Supreme Court in

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186 See Dreyfuss & Evans, *supra* note 110, at 1359; Strandburg, *supra* note 13, at 565.

187 *Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014) (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1301 (2012)).

188 *Id.* at 2355 (quoting *Mayo*, 132 S. Ct. at 1294).

189 See Burk, *supra* note 7, at 747–48.

both *Flook* and *Mayo* has invalidated claims that were unlikely to preempt a wide swath of anything.<sup>190</sup> The language of *Mayo* suggests that it is the type of claim, rather than the expected effect of any given claim, that triggers the exclusion.<sup>191</sup> Probably, then, the tendency to preempt is a marker rather than a justification; the issue is not so much avoiding a type of technological monopoly as it is identifying problematic claims by virtue of their potential to preempt future development. In *Myriad*, Justice Thomas stresses, via multiple repetitions, an underlying policy rationale that some inputs to innovation are so fundamental that they must remain unencumbered by exclusive rights.<sup>192</sup> Claims that would forestall the development of future technologies are likely also those that, due to their breadth, would cover those future technologies.

As indicated above, one response to past subject matter decisions has been to draft around them; to reformulate process claims as the instantiation of material products.<sup>193</sup> Viewing the Supreme Court's subject matter jurisprudence as a jeremiad against preemption once again implies that the abstract ideas and principles of nature doctrines are indeed drafting problems: *Myriad* or *Prometheus* might not have lost process claims that were drafted more narrowly, in terms of a discrete mechanism or particular apparatus. The Court has said that the addition of "insignificant postsolution activity" to impermissibly abstract claims is not enough to pass subject matter muster,<sup>194</sup> but that admonition simply shunts the drafting in a particular direction. More limited claims might be patent eligible as not having been drawn to a natural principle *per se*. This is, again, similar to the position reached in the European Patent Office, which seems resigned to allowing claims that recite any physical instantiation, even if it then disallows them on other grounds.<sup>195</sup>

But if the breadth of the claims is the problem, then we have already seen that the commensurability principle of § 112, that the inventor can only claim what she teaches,<sup>196</sup> provides a workable limit on claim breadth that seems to obviate the need for an additional § 101 limit. Additionally, this rationale for a principle of nature limitation leaves the question of subject matter very much dependent on the skill of the "draftsman" in the fashion that the Court has repeatedly deplored.<sup>197</sup> The Supreme Court has said on several occasions, most recently in *Alice Corp.*, that the provenance of patent-

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190 See Strandburg, *supra* note 13, at 583–84; see also Rai, *supra* note 14, at 113 (discussing the "bright-line" approach in *Mayo*).

191 *Mayo*, 132 S. Ct. at 1303.

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

193 See *supra* text accompanying note 171.

194 *Diamond v. Diehr*, 450 U.S. 175, 191–92 (1981); see *Mayo*, 132 S. Ct. at 1298 (quoting *Diehr*, 450 U.S. at 191–92).

195 See *supra* text accompanying notes 146–50.

196 See *supra* text accompanying note 170.

197 *Mayo*, 132 S. Ct. at 1294 (quoting *Parker v. Flook*, 437 U.S. 584, 593 (1978)); *Diehr*, 450 U.S. at 192.

ble subject matter should not be dependent on canny drafting,<sup>198</sup> and yet the rule articulated in *Mayo* seems to push the patentee toward exactly such drafting.

Either the Court is unaware of the tension between its insistence that patent eligibility not be subordinated to draftsmanship and its insistence that subject matter not “preempt” general principles, or it seems to be favoring draftsmanship of a *certain kind*. The *Alice Corp.* opinion stresses the ineligibility of inventions that are “fundamental”;<sup>199</sup> the line of cases running from *Mayo* back to *Benson* suggests that claims to tangible embodiments will pass muster under the laws of nature analysis and so must not be “fundamental.”<sup>200</sup> The two-part subject matter test articulated in *Mayo* and *Alice Corp.* suggests that a narrow, specific instantiation of an otherwise abstract invention might survive the second step.<sup>201</sup> One might conclude that the jurisprudence of “laws of nature” is intended to push patentees toward narrower, more specific claims on tangible instantiations.

This policy of maintaining fundamental access to critical constructs is probably correct, and is perhaps the most sensible reading of the process subject matter cases.<sup>202</sup> In previous work with Mark Lemley, I have suggested that the cluster of doctrines around the laws of nature exclusion may act as judicial “policy levers,” by which we meant a type of flexible doctrine that courts can use to modulate an otherwise uniform patent statute to the innovation needs of particular technologies.<sup>203</sup> Excluding conceptual inventions from patent eligibility pushes exclusivity further downstream to the stage of finished products, requiring narrower claims on concrete implementations, rather than allowing conceptual patents early in the development of a technology.<sup>204</sup>

This rationale makes far more sense than to claim that certain ideas are off-limits to the patent system because they are not the product of human invention. As discussed above, the models articulated by Newton, Bohr, or others are certainly the product of human ingenuity, and casting them as found rather than built is at best a convenient epistemological fiction.<sup>205</sup> Rather, such models are better viewed as off-limits because they are essential components to all applied innovation. Under this logic, to the extent that their models of causal ordering are useful or necessary to applied innovation, those expressions remain unpatented and available; once they are super-

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198 *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2360 (2014).

199 *Id.* at 2355–57.

200 See *supra* notes 159–60 and accompanying text.

201 See *Alice Corp.*, 134 S. Ct. at 2359–60.

202 See Burk & Lemley, *supra* note 79, at 407–08.

203 DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 95 (2009) (quoting Pamela Samuelson & Suzanne Scotchmer, *The Law and Economics of Reverse Engineering*, 111 YALE L.J. 1575, 1581 (2002)).

204 *Id.* at 122–24. Professor Lemley has subsequently elaborated on this argument with an expansive cohort of co-authors. See Mark A. Lemley et al., *Life After Bilski*, 63 STAN. L. REV. 1315, 1328–29 (2011).

205 See *supra* text accompanying notes 88–90.



seded or fall into desuetude, a patent controlling their use would be unnecessary anyway.

What is perhaps more troubling is that although nothing about this policy is extant in § 101, as observed above, it is a theme that crops up more explicitly in other sections of the statute, which seem to be designed to guard against much the same problem that the products of nature doctrine might be said to embody. In particular, I have already noted the problem that § 112 precludes patent claims that are not enabled or fairly described by the specification.<sup>206</sup> Claims that read on fundamental laws or principles are almost certainly not supported by their accompanying disclosure, which cannot feasibly enable or describe all technologies that might be based on such a discovery.<sup>207</sup> Thus, to take again Justice Stevens's example of the qualities of metals, discussed above,<sup>208</sup> one who attempted to claim characteristics such as a certain ductility or resistance would face the impossible task of enabling all instances of such at the time the claims were filed. Thus, among its other functions, enablement acts as a type of temporal brake, forestalling claims that are premature. Why then replicate this function by creating a similar doctrine within the § 101 subject matter inquiry?

The answer may lie in the applicability of the two rules to differing situations. First, unlike the § 112 disclosure doctrines, the cluster of "abstract ideas" doctrines polices the upstream availability of fundamental technologies on an invention-by-invention basis, rather than as a blanket rule applied to an entire technological sector.<sup>209</sup> Because § 112 is statutorily calibrated to the level of skill in the art,<sup>210</sup> commensurability grounded in that section will apply to entire fields of technology. Although certain technologies are more likely to lend themselves to the rule on abstractions, nothing in § 101 requires blanket application to an entire field. Additionally, since patent eligibility is an antecedent question to patentability, a doctrine situated in § 101 analysis is typically antecedent to § 112 analysis. This may be attractive from the standpoint of judicial economy or simply judicial preference.<sup>211</sup> A narrowing doctrine drawn from § 101 may obviate the need for detailed exami-

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206 See *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1070 (Fed. Cir. 2005); *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1336–37 (Fed. Cir. 2005).

207 Cf. *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 124 (1854) (invalidating overbroad claims that encompassed all applications of electromagnetic communication). The *Morse* case is often cited, including by the Court in *Mayo*, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012), for the proposition that laws of nature lie outside patentable subject matter, when in fact it is better read for the principle of commensurability between claims and disclosure.

208 See *supra* notes 65–66 and accompanying text; see also *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

209 See BURK & LEMLEY, *supra* note 203, at 122–24.

210 35 U.S.C. § 112(a) (2012).

211 *Contra* Dennis Crouch & Robert P. Merges, *Operating Efficiently Post-Bilski by Ordering Patent Doctrine Decision-Making*, 25 BERKELEY TECH. L.J. 1673, 1674 (2010); Lemley et al., *supra* note 204, at 1342 (arguing that patentability should be assessed before patent eligibility).

nation of the patent disclosure, which may be attractive if a court is reluctant to wade into the details of a technology—particularly, for example, the Supreme Court.

## VI. PRODUCTS AND PREEMPTION

What we have seen to this point about the purpose and effect of excluding natural processes from patenting suggests that the Court expects that the *products* of nature doctrine should be enrolled toward a similar purpose, limiting patent scope by pushing patent eligibility away from fundamental materials and toward completed products.<sup>212</sup> If this parallel to *Mayo* and its antecedents is to be accepted, then just as the Supreme Court believes that certain observations describing patterns of causal occurrence are so fundamental to innovation that they must remain free of patent encumbrance, so it seems it believes that certain substances or materials are sufficiently fundamental to applied innovation that they must be similarly off-limits to the patent system. This purpose also implies other correspondences of the *Myriad* opinion's products of nature doctrine to the laws of nature doctrine, such as the need for a separate invention-by-invention policy lever that might be more appropriate than the § 112 disclosure doctrines for limiting fundamental product claims.

Yet if avoiding preemption of downstream technologies is to be the justification for the products of nature doctrine, it is critical to recognize just how such preemption may differ from that of the established laws of nature doctrine. As an initial matter, it is a little difficult to see why the doctrine should be a product of nature doctrine. Effectively, the target of the doctrine is the § 101 category of compositions of matter—where products “of nature” are concerned, we must be considering either exclusively or primarily the § 101 category of compositions of matter. As indicated above, the categories of machines and manufactures inherently carry the connotation of human creation; there is unlikely to be concern over “manufactures of nature” or “machines of nature.”<sup>213</sup> And yet it is unclear why compositions of matter should be necessarily more fundamental, or more the building blocks of downstream innovation, than certain machines or manufactures, or why machines and manufactures are better limited by § 112 commensurability than by subject matter.

Relatedly, this rationale for a products of nature doctrine requires us to ask whether one can have a pristinely artificial or “non-natural” composition of matter—just as every process is ultimately a “natural” physical process, so every composition is a “naturally” occurring material. It is a big planet, a

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212 Cf. Rebecca S. Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783, 785 (2000) (“The standard patent lawyer’s response to the ‘products of nature’ limitation is to treat it as a technical, claim-drafting problem.”).

213 See *supra* note 186 and accompanying text.

bigger solar system, an immense universe.<sup>214</sup> Given enough time and enough heat, any possible composition will be generated somewhere by physical processes, without human direction.<sup>215</sup> Thus all compositions will be found in nature if only you look far enough. An inherency rationale would exclude such fortuitous synthesis from consideration of patent eligibility as well as patentability,<sup>216</sup> and the Supreme Court appears to have endorsed such a rationale in *Myriad*,<sup>217</sup> but that rationale suggests that natural occurrence is really beside the point. Natural occurrence does not and cannot serve as a marker for preemption; some other indicia of benefit or detriment of a product patent to downstream innovation is necessary.

It would also seem that the need for a laws or processes of nature doctrine is far more compelling than the need for products of nature doctrine. Principles of nature are antecedent to material interactions, whatever degree of human intervention may characterize them. A mineral in the earth, or extracted ore containing the mineral, or compound smelted from the ore, or component forged from the compound, or machine constructed from such components all behave according to the causal observational statements we call natural law. DNA molecules, whether cDNA or gDNA, and whether considered “natural” or “artificial,” follow the same principles of chemistry and physics. Thus there is a need to maintain access to fundamental principles at every stage of innovative activity, but this is not necessarily the case where materials are concerned. All inventions rely on fundamental principles, but not all inventions rely on fundamental compositions. The applicability of a fundamental compositions doctrine would seem more limited than that for fundamental principles.

It may be that compositions, like processes, are somewhat more likely to be antecedent to the other § 101 subject matter categories—everything must be made of something, just as everything must operate according to some causality. This is perhaps an argument for some type of common pool rationale, what the Supreme Court has rather breezily dubbed the “storehouse of knowledge,”<sup>218</sup> by which fundamental compositions are excluded from patent eligibility so as to maintain public availability. But it is not necessarily an argument informed by downstream preemption, since as we have just seen, the applicability of the fundamentality rationale is likely to be far more sparse for compositions than for processes. Everything must be composed of some-

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214 Cf. DOUGLAS ADAMS, *THE HITCHHIKER'S GUIDE TO THE GALAXY* 76 (1979) (“Space . . . is big. Really big. You just won't believe how vastly hugely mind-bogglingly big it is. I mean, you may think it's a long way down the road to the chemist, but that's just peanuts to space.”).

215 See Burk, *supra* note 126, at 95–97.

216 *Id.*; see Burk & Lemley, *supra* note 79, at 404–06 (arguing for an inherency rationale regarding products of nature).

217 *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119 n.8 (2013) (“The possibility that an unusual and rare phenomenon *might* randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable.”).

218 *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

thing, but we decidedly do *not* want to categorically exclude *all* compositions from patent eligibility the way that we want to exclude all abstract principles.

Additionally, the applicability of a fundamental products doctrine may be altered by the different developmental role or position played by compositions as opposed to fundamental processes. For example, looking at laws of nature, the development of fundamental concepts and their embodiments is not likely to follow a clean linear progression from concept to applications. It may be that Newton first develops his laws of motion, and others then find ways to apply them to new inventions. But it is far more likely, both as a practical and historical matter, that many inventions are developed that incorporate these unarticulated laws before Newton eventually formulates his general statements as to how such inventions behave. In fact, Newton may well be relying on the accumulated knowledge regarding previous technologies in developing his articulation of their causality.

In contrast, development of technology from fundamental *materials* is more likely to proceed in a cumulative progression from discovery to application—one needs to have the basic materials in hand as a starting point or fundament on which to build specific implementations. There may of course be cases where technologies comprising certain materials are developed ahead of the materials' discovery, where applied invention unwittingly incorporates later-identified materials. But in the cases where this *does* occur, the doctrine of inherency will determine as a matter of novelty whether we allow a patent on an invention that was already present, based upon whether the public was already benefitting from the unidentified invention.<sup>219</sup> The policies behind inherency may have a bearing on how we treat products of nature, militating in favor of patents where some new benefit is realized by the discovery.<sup>220</sup>

From the standpoint of patent law, this means that patent claims covering a *law* of nature are far more likely to take something away from the public, something that is already in common use. Existing inventions will follow the principles articulated by Newton or Maxwell or Boltzmann prior to their discovery by those theorists—there is in fact no other way that the existing inventions *could* work—and granting a broad right in the principle would constrain or remove something already conferring a benefit. A number of doctrines in American patent law, including the inherency principle, are designed to prevent exactly such removals from the public domain,<sup>221</sup> and the law of nature doctrine seems coherent with this general policy. The same is not necessarily true for products of nature, which may convey something new to the public, and which are more likely to require investment to move the material from initial synthesis to applied technology. This militates in

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219 Burk & Lemley, *supra* note 79, at 379–84.

220 See Burk, *supra* note 141, at 113–14; Burk & Lemley, *supra* note 79, at 407.

221 See, e.g., Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1377 (Fed. Cir. 2003) (inherent anticipation); Abbott Labs. v. Geneva Pharm., Inc., 182 F.3d 1315, 1318 (Fed. Cir. 1999) (on-sale bar).

favor of a far more nuanced products of nature doctrine than law of nature doctrine.

This observation highlights the difficulty in identifying which products are fundamental. Identifying when a product claim lies sufficiently far upstream in the innovation process to merit treatment as a product of nature will require a different metric than that applicable to a law of nature. Recognizing when a claim is overly abstract, drawn to a fundamental principle, is, as we have seen, a somewhat problematic exercise,<sup>222</sup> but courts can likely make a good guess as to when process claims lack the necessary substance to qualify as patentable subject matter. The degree of abstraction serves as a rough metric of the sort of claim breadth likely to preempt future uses.

A similar estimate for the essentiality of a *product* seems a far more difficult exercise; abstraction or conceptuality are not necessarily characteristic of preemptive material claims. To take the instant example, far from being couched in abstraction, the Myriad DNA claims were quite precisely delineated to a particular and defined set of structures; indeed the trial court's rationale that the specific sequences constituted "information" rather than material was largely a rhetorical move intended to cast the claims as somehow conceptual in a new or different fashion.<sup>223</sup> Here, the puzzling vacillation of the Supreme Court's *Myriad* opinion between structure and function puts the whole preemption exercise in doubt. It is not at all clear how gDNA is in any sense more fundamental or essential than its corresponding cDNA, and the *Myriad* opinion certainly gives no concrete guidance as to what might make one more essential than the other.

To state the matter somewhat differently, although the more recent *Alice Corp.* opinion is as silent as Holmes's hound about how *Myriad* is supposed to fit into the *Mayo* framework, every indication is that Justice Thomas somehow expected it to do so.<sup>224</sup> The unarticulated implication of the opinion seems to be that products will be measured by the two-step *Mayo/Alice Corp.* test just as processes are: first assess whether the material is a "building block" product of nature, and then if it is, assess the patent for an "inventive concept" that makes the patent more than a claim to the prohibited fundamental category.<sup>225</sup>

It is nearly impossible to comprehend how this might work in the case of products. I have already outlined above how difficult it will be to recognize

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222 See text accompanying notes 53–59 and accompanying text.

223 Thus the parallel drawn by Lemley et al. between laws of nature and products of nature—that "the analysis [in each case] turns on whether the patent claims describe the application of human knowledge to a practical end, rather than merely identification of the existence of useful properties"—is too facile. See Lemley et al., *supra* note 204, at 1329. This falls into the *Funk Bros.* error of confusing product characteristics, which are not claimed, with the product claims themselves. See *supra* notes 64–66 and accompanying text. The unpatentable Myriad claims were directed to specific structures, not to specific properties.

224 See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116–18 (2013).

225 *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354–55 (2014).

claims to a preemptive “building block” material; it will not have the indicia the Court has suggested might be used to identify “building block” principles.<sup>226</sup> Some commentators have suggested that factors such as the breadth of claims, the number of disclosed embodiments, and the likelihood of cumulative improvements might be used to determine what should fall under the abstract ideas or laws of nature exceptions.<sup>227</sup> There is considerable merit to such suggestions, but I am chary of their potential application to determine the “building block” status for products of nature. As I have just shown, product claims will not have the proxy of process abstraction to signal over-breadth, and it is far less clear what it might mean for a claim to a substance to be impermissibly broad. Since the temporality of fundamental materials discovery is different than that of fundamental principles discovery, the likelihood of future cumulative innovation may be difficult to assess.<sup>228</sup> The Supreme Court may treat products and laws of nature as equivalent, but the reality of product and process claiming means they will not be equivalent in practice.

And on the second step, it is difficult to imagine what might constitute the necessary “inventive concept” to carry claims beyond whatever the material analog for “insignificant post-solution activity” might be. In *Alice Corp.*, the Court hints that some specialized hardware or advance in computer technology might have satisfied the inventive concept requirement, where routine implementation in a general computer system did not.<sup>229</sup> The analog for compositions seems opaque. Specifically, taking the analysis of *Myriad* as exemplar, gDNA apparently failed the *Mayo/Alice Corp.* test where cDNA did not. Since both had the same “building block” information, apparently the cDNA claims entailed an inventive concept. But if the “information”—which is to say, the nucleotide sequence—of the BRCA1 gene constitutes an ineligible “building block,” then it is difficult to see how removal of intervening sequences via reverse transcription is inventive enough to make the information patent eligible as cDNA. If anything, this seems entirely routine and uninventive.

#### CONCLUSION

My goal here has been to divine the implicit connection that the Supreme Court has suggested should be found between the patentable subject matter doctrines regarding products of nature and laws of nature. Doing so requires, as an initial matter, imposing some degree of conceptual coher-

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226 See *supra* text accompanying notes 222–23.

227 See Lemley et al., *supra* note 204, at 1334 (suggesting a multi-factor test to identify “fundamental” abstract ideas); Ted Sichelman, Funk *Forward*, in INTELLECTUAL PROPERTY AT THE EDGE 361, 377–80 (Rochelle Cooper Dreyfuss & Jane C. Ginsburg eds., 2014) (delineating a “multi-factored, policy-driven test for patentable subject matter”); see also Jacob S. Sherkow, *The Natural Complexity of Patent Eligibility*, 99 IOWA L. REV. 1137, 1180 (2014) (suggesting a similar multi-factor test to identify patent ineligible laws of nature).

228 See *supra* text accompanying notes 218–19.

229 *Alice Corp.*, 134 S. Ct. at 2359–60.

ence on the Court's laws of nature jurisprudence in order to see what correspondence might exist between the two doctrines. Probably the best explanation of the laws of nature cases remains the theory that the doctrine operates as a doctrinal lever intended to force abstract, fundamental claims toward specific, narrowed claims over downstream products.

But as I have shown here, the operation of this lever is intimately bound up in the distinction between product and process. However often the Court may casually throw processes and products of nature together in the same passage, the two cannot be treated identically. As matters stand now, the lack of any statutory guidance, not to mention the lack of judicial coherence, makes such a policy on fundamental *products* nearly impossible to administer as there are no discernable criteria as to what materials are fundamental or essential and what materials are not. *Myriad* affirms the existence of the products of nature doctrine and points toward a parallel with the preemption rationale of the laws of nature doctrine, but offers no guidance as to how such a rationale might function. The Supreme Court's silence on that score, far from offering a clue as to the doctrine's intended purpose, seems simply to be a void that the lower courts have been left to fill.