

SEEKING A BETTER PRESCRIPTION FOR PHYSICIANS: PATENT ELIGIBILITY FOR DIAGNOSTIC METHODS IN A POST-*BILSKI* AND *PROMETHEUS* ERA

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I. INTRODUCTION

Many postulated that 2010 would drastically alter the landscape of subject matter eligibility under § 101 of the Patent Act, finally providing clarity to this area of the law.¹ Despite such hopes, this anticipation was eventually met with the realization that perhaps the judiciary is not the appropriate vehicle to provide meaningful answers to the ambiguities inherent in patent law.² The Federal Circuit's decision in *Prometheus v. Mayo*³ represented what should be the final significant § 101 case to impact process patents for diagnostic testing. Despite the multitude of case law before the courts last year, patentees are still left with the same uncertainty that existed when this issue developed at the forefront of patent disputes several years ago.⁴ Although the Supreme Court's consideration of *Bilski v. Kappos*⁵ determined that the machine-or-transformation (hereinafter "MOT") test created by the Federal Circuit would no longer represent the exclusive standard for which method patents may be measured,⁶ courts remain encumbered by decades-worth of patent eligibility tests and no definitive formula to apply such standards.

Despite this lack of clarity, the progression of case law demonstrates the likelihood that diagnostic method claims will pass muster under § 101 where such claims are determined not to preempt a fundamental principle. This illuminates the concern that where such methods are deemed patentable, liability will attach where a physician performs a patented diagnostic method. Rather than leaving this matter to the courts, resulting in protracted litigation and fostering uncertainty among would-be patentees, the appropriate solution may lie with Congress. Over the past ten years, legislation has been introduced in Congress aimed at preventing physicians from facing legal consequences due to their use of patented genetic testing, in terms of

¹ Dan Vorhaus & John Conley, *Bilski and Biotech: Business As Usual, For Now*, GENOMIC LAW REPORT (June 28, 2010), <http://www.genomicslawreport.com/index.php/2010/06/28/bilski-and-biotechnology/>.

² *Prometheus v. Mayo*, 628 F.3d 1347 (Fed. Cir. 2010); Dan Vorhaus & John Conley, *Prometheus Unbound — Again*, GENOMIC LAW REPORT (Dec. 17, 2010), <http://www.genomicslawreport.com/index.php/2010/12/17/prometheus-unbound-again/>.

³ *Prometheus*, 628 F.3d 1347.

⁴ Subject matter eligibility was a key issue in the Federal Circuit's ruling in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008).

⁵ *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

⁶ *Id.* at 3227.

both the patented composition of matter and the diagnostic tests relating to such genetic determinations.⁷ While the extensive nature of such legislation may have deleterious consequences for gene-based patents,⁸ it can provide instruction for a more narrowly tailored legislative effort to exempt physicians from infringement liability in certain situations.

In the past, where a patent claim met one of the defined categories — machine, manufacture, composition of matter, or process — the claim was presumed eligible under § 101.⁹ In fact, regarding biotechnical claims, “[s]o long as there was some element of human intervention, such as isolation of a gene sequence or genetic engineering of a living organism, biotechnology inventions were generally assumed to be eligible for patent protection.”¹⁰ With the rapid development of biotechnology and the related patents, so too grows the fear that such inventions cover not only human discoveries, but also the natural biological associations upon which the inventions are claimed.

The concern for patentees generated by the recent § 101 debate is twofold. First, there is still a fear that the Federal Circuit will continue to apply the MOT test based on the Supreme Court’s pronouncement of the test as an “investigative tool.”¹¹ Second, if the patentability of diagnostic methods is put into doubt, this will severely disincentivize funding for research and development. On the other end of the spectrum, opponents of a more broadly defined patentability requirement fear the detrimental effects that the privatization of diagnostic testing will have on the healthcare industry, both in terms of patient care and rising costs. The inherent conflict created for physicians may,

[I]nhibit doctors from using their best medical judgment; . . . force doctors to spend unnecessary time and energy to enter into license agreements; . . . divert resources from the medical task of healthcare

⁷ See Genomic Research and Accessibility Act, H.R. 977, 110th Cong. (2007) [hereinafter GRAA]; Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002) [hereinafter GRDAA].

⁸ See *infra* Part IV(B) and (C).

⁹ Maayan Filmar, *A Critique of In Re Bilski*, 20 DEPAUL J. ART TECH. & INTELL. PROP. L. 11, 11 (2009) (“Industrial age inventions fell easily into at least one of these four statutory categories. Information age inventions, however, complicate the analysis under section 101 and blur the boundaries of its enumerated categories.”).

¹⁰ Christopher M. Holman, *The Impact of Bilski on Biotechnology*, HOLMAN’S BIOTECH IP BLOG, (Jul. 3, 2010, 11:22 AM), <http://holmansbiotechblog.blogspot.com/2010/07/impact-of-bilski-on-biotechnology.html>.

¹¹ *Bilski*, 130 S. Ct. at 3227.

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to the legal task of searching patent files for similar simple correlations; [and,]¹² raise the cost of healthcare while inhibiting its effective delivery.

This Note concludes that the Patent Office and courts will continue to find diagnostic tests patent-eligible based on recent case law. In an effort to better balance the competing policy rationales between bestowing inventors with necessary property rights in their inventions, and a physician's right to give — and a patient's corresponding right to receive — a proper medical diagnosis, Congress should impose meaningful limitations on liability for physicians who perform such tests. While performance would still constitute patent infringement, liability would not attach for physicians as it would if the patented tests were performed in a research setting.

This Note will begin in Part II with a discussion of the relevant statutory provisions within the Patent Act, specifically the subject matter eligibility requirement and its application to process claims. Part III will discuss the case law leading up to the Federal Circuit's decision in *Prometheus II*. Part IV will introduce the Medical Practitioner Exception and legislative measures that could amend the exception to better serve the relevant policy rationales. This Note will conclude in Part V that certain amendments can be made to the Medical Practitioner Exception that would allow diagnostic methods to retain patentability so crucial to the biotechnology industry, but afford physicians a modicum of protection where patented methods are used in the course of diagnosis or treatment of patients.

II. PATENT ELIGIBILITY AND ITS LIMITATIONS

The Patent Act's subject matter requirement, § 101, ensures that a claim is derived from discoveries or inventions in which human innovation acted as the primary driver.¹³ Even with this limitation, the subject matter requirement has been read broadly by the Supreme Court to make patentable “anything under the sun that is made by man,”¹⁴ with narrow exclusions for natural phenomena, laws of nature, and abstract

¹² *Lab. Corp. of Am. Holdings v. Metabolite*, 548 U.S. 124, 138 (2006) (Breyer, J., dissenting).

¹³ 35 U.S.C. § 101 (2008). “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” *Id.*

¹⁴ S. REP. NO. 1979, at 5 (1952).

ideas.¹⁵ This line is often blurred in medical and biotechnical patent claims due to the complex endeavor of melding scientific inquiry and discovery with the laws of nature.¹⁶ Frequently the ineffective distinction between what constitutes a natural, as opposed to man-made, process forms the basis for process claim rejections.

While common sense definitions of machine, manufacture and composition of matter are generally uncontested, defining what constitutes a “process claim” remains somewhat more complicated. Although § 100(b) provides a statutory definition,¹⁷ case law provides a more detailed attempt to distill the components of a process. The Supreme Court, in *Cochrane v. Deener*,¹⁸ found that a process is “a mode of treatment of certain materials to produce a given result. . . [and] it is an act, or a series of acts, performed upon the subject matter to be transformed and reduced to a different state or thing.”¹⁹ From this, the Federal Circuit and the Supreme Court have enunciated several tests for process claims, but cautioned against limiting the inquiry to a single test.²⁰ Despite differences among these tests, each has been understood to represent the rule against patenting natural phenomena, laws of nature, and abstract ideas.²¹

III. 35 U.S.C. § 101: THE SHIFT IN THE SUBJECT MATTER ELIGIBILITY DOCTRINE FOR PROCESS PATENTS AS IT HAS DEVELOPED BEFORE AND AFTER BILSKI AND PROMETHEUS

Originally, the term “useful art” as it is applied in § 101 was thought to refer to technological innovation.²² Courts have long referred to patent protection as existing specifically to ensure technological

¹⁵ *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

¹⁶ Jeffery M. Kuhn, *Patentable Subject Matter Matters: New Uses for an Old Doctrine*, 22 BERKELEY TECH. L. J. 89, 103 (2007).

¹⁷ 35 U.S.C. § 100(b) (2008). “The term ‘process’ means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.” *Id.*

¹⁸ *Cochrane v. Deener*, 94 U.S. 780, 780 (1876).

¹⁹ *Id.*

²⁰ *See infra* Part II(B).

²¹ *In re Bilski*, 545 F.3d 943, 1013 (Fed. Cir. 2008).

²² *In re Comiskey*, 499 F.3d 1365, 1375 (Fed. Cir. 2007) (citing *Paulik v. Rizkalla*, 760 F.2d 1270, 1276 (Fed. Cir. 1985)).

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expansion and innovation.²³ Although never explicitly cabining patent law to a particular field, “several of [the Supreme Court’s] decision[s] implicitly tether patentability to technological innovations.”²⁴ This narrow view of available subject matter has since expanded opening up the possibility that § 101 can cover any process, no matter the field from which it is derived.²⁵

Beginning in 1980, the Supreme Court embarked on what has been three decades of patent-eligibility expansion, starting with its rulings in *Diamond v. Chakrabarty*²⁶ and *Diamond v. Diehr*.²⁷ In *Chakrabarty*, the Court was faced with a reoccurring patent eligibility question regarding engineered bacteria. *Chakrabarty* “manufactured” bacteria capable of breaking down the components of crude oil, extremely useful in the cleanup of oil spills.²⁸ These particular bacteria did not previously exist in nature and no other existing bacteria was said to perform the same function. The Court had faced the issue of engineered bacteria several decades earlier in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*,²⁹ where the majority found that although the bacteria in question did not exist in nature, the inventor simply sought to patent nature’s handiwork through the combination of living organisms.³⁰ The holding in *Chakrabarty*, in contrast, specifically found that human-made living organisms satisfied § 101.

While declining to specifically overrule *Funk Brothers*, its continued viability in light of *Chakrabarty* is put into doubt. The Court stressed the difference as lying in human intervention — whereas in *Funk Brothers* the claim was drawn to bacteria resulting from a mixture of selected strains the result of which failed to produce different characteristics, *Chakrabarty* intentionally intervened to create a new strain of bacteria with traits never before observed.³¹ Perhaps the real fault with the underlying claim in *Funk Brothers* was the failure of the

²³ *Bilski*, 545 F.3d at 1001 (Mayer, J., dissenting).

²⁴ *Id.* at 1002 (citing *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998); *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)).

²⁵ *State St. Bank v. Signature Fin. Grp., Inc.* 149 F.3d 1368, 1376 (Fed. Cir. 1998).

²⁶ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

²⁷ *Diamond v. Diehr*, 450 U.S. 175 (1981).

²⁸ *Chakrabarty*, 477 U.S. at 305.

²⁹ *Funk Bros.*, 333 U.S. at 131.

³⁰ *Id.*

³¹ *Chakrabarty*, 447 U.S. at 310.

new bacteria to meet the usefulness requirement.³² In determining that the bacteria constituted a product of nature, the Court relied on a finding that the organisms “perform[ed] in their natural way.”³³ Therefore, instead of first examining the patent for its subject matter, the Court combined an analysis under §101 with an obviousness analysis properly construed under 35 U.S.C. § 103.³⁴ Since the bacteria had not existed in that particular form prior to the combination of the selected strains it is hard to characterize the result as a product of nature.

Chief Justice Burger declined the invitation inherent in the petitioner’s argument to engage in a balancing test considering the hazards of allowing patent rights in certain subject matter versus the goal of promoting progress in the useful arts.³⁵ Instead, Justice Burger stressed the importance of such concerns and the inability of the Court to entertain such policy matters which are better left for “resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot.”³⁶ The Court’s task is simply to determine Congress’ meaning through its words and intent, and “once that is done [the Court’s] powers are exhausted.”³⁷

In the year following *Chakrabarty*, the Supreme Court confronted another § 101 issue in *Diamond v. Diehr*, this time involving a process

³² See generally *Brenner v. Mason*, 383 U.S. 519, 534-35 (1966) “Unless and until a process is refined and developed to this point — where specific benefit exists in currently available form — there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.” *Id.*

³³ *Funk Bros.*, 333 U.S. at 131.

³⁴ See Brief for Alnylam Pharmaceuticals, Inc as Amicus Curiae Supporting Appellants at 13, *Ass’n of Molecular Pathology v. U.S. Patent and Trademark Office et al.*, No. 2010-1406 (Fed. Cir. Aug. 19, 2010), available at <http://patentdocs.typepad.com/files/alnylam-amicus-brief.pdf>.

The terminology used before the 1952 Patent Act speaks of ‘invention’ to describe the necessary advance in the art beyond novelty to establish patentability. This was superseded four years later in the 1952 Patent Act by the statutory test of ‘nonobviousness’ under what is today Section 103(a). Prior to the 1952 Patent Act, an invention which was ‘obvious’ was instead termed to lack patentable ‘invention.’ In *Funk [Bros.]* the Court found a patent to a mixture of known bacteria lacked ‘invention’ – in other words, that it was obvious.

Id.

³⁵ *Chakrabarty*, 447 U.S. at 317.

³⁶ *Id.*

³⁷ *Id.*

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claim.³⁸ The patent application in *Diehr* claimed a method for molding rubber into specific forms using a mathematical equation to determine when the molds had properly cured.³⁹ The Court determined that a process utilizing a mathematical formula is not rendered unpatentable when it also transforms or reduces an article to a different state or thing.⁴⁰ Although the process incorporated the Arrhenius equation into its claim to calculate the relationship between time and temperature in the cooling process, a “process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.”⁴¹

This decision paved the way for biological and medical patents currently flooding into the system. The Court seems to be borrowing a theme from copyright law which recognizes copyright protection for compilations.⁴² Although independently some or all of the components of a compilation might belong to the public domain, together they may constitute a work of original authorship. While patent law differs in many respects from copyright law, the underlying policy concept is similar — that which belongs in the public domain cannot be usurped into a privatized right.⁴³ So long as a claim is read in its entirety and not in terms of its constituent parts considered apart from the whole, a claim for a process involving a law of nature, natural phenomenon, or abstract idea can still satisfy a § 101 inquiry.⁴⁴

Prior to the Federal Circuit’s ruling in *State Street v. Signature Financial Group*, several opinions construing § 101 referenced a judicially-created doctrine in finding business methods ineligible for patent protection.⁴⁵ The system at issue in *State Street* concerned a “hub and spoke” investment strategy whereby several mutual funds would pool their resources into a central portfolio thereby decreasing

³⁸ *Diamond v. Diehr*, 450 U.S. 175, 177 (1981).

³⁹ *Id.*

⁴⁰ *Id.* at 184.

⁴¹ *Id.* at 187 (quoting *Parker v. Flook*, 437 U.S. 584, 590 (1978)).

⁴² Copyright Act, 17 U.S.C. § 101 (1978). A “‘compilation’ is a work formed by the collection and assembling of preexisting materials or of data that are selected, coordinated, or arranged in such a way that the resulting work as a whole constitutes an original work of authorship.” *Id.*

⁴³ See generally *Baker v. Selden*, 101 U.S. 99 (1879) (introducing the idea/expression dichotomy into American Copyright jurisprudence, stating that ideas themselves are not copyrightable, while original expression is subject to copyright protection).

⁴⁴ *Diehr*, 450 U.S. at 193.

⁴⁵ *State St. Bank v. Signature Fin. Grp., Inc.* 149 F.3d 1368, 1375-76 (Fed. Cir. 1998) (citing *In re Schrader*, 22 F.3d 290, 294 (Fed. Cir. 1994)).

administrative costs and benefiting from the tax benefits associated with partnership.⁴⁶ The district court dispensed with the patent claim on summary judgment relying on the “business method exception,” or in the alternative the “mathematical algorithm exception.”⁴⁷ On appeal to the Federal Circuit, the court refused to endorse a judicially-created exception to § 101, stating that “it was Congress’s intent not to place any restrictions on the subject matter for which a patent may be obtained beyond those specifically recited” in the statute.⁴⁸ Looking at the plain language of the statute, the Congressional record and the Manual of Patent Examining Procedures,⁴⁹ Judge Rich inferred that without express limitations dictated by Congress, the “first door” to patentability should be left wide open, thereby striking down the “exceptions” relied on by the lower court.⁵⁰

Returning to language from *Chakrabarty* and *Diehr*, the court stressed that beneath all processes lies a mathematical equation, a law of nature or an abstract idea.⁵¹ While those underlying concepts or ideas are not patentable, that which is created utilizing such knowledge can be subject to patent protection so long as it meets the other requirements of the Patent Act, specifically novelty, nonobviousness, and adequate notice and disclosure.⁵² The court correctly identified that although the claimed method in *State Street* may be overly broad, this is not a requirement under § 101, but rather under §§ 102, 103, and 112.⁵³ Considered as the turning point in the expansion of the subject matter eligibility discussion, the *State Street* opinion received endless criticism and is subject to continued debate.⁵⁴

The development of patentable subject matter for processes has greatly increased in breadth over the past half century to include various

⁴⁶ *Id.* at 1371.

⁴⁷ *Id.* at 1372.

⁴⁸ *Id.* at 1373.

⁴⁹ *Id.* at 1377 (quoting Examination Guidelines, 61 Fed. Reg. 7478, 7479 (1996) (“Claims should not be categorized as methods of doing business. Instead such claims should be treated like any other process claims.”)).

⁵⁰ *Id.* at 1372 n.2 (citing *In re Bergy*, 596 F.2d 952, 960 (C.C.P.A. 1979)).

⁵¹ *State Street*, 149 F.3d at 1374.

⁵² *Id.* at 1375.

⁵³ *Id.* at 1377.

⁵⁴ See Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263 (1999) (discussing the disconnect between business method patents and the goals of the patent system in general).

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genres, from manufactured biological processes⁵⁵ to business method patents,⁵⁶ even to the absurd.⁵⁷ Furthermore, in addition to seeking patents for machines, manufactures or compositions of matter, inventors seek to fully monopolize the field by patenting the related process as well. Many respond negatively to patents on both products and processes in the biotechnology field due to the implications of such information on healthcare.⁵⁸ However, on balance, those within the biotechnology field as well as other up-and-coming industries, are concerned that limiting patent eligibility at the outset of a claim examination will effectively push out claims from emerging fields based on an inability to conform to an outmoded conception of “process.”⁵⁹ As opposed to other industries, which may or may not require extensive funding,⁶⁰ the cost of research and development in the biotech industry reaches into the billions⁶¹ and in turn relies on its exclusive rights for profit and capital to continue developing new products. Limiting patent eligibility in this field would seemingly reduce innovation and increase secrecy until patentability could be assured.

The line of cases leading up to the Supreme Court’s review of *Bilski v. Kapos* and the Federal Circuit’s rehearing of *Prometheus*, delineates the debate over where to draw the line for biotechnical process claims. Although the concern over the continued viability of business method patents struck fear into the hearts of large corporations, the uncertainty for diagnosis and treatment method patents affected not

⁵⁵ See discussion *supra* of *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁵⁶ See BANK OF AMERICA, <https://www.bankofamerica.com/deposits/special-programs/keep-the-change.go> (last visited Apr. 24, 2011) (stating that currently Bank of America’s “Keep the Change Program” is listed as patent-pending).

⁵⁷ TOTALLY ABSURD INVENTIONS, <http://totallyabsurd.com> (last visited Apr. 29, 2011).

⁵⁸ See Brief for Appellees at 5-6, *Ass’n of Molecular Pathology v. U.S. Patent and Trademark Office et al.*, No. 2010-1406 (Fed. Cir. Aug. 19, 2010), available at <http://patentdocs.typepad.com/files/brief-for-the-appellees.pdf> (“[T]hese patent claims stifle vital clinical and research practices to the detriment of women’s health and scientific progress.”).

⁵⁹ See *Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 548 U. S. 124 (2006) (Breyer, J., dissenting); *In re Bilski*, 545 F.3d. 943 (Fed. Cir. 2008) (Rader, J., dissenting); *infra* Part III.

⁶⁰ See Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1581-82 (2003) (discussing the industry-specific nature of research and development expenses and ultimately the incentive-based differences between some fields of innovation versus others).

⁶¹ 2008 *Investment in U.S. Health Research*, RESEARCH AMERICA, <http://www.researchamerica.org/uploads/healthdollar08.pdf> (last visited Apr. 24, 2011).

only those corporations controlling the industry but also physicians and patients alike.

*A. Labcorp v. Metabolite*⁶²

Researchers at University Patents Inc. created and patented a process for testing for homocystine (an amino acid), and then correlating the concentration with Vitamin B levels in the body to determine vitamin deficiency ('658 patent).⁶³ Claim 13 covered any process (patented or unpatented) for measuring homocystine levels and "correlating" the level with a deficiency in Vitamin B.⁶⁴ For example, a physician can satisfy the correlation step when she notes the test level and makes a mental comparison to a normal level. Metabolite acquired the '658 patent, and in 1991 sublicensed Labcorp to use the process in its research.⁶⁵ The agreement contained a provision allowing Labcorp to terminate the agreement if "a more cost effective commercial alternative is available that does not infringe a valid and enforceable claim of" the patent.⁶⁶ In 1998, Labcorp began using the Abbot Test, a new method for measuring homocystine levels, and ceased paying royalties to Metabolite.⁶⁷

Metabolite brought suit against Labcorp claiming patent infringement and breach of the license agreement. The jury found that Labcorp's use of the Abbot Test infringed Claim 13 of the '658 patent and awarded damages for unpaid royalties of more than \$4.6 million plus enhanced damages.⁶⁸ The district court also enjoined Labcorp from performing homocystine tests, including the Abbot Test. Labcorp appealed to the Federal Circuit on the theory that Claim 13 was "invalid for indefiniteness, lack of written description, non-enablement,

⁶² *Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 548 U.S. 124 (2006) (Breyer, J., dissenting).

⁶³ *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1358 (Fed. Cir. 2004). This type of deficiency can cause numerous ailments including "vascular disease, cognitive dysfunction, birth defects and cancer. If detected early enough, however, vitamin supplements readily treat the deficiency." *Id.*

⁶⁴ *Id.*

⁶⁵ *Lab. Corp.*, 548 U.S. at 128 (Breyer, J., dissenting).

⁶⁶ *Id.*

⁶⁷ *Id.* at 129. Labcorp claimed that the new test was a better alternative to the '658 patent and therefore could take advantage of the termination provision in the licensing agreement. *Id.*

⁶⁸ *Metabolite*, 370 F.3d at 1359.

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anticipation, and obviousness.”⁶⁹ Furthermore, Labcorp argued that allowing Claim 13 to stand would allow Metabolite to “improperly gain a monopoly over a basic scientific fact rather than a novel invention of its own.”⁷⁰ The Federal Circuit rejected these arguments, finding Claim 13 to be patentable.⁷¹ The court declined to address Labcorp’s assertion that allowing Claim 13 to stand is tantamount to allowing a patent for a law of nature.⁷² The Supreme Court granted certiorari but later dismissed the case as improvidently granted based on a procedural fault:⁷³ Labcorp, although referring to the issue, had never specifically asserted that Claim 13 violated 35 U.S.C. § 101 in the lower courts.⁷⁴

Despite the dismissal of the writ, both the Supreme Court’s willingness to grant certiorari and Justice Breyer’s heated dissent joined by two other justices, demonstrate the current uncertainty surrounding the scope of subject matter eligibility for process claims in the biotechnology field. In his dissent, Justice Breyer stated that “[C]laim 13 is invalid no matter how narrowly one reasonably interprets” the phenomenon of nature doctrine.⁷⁵ Furthermore, the relationship between the process for measuring homocystine levels using either a patented or unpatented test and a vitamin deficiency is a natural occurrence observed through biology.⁷⁶ Justice Breyer argued that the ability to patent a determination made in the mind of a physician extends patent law too far and subverts the purpose of this body of law.⁷⁷ Breyer concluded his dissent with a policy argument for limiting the scope of patentability in order to protect the medical profession.⁷⁸ Articulating the “anti-commons argument,”⁷⁹ Breyer focused on the high transaction

⁶⁹ *Id.* (citing Brief for Appellant, at 38).

⁷⁰ *Id.* (citing Brief for Appellant, at 41).

⁷¹ *Id.* at 1358.

⁷² *Lab. Corp.*, 548 U.S. at 131 (Breyer, J., dissenting).

⁷³ *Id.* at 125.

⁷⁴ *Id.* at 132 (Breyer, J., dissenting). (Justice Breyer also found sufficient procedural grounds upon which the Court should have heard the case, citing both the parties’ briefs to the Court and their arguments below as evidence of a prior dispute as to subject matter eligibility).

⁷⁵ *Id.* at 135.

⁷⁶ *Id.*

⁷⁷ *Id.* at 136.

⁷⁸ *Lab. Corp.*, 548 U.S. at 138. (The Court’s failure to invalidate this patent claim “threatens to leave the medical profession subject to the restrictions. . .”).

⁷⁹ See generally Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* 698 (1998), available at <http://www.sciencemag.org/cgi/content/full/280/5364/698> (discussing how the

costs associated with an increased distribution of patents. The transaction costs of exclusivity affect physicians' abilities to practice medicine efficiently by imposing time, energy and financial constraints.⁸⁰ Consequently, the overflow of these problems hinders the healthcare system as a whole. To avoid confusion or decreased investment due to uncertainty, Breyer reasoned that the Court should address this issue to provide clarity as to the legal rights and obligations of medical practitioners.⁸¹

*B. In re Bilski*⁸²

Considered the perfect opportunity for the Supreme Court to narrow the scope of §101, *Bilski* focused not on a biotechnical process, but rather on a method of doing business. The claim at issue was drawn on a method for hedging risk in commodities markets.⁸³ The process required an intermediary to buy from both the supplier and the consumer at fixed costs thereby assuring quantity and price while hedging the risk involved in the commodities market.⁸⁴ The U.S. Patent and Trademark Office examiner and later the Board of Patent Appeals, rejected the claim, finding that it failed to demonstrate a meaningful transformation because it entails only intangible elements — “non-physical financial risks and legal liabilities of the commodity provider, the consumer, and the market-participants.”⁸⁵ In other words, the method attempted to claim an abstract idea.

On appeal, the Federal Circuit considered several judicially-created tests for determining subject matter eligibility for process claims. The first of these tests, the Freeman-Walter-Abele Test, was defined and articulated over the course of three opinions arising out of the United States Court of Customs and Patent Appeals.⁸⁶ The test sets forth two steps: (1) determine whether the claim recites an “algorithm;” and, (2)

privatization and exclusivity of patent rights can actually hinder innovation downstream when researchers require multiple licenses to perform those tasks necessary to bring about a new innovation).

⁸⁰ *Lab. Corp.*, 548 U.S at 138.

⁸¹ *Id.*

⁸² *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc).

⁸³ *Id.* at 949.

⁸⁴ *Id.* at 950.

⁸⁵ *Id.*

⁸⁶ See, e.g., *In re Abele*, 684 F.2d 902 (C.C.P.A. 1982); *In re Walter*, 618 F.2d 758 (C.C.P.A. 1980); *In re Freeman*, 573 F.2d 1237 (C.C.P.A. 1978).

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determine whether that algorithm is “applied in any manner to physical elements or process steps.”⁸⁷ The Federal Circuit in *State Street* doubted whether this test had survived Supreme Court scrutiny after *Diehr* and *Chakrabarty*.⁸⁸ Relying on these opinions, the majority in *Bilski* concluded that the Freeman-Walter-Abele test is “inadequate” in that “a claim failing [this] test may nonetheless be patent-eligible.”⁸⁹

The court in *State Street* referred to the second of these tests, the “useful, concrete, and tangible result,” as a way of showing that certain types of nonconforming subject matter — i.e. mathematical algorithms — are nothing more than abstract ideas until given a practical application at which point they satisfy § 101.⁹⁰ While in certain instances this test provided clarity as to whether a claim was drawn to a fundamental concept, the court in *Bilski* found it insufficient to determine patent eligibility.⁹¹ The third and final test considered by the court, a technological arts test, represented a quasi-attempt to reinstate specific field exceptions. Although dissimilar from the business method and mathematical algorithm exceptions proposed in *State Street*, which sought to exclude certain subject matter, a technological arts test would restrict subject matter to only those inventions involving applied science or mathematics.⁹² The court refused to adopt such a test on the premise that that defining “technological arts” and “technology” proved far too “ambiguous and ever-changing.”⁹³ Further, the court would not entertain implementing “field-of-use” limitations, stating that such limitations could not transform a claim for a fundamental process into a patentable claim.⁹⁴

The Federal Circuit resolved the conflict over which test to apply by holding that the MOT test is the sole test by which subject matter eligibility should be determined.⁹⁵ The court did acknowledge that this test perhaps contradicted prior standards enunciated in the Supreme

⁸⁷ *Bilski*, 545 F.3d at 959 (quoting *In re Abele*, 684 F.2d at 905-07).

⁸⁸ *State St. Bank v. Signature Fin. Grp., Inc.* 149 F.3d 1368, 1374 (Fed. Cir. 1998).

⁸⁹ *Bilski*, 545 F.3d at 959.

⁹⁰ *State Street*, 149 F.3d at 1373 (quoting *In re Alappat*, 33 F.3d (Fed. Cir. 1994) (en banc)).

⁹¹ *Bilski*, 545 F.3d at 959-60.

⁹² *Id.* at 960.

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.* at 954.

Court,⁹⁶ even suggesting that its own test would require refinement in light of future technology.⁹⁷ Judge Michel began his opinion by discussing “process” claims (conceding that *Bilski*’s claim would meet the literal definition found in § 101), and delineating three instances where such claims can never constitute patentable subject matter: those that attempt to preempt laws of nature, natural phenomenon, or abstract ideas.⁹⁸ The real issue requires determining whether the claim “recites a fundamental principle, and, if so, whether it would pre-empt substantially all uses of that fundamental principle.”⁹⁹ Determining whether the claim is sufficiently limited in scope requires that the court adopt a test that efficiently cabins claims for abstract ideas. The court based its reasoning on the theory that where a claim is drawn to a machine or involves a transformation, it transcends abstract subject matter to create a tangible, useful method or process. While this is somewhat similar to the “useful, concrete, and tangible result” promulgated by *State Street*,¹⁰⁰ the *Bilski* test extends one step further by defining how such a result can be obtained.

The MOT test is a two-pronged inquiry whereby an applicant can satisfy either by demonstrating that his or her claim is (1) tied to a particular machine or apparatus, or (2) transforms a particular article into a different state of thing.¹⁰¹ Two limitations apply to this test. First, the use of a specific machine or transformation of an article must impose meaningful limits on the claim’s scope to impart patent-eligibility.¹⁰² Second, the machine or transformation step cannot be an insignificant extra-solution activity,¹⁰³ an example of which is an insufficient data-gathering step used to disguise a claim drawn to an algorithm as a patent-eligible claim.¹⁰⁴ The court stressed that the

⁹⁶ *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972) (the Court supplemented its holding by stating that it “[did] not hold that no process patent could ever qualify if it did not meet the requirements of [its] prior precedent.”).

⁹⁷ *Bilski*, 545 F.3d at 955-56 (“Nevertheless, we agree that future developments in technology and the science may present difficult challenges to the machine-or-transformation test . . . the Supreme Court may ultimately decide to alter or perhaps even set aside this test to accommodate emerging technologies[.]”).

⁹⁸ *Id.* at 952.

⁹⁹ *Id.* at 954.

¹⁰⁰ *State St. Bank v. Signature Fin. Grp., Inc.* 149 F.3d 1368, 1373 (Fed. Cir. 1998).

¹⁰¹ *Bilski*, 545 F.3d. at 961.

¹⁰² *Id.* (citing *Benson*, 409 U.S. at 71-72).

¹⁰³ *Id.* (citing *Parker v. Flook*, 437 U.S. 584, 590 (1978)).

¹⁰⁴ *See In re Gram*, 888 F.2d 835, 837 (Fed. Cir. 1989). *But see In re Abele*, 684 F.2d

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“transformation must be central to the purpose of the claimed process.”¹⁰⁵ Accordingly, at least two specific processes automatically qualify as a transformation: chemical or physical transformations of a physical object or substance,¹⁰⁶ and an electronic transformation of data into a visual depiction so long as the claim is limited to a practical application of the fundamental principle.¹⁰⁷ The court elaborated further on the concept of “insufficient data-gathering” by repeating its holding from *In re Gram* that the process of performing clinical tests and subsequently determining results and causes is not sufficiently transformative.¹⁰⁸

Applying the MOT test to the claim at hand, the Federal Circuit concluded that *Bilski* could not satisfy either prong.¹⁰⁹ The process lacked involvement of any physical objects and/or substances. The only transformation to occur would shift an intangible concept of risk. The real exchange is that of “legal rights.”¹¹⁰ Because the *Bilski* claim neither was tied to a machine nor transformed an article, it could not satisfy the court’s new patent-eligibility standard. Furthermore, as a matter of policy, the claim was drawn on a purely mental process involving a mathematical calculation of risk in the mind of the intermediary, and then action on such a determination by consummating the sale.¹¹¹ If the claimed process could be patented, it would preempt “any application of the fundamental concept of hedging.”¹¹²

Three judges responded with strong dissents specifically disagreeing with the adoption of the MOT test and the unwillingness of the court to follow prior precedent (*State Street*), or in the alternative overrule it. Judge Newman charged the majority with rewriting the term “process” in § 101 by limiting this category of patent claims to the MOT test in light of an ever-expanding technological climate.¹¹³ She

902, 909 (C.C.P.A. 1982).

¹⁰⁵ *Bilski*, 545 F.3d at 962.

¹⁰⁶ *Id.*; see also *Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (involving a patent for a process of curing rubber).

¹⁰⁷ *Bilski*, 545 F.3d at 962-63 (discussing the holding in *Abele*, involving the two-dimensional depiction of X-ray data of bones, organs and other tissue).

¹⁰⁸ *Id.* at 963.

¹⁰⁹ *Id.* at 963-64.

¹¹⁰ *Id.* at 964.

¹¹¹ *Id.*

¹¹² *Id.* at 965.

¹¹³ *Bilski*, 545 F.3d at 976 (Newman, J., dissenting) (“This exclusion of process inventions is contrary to statute, contrary to precedent, and a negation of the constitutional

reasoned that “uncertainty is the enemy”¹¹⁴ when it comes to emerging fields of art, which in turn will disincentivize innovation.¹¹⁵ The court should have concerned itself with a forward-looking perspective as to the effects on innovation-based commerce.¹¹⁶ The test should remain as it is stated in the statute — requiring new and useful processes — and recognize as ineligible only “fundamental truths, laws of nature, and abstract ideas.”¹¹⁷ Bilski’s claim, in Judge Newman’s opinion, has yet to be evaluated for patentability.¹¹⁸

Judge Mayer took a different approach, suggesting the majority had not gone far enough and called for *State Street* to be overruled, thereby excluding all business methods from patent protection.¹¹⁹ Applying the “technological arts test,” Judge Mayer looked to the Constitution for Congress’ authority to protect the “useful arts,” a term we now interpret to mean technological innovations.¹²⁰ Judge Mayer also engaged in an incentives-based analysis comparing business method patents like that at issue in *Bilski* to pharmaceutical industry patents.¹²¹ Whereas businesses have a built-in incentive to “stay ahead of [the] competition, and to make more profit,”¹²² the front-end costs and the high risks associated with the drug industry demand a reliance on strong patent protection.¹²³ Because Bilski’s claim was based on business principles, it would not fall within patent eligible criteria.¹²⁴

Lastly, Judge Rader expressed in his dissent that this case could have been decided simply on the premise that Bilski attempted to claim an abstract idea.¹²⁵ He believed that the majority relied on portions of previous Supreme Court opinions, taken out of context, to create a test that “ties our patent system to dicta from an industrial age decades

mandate. Its impact on the future, as well as on the thousands of patents already granted, is unknown.”).

¹¹⁴ *Id.* at 977.

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 995.

¹¹⁷ *Id.* at 997.

¹¹⁸ *Id.*

¹¹⁹ *Bilski*, 545 F.3d at 998 (Mayer, J., dissenting).

¹²⁰ *Id.* at 1001 (citing *Paulik v. Rizkalla*, 760 F.2d 1270, 1276 (Fed. Cir. 1985) (en banc)).

¹²¹ *Id.* at 1005-06.

¹²² *Id.* at 1005.

¹²³ *Id.*

¹²⁴ *Id.* at 1010.

¹²⁵ *Bilski*, 545 F.3d. at 1011.

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removed from the bleeding edge.”¹²⁶ The approach taken by the majority does little to explain why the expansive language found in § 101 should suddenly be confined to the MOT test.¹²⁷ In other words, “why should some categories of invention deserve no protection?”¹²⁸ The Supreme Court has determined that the only limitations to the eligibility requirement in § 101 apply to natural laws, natural phenomena, and abstract ideas.¹²⁹ These concepts encompass those things that cannot be invented at all.¹³⁰ Finally, § 101 was purposefully written as a broad gatekeeper.¹³¹ This section still requires that the claim meet the other “conditions and requirements” of Title 35.¹³²

Toward the end of his dissent, Judge Rader dovetailed the § 101 discussion in *Bilski* with Justice Breyer’s *Labcorp* dissent.¹³³ He pointed to a clear distinction between the unpatentable relationship between homocysteine levels and low folate as opposed to the patentable method of detecting and treating said condition.¹³⁴ As important as considering the language of the statute (which, in terms of § 101, Rader found the process in *Labcorp* patentable) is a reliance on the policy justifications derived from the Constitutional mandate — to utilize patents for the advancement of science and the useful arts.¹³⁵ The MOT test leaves potential innovators unsure of the current law and understandably wary about investing large sums of money for potentially unpatentable processes.¹³⁶ The far-reaching consequences of this decision risk “hobbling” advances and “may not incentivize, but [instead] complicate our search for the vast secrets of nature.”¹³⁷ While the subject matter of

¹²⁶ *Id.*

¹²⁷ *Id.* at 1012.

¹²⁸ *Id.*

¹²⁹ *Id.* at 1012-13 (citing *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).

¹³⁰ *Id.* at 1013.

¹³¹ *Bilski*, 545 F.3d. at 1012.

¹³² *Id.* at 1014.

¹³³ *See infra* Part III(A).

¹³⁴ *Bilski*, 545 F.3d at 1014 (Rader, J., dissenting).

¹³⁵ *Id.*; *see also* Burk & Lemley, *supra* note 60 at 1581-82.

¹³⁶ *Bilski*, 545 F.3d at 1014 (Rader, J., dissenting) (expressing his concern that research for conditions such as Lou Gerhrig’s disease or Parkinson’s will taper off due to such instability in the system); *see also* 35 U.S.C. § 271(e)(1) (2008) (the statutory safe harbor provision protecting those uses “reasonably related to the development and submission of information to the FDA”). *But see* Marcia Angell, *The Truth about Drug Companies*, 51 N.Y. REV. OF BOOKS 12, Jul. 15, 2004, available at <http://www.nybooks.com/articles/17244> (discussing the billions of dollars earned by pharmaceuticals in the drug industry).

¹³⁷ *Bilski*, 545 F.3d at 1015 (Rader, J., dissenting).

Bilski's business method patent "is seemingly far removed from diagnostic claims,"¹³⁸ the underlying determination of whether § 101 is met will have to conform to the same test regardless of whether the claims arise out of very different fields.

The Supreme Court granted a writ of certiorari and more than seven months after hearing arguments for *Bilski v. Kappos*,¹³⁹ the Court issued its opinion in June 2010 affirming the Federal Circuit's finding that Bilski's patent could not meet the § 101 standard.¹⁴⁰ The Court, however rejected the notion that the MOT test could be the sole test for patent eligibility, providing little in the way of guiding precedent.¹⁴¹ Specifically, the Court concluded that, "the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101."¹⁴²

While all nine Justices agreed that the patent claim failed under § 101, four Justices, in a concurrence written by Justice Stevens, expressed a strong sentiment that business methods should not be patent-eligible at all.¹⁴³ The majority opinion, authored by Justice Kennedy, focused mostly on discrediting a narrow reading of patent eligibility by reference to prior case law and interpreting the statutory wording in its "ordinary, contemporary, common meaning."¹⁴⁴

The Court, in refusing to define a test for patentability, succeeded only in endorsing the possibility that business methods could be patent eligible, while maintaining the current uncertainty regarding the patentability of diagnostic methods.¹⁴⁵ This reasoning was subject to harsh criticism from Stevens in his concurrence. The majority's reliance on prior patent case law coupled with its insistence on not limiting the doctrine beyond the literal word in the Patent Act, means that the "analysis (or lack thereof) may have led to the correct outcome in this case, but it also means that the Court's musings on this issue stand for

¹³⁸ Kevin E. Noonan, *Applying In re Bilski to Diagnostic Method Claims*, PATENT DOCS (Feb. 5, 2009, 3:07 PM), <http://www.patentdocs.org/2009/09/applying-in-re-bilski-to-diagnostic-method-claims.html>.

¹³⁹ *Bilski v. Kappos (Bilski II)*, 130 S. Ct. 3218 (2010).

¹⁴⁰ *Id.* at 3231.

¹⁴¹ *Id.*

¹⁴² *Id.* at 3227.

¹⁴³ *Id.* at 3232 (Stevens, J., concurring) ("More precisely, although a process is not patent-ineligible simply because it is useful for conducting business, a claim that merely describes a method of doing business does not qualify as a 'process' under § 101.").

¹⁴⁴ *Id.* at 3226 (citing *Diamond v. Diehr*, 450 U.S. 175, 182 (1981)).

¹⁴⁵ *Bilski II*, 130 S. Ct. at 3228.

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very little.”¹⁴⁶ What this opinion means for diagnostic tests would be the focus of the next two cases, *Prometheus Laboratories v. Mayo Collaborative Services* and *Classen Immunotherapies, Inc. v. Biogen*, each to be considered for a second time in the Federal Circuit upon the Supreme Court’s issuance of GVR Orders one day after deciding *Bilski*.¹⁴⁷

*C. Prometheus Laboratories v. Mayo Collaborative Services*¹⁴⁸
(*Prometheus I and II*)

The first of these cases, *Prometheus Laboratories v. Mayo Collaborative Services*, involves a process for determining the correct dosage for thiopurine drugs used in the treatment of gastrointestinal and non-gastrointestinal autoimmune disorder.¹⁴⁹ After the drug is administered to a patient, the body breaks it down into its metabolite components, specifically 6-MMP and 6-TG,¹⁵⁰ commonly used for their immunosuppressive properties.¹⁵¹ Calibrating the correct dosage for use in patients suffering from Crohn’s Disease and inflammatory bowel diseases require a patient-specific analysis to “optimize therapeutic efficacy while minimizing toxic side effects.”¹⁵² As such, the process involves two steps: (1) administering the drug to the subject, and (2) determining the level of the drug’s metabolites and comparing those measurements to pre-determined levels in order to adjust the level

¹⁴⁶ *Id.* at 3236 (Stevens, J., concurring).

¹⁴⁷ Aaron-Andrew P. Bruhl, *The Supreme Court’s Controversial GVR- And an Alternative*, 107 MICH. L. REV. 711, 712 (2009) (“[T]he procedure for summarily granting certiorari, vacating the decision below without finding error, and remanding the case for further consideration by the lower court. The GVR is most commonly used when the ruling below might be affected by one of the Court’s recently rendered decisions, which was issued after the lower court ruled.”).

¹⁴⁸ *Prometheus Labs., Inc. v. Mayo Collaborative Servs. (Prometheus II)*, 628 F.3d 1347 (Fed. Cir. 2010); *Prometheus Labs., Inc. v. Mayo Collaborative Servs. (Prometheus I)*, 581 F.3d 1336 (Fed. Cir. 2009).

¹⁴⁹ *Prometheus I*, 581 F.3d. at 1339.

¹⁵⁰ These stand for 6-mthyl-mercaptopurine and 6-thioguanine. Significant research regarding 6-TG has determined that it can very often lead to toxicity if not monitored with extreme care. Chris J.J. Mulder, et al., *On Tolerability and Safety of a Maintenance Treatment with 6-Thioguanine in Azathioprine or 6-Mercaptopurine Intolerant IBD Patients*, 11(35) WORLD J. GASTROENTEROLOGY 5540 (2005), available at <http://www.wjgnet.com/1007-9327/11/5540.asp> (suggesting the importance of providing for a specific system of administration and analysis).

¹⁵¹ *Prometheus I*, 581 F.3d at 1339.

¹⁵² *Id.*

accordingly.¹⁵³ The Mayo Clinic had previously received a license to use Prometheus' test, but in 2004 announced that it would begin utilizing its own test, which used different levels to determine toxicity.¹⁵⁴

On granting Mayo's motion for summary judgment, the district court found significant bars to eligibility under § 101. The court began by characterizing the test as a combination of "'administering' and 'determining' steps [that] are merely necessary data-gathering steps for any use of the correlations and that as construed, the final step — the 'warning' step. . . is only a mental step."¹⁵⁵ According to the district court, this correlation represented an expression of a natural process, "and the inventors merely observed the relationship between these naturally produced metabolites and therapeutic efficacy and toxicity."¹⁵⁶ Since the patent was drawn to the correlations specifically, it would wholly preempt a natural phenomenon and was thus ineligible under § 101.

1. Prometheus I

Applying the *Bilski* machine or transformation test, the Federal Circuit disagreed, finding the claims patentable because they satisfied the transformation prong of the MOT test at two different junctures in the process.¹⁵⁷ First, the court found that the *administration* of the drug into the body creates a transformation of the drug, and "various chemical and physical changes of the drug's metabolites that enable their concentrations to be determined."¹⁵⁸ Where the court below framed the claim as one involving a process of correlations, Judge Lourie viewed the claims as "methods of treatment, which are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition."¹⁵⁹ Innately this process should be characterized as a treatment, the goal of which is a

¹⁵³ *Id.*

¹⁵⁴ *Id.* at 1340.

¹⁵⁵ *Id.* at 1341 (quoting *Prometheus Labs. v. Mayo Collaborative Servs.*, No. 04cv1200, 2008 U.S. Dist. LEXIS 25062, at *6 (S.D. Cal. Mar. 28, 2008)).

¹⁵⁶ *Id.*

¹⁵⁷ *Prometheus I*, 581 F.3d at 1345-46. Prometheus also attempted to persuade the court that a third transformation occurred when the "metabolite levels are *transformed* into a warning for a doctor to alter the dosage," but the court affirmed the lower court's determination that this represented merely a mental step. *Id.*

¹⁵⁸ *Id.* at 1346.

¹⁵⁹ *Id.*

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transformation in the body.¹⁶⁰ In its argument on appeal, Prometheus distinguished the transformation that occurs as the result of the administration of the drug, rather than as a result of a natural process.¹⁶¹ Agreeing with this assertion, the court relied on *Bilski I* for approval in that “it is virtually self-evident that a process for a chemical or physical transformation of *physical objects or substances* is patent-eligible subject matter.”¹⁶²

Second, the court found that the determining step is also transformative because it involves manipulation of the data in such a way that “at the end of the process, the human sample is no longer human blood; human tissue is no longer human tissue.”¹⁶³ These measurements are an integral part of making the determination.¹⁶⁴ The manipulation of both the chemical and physical properties of the physical samples is sufficient to meet the *Bilski* transformation prong.¹⁶⁵

The court also addressed the secondary limitation imposed by the MOT test: the process must not be “merely insignificant extra-solution activity.”¹⁶⁶ As explained above, the court considered these transformations the primary objective of the process, without which there would be no claim. The court distinguished this type of diagnostic test from that claimed in *In re Gram*.¹⁶⁷ In *Gram*, the applicant sought to patent a process involving (1) clinical testing, and (2) a determination of whether an abnormality existed based on the findings.¹⁶⁸ Based on those facts the court found only a mathematical algorithm combined with a data-gathering step, rather than the series of transformative steps found in Prometheus’ process.¹⁶⁹ Unlike the clinical test in *Gram*,

¹⁶⁰ *Id.*

¹⁶¹ *Id.* Prometheus attempts to draw clear distinctions similar to those discussed in Judge Rader’s dissent in *Bilski*. Science in general involves the manipulation of natural principles arising out of physics, chemistry, and so on. Even when man-made inventions put these principles to use, it is the ultimate representation of progress — a deeper understanding of the world and its inner workings. *Id.*

¹⁶² *Id.* at 1346-47 (quoting *In re Bilski*, 545 F.3d 943, 962 (Fed. Cir. 2008)).

¹⁶³ *Prometheus I*, 581 F.3d at 1347 (quoting the Declaration of Prometheus’ expert, Dr. Yves Théorêt).

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ See *In re Bilski*, 545 F.3d at 962 (quoting *Parker v. Flook*, 437 U.S. 584, 590 (1978)).

¹⁶⁷ *In re Gram*, 888 F.2d 835 (Fed. Cir. 1989).

¹⁶⁸ *Prometheus I*, 581 F.3d at 1348.

¹⁶⁹ *Id.*

“Prometheus’s claimed methods are not ‘merely’ data-gathering steps or ‘insignificant extra-solution activity’; they are part of treatment regimes for various diseases using thiopurine drugs.”¹⁷⁰

As a final consideration, the court dismissed any notion that the inclusion of a mental step within the process could be dispositive stating that, “a subsequent mental step will not negate the transformative nature of prior steps.”¹⁷¹ The claim must be viewed as a whole.¹⁷² Specifically, the final step in the Prometheus test, the “warning” step, does not invalidate the transformative nature of the whole process.¹⁷³

2. Prometheus II

The Supreme Court issued a GRV order summarily granting certiorari, vacating the court of appeals’ judgment, and remanding to the Federal Circuit based on the court’s holding in *Bilski II*.¹⁷⁴ Because the *Bilski II* opinion made it clear that the MOT test could still provide useful guidance on the patentability issue, the Federal Circuit saw no need to reanalyze *Prometheus* under a different standard.¹⁷⁵ While the court did apply the MOT test in *Prometheus I* in finding a transformation on two levels, it also determined that the claim was not drawn to a law of nature or natural phenomenon and therefore could not preempt all uses of the recited correlations.¹⁷⁶ Revisiting this language in *Prometheus II*, the court,

[D]id not think that either the Supreme Court’s GVR Order or the Court’s *Bilski* decision dictates a wholly different analysis or a different result on remand. The Supreme Court’s decision in *Bilski* did not undermine our preemption analysis of Prometheus’s claims and it rejected the machine-or-transformation test only as a definitive test. The Court merely stated that “[t]he Court of Appeals incorrectly concluded that this Court has endorsed the machine-or-

¹⁷⁰ *Id.*

¹⁷¹ *Id.* at 1348.

¹⁷² *Id.* at 1349 (quoting *In re Bilski*, 545 F.3d 943, 958 (Fed. Cir. 2008) (“[E]ven 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 section 101.”).

¹⁷³ *Id.*

¹⁷⁴ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 130 S. Ct. 3543 (2010) (mem.).

¹⁷⁵ *Prometheus Labs., Inc. v. Mayo Collaborative Servs. (Prometheus II)*, 628 F.3d 1347, 1355 (Fed. Cir. 2010).

¹⁷⁶ *Id.*

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transformation test *as the exclusive test*.” 130 U.S. at 3226 (emphasis added). . . . Thus, the Court did not disavow the machine-or-transformation test. And, as applied to the present claims, the “useful and important clue, an investigative tool,” leads to a clear and compelling conclusion, *viz.*, that the present claims pass muster under § 101. They do not encompass laws of nature or preempt natural correlations.¹⁷⁷

The opinion leaves little doubt that the patent eligibility issue has yet to be resolved, despite the Federal Circuit’s willingness to seemingly broaden its view of diagnostic method patents under § 101. The court even referenced the multiple citations in *Bilski II* to Justice Breyer’s strong dissent in *Labcorp*, regarding the dangers of patenting biomedical correlations, as “fail[ing] to transform a dissent into controlling law.”¹⁷⁸ Without limitations imposed from the outside, it is unlikely that the Federal Circuit will independently narrow its analysis of similar biotechnology process claims.

*D. Classen Immunotherapies, Inc. v. Biogen*¹⁷⁹

Currently on remand from the Supreme Court, *Classen* involves a series of patents held by Classen for a process of evaluating and improving the safety of immunization schedules.¹⁸⁰ Classen claimed Biogen infringed these patents when Biogen examined the correlation between certain vaccination schedules and immune deficiencies and ultimately developed a vaccine using this data. The district court relied on the natural phenomenon exclusion discussed in *Diamond v. Diehr* in finding that the patent attempted to claim a natural phenomenon.¹⁸¹ The court stated that determining patentability requires looking at the patent as a whole, and while variation on a previous process may still qualify, “[i]nsignificant post-solution activity will not transform an unpatentable principle into a patentable process.”¹⁸² The court analyzed the limitations

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at 1356 n.2.

¹⁷⁹ *Classen Immunotherapies, Inc. v. Biogen Idec*, 304 F. App’x 866 (Fed. Cir. 2008) (unpublished decision).

¹⁸⁰ *Classen Immunotherapies, Inc. v. Biogen Idec*, Civ. No. WDQ-04-2607, 2006 U.S. Dist. LEXIS 98106, at *3 (D. Md. Aug. 16, 2006).

¹⁸¹ *Id.* at *11-14 (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (“Einstein could not patent his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity. Such discoveries are manifestations of nature free to all men and reserved exclusively to none.”)).

¹⁸² *Id.* at *12 (citing *Diehr*, 450 U.S. at 188).

inherent in patenting both abstract ideas and natural phenomenon, and, declining to consider each theory separately, concluded that Classen's patent involved merely "thinking about" the connection between vaccination schedules and immune deficiency — a correlation determined by biology, not human ingenuity.¹⁸³

The opinion is somewhat unclear as to why the court ultimately relied on the "natural phenomenon" principle. In a single-line, unpublished affirmation of the decision, the Federal Circuit cited its holding in *Bilski* as controlling.¹⁸⁴ The court provided no further explanation as to why Dr. Classen's patent failed to meet the transformation test. The Supreme Court also issued a GVR Order for Classen based on the Court's holding in *Bilski*.¹⁸⁵ As of the date of this Note, the Federal Circuit has yet to issue another opinion with regards to *Classen*.

IV. FINDING A PROPER BALANCE TO THE COMPETING POLICY INTERESTS UNDERLYING THE DEBATE OVER ELIGIBILITY OF DIAGNOSTIC METHOD PATENTS UNDER § 101

The inability of other mechanisms to successfully incentivize spending for research and development in the biotechnology industry suggests that patent protection for diagnostic methods is the best means of encouraging the progress of the useful arts.¹⁸⁶ Private rights afford exclusivity, which in turn provides the economic incentive to invest in burgeoning innovations. Without such security, the billions of dollars¹⁸⁷ invested in the industry would undoubtedly decrease. The tradeoff for exclusivity contemplated by Congress is the supposed benefit derived

¹⁸³ *Id.* at *15. The district court's exact language uses a combination of terms in its decision, finding that "it would appear that the 139 and 739 patents are an indirect attempt to patent the *idea* that there is a relationship between vaccine schedules and chronic immune mediated disorders, the Court finds they are an attempt to patent an unpatentable *natural phenomenon*." *Id.* (emphasis added).

¹⁸⁴ *Classen Immunotherapies*, 304 F. App'x at 867 ("In light of our decision in *In re Bilski*, we affirm the district court's grant of summary judgment that these claims are invalid under 35 U.S.C. § 101. Dr. Classen's claims are neither 'tied to a particular machine or apparatus' nor do they 'transform[] a particular article into a different state or thing.' Therefore we *affirm*." (citations omitted)).

¹⁸⁵ *Id.*

¹⁸⁶ See DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 41 (2009).

¹⁸⁷ See 2008 *Investment in U.S. Health Research*, *supra* note 61.

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from new and useful inventions later bestowed upon society. Because of the diverse and unique nature of a patent system that applies to many different industries, amending the Patent Act to reflect varying eligibility requirements or adopting overly restrictive tests, such as the MOT test, would undermine the purposefully broad sweep of the Patent Act.

Given the rationales for patent protection, coupled with the Federal Circuit's application of the MOT test in *Prometheus II*, the future of patentability for diagnostic method patents looks promising. A claim will almost assuredly meet the § 101 standard where the process is similar to that in *Prometheus*, in which the court considered either the "administering" step or the "determining" step transformative. As the Federal Circuit stated in *Prometheus*, "methods of treatment . . . are *always* transformative when . . . drugs [are] administered to the body to ameliorate the effects of an undesired condition."¹⁸⁸

The relevant policy concerns for the disallowance of patent protection for diagnostic methods focus on the fear that privatizing diagnostic methods will impede the practice of medicine and significantly increase costs for patients. In order to balance the competing rationales of incentivizing the industry and promoting the public welfare, this Note suggests that Congress consider an amendment to the Medical Practitioner Exception under 35 U.S.C. § 287(c), which would eliminate the availability of a remedy where a physician infringes a pure process patent or a biotechnology process patent.¹⁸⁹ This would meet the competing demands halfway by still prohibiting the infringement of a valid patent and protecting the patentee from unlawful use of the patented process by research competitors or even third parties who facilitated infringement, but would now recognize the importance of allowing physicians to diagnose and treat patients by the most appropriate means available.

¹⁸⁸ *Prometheus Labs., Inc. v. May Collaborative Servs. (Prometheus I)*, 581 F.3d 1336, 1346 (Fed. Cir. 2010) (emphasis added).

¹⁸⁹ Aaron S. Kesselheim & Michelle M. Mello, *Medical Process Patents — Monopolizing the Delivery of Health Care*, 355 NEW ENG. J. MED. 2036, 2039 (2006), available at http://www.hsph.harvard.edu/faculty/michellemello/files/Labcorp_published_version.pdf.

A. The Medical Practitioner Exception to Patent Infringement Remedies

Although the harmonizing of United States patent law with international law is a complex topic outside the scope of this Note, Congress' addition of § 287(c) to the Patent Act, in light of the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter "TRIPS"),¹⁹⁰ suggests an unwillingness to deny patents for diagnostic testing.¹⁹¹ Specifically, TRIPS Article 27.3 allows members to deny patentability for "diagnostic, therapeutic and surgical methods for the treatment of humans or animals."¹⁹² Originally, Congress refused to adopt any portion of Article 27.3.¹⁹³ However, public outrage over a surgical patent lawsuit sparked reform,¹⁹⁴ resulting in the adoption of legislation designed specifically to protect physicians and other healthcare providers from patent infringement liability pertaining to the use of certain medical procedures.¹⁹⁵ Even though Congress carved out this exception, it did so while preserving the prohibition against unlicensed use of a process patent.¹⁹⁶ Specifically, the rule defines exempted "medical activity" as,

[T]he performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the *practice of a process in violation of a biotechnology*

¹⁹⁰ See generally Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27.3(a), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 81 [hereinafter "TRIPS"]; *WTO and the TRIPS Agreement*, WORLD HEALTH ORG. http://www.who.int/medicines/areas/policy/wto_trips/en/index.html (last visited Apr. 29, 2011).

¹⁹¹ John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685, 722-23 (2002).

¹⁹² TRIPS, *supra* note 190.

¹⁹³ Duffy, *supra* note 191, at 722.

¹⁹⁴ *Id.* at 722 n.121 ("Method of Making Self-Sealing Episcleral Incision," U.S. Pat. No. 5,080,111 (issued Jan. 14, 1992)).

¹⁹⁵ 35 U.S.C. § 287 (1999). The statute states, in relevant part:

With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

¹⁹⁶ 35 U.S.C. § 287(c)(2)(A)(iii).

*patent.*¹⁹⁷

The Medical Practitioner Exception represents a Congressional understanding that while some medical procedures are viable candidates for patentability, patent enforcement against physicians can represent an unfair burden on the medical profession.¹⁹⁸ Furthermore, where a patient requires surgical treatment, such necessity reaffirms the principle that the “embarrassment of a patent” must yield in certain circumstances.¹⁹⁹ As currently written, however, § 287(c) narrowly covers only medical or surgical procedures, while excluding the practice of patented biotechnology processes — an often necessary component to medical diagnosis and treatment. In order to better reflect the policy rationales underlying the medical practitioner carve-out, a legislative solution is necessary.

B. The Genomic Research and Diagnostic Accessibility Act of 2002

Recent reform measures have attempted to incorporate this concept by amending the infringement liability section of the Patent Act to limit the impact of gene patenting on the medical community. While such measures have yet to garner significant support, one in particular can provide a germane perspective on how the Medical Practitioner Exception to patent infringement could be amended so as to exempt physicians from liability for the use of certain biomedical process patents. Specifically, in an initial attempt to amend § 287, Representative Lynn Rivers (Democrat-MI) introduced The Genomic Research and Diagnostic Accessibility Act of 2002 (hereinafter “GRDAA”),²⁰⁰ aimed at establishing “limited exemptions from liability for certain uses of patented genetic sequences and genetic sequence

¹⁹⁷ *Id.* (emphasis added).

¹⁹⁸ *Emtel, Inc. v. LipidLabs, Inc.*, 583 F. Supp. 2d 811, 822 (S.D. Tex. 2008) (citing statements of Senator Frist: “My legislation would prevent the enforcement of so-called pure medical procedure patents against health professionals . . . [T]his narrowly tailored legislation would in no way discourage the important research being done in these areas of medicine. . . . My legislation is very narrow in scope. It would simply prevent the enforcement of patents against health professional or their affiliated facilities for pure procedure patents . . .”).

¹⁹⁹ *Id.*; Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), available at http://press-pubs.uchicago.edu/founders/documents/a1_8_8s12.html (“Considering the exclusive right to invention as given not of natural right, but for the benefit of society, I know well the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent.”).

²⁰⁰ GRDAA, *supra* note 7.

information in the context of basic research and genetic diagnostic testing.”²⁰¹ In relevant part, the GRDAA proposed an exemption from “infringement remedies” for the performance by a medical practitioner of any “genetic diagnostic, prognostic, or predictive test or a medical or surgical procedure.”²⁰²

As the first among many attempts to regulate gene patenting and associated process patents, the GRDAA focuses solely on genetic correlations, but excludes “pure process patents”²⁰³ such as the vitamin deficiency correlations in *Labcorp* or the treatment method comprising measurement of metabolites and dosage regulation in *Prometheus*. Furthermore, the effectiveness of this provision is rendered moot where the patentee also owns a patent for the underlying product or drug. For example, in a case currently on appeal to the Federal Circuit, *Ass’n for Molecular Pathology v. United States Patent and Trademark Office*, Myriad’s patent claims both isolated DNA for the BRCA gene and a corresponding method for comparing DNA.²⁰⁴ Liability would still attach for a physician in these scenarios because testing involves using both the gene and the process.²⁰⁵

As compared to later, more aggressive legislation aimed at completely barring gene-related patents,²⁰⁶ GRDAA focuses narrowly on addressing the concerns of gene patent critics especially in relation to the impact on the medical community. The exception for infringement liability would only apply to physicians, while third parties performing the test (for example, test kit suppliers) would still face liability under

²⁰¹ Christopher M. Holman, *Recent Legislative Proposals Aimed at the Perceived Problem of Gene Patenting*, 2008 A.B.A. SEC. OF SCI. & TECH. L. 2, available at http://www.americanbar.org/content/dam/aba/migrated/scitech/biotech/pdfs/recent_legislative_chris_holman.authcheckdam.pdf.

²⁰² GRDAA, *supra* note 7.

²⁰³ Kesselheim & Mello, *supra* note 189, at 2039.

²⁰⁴ *Ass’n for Molecular Pathology v. United States Patent & Trademark Office et al.*, No. 09 Civ. 4515, 2010 U.S. Dist. LEXIS 35418, at *149 (S.D.N.Y. Apr. 5, 2010). As of the date of this Note’s publication, the Federal Circuit is currently considering the issue of the subject matter eligibility for DNA as a composition of matter as well as the patentability of the corresponding method claim. See *Federal Circuit Hears Myriad Gene Patent Case*, PATENTLY-O (Apr. 4, 2011, 6:45 AM), <http://www.patentlyo.com/patent/2011/04/federal-circuit-hears-myriad-gene-patent-case.html>.

²⁰⁵ 35 U.S.C. § 271(a) (2010) (“Except as otherwise provided in this title, whoever without authority makes, *uses*, offers to sell, or sells any patented invention. . . infringes the patent.”) (emphasis added).

²⁰⁶ See generally Genomic Research and Accessibility Act, H.R. 977, 110th Cong. (2007).

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direct or indirect infringement.²⁰⁷ Despite the GRDAA's modest focus, Congress did not amend the Medical Practitioner Exception.

C. Proposals for Amending § 287(c)

In a 2006 New England Journal of Medicine article, written in response to *Labcorp*, Aaron Kesselheim and Michelle Mello discuss the impact of process patents from a clinician's perspective.²⁰⁸ The article identified three categories of process patents encountered by physicians: pure process patents, processes related to patented drugs or products, and techniques used to isolate compounds or build devices.²⁰⁹ With regards to the first type, pure process patents, the patent is only drawn to the process and not to an underlying patented product. The problem associated with such patents illuminates the same issues targeted by Justice Breyer in his *Labcorp* dissent. While ordering the test would constitute infringement, "it would be malpractice for a doctor to receive an assay result showing elevated total homocysteine levels and not consider cobalamin or folate deficiency as a cause."²¹⁰

In order to eliminate this exposure to risk, the article targets the first two categories of processes utilized by physicians and suggests that appropriate action must be taken either by the courts or Congress. First, the Patent Office and the courts should apply a "more critical eye" to such process claims and invalidate patents where the process involves only a procedural step instead of an actual transformation. As the case law has demonstrated, this result is unlikely. In the alternative, the article offers a legislative solution whereby § 287(c) would be amended to expand the definition of "medical activity" to include pure process patents and those patents involving use of a patented product or drug.²¹¹ This amendment reflects a more comprehensive protection for physicians than that offered by the GRDAA by extending the exception to all processes instead of only gene-related processes. In truth, the authors consider abolition of patent protection for most medical process patents the most appealing alternative, but they recognize that a "sea

²⁰⁷ Holman, *supra* note 201, at 3.

²⁰⁸ Kesselheim & Mello, *supra* note 189, at 2039.

²⁰⁹ *Id.* at 2039-40. The third type of process, "techniques used to isolate compounds or build devices," is an important research tool and can contribute to innovations in the development of diagnostic test, but does not directly impact patient care. *Id.*

²¹⁰ *Id.* at 2039 (quoting *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1364 (Fed. Cir. 2004)).

²¹¹ *Id.* at 2040.

change” in the law is unlikely and probably too severe a measure considering the harmful impact on business arrangements and existing patents.²¹²

It is the middle ground that affords the best opportunity to meet the goals of patent law while safeguarding physicians from unethical intrusions into the practice of medicine. Exempting pure process patents and biotechnology process patents from infringement liability for physicians would cover correlations and diagnostic and treatment methods that form the basis for personalized medical care, an integral component to better and more effective patient care. A narrowly tailored exemption, one that would not cover processes related to patented drugs and devices specifically, resembles many of the same concerns inherent in § 287(c): allowing the unhindered practice of medicine while not declaring such patents invalid.²¹³

V. CONCLUSION

The progression of process patent case law over the past few years lends credence to the theory that subject matter eligibility will once again fade into the background of patent litigation. The anticipation leading up to the Supreme Court’s hearing of *Bilski* only resulted in reestablishing the § 101 doctrine as it existed previously, while endowing the Federal Circuit with the ability to apply the MOT test but refrain from labeling it the exclusive test for determining patentability. When all was said and done, both *Bilski* and *Prometheus* achieved the same result. With these cases laid to rest, it appears that diagnostic method patents, as a category, may be safe from § 101 invalidity so long as the claim is found not to preempt a fundamental principle.

Once patentability is established, it is the duty of Congress to weigh the competing policy rationales underlying the protection of this viable form of patents, while preventing their misuse against physicians practicing within the parameters of proper patient care. A physician who is prevented from making certain determinations based on a failure to obtain a license to use the patented process, retarding the care of a patient as a consequence, faces an unfair restraint and makes all the more clear that infringement liability should not be the measure of healthcare. Amending § 287(c) to include the practice of pure process

²¹² *Id.*

²¹³ Leisa Talbert Peschel, *Revisiting the Compromise of 35 U.S.C. § 287(c)*, 16 TEX. INTEL. PROP. L. J. 299, 300 (2008).

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patents and biotechnology process patents under the definition of exempted medical activities meets the needs of all involved by seeking an ethical solution while not compromising the stature of diagnostic methods as patentable processes. The ever-evolving nature of scientific advances and biotechnology inventions demands that Congress should take care in reforming patent law. With that in mind, “limited changes aimed at making the . . . litigation of biotechnology patents . . . more efficient could strengthen the patent system and foster greater innovation.”²¹⁴

²¹⁴ CLAUDE BARFIELD & JOHN E. CALFEE, *BIOTECHNOLOGY AND THE PATENT SYSTEM: BALANCING INNOVATION AND PROPERTY RIGHTS* 91 (2007).