

DEVELOPMENTS IN INTELLECTUAL PROPERTY LAW

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INTRODUCTION

Over the survey period, intellectual property law changed in a number of important cases and other changes in intellectual property came down. The federal courts and the U.S. Patent and Trademark Office (PTO) have further expounded upon the boundaries of patentable subject matter, and the Supreme Court is set to revisit that issue. Further, a new PTO director is suggesting that some significant changes in the practicalities of prosecution may lead at least to a less-adversarial environment. These and other developments will be of interest to Indiana legal practitioners and others concerned with protection of intellectual property.

I. *IN RE BILSKI*¹

The U.S. Court of Appeals for the Federal Circuit in *In re Bilski* reversed or at least substantially curtailed the patentability of business methods affirmed in 1998 in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*² In *State Street*, the Federal Circuit had analyzed a number of opinions interpreting § 101 of the Patent Act in coming to the conclusion that methods of doing business were patentable subject matter.³ In the words of the *State Street* court, “the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a [patent-eligible invention] because it produces ‘a useful, concrete and tangible result.’”⁴ Based on *State Street*, many thousands of patent applications have been filed seeking to protect a variety of methods of doing a variety of tasks.⁵

Ten years later, the Federal Circuit revisited the idea of opening the patent gates to any type of method in *In re Bilski*. *Bilski* pitted inventors of a method of hedging investments against the PTO. The PTO examiner and Board of Patent Appeals and Interferences had held that the inventors’ patent application did not claim subject matter eligible under the statute for patent protection.⁶ The inventors argued throughout prosecution at the PTO, and in their appeal to the Federal Circuit, that the statute allowed “processes” to be patented, and that the *State Street* decision and Supreme Court authority that preceded it permitted any

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1. 545 F.3d 943 (Fed. Cir. 2008), *cert. granted*, 129 S. Ct. 2735 (2009).

2. 149 F.3d 1368 (Fed. Cir. 1998).

3. *Id.* at 1375.

4. *Id.* at 1373.

5. *Bilski*, 545 F.3d at 1004 (Mayer, J., dissenting) (citing information available as of January 2008 from the PTO).

6. *Id.* at 950.

methods to be considered for patent protection.⁷

The inventors sought to patent methods “for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price” including steps of initiating transactions between the commodity provider and consumers, identifying market participants having a different risk position to those consumers, and initiating transactions between the commodity provider and those market participants so as to balance the risk position.⁸ These claims recited ways of manipulating risk and arranging transactions, strictly handling intangible concepts. The claims did not suggest any actual transfer of any commodity, nor any change of a commodity from one state to another.⁹

The PTO examiner rejected the claims under § 101 as “not directed to the technological arts,” because the claimed methods were not performed by a particular device (e.g. a computer) and were directed simply to an “abstract idea” or “mathematical problem without any limitation to a practical application.”¹⁰ The Board questioned the examiner’s rationale, saying that such a “technological arts” test has no legal support, and that a method can still be “patent-eligible subject matter ‘if there is a transformation of physical subject matter from one state to another.’”¹¹ Nevertheless, the Board agreed with the examiner’s rejection because the claims did not recite a patent-eligible transformation. In the Board’s words, a transformation of “non-physical financial risks and legal liabilities” is not the stuff of which patents are made.¹² The attempt by the inventors to cover all possible ways—human, machine and otherwise—of carrying out the listed steps indicated that an abstract idea was claimed, and abstract ideas are not patentable. The lack of a “useful, concrete and tangible result” formed a further reason for the Board to reject the claims as not proper subject matter for a patent.¹³

The Federal Circuit’s legal analysis began with a review of the statute, which recites four types of subject matter for which patents will be issued: machines, processes, manufactures and compositions of matter.¹⁴ Noting that the issue revolved around the meaning of “process,” and that the statutory definition was unhelpful in its circularity,¹⁵ the court examined Supreme Court decisions holding

7. *Id.* at 959-60.

8. *Id.* at 949.

9. *Id.* at 950.

10. *Id.* (quoting *Ex parte Bilski*, No. 2002-2257, 2006 WL 5738364, at *3 (B.P.A.I. Sept. 26, 2006) (*Board Decision*)).

11. *Id.* (quoting *Board Decision*, at *42).

12. *Id.* (quoting *Board Decision*, at *43).

13. *Id.* (quoting *Board Decision*, at *49-50).

14. 35 U.S.C. § 101 (2006). “Whoever 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, subject to the conditions and requirements of this title.” *Id.*

15. *Bilski*, 545 F.3d at 951 & n.3 (“The term ‘process’ means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.” (quoting 35 U.S.C. § 100(b) (2006))).

that the legal meaning of “process” in this context was narrower than the standard dictionary definition.¹⁶ Specifically, even though they might fall within a common definition of “process,” such notions as natural laws and phenomena, abstract ideas and mental processes are “fundamental principles” that “are not patentable, as they are the basic tools of scientific and technological work.”¹⁷

To determine whether subject matter is a potentially-patentable process or a “fundamental principle,” the Federal Circuit turned to *Gottschalk v. Benson*¹⁸ and *Diamond v. Diehr*¹⁹ for guidance on the proper test for the PTO and courts to apply. In *Diehr*, the Supreme Court permitted claims that recited use of a particular equation in a process for treating rubber.²⁰ The *Bilski* court noted that the claims at issue in *Diehr* did not pre-empt all uses of the particular equation, just those within the rubber-treating process as further defined in the claims.²¹ The *Bilski* court noted that in *Benson*, however, the Supreme Court did not permit claims to an algorithm for converting data in one particular format to another format because doing so would withhold from the public all uses of that algorithm.²² Noting the difficulty in assessing whether all uses of an idea or algorithm would be pre-empted by a claim, and the limited utility of comparing particular fact patterns to those of *Diehr* and *Benson*, the *Bilski* court distilled from these and other cases a “definitive test” for whether a claimed process covers a limited use or the whole field of a fundamental principle.²³

As announced by the court, a 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.”²⁴ The connection of the fundamental principle, whether an abstract idea, natural phenomenon, or other such abstraction, to a concrete device or to the change of an item is plainly an indication that uses of the abstraction with a different device or to change a different item (or the same item in a way not claimed) are not pre-empted. Comparing this formulation to the facts in *Diehr*, the court saw the claimed process as using an equation specifically to transform raw rubber into particular

16. *Id.* at 951-52.

17. *Id.* at 952 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

18. 409 U.S. 63 (1972).

19. 450 U.S. 175 (1981).

20. *Diehr*, 450 U.S. at 188-89.

21. *Bilski*, 545 F.3d at 952-53 (citing *Diehr*, 450 U.S. at 187-88).

22. *Id.* at 953-54 (citing *Benson*, 409 U.S. at 65).

23. *Id.* at 954.

24. *Id.* (citing *inter alia Diehr*, 450 U.S. at 192 (holding that using mathematical formula in “transforming or reducing an article to a different state or thing” is patent-eligible); *Parker v. Flook*, 437 U.S. 584, 589 n.9 (1978) (arguably the Supreme 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’”); *Benson*, 409 U.S. at 70 (“Transformation 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.”)).

products, hence the result in *Diehr* of proper subject matter for a patent.²⁵ The court viewed another case²⁶ as considering use of a formula to determine an “abnormal condition during an unspecified chemical reaction,” and without limits on the conditions, reactions or devices in question, the claims were not drawn to proper subject matter.²⁷ After briefly reviewing how the facts of other Supreme Court cases fit the test, the Federal Circuit noted the “difficult case” in *Benson*, which claimed a process operated on a particular device, a computer.²⁸ Nonetheless, the claims in *Benson* were not to proper subject matter, according to the court, because the device recitation did not provide any meaningful limitation insofar as the algorithm at issue had no other usefulness outside of a computer.²⁹ Merely reciting the computer, without further context (such as *Diehr*’s vulcanizing process) did not “reduce the pre-emptive footprint” of the claim in *Benson*.³⁰

The language used in the test cited above suggests that machine-or-transformation is a *sufficient* condition for patentable subject matter. The Federal Circuit went on to say that it is also a necessary condition, rejecting arguments that other tests may also be used to determine whether a patent claim satisfies § 101.³¹ Although the Supreme Court’s *Benson* opinion said “transformation 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,”³² the Federal Circuit noted that statement seemed initially equivocal. Later Supreme Court decisions removed that equivocation, according to the court. Further, the court found no basis to reach beyond the machine-or-transformation test, even while recognizing that future technological developments (or reconsideration by the Supreme Court) could provide changes or alternative tests.³³

Further, the Federal Circuit viewed Supreme Court precedent to hold that a “fundamental principle” cannot be made patentable by limitation to a field of use, outside of the machine-or-transformation test.³⁴ Such a pre-emption within an entire field demonstrates that “the claim is not limited to a particular application

25. *Id.* at 954-55 (citing *Diehr*, 450 U.S. at 184).

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

27. *Bilski*, 545 F.3d at 955 (citing *Flook*, 437 U.S. at 586).

28. *Id.*

29. *Id.*

30. *Id.* (citing *Benson*, 409 U.S. at 71-72).

31. *Id.* at 955-56.

32. *Id.* at 956 (quoting *Benson*, 409 U.S. at 70 (emphasis added)).

33. *Id.* at 956. Note *id.* at 958-59, in which the court calls “inadequate” the prior *Freeman-Walter-Abele* test focusing on whether an algorithm is applied to “physical elements or process steps” (see *In re Freeman*, 573 F.2d 1237 (C.C.P.A. 1978); *In re Walter*, 618 F.2d 758 (C.C.P.A. 1980); and *In re Abele*, 684 F.2d 902 (C.C.P.A. 1982)), and in which the court calls “insufficient” the “useful, concrete, and tangible result” test suggested in *In re Alappat*, 33 F.3d 1526, 1544 (Fed. Cir. 1994) and *State Street Bank & Trust Co. v. Signature Financial Group*, 149 F.3d 1368, 1373 (Fed. Cir. 1998).

34. *Id.* at 957 (citing *Diehr*, 450 U.S. at 191-92).

of the principle.”³⁵ Accordingly, whether a claimed process is narrowly tailored seems of primary importance to the current Federal Circuit. That narrow tailoring must be presented as a meaningful limitation of the operative steps or solution presented by the claimed process as well. The court asserted that *Diehr* confirmed the proposition that a fundamental principle cannot be made patentable merely by additionally claiming “insignificant postsolution activity.”³⁶ Mere recitation of a machine or a transformation does not automatically equate to proper subject matter, without an indication that the machine or transformation is an important part of the technological solution or answer provided by the process.

Regarding implementation of the machine-or-transformation test, the Federal Circuit first noted that the “machine” branch of the test was not implicated by the applicants’ claims at issue, and so “elaboration of the precise contours of machine implementation” in satisfaction of the test was left for future decisions.³⁷ On the “transformation” side of the test, the court noted again that the transformation must be central or important to the claimed process, but focused most on what might be an “article,” the transformation of which would be patent-eligible.³⁸ Sensibly, a transformation of physical objects or substances will meet the test. Questions remain as to whether “[t]he raw materials of many information-age processes . . . electronic signals and electronically-manipulated data,” or such concepts or intangible items as “legal obligations, organizational relationships, and business risks,” are things for which a transformation will permit patent protection.³⁹

The court chose not to depart from its previous “measured approach” on this question.⁴⁰ Its *Abele* decision found a general claim reciting “graphically displaying variances of data from average values” not to include patent-eligible subject matter.⁴¹ On the other hand, a more specific claim in which the data was x-ray related data produced by a computed tomography (CT) device recited proper subject matter.⁴² According to the court, the particular data in *Abele*, representing particular objects and relationships, was sufficiently changed to permit consideration for patent protection. Limiting the scope of the claim to specific data in a specific context (i.e. representing bones or other tissues) eliminated the possibility of pre-empting all uses of a fundamental principle—graphic display—at issue.⁴³

Although transforming data in an appropriately narrow context is patent-eligible, the court reiterated an earlier holding that gathering data is generally not

35. *Id.*

36. *Id.*

37. *Id.* at 962.

38. *Id.*

39. *Id.*

40. *Id.*

41. *Id.* (citing *In re Abele*, 684 F.2d 902, 909 (C.C.P.A. 1982)).

42. *Id.* at 962-63.

43. *Id.* (citing *Abele*, 684 F.3d at 908-09).

a transformation of the data or other article(s).⁴⁴ The court would also consider gathering data for analysis “insignificant extra-solution activity,” because the solution is apparently the analysis or manipulation of the data.⁴⁵ Merely reciting the gathering of data, without a context, device or other explanation of the technique of data gathering, will not make an otherwise ineligible subject matter patent-worthy.

With respect to the patent application before the court, the Federal Circuit considered whether the claims at issue fit the transformation branch of the test, and held they did not.⁴⁶ The obligations, risk and relationships identified the claims were not physical items nor were they representative of physical items, and so are not proper “articles” or “things” the transformation of which would be proper subject matter for a patent. In essence, the court required whatever was part of the claimed transformation to be physical or so related to physical object(s) or substance(s) as to represent them.⁴⁷ Transformation of intangible items, in the sense that such items are not at least stand-ins for physical “stuff,” is not the “stuff” of which patents are made, according to this court.⁴⁸

The court further considered some of its prior opinions finding claims non-patentable under § 101. In *In re Comiskey*,⁴⁹ the court held that a claimed process for arbitration of disputes was not eligible for a patent because it was directed only to a mental process for arbitration, i.e. a fundamental principle. Without a machine or a process to transform physical objects, the arbitration process was not a “process” under the meaning of the patent statutes. The court analogized the present case, characterizing it as “directed to the mental and mathematical process of identifying transactions that would hedge risk.”⁵⁰ In *In re Meyer*,⁵¹ the court held claims for “diagnosing the location of a malfunction in an unspecified multi-component system” that included assigning and updating values for each component based on testing the components to be improper for patent protection.⁵² Once again, the claims in *Meyer* were deemed to be drawn to a mental process only, and the court analogized the claims in *Bilski*’s application.

Three judges provided separate dissenting opinions totaling seventy-six slip-opinion pages. The dissents express to varying degrees a concern that the

44. *Id.* at 963.

45. *Id.*

46. *Id.* at 963-64.

47. *Id.* at 964 (holding that “claim 1 does not involve the transformation of any physical object or substance, or an electronic signal representative of any physical object or substance”).

48. *Id.*

49. 499 F.3d 1365 (Fed. Cir. 2007), *vacated en banc* 554 F.3d 967 (Fed. Cir. 2009). Notably, the *en banc Comiskey* court did not refer to *Bilski* in its discussion of patentable subject matter under 35 U.S.C. § 101 (2006). Certain claims were affirmed as unpatentable because not directed to proper subject matter, and others were remanded to the patent examiner for determination of whether Section 101 was satisfied. 554 F.3d at 981-82.

50. *Bilski*, 545 F.3d at 965.

51. 688 F.2d 789 (C.C.P.A. 1982).

52. *Bilski*, 545 F.3d at 965 (citing *Meyer*, 688 F.2d at 792-93).

“machine-or-transformation” test is too narrow for the technology and innovations of the twenty-first century and beyond. Judge Newman’s dissent suggests that the test, which is necessarily considered without regard to novelty, unobviousness, utility or other tests of the patent law, at least introduces uncertainty as to patentability of methods within the “knowledge economy” and at most eliminates protection for inventions applying “electronic and photonic technologies, as well as other processes that handle data and information in novel ways.”⁵³ She draws from many of the same Supreme Court decisions used by the majority to reach opposite conclusions, arguing that *Benson* and *Flook* do not support an exclusive machine-or-transformation test.⁵⁴ Even returning to an analysis of the English Statute of Monopolies and evolution of protection for processes in U.S. law, Judge Newman comes to the conclusion that § 101 permits protection for any “process invention that is not clearly a ‘fundamental truth, law of nature, or abstract idea.’”⁵⁵

Judge Mayer’s twenty-five-page dissent, however, argues forcefully that the *State Street* case should be overruled, and asserts unequivocally that the patent system aims to “protect and promote advances in science and technology, not ideas about how to structure commercial transactions.”⁵⁶ His basic principle is that business methods are not “useful arts” and are thus not within the Constitutional scheme for patent protection.⁵⁷ Where the innovative method is “entrepreneurial rather than . . . technological,” in his view, no patent protection is available.⁵⁸ The majority did not go far enough, according to Judge Mayer, to categorically repudiate *State Street* and “recalibrate the standards for patent eligibility.”⁵⁹

Judge Rader’s dissent agreed with the principle that the claims at issue are unpatentable as abstract ideas, but expressed concern that the majority opinion “disrupts settled and wise principles of law.”⁶⁰ Similar to Judge Newman, Judge Rader was concerned that views and arguments expressed in earlier cases are too limiting for present-day technological conditions. “Process,” in his view, is broadly given in the statute and should not be circumscribed by judge-made limitations.⁶¹

These dissents agree that “fundamental principles” or “natural laws” cannot be patented, but diverge as to what might fit into those intellectual categories. Judges Newman and Rader would allow a broad understanding of “process” foreclosed by the majority opinion, at least insofar as technology continues to evolve and as Congress has not limited the reach of the statutory term “process.”

53. *Id.* at 976-77 (Newman, J., dissenting).

54. *Id.* at 978-80.

55. *Id.* at 997.

56. *Id.* at 998 (Mayer, J., dissenting).

57. *Id.* at 999, 1001-02.

58. *Id.* at 1002-04.

59. *Id.* at 1011.

60. *Id.* (Rader, J., dissenting).

61. *Id.* at 1012-13.

Judge Mayer, on the other hand, seeks a return to a pre-*State Street* time, and considered that the device on which the business method is performed may be patentable, but the commercial nature of the method itself is outside the Constitutional scope. The majority came to the question somewhat from the negative side, defining what is *not* a “fundamental principle,” namely processes tied to a machine or transform a physical article or its representation into a different state or article.

In re Bilski is currently under consideration by the U.S. Supreme Court.⁶² Several dozen amicus briefs were filed, in testament to the high feelings and wide potential for effect to industries such as the pharmaceutical and software industries. On November 9, 2009, the case was argued to the Court,⁶³ and so an opinion could be rendered at any time.

In the meantime, however, the Federal Circuit and the USPTO are proceeding to apply the rule in *Bilski* as it stands. In *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*,⁶⁴ the Federal Circuit examined a patent claiming methods for establishing proper dosages of drugs used for treating autoimmune diseases. A representative claim defined a method of “optimizing therapeutic efficacy” in treatment of a disorder by using the steps of administering a drug that provides a certain metabolite and determining the level of the metabolite in the patient, where a level of the metabolite below a particular threshold value indicates a need for more drug in subsequent administrations, and a level below another threshold value indicates a need for less drug in subsequent administrations.⁶⁵ Mayo had at one time purchased the patented test from Prometheus. But once Mayo stopped buying the test and began using its own method, Prometheus sued for patent infringement. According to the court’s recitation of facts, Mayo’s test assessed the same metabolites as in Prometheus’ claims, but used different threshold levels than those recited in Prometheus’ claims.⁶⁶

In the district court, Prometheus won a summary judgment of infringement, but Mayo won a summary judgment of invalidity based on its argument that Prometheus’ claims did not claim proper subject matter under § 101. In the Federal Circuit’s words, Mayo contended “that the patents impermissibly claim natural phenomena—the correlations between, on the one hand, thiopurine drug metabolite levels and, on the other hand, efficacy and toxicity—and that the claims wholly preempt use of the natural phenomena.”⁶⁷ The district court agreed with Mayo, finding that the claims merely recite administering drug and determining metabolite levels, which it considered only data-gathering steps.⁶⁸ The final portions of the claims, warning that changes to the dosage were needed,

62. *Bilski v. Doll*, 129 S. Ct. 2735 (2009).

63. See Transcript of Oral Argument, *Bilski v. Kappos*, 129 S. Ct. 3735 (No. 08-964), available at http://www.supremecourt.gov/oral_arguments/argument_transcripts/08-964.pdf.

64. 581 F.3d 1336 (Fed. Cir. 2009).

65. *Id.* at 1340.

66. *Id.*

67. *Id.* at 1340-41.

68. *Id.* at 1341.

formed merely a “mental step” according to the district court. Because the physician can tell that changes should be made from the metabolite levels themselves, according to natural body processes, the district court found that the inventors did not “invent” the method but “merely observed the relationship between these naturally produced metabolites and therapeutic efficacy and toxicity.”⁶⁹ The claims pre-empted the use by others of a natural process—the correlation of the particular metabolite and patient condition—and thus could not be proper subject matter for a patent.

The Federal Circuit began its analysis with the statutory language of § 101, repeating its pronouncement in *Bilski* that the statutory definition of “process” is circular.⁷⁰ It noted the Supreme Court’s language that proper subject matter is “anything under the sun that is made by man,” as well as the Court’s exceptions to that broad language preventing protection for laws or “manifestations” of nature, natural phenomena or abstract ideas.⁷¹ The line to be drawn in the present case, according to the court, is whether the claims were drawn to a “fundamental principle” or phenomenon or the *application* of such a principle or phenomenon.⁷² The court accordingly repeated its *Bilski* test, that methods are patentable if they are either tied to a particular machine or result in a transformation of a particular article.

Beyond that base rule, the court focused further on two additional aspects of its *Bilski* decision. Even if the involvement of a machine or the existence of a transformation has been shown, that involvement or existence must provide “meaningful limits” and must not be “insignificant extra-solution activity.”⁷³ A step merely meant to gather data is not one that will provide patent-worthiness to an entire method, because such a step is not part of the technical solution the method provides to a problem.⁷⁴ Even so, such a step cannot be ignored in the analysis, because “patent eligibility of a claim as a whole should not be based on whether selected limitations constitute patent-eligible subject matter.”⁷⁵

Prometheus argued that its claims included both “machine” connections as well as “transformations” of articles. As to machines, Prometheus took the position that there were machines on which the claimed steps “inextricably rely” by the nature of the steps themselves and insofar as dependent claims recited certain machines.⁷⁶ Further, it argued that the term “machine” as used in *Bilski* should be interpreted to mean any type of patentable subject matter, and therefore the connections between its claims and pharmaceutical compositions meant that

69. *Id.*

70. *Id.* at 1341-42.

71. *Id.* at 1342 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 304 (1980)).

72. *Id.*

73. *Id.* at 1342-43.

74. *Id.* at 1343.

75. *Id.* (citing *In re Bilski*, 545 F.3d 943, 958 (2008); *In re Diehr*, 450 U.S. 175, 188 (1981); *Parker v. Flook*, 437 U.S. 584, 594 (1978)).

76. *Id.*

the claims were sufficiently connected to particular matter.⁷⁷ The transformations Prometheus asserted were a transformation of the patients biochemistry through administering a drug, the transformation of a bodily sample in determining metabolite levels, and transformation of those levels into a “warning . . . to alter the dosage.”⁷⁸ The court considered three potential “transformations” Prometheus argued were present in its claims and satisfied the *Bilski* test.

The court did not consider whether the claims met the “machine” prong of the *Bilski* test because it agreed that the claims recited a proper transformation, and therefore met that prong of the test.⁷⁹ That “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.”⁸⁰ The consideration of the human body as an “article” the transformation of which would allow a claimed method to meet the *Bilski* test is clearly enunciated by the Federal Circuit. The court gave the broad principle that “methods of treatment . . . are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition.”⁸¹ The administration of a drug and its transformation in the body—and transformation of the body’s chemistry by adding a metabolite—to combat disease is the very purpose of the claimed subject matter. The transformation and its centrality to the overall claim is what makes the claim patent-eligible.

The court also agreed that the determination of metabolite levels from samples taken from patients is also sufficiently transformative. The opinion noted that these levels could not be found by “mere inspection,” but required “[s]ome form of manipulation” in order to come to a measurement.⁸² Simply looking and seeing a result is not a “transformation” that will make a method patent-eligible. Taking a sample and performing an operation on it so as to be able to tell some characteristic about it, however, will constitute a proper transformation. It would appear that court believes that the particular context—the machine or particular conditions or articles used in that operation—will permit the claim to meet the transformation test. The analysis of the samples is not merely data-gathering, as Mayo argued.⁸³ Rather, the court found that analysis to be central to the claim because it performed a “significant” role in the claimed method of treatment.⁸⁴ The analysis of the samples is what permits the last step of the claim to be performed, and on that basis the court finds

77. *Id.*

78. *Id.* at 1343-44.

79. *Id.* at 1345-46.

80. *Id.* at 1346.

81. *Id.* Notably, in the third footnote, the court distinguished Justice Breyer’s dissent from a dismissal of certiorari in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006), the reasoning of which the lower court in *Prometheus* found persuasive. *Prometheus*, 581 F.3d at 1346 n.3.

82. *Id.* at 1347.

83. *Id.*

84. *Id.* at 1347-48.

the analysis step to be part of the solution, and not “insignificant extra-solution activity.” By “sufficiently confin[ing] the patent monopoly,” the administration and analysis steps permitted the claim to satisfy the *Bilski* test.⁸⁵

The court noted that there were “mental steps” included in “wherein” clauses of the claims at issue, but held that “a subsequent mental step does not, by itself, negate the transformative nature of the prior steps.”⁸⁶ That is, the mere presence of a mental step or algorithm does not defeat the patentability of methods that meet the machine-or-transformation test in one or more other steps. It is not clear why the court chose to include the terms “subsequent” and “prior” in its holding, and this author sees no reason why the temporal positioning of a mental step or algorithm with respect to other method steps should be controlling.

Prometheus can be seen as a confirmation that *Bilski* is a refutation of the idea that a method addressing intangibles such as legal relations or financial obligations can be patented. Broadly speaking, both cases considered a method of “treatment” or addressing a problem. In *Bilski*, the problem or “disease” centered around risk incurred by one party and the method claimed was how to relieve or address that disease. Additionally, it would appear that the consideration or analysis of the risk in the application’s claims could be undertaken by human thought or examination without specialized devices. *Prometheus*, on the other hand, specified the tangible body and its chemistry or disease condition as the context of the claims, and provided a transformation that had to be viewed through technical means rather than direct human observation. These features satisfied the court that a resulting patent would not wholly pre-empt use of a “fundamental principle.”

II. CHANGE AT THE U.S. PATENT AND TRADEMARK OFFICE

Much has been written and argued concerning proposed rule changes promulgated by the PTO concerning continuing application practice and numbers of claims permitted in applications.⁸⁷ The proposed rules, which limited filing of continuing applications and requests for continued examination and forced applicants to provide a substantial amount of examination information for applications in which more than five independent claims or twenty-five total claims were filed, were challenged by the pharmaceutical company GlaxoSmithKline and an independent inventor in U.S. District Court for the Eastern District of Virginia. The District Court struck down these rules as outside of the PTO’s authority,⁸⁸ and the PTO appealed to the Federal Circuit.

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

86. *Id.* at 1348.

87. *See, e.g.*, Christopher A. Brown, *Survey of Developments in Intellectual Property Law*, 40 IND. L. REV. 987, 987-92 (2007). Also note rule changes relating to appeal and interference practice cited in Christopher A. Brown, *Recent Developments in Intellectual Property Law*, 38 IND. L. REV. 1181, 1181-96 (2005).

88. *See Tafas v. Dudas*, 541 F. Supp. 2d 805, 807 (E.D. Va. 2008), *appeal dismissed*, 586 F.3d 1369 (Fed. Cir. 2009) (en banc).

Before the Federal Circuit issued an opinion, however, the Obama Administration appointed a new Under Secretary of Commerce for Intellectual Property and Director of the PTO, David Kappos. Confirmed by the Senate on August 7, 2009, Kappos' background is as an electrical and computer engineer and intellectual property lawyer with IBM. He has served on the boards of the American Intellectual Property Law Association (AIPLA), the Intellectual Property Owners Association, and the International Intellectual Property Society, and he has served as Vice President of the Intellectual Property Owners Association.⁸⁹

Among the other issues facing the new Director was how to handle the continuation and claim rules and the lawsuit with appeal they had spawned. To the delight of patent prosecutors nationwide, the PTO under Kappos has issued a new final rule rescinding the proposed regulations.⁹⁰ Concurrently, the PTO and GlaxoSmithKline moved to dismiss the pending appeal and to vacate the lower court's decision striking down the rules, while another party (Tafas) joined the motion to dismiss but objected to vacatur. In *Tafas v. Kappos*,⁹¹ the Federal Circuit dismissed the appeal but did not vacate the district court's decision.⁹²

The end result is that the rules and policies governing continuations and required information to accompany patent applications will remain as they have been, with the previously proposed rules enjoined per the district court's holding. Continuation applications may be freely filed, with the statutory requirements of 35 U.S.C. § 120 governing whether such applications are entitled to priority from the earlier-filed applications.⁹³ No ab initio requirement for analysis of claims, searching for or analyzing references exists regardless of how many claims are filed. The PTO may still request information and handle continuation applications as appropriate under existing rules, and practical considerations will still govern or affect how applicants prepare and prosecute their applications. The legal burdens of the erstwhile rules, however, are no longer at issue.

Director Kappos has also signaled some additional changes in PTO practice that may be considered cultural rather than legal. The PTO naturally has something of an adversarial role to play with respect to patent applications, insofar as it is the examiners' principle task to ask hard questions about patent applications and act as a filter for those not entitled to protection. Over the past several years, it has appeared to many (including the author) that the PTO had taken that adversarial position to an extreme, taking and holding positions rejecting applications of questionable merit. The desire to make and maintain rejections arose, it is believed, from criticisms of the PTO concerning numbers

89. President Obama Nominates David Kappos as Patent and Trademark Director, <http://www.uspto.gov/main/homepagenews/2009jun19.htm> (last visited June 5, 2010).

90. Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 74 Fed. Reg. 52686 (Oct. 14, 2009) (to be codified at 37 C.F.R. pt. 1).

91. 586 F.3d 1369 (Fed. Cir. 2009).

92. *Id.* at 1371.

93. 35 U.S.C. § 120 (2006).

of patents held invalid in court proceedings, and from resulting increased review of examiners' allowances of applications and negative incentives to examiners where an allowance was deemed to be improper. Rather than recommending allowance and have his or her performance review substantially affected if the recommendation was rejected, an examiner would find it much safer simply to continue to reject an application, with little or no risk to him or her from an overturning of the rejection on appeal.

The new word from the new Director is that quality assurance in the PTO is a function of not only proper rejections, but also proper allowances. In Kappos' words, "patent quality does not equal rejection. In some cases this requires us to reject all the claims when no patentable subject matter has been presented. . . . In other cases this means granting broad claims when they present allowable subject matter."⁹⁴ To reach proper results, Kappos is encouraging both examiners and applicants to "share the responsibility" to "expeditiously identify and resolve issues of patentability . . . to find the patentable subject matter and get it clearly expressed in claims that can be allowed."⁹⁵ Early engagement between examiners and applicants, as in proposals for early interviews and for performance credit for examiners for interviews, is a clear goal for Director Kappos going forward.

These and other proposals from the Director are intended to have a positive effect on the backlog of cases before the PTO. Certainly any effort on the part of examiners and applicants to work together to find patentable subject matter in an application and move the application more quickly to allowance will enable average pendency of applications to be reduced.

III. REVIEW OF WRITTEN DESCRIPTION REQUIREMENT

On August 21, 2009, the Federal Circuit issued its grant of a motion for *en banc* review in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*⁹⁶ The court gave two particular additional questions for briefing: (1) whether 35 U.S.C. § 112, paragraph 1 contains a written description requirement that is separate from enablement, and if so, (2) what the scope and purpose of the written description requirement is. The order vacated an earlier appellate opinion in the case,⁹⁷ and set the stage for consideration of a fundamental question of patent law.

It has been black-letter law since at least 1952 that three basic requirements exist for the disclosure in a patent application. For patent claims to be properly supported, the specification in the patent must

contain 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

94. See PatentlyO, <http://www.patentlyo.com/patent/2009/08/director-kappos-patent-quality-equals-granting-those-claims-the-applicant-is-entitled-to-under-our-laws.html> (Aug. 25, 2009, 8:00).

95. *Id.*

96. 595 F.3d 1329 (Fed. Cir. 2009) (*en banc*).

97. 560 F.3d 1366 (Fed. Cir. 2009).

with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.⁹⁸

This language is parsed into “written description,” “enablement,” and “best mode” requirements, each of which have separate considerations even if they might overlap significantly in particular situations. The written description requirement has been deemed a test of the inventor’s knowledge or state of mind. That is, the inventor was considered to have had in mind all of the material stated in the application and shown in the drawings, and conversely was considered not to have invented anything outside of the document. Accordingly, the inventor could not obtain protection for subject matter not particularly identified in his or her application. The enablement requirement is thought of as the test for whether the inventor has met his end of the patent bargain, i.e. that he or she has given a better technological way or solution to the public in exchange for the exclusionary rights embodied in a patent. The best mode requirement is a policy that the patent bargain should include not just any way to accomplish the inventor’s solution, but the best way in the inventor’s mind to accomplish the solution.

This tripartite way of reviewing a patent disclosure to ensure that the public gets sufficient technological information in a patent has been questioned periodically but not seriously changed at least since the enactment of the current statute in 1952. The *Ariad* case now is poised not only to consider whether the current system is the correct analytical method but also potentially to create new frameworks for considering the sufficiency of a patent disclosure. Further, because the court is considering these questions *en banc*, there is some potential for reconsideration of a number of cases that have addressed the interconnected questions of written description, enablement and best mode. It is certainly possible that the resulting opinion will simply confirm the existing legal theories regarding patent specifications, if for no other reason than to maintain certainty and consistency that have existed in this area of the law over past decades. Nonetheless, a decision in this case is eagerly awaited and has the potential to recast a significant portion of the patent law.

IV. SECTION 271(F) DOES NOT APPLY TO PATENTED METHODS

The Federal Circuit limited the reach of a part of the infringement section in *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*⁹⁹ In this opinion, the court considered a rulings from the Southern District of Indiana concerning claim invalidity and damages.¹⁰⁰ Among other decisions taken by the appellate panel, a particular question as to the applicability of 35 U.S.C. § 271 to methods was

98. 35 U.S.C. § 112, ¶ 1 (2006).

99. 576 F.3d 1348 (Fed. Cir. 2009) (en banc).

100. *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 483 F. Supp. 2d 734 (S.D. Ind. 2007); *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 418 F. Supp. 2d 1021 (S.D. Ind. 2006).

considered *en banc*, resulting in a reversal of the trial court on that question.¹⁰¹

In the pertinent section of the opinion, the court began by tracing the development of the law of infringement in cases in which an infringement is “completed” outside of the United States.¹⁰² In *Deepsouth Packing Co. v. Laitram Corp.*,¹⁰³ the Supreme Court determined that sending parts of a patented device abroad for assembly there was not an infringement. Section 271(f) of the Patent Act¹⁰⁴ was created to obviate the *Deepsouth* decision. In summary, it provides that one who sends to another country all or a “substantial portion” of components in an uncombined state, where combining them would infringe a U.S. patent, or who sends to another country a piece especially made for the patented invention and intends that it go into the patented invention, is an infringer.

The court then traced its consideration of § 271(f) through several opinions.¹⁰⁵ It noted that several cases reviewing the reach of the section considered both patent claims to devices and methods, and so were not entirely on point with respect to the present case, in which methods were the only claims at issue. However, in 2006 a panel of the court firmly faced a case of whether exporting a chemical catalyst for use in a claimed method could be infringement under § 271(f). In *Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co.*,¹⁰⁶ the court found that the catalyst was a “component of a patented invention” pursuant to the statute, and that its earlier decisions at least implied that the “patented invention” referred to in the statute could be a method.¹⁰⁷ The *Cardiac Pacemakers* court also noted an intervening Supreme Court decision in *AT&T Corp. v. Microsoft Corp.*,¹⁰⁸ which it characterized as sending “a clear message that the territorial limits of patents should not be lightly breached.”¹⁰⁹

The court’s treatment in the present analysis focused on what a “component” is, and finding that while method claims can have “components,” they are steps or actions and not tangible items like chemicals or device parts.¹¹⁰ The argument that the device or item that performs a method (or step of that method) is a component of the method was dispatched by the court through examining other parts of § 271 and noting its distinct notation of a component of a machine or product with “material or apparatus for use in practicing a patented process.”¹¹¹ Further, the use of the verb “supply” in § 271(f), in the court’s view, suggests a

101. *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348, 1364 (Fed. Cir. 2009).

102. *Id.*

103. 406 U.S. 518, 527, 531 (1972).

104. 35 U.S.C. § 271(f) (2006).

105. *Cardiac Pacemakers*, 576 F.3d at 1360-62.

106. 425 F.3d 1366 (Fed. Cir. 2005).

107. *Id.* at 1378.

108. 550 U.S. 437 (2007).

109. *Cardiac Pacemakers*, 576 F.3d at 1361-62.

110. *Id.* at 1363-64.

111. *Id.* at 1363-64 (quoting 35 U.S.C. § 271(c) (2006)).

transfer of a tangible item of some kind, not an intangible action or step.¹¹² The court forestalled the argument that its view of § 271(f) did not accord with the Congressional purpose of overruling the *Deepsouth* opinion, saying that *Deepsouth* concerned machines only, and so overruling that case did not require a statute that reached methods as well as devices.¹¹³ Consequently, the court rejected its prior *Union Carbide* holding and determined that the § 271(f) could not apply to patented methods.¹¹⁴ No infringement could lie for infringement of the method claim at issue for exported products.

V. NEW VIEWS ON FRAUD ON THE TRADEMARK OFFICE¹¹⁵

On the trademark side of the PTO, one principal development of the past year is in the treatment and analysis of allegations of fraud in acquiring trademark or service mark registrations. To this point, any error or irregularity in an application or other papers related to a registration could result in an opponent or the PTO raising the question of fraud on the Office, with the penalty of loss of the registration if proven.

As one example, note the case of *Medinol Ltd. v. Neuro Vaxx, Inc.*,¹¹⁶ which considered a mark registered for two types of goods but used by the registrant on only one of those types. The registrant argued that its erroneous description of goods in its application had been merely an oversight.¹¹⁷ The opponent took the position that if the registrant was allowed to keep its registration, the effect would be a lack of incentive to the registrant and other applicants to be honest with the PTO. Any false or fraudulent inclusion of goods in an application could simply be argued later to be a mistake, with the result being deletion of the mistake and effectively no penalty for the registrant.¹¹⁸ The Board cancelled the registration in its entirety, holding that knowledge that a mark is not being used on listed goods, or reckless disregard for the facts, is sufficient to find fraud in the procurement of a registration.¹¹⁹ Further, the Board held that it is not the registrant's subjective state of mind that is at issue, but the "objective manifestation of that intent."¹²⁰ The manifestation was including too many goods in the application, which the registrant signed, and that manifestation was enough to be considered fraudulent.

Even so, a later case provided a pathway to dealing with such alleged errors or "curing" what the PTO deemed to be fraud. In *Zanella Ltd. v. Nordstrom*,

112. *Id.* at 1364.

113. *Id.* at 1364-65.

114. *Id.* at 1365.

115. The author gratefully acknowledges the research and preparation of material in this section by James R. Blaufuss of Woodard, Emhardt, Moriarty, McNett & Henry LLC.

116. 67 U.S.P.Q.2d 1205 (T.T.A.B. 2003) (precedential).

117. *Id.* at 1206-07.

118. *Id.* at 1207.

119. *Id.* at 1209.

120. *Id.*

Inc.,¹²¹ the Board viewed correcting a false statement before a challenge to the registration would create a rebuttable presumption of lack of intent to defraud.¹²² The registrant had items in its registration that were not in fact being used. Under the *Medinol* standard, whether or not that is subjectively merely a mistake, the presence of the unused goods in a registration would appear to have been deemed fraudulent. Here, however, the registrant effectively corrected the registrations at issue by omitting its items on which the mark was not used from a later declaration of continued use.¹²³ Doing so prior to a challenge to the registration from another defused the fraud inquiry, giving the registrant the presumption of lack of intent to deceive the USPTO. A genuine issue remained as to registrant's intent, but the registrant had the benefit of the presumption.¹²⁴

The Board has also noted that a false statement that does not affect the PTO's decision on registration is not fraud. In *Kathleen Hiraga v. Sylvester J. Arena*,¹²⁵ a fraud had been alleged based on the registrant not having used the mark in commerce at the first use date given in the application. Holding that "the critical question in this case is whether the mark was in use in connection with the identified goods as of the filing date of his use-based application," the Board found no fraud.¹²⁶ The first use date was not "material to the Office's decision to approve a mark for publication,"¹²⁷ and so could not have resulted in an improper obtaining of a registration.

The beginnings of a change in fraud considerations were seen in *G&W Laboratories, Inc. v. G W Pharma Limited*.¹²⁸ In that case, fraud was alleged for registrations that listed goods and services, but it turned out that the registrant had never used the mark with respect to the services. Whereas the cancelled registration in *Medinol* concerned two types of goods in the same class, the Board took the view in *G&W* that applications in more than one class "can be viewed as a series of applications for registration of a mark in connection with goods or services in each class . . . [so that] the filer of such an application is in the same position it would be had it filed several single-class applications instead."¹²⁹ Drawing this distinction seems to be an overly legalistic view of registration applications, or perhaps it is an indication that the remedy of cancellation of an entire registration is draconian in some circumstances. The Board's consideration that fraud in one class—i.e. one application—is not necessarily fraud in all classes or applications may be sound logically and from a humanitarian perspective, but an equally logical conclusion would have been to say that the fraud in one application infects closely related applications as well.

121. 90 U.S.P.Q.2d 1758 (T.T.A.B. 2009) (not precedential).

122. *Id.* at 1761-62.

123. *Id.* at 1760-61.

124. *Id.* at 1762.

125. 90 U.S.P.Q.2d 1102 (T.T.A.B. 2009) (precedential).

126. *Id.* at 1107-08.

127. *Id.* at 1107.

128. 89 U.S.P.Q.2d 1571 (T.T.A.B. 2009) (precedential).

129. *Id.* at 1574.

In light of that background of recent fraud decisions of the Trademark Trial and Appeal Board, the Federal Circuit's decision on this topic in *In re Bose Corp.*¹³⁰ was all the more remarkable. The Board had cancelled a Bose registration on grounds of fraud in a declaration of continued use in support of a renewal of the registration.¹³¹ The declaration alleged continued use of the mark on tape players, which the declarant knew had in fact been discontinued, even though Bose continued to service such products.¹³² Although the declarant asserted a belief that Bose's transportation of repaired tape players was proper use of the mark in commerce, the Board found that belief unreasonable and cancelled the registration in its entirety.

The Federal Circuit, however, reversed the ruling of fraud, calling it error for the Board to have made simple negligence the standard for fraud "[b]y equating 'should have known' with a subjective intent."¹³³ In fact, the court viewed the record as being without substantial evidence that Bose intended to defraud the PTO in its declaration for renewal of the registration. Even if the registration needed some restriction in terms of its list of goods in order to reflect the reality of Bose's commercial situation, fraud was not a part of this calculation.

Nonetheless, the court left open the possibility of coming to the conclusion that fraud had been committed in an appropriate case. Because proof of a registrant's intent to deceive is "rarely available, such intent can be inferred from indirect and circumstantial evidence. But such evidence must still be clear and convincing, and inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement."¹³⁴ It also looked at precedent relied on in the *Medinol* case, *Torres v. Cantine Torresella S.r.l.*¹³⁵ Although the *Torres* opinion used the language "knows or should know" to characterize its analysis, the facts of that case clearly showed that the registrant made false statements that he knew to be false. The *Bose* court held that the *Medinol* board read *Torres* too broadly, and repeated that a subjective intent to deceive the PTO is an "indispensable element" in the question of fraud.¹³⁶

130. 580 F.3d 1240 (Fed. Cir. 2009).

131. *Id.* at 1242 (citing *Bose Corp. v. Hexawave, Inc.*, 88 U.S.P.Q.2d 1332 (T.T.A.B. 2007)).

132. *See id.*

133. *Bose*, 580 F.3d at 1244.

134. *Id.* at 1245 (quoting *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

135. 808 F.2d 46 (Fed. Cir. 1986).

136. *Bose*, 580 F.3d at 1245.