THE IMPLICATIONS OF *BILSKI*: PATENTABLE SUBJECT MATTER IN THE UNITED STATES

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ABSTRACT

The Federal Circuit's decision in *In re Bilski*, applying a machine-or-transformation test to determine whether a claimed process recites patentable subject matter, has had a significant impact in the courts and in the U.S. Patent and Trademark Office regarding the scope of what can be patented. Prior to *Bilski*, the Federal Circuit took an expansive view of what constitutes patentable subject matter, broadening the scope of protection compared to what had been applied by the Supreme Court in the 1970s and early 1980s. The *Bilski* decision narrows the scope of patentable subject matter, bringing the law closer to where it stood in the early 1980s, and closer to the views expressed recently by some Justices of the Supreme Court in dissenting opinions. At the very least, the Federal Circuit's machine-or-transformation test will have an impact on patents directed to business methods, software and research methods.

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INTRODUCTION

In October 2008, the Federal Circuit issued its highly anticipated *en banc* opinion in *In re Bilski*.[1] In *Bilski*, the court held that a process is patentable when it "is tied to a particular machine or apparatus[] or [when] it transforms a particular article into a different state or thing."[2] The *Bilski* decision provides a rich assortment of issues for discussion, including the extent to which the Federal Circuit articulated a new or shifting standard for the patentability of process claims relative to what the Supreme Court and the Federal Circuit had previously articulated. Perhaps more interesting, however, are implications *Bilski* raises for the future, including questions that are purposefully left unanswered by *Bilski*. This article examines the *Bilski* decision in the context of both Supreme Court and Federal Circuit jurisprudence over the last thirty years. Specifically, we will examine the most recent Supreme Court cases dealing with patentable subject matter, from *Gottschalk v. Benson*[3] through the decision to dismiss the grant of certiorari in the case of *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*[4] We will also examine the treatment of patentable subject matter by the Federal Circuit in cases leading up to *Bilski*, before discussing *Bilski* in more detail. Finally, we will discuss the implications of the *Bilski* decision, including questions *Bilski* leaves unanswered regarding the patentability of process claims in the areas of business methods, software and research methods.

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1 545 F.3d 943 (Fed. Cir. 2008).

2 *Id.* at 954.

3 409 U.S. 63 (1972).

4 548 U.S. 124 (2006) (per curiam).

I. HISTORY OF SUPREME COURT JURISPRUDENCE ON PATENTABLE SUBJECT MATTER

35 U.S.C. § 101 provides the basic contours of patentable subject matter: "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 therefore, subject to the conditions and requirements of this title."[5] Accordingly, to be patentable, an invention must fall within the four categories recognized by statute: "process, machine, manufacture, or composition of matter."[6] *Bilski* is concerned with the meaning of "process" in § 101.

Not every process falls within the meaning of § 101.[7] Specifically, the Supreme Court has historically found that principles of nature, such as natural phenomena, abstract ideas and mental steps are not considered patentable subject matter.[8] These concepts are considered basic tools of research.[9] Granting patent protection would preclude their use by others in the field, thereby inhibiting further scientific advancement. Despite these distinctions, the line between what is patentable and what is not is not always clear. The Supreme Court addressed this line in a series of decisions that are now more than twenty-five years old: *Benson*, *Parker v. Flook*[10] and *Diamond v. Diehr*.[11]

In *Benson*, the Court unanimously held that claims directed to a method for converting binary-coded decimal numbers into pure binary numbers were not patentable "processes" within the meaning of the statute.[12] The Court noted that the claims were not limited to a particular apparatus or end use and that the mathematical procedures for performing the conversion could be carried out with existing computers or even without a computer.[13] The Court found the

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5 35 U.S.C. § 101 (2006).

6 *Id.*

7 *See Bilski*, 545 F.3d at 952; *see also* Parker v. Flook, 437 U.S. 584, 588–89 (1978).

8 *Benson*, 409 U.S. at 67 ("A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right. Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." (internal quotation marks and citation omitted)).

9 *Bilski*, 545 F.3d at 952 (citing *Benson*, 409 U.S. at 67).

10 437 U.S. 584 (1978).

11 450 U.S. 175 (1981).

12 *Benson*, 409 U.S. at 67, 71, 73. Justices Stewart, Blackmun and Powell took no part in the case.

13 *Id.* at 64, 67 (noting also that the claims did not limit themselves "to any particular art or technology, to any particular apparatus or machinery, or to any particular end use").

claimed method "would wholly pre-empt the mathematical formula" of the claims because it had no substantial practical application except in connection with a digital computer.[14] Thus, the practical effect "would be a patent on the algorithm itself," in violation of the prohibition against patenting an idea.[15]

In rendering its decision, the Court surveyed prior decisions relating to patentable subject matter.[16] In addition to the familiar prohibitions against abstract ideas and laws of nature, the Court also commented on the nature of patentable processes.[17] For example, the Court held that invention "come[s] from the application of the law of nature to a new and useful end."[18] The Court reasoned further that "[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."[19] The Court continued:

> 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 requirement of our prior precedents.[20]

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.[21]

Six years later, in *Flook*, the Supreme Court again struck down method claims containing an algorithm as being unpatentable.[22] The claims in *Flook* were directed to a method for calculating and updating alarm limits used during a catalytic conversion process.[23] The method required the steps of measuring a process variable such as temperature, "[using] an algorithm to calculate an updated alarm limit value," and adjusting "the actual alarm limit . . . to the updated

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14 *Id*. at 71–72.

15 *Id*. at 72.

16 *See id*. at 67–72.

17 *Id*.

18 *Id*. at 67.

19 *Id*. at 70 (internal quotation marks omitted).

20 *Id*. at 71 (internal quotation marks omitted).

21 *See generally id*.

22 *See generally* Parker v. Flook, 437 U.S. 584 (1978).

23 *Id*. at 585.

value."[24] The Court found that the only novel feature of the method was the algorithm—a "new and presumably better method for calculating alarm limit values."[25] Because the catalytic conversion process itself was not new, the use of the algorithm in the catalytic conversion process was not patentable.[26] Thus, the method was nonstatutory, as it was "directed essentially to a method of calculating, using a mathematical formula."[27]

In holding the method unpatentable, the Court rejected the applicant's arguments that the method did not "wholly preempt the mathematical formula" and that it also included post-solution activity.[28] As the Court stated, "if a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory."[29] With regard to post-solution activity in particular, the Court found that this feature in itself was insufficient to confer patentability on the claims: "The 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. A competent draftsman could attach some form of post-solution activity to almost any mathematical formula."[30]

Finally, in *Diehr*, the Supreme Court held that process claims for curing rubber that included the use of a known equation were patentable.[31] The claims were directed to a process for shaping uncured rubber in a mold under heat and pressure and then curing the rubber in the mold so that it will retain its shape.[32] In particular, the claimed process constantly measured the temperature inside the mold (a step that was previously not possible) and, using the actual temperatures, repeatedly recalculated the cure time by using the known Arrhenius equation.[33] The Court found that the claims involved transformation of an article (*i.e.*, uncured rubber) into a different state and, therefore, fell within the scope of

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24 *Id.*

25 *Id.* at 588, 594–95.

26 *See id.* at 594–95 (stating that patentability required more than applying an algorithm to a known catalytic conversion process).

27 *Id.* at 595 (quoting *In re* Richman, 563 F.2d 1026, 1039 (C.C.P.A. 1977)) ("Very simply, our holding today is that a claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under § 101.").

28 *Id.* at 589–90.

29 *Id.* at 595 (quoting *Richman*, 563 F.2d at 1039).

30 *Id.* at 590.

31 Diamond v. Diehr, 450 U.S. 175, 184 (1981).

32 *Id.* at 185.

33 *Id.* at 178.

patentable subject matter defined by § 101.[34] The use of a mathematical equation and a computer in the claimed process did not change this conclusion.[35]

The Court in *Diehr* distinguished *Benson* and *Flook*, respectively, as being directed to algorithms or mathematical formulae themselves.[36] In contrast, the claims of *Diehr* were directed to a process of curing rubber, "not as an attempt to patent a mathematical formula."[37] The Court noted that the applicants "seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process."[38] The Court reiterated that the use of a computer or an algorithm in a claimed process did not render the process unpatentable, so long as the claimed process was drawn to statutory subject matter—that is, that the invention came "from the application of the law of nature to a new and useful end."[39] Moreover, the appropriate analysis for determining patent eligibility is to consider the claims as a whole.[40] "It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis."[41]

The Court reaffirmed its analysis from *Benson* and *Flook*. Citing *Benson* and *Flook*, the Court explained that a "mathematical formula as such is not accorded the protection of our patent laws, and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment."[42] Further, "insignificant post-solution activity will not transform an unpatentable principle into a patentable process. To hold otherwise would

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34 *Id*. at 184 (citing Gottschalk v. Benson, 409 U.S. 63, 70 (1972) for the proposition that "[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" (internal quotation marks omitted)).

35 *Id*. at 185.

36 *Id*. ("In *Benson*, we held unpatentable claims for an algorithm used to convert binary code decimal numbers to equivalent pure binary numbers."); *id.* at 187 ("In contrast [to *Flook*], the respondents here do not seek to patent a mathematical formula."); *see id.* (identifying language in both cases stating that algorithms and computer programs are not per se unpatentable).

37 *Id*. at 191.

38 *Id*. at 187.

39 *Id*. at 188 ("Arrhenius' equation is not patentable in isolation, but when a process for curing rubber is devised which incorporates in it a more efficient solution of the equation, that process is at the very least not barred at the threshold by § 101.").

40 *Id*. at 193.

41 *Id*. at 188.

42 *Id*. at 191 (citation omitted).

allow a competent draftsman to evade the recognized limitations on the type of subject matter eligible for patent protection."[43]

However, the Court explained when mathematical formulae are appropriate:

> [W]hen a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, 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), then the claim satisfies the requirements of § 101.[44]

Most recently, the Court in *Metabolite* declined to revisit the issue of patentable subject matter when it dismissed certiorari as improvidently granted.[45] Three Justices dissented from the dismissal, however, and their dissenting opinion provides some clues regarding the Court's current view of patentable subject matter. In *Metabolite*, the claim at issue was not directed to a mathematical formula, but rather to a process for diagnosing vitamin deficiencies.[46] The process included measuring the level of homocysteine in a body fluid and correlating an elevated level of total homocysteine with a deficiency of cobalamin or folate.[47] The dissent concluded that the claim was directed to a natural phenomenon.[48] The dissent rejected arguments that the claims were directed to an application of a law of nature that entailed physical transformation of matter (*i.e.*, alteration of a blood sample during testing) because the claim did not describe a process for transforming blood.[49] Rather, the dissent characterized the process as including the steps of "(1) obtain[ing] test results and (2) think[ing] about them," where the user could "use any test at all."[50] When characterized in this manner, there is no physical transformation and, accordingly, the process is not patentable.[51]

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43 *Id.* at 191–92 (citation omitted).

44 *Id.* at 192.

45 Lab. Corp. of Am. Holdings v. Metabolite Labs., 548 U.S. 124 (2006) (per curiam).

46 *Id.* at 128 (Breyer, J., dissenting).

47 *Id.* at 129. Claim 13 sought protection for "[a] method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate." *Id.*

48 *Id.* at 135.

49 *Id.* at 136.

50 *Id.*

51 *See id.* at 135–36 (considering the claim unpatentable in this context as directed to a natural phenomenon, and not including "a process for transforming blood or any other matter").

The dissent also expressed doubt about the Federal Circuit's formulation in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*,[52] that a process is patentable if it produces "a useful, concrete and tangible result."[53] That reasoning "would cover instances where this Court has held the contrary."[54] In any event, the dissent concluded that the claim at issue was directed to a natural phenomenon and, as such, was nonstatutory.[55]

In *Flook*, the Court discussed why natural phenomena and scientific principles "are not the kind of 'discoveries' that the statute was enacted to protect."[56] Specifically, laws of nature "reveal[] a relationship that has always existed."[57] The Court continued:

> "[M]ere" recognition of a theretofore existing phenomenon or relationship carries with it no rights to exclude others from its enjoyment. . . . Patentable subject matter must be new (novel); not merely heretofore unknown. There is a very compelling reason for this rule. The reason is founded upon the proposition that in granting patent rights, the public must not be deprived of any rights that it theretofore freely enjoyed.[58]

The dissenting opinion in *Metabolite* expanded on this rationale.[59] To the dissenters, "the reason for the exclusion" of laws of nature, natural phenomena and abstract ideas from patentable subject matter "is that sometimes *too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection."[60] While acknowledging that patents can "encourage research by providing monetary incentives for invention," the dissent explained that patents also "can discourage research by impeding the free exchange of information."[61]

II. THE FEDERAL CIRCUIT'S APPROACH BEFORE *BILSKI*

In applying Supreme Court precedent, the Federal Circuit further developed the concept of patentable subject matter. In *State Street*, the court rejected

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52 149 F.3d 1368 (Fed. Cir. 1998).

53 *Metabolite*, 548 U.S. at 136 (Breyer, J., dissenting) (citing *State St. Bank*, 149 F.3d at 1373).

54 *Id*.

55 *Id*. at 137–38.

56 Parker v. Flook, 437 U.S. 548, 593 (1978).

57 *Id*. at 593 n.15.

58 *Id*. (quoting P. ROSENBERG, PATENT LAW FUNDAMENTALS, § 4, p. 13 (1975)).

59 *See Metabolite*, 548 U.S. at 126–27 (Breyer, J., dissenting).

60 *Id*.

61 *Id*. at 127.

the "business method" exception, which was a further exception to patentable subject matter that had appeared in earlier case law.[62] The court also put forward a new touchstone for statutory subject matter: whether processes produce "useful, concrete and tangible result[s]."[63]

The *State Street* patent was directed to a "Hub and Spoke" investment scheme which provided a system for centrally monitoring and recording financial information for a portfolio of investment funds, while at the same time allocating the financial information for each individual fund.[64] As an initial matter, the court observed that the claims were directed to a machine, which is one of the categories of statutory subject matter under § 101.[65] Although mathematical algorithms are not patentable, "data[] transformed by a machine through a series of mathematical calculations . . . constitute[s] a practical application of an abstract idea (a mathematical algorithm, formula, or calculation), because it produce[s] a useful, concrete and tangible result."[66] That is, an algorithm that is merely an abstract idea "constituting disembodied concepts or truths" is not patentable, but if an algorithm is applied "in a useful way," the application is patentable despite including an algorithm.[67] The claimed machine was a practical application of a mathematical algorithm because it transformed data (discrete dollar amounts) into a "final share price momentarily fixed for recording and reporting purposes."[68] Accordingly, it produced a useful, concrete and tangible result and was therefore patentable.[69]

Similarly, in *AT&T Corp. v Excel Communications*,[70] the Federal Circuit upheld claims directed to a process involving mathematical algorithms as patentable subject matter.[71] The court noted that the scope of § 101 is the same whether the claims recite a machine or a process: "[W]e consider the scope of § 101 to be the same regardless of the form—machine or process—in which a particular claim is drafted."[72] The invention was directed to a method of storing

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62 State St. Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368, 1375, 1377 (Fed. Cir. 1998), *abrogated by In re* Bilski, 545 F.3d 943 (2008).

63 *Id*. at 1373.

64 *Id*. at 1371.

65 *Id*. at 1372.

66 *Id*. at 1373 (internal quotation marks omitted).

67 *Id*. (internal quotation marks omitted).

68 *Id*.

69 *Id*.

70 172 F.3d 1352 (Fed. Cir. 1999), *abrogated by In re* Bilski, 545 F.3d 943 (2008).

71 *Id*. at 1361.

72 *Id*. at 1357.

information related to long-distance calls.[73] Specifically, the claims included a step of "generating a message record" for long-distance calls that included information about a caller's "primary interexchange carrier (PIC)," which aided in differential billing of callers.[74] The proscription against patenting mathematical algorithms "to the extent such a proscription still exists, is narrowly limited to mathematical algorithms in the abstract."[75] The patented process produced a useful, concrete and tangible result (determining the value of the PIC indicator which facilitated differential billing), "without pre-empting other uses of the mathematical principle."[76] Accordingly, the claims were patentable.[77] It was not necessary for the process to physically transform or convert information from one state into another, as the "physical transformation" principle is "but merely one example of how a mathematical algorithm may bring about a useful application."[78]

III. THE *BILSKI* DECISION

As mentioned previously, the *Bilski* decision reiterated that the standard for patentable subject matter is whether the claimed process is tied to a particular machine or apparatus or whether it transforms a particular article into a different state or thing.[79] *Bilski* also rejected as insufficient the "useful, concrete and tangible result" test articulated in *State Street* and *AT&T*.[80]

The *Bilski* patent application claimed a method for hedging risk in commodities trading.[81] The claim recited a series of steps that included "(a) initiating a series of transactions between [a] . . . provider and consumers . . . at a fixed rate . . . ; (b) identifying market participants . . . having a counter-risk position . . .; and (c) initiating a [second] series of transactions . . . at a second fixed rate" with the second group (providers and market participants).[82] Thus, if there is a spike in prices, the method allows a provider to sell to the participants at a disadvantageous price, while at the same time purchase at an advantageous

73 *Id*. at 1353.

74 *Id*. at 1353–54.

75 *Id*. at 1356.

76 *Id*. at 1358.

77 *Id*. at 1361.

78 *Id*. at 1358.

79 *In re* Bilski, 545 F.3d 943, 955–56 (Fed. Cir. 2008).

80 *Id*. at 959.

81 *Id*. at 949.

82 *Id*.

price.[83] The claim was not limited by the type of commodity, or even that it be an actual commodity, nor was it tied to the use of a computer.[84]

As explained in *Bilski*, the critical inquiry regarding patentable subject matter is whether a claim that recites a "fundamental principle" would preempt substantially all uses of the fundamental principle if allowed.[85] If so, the claim is nonstatutory.[86] The machine-or-transformation test, articulated above, is the "definitive test" to determine whether a claim preempts all use of a fundamental principle.[87] The court held open the possibility that future developments would render the machine-or-transformation test inapplicable in certain circumstances, or that the Supreme Court could modify the test in the future.[88] Nevertheless, it held that the machine-or-transformation test was the governing test for determining patent eligibility.[89]

The court noted that there were two corollaries to the machine-or-transformation test.[90] First, field-of-use limitations, limiting the claim to specific purposes or uses, are insufficient to render otherwise ineligible process claims patent-eligible.[91] Second, "insignificant postsolution activity will not transform an unpatentable principle into a patentable process."[92]

The court identified two additional aspects of the Supreme Court's jurisprudence. First, the Supreme Court "has held that whether a claimed process is novel or non-obvious is irrelevant to the § 101 analysis. Rather, such considerations are governed by 35 U.S.C. § 102 (novelty) and § 103 (non-obviousness)."[93]

Second, it is "inappropriate to determine the patent-eligibility of a claim as a whole based on whether selected limitations constitute patent-eligible sub-

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83 *See id*. at 950 ("And the provider has thus hedged its risk; if demand and prices skyrocket, it has sold . . . at a disadvantageous price but has bought . . . at an advantageous price, and vice versa if demand and prices fall.").

84 *Id*.

85 *Id*. at 954. The court used "fundamental principles" to refer to "laws of nature, natural phenomena, and abstract ideas." *Id.* at 952 n.5.

86 *Id*. at 954 (citing the holding in O'Reilly v. Morse, 56 U.S. 62, 113 (1853) that invalidated a patent claim "pre-empting all uses of electromagnetism to print characters at a distance").

87 *Id*.

88 *Id*. at 956.

89 *Id*.

90 *Id*. at 957.

91 *Id*.

92 *Id*. (quoting Diamond v. Diehr, 450 U.S. 175, 191–92 (1981)) (internal quotation marks omitted).

93 *Id*. at 958 (citation omitted).

ject matter."[94] As the court explained, "even though a fundamental principle itself is not patent-eligible, processes incorporating a fundamental principle may be patent-eligible. Thus, it is irrelevant that any individual step or limitation of such processes by itself would be unpatentable under § 101."[95]

In applying the machine-or-transformation test, the specific machine or transformation "must impose meaningful limits on the claim's scope" and cannot "merely be insignificant extra-solution activity."[96] The court did not address the machine-implementation prong of the test, as the *Bilski* claims admittedly were not limited to a particular apparatus. The court also explicitly declined to rule on whether the recitation of a computer is sufficient to tie a process claim to a particular machine.[97]

Under the transformation prong of the machine-or-transformation test, a "claimed process is patent-eligible if it transforms an article into a different state or thing."[98] To qualify, the transformation must be central to the purpose of the claimed process.[99] The court then sought to clarify what an "article" could be. A process that transforms physical objects or substances (such as through chemical or physical transformations) is patent-eligible.[100] The court noted that the "raw materials of many information-age processes, however, are electronic signals and electronically-manipulated data," and addressed the transformation of data.[101] Electronic transformation of data into a particular visual depiction, where the data is representative of physical or tangible objects, is sufficient to convey patent eligibility, even without a transformation of the object the data represents.[102] The court explained its rationale:

> So 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, there is no

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94 *Id.* (citing Parker v. Flook, 437 U.S. 584, 594 (1978) and *Diehr*, 450 U.S. at 188).

95 *Id.*

96 *Id.* at 961–62.

97 *Id.* at 962 ("As to machine implementation, Applicants themselves admit that the language of claim 1 does not limit any process step to any specific machine or apparatus. As a result, issues specific to the machine implementation part of the test are not before us today. We leave to future cases the elaboration of the precise contours of machine implementation, as well as the answers to particular questions, such as whether or when recitation of a computer suffices to tie a process claim to a particular machine." (citation omitted)).

98 *Id.*

99 *Id.*

100 *Id.*

101 *Id.*

102 *Id.* at 963.

> danger that the scope of the claim would wholly pre-empt all uses of the principle.[103]

However, as with post-solution activity, the addition of a data-gathering step is insufficient to convey patent eligibility:

> We note that, at least in most cases, gathering data would not constitute a transformation of any article. 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. Further, the inherent step of gathering data can also fairly be characterized as insignificant extra-solution activity.[104]

In addition to rejecting the "useful, concrete and tangible result" test of *State Street*, the court in *Bilski* also repudiated both the *Freeman-Walter-Abele* test developed by the Court of Customs and Patent Appeals (and initially followed by the Federal Circuit) and the "technological arts test," or any test that would expand the categorical exclusions of patentable subject matter (such as to exclude all business methods).[105] The *Freeman-Walter-Abele* test required determining whether a claim recited an algorithm and then determining whether the algorithm "is 'applied in any manner to physical elements or process steps.'"[106] The court concluded that the technological arts test is unwieldy to apply in application because the meaning of "technological arts" and "technology" "are both ambiguous and ever-changing."[107]

Finally, the court held that there was no "physical steps" test for patentable subject matter, as some commentators suggested was applied in *In re Comiskey*.[108]

> [T]he 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. As a result, even a claim that recites "physical steps" but neither recites a particular machine or apparatus, nor transforms any article into a different state or thing, is not drawn to patent-eligible subject matter. Conversely, a claim that purportedly lacks any "physical steps" but is still tied to a machine or achieves an eligible transformation passes muster under § 101.[109]

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103 *Id*.

104 *Id*.

105 *Id*. at 959–60.

106 *Id*. at 959 (quoting *In re* Abele, 684 F.2d 902, 906 (C.C.P.A. 1982)).

107 *Id*. at 960.

108 *Id*. at 960–61 (discussing *In re* Comiskey, 499 F.3d 1365 (Fed. Cir. 2007), *aff'd in part and vacated in part en banc*, 554 F.3d 967 (Fed. Cir. 2009)).

109 *Id*. at 961.

However, mental steps alone will not suffice. A "claimed process wherein all of the process steps may be performed entirely in the human mind is obviously not tied to any machine and does not transform any article into a different state or thing. As a result, it would not be patent-eligible under § 101."[110]

Turning to the facts of Bilski's claim, the court found that the claimed process for hedging risk did not have the requisite transformation: "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."[111] The claimed process involved an exchange of options, which are legal rights. It was directed to "the mental and mathematical process of identifying transactions that would hedge risk"; it did not involve transformation of a physical substance.[112]

In rejecting Bilski's claims, the court analogized to claims directed to diagnosing a malfunction or abnormal condition. The court discussed *In re Meyer*,[113] in which "the applicant sought to patent a method of diagnosing the location of a malfunction in an unspecified multi-component system that assigned a numerical value, a 'factor,' to each component and updated that value based on diagnostic tests of each component."[114] The court noted that "the diagnostic tests were not identified, and the 'factors' were not tied to any particular measurement; indeed they could be arbitrary. . . . [T]he claim was effectively drawn only to 'a mathematical algorithm representing a mental process,'" and the court affirmed the PTO's rejection on § 101 grounds.[115] The court concluded that the "claim effectively sought to pre-empt the fundamental mental process of diagnosing the location of a malfunction in a system by noticing that the condition of a particular component had changed."[116] The court then briefly discussed *In re Grams*,[117] which it described as rejecting a claim to a process of diagnosing an abnormal condition in a person by "identifying and noticing discrepancies in

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110 *Id*. at 961 n.26.

111 *Id*. at 963–64.

112 *Id*. at 965 (comparing the claims to those of *Comiskey* and *Metabolite*: "Applicants here seek to claim a non-transformative process that encompasses a purely mental process of performing requisite mathematical calculations without the aid of a computer or any other device, mentally identifying those transactions that the calculations have revealed would hedge each other's risks, and performing the post-solution step of consummating those transactions.").

113 688 F.2d 789 (C.C.P.A. 1982).

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

115 *Id*. (quoting *Meyer*, 688 F.2d at 790).

116 *Id*.

117 888 F.2d 835 (Fed. Cir. 1989).

results of unspecified clinical tests of different parts of [the] body."[118] The court then directly compared the *Grams* and *Bilski* claims (which the court identified as "similar") to those in *Metabolite*: "We note that several Justices of the Supreme Court, in a dissent to a dismissal of a writ of certiorari, expressed their view that a similar claim in [*Metabolite*] was drawn to unpatentable subject matter."[119] Thus, the Federal Circuit suggested that claims like those in *Metabolite* will not meet § 101.

IV. IMPLICATIONS AND OPEN QUESTIONS OF THE *BILSKI* DECISION

A. Patent Eligibility

Without a doubt, *Bilski* will have a significant impact on patent law, not only in the areas of software and business methods, but also in other fields, such as life sciences and diagnostics. In the first instance, *Bilski*'s express holdings will impact patent eligibility and the way patents are written in the future. Under *Bilski*, generally tying a claim to a digital computer, without more, is not sufficient to confer patent eligibility. Regardless of whether a process recites the use or application of a computer, if the claim would preempt substantially all uses of the algorithm, it would not be patent-eligible. Similarly, after *Bilski*, field-of-use limitations, by themselves, will not be sufficient to confer patent eligibility.

Accordingly, in drafting the claims as well as the rest of the application, practitioners should consider including details about specific applications, details regarding the technical aspects of the invention, and a range in the level of specification that provides for the possibility of fall-back positions in the event that broadly worded claims are considered unpatentable. Describing transformed data with specificity as to physical features may also be successful. For example, in *In re Abele*,[120] the broadest claim calculated the difference between two data values, while a dependent claim specified the data was x-ray attenuation data produced in a two-dimensional field.[121] The broad claim was held unpatentable because the display of the data was insignificant post-solution activi-

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118 *Bilski*, 545 F.3d at 965 (citing *Grams*, 888 F.2d at 839–40).

119 *Id.* at 965 n.27.

120 684 F.2d 902 (C.C.P.A. 1982), *abrogated by In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008).

121 *Id.* at 908.

ty.[122] In contrast, the dependent claim transformed the data into "a particular visual depiction of a physical object" and was patentable.[123]

In including such details, however, one must take care to avoid simply adding insignificant "extra-solution" activity, such as data-gathering steps or post-solution activity, which are insufficient to convey patentability. "[T]he use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility."[124]

Bilski will also likely impact arguments that are made in favor of and against patentability of certain claims. First, arguments against the patentability of patent claims must take into account the claims as a whole. It is improper to look at whether individual steps would be patent-eligible. In addition, patentability arguments relying on "physical steps" present in the claims are uncertain under *Bilski*. Unless such steps are tied to a particular machine or apparatus or are transformative, they will not be sufficient to support a patentability argument. Conversely, claims that do not recite physical steps are still potentially patentable, if they are tied to a particular machine or achieve an appropriate transformation.

As the court rejected other tests as insufficient or unwieldy, practitioners will not be able to rely on them in arguing for or against patentability. Thus, (1) identifying whether a claim recites an algorithm and, if so, whether the algorithm is applied to physical elements or process steps (the *Freeman-Walter-Abele* test), is not determinative; (2) determining whether the claim produces useful, concrete and tangible results (the *State Street* test) is not determinative; (3) determining whether the claim includes a "technological" component (the proposed technological-arts test) is not determinative; and (4) identifying a claim as directed to particular subject matter (such as a business method) beyond what has already been established (mental steps, abstract ideas) is not determinative.[125]

In rejecting these other tests, the court did not indicate whether the claims in those cases would be patent-eligible under the machine-or-transformation test. Thus, patent-eligibility in many fact patterns will remain uncertain until additional cases are decided.

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122 *Id.*

123 *Bilski*, 545 F.3d at 963.

124 *Id.* at 961.

125 *Id.* at 958–61.

B. Software and Business Methods

As *Bilski* refused to impose categorical restrictions on patentable subject matter, software and business methods patents, at least in principle, survive. Business method claims are subject to the same requirements as other process claims, meaning they must also meet the machine-or-transformation test, which may be more challenging for these types of claims than for software claims. Computer product and apparatus claims will be easier to patent than process claims, given that they are inherently tied to a particular machine. However, as discussed further below, the logic of *Bilski* could apply equally to apparatus claims, particularly in view of the statement in *AT&T* that the scope of § 101 is "the same regardless of the form—machine or process—in which a particular claim is drafted."[126]

Process claims directed to software and business methods must adhere to the machine-or-transformation test and the guidelines outlined above. But what are the practical implications? With regard to software, claims directed to an operating system and thus directed to the operation of the computer probably will be adequately tied to a particular machine. Moreover, as described above, reciting physical steps is not necessary, so long as the claim is tied to a particular machine or is transformative. With computer applications, claims directed to transforming data into a particular visual depiction of a physical object should be able to meet the transformative prong of the test. However, claims that simply refer generally to a general-purpose computer or whose ties to a computer are only data-gathering steps, mathematical calculations or the display of the results of calculations may not be considered to recite patent-eligible subject matter. Therefore, it may be helpful to include descriptions of particular computer functions or modules, where possible.

Bilski made clear that software claims cannot cover all uses of an algorithm. If they do, they will be considered unpatentable. This inquiry is of course dependent on the definition of the algorithm. If the algorithm is just part of a process of curing synthetic rubber, as in *Diehr*, the process is not considered unpatentable simply because it uses the Arrhenius equation—it is not attempting to patent all uses of the equation. If, however, the claim is to an improved algorithm for calculating an alarm limit, as in *Flook*, it is not patentable.

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[126] AT&T Corp. v. Excel Commc'ns, 172 F.3d 1352, 1357 (Fed. Cir. 1998), *abrogated by In re* Bilski, 545 F.3d 943 (2008); *see* State St. Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368, 1375 (Fed. Cir. 1998) ("The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to . . . ."), *abrogated by In re* Bilski, 545 F.3d 943 (2008).

This analysis brings to mind the idea/expression dichotomy of copyright law, which provides that ideas (algorithms) do not receive copyright protection, but expression of ideas (applications of algorithms) do receive copyright protection.[127] Copyright cases can turn on where the line is drawn between unprotected ideas and protected expression, and on which side of that line what is sought to be protected falls. Similarly, the prohibition that a process claim cannot preempt all uses of an algorithm may result in more argument (whether before the Patent Office or in the courts) over the definition of the algorithm. Therefore, practitioners should consider how to define the algorithm of software process patents to survive a patentability challenge.

C. Life Sciences – Diagnostic Testing

While the *Bilski* claims were directed to a business method, the language of the court's decision is not so limited. The question of whether a process preempts an algorithm is equally applicable to the question of whether a method preempts a law of nature or a natural phenomenon, an issue that arises with some frequency in life sciences cases, particularly those involving research methods and diagnostic testing. The most recent of those cases to garner significant attention was *Metabolite*. Although by dismissing the writ of certiorari the Supreme Court allowed these claims to stand, the three dissenting Justices argued that claims such as those in *Metabolite* would not pass the machine-or-transformation test: "[T]he process described in claim 13 is *not* a process for transforming blood or any other matter. Claim 13's process instructs the user to (1) obtain test results and (2) think about them."[128] In *Bilski*, the Federal Circuit appears to agree:

> [T]he claimed process [in *Bilski*] as a whole is directed to the mental and mathematical process of identifying transactions that would hedge risk. . . . We have in fact consistently rejected claims like those in the present appeal and in *Comiskey*. . . . We note that several Justices of the Supreme Court . . . expressed their view that a similar claim in [*Metabolite*] was drawn to unpatentable subject matter.[129]

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127 *See* Mazer v. Stein, 347 U.S. 201, 217 (1954).

128 Lab Corp. of Am. Holdings v. Metabolite Labs., 548 U.S. 124, 136 (2006) (Breyer, J., dissenting); *see also id.* at 137 ("At most, respondents have simply described the natural law at issue in the abstract patent language of a 'process.' But they cannot avoid the fact that the process is no more than an instruction to read some numbers in light of medical knowledge.").

129 *Bilski*, 545 F.3d at 965 & n.27.

After *Bilski*, the Federal Circuit affirmed (in a one-paragraph, non-precedential opinion) a grant of summary judgment of invalidity under § 101 for claims directed to methods of selecting vaccine regimens less likely to cause chronic autoimmune disorders in *Classen Immunotherapies, Inc. v. Biogen IDEC*.[130] The district court found the claims unpatentable as an attempt to patent a natural phenomenon.[131] Claim 1 of the Classen patent recited

> [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.[132]

Like the claims discussed in *Bilski*, the Classen claims are not restricted to a particular method of immunizing or the use of a particular immunogen or immunization schedule. Rather, to follow the formulation the dissenters used in *Metabolite*, the claim instructs one to immunize mammals (in any way) and "think about" the results. These decisions suggest that, while a claim that includes a limitation directed to the testing or transformation of a sample may be patent-eligible, claims directed to a diagnosis or analysis of data, even with what are essentially data-gathering or post-solution steps, may not be patent-eligible.

Two other cases also involving patents directed to inventions in the life science sector and including claims that may be implicated by the *Bilski* decision are *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*[133] and *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*.[134] The *Ariad* claims are directed to methods for inhibiting expression of a gene, but arguably relate to a natural process in cells.[135] Following a trial in 2007, the claims were found to be patentable under § 101,[136] and the case was being closely watched for how the Federal Circuit would address the § 101 issue. The Federal Circuit recently issued its decision in the *Ariad* case, finding the patent invalid under 35 U.S.C.

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130 304 F. App'x 866 (Fed. Cir. 2008).

131 Classen Immunotherapies, Inc. v. Biogen Idec, Civ. No. WDQ-04-2607, 2006 WL 6161856, slip op. at 5 (D. Md. Aug. 16, 2006).

132 U.S. Patent No. 5,723,283 (filed May 31, 1995).

133 No. 2008-1248, 2009 WL 877642 (Fed. Cir. Apr. 3, 2009).

134 No. 04cv1200 JAH (RBB), 2008 WL 878910 (S.D. Cal. Mar. 28, 2008).

135 U.S. Patent No. 6,410,516 (filed June 5, 1995).

136 No. 02-11280-RWZ, 2007 WL 2712087, at *1 (D. Mass. Sept. 10, 2007).

§ 112 for lack of written description.[137] Interestingly, the court did not address the patentability of the claims under § 101.[138] *Prometheus* is currently pending before the Federal Circuit. The *Prometheus* claims are directed to methods for optimizing the therapeutic efficacy of certain drugs by determining the level of a specific metabolite in a patient following drug administration, which indicates whether the drug dosage needs to be adjusted.[139] The *Prometheus* claims were held unpatentable as being directed to natural phenomena (a correlation between metabolite levels and therapeutic efficacy and toxicity).[140] With *Ariad* having been decided on other grounds, *Prometheus* continues to be watched closely to determine the full impact of *Bilski* on method claims in the life sciences sector.

D. Unanswered Questions

Finally, the *Bilski* case also left a number of questions unanswered. Because the claims in *Bilski* were admittedly not tied to a particular machine, the court did not elaborate on this part of the machine-or-transformation test.[141] Accordingly, practitioners are left with little guidance to help them determine what is sufficient to tie a claim to a particular machine, or when the use of a specific machine "impose[s] meaningful limits on the claim's scope to impart patent-eligibility."[142]

In affirming the patentability of claims reciting transformation of data into a particular visual depiction of a physical object, *Bilski* gave a big clue as to processes that will be considered sufficiently transformative to be patentable. What remains unclear, however, is the breadth of that analysis. Under what circumstances is a display of process results considered such a transformative process? And how broadly will courts interpret the requirement that the data be representative of physical objects?

The *Bilski* court noted the decision was specific to process patents, because there were no machine or apparatus claims pending. However, at least with regard to algorithms, *Bilski* is clear that the fundamental inquiry is whether

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137 No. 2008-1248, 2009 WL 877642, at *12 (Fed. Cir. Apr. 3, 2009).

138 *Id*.

139 U.S. Patent Nos. 6,355,623 (filed April 8, 1999) and 6,680,302 (continuation of '623 patent).

140 Prometheus Labs. v. Mayo Collaborative Servs., No. 04cv1200 JAH (RBB), 2008 WL 878910, at *3–9 (S.D. Cal. Mar. 28, 2008).

141 *In re* Bilski, 545 F.3d 943, 962 (Fed. Cir. 2008) ("We leave to future cases the elaboration of the precise contours of machine implementation, as well as the answers to particular questions, such as whether or when recitation of a computer suffices to tie a process claim to a particular machine.").

142 *Id*. at 961.

the claim preempts all use of a fundamental principle. Could an apparatus or product claim that includes an algorithm violate this rule? If so, what is the result? A court could consider a product claim that appears to preempt all use of a fundamental principle an unpatentable attempt to patent a law of nature, natural phenomenon, or abstract idea. Alternatively, such a claim could be considered a patentable invention of a new machine or a practical application of the fundamental principle. In considering this issue, it may be helpful to consider the claims in the *Bilski* case. Those claims were drafted as process claims and held to be unpatentable. However, those claims possibly could have been written as apparatus claims, with the steps implemented on a computer, such as by inserting "means for" before each process step, making the claims look more like the claims in the *State Street* case. This rewrite is illustrated below, showing deletions in brackets and insertions in italics:

> A *data processing system* [method] for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising [the steps of]:
>
> (a) *means for* initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;
>
> (b) *means for* identifying market participants for said commodity having a counter-risk position to said consumers; and
>
> (c) *means for* initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.[143]

While giving up the ability to carry out the steps without a computer, in practice the *Bilski* method may require the use of a computer. If that is the case, writing the claim using means-plus-function language or "a processor for" carrying out each function would provide similar practical coverage. Similarly, the claim could have been written as a computer program product:

> A [method] *computer program product*, for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising *a computer usable medium having a computer readable program code for causing a computer to* [the steps of]:
>
> (a) [initiating] *initiate* a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase

[143] This is a rewrite of Claim 1 in Bilski's application, *id.* at 949, showing deletions in brackets and insertions in italics.

> said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;
>
> (b) [identifying] *identify* market participants for said commodity having a counter-risk position to said consumers; and
>
> (c) [initiating] *initiate* a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.[144]

Does converting the claims to recite an apparatus automatically confer patentability? Given what the Federal Circuit in *State Street* and *AT&T*, as well as the Supreme Court in *Benson*, said about treating process and product claims the same for purposes of § 101, and the *Bilski* court's concerns with pre-empting a fundamental principle, a claim may not be patentable for purposes of § 101 merely because it is written as an apparatus claim. Although the Federal Circuit has not yet addressed this question, the Board of Patent Appeals and Interferences declined "to support the rejection" of computer program product ("Beauregard") claims that recited particular software modules:

> It has been the practice for a number of years that a "Beauregard Claim" of this nature be considered statutory at the USPTO as a product claim. Though not finally adjudicated, this practice is not inconsistent with *In re Nuijten*. Further, the instant claim presents a number of software components, such as the claimed logic processing module, configuration file processing module, data organization module, and data display organization module, that are embodied upon a computer readable medium. This combination has been found statutory under the teachings of *In re Lowry*. In view of the totality of these precedents, we decline to support the rejection under 35 U.S.C. § 101.[145]

Bilski also did not fully address the interplay of § 101 and § 103 when analyzing claims. According to *Bilski*, "whether a claimed process is novel or non-obvious is irrelevant to the § 101 analysis."[146] At the same time, conventional or insignificant data gathering or post-solution activity does not render a

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144 This is a rewrite of Claim 1 in Bilski's application, *id.* at 949, showing deletions in brackets and insertions in italics.

145 *Ex parte* Li, U.S.P.Q.2d (BNA) 1695, 1698–99 (B.P.A.I. 2008) (citations omitted). Three weeks later, in *Ex parte Halligan*, the Board considered the rejection of apparatus claims under § 101 (lack of patentable subject matter) and § 112 (as indefinite), and because of prior art. 89 U.S.P.Q.2d (BNA) 1355, 1357–58 (B.P.A.I. 2008). The claims had a series of elements of the form "means within the programmed computer for." *Id.* at 1357. The Board concluded that those claims were indefinite and essentially vacated the § 101 rejection, stating that its "reversal [under § 101] is based on the indefiniteness of the claimed subject matter and does not reflect on the merits of the underlying rejection." *Id.* at 1365.

146 *Bilski*, 545 F.3d at 958.

claim patent-eligible.[147] This suggests that some comparison of the prior art to the claims is necessary.[148] The line between adding conventional data gathering or post-solution steps (not patent-eligible), and adding unconventional or non-obvious data gathering or post-solution steps (possibly rendering a claim patent-eligible under § 101) is not clear, nor are the full ramifications for obviousness in these circumstances.

Finally, it remains to be seen whether the machine-or-transformation test will adequately address new technology or developments, or even computer software. Future decisions may clarify whether *Bilski* will better assist in defining the boundaries of patentable subject matter, and whether (or when) it will require refinement.

V. CONCLUSION

The *Bilski* machine-or-transformation test has narrowed (and provided some clarification to) the question of when a process (or even an apparatus) claims patentable subject matter. At the same time, as the Federal Circuit itself recognized in describing questions it was not answering, it has left a lot of uncertainty as to the scope of patentable subject matter and as to the validity of many software, business method and diagnostics patents. Further, until the Supreme Court addresses the issue, the test itself will remain in question, leaving the proper strategy for dealing with the scope of patentable subject matter difficult to determine. In preparing the specification and claims, some patent applicants will need to consider the many possible tests that could end up applying for the life of a patent they obtain, while others will be confronted with difficult decisions in assessing the validity of issued patents.

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147 *Id*. at 957 & n.14, 963.

148 *See* Parker v. Flook, 437 U.S. 584, 590 (1978) ("The 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."); *id*. at 594 ("Respondent's process is unpatentable under § 101, not because it contains a mathematical algorithm as one component, but because once that algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention.").