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Angela D. Follett

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THE PROBLEM WITH *BILSKI*: MEDICAL DIAGNOSTIC PATENT CLAIMS REVEAL WEAKNESSES IN A NARROW SUBJECT MATTER TEST

ANGELA D. FOLLETT*

INTRODUCTION

The Constitution grants Congress broad power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹ This grant created the U.S. Patent System, subsequently codified in Title 35 of the United States Code.² Courts consider compliance with 35 U.S.C. § 101, the patentability and utility requirement, to be a threshold requirement to the grant of a patent.

35 U.S.C. § 101 states: “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor [sic], subject to the conditions and requirements of this title.”³ The first clause of this section provides a preliminary bar to patentability, while the second requires compliance with other sections of the title, namely §§ 102, 103, and 112, that provide detailed standards for patentability.⁴ The inquiry under § 101 is, however, not trivial; while it is considered by some to be “a threshold inquiry,” any patent which fails to meet the requirements of this section will be rejected regardless of whether or not it meets the other

* Gustavus Adolphus College, BA 2001, University of Minnesota, PhD 2006, University of St. Thomas, JD Candidate 2011. The author would like to thank Dean Thomas Berg for his help in directing the scope and preparation of this article.

1. U.S. CONST. art. I, § 8, cl. 8.
2. 35 U.S.C. (2006).
3. 35 U.S.C. § 101 (2006).
4. See 35 U.S.C. §§ 102, 103, 112 (2006). Section 102 requires an invention to be novel, or, in other words, it must be new (i.e., neither patented nor published in the United States or a foreign country). 35 U.S.C. § 102. Section 103 renders an invention obvious if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103. Section 112 places requirements on the description of an invention, requiring “a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.” 35 U.S.C. § 112.

requirements of the code.⁵ Both the Supreme Court and the Federal Circuit⁶ have struggled to define a clear and concise test for assessing patentability under this section.⁷

The Federal Circuit's decision of *In re Bilski* highlights one aspect of this struggle: namely, defining the metes and bounds of the word "process" within § 101.⁸ The statute defines a "process" in 35 U.S.C. § 100(b) as a "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."⁹ When § 101 was originally drafted in the Patent Act of 1793, Thomas Jefferson defined statutory subject matter to include "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]."¹⁰ The statutory language remained unchanged until the Patent Act of 1952 when Congress implemented the word "process" in place of "art."¹¹ Accompanying this change, the Committee Reports indicate "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"¹²

Regardless of Congress' broad intentions for statutory patentability, as a general principle, the Supreme Court has found that natural principles, mental thoughts and ideas, and abstract concepts are not patentable, in part, because these concepts form the basic tools of scientific research.¹³ Using this principle as a guide, both the Supreme Court and the Federal Circuit have decided a series of cases attempting to hone a definition for a patentable "process" and determine its function in deciphering which inventions are, in fact, patentable under § 101 and which are not. Prior to the decision in *Bilski*, § 101 functioned primarily as a low-bar threshold to patentability, represented, in part, by the standard provided in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*¹⁴ This standard interpreted the requirements of § 101 broadly, requiring only that a

5. *In re Comiskey*, 499 F.3d 1365, 1371 (Fed. Cir. 2007).

6. Patent cases, unlike most other federal cases, have all appeals heard at a singular appellate court, the Court of Appeals for the Federal Circuit. Filing of patent suits may occur in any regional district court, but the appeal is always heard at the Federal Circuit and not in the regional circuit court.

7. Rajendra K. Bera, *Patentable Subject Matter Under the US Patent Act, 1952: Cases*, 95 CURRENT SCI. 1421, 1421 (2008).

8. *In re Bilski*, 545 F.3d 943, 951 (Fed. Cir. 2008).

9. 35 U.S.C. § 100(b) (2006). Part of the difficulty associated with interpreting this particular word in the statute may be attributed to the use of the word in its own definition.

10. *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (quoting the Act of Feb. 21, 1793, § 1, 1 Stat. 319).

11. *Id.* at 309 (quoting S. REP. NO. 82-1979, at 5 (1952) and H.R. REP. NO. 82-1923, at 6 (1952)).

12. *Id.*

13. *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

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

patentable process produce a “useful, concrete and tangible result.”¹⁵ For more than ten years, this broad standard governed application of § 101. *Bilski* changed all that by implementing a definitive test that does not focus on the essential characteristics of the subject matter, but instead required that a patentable process either (1) ties to a particular machine or apparatus, or (2) transforms a particular article into a different state or thing.¹⁶ With a singular decision, the Federal Circuit changed the scope and standards of a patentable process under § 101.

This imposed requirement for a process patent—the “machine-or-transformation” test—has presented many questions regarding its application, particularly to areas of patent law outside the business method claims that framed the case. This article explores the jurisprudence leading up to the Federal Circuit decision in *Bilski* and the ramifications of applying the resulting “machine-or-transformation” test to biotechnology and medical diagnostic claims. Application of the *Bilski* test to this class of claims illustrates the underlying difficulty of crafting a rigid test to determine the patentability of process patents under § 101 that can be applied to the broad range of technologies seeking patent protection. The Supreme Court, in its *de novo* review of *Bilski*, should articulate a broad threshold standard for 35 U.S.C. § 101, removing the rigid bar to patentability set by the Federal Circuit and returning to a standard that is consistent with precedent and the statute’s original legislative design. Such a move would alleviate many of the problems associated with *Bilski*; for example, the broad sweeping effect it imposes on biotechnology processes and medical diagnostic claims through the ill-defined requirement of a tie to a particular machine or transformation.

Part I of this paper introduces the major problem with the *Bilski* decision, namely its misreading of and departure from precedent in the creation of the “machine-or-transformation” test. Part II discusses the decision in *Bilski*, including the Federal Circuit’s purported rationale behind its implementation of the “machine-or-transformation” requirement. Part III extends the application of this new standard to medical diagnostic claims; specifically, comparing the decision in *Classen v. Biogen*¹⁷ to *Prometheus v. Mayo*.¹⁸ Finally, Part IV presents public policy considerations and proposed changes to the patentable subject matter analysis that the Supreme Court should consider as it determines the scope and reach of the “machine-or-transformation” test.

15. *Id.* at 1374, 1377.

16. *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008).

17. *Classen Immunotherapies v. Biogen IDEC*, 304 F. App’x 866 (Fed. Cir. 2008).

18. *Prometheus Lab., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009).

I. THE ROAD TO *BILSKI*

The Federal Circuit justified its narrow “machine-or-transformation” test by misreading and misapplying a series of cases decided by the Supreme Court. Although the *Bilski* court claims to conjure support for its new test within these prior decisions, these cases are better read as articulating a clear and wide-ranging standard of review that maintains the broad and embracing character of § 101 intended by Congress. Prior to *Bilski*, process patents that avoided the narrow delineated group of disallowed subject matter (i.e., natural principles, mental thoughts and ideas, and abstract concepts¹⁹) could successfully pass over § 101’s threshold bar of patentability and test their invention against the remaining sections of Title 35.²⁰ In her dissent to *Bilski*, Judge Newman summed up well the fundamental problems with the “machine-or-transformation” test: “[t]his exclusion of process inventions is contrary to statute, contrary to precedent, and a negation of the constitutional mandate. Its impact on the future, as well as on the thousands of patents already granted, is unknown.”²¹

When statutory interpretation is involved, *stare decisis* is generally given considerable weight because, unlike constitutional interpretation, the court must analyze and critique the work of the legislative branch.²² In the case of § 101, in particular, Congress has not modified the statute in over 20 years, making *stare decisis* all the more significant.²³ According to Judge Newman, “[t]he only announced support for today’s change appears to be the strained new reading of Supreme Court quotations. But this court has previously read these decades-old opinions differently, without objection by either Congress or the Court. My colleagues do not state a reason for their change of heart.”²⁴ As an example of what Judge Newman termed “strained new readings,” the Federal Circuit claims the Supreme Court first articulated its dispositive “machine-or-transformation” test in *Gottschalk v. Benson*.²⁵ Although the *Benson* court did provide that the “machine-or-transformation” test is a clue to the patentability of a process invention, what the Federal Circuit chose to gloss over was the Court’s clarification that while

[i]t is argued that a process patent must either be tied to a particular machine or apparatus or must operate to change articles or materials

19. *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

20. M.J. Edwards & Donald Steinberg, *The Implications of Bilski: Patentable Subject Matter in the United States*, 49 IDEA 411, 414 (2009).

21. *Bilski*, 545 F.3d at 976 (Newman, J., dissenting).

22. *Id.* at 993.

23. *Id.*

24. *Id.*

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

to a ‘different state or thing[,]’ [w]e do not hold that no process patent could ever qualify if it did not meet the requirements of our prior precedents.²⁶

The Supreme Court made similar qualifications in its later decisions in *Parker v. Flook* and *Diamond v. Diehr*.²⁷ The Federal Circuit, however, disregarded these statements just as they did in *Benson*, stretching the records to support its decision.

The *Bilski* decision fundamentally altered § 101, moving away from a wide and embracing threshold standard toward a rigid bar to patentability. Imposition of the *Bilski* exclusion to patentability occurs before examination of an invention on its merits—in other words, before finding the invention to be novel, non-obvious, enabled, described, or particularly claimed.²⁸ Prior to this decision, compliance with § 101 required little more than general subject matter eligibility; it had never been truly considered an independent condition of patentability.²⁹ Such a change in the status quo of statutory patentability will undoubtedly have unpredictable implications on patents issued under the old standard, applications currently pending in the Patent and Trademark Office, and on inventions not yet conceived.

In the discussion that follows, the Court’s reluctance to place a rigid bar to patentability under § 101 is clearly illustrated through the progression of the *Benson*, *Flook*, and *Diehr* decisions. These cases combine to articulate a clear and wide-ranging standard of review, which the *State Street Bank* “useful, concrete and tangible result” test expressed.³⁰ While this test is far from perfect, it maintained the broad and embracing character of § 101 intended by Congress and defined by precedent. The clarity afforded by this broad standard provided the statute with the flexibility to embrace not only current technology, but also innovations not yet achieved. Such clarity, and its accompanying stability, however, was lost when the decision of *In re Bilski* came down. Biotechnology patents particularly feel this loss, and the confines of a “machine-or-transformation” test place unreasonable limits on the potential for advancement that this technology area holds.

In its review of *Bilski*, the Supreme Court must return the analysis under § 101 to “[a] straightforward, efficient, and ultimately fair approach to the evaluation of ‘new and useful’ processes—quoting Section 101—[that recognizes] that a process invention that is not clearly a ‘fundamental truth, law of nature, or abstract idea’ is eligible for examination for

26. *Id.* at 71.

27. *Parker v. Flook*, 437 U.S. 584, 589 n.9 (1978); *Diamond v. Diehr*, 450 U.S. 175, 192 (1981).

28. *Bilski*, 545 F.3d at 976 (Newman, J., dissenting).

29. *Id.* at 977 (quoting *Diehr*, 450 U.S. at 189–90).

30. *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998).

patentability.”³¹

A. *Gottschalk v. Benson: Defining What Is Not a Process Under 35 U.S.C. § 101*

Gottschalk v. Benson is the first in a series of cases leading up to *Bilski*, which, when taken together, culminate in an expansive standard for patentability under § 101. Running through these decisions is a theme of broad inclusion and a resistance to a rigid bar to patentability. *Benson* established the general standard that one may not patent a natural principle (e.g., a formulation or mathematical algorithm) per se.³² The Court held that claims directed to a formula for converting binary-coded decimal numbers into pure binary numbers represented an unpatentable process within the meaning of the statute.³³ In its opinion, the Supreme Court stated that the mathematical formula that formed the crux of the claims had little practical application beyond its claimed use in a digital computer³⁴ and allowing a claim to the formula would preempt its only practical use and would in effect be a patent to the algorithm itself.³⁵

In discussing the scope of a patentable process under §101, the Court highlighted that in some cases, a patentable process will require a direct connection between the process and the instrumentalities of its implementation.³⁶

Such a link, however, is not the sole distinction of a patentable process. A natural process, for example, may be patentable if the basis of the invention is “the application of the law of nature to a new and useful end.”³⁷ This “new and useful end” need not necessarily be limited to tying the process to a particular machine. Instead, the process claim can stake its patentability on the “[t]ransformation and reduction of an article ‘to a different state or thing.’”³⁸ Transformation of the article serves as “the clue to the patentability of a process claim that does not include particular machines.”³⁹ Although initially this review of prior decisions may appear to lay the groundwork for a rigid test of patentability under § 101, the Court clarified by stating that

[i]t 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

31. *Id.* at 997.

32. *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972).

33. *Id.*

34. *Id.*

35. *Id.* at 71–72.

36. *Id.* at 69–70.

37. *Id.* at 67 (quoting *Funk Bros. Seed Co. v. Kalo Co.*, 333 U.S. 127, 130 (1948)).

38. *Benson*, 409 U.S. at 70.

39. *Id.* at 70.

could ever qualify if it did not meet the requirements of our prior precedents.⁴⁰

Scholars have deciphered the discussion of processes in *Benson* as an effort by the Court to avoid articulating a test of patentability or a definition of a “process,” and instead to provide various factors that lead to finding a particular process unpatentable.⁴¹ Such factors include: broad claims that preempt alternative uses of an algorithm, claims which do not result in a new and useful end product from the application of an algorithm, claims which are not directly linked to a particular machine, and claims which do not transform a particular article to a different state or thing.⁴² The holding in *Benson* is an indication of the Court’s hesitancy to delineate a precise test for a process and, as such, the Court provides neither an authoritative definition of the term process nor a bright-line standard for its review. Instead, the Court describes inventions that fall outside the meaning of “process,” making it possible to interpret the term broadly.

B. Beginning to Raise the Bar: Incorporating Novelty and Obviousness into § 101

The Court addressed the issue of algorithm patentability again six years later in its decision in *Parker v. Flook*, holding that a method for updating alarm limits, which implemented a mathematical formula for computing those limits, was unpatentable under § 101.⁴³ Conventional methods of altering alarm limits and the disputed claims differed solely in the application of a “new and presumably better method for calculating alarm limit values” (i.e., the mathematical formula employed in the method’s second step).⁴⁴ Applying *Benson*, the Court held the claims unpatentable because, although the algorithm was new, the process of adjusting alarm limits was not; the claims, therefore, were “directed essentially to a method of calculating, using a mathematical formula.”⁴⁵

The respondent argued that *Benson* should not apply in this case because the method claims do not “wholly preempt the mathematical formula.”⁴⁶ The claims were directed to a process within the realm of the

40. *Id.* at 71.

41. “Thus, in *Benson*, the Supreme Court articulated various factors that could lead to the conclusion that the method claims were unpatentable: the claims were so broad that they would preempt the algorithm itself, the claims did not result in the application of the algorithm to a new and useful result, the claims did not transform a particular article to a different state or thing, and the claims were not tied to a particular machine or apparatus.” Edwards & Steinberg, *supra* note 20, at 414.

42. *Id.*

43. *Parker v. Flook*, 437 U.S. 584 (1978).

44. *Id.* at 588, 594–95.

45. *Id.* at 594–95.

46. *Id.* at 589–90.

petrochemical and oil-refining industries, consequently leaving open alternative applications of the formula within the public domain.⁴⁷ Moreover, according to the respondent, the latter step of the process—adjusting the alarm limit based on the value computed by the formulation—presented “post-solution” activity that distinguished the case from *Benson*. The Court disagreed, stating that “[t]he notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance.”⁴⁸ A claim that is “directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose” is unpatentable under § 101.⁴⁹

Although the majority maintained a broad standard for § 101 analysis, Justice Stewart, in his dissent, argued that the majority expanded the restriction against patenting mathematical formulas and had, in fact, struck a “damaging blow at basic principles of patent law by importing into its inquiry under 35 U.S.C. § 101 the criteria of novelty and inventiveness.”⁵⁰ The issue in this case was whether the patentability of a claimed process is preempted if one step in the process “would not be patentable subject matter if considered in isolation.”⁵¹ He stated that “[s]ection 101 is concerned only with subject-matter patentability. Whether a patent will actually *issue* depends upon the criteria of §§ 102 and 103, which include novelty and inventiveness, among many others.”⁵² The dissent illustrates that in broadening the stringent exemptions to the statutory requirements of § 101,⁵³ the Court imported standards into the statutory definition of a patentable process already covered by other sections of the Code. Such a step begins to narrow the standard previously upheld by the Court, but this move does not endure.

C. Diehr: An Unacceptable Use of Otherwise Unpatentable Subject Matter

In the decision of *Diamond v. Diehr*, the Court refined its holdings in *Benson* and *Flook* regarding the patentability of claims having mathematical formulas.⁵⁴ The claims involved a method of curing synthetic rubber, which included continually measuring the temperature within the curing press, a step the industry had not previously been able to accomplish, and applying a well-known equation (the Arrhenius equation) to calculate

47. *Id.*

48. *Id.* at 590.

49. *Flook*, 437 U.S. at 595.

50. *Id.* at 600 (Stewart, J., dissenting).

51. *Id.* at 599.

52. *Id.* at 600.

53. For example: natural principles and mathematical formulas, mental thoughts and ideas, and abstract concepts.

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

an exact cure time for the rubber. The Court found the claims patentable, regardless of the fact that they included a well-known mathematical formula.⁵⁵ In reconciling the instant claims with those in *Benson* and *Flook*, the Court argued that the claims

do not seek to patent a mathematical formula. Instead they seek patent protection for a process of curing synthetic rubber. Their process admittedly employs a well-known mathematical equation, but they do not seek to pre-empt the use of that equation. Rather, they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process.⁵⁶

In this case, the claims were found to involve the “transformation of an article,” and therefore the physical and chemical changes required for synthetic rubber molding placed the invention within the bounds of patentable subject matter under § 101.⁵⁷

In deciding *Diehr*, the Court refined and reiterated its earlier holdings by providing that a process claim that uses a mathematical formula is not automatically rendered unpatentable by such inclusion.⁵⁸ A claim will only fail the standards of § 101 when the claim seeks to cover the mathematical formula per se—unpatentability of this type “cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.”⁵⁹ Claims implementing a mathematical formula are patentable under § 101 when, “considered as a whole, [the invention is] performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing).”⁶⁰ Examination of claims solely to determine compliance with statutory subject matter effectively eliminated the incorporation of novelty into § 101 introduced by *Flook* and reintroduced the broad and inclusive scope into § 101 analysis.⁶¹

Through this decision, and in response to the dissent in *Flook*, the Court lowered the threshold of § 101 and, in applying the transformation test of *Benson*, allowed for the acceptance of natural laws, or mathematical formulas, as statutory subject matter. Reflecting *Diehr*'s broad interpretation of § 101, the Federal Circuit created a standard for review in *State Street Bank Trust Co. v. Signature Financial Group, Inc.* that defined patentable processes for over ten years.⁶²

55. *Id.* at 177–78, 191.

56. *Id.* at 187.

57. *Id.* at 184.

58. *Id.* at 187.

59. *Id.* at 191 (citing *Parker v. Flook*, 437 U.S. 584 (1978)).

60. *Diehr*, 450 U.S. at 192.

61. *Id.* at 188–90.

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

D. A Utility Standard for § 101

The Federal Circuit decided *State Street Bank & Trust Co. v. Signature Financial Group, Inc.* in 1998, and its holding formed the backbone of § 101 analysis for process claims up until the decision in *Bilski*.⁶³ The claims at issue in *State Street* involved a system for monitoring and recording financial information flow; specifically, the system made all of the necessary calculations for maintaining a partner fund financial services configuration.⁶⁴ The nature of the business required quick and accurate performance of the calculations and, given their complexity, a computer was essentially required to accomplish the task.⁶⁵ The lower court had held that the claimed invention “fell into one of two alternative judicially created exceptions to statutory subject matter:” the “mathematical algorithm” exception or the “business method” exception.⁶⁶

On appeal, the Federal Circuit focused on the broad nature of § 101 and the distinctiveness of this particular section compared to those focused on the patentability of a claimed invention—namely §§ 102, 103, and 112.⁶⁷ Specifically, the court examined the construction of § 101, stating that “[t]he plain and unambiguous meaning of § 101 is that any invention falling within one of the four stated categories of statutory subject matter [i.e., any process, machine, manufacture, or composition of matter] may be patented, provided it meets the other requirements for patentability set forth in Title 35, i.e., those found in §§ 102, 103, and 112, ¶ 2.”⁶⁸ Congress’s repetitive use of the term “any” throughout § 101 provides textual evidence to support this broad interpretation, which the court relied upon in prohibiting additional restrictions on patentable subject matter.

Accordingly, the court held that although a mathematical algorithm, calculation, or formula, being an abstract idea, is not, by itself, patentable, this deficiency can be overcome if, in fact, the algorithm produces “a useful, concrete and tangible result.”⁶⁹ The holding moved the focus of finding statutory patentable subject matter from determining whether a strict physical transformation of the data occurred to determining whether the transformation of the data was, in fact, “useful.”⁷⁰ The court further clarified its position on § 101 and proposed a move away from strict construction toward a broad utility requirement: “[t]he question of whether a claim encompasses statutory subject matter should not focus on *which* of

63. *Id.*

64. *Id.* at 1371.

65. *Id.*

66. *Id.*

67. *Id.* at 1377.

68. *State St.*, 149 F.3d at 1372.

69. *Id.* at 1373–74.

70. *Id.* at 1374.

the four categories of subject matter a claim is directed to—process, machine, manufacture, or composition of matter [although it must, obviously, fall into one of them]—but rather on the essential characteristics of the subject matter, in particular, its practical utility.”⁷¹ Under this standard, the court found it unnecessary to classify the claims under either the “mathematical algorithm” or “business method” exception articulated by the lower court.⁷² The “useful, concrete and tangible result” standard for § 101 and its focus on utility was significantly narrowed and refocused by the decision in *Bilski*.

Critics have chastised the *State Street* standard for permitting claims to inventions that do not involve technology per se: for example, financial methods, arbitration methods, teaching methods, and even methods for simple routines such as swinging on a playground swing.⁷³ In spite of this criticism, the decision in *State Street* provided a test for patentability that applied as well to the business method claims as it did to biotechnology and medical diagnostic claims. This broad standard properly placed the crux of an invention’s patentability on its merits, namely novelty and nonobviousness. In biotechnology, where an innovation may not rely on the use of a particular machine or the transformation of an article, a broad standard facilitates patentability. The bulk of patentability may instead focus on the novelty and nonobviousness of the innovation and not on compliance with a narrow standard written with only a business method in mind. The decision in *In re Bilski*, especially when viewed from the perspective of biotechnology and medical diagnostics, compounded the weaknesses of *State Street* while simultaneously taking away its strengths.

II. BILSKI AND THE “MACHINE-OR-TRANSFORMATION” TEST

In deciding *In re Bilski*, the Federal Circuit eliminated over ten years of relative stability in the jurisprudence surrounding § 101 analysis when it overruled its previous decision in *State Street*, replacing the “useful, concrete and tangible result” test with its newly minted “machine-or-transformation” test.⁷⁴ Under the “machine-or-transformation” test, “[a] claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.”⁷⁵

The test arose from the analysis of *Bilski*’s patent claiming “[a] method for managing the consumption risk costs of a commodity sold by a

71. *Id.* at 1375 (citation omitted).

72. *Id.* at 1374, 1377.

73. Lilly He, *In re Bilski En Banc Rehearing on Patentable Subject Matter: Farewell to Business Method Patents?*, 14 B.U. J. SCI. & TECH. L. 252, 254 (2008).

74. *In re Bilski*, 545 F.3d 943, 959–961 (Fed. Cir. 2008).

75. *Id.* at 954.

commodity provider at a fixed price.”⁷⁶ The court explained the nature of the invention through the following example.

[C]oal power plants (i.e., the “consumers”) purchase coal to produce electricity and are averse to the risk of a spike in demand for coal since such a spike would increase the price and their costs. Conversely, coal mining companies (i.e., the “market participants”) are averse to the risk of a sudden drop in demand for coal since such a drop would reduce their sales and depress prices. The claimed method envisions an intermediary, the “commodity provider,” that sells coal to the power plants at a fixed price, thus isolating the power plants from the possibility of a spike in demand increasing the price of coal above the fixed price. The same provider buys coal from mining companies at a second fixed price, thereby isolating the mining companies from the possibility that a drop in demand would lower prices below that fixed price. And the provider has thus hedged its risk; if demand and prices skyrocket, it has sold coal at a disadvantageous price but has bought coal at an advantageous price, and vice versa if demand and prices fall.⁷⁷

The claim does not recite how the method is to be implemented and is not tied to the use of a computer;⁷⁸ in fact, “[n]o hardware is required to perform the method, although performing the steps on a machine would infringe.”⁷⁹ In addition, the claim is not limited by a particular type of commodity⁸⁰—it is not even tied expressly or impliedly to any physical subject matter, tangible or intangible.⁸¹ These factors, and the application of the “machine-or-transformation” test, led the court to affirm the decision of the Board of Patent Appeals and Interferences and find the claims unpatentable.⁸²

A. *The Majority’s “Machine-or-Transformation” Test*

The court framed the issue in *Bilski* as a question of whether Applicant’s claims were drawn to a fundamental principle and, if so, whether the claims, if allowed, would effectively preempt all uses of that fundamental principle.⁸³ In answering these questions, the court concluded that § 101 requires a claim to be limited to particular applications of a fundamental principle, and therefore renders unpatentable any claim to a

76. *Id.* at 949.

77. *Id.* at 949–50.

78. *Id.* at 950.

79. Benjamin J. McEniery, *The Federal Circuit in Bilski: The Machine-or-Transformation Test*, 91 J. PAT. & TRADEMARK OFF. SOC’Y 253, 254 (2009).

80. *Bilski*, 545 F.3d at 950.

81. *Id.*

82. *Id.* at 949.

83. *Id.* at 952.

fundamental principle itself.⁸⁴ To reach this conclusion, the court disavowed the long-standing “useful, concrete and tangible result test,” finding its application potentially useful as an indicator of patentability, but wholly insufficient to ensure the limitations required under the statute.⁸⁵

In reframing an analysis of statutory subject matter, the majority in *Bilski* attempted to rely solely on an application of existing Supreme Court precedent. In particular, the court relied heavily on many of the decisions discussed supra—namely, *Gottschalk v. Benson*, *Diamond v. Diehr* and *Parker v. Flook*. In interpreting these cases, the majority determined that the Supreme Court had laid down a definitive test for process patentability,⁸⁶ stating “the proper inquiry under § 101 is not whether the process claim recites sufficient ‘physical steps,’ but rather whether the claim meets the “machine-or-transformation” test.”⁸⁷

As stated above, the “machine-or-transformation” test requires a claimed process to be either (1) directly tied to a particular machine or apparatus or (2) involve the transformation of a particular article into a different state or thing.⁸⁸ In addition, the court articulated two corollaries to the test.⁸⁹ First, field-of-use limitations, those which would limit the claim to a particular use or purpose, are not sufficient to supply patentability to an otherwise unpatentable process.⁹⁰ Second, the involvement of a machine or transformation to the claimed process must provide meaningful limitations to the claim and amount to more than “insignificant postsolution activity.”⁹¹

The majority provided limited guidance on the test’s application. With regard to the machine prong of the test in particular, the court did little to explain its application and scope as the language of the *Bilski* claims were not limited to a particular machine or apparatus.⁹² The court, therefore, felt it was appropriate to “leave to future cases the elaboration of the precise contours of machine implementation, as well as . . . whether or when recitation of a computer suffices to tie a process claim to a particular machine.”⁹³

84. *Id.* at 954 (“A claimed process involving a fundamental principle that uses a particular machine or apparatus would not pre-empt uses of the principle that do not also use the specified machine or apparatus in the manner claimed. And a claimed process that transforms a particular article to a specified different state or thing by applying a fundamental principle would not pre-empt the use of the principle to transform any other article, to transform the same article but in a manner not covered by the claim, or to do anything other than transform the specified article.”).

85. *Id.* at 959.

86. *Bilski*, 545 F.3d at 954.

87. *Id.* at 961.

88. *Id.* at 954.

89. *Id.* at 957.

90. *Id.* at 957, 961.

91. *Id.* at 957, 962.

92. *Bilski*, 545 F.3d at 962.

93. *Id.*

The decision in *Bilski* focused instead on the second prong of the test, whether the claims included a transformation of an article to a different state or thing.⁹⁴ In articulating the spectrum of patentable transformations, the court held at one end the “virtually self-evident” processes involving “chemical or physical transformation of *physical objects or substances*” as clearly eligible subject matter. At the other end of the spectrum, processes involving the transformation of electronic data representing abstract constructs or intangibles are ineligible.⁹⁵ Recognizing the importance of inventions involving electronic transformations of data, the court clarified that while the addition of a data-gathering step is insufficient to render an algorithm patentable,⁹⁶ “[s]o long as the claimed process is limited to a practical application of a fundamental principle to transform specific data, and the claim is limited to a visual depiction that represents specific physical objects or substances,” the claim is patentable and avoids the dangers of patenting a fundamental principle.

B. Development of the “Machine-or-Transformation” Test

The Federal Circuit claims that the “machine-or-transformation” test was born—albeit indirectly—out of the decision in *Benson*, where the Supreme Court stated the “[t]ransformation and reduction of an article ‘to a different state or thing’ is the clue to the patentability of a process claim that does not include particular machines.”⁹⁷ The Court in *Benson* went on to articulate that compliance with the “machine-or-transformation” test was not the sole requirement for a patentable process:

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 requirements of our prior precedents.⁹⁸

In *Bilski*, however, the Federal Circuit interpreted the Court’s application of the *Benson* test in *Flook* and *Diehr* to indicate the Supreme Court’s intention that the “machine-or-transformation” test become the requirement for all patentable processes under § 101.⁹⁹ In addressing its reliance on the test in *Benson*, the Federal Circuit court stated:

We believe that the Supreme Court spoke of the machine-or-

94. *Id.* at 962.

95. *Id.*

96. *Id.* at 963 (“A requirement simply that data inputs be gathered—without specifying how—is a meaningless limit on a claim to an algorithm because every algorithm inherently requires the gathering of data inputs.”).

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

98. *Id.* at 71.

99. *Bilski*, 545 F.3d at 955–56.

transformation test as the “clue” to patent-eligibility because the test is the tool used to determine whether a claim is drawn to a statutory “process”—the statute does not itself explicitly mention machine implementation or transformation. We do not consider the word “clue” to indicate that the machine-or-implementation test is optional or merely advisory. Rather, the Court described it as *the* clue, not merely “a” clue.¹⁰⁰

The rationale discussed by the majority, and their apparent interpretation and application of precedent, was met with resistance. Judge Newman, as one example, argued in her dissent that the majority missed its target of framing a rule in reliance on Supreme Court precedent and instead clearly violated it.¹⁰¹ In particular, she focused on the clear statements of the Court emphasizing its desire to avoid an all-encompassing rule based, in part, on the broad nature of § 101. For example, Judge Newman quoted the Court in *Flook*, where it stated:

The statutory definition of “process” is broad. An argument can be made, however, that this Court has only recognized a process as within the statutory definition when it either was tied to a particular apparatus or operated to change materials to a “different state or thing.” As in *Benson*, we assume that a valid process patent may issue even if it does not meet one of these qualifications of our earlier precedents.¹⁰²

Judge Newman argued that, in ignoring the initial statement “[a]n argument can be made” and the qualifying sentence that follows, the majority manipulated the precedential cases to create an all-encompassing test not envisioned by the Court.¹⁰³ Referring to the majority’s justification explaining away the apparent equivocal nature of the *Benson* decision, she bluntly states, “there is nothing equivocal about ‘We do not so hold.’”¹⁰⁴

The majority, however, stood firm in its application of its version of Supreme Court precedent, with only one caveat:

[W]e agree that future developments in technology and the sciences may present difficult challenges to the machine-or-transformation test, just as the widespread use of computers and the advent of the Internet has begun to challenge it in the past decade. Thus, we recognize that the Supreme Court may ultimately decide to alter or perhaps even set aside this test to accommodate emerging technologies. And we certainly do not rule out the possibility that this court may in the future refine or augment the test or how it is

100. *Id.* at 956 n.11.

101. *Id.* at 976 (Newman, J., dissenting).

102. *Id.* at 979 (quoting *Parker v. Flook*, 437 U.S. 584, 589 n.9 (1978)).

103. *Id.* at 979 n.1, 980.

104. *Id.* at 979.

applied. At present, however, and certainly for the present case, we see no need for such a departure and reaffirm that the machine-or-transformation test, properly applied, is the governing test for determining patent eligibility of a process under § 101.¹⁰⁵

This statement did away with all other constructions of § 101 and created in their stead a definitive test for patentability.

C. The Test Applied to Bilski and Its Effect on the Stability of the Patent Process

Caveats and exceptions aside, the “machine-and-transformation” test, as applied to the claims at issue in *Bilski*, resulted in an affirmation of the Board’s finding of unpatentability. The claimed process of hedging risk did not involve a transformation of a physical substance as required under the test.¹⁰⁶ “Purported transformations or manipulations simply of public or private legal obligations or relationships, business risks, or other such abstractions cannot meet the test because they are not physical objects or substances, and they are not representative of physical objects or substances.”¹⁰⁷ The majority declared that *Bilski*’s claims, if allowed, “would effectively pre-empt any application of the fundamental concept of hedging and mathematical calculations inherent in hedging (not even limited to any particular mathematical formula).”¹⁰⁸ Given that the claims admittedly did not involve the application of a particular machine or apparatus, the claims failed the “machine-or-transformation” test and therefore did not qualify under the Federal Circuit’s newly-implemented bounds of § 101.¹⁰⁹

The “useful, concrete and tangible result” espoused in *State Street* was not without its flaws. Following the *State Street* decision, the Patent Office was overwhelmed with claims that did not involve technology, per se.¹¹⁰ Instead, the applications, which met the standards of *State Street*, related to financial methods, arbitration methods, teaching methods, and even methods for simple routines such as swinging on a playground swing.¹¹¹ In the years following *State Street*, the patent office and the courts worked to create confines for patentable processes and offer transparent guidelines.¹¹² This work provided strong motivation for the rigid *Bilski* standard.

The decision in *Bilski*, however, left many open questions regarding the

105. *Bilski*, 545 F.3d at 956.

106. *Id.* at 965.

107. *Id.* at 963–64.

108. *Id.* at 965–66.

109. *Id.* at 966.

110. *He*, *supra* note 73, at 254.

111. *Id.*

112. *Id.*

impact of the “machine-or-transformation” requirement on future patents and those that were issued under the *State Street* standard. Judge Newman summarized it well when she stated in her dissent, “[i]ndeed, the full reach of today’s change of law is not clear Uncertainty is the enemy of innovation. These new uncertainties not only diminish the incentives available to new enterprise, but disrupt the settled expectations of those who relied on the law as it existed.”¹¹³ Scholars have contended that “the Federal Circuit succeeded in bringing an element of predictability to the jurisprudence of 35 U.S.C. § 101, [however,] it also placed a cloud of invalidity over a substantial number of issued method claims” which may not meet the narrow *Bilski* standard.¹¹⁴

Claim 1 in U.S. Patent No. 7,514,221 (entitled, “Diagnostic Assay and Method of Treatment Involving Macrophage Inhibitory Cytokine-1 (MIC-1)”) provides but one example of such a claim:

1. A method of diagnosis of colonic cancer or rectal cancer characterized by an increased level of expression of MIC-1, said method comprising;
 - (i) determining the amount of MIC-1 present in a body sample taken from a human test subject,
 - (ii) comparing said determined amount against the amount, or range of amounts, of MIC-1 present in equivalent body sample(s) from normal subject(s), and
 - (iii) diagnosing colonic cancer or rectal cancer when the amount of MIC-1 determined in step (i) is increased compared to said amount, or range of amounts, of MIC-1 present in equivalent body sample(s) from normal subject(s) and wherein said amount determined in step (i) is greater than 1050 pg/ml; wherein said body sample is a sample of blood serum or plasma.¹¹⁵

This claim would presumptively fail to meet the requirements of the “machine-or-transformation” test. It is neither tied to a particular machine, nor, as will be discussed in more detail below, does the transformation described appear to meet the necessary requirements of the test.¹¹⁶

Biotechnology is but one example of the far-reaching implications of the *Bilski* decision cautioned by Judge Newman. The following section of this paper will explore two recent decisions involving medical diagnostic claims—*Classen Immunotherapies v. Biogen IDEC*¹¹⁷ and *Prometheus*

113. *Bilski*, 545 F.3d at 977 (Newman, J., dissenting).

114. Eric D. Kirsch & Elizabeth Reilly, *The Emperor Bilski’s Wearing No Clothes*, in 2 PRACTISING LAW INSTITUTE, PATENT LITIGATION 2009, at 71, 91–92 (2009).

115. *Id.* at 90.

116. *Id.* at 90–91.

117. *Classen Immunotherapies v. Biogen IDEC*, 304 Fed. App’x 866 (Fed. Cir. 2008).

*Laboratories, Inc., v. Mayo Collaborative Services*¹¹⁸—and the inconsistent application of the “machine-or-transformation” test used to arrive at their ultimate holdings. The Supreme Court granted *writ of certiorari* to hear the *Bilski* case, and may provide yet another change to the statutory framework defined by § 101. The problems highlighted by the decisions in *Classen* and *Prometheus* illustrate the greater implications of defining statutory subject matter when it evaluates this “definitive” test.

III. APPLYING THE “MACHINE-OR-TTRANSFORMATION” TEST TO MEDICAL DIAGNOSTIC CLAIMS

Two medical diagnostic cases have been decided since the implementation of the *Bilski* “machine-or-transformation” test for statutory subject matter—*Classen* and *Prometheus*. The former was a non-binding, single-paragraph decision, while the other received full review and discussion by the Federal Circuit. These decisions provide only two examples of the inherent problems with the *Bilski* standard but together argue strongly for a thorough overhaul of the “machine-or-transformation” test by the Supreme Court.

A. Immunizations Are Not Transformative

The Federal Circuit declared the *Classen* claims invalid in a short and seemingly off-hand decision. As stated above, the opinion came down as a single paragraph stating, “In light of our decision in *In re Bilski* . . . we affirm . . . that these claims are invalid under 35 U.S.C. § 101. Dr. Classen’s claims are neither ‘tied to a particular machine or apparatus’ nor do they ‘transform[] a particular article into a different state or thing.’”¹¹⁹ The claims at issue involved a method of determining an immunization schedule, and read:

A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.¹²⁰

Prior to the decision in *Bilski*, the broad *Classen* claims may well have been found unpatentable based on the precedents already in front of the

118. *Prometheus Lab., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009).

119. *Classen*, 304 Fed. App’x at 867.

120. U.S. Patent No. 5,723,283, claim 1 (filed Aug. 4, 1994).

court. Applying the preemption test in *Benson* and *Flook*, these sweeping claims improperly preempt all uses of the broad and basic comparison claimed.¹²¹ This determination follows from recognition that every other activity described in the claims, apart from the comparison of the two test groups, is no more than data gathering necessary to make the comparison. The Federal Circuit, however, in creating its definitive test in *Bilski*, has effectively rendered the preemption test meaningless by making its own test controlling. Admittedly, the *Classen* claims do not tie to a particular machine or apparatus, but the question of whether or not there is a transformation of an article to a different state or thing is less clear.

Dr. Warren D. Woessner, an immunologist, for one, argues that the Federal Circuit's simplistic dismissal of the claims in *Classen* was improper.¹²² He contends that the step of mammal immunization inherently involves the transformation of the mammal from "a nonimmune state to an immune state. More particularly, the process of immunization, also known as vaccination, involves the transformation of naïve immune cells into mature immune cells."¹²³ This process would appear to meet the requirements of a transformation under the *Bilski* standard.¹²⁴

Although this decision was non-precedential, it placed the application of the "machine-or-transformation" test in apparent flux. It begs the question: what is required for a patentable transformation under *Bilski*? Richard Sybert and David Heckadon have argued that the claims in *Classen* would have met the standard if the forefront of the claim included the inherent transformation; for example, the claim may have been more successful had it recited: "Physically transforming mammals into an immunized state by applying . . ."¹²⁵ The claims in *Classen* are representative of many types of diagnostic claims in their lack of

121. *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972).

122. Warren D. Woessner & Tania A. Shapiro-Barr, *Federal Circuit Applies Bilski Standard in Classen*, 9 PAT. STRATEGY & MGMT. 1 (Mar. 2009).

123. *Id.* ("When a mammal is vaccinated, a small amount of a 'non-self' antigen (or immunogen), typically derived from a disease-causing organism, is introduced into the mammal's system. Upon encountering the non-self antigen, naïve T cells (a type of immune cell) are transformed into mature T cells. Mature T cells either act directly to eliminate the non-self antigen, or they effect the transformation of naïve B cells (another type of immune cell) into active B cells. Active B cells produce antibodies that attack the non-self antigen. Once B cells and T cells have been activated, some are transformed into memory cells. Memory cells serve throughout the lifetime of the mammal as reserve forces ready to attack a previously encountered antigen. In this way, the immune response to a second and subsequent exposure to an antigen is faster and stronger, which is the purpose of immunization.").

124. *Id.*

125. RICHARD SYBERT & DAVID HECKADON, THE IMPACT OF *BILSKI* ON BUSINESS METHOD PATENTS LEADING LAWYERS ON NAVIGATING PROCEDURAL CHANGES, FORMING NEW PATENT FILING STRATEGIES, AND FORECASTING FUTURE DEVELOPMENTS: THE PRESENT AND FUTURE IMPACT OF THE *BILSKI* DECISION AND ITS RECENT APPEAL TO THE SUPREME COURT 11 (Aspatore ed., Aug. 2009), available at 2009 WL 2510889.

attachment to a particular type of machine.¹²⁶ In addition, many types of diagnostic claims do not benefit from a transformation.¹²⁷ The diagnostic method claims of U.S. Patent No. 7,514,221 discussed above are but one example of issued claims that, on their face, do not meet the standards set forth in *Bilski*. The lack of a clear rationale behind the court's holding in *Classen* has left the fate of such claims under the "machine-or-transformation" test unclear.

B. An Apparently Patentable Transformation

Prometheus v. Mayo presents an alternative interpretation of a patentable process involving a transformation under the *Bilski* test. The claims at issue in *Prometheus* involved a method of optimizing the therapeutic effect of 6-mercaptopurine (6-MP) and its prodrug, azathiopurine (AZA), to minimize toxic side effects.¹²⁸ Claim 1 of U.S. Patent No. 6,355,623, which is representative of the asserted claims, reads:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.¹²⁹

The claims can be summarized as having three steps: (1) administer the drug; (2) determine the resulting metabolite levels; and (3) recognize that a dosage adjustment may be needed.¹³⁰

Similar to *Bilski*, the issue of this case was whether the claims preempted a fundamental principle or the application of a fundamental principle.¹³¹ Applying the "machine-or-transformation" test to the claims presented, the Federal Circuit decided, contrary to *Classen*, that "the methods of treatment claimed in the patents in suit squarely fall within the

126. Woessner & Shapiro-Barr, *supra* note 122.

127. *Id.*

128. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1339 (Fed. Cir. 2009).

129. *Id.* at 1340.

130. *Id.* at 1341.

131. *Id.* at 1342.

realm of patentable subject matter because they ‘transform an article into a different state or thing,’ and this transformation is ‘central to the purpose of the claimed process.’”¹³²

The court went on to explain its holding by clarifying that “[t]he transformation is of the human body following administration of a drug and the various chemical and physical changes of the drug’s metabolites that enable their concentrations to be determined.”¹³³ The fact that the transformation is facilitated entirely by the natural processes occurring within the body does not prevent the patentability of the method. Instead, by the courts rationale, the physical administration of an artificial substance (in this case, the drug) initiates the natural process, and the administration itself triggers the subsequent transformations.¹³⁴ Allowance of these claims does not threaten the natural processes themselves because the claims do not preempt the processes; instead, the invention uses the body’s natural response in a series of well-defined steps with the goal of treating various diseases.¹³⁵ According to the Federal Circuit, “[i]t is clear that these methods of treatment are § 101 patentable subject matter.”¹³⁶

C. A Fundamental Divergence

The decision in *Classen* left much to be desired, but the Federal Circuit’s recent decision in *Prometheus* provided greater scrutiny of medical diagnostic claims. The inconsistent interpretation of a patentable transformation between these two decisions, however, afforded little clarity for future applications of *Bilski* to this particular subset of claims. In *Prometheus*, the court made a point of stating that “[t]he asserted claims are in effect claims to methods of treatment, which are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition.”¹³⁷ Comparison of the claims in *Classen* and *Prometheus*, however, leaves many questions about how their minimal differences could lead to such varied results. First, both *Classen* and *Prometheus* involved the physical administration of a foreign substance to a mammal; in the case of *Classen*, the substance was an immunogen, while in *Prometheus*, the substance was a therapeutic drug. Second, both substances initiated a series of natural processes within the mammal, which, under the standards set forth in *Prometheus*, should constitute a patentable transformation. Third, both sets of claims represent a “method of treatment.” The claims in *Prometheus* clearly classify themselves as such in

132. *Id.* at 1345 (quoting *In re Bilski*, 545 F.3d 943, 962 (Fed. Cir. 2008)).

133. *Id.* at 1346.

134. *Prometheus*, 581 F.3d at 1346–47.

135. *Id.* at 1347–49.

136. *Id.* at 1350.

137. *Id.* at 1346.

the preamble of the claim and further define the scope of the claim as preventing toxic side reactions related to administration of the drug;¹³⁸ but it is hardly inconsistent to consider the prevention of chronic immune-mediated disorders through immunization any less of a treatment method.

As was suggested by one scholar following the *Classen* decision, perhaps the decision simply requires framing an invention using the right words.¹³⁹ This concern has also been voiced with respect to the machine prong of the Federal Circuit's test.¹⁴⁰ In 2001, following the decision in *Diamond v. Diehr*, Cohen and Lemly identified a similar response to that decision as "the doctrine of the magic words."¹⁴¹ These scholars claim that the patentability of software patents following the *Diehr* decision came to hinge on whether or not the patent applications and corresponding claims purported to patent something entirely different from software.¹⁴² In fact, "knowledgeable patent attorneys did exactly that, claiming software inventions as hardware devices, pizza ovens, and other 'machines.'"¹⁴³ Similarly, medical diagnostic claims may need to be recast as "a method of treatment" or as "a process of transforming a mammal" to traverse the barrier created by *Bilski*. Skillful patent attorneys and agents will need to develop ways to make the abstract ideas appear to conform to the standards set by the "machine-or-transformation" test, but, as can be seen by the aftermath of *Diehr*, such has been accomplished before.¹⁴⁴

IV. A NEW REVIEW OF THE ANALYSIS FOR § 101

The *Bilski* decision is not yet an irreversible standard upon which patentable subject matter under § 101 will be judged. On June 1st, 2009, the Supreme Court granted *writ of certiorari* in *Bilski v. Doll*.¹⁴⁵ While the Court approved two issues for review, the remainder of this paper discusses the first issue:¹⁴⁶ whether the Supreme Court's historical avoidance of unnecessary limitations to the broad inclusiveness of § 101 renders the

138. The court relies on this fact in its argument stating that "[t]he invention's purpose to treat the human body is made clear in the specification and the preambles of the asserted claims." *Id.* at 1345.

139. SYBERT & HECKADON, *supra* note 125.

140. Stefania Fusco, *Is In Re Bilski a Déjà Vu*, 2009 STAN. TECH. L. REV. 1, 8 (2009).

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

142. *Id.*

143. *Id.*

144. Fusco, *supra* note 140, at 8.

145. *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), *cert. granted sub nom.* *Bilski v. Doll*, 129 S. Ct. 2735, 2735 (2009).

146. Petition for Writ of Certiorari in *i, Bilski v. Doll*, No. 08-964 (2009), 2009 WL 226501; the second issue for review is "[w]hether the Federal Circuit's 'machine-or-transformation' test for patent eligibility, which effectively forecloses meaningful patent protection to many business methods, contradicts the clear Congressional intent that patents protect 'method[s] of doing or conducting business.'" *Id.*

Federal Circuit's "machine-or-transformation" test inappropriate and inconsistent with precedent.¹⁴⁷ Given the inherent problems with the "machine-or-transformation" test highlighted in its application to diagnostic method claims, for example, the Court must consider the implications of such a strict and narrow standard in deciding its fate. Should the Court decide to restate the standards upon which patentable subject matter is to be judged, it would be appropriate to rely not only upon its own jurisprudence, but to also consider policy implications, something the Federal Circuit failed to do.

A. Public Policy: The Unconsidered Factor in Bilski

In framing its decision as an application of existing Supreme Court precedent, the clear lack of any policy-based analysis in the Federal Circuit's decision is apparent. The Federal Circuit grounds this practice in the belief that public policy considerations lie solely within the domain of the legislature and the Supreme Court.¹⁴⁸ In fact, its reluctance to address or admit the patent policy created by its decisions has spurred scholars to argue that, specifically in the industries of biotechnology and software, "the Federal Circuit has gotten the policy precisely backwards, perhaps because it is not making industry-specific patent policy intentionally."¹⁴⁹ Ignoring the pressures and considerations of public and patent policy has moved the Federal Circuit, as is confirmed with its decision in *Bilski*, away from a flexible approach to one that revels in bright-line rules.¹⁵⁰ The rules are often inconsistent and inappropriate with the technology-neutral design of statutory patent law.¹⁵¹ The Supreme Court, however, has not imposed such limitations and should consider the public policy behind decision of whether or not to grant particular patents.

1. A Balance of Interests

To discuss the public policy behind patenting, consideration must be given to the fact that the patent system was mandated by the U.S. Constitution to "promote the Progress of Science and the useful Arts."¹⁵² To accomplish this goal, the patent system rewards the creative activity of authors and inventors through the provision of a limited monopoly balanced by requiring full public access to the innovation upon its expiration.¹⁵³ Such

147. *Id.*

148. McEniery, *supra* note 79, at 255.

149. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1578 (2003).

150. *Id.* at 1579.

151. *Id.* at 1576–77.

152. U.S. Const. art. I, § 8, cl. 8.

153. Michael A. Shimokaji & Philip L. Gahagan, *Mind over Matter: The Bilski Decision, Like Others Before It, Reveals How Courts Have Frequently Kept Patent Law Lagging Behind*

a balance is not struck freely, and

[p]atent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten. One way in which patent law seeks to sail between these opposing and risky shoals is through rules that bring certain types of invention and discovery within the scope of patentability while excluding others.¹⁵⁴

Biotechnology, including medical diagnostics, clearly illustrates the tension between the inventor and the public good. On one side of the issue are the inventors and the biotech industry. Unlike other technology areas (for example, the software and financial services industries discussed directly in *Bilski*), “the biotech industry relies very heavily on its intellectual property for sustainability.”¹⁵⁵ One explanation for this reliance is the amount of time and money required for the development and implementation of a new drug or diagnostic. The process of bringing a new drug to market can take, on average, a decade or more and cost hundreds of millions of dollars.¹⁵⁶ Patents, and the monopoly afforded by them, provide incentive for the financial gamble taken by these innovators. If, however, the ability to obtain patents and guarantee the protection of their intellectual property is eliminated, “it will likely become more difficult for biotech companies to attract investors, which will in turn discourage invention and the advancement of science.”¹⁵⁷

The other side of the balancing scale holds researchers and the public. They argue that the monopoly afforded by patents offers control over innovation that results in more harm than good.¹⁵⁸ As one example, the American Civil Liberties Union has gathered a group of plaintiffs composed of medical and scientific organizations, individual researchers and physicians, and cancer patients to challenge a series of patents held by Myriad Genetics.¹⁵⁹ These patents are directed to the breast cancer susceptibility genes BRCA1 and BRCA2; as a result of these patents, research and diagnostic testing involving these genes require the approval of, and generally some payment to, Myriad.¹⁶⁰ The complaint argues that

Technology, 32 L.A. LAW 36, 39 (2009) (quoting *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 429 (1984)).

154. Kirsch & Reilly, *supra* note 114, at 71 (quoting *Laboratory Corp. v. Metabolite Laboratories, Inc.*, 548 U.S. 124, 127 (2006) (Breyer, J., dissenting), *cert. dismissed as improvidently granted*).

155. Marc S. Friedman et al., *Biotech’s Biggest Fear Might Come True: Pure Method Patents Might Become Extinct*, 196 N.J. L.J. 65, 65 (2009).

156. Burk & Lemley, *supra* note 149, at 1581.

157. Friedman et al., *supra* note 155, at 65.

158. *See Ass’n for Molecular Pathology v. Myriad*, No. 09-4515 (S.D.N.Y. filed May 12, 2009).

159. *Id.*

160. *Id.*

control over something as fundamental as genetic material prevents the progression of important scientific discoveries and significantly hinders the operation of doctors and their patients towards finding a cure.¹⁶¹ This case draws a picture of the less flattering side of the patent monopoly.

The *Myriad* case is not the first time advances in biotechnology and medicine have been challenged on public policy grounds. As one example, when the Patent & Trademark Office issued the first patent to a surgical method, healthcare practitioners voiced their concerns about their ability to treat their patients without the threat of being sued for infringement.¹⁶² Instead of excluding such methods from the category of statutory subject matter, however, Congress provided a new provision to the Patent Act¹⁶³ that “permitted health practitioners and health care facilities to engage in ‘medical activity’ that infringed a patent without fear of being sued for infringement.”¹⁶⁴ The nature of the claims in *Myriad* do not permit this provision to exempt medical practitioners from infringement, but this action by Congress provides one example of how the interests of both the inventors and the public can be served without placing unnecessary limitations on the grant of patents.

Upholding the decision in *Bilski* may threaten the progress of science by hindering the ability of biotech companies to realize a return on their substantial investment. This industry “is developing critically important ways to diagnose and treat diseases and screen for compounds that often involve processes that could very well fail *Bilski*’s ‘matter or transformation’ test.”¹⁶⁵ This begs the question of whether this is a cost that the public can afford.

2. *There Is Something to Be Said for Stability*

The decision in *Bilski* undid a period of relative stability in the jurisprudence surrounding patentable subject matter under § 101. As was discussed above, the “useful, concrete and tangible result” inquiry had provided the standard for review over the last decade and offered guidance for issued patents in a variety of technology areas. The implementation of the “machine-or-transformation” test ushered in an uncertainty not only to those patents not yet written, but more importantly, the decision has left the validity of many issued patents in doubt.¹⁶⁶ The retroactive application of the *Bilski* test leaves this latter group without the ability to develop new

161. *Id.*

162. Robert Green Sterne & Lawrence B. Bugaisky, *The Expansion of Statutory Subject Matter Under the 1952 Patent Act*, 37 AKRON L. REV. 217, 226 (2004).

163. 35 U.S.C. § 287 (2001).

164. Sterne & Bugaisky, *supra* note 162, at 226.

165. Friedman et al., *supra* note 155, at 65.

166. Fusco, *supra* note 140, at 9.

patent practices directed to drafting around the new requirements.¹⁶⁷ Judge Newman brought this argument to the forefront in her dissent arguing:

Unstable law is the enemy of innovation. These new uncertainties not only diminish the incentives available to new enterprise, but disrupt the settled expectations of those who relied on the law as it existed. . . . I don't know how much human creativity and commercial activity will be devalued by today's change in law; but neither do my colleagues.¹⁶⁸

The Supreme Court needs to consider many aspects of patentability, both existent law and the framework needed to support the public policy requirements for patents. Judge Newman had the right idea when she argued that “[a] straightforward, efficient, and ultimately fair approach to the evaluation of ‘new and useful’ processes is to recognize that a process invention that is not clearly a ‘fundamental truth, law of nature, or abstract idea’ is eligible for examination for patentability.”¹⁶⁹ This is the standard that framed the drafting of § 101 and remained untouched for nearly 200 years; it should stay that way.

B. Viable Alternatives

The Supreme Court has many options to consider in redesigning the utility standard under § 101. First, the Court could revert to the “useful, concrete and tangible result” of *State Street*, but, as was discussed supra, the standard was not a perfect one. The Court must address the influx of business method patents, but it is merely one of many factors for the Court's consideration as it develops a standard that provides certainty, clarity, and flexibility to process patentability. In the wake of *Bilski*, many scholars have stepped forward to propose alternatives to the “machine-or-transformation” test. A few of these alternatives will be addressed briefly, and their implications considered.

One approach that has been proposed involves modeling the current U.S. patent system on the more restrictive European system.¹⁷⁰ The European Patent Office (EPO) requires patents to claim only those inventions that make a *technical contribution*.¹⁷¹ This requirement was added with the intention of focusing patent law towards those inventions which are intuitively seen as technical in nature¹⁷² and it is supplemented with a series of expressly excluded categories of subject matter:

167. *Id.*

168. *In re Bilski*, 545 F.3d 943, 977, 992–93 (Fed. Cir. 2008) (Newman, J., dissenting).

169. *Id.* at 997.

170. Reinier B. Bakels, *Should Only Technical Inventions be Patentable, Following the European Example?*, 7 NW. J. TECH. & INTELL. PROP. 50, ¶ 4 (2008).

171. *Id.* at ¶ 11.

172. *Id.* at ¶ 14.

(a) mere discoveries, scientific theories and mathematical models, (b) aesthetic creations, (c) schemes, rules and methods for performing mental acts, playing games or doing business and programs for computers, (d) presentation of information, (e) methods of treatment of the human or animal body, and (f) plant or animal varieties or essentially biological processes for the production of plants or animals.¹⁷³

The addition of a technology requirement, however, has not proved to be a perfect solution, and has not provided a clear definition of patentable subject matter or prevented the issuance of patents that exceed its traditional boundaries, however they are defined.¹⁷⁴ In fact, the requirement “has led to complicated rules and legal uncertainty” and simply provides a restatement of the struggle between age-old principles and the influx of new, and yet undefined, inventions.¹⁷⁵ Such a rule provides little guidance to the patentability of process claims; as has been shown in Europe, without a legal definition of a “technical contribution,” the determination of patentable subject matter remains unclear.

Taken whole cloth, the European method of analyzing patentability spells the death of medical diagnostic claims as they are currently known. Additional subject matter exclusions, such as the methods of treatment exclusions described above, could likely result in a return of “the magic words” doctrine. To avoid the pitfalls of the excluded subject matter, claim drafters would be required to characterize their inventions as including technical contributions or draft their claims to maintain the appearance of claiming something other than the prohibited invention. Since the European modifications to patentable subject matter exclude diagnostic and method of treatment claims and have not provided much-needed clarity, other methods of analysis should be explored by the Court.

Michael Risch proposes a different approach in his article, *Everything is Patentable*.¹⁷⁶ He argues that the Supreme Court should implement a single rule:

[A]ny invention that satisfies the Patent Act’s requirements of category, utility, novelty, nonobviousness, and specification is patentable. In other words, if a discovery otherwise meets the requirements of patentability, then the discovery will be properly patentable without need to consider non-statutory subject matter restrictions such as the bars against mathematical algorithms, products of nature, or natural phenomena.¹⁷⁷

173. Sterne & Bugaisky, *supra* note 162, at 219.

174. Bakels, *supra* note 170, at ¶ 43.

175. *Id.*

176. Michael Risch, *Everything is Patentable*, 75 TENN. L. REV. 591 (2008).

177. *Id.* at 591.

His rule finds its support in the language of the statute¹⁷⁸ and ignores the inconsistencies of current patentable subject matter jurisprudence, which, he argues, “if extended to logical conclusions, would bar patentability of almost any invention or discovery, which certainly would present a suboptimal outcome.”¹⁷⁹ Implementing a threshold standard for statutory subject matter, with the only requirement that an invention meet the boundaries of a “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,” would alleviate much of the controversy and inconsistent interpretation of this gatekeeper section.¹⁸⁰

Risch argues that any question regarding the patentability of new technologies “should be answered by the general criteria that Congress has established—criteria that have worked for over 150 years—to determine whether a particular patent claim should be allowed.”¹⁸¹ He believes that such a change would allow the Patent and Trademark Office and the courts to better focus their energies on “how best to apply rigorous standards of novelty, nonobviousness, utility, and specification with a scalpel rather than simply eliminating broad swaths of innovation with a machete.”¹⁸² There is something to be said for a system that allows a patent to speak for itself on its own merits—through a meeting of the requirements of novelty, nonobviousness, written description, and enablement—rather than simply barring its entrance at the door.¹⁸³ The downside of this approach is the Constitutional implications it may have. The Constitution requires an invention to secure a patent.¹⁸⁴ Without a standard for determining whether or not the subject matter itself is patentable, the original and basic regulations of the U.S. patent system are not met.

Medical diagnostic claims, and biotechnology as a whole, could benefit from Risch’s broad rule. Creating a low bar to patentable subject matter allows the decision of whether or not to grant a particular patent to be based on the merits of the invention rather than its compliance with a rigid test. The low threshold afforded § 101 does not render the section meaningless, but instead gives it the breadth envisioned by Congress and places the burden of patentability on those sections that function to evaluate a patent for more than its objective subject matter.

One final approach to consider is the implementation of flexible legal standards, or “policy levers”, proposed by Dan Burk and Mark Lemley.¹⁸⁵

178. *Id.* at 594.

179. *Id.* at 592.

180. *See id.* at 593–94.

181. *Id.* at 657.

182. Risch, *supra* note 176, at 658.

183. *See Sterne & Bugaisky, supra* note 162, at 220.

184. U.S. CONST., art. I, § 8, cl. 8.

185. Burk & Lemley, *supra* note 149.

This approach proposes recognition and increased implementation of flexible legal standards, most of which are already operating in patent law, to take account of the varied types of innovations present in the different industries operating under the monolith of U.S. Patent Law.¹⁸⁶ Some “levers operate at an industry-wide or ‘macro’ level, treating different industries differently as a whole . . . [while others] work at a case-by-case ‘micro’ level, treating some kinds of inventions differently than others without explicit regard to industry, but in a way that has disproportionate effects on certain industries.”¹⁸⁷ The strength of their proposal comes from its inherent flexible application to a wide variety of industries and technologies. Unlike the inflexible, bright-line rules favored by the Federal Circuit (of which the “machine-or-transformation” test is a perfect example), legal standards are, by their very nature, “case-by-case decisional criteria that can take situational variance into account.”¹⁸⁸ The indeterminate nature of this approach is likely to create uncertainty, especially when compared to a bright-line rule. Although the authors argue that standards provide the court with the ability to balance the interests of a particular industry with its effect on the public in a consistent and specific manner,¹⁸⁹ they do not address the issue of technologies that cross technological boundaries or the uncertainty in areas where standards have not yet been established. The effects on the stability of the patent system and its implications on upcoming technologies are unclear.

Unlike the rigid test in *Bilski*, however, a move towards the application of industry specific standards of patentability would prevent the inherent problems and inconsistencies exemplified by the decisions in *Classen* and *Prometheus*. Such an approach would take the analysis of § 101 back to its initial broad standard, but would elevate the analysis to encompass and control the varied technologies it covers. Medical diagnostic claims would benefit from such a system as it offers the Court and Congress the ability to tailor standards to address, for example, the diverging public policy interests of the biotech industry and the public as a whole.

V. CONCLUSION

In a single action, the Federal Circuit overturned more than a decade of relative stability in rejecting the *State Street* “useful, concrete and tangible result” standard in favor of a new “machine-or-transformation” test. As illustrated by the decisions in *Classen* and *Prometheus*, the rigid *Bilski* standard poses a significant threat of inconsistent application and uncertainty. Accordingly, the Supreme Court must articulate a new

186. *Id.* at 1576–79.

187. *Id.* at 1579.

188. *Id.* at 1639.

189. *Id.*

standard, or, at the very least, return to the status quo of *State Street*, restoring 35 U.S.C. § 101 to a broad utility standard that is consistent with public policy, precedent, and the statute's original legislative design.