

2013

# A Conversation on Judicial Decision Making

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## Recommended Citation

Robin Cooper Feldman, *A Conversation on Judicial Decision Making*, 5 *Hastings Science & Technology Law Journal* 1 (2013).  
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# A Conversation on Judicial Decision-Making

by ROBIN FELDMAN\*

In recent years, the Supreme Court has agreed to hear a number of cases concerning patentable subject matter. An area that can be both breathtakingly broad and minutely particular, patentable subject matter asks us to consider which innovations are of the type that we might entertain the question of whether they should be granted patent protection. Do we include living creatures, for example? How about the components of life, such as genes and antibodies? Are mathematical algorithms, computer models, and computer software included? And just what is an algorithm anyway? These are the types of questions that the Court must delve into when it grapples with patentable subject matter.

There are many interesting elements of the Supreme Court's modern jurisprudence on patentable subject matter, but one of the most fascinating aspects is the conversation that emerges across time between the Supreme Court and the Federal Circuit. It is a conversation not just about the nature of patents, but also about the nature of judicial decision-making. It implicates how one goes about crafting the rules within an area of law, what approaches are tenable, and what is the appropriate relationship among the various courts.

The conversation has the feel of an exchange between a teacher and a student, or perhaps between an adult and an adolescent, because after all, the Federal Circuit has been around only a few short decades.<sup>1</sup> As with any conversation of this kind, much of the talking is done by the one who has the wisdom conferred by virtue of

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1. See Federal Courts Improvement Act of 1982, Pub. L. 97-164. The Act "established the United States Court of Appeals for the Federal Circuit (CAFC), effective October 1, 1982, and transferred to this Court the jurisdiction previously vested in the U.S. Court of Customs and Patent Appeals to review Patent and Trademark Office decisions." Court Review of Patent and Trademark Office Decisions, 47 Fed. Reg. 47380-01.

superior status, but there are occasional replies and rejoinders from below.

We are nowhere near the end of the conversation. Rather, I suspect that the 2010 *Bilski*<sup>2</sup> decision and the *Mayo v. Prometheus*<sup>3</sup> decision in the spring of 2012 are the first two of what will someday be called a quartet of Supreme Court cases on patentable subject matter. The third is likely to be the Myriad gene patenting case,<sup>4</sup> after the Federal Circuit has decided it, yet again, on remand, or another case involving patenting of genes. The fourth will be some yet to be chosen case on patentability of computer software.

What is the reason for this extended conversation? The Federal Circuit, in its carefree, adolescent life, has developed a habit of resting on rules of convenience. The cases make distinctions to try to reach a particular result, but the rules (and the distinctions within those rules) lack general applicability and defensible logic. The approach feels comfortable because of the end result, but it is intellectually and operationally unsatisfying. Worse yet, the cases all too often produce what I would call death by tinkering—change a little piece here and a little piece there until the entire area threatens to collapse of its own weight.

This is a problem in many areas of Federal Circuit jurisprudence, but it is particularly evident in patentable subject matter. And it is there, in the broad thematic spaces of patentable subject matter, that the Supreme Court has engaged in its most detailed conversation yet with the Federal Circuit.

There are those who may argue that judicial decision-making can never be anything *but* the post-hoc justification of results to which judges are inclined based on their backgrounds and perspectives.<sup>5</sup> I

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2. *Bilski v. Kappos*, 561 U.S. \_\_\_\_, 130 S. Ct. 3218 (2010).

3. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. \_\_\_\_, 132 S. Ct. 1289 (2012).

4. *Ass'n for Molecular Pathology v. USPTO*, 689 F.3d 1303 (Fed. Cir. 2012). This case is commonly called the “Myriad” case, in reference to the name of the company holding the patents at issue.

5. See, e.g., Joseph C. Hutcheson, Jr., *The Judgment Intuitive: The Function of the “Hunch” in Judicial Decision*, 14 CORNELL L. REV. 274 (1929); JEROME FRANK, *LAW AND THE MODERN MIND* (1930). See generally Oliver Wendell Holmes, Jr., *The Path of the Law*, 10 HARV. L. REV. 457 (1897); Charles G. Haines, *General Observations on the Effects of Personal, Political, and Economic Influences in the Decisions of Judges*, 17 ILL. L. REV. 96 (1922); Joel B. Grossman, *Social Backgrounds and Judicial Decision-Making*, 79 HARV. L. REV. 1551 (1966); Dan Simon, *A Psychological Model of Judicial Decision Making*, 30 RUTGERS L.J. 1 (1998); cf. Gregory C. Sisk et al., *Charting the Influences on the Judicial Mind: An Empirical Study of Judicial Reasoning*, 73 N.Y.U. L. REV. 1377

will leave that jurisprudential argument for another day. At the very least, the crafting of reasoned, orderly structures of logic has the potential to create the appearance of fair and rational decision-making and to inspire the confidence upon which the consent of the governed may be based.

From the opposite perspective, to those who may suggest that arguing about whether objectivity in judicial decision-making can exist is passé, a relic of a bygone era,<sup>6</sup> I can only note that I continue to hear the argument raised in conversations among colleagues that in this post-realist world, everyone should know that decision-making is never fully objective, and decision-makers will never escape their biases. I suggest, at the very least again, that even if perfection is not ours to have, we can make considerable progress towards that goal, and we certainly cannot approach it if we do not make a concerted effort.

Encouraging considerable progress may be on the minds of the Justices as well. Implicit in the Supreme Court's discussion of patentable subject matter is the message that judicial decision-making can be done better.

In particular, one of the most striking parts of a recent Supreme Court decision on Section 101 of the Patent Code, which is the section on Patentable Subject Matter, occurs when the majority says the following:

Nothing in today's opinion should be read as endorsing interpretations of section 101 that the Court of Appeals for the Federal Circuit has used in the past.<sup>7</sup>

"In other words," the Supreme Court justices are saying to the Federal Circuit, "we disagree with everything you have ever had to say about the topic in your 30-year history." Implicit in such criticism may be the suggestion that the Federal Circuit is going about its work in the wrong way, and this essay will highlight other suggestions in the case law to the same effect.

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(1998) (hypothesizing that extralegal factors have a "modest" effect on judicial behavior); Chris Guthrie et al., *Blinking on the Bench: How Judges Decide Cases*, 93 CORNELL L. REV. 1 (2007) (positing that judges sometimes override their intuitions by deliberation).

6. See Stephen J. Morse, *An Accurate Diagnosis, But Is There a Cure?: An Appreciation of The Role of Science in Law by Robin Feldman*, 3 HASTINGS SCI. & TECH. L.J. 157, 160 (2011) ("These claims are 'crit tics,' which are boilerplate-type observations arising from critical theory.")

7. *Bilski*, 561 U.S. \_\_\_, slip. op. at 4.

In short, this essay looks at the way in which the Federal Circuit has been going about its work in patentable subject matter and the criticisms embodied in the Supreme Court's disapproval of that approach. It also sets out potential approaches to make the content of patentable subject matter jurisprudence consistent with the Supreme Court's desires. Part I of the essay describes recent Supreme Court cases on patentable subject matter, and those who are familiar with the topic may wish to skip this section. Part II illuminates the underlying conversation between the Supreme Court and the Federal Circuit, describing what the Supreme Court is striving for and the ways in which the Federal Circuit's decision-making falls short. This part also discusses the ways in which the Supreme Court's most recent attempt to demonstrate its jurisprudential approach falls short of its own dictates. Finally, Part III describes an approach to patentable subject matter that solves the devilishly difficult problems in patentable subject matter in a manner that is consistent with the Supreme Court's aspirations.

### **I. Recent Supreme Court Cases in Patentable Subject Matter**

The current morass in patentable subject matter lies at the tangled intersection of computer technology, life sciences, financial services, and the Internet. Just listing the types of inventions involved—not to mention the range of private, commercial, and public interest actors with a stake in the outcome—is enough to give anyone a headache, and the flood of amicus briefs filed with the cases reflects the level of interest and anxiety.

Section 101 of the Patent Act, which is understood to delineate the boundaries of patentable subject matter, notes only that “whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter” may obtain a patent.<sup>8</sup> Limitations on patentable subject matter have emerged, not from the language of the statute itself, but through case law. Although the words used to describe the categories of things that do not constitute the proper subject matter of a patent have shifted from one Supreme Court case to another, the forbidden categories at various times have included laws of nature, natural phenomena, mathematical formulas, mental steps, and abstract ideas.<sup>9</sup>

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8. See 35 U.S.C. § 101 (West 2012).

9. See *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) (listing all of these categories); *Diamond v. Diehr*, 450 U.S. 175, 185, 195 (1981) (listing all of these categories); *Bilski*, 561

The current confusion centers on patents related to methods of doing things.<sup>10</sup> The seeds were planted by a Federal Circuit decision in 1998 that allowed patents on business methods. For much of the 20th century, courts had excluded methods of doing business from the list of patentable subject matter, but in 1998, the Federal Circuit upheld business methods as a legitimate subject for patents in the *State Street Bank* case,<sup>11</sup> finding that prior cases had actually rested on concerns unrelated to patentable subject matter. The patent that the Federal Circuit upheld in *State Street* concerned a computerized hub and spoke accounting system for structuring mutual fund investments, but many business method patents granted in the subsequent years covered far less sophisticated inventions. These included a method of teaching janitors how to vacuum and a method of making toilet reservations for airplane travelers.<sup>12</sup> As one dissenting judge noted, “[p]atents granted in the wake of *State Street* have ranged from the somewhat ridiculous to the truly absurd . . . producing a thunderous chorus of criticism.”<sup>13</sup>

The question of whether or how to limit business method patents, however, implicates a number of other areas of invention. Business methods are essentially ways of going about doing something. Language that might limit business method patents,

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U.S. \_\_\_\_, 130 S. Ct. 3218, 3221, 3230, 3233 (2010) (listing all of these categories); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (listing laws of nature, physical phenomena, and abstract ideas); *Le Roy v. Tatham*, 55 U.S. 156, 14 How. 156, 175 (1853) (listing only abstract principles); *O’Reilly v. Morse*, 56 U.S. 62, 15 How. 62, 132 (1854) (listing only principles of nature).

10. See ROBIN FELDMAN, *RETHINKING PATENT LAW*, at ch. 4, *Where Do Processes of Nature End and Processes of Human Invention Begin?* (Harvard 2012), for a detailed history of the unfolding of the modern problems in patentable subject matter. The recent academic literature on patentable subject matter is even more voluminous than the amicus briefs. See also Rebecca Eisenberg, *Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After In re Bilski*, 3 CASE W. RES. J.L. TECH. & INTERNET 1 (forthcoming 2012), available at <http://www.patentlyo.com/files/eisenberg.wisdomordeadhand.patentlyo.pdf>, for a particularly thorough and interesting review of the cases, and one cited by the Supreme Court itself.

11. See *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998).

12. See U.S. Patent No. 5,851,117 (filed Apr. 23, 1997); U.S. Patent No. 6,329,919 (filed Aug. 14, 1999) (patenting a system and method for providing reservations for restroom use). IBM later renounced the patent, declaring that “We dedicated that patent to the public so that we could continue focusing on our high-quality patent portfolio.” See Troy Wolverton, *IBM Flushes Restroom Patent*, CNET NEWS (Oct. 11, 2002), <http://news.cnet.com/2100-1017-961803.html>.

13. See *In re Bilski*, 545 F.3d 989, 1004 (Fed. Cir. 2008) (en banc) (Mayer, J., dissenting).

therefore, might also be applied to patents on computer software, which may be expressed in terms of ways of going about getting a machine to do something. Limitations on business methods might also implicate diagnostic and therapeutic patents in the biotechnology space, which may be expressed as methods of diagnosis and treatment by doing something. Such limitations could also implicate patents on things like genes and antibodies, which, as I will describe below, are a strange combination of a product and a method of going about doing something.

In cases following *State Street*, the lower courts struggled to establish a test for patentable subject matter that could successfully navigate all of these areas while remaining faithful to the few Supreme Court cases in the arena. The Federal Circuit considered a “physical transformation” test, then tried out a “useful, concrete, and tangible” test, and finally moved on to the “machine or transformation test,” with none of these remotely capable of addressing the issues in a consistent and comprehensive manner.<sup>14</sup>

Problems in the area were compounded by the few pronouncements that the Supreme Court had made on the topic. In the late 1970s and early ‘80s, the Court handed down a series of patentable subject matter cases in an attempt to deal with the strange new worlds of computers and genetic engineering. Reflecting deep divisions among the Justices, the decisions were less than a model of clarity, and the Court retreated into silence on the issue for decades.

The following discussion will describe those cases from the 1970s and 1980s, and explain the lack of clarity for the lower courts. Specifically, in the biotechnology arena, the Supreme Court in 1980 had granted patent protection to a living organism in the case of *Diamond v. Chakrabarty*.<sup>15</sup> The patent holder in *Chakrabarty* had claimed a new bacterium obtained through genetic engineering. The bacterium was capable of breaking down multiple components of crude oil, something that no naturally occurring living organism could do. The general view at the time was that the Patent & Trademark Office wanted to grant patents to newly created living organisms but felt that the legal precedents were insufficient and that, as a regulatory body, it lacked the authority to reach that far. Thus, although denying the patent, the PTO was hoping that its decision

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14. See *In re Alappat* 33 F.3d 1541 (Fed. Cir. 1994); *In re Bilski*, 545 F.3d 989 (Fed. Cir. 2008). See also FELDMAN, *supra* note 10, for a more detailed discussion of the evolution of these tests.

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

would be reversed and that courts would open the door for the patenting of new living organisms.

One could suggest, perhaps, that *Chakrabarty* is an example of what happens when both sides of the courtroom want the same result and neither is pressing too hard on the logic required to get there. Perhaps overstates the case, given that four Justices did file a dissenting opinion. Nevertheless, there were curious moments in the opinion, of the type that one would not expect to see in a fully adversarial process. For example, in support of its conclusion that “the relevant legislative history . . . supports a broad construction” of patentable subject matter, the Court noted the following:

The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to “include anything under the sun that is made by man.”<sup>16</sup>

The quote, however, which may have been taken from one of the parties’ briefs, is out of context.<sup>17</sup> The original words were intended not to convey a broad notion of patentable subject matter but to convey the opposite. The full quote is the following:

A person may have “invented” a machine or a manufacture, which may include anything under the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled.<sup>18</sup>

It is an error that the Supreme Court finally rectified 32 years later, in the 2012 *Prometheus* opinion.<sup>19</sup>

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16. *Id.* at 308-09 (citing S. Rep. No. 82-1979, at 5 (1952); H. R. Rep. No. 82-1923, at 6 (1952)).

17. The following briefs use the truncated quote in support of an expansive interpretation of the statute. See Brief for Respondent at 38, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (No. 79-136); Brief on behalf of Genentech, Inc. as Amicus Curiae at 6, *Chakrabarty*, 447 U.S. 303 (1980) (No. 79-136); Brief on Behalf of the New York Patent Law Association, Inc. as Amicus Curiae at 9, *Chakrabarty*, 447 U.S. 303 (1980) (No. 79-136); Brief of Dr. Leroy E. Hood et al. as Amici Curiae at 18, *Chakrabarty*, 447 U.S. 303 (1980) (No. 79-136); Brief of Cornell D. Cornish as Amicus Curiae at 6, *Chakrabarty*, 447 U.S. 303 (1980) (No. 79-136).

18. See S. Rep. No. 82-1979, at 5 (1952), reprinted in 1952 U.S.C.C.A.N. 2399; H.R. Rep. No. 82-1923, at 6 (1952), reprinted in 1952 U.S.C.C.A.N. 2399.

19. For one of the few judicial opinions to note the error, see, for example, *In re Bilski*, 545 F.3d at 1000 (Mayer, J., dissenting) (recognizing that although the quote is used to suggest that Congress intended anything under the sun to be patentable, the legislative history says no such thing). For the language in the *Prometheus* case reflecting the full



In the end, the Supreme Court noted in *Chakrabarty* that the relevant distinction was not between living organisms and inanimate objects, but between products of nature and human-made inventions.<sup>20</sup> If the patent holder has produced a new organism “with markedly different characteristics from any found in nature and one having the potential for significant utility,” the Court concluded “[h]is discovery is not nature’s handiwork, but his own” and therefore patentable subject matter.<sup>21</sup> Thus, *Chakrabarty* ushered in the era of biotechnology patents. The lower courts would expand the *Chakrabarty* decision, granting patents to higher order creatures, such as mice and sheep, and to the components of life, such as genes, proteins, and antibodies.

In the computer arena, the Supreme Court decided two cases that seem almost indistinguishable in every way, other than the fact that the Court reached the opposite result in each. The 1978 case of *Parker v. Flook*<sup>22</sup> concerned catalytic conversion systems, which reduce the toxicity of emissions released by many types of vehicle engines. The Court in *Flook* rejected a patent on a process for programming an alarm to signal that the conversion is reaching a danger point, which would allow the engine to suspend the conversion at the optimal time. The process used a computer formula and a set of steps to constantly recalculate the proper moment to trigger the alarm, based on a series of changing factors.

The Court in *Flook* decided that the formula in the process was a computer algorithm. The court then ruled that a computer algorithm is analogous to a mathematical formula or a law of nature, and that as such, it falls outside patentable subject matter. Given that all other elements of the process were well-known, and the Court had ruled the algorithm unpatentable, the Court rejected the patent. Justice Stevens authored the opinion.

The decision in *Flook*, however, stood in contrast to developments throughout modern technology at the time. Computer programs may have been strange new beasts in patent law, but they were rapidly becoming integral to the types of industrial inventions

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quotation in its proper context, see *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. \_\_\_\_, 132 S. Ct. 1289, 1303-04 (2012).

20. See *Chakrabarty*, 447 U.S. at 313.

21. *Id.* at 310.

22. *Parker v. Flook*, 437 U.S. 584 (1978). As mentioned above, I have described the history, content, and implications of these cases [before, and] in far greater detail, in FELDMAN, *supra* note 10.

more familiar to the Court. A categorical denial of patent protections for computer programs seemed more and more discordant, as the introduction of computer programs throughout ordinary industrial inventions made these programs look more like a type of applied art than an abstraction or a law of nature.

A mere three years after *Flook*, the Supreme Court headed in a very different direction in the case of *Diamond v. Diehr*.<sup>23</sup> This time, Justice Stevens could only author a dissent, in the face of a majority that was willing to uphold the patent.

In *Diehr*, the patent holder claimed the process of constantly measuring the actual temperature inside a rubber-curing mold and feeding those measurements into a computer that would use a formula to repeatedly recalculate the time limit for the mold to be opened. The majority found the invention patentable, deciding that although the invention included an equation, the inventors were merely patenting a process for curing rubber, rather than trying to patent an equation itself.

An endless stream of commentators have noted that the inventions were quite similar, a similarity that I would describe in the following manner: *Diehr* was a process for updating the moment that rubber-curing should end, using a computerized formula and a set of steps to constantly recalculate the relevant moment to open the mold, based on a series of changing factors. *Flook* was a process for updating the moment that catalytic conversion should end, using a computerized formula and a set of steps to constantly recalculate the relevant moment, based on a series of changing factors. Expressed in terms like these, the inventions are strikingly similar. Nevertheless, the Supreme Court upheld the patent in *Diehr*, concluding that it was a different kind of invention from the one denied in *Flook*. The Court characterized the invention in *Diehr* as “an improved process for molding rubber articles,” while it described the *Flook* invention as nothing more than a formula for computing a number.<sup>24</sup>

The Federal Circuit later extended the logic of the *Diehr* opinion to cover not only computer programs imbedded in industrial machinery but also computer programs standing alone. The Supreme

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23. See *Diamond v. Diehr*, 450 U.S. 175 (1981).

24. Compare *id.* at 181, with *id.* at 186.

Court, however, would say nothing further on patentable subject matter for the next 24 years.<sup>25</sup>

The Supreme Court's first modern indication of its interest in patentable subject matter cases appeared in an aborted attempt to address the issue in 2005, by granting certiorari in the case of *LabCorp v. Metabolite*.<sup>26</sup> The patent in *LabCorp* revolved around homocysteine, an amino acid that is produced through natural processes in the human body.<sup>27</sup> For more than 50 years, doctors have known that high levels of homocysteine are associated with numerous serious health problems, but the reasons for that connection remain unclear. The patent holders were able to figure out a piece of that elusive connection by determining that high levels of total homocysteine are indicative of deficiencies in folic acid and vitamin B12.

Doctors already knew that deficiencies in folic acid and B12 could be linked to serious health problems. In particular, pregnant women who lack sufficient amounts of folic acid in their system run a far greater risk of delivering a baby with the severe birth defect spina bifida. Measuring folic acid and B12 in the body, however, is difficult. Thus, finding a correlation between high homocysteine levels, which can be measured in the blood, and deficiencies in folic acid and B12 allowed doctors to search for these vitamin deficiencies indirectly by measuring total homocysteine in the blood.

The accused infringer filed for certiorari on issues related to patentable subject matter, arguing that the patent holder was trying to claim a monopoly over a basic scientific relationship.<sup>28</sup> Perhaps anticipating the firestorm that would emerge, the Solicitor General's office recommended against taking the case, suggesting that the issues necessary to address the question had not been fully argued below. In particular, the Solicitor General noted pointedly that, "if this Court were to consider reevaluating almost a quarter-century of

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25. Although I have ordered these cases by category, their history is more intricately intertwined. For a detailed description of their history, see the summary in *Chakrabarty*, 447 U.S. at 306-07.

26. See *Labcorp v. Metabolite*, 548 U.S. 124 (2006).

27. I discuss this and other patentable subject matter cases in detail in FELDMAN, *supra* note 10.

28. See *LabCorp*, 548 U.S. at 125 (Breyer, J. dissenting).

administrative practice and lower court jurisprudence, it should do so based on a full record.”<sup>29</sup>

The Court politely ignored the suggestion, granting certiorari in the fall of 2005. By the time the Justices heard oral argument in the case in early 2006, much had transpired. A flood of amicus briefs poured into the Court from academics, medical professionals, the biotechnology industry, business organizations, financial service organizations, computer manufacturers, and software manufacturers.<sup>30</sup> Each group worried about the possible implications any *LabCorp* decision might have on patents in its domain. In addition to the cacophony of concerns, the makeup of the court had changed, with Justice Alito replacing Justice Sandra Day O’Connor in January of 2006. Following oral argument, a majority of the Court belatedly accepted the Solicitor General’s suggestion, dismissing the case as improvidently granted without further comment.

Justice Breyer, however, authored a dissent to the dismissal that was joined by Justices Stevens and Souter. The fact that only three Justices signed the dissent is interesting, given that a new Justice had arrived on the Court since the Court had accepted the case. It takes four votes to grant certiorari.<sup>31</sup> I will always wonder whether Justice O’Connor filed the fourth vote for granting certiorari in the case, leaving the other three to soldier on without her in the case when she left the Court.

The three dissenting Justices saw sufficient information in the record to deny patentability to the invention as falling outside the scope of patentable subject matter. Specifically, the Justices argued that the correlation between homocysteine and vitamin deficiency constitutes no more than a natural phenomenon.<sup>32</sup>

Perhaps the most interesting sections of the dissent can be found in the Justices’ discussion of why they felt their brethren should not have dismissed the case. The dissenting Justices argued that, “[e]ven if [our analysis] is wrong, it still would be valuable to decide this case,” because it would “help diminish legal uncertainty in the area”

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29. See Brief for the United States as Amicus Curiae at 19, *LabCorp*, 548 U.S. 124 (2006) (No. 04-607).

30. For a summary of the issues raised in amicus briefs by the various interest groups, see FELDMAN, *supra* note 10.

31. See PUBLIC INFORMATION OFFICE OF THE SUPREME COURT OF THE UNITED STATES, A REPORTER’S GUIDE TO APPLICATIONS PENDING BEFORE THE SUPREME COURT OF THE UNITED STATES 3 (2010) (explaining that “the votes of only four Justices are required to grant certiorari”).

32. See *LabCorp*, 548 U.S. at 135 (Breyer, J., dissenting).

and help Congress determine whether legislation might be needed, for example, to protect doctors from liability.<sup>33</sup>

The dissenting Justices also sent a pointed message to the Federal Circuit about the approach it had been taking in patentable subject matter. Given that the Federal Circuit had not directly addressed patentable subject matter, it had not directly applied any patentable subject matter test in *LabCorp*. Nevertheless, the dissenting Justices took the opportunity to express their disapproval of a test that the Federal Circuit had been using in other patentable subject matter cases, including those outside of biotechnology. Talking about the Federal Circuit's notion that a process is patentable if it produces a useful, concrete, and tangible result, the dissenting Justices commented that "this Court has never made such a statement and, if taken literally, the statement would cover instances where this Court has held to the contrary."<sup>34</sup>

In short, the Justices signaled quite strongly their view that the Federal Circuit's jurisprudence in patentable subject matter was in unacceptable disarray and that the Court had been silent long enough. It would simply be a matter of time before the right case came along.

That case arrived in the form of a business method case titled, *Bilski v. Kappos*.<sup>35</sup> The patent holder in *Bilski* claimed a patent on a method of hedging risk in the energy commodity industry. The Federal Circuit had upheld the patent, applying the latest in its series of tests for patentable subject matter. This latest approach was the so-called "machine-or-transformation test."

The flood of amicus briefs in *Bilski* made the ones in *LabCorp* look like a gentle stream. More than 70 briefs were filed—supporting one side, supporting the other side, or supporting no sides. They were filed by interest groups, industry groups, academics, individual entities, and more. As described above, any decision in the case, and any language used, had the potential to significantly impact not only business method patents but also patents in biotechnology, software, and a host of other areas.

While the *Bilski* case was pending at the Supreme Court, the Federal Circuit decided the case of *Prometheus v. Mayo*.<sup>36</sup> The patent

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33. *Id.* at 138.

34. *Id.* at 136.

35. *Bilski v. Kappos*, 561 U.S. \_\_\_\_, 130 S. Ct. 3218 (2010).

36. *See Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009). I have described the *Prometheus* case at length in other works as well. *See*

at issue in *Prometheus* concerned methods for calibrating the proper dosage of a certain category of medicines for gastrointestinal disorders. The method involved administering the drug to a patient, determining the level of the drug's metabolites in the patient's system, and then correlating the level of the metabolite in the blood with ranges that the inventor had determined to decide whether the drug needed to be increased or decreased.

In upholding the patent, the Federal Circuit used a remarkably flexible interpretation of the notion of "transformation" in its machine-or-transformation test. Prior to *Prometheus*, the Federal Circuit had described the transformation prong of the test as a consideration of whether the invention "transforms" a particular article into a different state or thing. This notion fit well with the Supreme Court's suggestion that the rubber-curing invention in *Diehr* was proper. There, one could clearly see an industrial process transforming raw ingredients into perfectly molded rubber.

In *Prometheus*, however, the Federal Circuit applied a far more expansive notion of "transformation," and one that arguably stretched it to the breaking point. The Federal Circuit found that the invention constituted transformation because the drugs were transformed as they were metabolized in the patient's body and the patient's body was transformed by receiving the drug. Under this interpretation, most inventions in the field of life sciences could pass muster; all of them would involve transformation of a human patient through treatment, although not all as directly as the transformation involved in digesting a medication.

The Federal Circuit may, indeed, have intended such a sweeping result. Recall that the Federal Circuit's decision in *Prometheus* came down during the time that *Bilski* was pending at the Supreme Court. A number of amicus briefs in *Bilski* had raised concerns that the Federal Circuit's machine-or-transformation test would be devastating for inventions in biotechnology and the life sciences. The Federal Circuit's opinion in *Prometheus* may have been the Circuit's way of trying to signal the Supreme Court that all would be well under the machine-or-transformation test. "Health care has nothing to worry about; we will get this right," was the implicit message.

A test that simply swept up all inventions in the life sciences had the virtue of protecting innovations in this important arena, but it

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FELDMAN, *supra* note 10, at 117-29; Robin Feldman & Deborah Furth, *The Intellectual Property Landscape for iPS Cells*, 3 STANFORD J.L. SCI. & POLICY 16 (2010) (peer review).

came at the price of defensible logic. How could the test offer courts the ability to clearly differentiate between patentable and non-patentable subject matter if it could be molded so drastically in different circumstances. As one would see across time, the *Prometheus* plea would be insufficient to save either the machine-or-transformation test or the invention in *Prometheus*.

Returning to the *Bilski* case, which was still pending when the Federal Circuit sent up its *Prometheus* smoke signals, *Bilski* was argued before the Supreme Court in October of 2009. Patent bloggers and patent mavens began watching for the opinion in the winter of 2010. As the weeks dragged on, however, it was clear that the Justices were having some difficulty coming to a meeting of the minds. In fact, the decision would not be released until the following summer, in the last week of the Court's term.

The claims in the *Bilski* patent were so broad and general that most people expected the Supreme Court to invalidate the patent and overturn the Federal Circuit. Indeed, all of the Justices did agree that the patent should be invalidated, but they agreed on very little else. There were three separate opinions, with two of them oddly bifurcated. Justice Kennedy delivered the opinion of the Court, which stood as the opinion of the court, except as to Parts II.B.2 and II.C.2. Justice Scalia declined to join those parts, although he joined the remainder of Justice Kennedy's opinion. Chief Justice Roberts and Justices Thomas and Alito joined Justice Kennedy for the full opinion.

Justice Stevens filed an opinion concurring in the judgment, joined by Justices Ginsburg, Breyer, and Sotomayor. Justice Breyer also filed a concurring opinion in which Justice Scalia joined only as to Part II.

Justice Stevens' opinion reads as if it had originally been written as the opinion of the Court. Justice Stevens, of course, had authored the dissenting opinion in *Diehr*, where he would have invalidated the computer-related rubber-curing invention. Numerous scholars and commentators have speculated that the Stevens opinion was originally intended as the majority opinion but that he could not obtain a sufficient coalition, so the majority shifted to Kennedy.<sup>37</sup>

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37. See, e.g., Joseph J. Berghammer et al., *Bilski v. Kappos: Some Business Methods Still Patentable After All These Years*, 3 LANDSLIDE 26, 28 (2010); Michael Risch, *Forward to the Past*, 2010 CATO S. CT. REVIEW 333, 351 (2010); John Duffy, *Bilski, Kenny Rogers, and Supreme Court Rule 46*, PATENTLY-O BLOG (June 25, 2010), <http://www.patentlyo.com/patent/2010/06/bilski-kenny-rogers-and-supreme-court-rule-46.html>; Tom Goldstein,

The majority's opinion in *Bilski* left many questions unanswered. The Supreme Court did not overturn the machine-or-transformation test completely. However, the Court opined that while machine-or-transformation may be an "important clue" or "investigative tool" for determining patentability, it could not be the sole measure.<sup>38</sup> The Court directed the Federal Circuit's attention back to the line of cases that included *Flook* and *Diehr* for the notion that abstract ideas do not constitute the proper subject matter for patents, but the Supreme Court left to the Federal Circuit the task of developing additional tests in the arena.

Perhaps the only clear messages to emerge from the *Bilski* opinion were the following: First, the notion of preemption would be key to any determinations in patentable subject matter. The Court's core concern revolved around whether granting the patent at issue would preempt or block out an entire abstract idea. Second, the Supreme Court disapproved of everything that the Federal Circuit had said in this arena, which is evident from the striking quote discussed above.<sup>39</sup>

Following the decision in *Bilski*, the Supreme Court remanded *Prometheus* to the Federal Circuit for reconsideration. The Federal Circuit on remand, however, did not show much of an inclination to change its ways in response to the Court's admonitions in *Bilski*. Rather, the Federal Circuit emphasized that although the Supreme Court had not endorsed machine-or-transformation as the sole test, it also had not overturned the test. Thus, the Federal Circuit decided that machine-or-transformation was still the appropriate test for the circumstances in the *Prometheus* medicine calibration case.<sup>40</sup> It upheld the patent again.

The Federal Circuit did add one more detail in its decision after remand in *Prometheus*. The Circuit held that not only did the invention satisfy the transformation prong of the test by transforming

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*Business Method Patents Nearly Bite the Dust*, SCOTUSBLOG (July 6, 2010), <http://www.scotusblog.com/2010/07/business-method-patents-nearly-bite-the-dust/>; John Schwartz, *Justices Take Broad View of Business Method Patents*, N.Y. TIMES (June 28, 2010), [http://www.nytimes.com/2010/06/29/business/29patent.html?\\_r=0](http://www.nytimes.com/2010/06/29/business/29patent.html?_r=0). See also Kedar Bhatia, *The Odd Opinion Distribution of OT 09*, DAILY WRIT (July 6, 2010), <http://dailywrit.com/2010/07/the-odd-opinion-distribution-of-ot-09/> (noting that Justice Stevens did not author any majority opinions in November 2009).

38. See *Bilski*, 561 U.S. \_\_\_\_, 130 S. Ct. at 3221.

39. See *supra* text accompanying note 7.

40. See *Prometheus Labs, Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1355 (Fed. Cir. 2010).



the patient, the invention also satisfied the transformation prong of test because blood was transformed in the lab during the process of testing for the level of the metabolite.

The court added this point to deal with a problem that had arisen in the Patent & Trademark Office's (PTO) interpretation of the original *Prometheus* decision. Although the court intended *Prometheus* to grant broad patentability to all life science innovations, the PTO had taken a narrow stance. The PTO had interpreted the notion that "a patient is transformed in the course of the invention" to mean that approval would be granted to only those inventions in which the physician decided to treat the patient. For inventions in which the physician ran the test, interpreted the results, and chose not to treat a patient with the particular approach, the PTO would deny patentability on the grounds that no transformation had occurred.<sup>41</sup> Under this interpretation, the PTO would be denying numerous inventions in the medical diagnostic space in which one might evaluate certain physical or genetic factors for a patient and decide that a particular course of treatment might not be beneficial. The Federal Circuit solved this pesky problem by adding the notion that the blood is transformed during the testing so that transformation could be found even if the physician chose not to use a particular treatment.

In adding the new twist, however, the Federal Circuit ran up against its earlier decision in the case of *In re Grams*.<sup>42</sup> The *Grams* inventor had listed a claim with a tremendously broad reach. Specifically, the inventor claimed, as a general matter, the process of (1) performing a clinical test on individuals, and (2) based on the data from that test, determining if an abnormality existed, and (3) determining possible causes of any abnormality by using an algorithm. The Federal Circuit, not surprisingly, had rejected the patent in *Grams*.

One could argue that in carrying out the *Grams* invention, the medical professionals who performed the clinical tests, by necessity, would have transformed the blood or other tissue samples. Thus, under the Federal Circuit's approach in *Prometheus*, the *Grams* invention would have satisfied the "transformation" prong of the test.

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41. See, e.g., U.S. Patent and Trademark Office, "Office Action," Application No. 11/338,957 (Mar. 3, 2010), at 4-6. For additional explanation of how this approach was playing out in PTO decisions, see FELDMAN, *supra* note 10, at text accompanying ch. 4 note 99.

42. See *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989).

The Federal Circuit tried to resolve the tension with some creative hand-waving, by suggesting that the clinical tests in *Grams* were for the purposes of obtaining data while the clinical tests in *Prometheus* were for the purposes of treating the patient. The ultimate aim of both inventions, however, involved the treatment of the human patient, making the Federal Circuit's distinction difficult to discern.<sup>43</sup>

The *Prometheus* decision after remand offers an example of what I described in the opening as "death by tinkering." Here, the Federal Circuit had a problem with its stated test, a problem indicative of weakness in the underlying logic. Rather than rethinking the test, the Circuit made a small adjustment that appeared to solve its immediate problem, while creating even greater inconsistency and illogic throughout the doctrinal area.

Following the Federal Circuit's decision on remand, the Supreme Court again granted certiorari in the case, now styled *Mayo v. Prometheus*. In an opinion written by Justice Breyer, the Court reversed the Federal Circuit, finding that the invention in *Prometheus* did not constitute patentable subject matter.

In surprising contrast to the divided opinions of *Bilski*, the decision in *Prometheus* was unanimous. The unanimity of the court, as well as authorship of the opinion by Justice Breyer, could suggest that *Prometheus* was the case for which Justice Breyer had been waiting and preparing his colleagues since his original shot across the bow in *LabCorp*. Both of the cases concern approaches to diagnosing and treating a patient based on correlations that the inventor had developed between the level of certain substances in the blood and the patient's disease state. Broadly speaking, both are examples of the emerging field of personalized medicine, which I will discuss further below.

The Supreme Court's unanimous decision in *Mayo v. Prometheus* opens with a discussion of the Court's prior decisions in patentable subject matter. It reads almost like a tutorial—one on putting together a group of cases to form a coherent doctrinal path or a brief to an appellate court. Of particular note in the opening section is the Court's admonition that patent eligibility cannot "depend simply on the draftsman's art."<sup>44</sup> The Court also characterizes its prior precedents as warning against upholding

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43. See FELDMAN, *supra* note 10, at 120–21 (describing problems with the Federal Circuit's treatment of *In re Grams* in the *Prometheus* decision).

44. See *Mayo Collaborative Servs., v. Prometheus Labs., Inc.*, 566 U.S. \_\_\_\_, slip op. at 3, 132 S. Ct. 1289 (2012).

process patents that preempt the use of a natural law.<sup>45</sup> These precedents, explains the Court, insist that process claims contain some inventive concept sufficient to ensure that the patent amounts to significantly more than a patent on the natural law itself.<sup>46</sup>

The Court found that the range of levels at which a particular drug's metabolite would indicate a need for more or less medication should be considered a natural law. Therefore, upholding the patent would risk disproportionately tying up the use of the natural law.<sup>47</sup> In addition, outside of the part of the patent that had been found to constitute a natural law, the Court found that the invention consisted of no more than well-known, routine steps.<sup>48</sup>

Regarding the machine-or-transformation test, the Court disagreed with the result that the Federal Circuit reached in applying the test and also with the Federal Circuit's decision under the circumstances to apply the test in the first place. First, the Supreme Court explained that the invention would not satisfy the transformation prong of the machine-or-transformation test because the types of transformation identified by the Federal Circuit in the case were insufficient.<sup>49</sup> On the Federal Circuit's notion of transforming the patient by administering the drug, the Supreme Court found that such activity is "irrelevant" to the transformation question.<sup>50</sup> Rather, the Supreme Court focused on the "administering" aspect of the activity and argued that administering the drug involved no more than helping to "pick out the group of individuals . . . interested in applying the law of nature."<sup>51</sup> Although the opinion does not specify, the Justices appeared to be thinking of the patients taking the drug as being the individuals applying the law of nature. At other places in the opinion, the Justices suggest that the doctors, rather than the patients, are the relevant audience interested in applying the law of nature.<sup>52</sup> Thinking of doctors, who are practicing their scientific craft, as the audience interested in applying the law of nature makes more sense intuitively than the notion of the

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45. *Id.*

46. *Id.*

47. *Id.* at 4.

48. *Id.* at 9.

49. *Id.* at 19-20.

50. *Id.* at 19.

51. *Id.*

52. *Id.* at 9.

patient as the one applying the law of nature. The latter conjures up the notion of patients treating themselves.

On the Federal Circuit's suggestion that the "transformation" also occurs because the blood sample necessarily is transformed in the process of testing it to determine the metabolite level, the Supreme Court ruled that this step has the potential to be satisfied without any transformation, if science develops a way to measure metabolite levels without a blood test. Thinking about technology that does not exist is an unusual approach in patent law, but the Justices may have been thinking about problems that can occur when the law allows patents to reach beyond the state of the art at the time of the invention.<sup>53</sup> The Justices may have been suggesting broadly that in defining the appropriate range of patentable subject matter, one should contemplate not only the preemptive effects that might occur today but also the preemptive effects that might occur in the future as technology advances. This could be a fruitful concept for lower courts to keep in mind in the context of defining questions about the scope of patents and the breadth of patentable subject matter.<sup>54</sup>

In addition to rejecting the Federal Circuit's interpretation of the concept of transformation, the Supreme Court also held that the entire machine-or-transformation test was irrelevant for the case:

[In] stating that the "machine-or-transformation" test is an "important and useful clue" to patentability, we have neither said nor implied that the test trumps the "law of nature" exclusion. That being so, the test fails here.<sup>55</sup>

In other words, the invention would fail the test if the court were to apply it, but the test itself fails to fit the analysis required in the case. With these pronouncements, the Supreme Court reversed the Federal Circuit and rejected the patent, leaving courts and commentators to pour over every word of the opinion in search of clues to what might satisfy the Court in patentable subject matter in the future.

Shortly after the decision in *Prometheus*, the Supreme Court remanded the case of *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office* for reconsideration in light of *Prometheus*.

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53. See FELDMAN, *supra* note 10, at ch. 6, Beyond the State of the Art.

54. See *id.* (arguing that patents should not be defined to reach beyond the state of the art at the time of the invention).

55. See *Prometheus*, 566 U.S. \_\_\_\_, slip op. at 19 (citations omitted).

Colloquially known as the Myriad case, *Ass'n for Molecular Pathology* considered whether patents on isolated gene sequences and related products could constitute patentable subject matter. The case also included diagnostic claims similar to the ones in *Prometheus* as well as other types of claims. The remand signaled that the Supreme Court intended *Prometheus* and *Bilski* to apply broadly to a variety of subject matter patentability questions, not just the categories of inventions specifically at issue in those cases.

## II. The Conversation

The prior section of this essay set out the details of the cases through which the Supreme Court and the Federal Circuit have carried out their conversation. This section will describe the conversation itself.

Following the aborted attempt in *LabCorp*, the conversation between the Supreme Court and the Federal Circuit began in earnest in *Bilski*. (*Bilski* is the case that concerned patentability of a business method for commodity hedging.) As described above, in reversing the Federal Circuit, five Justices signed portions of the *Bilski* opinion that included language expressing simple and complete disapproval of everything the Federal Circuit has ever said about patentable subject matter.<sup>56</sup> How is it possible that the Federal Circuit has said nothing that the Supreme Court Justices wish to support?

Implicit in this mild-mannered but remarkably stark criticism is the suggestion that the Federal Circuit has been going about its work in the wrong way. What is it, then, that the Circuit has been doing improperly?

Understanding the content of the message requires putting *Bilski* and *Prometheus* together, and the message plays out in three different, but related, strands. The first strand concerns the appropriate way to create doctrinal tests, such as the one the Federal Circuit crafted when it designated “machine-or-transformation” as the way to determine whether a claimed invention constitutes a law of nature. One could describe what the Supreme Court is complaining about as logical faithfulness—that is, in creating the doctrinal test, are you faithful to the underlying legal concept?

The Supreme Court’s message begins in *Bilski*, when the Court explained that machine-or-transformation is an important and useful

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56. See *Bilski v. Kappos*, 561 U.S. \_\_\_, slip op. at 4 (2010).

clue, and an investigative tool, but not the sole test.<sup>57</sup> When the Federal Circuit failed to respond as the Justices had hoped, the Justices amplified that comment in *Prometheus* by saying the following:

[I]n stating that the “machine-or-transformation” test is an “*important and useful clue*” to patentability, we have neither said nor implied that the test trumps the “law of nature” exclusion.<sup>58</sup>

It is as if the Justices were saying to the Federal Circuit, “you are not asking the questions right. Yes, you have a piece of the puzzle, but there is a problem with your use of proxies (such as machine-or-transformation; useful, concrete, and tangible, etc.). It isn’t that everything embodied in the proxy is wrong; the problem is that you are forgetting what the proxies are testing for and allowing the proxies to take on a life of their own.”

In the second strand of the message, the Supreme Court took aim at the Federal Circuit’s willingness to drift unmoored from precedent—be it legislative or judicial. On the issue of fidelity to legislative language, the Supreme Court chided the Federal Circuit, arguing that adopting machine-or-transformation as the sole test for patentable subject matter for process patents would violate principles of statutory interpretation.<sup>59</sup> The Court pointed out that the Patent Act specifically defines the term “process” to mean “process, art or method[.]”<sup>60</sup> The Court then noted dryly that it was unaware of any ordinary meaning of the definitional terms “process, art or method” that would require them either to be tied to a machine or to transform an article.<sup>61</sup>

On the judicial front, the Supreme Court turned to *Gottschalk v. Benson*, its own 1972 case from which the Federal Circuit would eventually derive the requirement that all process patents must constitute either a machine or transformation. The Justices pointed out that the *Benson* opinion explicitly rejects that notion.<sup>62</sup>

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57. *Id.* at 8.

58. *Id.* at 19 (citations omitted).

59. *Id.* at 6-7.

60. *Id.* at 7; 35 U.S.C. § 100(b).

61. See *Bilski*, 561 U.S. \_\_\_\_, slip. op. at 7.

62. *Id.*

It is argued that a process patent must either be tied to a particular machine or apparatus or must operate to change articles or materials to a “different state or thing.” We do not hold that no process patent could ever qualify if it did not meet the[se] requirements . . . .<sup>63</sup>

In general, the Federal Circuit has been extraordinarily sloppy about following precedent, either its own or precedent set by the Supreme Court. Failing to keep its own house in order, the Circuit has allowed open splits to languish for extended periods of time, as some panels flatly refuse to follow the path established by prior panel decisions.<sup>64</sup> Moreover, Federal Circuit decisions have been less than faithful to precedent from above.<sup>65</sup>

Although there are multiple causes for the Federal Circuit’s difficulties, to some extent, the problems reflect the Federal Circuit’s tolerance for discordance. This is apparent both procedurally, in terms of not cleaning up its own deviations, and substantively, in terms of doctrinal areas that do not work together as a logical whole. The notion of discordance leads to the third and most important

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63. *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972).

64. *See, e.g.*, *Atl. Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279, 1281 (Fed. Cir. 1992) (Rich, J., dissenting from denial of reh’g en banc) (arguing that a later panel’s refusal to follow circuit precedent was not only insulting to colleagues, “it is mutiny. It is heresy. It is illegal.”); *Univ. of Rochester v. G. D. Searle & Co.*, 375 F.3d 1309 (Fed. Cir. 2004) (Rader, J., dissenting) (denial of reh’g en banc) (citing a 2002 government brief politely point out that “although this Court has addressed the ‘written description’ requirement of section 112 on a number of occasions, its decisions have not taken a clear and uniform position regarding the purpose and meaning of the requirement.”). *See also* Robin Feldman, *Plain Language Patents*, 17 TEXAS INTELL. PROP. L.J. 289, 300–01 (2009) (discussing unresolved splits in the product-by-process doctrine and the written description doctrine that persisted for an extended period of time); Albert Tramosch, *The Dilemma of Conflicting Precedent: Three Options in the Federal Circuit*, 17 AIPLA Q.J. 323 (1989) (describing three options for efficient resolution of conflicting precedent); Gregory S. Maskel, *Product-by-Process Patent Claim Construction: Resolving the Federal Circuit’s Conflicting Precedent*, 17 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 115 (2006) (describing split concerning process patents and offering a resolution); Michael A. Leonard II, *The Death of the Written Description Requirement? Analysis and Potential Outcomes of the Ariad Case*, 158 INTELL. PROP. COUNSELOR ARTICLE II (2010) (explaining conflicting rulings on the written description requirement).

65. *See, e.g.*, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 72 F.3d 857 (Fed. Cir. 1997), *rev’d by* 535 U.S. 722 (2002) (deviating from decision of Supreme Court on the grounds that it found the test unworkable); *cf. Maropakis Carpentry, Inc. v. United States*, 609 F.3d 1323 (Fed. Cir. 2010) (majority panel opinion noting that the dissenting judge relied upon a case that stands for the opposite proposition). *See also* Feldman, *supra* note 64 (describing failure to follow precedent in doctrine of patent misuse that continues today).

strand in the Supreme Court's message to the Federal Circuit. One could describe this line of complaint as related to logical coherence.

As described in Part I, the Federal Circuit all too frequently has been drawn towards doctrinal rules that resolve the issue of the moment but lack general applicability and logical coherence. The approach feels comfortable, because the outcome of the case is acceptable, but the resulting doctrines are intellectually and operationally unsatisfying. Moreover, the cases produce what I would describe as death by tinkering—change a little piece here and a little piece there until the entire area threatens to collapse of its own weight.

A classic example of the approach can be seen in the Federal Circuit's decision in the gene patenting case, *Ass'n for Molecular Pathology*. In a concurring opinion, Judge Moore noted that although gene sequences when isolated in a lab do have literal chemical differences from gene sequences as they exist in the human body, it is not clear that these distinctions make any meaningful difference.<sup>66</sup>

Identifying a literal difference is an insufficient basis for any legal decision.<sup>67</sup> One must ask why the difference matters in the full doctrinal framework of the question: What are we really trying to establish, not just for gene sequences or even life science patents, but for patents as a whole?

The same type of problem arose in the Federal Circuit's analysis of the invention in *Prometheus*. Recall that the Federal Circuit on remand had determined that the invention satisfies the transformation prong of the machine-or-transformation test because the process involves transformation of the human body or transformation of blood taken from the human body.<sup>68</sup> As noted above, the test stretches the notion of transformation to the breaking point, potentially sweeping all medical inventions under the protective wing of transformation.<sup>69</sup> The interpretation also conflicts

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66. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1364-65 (Moore, J., concurring), *vacated, appeal reinstated by Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 467 Fed.App'x 890 (Fed. Cir. 2012).

67. See FELDMAN, *supra* note 10, at 111 (noting that while scientists can tell us how things are different, they cannot tell us whether that difference should matter in the context of the legal doctrines at hand).

68. See *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1355 (Fed. Cir. 2010).

69. See *supra* text accompanying notes 36-37. See also *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. \_\_\_\_, slip. op. 19 (noting that the transformation of



with other Federal Circuit decisions, further indicating weakness in the underlying logic of the test.<sup>70</sup> Nevertheless, the Federal Circuit reaffirmed the test, making a small adjustment to resolve the immediate problems, which created ever more inconsistency and unworkable logic throughout the doctrine.

In response, the Supreme Court's opinion in *Prometheus* is rife with language pushing the Federal Circuit towards improving its doctrinal approach. When the Court said that it wanted to see "practical assurance that the process is more than a drafting effort," and later when the Court complained about patent language that has the effect of "simply appending conventional steps specified at a high level of generality," the Court was partly speaking to the patent bar about the documents it had drafted. The Court also, however, appeared to be speaking to the Federal Circuit, suggesting that it should straighten up the mess that its decisions have wrought.

One could characterize the Supreme Court's pronouncements as a preference for flexible standards rather than bright-line rules.<sup>71</sup> The Supreme Court certainly has rejected the bright-line approaches, such as machine-or-transformation and concrete/useful/tangible, that the Federal Circuit has offered. My own view is that the Supreme Court's decisions are an encouragement towards systems of more comprehensive logic. The Court is not saying that you may not have bright-line rules; it is saying that you cannot have rules of convenience—ones that have so little coherence at their core that they can be manipulated to reach any result.

Perhaps it is not surprising to see a court of specialization relying on minute distinctions of questionable value, particularly a court with science as its domain. In many circumstances, courts have manifested the irresistible urge to deflect difficult decisions by cloaking themselves in a veil of scientific distinctions, regardless of whether those distinctions speak to the legal issue at hand.<sup>72</sup> With a court of specialization, buffered by its own dialect and isolated from the more

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human body is irrelevant and the transformation of human blood could become unnecessary with hypothetical scientific advances).

70. See *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989); see also *supra* text accompanying notes 44–45 (describing the way in which *Prometheus* is inconsistent with the *Grams* precedent).

71. See Eisenberg, *supra* note 10, at 23 (describing the Federal Circuit's approach in patentable subject matter as characteristic of bright-line rules, with the Supreme Court's approach expressing a preference for flexible standards).

72. See ROBIN FELDMAN, *THE ROLE OF SCIENCE IN LAW* (Oxford 2009) (chronicling this history).

frequent channels of review that provide discipline for other courts, such difficulties may be structurally predictable.<sup>73</sup> As I have noted in the past, this type of court can easily lose itself in the technical aspects of a case, providing camouflage for the failure to resolve issues or to resolve them in a rational manner. Most important, the parties tend to shroud themselves in jargon, which can obscure the relevant issues for the court itself and for the Supreme Court justices who might consider wading into the issues. Regardless of these temptations, the Supreme Court appears to be reminding the Federal Circuit that logic and coherence should prevail.

Of course, wisdom can be easier to expound than to live by. When the Supreme Court tries to demonstrate the outlines of a test for patentable subject matter, the Court runs into its own problems in trying to construct a framework of general applicability that displays logical consistency. In an effort to draw together the precedents in patentable subject matter to form the basis of a coherent approach, the Court stumbled when it insisted on preserving both the *Flook* and the *Diehr* opinions, trying to articulate a principled distinction between the two.

As described above, the two cases really are quite difficult to distinguish. First we have *Diehr*:

a process for updating the moment that rubber-curing should end, using a computerized formula and a set of steps to constantly recalculate the relevant moment, based on a series of changing factors.

With remarkable similarity, we have *Flook*:

a process for updating the moment that catalytic conversion should end, using a computerized formula and a set of steps to constantly recalculate the relevant moment, based on a series of changing factors.

Expressed in this manner, the two are strikingly similar, and it is difficult to understand why the Supreme Court would reject one and uphold the other. And for that matter, if the process of constantly calculating the curing of rubber and determining when to open the mold is patentable, why can't we think of the invention in *Prometheus*

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73. See *id.* at 193 (describing problems at the Federal Circuit as structurally predictable, as explained in the remainder of the paragraph above).

as the process of determining the moment that the patient has been properly cooked?

I believe the Supreme Court in *Prometheus* was trying to say something like the following: “The rubber process inventor put together a series of steps. These steps were not standard practice before, because it was not possible to perform them without the advent of computers. Just adding a computer program element in and of itself, however, does not create a patentable subject matter problem. The issue turns on what the inventor is trying to claim. Is the inventor trying to claim a specific process or is the inventor trying to claim the computer program, or this type of computer program, in general?”

The distinction above is a difficult one to maintain, however, given the similarity of the facts in *Flook* and *Diehr*. Moreover, if the Supreme Court wanted to make the point that one should not get lost in the niceties of framing and draftsmanship, *Flook* and *Diehr* were an unfortunate choice for manifesting the proper doctrinal approach. One could easily argue that the different result in the two cases rested on better lawyering rather than any difference in the character of the inventions.<sup>74</sup>

Moreover, the Supreme Court’s criticism of the Federal Circuit, for failing to faithfully follow the language of the Patent Act, rings somewhat hollow. Recall that the Justices chided the Federal Circuit for finding machine and transformation limitations hidden in the folds of the Patent Act’s language defining the term “process” to mean “process, art or method.”<sup>75</sup> By the same token, one would have to ask how the Supreme Court’s own limitations on patentable subject matter have arisen from Patent Act language. As one scholar has commented, one could argue that the Court’s limitations on patentable subject matter, such as those prohibiting the patenting of laws of nature or mathematical formulas, seem to have simply emerged from the primordial ooze of the 19th century.<sup>76</sup>

Nevertheless, in its patentable subject matter communications to the Federal Circuit, the Supreme Court has quite clearly conveyed a series of messages, as well as indicated its intent to continue the conversation. Now that the Supreme Court has remanded the *Myriad*

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74. FELDMAN, *supra* note 10.

75. *See supra* text accompanying notes 61–63.

76. This wonderfully colorful comment was made by Peter Menell at the Berkeley Center for Law & Technology Conference on Patentable Subject Matter in the Health Sciences in April 2012.

case on gene patenting, with instructions that the Federal Circuit reconsider its decision in light of *Prometheus*,<sup>77</sup> one can anticipate the likelihood of further conversation through this medium.

Software manufacturers who have watched *Bilski* and *Prometheus* with trepidation and who face calls for the elimination of patents on software will be parsing every word of the opinions for clues to the future. As a software manufacturer, one could nurture hope in the fact that in reaffirming *Diehr*, the Court implicitly suggested that not *all* computer-related inventions should be treated as natural laws or abstract ideas and that some will pass muster. Nevertheless, looking at the Court's distain in *Prometheus* for "conventional steps specified at a high level of generality," I would be very worried if I were a software maker. The phrase "conventional steps specified at a high level of generality" could describe many software patents that have been issued by the PTO across time. As noted above, I would predict that *Ass'n for Molecular Pathology* and one yet-to-be-determined case on software patents are likely to form the third and fourth legs of the court's table in this realm.

### III. Finding the Solution

In anticipation of the further conversation ahead, this section suggests a doctrinal approach to provide logical coherence throughout patentable subject matter. The approach also has the potential for harmonizing, to the greatest extent possible, the Supreme Court's past precedents.

Much of this essay has focused on process patents—that is, patents on a process of doing something. Patent courts and commentators generally divide inventions into two separate types: (1) patents on processes and (2) patents on products. I would argue, however, that everything in the world of innovation does not fall so neatly into those two categories.

Consider genes, for example. Patents on gene sequences are treated as product patents, and genetic material in a laboratory petri dish is certainly as tangible as any drop of chemical in that dish would be. Nevertheless, genes are a strange type of product. Human genes are literally a sequence of nucleotides that operate as a set of

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77. To add to its confusing history, the case has been renamed, once again, and is now styled as *Ass'n for Molecular Pathology et al. v. Myriad Genetics, Inc.* See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (March 26, 2012) (vacating and remanding to the Federal Circuit in light of the Court's decision in *Mayo Collaborative Services et al. v. Prometheus Laboratories, Inc.*).

instructions for carrying out some function in the human body.<sup>78</sup> Normally, a set of instructions is considered a process, rather than a product, but once again, genes are as tangible as any product one might create.

It takes a certain amount of mental gymnastics to contemplate a thing whose nature combines both product and process. If one could create an instruction manual that operated on its own, for example, would it be a process or a product? One could argue that software, to some extent, is an example of another hybrid of this kind. Software itself could be thought of as a set of instructions. It is a set of instructions, however, that is designed to operate itself, to produce a set of results.

It is possible that within this strange world of hybrids, at the intersection of biology and software, one could find a solution to patentable subject matter. Personalized medicine actually falls at this intersection, and inventions in the field may offer a road map for a solution. Although the Supreme Court did not find patentability in the personalized medicine invention in *Prometheus*, more sophisticated personalized medicine inventions may pass muster. In addition, the marriage of biology and software is the perfect opportunity to highlight where the law has gone off course in patentable subject matter and how to fix the problem.

A key aspect of the problem unfolded as computer and software inventors in the 1980s tried to figure out how to craft claims that the Supreme Court would be willing to accept. One thing was clear from the Court's decision: the claims had to avoid looking anything like mathematics or they would risk being labeled algorithms. As a result, patent practitioners began drafting patents claims by describing what the computer or software was doing in simple English terms. The approach had the incidental effect of covering many different ways of accomplishing the same result, giving the patent holder control of a tremendously broad swath of territory.<sup>79</sup>

The patent system continues to strain under this legacy. Consider, for example, a recent patent on a user interface. Following

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78. For a more complete discussion of genes in this manner, an in-depth discussion of possible solutions in the *Association for Molecular Pathology* case, and additional discussion of the personalized medicine concepts raised here, see Robin Feldman, *Whose Body Is It Anyway? Human Cells and the Strange Effects of Property and Intellectual Property Law*, 63 STANFORD L. REV. 1377 (2011).

79. I have described this history and its effects in additional detail in FELDMAN, *supra* note 10, at 108–13.

is the actual claims language from the patent. The patent claims a monitor, a memory, and a transmitter and a processor configured to: Monitor a product for a predefined trigger event, increment a counter, cause the display of a user interface, and if the counter exceeds a threshold, cause the memory to store an input received from the interface and cause the transmitted to transmit the input to a server.<sup>80</sup>

This language in this patent is incredibly broad. The point is that using simple prose to describe what a computer is accomplishing has the effect of granting a huge swath of territory to the inventor, with the potential to reach well beyond what the inventor actually has accomplished up to that point. Such is the legacy of our aversion to math.

One effective pathway for limiting the reach of patents in software or bioinformatics has been blocked by Supreme Court language expressing disapproval of so-called “field of use” restrictions. Rejection of field of use restrictions flows from the notion that if a patent claims a law of nature, one cannot save the patent by limiting use of that law of nature to a particular field. For example, a patent claiming the law of gravity cannot be saved by limiting use of the law of gravity to the field of building bridges.<sup>81</sup> Nevertheless, all inventions, to some extent, involve specific applications of natural laws. It would be difficult to imagine any mechanical invention, for example, that did not apply the law of gravity in some aspect.

The key is distinguishing between two types of patents. On the one side are those patents in which the field of use restriction does no more than mask preemption of the natural law in a specific area. On the other side are those patents that represent an application of that natural law in a particular commercial endeavor.

The Supreme Court’s general rejection of field of use restriction continues to echo throughout modern Supreme Court language. For example, the Court in *Prometheus* quoted its own language from *Bilski*, quoting its own language from *Flook*, that “limiting an abstract idea to one field of use . . . did not make the concept patentable.”<sup>82</sup> In crafting this quote, the Court indicates a long legacy against field of use restrictions. I would suggest that this legacy—long standing as it

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80. See U.S. Patent No. 7620565.

81. See Feldman, *supra* note 78, at 1400–01 (using the bridge building example).

82. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. \_\_\_, 132 S. Ct. 1289, 1301 (2012).

is—rests on fundamental misconceptions about what an algorithm is, how a computer program operates, and the avenues available for limiting the reach of computer claims.

In computer science, an algorithm is defined as a series of steps performed on input data by a computer.<sup>83</sup> A series of steps performed on input data by a computer will raise preemption concerns in some circumstances and not in others. One must know much more about a computer program—beyond the term “algorithm”—to determine whether granting a patent on the program would result in preemption problems. For example, some computer algorithms are based on properties of particular types of data. This sort of algorithm, one that can be used on a variety of types of data, threatens to create preemption problems. If we are asked to grant a patent on a software program that works with entire sets of numbers or types of data, we should have concerns about the breadth of inventions that would be blocked out as a result. In contrast, a computer algorithm applied to a specific type of input data in an effort to reach specific types of output data would not raise the same preemption concerns.

As long as the patent system’s approach to software revolves around broad, prose language descriptions of what the software does, field of use restrictions will remain the most effective way to ensure that inventors are limiting their patents to a particular application of natural laws. At its core, this is the distinction that the Supreme Court is struggling to make out of *Flook* and *Diehr*. The Court’s decisions in these two cases can be characterized as focusing on whether the inventor was trying to claim a type of computer program in general, rather than a specific application and a specific way to apply the type of program.

In perfect candor, a completely satisfying resolution of *Flook* and *Diehr* would benefit from an acknowledgment that while the expressions of the claims and the discussion of their preemption risks diverged, the facts of the two cases were quite similar. Sections of *Flook* are simply incompatible with the decision in *Diehr*, and one could argue that the court would be better served by retreating from its first, and perhaps imperfect, foray into computer-related inventions in *Flook*.

In my view, the proper test for determining patentable subject matter should focus both on preemption and on the tests for

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83. See FELDMAN, *supra* note 10, at 132–34 (describing algorithms and expanding on the concepts briefly discussed here concerning how different types of algorithms raise differing levels of preemption concerns).

patentability as a whole. I would express the basic inquiry in the following manner: Considering the limitations of the patent system as a whole, are we likely to have preemption problems with the subject matter of this patent?<sup>84</sup>

Just as the test above would yield different results for different types of computer algorithms, so should it yield different results for different types of personalized medicine inventions. Personalized medicine inventions vary greatly in their composition and sophistication. *LabCorp* could be characterized as a relatively simple one, in which a single biomarker is measured and correlated with a disease state.

These inventions, however, can be vastly more complex. Some use hundreds of biomarkers combined with complex machine-learning algorithms to search out and identify patterns or groups of markers that may, to some measurable degree, indicate the benefit of a particular treatment or approach. The inventive models that result are probabilistic and interpretative. They do not reflect any individual's natural state, let alone the state of nature as a whole. They are not merely a reflection of nature; they are an interpretive model of nature.

Properly drawn, claims to the type of complex, personalized medicine invention described here would leave plenty of room for the development of competing models of nature, even competing models relating to that particular disease state. Thus, they should not raise the same types of preemption concerns.

As described above, a computer algorithm applied to a specific type of input data in an effort to reach specific types of output data should not raise preemption concerns. Similarly, a bioinformatics statistical model using a fixed set of markers to produce a specific diagnosis would not threaten to preempt the same diagnosis using different markers or different statistical models. Although neither *LabCorp* nor *Prometheus* could satisfy the Court's vision of a sufficient addition to what nature or laws of nature have to offer, perhaps the interpretive models of highly sophisticated personalized medicine inventions could.

In short, the Supreme Court is already deep into its conversation with the Federal Circuit, and it has so much more to say. Analyzing the issues as described above could help the Supreme Court's various forays into the world of computer-related inventions as well as create

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84. See Feldman, *supra* note 78, at 1391–95.



a doctrinal structure applicable across all areas of patentable subject matter with logical consistency.