IN RE BILSKI AND THE "MACHINE-OR-TRANSFORMATION" TEST: RECEDING BOUNDARIES FOR PATENT-ELIGIBLE SUBJECT MATTER

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ABSTRACT

In order for a hopeful applicant to be granted a patent over his invention, his application must satisfy several procedural and substantive requirements. Among the substantive hurdles that an applicant must clear is the mandate that patents only be issued to applications claiming statutory subject matter within the meaning of § 101 of the Patent Act. However, the Court of Appeals for the Federal Circuit (Federal Circuit) has not construed that Section consistently over the years. Since that court's formation in 1982, it has espoused two tests for statutory subject matter, and each time has substantially abrogated, if not overruled, the prior formulation. Most recently, the Federal Circuit has handed down the "machine-or-transformation" test in an attempt to redraft the limits of patent eligibility based on subject matter. This iBrief will explore the significant changes that this new test has brought to the patentability doctrine.

INTRODUCTION

¶1 The Intellectual Property Clause of the Constitution expressly vests Congress with the power "[t]o promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[2] That clause, however, is not an unqualified grant of power; and there are certain limitations on Congress's ability to grant such exclusive rights.[3] Congress began exercising its authority under the Intellectual Property Clause in 1790 by passing the original Patent Act.[4] The Act has undergone several revisions, the most recent of which was in 1952.[5] In an attempt not to exceed its constitutionally granted authority and to give effect to various policy concerns, Congress

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[1] J.D. Candidate, Duke University School of Law, 2010. Thanks to Professor Ken Sibley for his comments and guidance. Any mistakes or omissions are mine alone.

[2] U.S. CONST. art. I, § 8, cl. 8.

[3] Graham v. John Deere Co., 383 U.S. 1, 5 (1966).

[4] *Id.* at 6.

[5] *See* 35 U.S.C. §§ 101–376 (2006).

has incorporated several restrictions on which inventions may be protected.[6] Among those restrictions is a threshold limitation on the categories of subject matter eligible for patent protection.[7] That restriction, set forth in Section 101 of the Act, is the focus of this iBrief.

¶2 Section 101 provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."[8] While that language places certain limitations on statutory subject matter, Congress clearly intended those limitations to be minimal.[9]

¶3 Under Section 101, an invention will be deemed statutory subject matter if it meets the requirements for any one of four categories—processes, machines, manufactures, and compositions of matter.[10] The Supreme Court has recognized several other categories of subject matter, however, that are not patent-eligible. Those categories have been referred to collectively as "fundamental principles,"[11] and include: "laws of nature, natural phenomena, and abstract ideas."[12] No matter how recent or useful the discovery of any such principle, that discovery cannot be patented.[13] Giving somewhat more practical meaning to those categorical exclusions, the Court has also stated that "mental processes" are not eligible for patent protection.[14] Furthermore, in a recent interpretation of the Supreme Court's opinions, the Federal Circuit stated that "the patent statute does not allow patents on particular systems that depend for their operation on human intelligence alone."[15]

¶4 Several lower court opinions have alluded to additional categorical exclusions from statutory subject matter, specifically, the "mathematical algorithm exception" and "business method exception."[16]

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[6] *See, e.g.*, § 102 (requiring that the invention be novel); § 103 (protecting only non-obvious subject matter).
[7] *See* § 101.
[8] *Id.*
[9] *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (noting that "Congress intended statutory subject matter to include anything under the sun that is made by man").
[10] *See* § 101.
[11] *In re* Bilski, 545 F.3d 943, 952 (Fed. Cir. 2008).
[12] Diamond v. Diehr, 450 U.S. 175, 185 (1981).
[13] *See* Gottschalk v. Benson, 409 U.S. 63, 67 (1972).
[14] *Id.*
[15] *In re* Comiskey, 554 F.3d 967 (Fed. Cir. 2009).
[16] *See, e.g.*, State St. Bank & Trust, Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1373–75 (Fed. Cir. 1998) (discussing the "mathematical algorithm" and "business method" exceptions).

Those two "exceptions" deserve separate treatment, but one point that the Federal Circuit made very clear in *In re Bilski* was the rejection of any categorical exclusions beyond those already recognized by the Supreme Court.[17] The "mathematical algorithm exception," however, is not really a categorical exclusion. Rather, it is shorthand for the proposition that mathematical relationships, in the abstract, are fundamental principles, and thus, not patentable subject matter.[18] By contrast, the "business method exception" was purported to be a true categorical exclusion from statutory subject matter and has been expressly rejected by the Federal Circuit.[19]

¶5 In theory, statutory subject matter includes "anything under the sun that is made by man,"[20] and the only categorical exclusions to statutory subject matter are the three species of fundamental principles.[21] Therefore, the tests of statutory subject matter that the Federal Circuit has handed down over the years,[22] presumably, have been mere attempts to articulate a coherent rule with which to differentiate applications that claim *only* fundamental principles from those whose claims are drawn to *anything else*, so long as it is man-made. In *Bilski*, the Federal Circuit fashioned its latest articulation for parsing statutory subject matter, and that test—the "machine-or-transformation" test[23]—may be indicative of a significant shift in the statutory-subject-matter doctrine. Any shift that has occurred as a result of the new test, although affecting all process claims, will be especially pronounced in the area of "knowledge

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[17] *In re* Bilski, 545 F.3d 943, 960 (Fed. Cir. 2008).

[18] *See* Diamond v. Diehr, 450 U.S. 175, 187–88 (1981) (explaining that, while an application of a mathematical formula may be eligible for patent protection, the same formula in isolation would not be); *State Street*, 149 F.3d at 1373 (connecting the "mathematical algorithm" exception to the Court's analysis of mathematical formulae in *Diehr*).

[19] *Bilski*, 545 F.3d at 960.

[20] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

[21] *See supra* note 12 and accompanying text. Of course, "laws of nature, natural phenomena, and abstract ideas," *Diehr*, 450 U.S. at 185, are not really *made* by man; they are discovered.

[22] First, there was the "*Freeman-Walter-Abele*" test, which was designed to "identify unpatentable [disembodied] mathematical algorithms." *State Street*, 149 F.3d at 1374. Then came the "useful, concrete and tangible result" inquiry, which had a similar purpose to the former test. *Id.* at 1373. The "machine-or-transformation" test, set forth in *Bilski*, has replaced both of those earlier tests. *Bilski*, 545 F.3d at 959–60.

[23] *Bilski*, 545 F.3d at 959.

products."[24] Software, business methods, and diagnostic tests are three prime examples of knowledge products.

¶6 As Judge Newman pointed out, since the Federal Circuit issued its opinion in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, there have been a huge number of patent applications under Class 705, which is the class containing business method patents.[25] Also, that decision marked the beginning of a sharp increase in number of Class-705 *applications filed* per year.[26] And even though the rate of allowance dropped off over the past six years,[27] *State Street* also marked the beginning of a dramatic increase in the total number of *patents issued* under that class per year.[28] Thus, to the extent that those patents were issued on the basis of the now-abrogated authority of *State Street*, *Bilski* has introduced a great amount of uncertainty to the validity of many business method patents. Because of the practical similarities between business methods, and software and diagnostic tests, *Bilski* has also injected a substantial amount of uncertainty into those areas.

¶7 In *Bilski*, the application purported to claim a process[29]—specifically, a business method—for hedging risk in commodities transactions by having a middleman buy a commodity from a producer at a fixed price and then selling the commodity to a consumer at a fixed price.[30] Hence, the arrangement functions to insulate all of the parties from the risk of adverse market fluctuations.[31] Significantly, however, the claims were not limited to commodities, and could involve options

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[24] *In re* Comiskey, No. 2006-1286, 2009 U.S. App. LEXIS 400, at *41 (Fed. Cir. Jan. 13, 2009) (en banc) (per curiam) (Newman, J., dissenting). While Judge Newman may have limited her definition of "knowledge products" to business methods, her analysis is easily extended to the areas of software and diagnostic tests.

[25] *Id.* at *42. Class 705 is titled "Data Processing: Financial, Business Practice, Management, or Cost/Price Determination." U.S. PTO classification information is available at http://www.uspto.gov/go/classification.

[26] *See* Wynn W. Coggins, Group Director, USPTO, *Update on Business Methods for the Business Methods Partnership Meeting* 6 (2007), *available at* http://www.uspto.gov/web/menu/pbmethod/partnership.pps.

[27] *See id.*

[28] U.S. PTO statistical information available at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/index.html.

[29] *See In re* Bilski, 545 F.3d 943, 951 (Fed. Cir. 2008) (explaining that "it is undisputed that Applicants' claims are not directed to a machine, manufacture, or composition of matter). Thus, the only remaining possibility was that the claims were intended to be drawn to a process. *See* 35 U.S.C. § 101.

[30] *Id.* at 949–50.

[31] *Id.*

too.[32] Similarly, the claims were not limited to implementation by any particular machine or apparatus.[33]

¶8 Under *Bilski*'s "machine-or-transformation" test, "an applicant may show that a process claim satisfies § 101 either by showing that his claim is tied to a particular machine,"[34] or by showing that "it transforms an article into a different state or thing."[35] Referencing *Gottschalk v. Benson*,[36] the Federal Circuit expressed that "meaningful limits" must attach to the claims regardless of which route—machine or transformation—an applicant pursues.[37] Furthermore, "the involvement of the machine or transformation in the claimed process" must be more than "insignificant extra-solution activity."[38] Such "extra-solution activity" is mere clever draftsmanship by which an applicant might attempt to render an unpatentable fundamental principle patentable by "recit[ing] a specific machine or a particular transformation of a specific article."[39] Because the claims in *Bilski* were not drawn to any machine, the Federal Circuit did not elaborate further on the machine prong of the test.[40] In later cases, however, the Federal Circuit has given guidance on the definition of "machine" within the meaning of its new test.

¶9 *In re Ferguson* involved claims ostensibly drawn to processes;[41] thus, *Bilski* was directly on point. In short, the application claimed a network of relationships among businesses, in which one of the businesses—a marketing team—would market the products of multiple, independent manufacturers in return for a share of the profits from each manufacturer and an exclusive marketing agreement as to those products.[42] Applying the machine-or-transformation test, the Federal Circuit concluded that the process claims were "not tied to any particular machine or apparatus."[43] The court further explained that "a machine is a 'concrete thing, consisting of parts, or of certain devices and combination of devices . . . [that] includes every mechanical device or combination of

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[32] *Id.* at 950.
[33] *Id.* at 962.
[34] *Id.* at 961.
[35] *Id.* at 962.
[36] 409 U.S. 63, 71–72 (1972) (concluding that, because the mathematical algorithm involved in the case had "no substantial practical application except in connection with a digital computer," the patent, if upheld, would effectively preempt the algorithm itself, despite a claim tying the algorithm to a computer).
[37] *Bilski*, 545 F.3d at 961.
[38] *Id.* at 962 (citing Parker v. Flook, 437 U.S. 584, 590 (1978)).
[39] *See id.* at 957.
[40] *Id.* at 961–62
[41] No. 2007-1232, 2009 U.S. App. LEXIS 4526, at *7 (Fed. Cir. Mar. 6, 2009).
[42] *Id.* at *2–3.
[43] *Id.* at *8.

mechanical powers and devices to perform some function and produce a certain effect or result.'"[44] Specifically, the court stated that a "marketing force" was not a machine within the meaning of the test.[45]

¶10 Thankfully, *Bilski* itself provided significant insight into the contours of the transformation analysis. The Federal Circuit tells us that, in order for a process to meet the requirements of § 101 by way of the transformation prong, the transformation "must be central to the purpose of the claimed process."[46] While only time can tell what this statement really means, it appears to be a reiteration of the warning against evasive drafting techniques.[47] With refreshing bluntness, the *Bilski* opinion states that physical or chemical transformations of physical objects are always going to pass muster under § 101.[48] As the court recognizes, however, many modern functions that we generally think of as processes do not involve manipulation of physical objects.[49] Although a great deal of uncertainty remains in the precise application of the rule, *Bilski* is expressly *not* intended to "*expand* the boundaries of what constitutes patent-eligible transformations."[50]

¶11 It seems that, in order for a process to satisfy § 101 via the transformation prong (outside the context of physical or chemical manipulation of a physical object), the process must be sufficiently tied to a physical entity in some way. Transformation of electronic data to a visual depiction will work, but presumably only if the raw electronic data is representative of some actual physical entity.[51] The mere addition of a data-gathering step to an otherwise unpatentable fundamental principle, however, will not make the claims patentable.[52] In any case, the

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[44] *Id.* at *9 (quoting *In re* Nuijten, 500 F.3d 1346, 1355 (Fed. Cir. 2007)).
[45] *Id.*
[46] *In re* Bilski, 545 F.3d 943, 962 (Fed. Cir. 2008).
[47] *See id.* at 957 (citing Parker v. Flook, 437 U.S. 584, 590 (1978)).
[48] *See id.* at 962; Gottschalk v. Benson, 409 U.S. 63, 69–70 (listing examples of chemical and physical processes that would pass muster).
[49] *See Bilski*, 545 F.3d at 962 (offering electronics and business methods as examples).
[50] *Id.* (emphasis added).
[51] *See id.* at 963 ("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."). If electron data is representative of a physical entity and is transformed, there is no need for the process to transform the physical entity itself. *Id.*
[52] *Id.*

organization of relationships among individuals or legal entities will not satisfy the transformation prong of the test.[53]

¶12 While the purpose of the machine-or-transformation test is clear—"the prevention of pre-emption of fundamental principles"[54]—the current doctrine leaves many important questions unanswered. The discussion that follows is an analysis of *Bilski*'s effects on three types of "knowledge products," based on subsequent applications of the new test as well as an educated guess as to some areas that have not been fleshed out by the courts.

I. SOFTWARE

A. Before Bilski

¶13 In addition to sparking an increase in business method patents, *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*[55] was the catalyst for a large increase in software patents.[56] For over ten years, the Federal Circuit's permissive language from *State Street* had encouraged applications for both classes of patents. Although the independent claim in that case was drawn to a machine[57] as opposed to a process, the principles and test expressed in the case were applicable to both machines and processes.[58]

¶14 In *State Street*, the patent claimed a machine for managing mutual funds.[59] Specifically, the machine could pool mutual fund resources into a partnership, and thus impart both tax benefits and the advantage of "economies of scale."[60] The parties had been negotiating a license for use of the patented machine, but the litigation ensued after negotiations broke down.[61] The party that had been negotiating for the license then sought a declaratory judgment that the patent was invalid as non-statutory subject matter.[62]

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[53] *Id.*
[54] *Id.*
[55] 149 F.3d 1368 (Fed. Cir. 1998).
[56] *See* Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263, 267–68 (2000) (stating that *State Street* made business methods patentable, and discussing the bustle of activity in the area).
[57] *See State Street*, 149 F.3d at 1371.
[58] *See id.* at 1372.
[59] *Id.* at 1370.
[60] *Id.*
[61] *Id.*
[62] *Id.*

¶15 According to the Federal Circuit, a computer was "a virtual necessity" to the operation of the machine because of the complexity and requisite alacrity of the calculations of each mutual fund's share in the partnership.[63] Although it is still uncertain to what extent a hopeful applicant's *process* claims must *require* a machine for operation, the court's analysis of the related issue in *State Street* is worth noting. The court discussed its prior opinions in *In re Alappat*[64] and *Arrhythmia Research Technology, Inc. v. Corazonix Corp.*,[65] but the discussions point in two different directions when viewed from a post-*Bilski* standpoint. The court stated that the patent in *Alappat* passed statutory-subject-matter scrutiny because the mathematical algorithm was used to produce "a useful, concrete and tangible result."[66] The court was specifically referring to the result of a smooth wave form on a monitor.[67] While that analysis sounds very permissive and, if applied consistently, would provide most software with a route to patentability, the court's other example—*Arrhythmia*—is much more restrictive.

¶16 In *Arrhythmia*, "the transformation of electrocardiograph signals from a patient's heartbeat by a machine through a series of mathematical calculations" was held to be statutory subject matter because it corresponded to the patient's heartbeat.[68] Thus, *Alappat*, as discussed in *State Street*, is much broader than *Arrhythmia* because the analysis from *Arrhythmia* was based on the signal correlating to a physical entity—the patient's heartbeat. By contrast, *Alappat* merely required a transformation from raw data points to a curve, without the requirement that the curve represent a physical entity.

¶17 The "useful, concrete and tangible result" test was the most significant fallout from *State Street*,[69] but presumably, many of the software patents granted under that case's authority were based on the broad, permissive analysis of *Alappat*. In *Bilski*, however, the Federal Circuit adopted an approach much more akin to the more restrictive reasoning from *Arrhythmia*.

B. After Bilski

¶18 One glimmer of certainty from *Bilski* for software patent proponents was the fact that, despite recommendations by several amici to do so, the Federal Circuit refused to rule that software could never be

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[63] *Id.* at 1371.
[64] 33 F.3d 1526 (Fed. Cir. 1994).
[65] 958 F.2d 1053 (Fed. Cir. 1992).
[66] *State Street*, 149 F.3d at 1373 (citing *Alappat*, 33 F.3d at 1544).
[67] *Id.*
[68] *Id.*
[69] *See id.*

patented.[70] The general tenor of the opinion, however, did not bode well for software patent holders and appears to have adopted a more restrictive approach to that area.

¶19 In *Bilski*, the Federal Circuit told us that the physicality of the steps performed on a computer by software is irrelevant;[71] the inquiry is whether the process is tied to a particular machine or apparatus, or whether it transforms any article into a different state or thing.[72] For example, the court stated that transformation of electronic data to a visual depiction would satisfy statutory-subject-matter requirements, but only if the source data is representative of a physical entity.[73] The court was also clear that if the process could be performed entirely in the human mind, it would not be statutory subject matter.[74]

¶20 However, many questions remain in the area of software patents, most notably, the question of whether a general computer is a "particular machine" within the meaning of the test.[75] Assuming that a computer could function as a particular machine for purposes of the test, to what extent must a general computer be necessary to perform the process? For example, if each individual step in an algorithm could conceivably be performed within the human mind over a period of many years, but the combination of a piece of software and a computer could perform the process in a matter of seconds, would the software be tied to a particular machine? In short, what is meant by the phrase, "tied to a particular machine?"[76]

¶21 The majority in *Ferguson* did not directly address whether a computer could be a machine within the meaning of the test. However, the Board of Patent Appeals and Interferences (the Board), whose opinion the majority affirmed, rejected the process claims on §101 grounds, concluding that they "do not expressly or implicitly require performance of any of the steps by a machine, such as *a general purpose digital computer*."[77] Thus, the Board appears to view a computer as a "particular machine,"[78] at least in certain contexts. Moreover, in her concurrence, Judge Newman acknowledges that the Federal Circuit has

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[70] *In re* Bilski, 545 F.3d 943, 960 n.23 (Fed. Cir. 2008).
[71] *See id.* at 961.
[72] *Id.*
[73] *See id.* at 963.
[74] *Id.* at 961 n.26.
[75] The Federal Circuit specifically stated that it was leaving that critical question for another day. *Id.* at 962.
[76] *Id.* at 961.
[77] *In re* Ferguson, 558 F.3d 1359, 1362 (Fed. Cir. 2009) (citing *Ex parte* Ferguson, No. 2003-1044, slip op. at 13 (B.P.A.I. 2004)) (emphasis added).
[78] *Bilski*, 545 F.3d at 961.

left it as an open question, but suggests that a computer must be a "*Bilski*-acceptable machine[]" in some circumstances.[79]

¶22 Close analysis of the Supreme Court's opinion in *Gottschalk v. Benson*[80] yields additional insight into the possible effects of *Bilski* on the patentability of software. In *Benson*, the applicants sought a patent for a "method of programming a general-purpose digital computer" to convert signals from one format to another.[81] Significantly, the operations could be performed mentally.[82] The Court concluded, therefore, that a computer was unnecessary to the process.[83] That conclusion alone might have supported the Court's ultimate decision to reject the claims as not sufficiently tied to a machine.[84] However, the Court also stated that, because the only practical applications of the program would be in the context of a computer, granting a patent on the program (though limited to use on a computer) would preempt all uses of the mathematical operations themselves.[85] Thus, while the case law assumes that a computer *could* serve as an adequate machine for purposes of subject-matter scrutiny of a process claim, the cases also create a somewhat confusing paradox: The computer must not be mere post-solution activity, that is, it must be necessary to some extent; but when the process applies a fundamental principle, the computer must not be so necessary to the process as to entirely preempt the underlying fundamental principle.

¶23 Importantly, *Benson* is still good law. But while that opinion stopped short of adopting the machine-or-transformation test as *the* exclusive test for statutory subject matter in processes,[86] the *Bilski* opinion shut the door on possible exceptions.[87] Thus, the Federal Circuit seems to have adopted an even stricter approach than that of the Supreme

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[79] *Ferguson*, 558 F.3d at 1367 (Newman, J., concurring) (stating that, in *Bilski*, "the court recognized that the *State Street Bank* test was directed to processes performed by computer, thus meeting the *Bilski* test.").
[80] 409 U.S. 63 (1972).
[81] *Id.* at 65.
[82] *Id.* at 67.
[83] *Id.*
[84] If the conclusion that a computer was not necessary to the procedure had been coupled with an unequivocal statement from the Court that the program failed to be tied to a machine because a computer was not strictly necessary to its use, that would tend to suggest that it does not matter how impractical performance of a mathematical operation might be without the aid of a computer, so long as it was strictly possible. This secondary conclusion could threaten the validity of an even broader scope of software patents.
[85] *See id.* at 71–72.
[86] *See id.* at 71.
[87] *See In re* Bilski, 545 F.3d 943, 955–56 (Fed. Cir. 2008).

Court. Based on the language from *Bilski*, *Ferguson*, and *Benson*, it appears that many software patents may be in jeopardy either because they are not tied to a particular machine[88] or because they have no relationship with any physical entity.[89]

II. BUSINESS METHODS

A. Before Bilski

¶24 More than any other class, business method patents have been heavily criticized. Justice Kennedy has expressed concern over "[t]he potential vagueness and suspect validity of some . . . [business method] patents."[90] Broadly patenting business methods has arguably led to patents over very mundane practices.[91] Additionally, such patents have been criticized as doing nothing more than incorporating widely known practices into cyberspace.[92] There are also those who view business method patents as much more innocuous. For example, in her concurring opinion in *Ferguson*, Judge Newman criticizes the majority's "retreat into the methods of the past."[93] Following the logic of her opinion, the regime *from which* the majority must be retreating is *State Street*. And it is that opinion that fostered the issuance of so many business method patents. Thus, she must at least believe that most of those patents are worthy of the protection they have been given. However, *State Street* aside, the last one hundred years of patent jurisprudence has been highly unfavorable to methods of doing business.

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[88] This point is capable of multiple readings. A computer could be deemed to never suffice as a particular machine. Even if a computer could serve as a particular machine, it might be the case that only software whose operations absolutely required a computer for their performance would be deemed as sufficiently tied to the computer.

A related idea is that, while a computer could serve as a particular machine, if the software claimed mathematical algorithms and had no practical application outside of a computer, it might be construed to completely preempt the mathematical algorithm. Such an approach would render the software ineligible for patent protection. Logically, this concept must be limited to the context of process claims that involve application of fundamental principles (e.g., mathematical algorithms). It is still relevant to the current discussion, because this concept presupposes that computers may suffice as a machine in other scenarios.

[89] *See id.*

[90] eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 397 (2006) (Kennedy, J., concurring).

[91] *See* Dreyfuss, *supra* note 56, at 268.

[92] *Id.* at 279.

[93] *See In re* Ferguson, 558 F.3d 1359, 1368 (Fed. Cir. 2009) (Newman, J., concurring).

¶25 *Hotel Security Checking Co. v. Lorraine Co.*[94] is the case that is credited with the "business method exception" to statutory subject matter.[95] In that case, the patent claimed a system related to cash registers intended to prevent fraud and theft by employees of restaurants and hotels.[96] The basic idea was that each employee was assigned a number and that number was used to identify all transactions performed by the employee on behalf of the business.[97] The court held that "[a] system of transacting business disconnected from the means of carrying out the system is not . . . an art."[98] Thus, the business method exception was born; and *Lorraine* and its line were responsible for severely limiting the success of business method patents for ninety years.[99]

¶26 In 1998, the Federal Circuit's opinion in *State Street* marked the end of the quasi-prohibition against business method patents,[100] and in similar fashion, its effect on software patents, leading almost immediately to a significant increase in business method patent activity.[101] In *State Street*, the Federal Circuit rejected the notion that business methods, as a class, were not eligible subject matter for patent protection.[102] The court held that patent applications drawn to business methods were eligible so long as they met all the requirements of one of the categories of subject matter.[103]

¶27 The machine claimed in *State Street* for managing mutual funds was limited by the incorporation of a computer.[104] The court applied its "useful, concrete and tangible result" test and held that "the transformation of data, representing discrete dollar amounts, by a

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[94] 160 F. 467 (2d Cir. 1908).
[95] *See* William D. Wiese, *Death of a Myth: The Patenting of Internet Business Models After* State Street Bank, 4 MARQ. INTELL. PROP. L. REV. 17, 30 (2000). To clarify, Wiese merely cites *Lorraine* as the case *others* look to as the progenitor of the business method exception and actually concludes that the exception never, in fact, existed.
[96] *Lorraine*, 160 F. at 467.
[97] *See id.* at 467–69.
[98] *Id.* at 469. At the time, Congress had not yet replaced the term "art" with "process." *See In re* Bilski, 545 F.3d 943, 952 (Fed. Cir. 2008).
[99] *See* Wiese, *supra* note 95, at 30.
[100] *Id.*
[101] *See* Malla Pollack, *The Multiple Unconstitutionality of Business Method Patents: Common Sense, Congressional Consideration, and Constitutional History*, 28 RUTGERS COMPUTER & TECH. L.J. 61, 66 (2002).
[102] *See* State St. Bank & Trust Co. v. Signature Financial Group, Inc., 139 F.3d 1368, 1375 (Fed. Cir. 1998). Some have concluded that the "business method exception" never existed. *See* Wiese, *supra* note 95, at 18.
[103] *State Street*, 139 F.3d at 1375.
[104] *Id.* at 1371.

machine through a series of mathematical calculations into a final share price" is statutory subject matter within the meaning of the statute.[105] The court went on to explain that the process employed a mathematical algorithm toward a practical application by producing the requisite "useful, concrete and tangible result."[106] Specifically, the "result" was the accurate share price for each mutual fund based on the percentage stake in the partnership by the particular fund.[107]

B. After Bilski

¶28 In *Bilski*, the Federal Circuit affirmed its prior rejection of a categorical exclusion of business methods from patentable subject matter.[108] However, unlike the broadly inclusive language of *State Street*, the new opinion and its new test are very restrictive. While the court rejected the "*Freeman-Walter-Abele*" test, which required that a mathematical algorithm be connected to physical elements or process steps,[109] the "machine-or-transformation" test, nonetheless, seems to require an algorithm to be grounded in some physical element, at least in most cases. In discussing those cases of its predecessor court, the Federal Circuit alluded to the fact that it had held unpatentable a process for rendering a graphical representation of data,[110] yet held patent-eligible another patent because it was drawn to a process to electronically display images of a patient's bones and internal organs.[111] The critical difference for the court was the process's connection to physical elements.[112]

¶29 In *Ferguson*, the Federal Circuit made significant progress in explaining *Bilski*, especially in the context of business methods. Besides explaining, generally, the correct interpretations of both prongs of the new test,[113] the court also gave some insight as to the viability of *State Street*. The court said that *Bilski* did not overturn *State Street*, but that it did supersede the "useful, concrete, and tangible result" test with the "machine-or-transformation" test for all §101 determinations.[114] In

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[105] *Id*. at 1373.
[106] *Id*.
[107] *Id*. In its discussion of "so-called business methods" within *Bilski*, the Federal Circuit questioned whether processes dealing in "abstract constructs such as legal obligations, organizational relationships, and business risks" might qualify as statutory subject matter through the transformation prong of the transformation-or-machine test. *In re* Bilski, 545 F.3d 943, 962 (Fed. Cir. 2008).
[108] *Bilski*, 545 F.3d at 960.
[109] *Id*. at 959.
[110] *Id*. at 962.
[111] *Id*. at 962–63.
[112] *See id.* at 963.
[113] *See In re* Ferguson, 558 F.3d 1359, 1363–65 (Fed. Cir. 2009).
[114] *See id.* at 1364 n.3.

response to the applicant's argument that his process claims should be approved under *State Street* as business methods, the court was only willing to distinguish *State Street* on its facts by stating that the claims in that case were drawn to a machine.[115] It seems that the court intended to mummify *State Street* in order to allow it to replace the test without having to conclude that business methods are per se non-statutory subject matter.[116]

¶30 Thus, business methods will be facing many of the same challenges that software patents now face. After all, many business methods are inextricably intertwined with computers and software. Similar to the area of software patents, where the most pressing question after *Bilski* is whether, and in what context, a personal computer can serve as a machine, one of the questions in the realm of business method patents is what devices could serve as a machine. As a practical matter, if a personal computer cannot be the machine, then what other devices can business methods be linked to? Moreover, when will a business method transform an article to a different state or thing? The examples from the Supreme Court's opinion in *Benson*—"tanning, dyeing, making waterproof cloth, vulcanizing India rubber, smelting ores"[117]—are not likely intended to encourage business method patent applications.

III. DIAGNOSTIC ASSAYS

A. Before Bilski

¶31 In *Bislki*, the Federal Circuit discussed several precedents that dealt with diagnostic tests.[118] Specifically, it discussed *In re Meyer*,[119] *In re Grams*,[120] and Justice Breyer's dissent from dismissal of certiorari in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*[121]

¶32 The *Meyer* case involved a diagnostic process to determine the source of a malfunction in a complex system.[122] Although the process was not expressly limited to the field of neurology, neurology was one field in which the applicant claimed the process would have a useful

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[115] *See id.* at 1365.
[116] Further evidence of this conclusion is given in the language: "in *Bilski* this court refused to extend or even to take a broad reading of the holding in *State Street*." *Id.*
[117] *Bilski*, 545 F.3d at 962.
[118] *See id.* at 965.
[119] 688 F.2d 789 (C.C.P.A. 1982).
[120] 888 F.2d 835 (Fed. Cir. 1989).
[121] 548 U.S. 124 (2006) (Breyer, J., dissenting).
[122] *See Meyer*, 688 F.2d at 793.

application.[123] The court held the process ineligible for patent protection because it was preemptive of a fundamental principle—specifically, a mathematical algorithm.[124] Even as drafted, the claims probably would have passed scrutiny after *State Street* opened the floodgates for previously questionable patents, but especially if the claims had been limited to use on a computer.[125]

¶33 In *Grams*, the applicant's claims described a process to diagnose a patient by analyzing the levels of various constituents in his body fluids which were measured via laboratory testing.[126] As in *Meyer*, the court held that the claims were not drawn to statutory subject matter because they would preempt a mathematical algorithm.[127] If those same claims had been made with the addition of a claim to incorporate a computer to produce the result of the process, the claims would certainly have passed under *State Street*'s permissive rule. But, even as stated, the patent would probably have passed muster under *State Street*.

¶34 Justice Breyer, with two other justices, discussed the issue of diagnostic assay patentability in a dissenting opinion from a dismissal of certiorari in *Laboratory Corp*.[128] The facts of that case involved a patent application for a process to diagnose vitamin deficiencies by measuring the concentration of a particular amino acid in the patient's blood.[129] The lower courts had held that the patent was valid and enforced a judgment for infringement.[130] The Court granted certiorari, but then dismissed the case, concluding that certiorari had been improvidently granted.[131]

¶35 While the message to be gleaned from the Court dismissing the case is unclear, it seems that a reasonable conclusion would be that a majority of the Court would have upheld the patent. The three dissenters, however, expressed strong disapproval both of the dismissal of certiorari and of the validity of the diagnostic assay patent.

¶36 Citing *Diehr*, *Flook*, and many other cases, the dissent argued that the claims were not drawn to statutory subject matter because they were merely attempting to patent a biological relationship between the

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[123] *Id.* at 790–91.
[124] *Id.* at 796.
[125] In particular, *State Street*'s removal of any requirement for a limitation to a physical element would have made the claims in *Meyer* much stronger.
[126] *See Grams*, 888 F.2d at 836–37.
[127] *See id.* at 841.
[128] *See* Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc., 548 U.S. 124, 125 (2006) (Breyer, J., dissenting).
[129] *Id.*
[130] *Id.*
[131] *Id.* at 125–26.

concentration of the amino acid and the concentration of the two vitamins.[132] The application included claims drawn to novel methods for measuring the amino acid concentration—gas chromatography and mass spectrometry—but the lower courts construed the claims as not limited to those methods.[133] The dissent briefly discusses *State Street*, seemingly admitting that *State Street*'s "useful, concrete and tangible result" test would have supported the patent.[134] But the dissent also expressly disavowed ever adopting the test from *State Street*[135] and concluded that the claimed subject matter at issue in *Laboratory Corp.* was an "unpatentable 'natural phenomenon.'"[136]

¶37 There is significant doubt as to the take-away implications of the dismissal of the writ of certiorari, especially because the lower courts had not directly considered the statutory-subject-matter issue.[137] However, Breyer's dissent gives us some important insight into the view of three justices. Furthermore, if we assume that the majority of the Court would have upheld the patent, it would tend to establish the Court's endorsement of the Federal Circuit's decision in *State Street*. However, if we believe that the dismissal of certiorari was based on the technicality of not having the lower court directly address the § 101 issue, then the dismissal's meaning is much less certain. That uncertainty notwithstanding, it is fairly clear that at least the dissent believed that the claims would satisfy the "useful, concrete and tangible result" test but would not meet its own test of statutory subject matter.

B. After Bilski

¶38 *Bilski* is dispositive with respect to the § 101 analysis of all process patents, but it has unevenly restricted the patentability of diagnostic assays along with other "knowledge products." Under this more restrictive regime, when a diagnostic test is not tied to a particular measurement and is not limited to any particular machine or system, it may well be rejected as an attempt to preempt a fundamental principle.[138]

¶39 Upon inspection under the machine-or-transformation approach, it seems fairly obvious that neither the patent in *Meyer* nor the patent in *Grams* would survive scrutiny. Neither of the respective processes was transforming anything physically or chemically, nor was there any

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[132] *Id.* at 135.
[133] *Id.* at 125, 28.
[134] *See id.* at 136–37.
[135] *Id.* at 136.
[136] *Id.* at 138.
[137] *See id.* at 132.
[138] *See In re* Bilski, 545 F.3d 943, 965 (Fed. Cir. 2008).

physical limitation claimed in the applications.[139] Moreover, they were not limited to use in conjunction with a particular machine, not even a computer.[140]

¶40 It is also highly doubtful whether the claims in *Laboratory Corp.* would now pass the Federal Circuit's statutory-subject-matter scrutiny. The claim in dispute was not limited to any of the specialized laboratory methods or equipment[141] and thus would probably not be sufficiently tied to a machine. Further, it is difficult to imagine what transformation the process could be accomplishing by measuring the level of an amino acid in a blood sample.[142]

¶41 As mere illustrations of the probable effects of *Bilski* on § 101 analysis of diagnostic tests, those examples indicate that the patentability of this particular realm of subject matter has been substantially restricted. By adopting the machine-or-transformation test as the exclusive test for determining whether a process is patentable subject matter, the Federal Circuit has likely taken an even more restrictive approach to statutory subject matter than the Supreme Court.

CONCLUSION

¶42 By adopting the machine-or-transformation test for all process-patent claims, the Federal Circuit has significantly reduced the scope of § 101's coverage, but it has made it especially difficult for those applicants seeking patents over knowledge products. That court has clearly stated its purpose, which is to prevent the preemption of fundamental principles,[143] but it remains to be seen whether the test it has adopted will be too narrow. One's idea of a "good" test for determining statutory subject matter depends greatly upon whether one thinks patenting software, business methods, and diagnostic tests is generally a good idea. And regardless of whether the results of a particular test are interpreted as positive or negative for society as a whole, there will certainly be an impact from such a significant change.

¶43 In *Bilski*, the Federal Circuit alluded to the possibility that the Supreme Court may decide to alter the new test because of difficulties stemming from advances in technology.[144] Having granted certiorari in *Bilski*,[145] the Supreme Court has accepted the Federal Circuit's invitation

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[139] *See In re* Meyer, 688 F.2d 789, 790–93 (C.C.P.A. 1982); *In re* Grams, 888 F.2d 835, 836–37 (Fed. Cir. 1989).
[140] *See Meyer*, 688 F.2d at 790–93; *Grams*, 888 F.2d at 836–37.
[141] *See Laboratory Corp.*, 548 U.S. at 125 (Breyer, J., dissenting).
[142] *See id.*
[143] *Bilski*, 545 F.3d at 963.
[144] *Id.* at 956.
[145] Bilski v. Doll, 129 S. Ct. 2735 (2009).

to speak on the issue. As we await the Court's decision, it is important to consider that the Court has never expressly adopted the test formulated in *Bilski* and has, at least on one occasion, expressly stated that an application's failure to meet the test would not inevitably render the claims unpatentable.[146] However the Court decides the case, hopefully the opinion will bring needed certainty to this important area of law.

[146] *See* Gottschalk v. Benson, 409 U.S. 63, 71 (1972).