Northwestern Journal of Technology and Intellectual Property

Volume 9
Issue 3 *Fall*

Article 8

Fall 2010

An Uncertain Future: The Impact of Medical Process and Diagnostic Method Patents on Healthcare in the United States

Margaret Kubick

N O R T H W E S T E R N
JOURNAL OF TECHNOLOGY
AND
INTELLECTUAL PROPERTY

An Uncertain Future: The Impact of Medical Process and Diagnostic Method Patents on Healthcare in the United States

Margaret Kubick

Fall 2010 VOL. 9, NO. 3

Northwestern Journal of Technology and Intellectual Property
Volume 9, Number 3 (Fall 2010)

An Uncertain Future: The Impact of Medical Process and Diagnostic Method Patents on Healthcare in the United States

By Margaret Kubick*

I. INTRODUCTION

¶1 As the debate over the most effective method of healthcare reform in the United States rages, several key issues continue to receive attention. Among the most important is the need to control the escalating costs of healthcare. Although not an immediately obvious solution, tightening the patent-eligibility standards for medical diagnostic and therapeutic methods would prove immensely effective in cutting healthcare costs. With the passage of the Patient Protection and Affordable Care Act ("PPACA"), healthcare reform is now inevitable in the U.S. However, Congress and the Supreme Court would be well advised to take additional action to reform healthcare by limiting the patentability of medical processes and diagnostic methods.

¶2 There has been considerable confusion and uncertainty regarding patentable subject matter in recent years, particularly with respect to the Supreme Court's inconsistent treatment of process claims.[1] In the 1980s, the Supreme Court began to broaden the definition of patentable subject matter through a series of cases that upheld process-related patents (also known as "method patents").[2] These decisions led to a significant increase in patent applications related to new software, business methods, and medical diagnostic and therapeutic methods.[3] Method patents in the life sciences and medical fields have become particularly prolific and controversial in recent years, as health care providers and groups such as the American Medical Association have begun challenging their merit.[4]

¶3 In June 2009, the Supreme Court granted certiorari to hear *In re Bilski*.[5] The Court rendered its decision on appeal (as *Bilski v. Kappos*) on June 28, 2010.[6] This was the

* Northwestern University School of Law, J.D. Candidate 2011.

[1] *See* Amy Lynn Sorrell, *Lawsuits Test Boundary Rights of Medical Patents*, AM. MED. NEWS, July 6, 2009, at 15, *available at* http://www.ama-assn.org/amednews/2009/06/29/prsa0629.htm [hereinafter Sorrell, *Medical Patents*].

[2] *See* Diamond v. Diehr, 450 U.S. 175 (1981); Diamond v. Chakrabarty, 447 U.S. 303 (1980); Pallin v. Singer, 36 U.S.P.Q.2d (BNA) 1050 (T.T.A.B. 1995).

[3] *See* Terry Carter, *A Patent on Problems: New PTO Chief Has Strong Backing-And a Huge Backlog of Work*, ABA J., Mar. 1, 2010, at 42, *available at* http://www.abajournal.com/magazine/article/a_patent_on_problems/; Sorrell, *Medical Patents*, *supra* note 1; Amy Lynn Sorrell, *Tinkering with Patents: Decisions Muddy the Waters on Legal Rights*, AM. MED. NEWS (May 26, 2008), http://www.ama-assn.org/amednews/2008/05/26/prsa0526.htm [hereinafter Sorrell, *Tinkering with Patents*].

[4] *See* Sorrell, *Tinkering with Patents*, *supra* note 3.

[5] 545 F.3d 943 (Fed. Cir. 2008), *cert. granted*, 129 S. Ct. 2735 (2009).

[6] 130 S. Ct. 3218 (2010).

court's first opportunity to clarify the standards for method patent eligibility since 1981, when the Court opened the door to increasingly broad patents of medical diagnostic and therapeutic methods in *Diamond v. Diehr*,[7] discussed in detail below.

¶4 In *In re Bilski*, the Federal Circuit struck down a business method claim as ineligible patentable subject matter, because it failed to meet the heightened standards of the machine-or-transformation test.[8] The *In re Bilski* court held that in order to be considered patent-eligible under § 101 of the Patent Act,[9] a claimed process must be "tied to a particular machine or apparatus", or it must transform "a particular article into a different state or thing."[10]

¶5 The Federal Circuit's decision in *In re Bilski* resulted in a flurry of concern among the pharmaceutical and biotechnology industries and raised questions about the effect of the machine-or-transformation test on patents related to medical diagnostic methods and pharmaceutical treatments protocols.[11] Advocates of broad patentability argued that restricting process patents related to medicine, technology, and life sciences would stifle innovation because the financial incentives inherent in patent protection encourage research and development.[12] Meanwhile, hospitals, healthcare professionals, and public interest advocates have praised these new heightened standards for lowering costs and permitting broader use of new and helpful processes.[13]

¶6 On September 16, 2009, the Federal Circuit issued its decision in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services.*[14] In *Prometheus*, the Federal Circuit shifted direction away from *In re Bilski* by holding that methods of administering drugs to a patient and determining the level of the drug or its metabolites in the patient are patent-eligible subject matter, because they involve transformations of the human body.[15]

¶7 The Supreme Court affirmed the judgment of the Federal Circuit in *In re Bilski* when handing down its decision on appeal in *Bilski v. Kappos* on June 28, 2010.[16] However, the Court qualified this affirmation by holding that the machine-or-transformation test is not the sole test for determining the patent-eligibility of a process.[17]

---

[7] *Diehr*, 450 U.S. at 175.

[8] *Bilski*, 545 F.3d at 996.

[9] 35 U.S.C. § 101 (2006).

[10] *Bilski*, 545 F.3d at 954.

[11] *See* Matias Ferrario, *Medical Treatment and Diagnostic Claims are Patentable*, KILPATRICK STOCKTON LLP: LEGAL ALERT (Sept. 18, 2009), http://www.kilpatrickstockton.com/en/Knowledge_Center/Alerts_and_Podcasts/Legal_Alerts/2009/09/Medical_Treatment_and_Diagnostic_Claims_are_Patentable.aspx?device=pdf [hereinafter Ferrario]; John R. Van Amsterdam, *Federal Circuit Confirms Diagnostic and Therapeutic Methods Can Be Patentable Subject Matter*, BNA PHARM. L. & INDUS., Oct. 2009, *available at* http://www.wolfgreenfield.com/files/vanamsterdam_federal_circuit_confirms_diagnostic_oct_09_.pdf [hereinafter Van Amsterdam].

[12] *See* Sorrell, *Tinkering with Patents*, *supra* note 3.

[13] *Id.*

[14] 581 F.3d 1336 (Fed. Cir. 2009). While the court in *In re Bilski* set a high bar for method patent eligibility by requiring methods to pass the prohibitive machine-or-transformation test, the court's decision in *Prometheus* appears to backpedal on these stricter standards.

[15] *Id.* at 1348.

[16] 130 S. Ct. 3218 (2010). Note that the Federal Circuit is rehearing *Prometheus* in light of the Supreme Court's decision in *Bilski v. Kappos*.

[17] *Id.* at 3226–27.

Instead, the court characterized this test as "a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101."[18]

¶8 In light of these current developments, it appears that United States patent law stands at a crossroads. Since 1981, the courts have strayed into dangerous territory by allowing increasingly broad patents of medical diagnostic and therapeutic methods. Given the current economic downturn as well as the crisis of rising healthcare costs,[19] the outcome of the Supreme Court's decision in *Bilski v. Kappos* will be vitally important to the future of U.S. healthcare. There is an urgent need to strike a careful balance between encouraging innovation and protecting the quality of healthcare without further raising its cost. This can be accomplished by continuing to award patents for meritorious new inventions, but at the same time not overly-broadening the scope of patents.

¶9 In addition, Congress would be wise in amending the Patent Act itself to further protect these important public interests. The U.S. should look to the European Union for examples of how to amend its patent laws. For example, Article 52(4) of the European Patent Convention[20] limits the patentability of medical diagnostic methods practiced on the human body.[21] European patent law could serve as an ethical model for the U.S. to follow in designing technical patentability standards to help protect public interests.

¶10 In this Comment, I will examine the current state of U.S. law regarding the qualifications for patentable subject matter under 35 U.S.C. § 101, as well as the evolution of U.S. patent law regarding method patents. Next, I will examine the merits and drawbacks of method patents with particular focus on the impact of medical diagnostic and therapeutic process patents on U.S. health care. I will weigh arguments in favor of stricter patent standards against arguments supporting broad method patent eligibility. In addition, I will highlight the need for clarification by the Supreme Court regarding patentability standards, and present European patent law as a potential model for U.S. patent reform. Finally, I will examine the impact of *Bilski v. Kappos*, particularly regarding the current status of the machine-or-transformation test for determining patentability, as well as the potential impact of this case on the future of U.S. health care.

II. BACKGROUND INFORMATION

A. Acceptable Subject Matter for Patent Protection

¶11 35 U.S.C. § 101 sets forth what qualifies as patentable subject matter in the U.S.: "Whoever invents or discovers any new and useful process, machine, manufacture or

---

[18] *Id*. at 3227.

[19] *See, e.g.*, Eric Kimbuende, et al., *U.S. Health Care Costs: Background Brief*, KAISER FAMILY FOUNDATION (Mar. 2010), http://www.kaiseredu.org/topics_im.asp?imID=1&parentID=61&id=358; Betty Ann Bowser, *Study: Health Care Spending Will Continue Rising, but Modestly*, PBS NEWSHOUR: THE RUNDOWN (Sept. 9, 2010, 5:00 PM), http://www.pbs.org/newshour/rundown/2010/09/health-spending-may-jump-new-report-says.html.

[20] European Patent Convention art. 52(4), Oct. 5, 1973, 1065 U.N.T.S. 199 (revised version entered into force Dec. 13, 2007), *available at* http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/contents.html.

[21] David Rogers, Exclusion from Patentability of Diagnostic Methods Practised on the Human Body: Article 52(4) EPC, 2 J. INTELL. PROP. L. & PRAC. 60, 60–61 (2007).

composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." Congress intentionally designed this statutory definition to be very open and inclusive.[22]

¶12 Due to the open and ambiguous nature of this statutory definition, the United States Patent and Trademark Office ("USPTO") has issued interim guidelines to clarify what constitutes patentable subject matter.[23] These guidelines state that a claimed invention must be useful and have a practical application to be eligible for patent protection.[24] This requirement ensures that a patent possesses actual functional value, rather than representing "nothing more than an idea or concept, or simply [serving as] a starting point for future investigation or research."[25] Indeed, federal courts have held that 35 U.S.C. § 101 limits patent protection to four categories of subject matter: "a machine, manufacture, composition of matter or a process."[26] A claimed invention may involve a combination of these four categories. For example, a claim may involve a combination of devices or procedural steps which are utilized by some machine, combined with several specific functions performed by that machine. Rather than classifying such a claim as a hybrid of an apparatus and process claim, the court would consider the hybrid as "an apparatus claim including functional limitations."[27]

¶13 In addition, the guidelines assist in determining whether a claimed invention falls within one of the judicially recognized exceptions to statutorily patentable subject matter. For example, patent protection is denied for claimed inventions involving "nothing more than an abstract idea, law of nature, or natural phenomenon."[28] However, a claimed invention *is* eligible for patent protection if it involves a "practical application of a judicial exception to statutory subject matter."[29] A claimed invention would qualify as such a practical application if it "physically transforms an article or physical object to a different state or thing, or if [it] otherwise produces a useful, concrete, and tangible result."[30]

¶14 Within the "process" category of patentable subject matter, medical process patents have been particularly controversial. There are three types of process patents typically related to the medical field: (1) medical procedures that do not require the use of any patented medical products, (2) methods for using a patented drug or device, and (3) techniques for isolating chemical compounds or building devices.[31]

---

[22] Diamond v. Chakrabarty, 447 U.S. 303, 308–09 (1980) (explaining that Congress designed 35 U.S.C. § 101 to include "anything under the sun that is made by man").

[23] JOHN J. DOLL, USPTO, INTERIM GUIDELINES FOR EXAMINATION OF PATENT APPLICATIONS FOR PATENT SUBJECT MATTER ELIGIBILITY 2 (2005), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf (explaining that the guidelines "are based on the USPTO's current understanding of the law and are believed to be fully consistent with binding precedent of the Supreme Court, the Federal Circuit and the Federal Circuit's predecessor courts").

[24] *Id*. at 4 (stating that a claimed invention must produce a "useful, concrete, and tangible result" to be eligible for patent protection) (citation omitted).

[25] *Id.*

[26] *Id.* at 13.

[27] *Id.* at 15.

[28] *Id.* at 1.

[29] *Id.* at 1–2.

[30] *Id.* at 2.

[31] Aaron S. Kesselheim & Michelle M. Mello, *Medical-Process Patents—Monopolizing the Delivery of Health Care*, 355 NEW ENG. J. MED. 2036, 2039–40 (2006).

¶15 These three categories of medical process patents currently cover a slew of patents involving biologic, diagnostic, and genetic testing methods.[32] For example, the researchers who first sequenced the BCRA-1 gene, which is linked to breast and ovarian cancer susceptibility, received patent protection for the isolated DNA coding for the BRCA-1 polypeptide.[33]

¶16 Critics of such patents argue that many of these claimed medical process patents fall within the judicial exceptions to patentable subject matter, because they involve laws of nature, natural phenomena, and abstract ideas.[34] In defense of such patents, those within the biomedical industry argue that medical process patents involve the transformation of natural phenomena into new applications or products, thus qualifying as a practical application of one of the judicial exceptions to patentable subject matter.[35]

III. EVOLUTION OF US PATENT LAW CONCERNING METHOD PATENTS

¶17 Process patents first stirred controversy within the medical field in 1846, when a Boston dentist was granted a patent for a method of using ether as a surgical anesthetic.[36] Since then, this controversy has evolved but never gone away. There is significant confusion in the modern era regarding the scope of process and method patentability in the United States.[37] This confusion has its roots in the inconsistent treatment of method patents by the courts since the 1980s.

A. Notable Cases and Laws

¶18 In the 1980 case of *Diamond v. Chakrabarty*,[38] the Supreme Court supported a broad view of patentable subject matter by holding that a single-celled microbe injected with a DNA plasmid was eligible for patent protection.[39]

¶19 The Court further elucidated its ruling in *Chakrabarty* just one year later in *Diamond v. Diehr*.[40] *Diehr* involved a patent on an algorithm for use in "determining the proper time and temperature for curing rubber."[41] The defendant challenged the patent's focus on the natural phenomenon of "the physical properties of the molecular stability of rubber."[42] Nevertheless, the Court upheld this patent, reasoning that the inventor had integrated the physical properties of rubber "into the inventive process of transforming

---

[32] *See* Amy Lynn Sorrell, *Supreme Court Patent Case Could Affect Medical Research*, AM. MED. NEWS (Aug. 25, 2009), http://www.ama-assn.org/amednews/2009/08/24/prsc0825.htm [hereinafter Sorrell, *Supreme Court Patent*].

[33] Anja von der Ropp & Tony Taubman, *Bioethics and Patent Law: The Case of* Myriad, WIPO MAG., Aug. 2006, at 8, *available at* http://www.wipo.int/wipo_magazine/en/2006/04/article_0003.html.

[34] *See* Sorrell, *Medical Patents*, *supra* note 1.

[35] *Id.*

[36] Kesselheim & Mello, *supra* note 31, at 2040.

[37] Foley & Lardner LLP, *What Now for Patent Eligibility?: In* Bilski v. Kappos, *the Supreme Court Rejects Machine-or-Transformation as the Sole Test for Patent Eligibility of Processes*, FOLEY & LARDNER LLP LEGAL NEWS ALERT (June 2010), http://www.foley.com/abc.aspx?Publication=7243.

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

[39] Kesselheim & Mello, *supra* note 31, at 2036.

[40] Diamond v. Diehr, 450 U.S. 175 (1981).

[41] Kesselheim & Mello, *supra* note 31, at 2036.

[42] *Id.*

rubber into another state;" thus, the patent involved a practical application of a natural phenomenon.[43]

¶20 These two cases heralded the proliferation of medical process patents beginning in the 1980s. As Kesselheim and Mello explain, "These [new process] patents cover compositions of matter, such as drugs and DNA sequences, and health care-related processes. Process patents have protected intellectual property in research methods, techniques for isolating biologically active compounds and gene sequences, and medical and surgical techniques."[44]

¶21 Controversy erupted in 1995 over the case of *Pallin v. Singer*,[45] which involved a patent "for a method of performing cataract surgery that did not require stitches."[46] Samuel Pallin, an ophthalmologist who was granted this patent in 1992, sued for patent infringement when another ophthalmologist used his patented technique without first obtaining a license.[47] This case sparked a national controversy, leading the American Medical Association (AMA) to issue a policy statement criticizing medical process patents "as a violation of physicians' ethical obligation to share their discoveries with their peers."[48] The AMA expressed concerns that medical process patents could lead to inadvertent infringement by physicians who are unaware of the existence of patents on particular medical techniques.[49]

¶22 Congress amended the Patent Act in 1996 in response to this concern.[50] Under the new § 287(c), known as the "Ganske Compromise Law," health care practitioners could still be found liable for infringement, but barred patent-holders from seeking monetary damages or injunctions against them.[51] The amendment is limited is to "medical practitioners who infringe a patent in the course of medical activity."[52]

¶23 In the wake of these decisions, applications for method patents exploded in the U.S.[53] Meanwhile, health care practitioners and hospitals continued to fight against these patents due to their obstructive and cost-increasing effect on health care practice.[54] Hostile reactions to such broad process patents came to a head in *LabCorp v. Metabolite*.[55] *LabCorp* involved a patent for a process of diagnosing vitamin deficiencies

---

[43] *Id.*

[44] *Id.* at 2036–37.

[45] Pallin v. Singer, Civ. A. No. 2:93-CV-202, 1996 WL 274407 (D. Vt. Mar. 28, 1996).

[46] Kesselheim & Mello, *supra* note 31, at 2037.

[47] *Id.*

[48] *Id.*

[49] *Id.* (explaining that the AMA singled out the dangers of inadvertent infringement of medical process patents as more serious than patents on medical drugs and devices, since these drugs and devices integrate the cost of patent licenses into the cost of the product).

[50] *See* Warren D. Woessner & Michael A. Dryja, *U.S. Doctors Find Swift Relief in Patent Law Amendment*, IP WORLDWIDE, March/April 1997, *available at* http://www.dryjapat.com/doc.htm; Virginia Bennett, *Limitations on Patents Claiming Medical or Surgical Procedures*, MYERS BIGEL SIBLEY & SAJOVEC (1997), http://www.myersbigel.com/library/articles/MedicalorSurgical.pdf.

[51] *See* Woessner, *supra* note 50.

[52] *See* Bennett, *supra* note 50.

[53] *See* Sorrell, *Tinkering with Patents*, *supra* note 3.

[54] *See generally* Kesselheim & Mello, *supra* note 31, at 2039; Sorrell, *Tinkering with Patents*, *supra* note 3.

[55] 548 U.S. 124 (2006). *See also* Sorrell, *Tinkering with Patents*, *supra* note 3 ("The medical community claimed that the patent exceeded legal precedent and covered a basic scientific relationship. The AMA and others filed a friend-of-the-court brief in the case."); Kesselheim, *supra* note 31, at 2038

by using any test—patented or unpatented—to measure levels of homocysteine in the blood.[56] In 2006, the Supreme Court granted and later withdrew *certiorari*, which, in effect, allowed the patent to stand. As a result, Laboratory Corporation of America ("LabCorp") was found liable "for inducing infringement of the claim when it encouraged doctors to order diagnostic tests for measuring homocysteine."[57] In the order withdrawing certiorari, the Supreme Court "enjoined LabCorp from using any tests that would lead the doctors it serves to find a vitamin deficiency by taking account of elevated homocysteine levels."[58]

¶24 In Justice Breyer's dissent, he acknowledged the dangers of medical process patents and admonished the Court for failing to address the difficult question of "whether the patent claim is invalid on the ground that it improperly seeks to claim a monopoly over a basic scientific relationship."[59] According to Justice Breyer, patents are forbidden on "laws of nature, natural phenomena, and abstract ideas" because of the danger of impeding scientific progress through overly inclusive patent protection.[60] He argued that process patents may discourage research and the open exchange of information due to competition for monetary incentives.[61] Justice Breyer argued that the Court was wrong in choosing not to clarify the law relating to process patents.[62] He contended that the process patent at issue in *LabCorp* was invalid because the correlation between homocysteine and vitamin deficiency set forth in "[the] claim . . . is a natural phenomenon."[63] Furthermore, the public interest weighed against allowing such medical diagnostic patents because of their potential negative impact on the medical profession:

> Those restrictions may inhibit doctors from using their best medical judgment; they may force doctors to spend unnecessary time and energy to enter into license agreements; they may divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations; they may raise the cost of health care while inhibiting its effective delivery.[64]

The tide began shifting toward stricter standards for process patent eligibility after *LabCorp*. In *KSR International Co. v. Teleflex Inc.*, the Supreme Court reversed directions by tightening the criteria for determining whether an invention is non-obvious

---

(stating that "[m]any have criticized the expansion of patent protection overseen by the Federal Circuit, and the *LabCorp* case presented an opportunity for the Supreme Court to restrain that trend").

[56] *LabCorp*, 548 U.S. at 125–26.

[57] *Id.* at 124.

[58] *Id.*

[59] *Id.* at 125–26 (citation omitted).

[60] *Id.* at 126 (quoting Diamond v. Diehr, 450 U.S. 175, 185 (1981)).

[61] *Id.* at 126.

[62] *Id.* at 134 (arguing that "important considerations of the public interest—including that of clarifying the law in this area sooner rather than later—argue strongly for our deciding the question presented now").

[63] *Id.* at 135 (citation omitted). Justice Breyer's dissenting opinion is strongly supported by many members of the medical community. For example, Kesselheim and Mello, two physicians, argue:

> In our opinion, the Patent Office and the courts should follow Breyer's lead, applying a more critical eye to process-patent applications and reinvigorating the distinction articulated in Diehr between a claim to a process that is truly transformative and a claim that adds only a trivial procedural step to a process involving naturally occurring phenomena.

Kesselheim & Mello, *supra* note 31, at 2040.

[64] Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 138 (2006).

or distinct enough to qualify for patent protection.[65] In addition, federal legislators sought to revise patent-eligibility standards through the Patent Reform Act of 2007.[66] This legislation would have "[required] patent applicants to submit additional documentation that distinguishes their discoveries from existing ones"; "[b]roaden the standard of proof for awarding damages for infringement"; "[p]ermit third parties to challenge patent grants more quickly without going through the courts"; and "[a]llow increased damages for willful patent infringement."[67]

¶25 *In re Bilski* is the most explosive and potentially influential recent court decision regarding the future of medical process patents in the U.S.[68] On appeal, the Federal Circuit clarified the standard for patent-eligible subject matter and reaffirmed a more restrictive standard for process claims: the machine-or-transformation test.[69]

> The Supreme Court . . . has enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself. A claimed process is surely patent-eligible under § 101 if: (1) *it is tied to a particular machine or apparatus*, or (2) *it transforms a particular article into a different state or thing*.[70]

The Federal Circuit's holding created shockwaves across the biotechnology and pharmaceutical industries. Many researchers and companies feared their patents were at risk.[71] According to the court in *In re Bilski*, "mental processes, and abstract intellectual concepts are not patentable, as they are basic tools of scientific and technological work."[72] Thus, pharmaceutical and medical diagnostic claims "that merely inform patients of effects of treatments" are not eligible for patent protection, because they are "attempts to claim a monopoly on information."[73]

¶26 According to the court in *In re Bilski*, the real question being answered by the machine-or-transformation test is whether a claim is seeking to preempt the use of fundamental principles,[74] or whether it is only preventing others from using a certain application of a fundamental principle.[75] In the former situation, the claim does not cover

---

[65] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 427 (2007) (arguing that "as process beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts."). *See also* Sorrell, *Tinkering with Patents*, *supra* note 3.

[66] The Patent Reform Act of 2007 was introduced in the 110th Congress. It has yet to be passed into law. H.R. 1908, 110th Cong. (2007); S. 1145, 110th Cong. (2007).

[67] Sorrell, *Tinkering with Patents*, *supra* note 3.

[68] *In re* Bilski, 545 F.3d 943 (2008) (involving a claim for a method of hedging risk in business commodities trading).

[69] *Id.* at 954 (noting that this standard was first clarified in *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) and reaffirmed in *Diamond v. Diehr*, 450 U.S. 175, 191–92 (1981)).

[70] *Id.* (emphasis added).

[71] Marilyn Neiman, *Pharmaceutical Method Patents at Risk*, MANAGING INTELL. PROP., March 2009, at 45, 45.

[72] *Bilski*, 545 F.3d at 952.

[73] Neiman, *supra* note 71, at 45 (referencing cases in the aftermath of *In re Bilski* that have invalidated pharmaceutical patents for failing to pass the machine-or-transformation test).

[74] A process patent that blocks every possible way of performing the steps of the claimed process by any person or machine would be considered to preempt the use of the fundamental principle behind the process.

[75] *Bilski*, 545 F.3d at 953.

patent-eligible subject matter.[76] Furthermore, the court held that the particular machine or transformation involved in a process claim must constitute the *crux* of the claim, not just some "insignificant postsolution activity."[77] Since the multiple substeps involved in a process claim must be considered as one single process when determining patent eligibility, "it is irrelevant that any individual step or limitation of such processes by itself would be unpatentable under § 101."[78]

¶27 The court does acknowledge that future scientific developments may challenge the efficacy of the machine-or-transformation test, leading the Supreme Court to "alter or perhaps even set aside this test to accommodate emerging technologies."[79] For the present, however, the Federal Circuit saw no need for a departure from the machine-or-transformation test, which it considered to be the "governing test for determining patent eligibility of a process under § 101."[80]

¶28 In the aftermath of *In re Bilski*, patent eligibility standards for process claims were uncertain and ambiguous.[81] As a result, patent attorneys advising their business, pharmaceutical, and biotechnology clients recommended structuring claims to meet the standards of *In re Bilski* by emphasizing "particular machine implementations or the physical results of the claimed processes."[82] Some suggested that applicants could avoid the standards of the machine-or-transformation test "by redrafting their process claims as product or system claims without surrendering any claim scope."[83] Others further suggest that including details about specific applications, technical aspects, and ranges in specification levels would protect process claims from rejection for being overly broad and for seeking to preempt the use of fundamental principles.[84]

¶29 In response to threats to pre-existing patents and the uncertainty surrounding future patents, researchers and companies within the biotechnology and pharmaceutical industries filed briefs asking the Supreme Court to overturn the Federal Circuit's holding in *In re Bilski*.[85] Due to the implications of this case to parties across the spectrum of the medical and health care fields, interested parties filed dozens of briefs.[86] On June 1, 2009, the Supreme Court granted *certiorari* for *In re Bilski*.[87]

---

[76] *Id.* at 954 (explaining that, as in the latter situation, "a claimed process that transforms a particular article to a specified different state or thing by applying a fundamental principle" is still patent-eligible because it does not altogether preempt the use of a fundamental principle).

[77] *Id.* at 957 (citation omitted).

[78] *Id.* at 958.

[79] *Id.* at 956.

[80] *Id.*

[81] M.J. Edwards & Donald Steinberg, *The Implications of* Bilski*: Patentable Subject Matter in the United States*, 49 IDEA 411, 426 (2009).

[82] Orion Armon & Eamonn Gardner, *New Restrictions on the Patentability of Process Claims: Looking Beyond In Re* Bilski, J. INTERNET L., May 2009, at 1, 22 (suggesting that applicants draft claims "in a manner that provides a detailed description of specific uses of a fundamental principle").

[83] *Id.* at 18.

[84] Edwards & Steinberg, *supra* note 81, at 426.

[85] *See* Sorrell, *Supreme Court Patent*, *supra* note 32; Ferrario, *supra* note 11 (stating that amicus curiae briefs have been filed by interested organizations including Novartis Corporation, Myriad Genetics, American Intellectual Property Law Association, Biotechnology Industry Organization, Arup Laboratories, and the American College of Genetics).

[86] *See Ferrario*, *supra* note 11.

[87] Bilksi v. Doll, 129 S. Ct. 2735, 2745 (2009).

¶30 As mentioned previously, the Supreme Court issued its decision on *In re Bilski* on June 28, 2010 (as *Bilski v. Kappos).*[88] This case marks the first time since 1981 that the Supreme Court has re-examined process patent eligibility; therefore, the Court's clarification of what constitutes acceptable subject matter has been anxiously awaited by all interested parties. Although the Court affirmed the Federal Circuit's holding in *In re Bilski* that rejected a patent involving a business method, the Supreme Court went on to state that the machine-or-transformation test "is not the sole test for deciding whether an invention is a patent-eligible 'process.'"[89] According to Justice Kennedy,

> The machine-or-transformation test may well provide a sufficient basis for evaluating processes similar to those in the Industrial Age—for example, inventions grounded in a physical or other tangible form. But there are reasons to doubt whether the test should be the sole criterion for determining the patentability of inventions in the Information Age. As numerous amicus briefs argue, the machine-or-transformation test would create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals.[90]

There is a strong need for the court to strike a balance between encouraging innovation by awarding patents, while at the same time being careful to not overly-broaden the standards for patent eligibility. Although the court in *Kappos* acknowledges the need for such a balance, it fails to take any definitive stance.[91] Indeed, the court states that it is "not commenting on the patentability of any particular invention, let alone holding that any of the . . . technologies from the Information Age should or should not receive patent protection."[92]

¶31 The Supreme Court's decision to diminish the influence of the machine-or-transformation test in *Kappos*, as well as its failure to further clarify what technologies should be eligible for patent protection, has many physicians and other health care practitioners worried that the Court will once again support a broad standard for method patent eligibility.[93] The Federal Circuit reinforced this fear in *Prometheus Labs, Inc. v. Mayo Collaborative Services*, which was decided on September 16, 2009.[94] Reversing direction from its holding in *In re Bilski*, the court upheld two claims: (1) a method of administering a drug that results in the body's production of potentially-toxic metabolites, and (2) a method of determining the levels of these metabolites in the bloodstream by testing a sample of the patient's blood.[95] According to the court, these claimed methods

---

[88] 130 S. Ct. 3218 (2010).
[89] *Id.* at 3227.
[90] *Id.*
[91] *Id.* at 3228 ("With ever more people trying to innovate and thus seeking patent protections for their inventions, the patent law faces a great challenge in striking the balance between protecting inventors and not granting monopolies over procedures that others would discover by independent, creative application of general principles. Nothing in this opinion should be read to take a position on where that balance ought to be struck.").
[92] *Id*.
[93] Sorrell, *Supreme Court Patents*, *supra* note 32.
[94] 581 F.3d 1336 (Fed. Cir. 2009).
[95] *Id.* at 1349–1350.

satisfy the *Bilski* test because they involve "transformative steps utilizing natural processes."[96] The court reasoned that administering the drug caused a transformation of the human body, as well as a transformation of the drug within the body as the drug was metabolized.[97] According to the court, the transformation at issue "is the result of the physical administration of a drug to a subject to transform—i.e., treat—the subject, which is itself not a natural process."[98]

IV. DANGERS OF MEDICAL PROCESS PATENTS IN THE U.S.

A. Implications of Prometheus for Physicians

¶32 Essentially holding that medical diagnostic and treatment methods are patentable subject matter, the *Prometheus* decision was welcomed and praised by members of the biotechnology and pharmaceutical industries.[99] Representatives of medical and health care practitioners, on the other hand, viewed this decision as a direct blow to the practice of medicine in the U.S. In their *amicus curiae* brief in support of Mayo Collaborative Services, the American College of Medical Genetics, the American Medical Association and others argued that "allowing the enforcement of broad and unwarranted patent claims to the association between metabolite levels and drug toxicity and efficacy would . . . raise important ethical issues" and interfere with the goal of improving patient care.[100] In addition, they argued that the patent at issue in this case gave Prometheus exclusive private ownership of a scientific observation.[101] A physician would infringe this patent anytime the physician, having ordered and administered thiopurine drugs to a patient, measured the levels of metabolites produced in the body and considered adjusting the dosage of thiopurine.[102] According to the *amici*, the overly broad patent upheld in *Prometheus* will lead to increased health care costs and decreased treatment effectiveness, because it interferes with doctors' ability "to make informed treatment decisions based on the latest scientific knowledge."[103]

B. Other Arguments in Favor of Stricter Process Patent Standards

¶33 According to Aaron Kesselheim, patent lawyer and clinical fellow at the Harvard School of Public Health, patents can be dangerous to scientific progress "when they are granted in cases where a product is not innovative, [because] they can serve to increase costs and prevent access" to new alternative therapies by blocking competition.[104] Overly

[96] *Id.* at 1349.

[97] *Id.* at 1346 (arguing that "methods of treatment . . . are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition").

[98] *Id.*

[99] *See* Ferrario, *supra* note 11, at 1–2.

[100] Corrected Amici Curiae Brief for the American College of Medical Genetics et al. in Support of Defendants-Appellees at 9, Prometheus Labs., Inc. v. Mayo Collaborative Servs., 581 F.3d 1336 (Fed. Cir. 2009) (No. 2008-1403), 2009 WL 1307167.

[101] *Id.* at 1.

[102] *Id.* at 2 (emphasizing that "[s]uch a reading of the patent laws puts physicians in an untenable position since they could in some instances be liable for medical malpractice if they do *not* consider those relationships").

[103] *Id.* at 13.

[104] Sorrell, *Tinkering with Patents*, *supra* note 3 (citing the example of pharmaceutical companies that,

broad patents may deter health care workers from using particular treatments out of fear of involuntary infringement. Although existing laws prevent physicians from being sued for patent infringement during medical procedures, other groups including universities, medical education companies, and hospitals are still vulnerable to claims for involuntary infringement.[105]

V. ARGUMENTS IN FAVOR OF BROAD PROCESS PATENT PROTECTION

¶34 The challenges faced by physicians and hospitals in navigating a complex patent environment while trying to focus on patient care is just one side of the story. Indeed, researchers, pharmaceutical companies, and biotechnology entities will also be profoundly affected by the Supreme Court's clarification of process patent eligibility in *Bilski*. These interested players argue that process patents are vital in encouraging investment in research and development.[106] They insist that patents are necessary to the development of medicine, and future medical breakthroughs will suffer if the court goes too far in reigning in patent protection for medical processes and diagnostic methods.[107] In addition, many argue that patents actually promote communication within the scientific and medical communities.[108] They believe that stricter patent laws may lead the biotechnology industry to protect breakthroughs as trade secrets, thereby restricting exchanges of information.[109]

VI. THE NEED FOR CLARIFICATION AND REFORM

¶35 As some experts have noted, the issues involved in the debate over the scope of medical process patents will only grow larger and more contentious as personalized medicine and genomic analysis becomes more commonplace.[110] Given the importance of this issue for the future of patient care, there is a crucial need to recognize some middle ground between all interested parties. Indeed, while patents create obvious incentives for innovation, issuing too many patents may actually stifle innovation.[111] Thus, it is necessary to find some way to bridge this gap and provide a solution amenable to all.

A. "Truly Transformative" Eligibility Requirement for Process Patents

¶36 There are three main types of process patents: (1) pure process patents involving patented medical procedures, (2) process patents related to the use of a patented drug or device, and (3) process patents involving techniques for isolating compounds or building devices.[112] One possible way of alleviating the dangers involved with overreaching

---

rather than focusing on developing new drugs, make incremental adjustments to already existing drugs in order to extend their exclusive rights).

[105] *Id.*
[106] *See* Sorrell, *Medical Patents*, *supra* note 1.
[107] *Id.*
[108] Sorrell, *Tinkering with Patents*, *supra* note 3.
[109] *Id.*
[110] Sorrell, *Medical Patents*, *supra* note 1.
[111] Sorrell, *Tinkering with Patents*, *supra* note 3.
[112] Kesselheim & Mello, *supra* note 31, at 2039–40.

process patents is to follow the suggestion of Justice Breyer in *LabCorp* by requiring process patent applications to provide proof of a key transformation.[113] Drawing a bright-line distinction between a claimed transformation and the process of carrying out merely procedural steps to study a naturally occurring phenomena would ensure that patents are not improperly granted for natural correlations or routine data-gathering steps.

¶37 Congress should also consider broadening the scope of 35 U.S.C. § 287(c) to more adequately protect individuals and entities engaged in the practice of medicine from involuntary patent infringement. Currently, § 287(c) is limited to the protection of "medical practitioners who infringe a patent in the course of medical activity."[114] Under such incomplete protection, non-clinicians can be held liable for "contributing to infringement by others" by providing physicians with information or guidelines related to performing patented processes. Furthermore, researchers can be held liable for infringement if they utilize protected processes in the development of new drugs.[115] Two possible ways of amending § 287(c) to address these problems are (1) rewriting § 287(c) to include protection against infringement for process patents affiliated with the use of patented drugs or devices (§ 287(c) currently only provides infringement protection against pure process patents), and (2) rewriting § 287(c) to exclude medical procedures and diagnostic methods from patent protection.[116]

¶38 The second suggestion, while beneficial *in theory*, is much more revolutionary and would probably be incredibly difficult to enact into law. The first suggestion, however, is both feasible and appropriate given the fear of those in the health care industry of inadvertent infringement.[117] Providing enhanced infringement protection for health care practitioners via the first option could potentially lead to better patient care, decreased costs, and more open flow of information related to scientific and medical advancements. In addition, it would represent a compromise between the two opposing factions involved in this debate, since health care workers would be protected from infringement but medical process patents would still be allowed.

¶39 To solve the current state of confusion surrounding process patent eligibility in the wake of *In re Bilksi*, *Prometheus*, and *Bilski v. Kappos*, the Supreme Court or Congress needs to provide a clear rule for patent applicants to follow. Given the rise in health care costs in the U.S., ignoring the interests of physicians and hospitals regarding the scope of medical process patents would be unwise indeed. By failing to designate the machine-or-transformation test as a requirement for process patents, the Supreme Court in *Kappos* has endangered funding for medical advancements and potentially jeopardized the interests of health care workers on the front lines.

¶40 Not only does the Supreme Court need to clarify which emerging "process" or "method" technologies are patentable, Congress also needs to act. Congress' decision to pass the Patent Reform Act would be welcomed as a further clarification of stricter standards for patent eligibility. The Patent Reform Act of 2009[118] is very similar to the

---

[113] *Id.* at 2039.
[114] *Id.* at 2037 (citation omitted).
[115] *Id.*
[116] *Id.* at 2040.
[117] For example, a health care practitioner may perform certain steps when administering and determining the results of a medical diagnostic test without realizing these steps constitute a patented process for which the practitioner did not obtain a license to utilize.
[118] Patent Reform Act of 2009, S. 515, 111th Cong. (2009).

Patent Reform Act of 2007,[119] except with a few controversial sections removed. Most importantly, the 2009 Act proposes stricter criteria for proving willful infringement, limits damages, broadens the use of appeals for defendants accused of patent infringement, and provides a good faith defense for defendants who believe the patent was invalid or not infringed by their actions.[120]

B. European Patent Laws as a Model for U.S. Patent Reform

¶41 In considering how to best reform current U.S. patent law, specifically in regards to patent eligibility for medical processes and diagnostic tests, the Supreme Court and Congress could look to European patent laws as a potential model for change. In general, European patent law is stricter than U.S. patent law in interpreting what qualifies as an "inventive step" for patent eligibility.[121] Under Article 52(4) of the European Patent Convention ("EPC"),[122] diagnostic methods performed on the human body are excluded from patentability.[123] According to Article 52(4) EPC, "[t]he exclusion from patentability . . . applies to those elements of the claim that are (1) technical in nature, (2) practised [sic] on the human body and (3) the steps that are made prior to the purely intellectual deductive exercise of making a diagnosis."[124] The steps prior to diagnosis referenced by requirement (3) include: "(a) the examination phase involving the collection of data; (b) the comparison of these data with standard values; and (c) the finding of any significant deviation, i.e. a symptom, during the comparison."[125]

¶42 Article 52(4) was passed in Europe in response to public concerns that patents granting exclusive rights over medical tests and procedures would constrain access to new diagnostic methods.[126] The prohibition on patenting diagnostic methods involving the human body operates as a public safeguard by only granting patents for genuine advances in scientific knowledge.[127] The rationale behind this exclusion is that patents drafted too broadly result in "over-compensating the patentee by covering all future applications."[128]

¶43 The public interest rationale underlying Europe's restrictive patent laws is best understood by examining the controversial gene patents held by Myriad Genetics, Inc., a biopharmaceutical company headquartered in Salt Lake City, Utah. Myriad was first to sequence the BRCA-1 gene, which is linked to susceptibility for breast and ovarian

---

[119] Patent Reform Act of 2007, H.R. 1908, S. 1145, 110th Cong. (2007).

[120] Dennis Crouch, *Patent Reform Act of 2009*, PATENTLY-O (Mar. 3, 2009, 2:58 PM), http://www.patentlyo.com/patent/2009/03/patent-reform-act-of-2009.html; Patent Reform Act of 2009, S. 515, 111th Cong. (2009).

[121] Arnoud Engelfriet, *Differences Between US and European Patents*, IUS MENTIS (Oct. 1, 2005), http://www.iusmentis.com/patents/uspto-epodiff/ ("A European patent application involves an inventive step if it solves a technical problem in a non-obvious way. Note that this introduces two extra requirements: it must solve a problem (no problem solved means no inventive step), and that problem must be technical (solving economic problems means no inventive step).").

[122] European Patent Convention, *supra* note 20, at art. 52(4).

[123] Rogers, *supra* note 21, at 60.

[124] *Id.*

[125] *Id.*

[126] von der Ropp & Taubman, *supra* note 33.

[127] *Id.*

[128] *Id.*

cancer. When certain mutations occur in BRCA-1, the risk of these cancers increases.[129] The USPTO granted Myriad patents for the "isolated DNA coding for a BRCA-1 polypeptide and on a screening method" for this gene, as well as rights over several mutations in BRCA-1.[130] Controversy erupted when Myriad was also granted patents involving BRCA-1 in Europe (European Patent, EP 705902).[131] Invoking the restrictive criteria for patentability under the EPC, challengers filed oppositions to Myriad's European patents.[132] These challengers "raised concerns about the potentially limiting effects of the patents on further research, on the development of new tests and diagnostic methods, and on access to testing."[133]

¶44 In response to opposition proceedings, the European Patent Office revoked European Patent 699754 in 2004 because it involved an excludable method for diagnosis involving the human body.[134] Two other European patents on the BRCA-1 gene were amended so that they did not include such diagnostic methods.[135] The Myriad patent controversy demonstrates the difficulty in balancing overly inclusive and overly restrictive patents. While safeguarding the public interest is important, patents and the promise of market exclusivity are necessary to attract funding for important new discoveries.[136]

¶45 The handling of the Myriad case in Europe shows how the technical standards for patentability can be designed to safeguard the public interest and ensure that patents are only granted on genuine scientific advances, rather than to exclude access to new medical diagnostic procedures and tests.

VII. THE FUTURE OF HEALTH CARE REFORM

¶46 The high cost of medical care was one of the core issues of the healthcare reform debate. When a new biotechnology or life sciences product hits the market, it may enjoy market exclusivity under the protection of a patent. Patent protection allows the patent holder or assignee to sell the product at a premium in order to recover the costs expended by the manufacturer in bringing the product to market.[137] Indeed, "[t]he result of such market exclusivity is an artificially elevated sales price that, on average, enables innovators to recoup their initial investment through selling products that, even at prices far above marginal cost, are in high demand."[138]

---

[129] *Id.*

[130] *Id.* (referring to U.S. Patent No. 5,747,282 (filed June 7, 1995), U.S. Patent No. 5,710,001 (filed June 7, 1995), and U.S. Patent No. 5,693,473 (filed June 7, 1995)).

[131] *Id.*

[132] *Id.* (citing Switzerland's Social Democratic Party, Greenpeace Germany, Assistance Publique-Hôpitaux de Paris, the Belgian Society of Human Genetics, the Netherlands' Ministry of Health, and the Austrian Federal Ministry of Social Security as among the opponents to the European patents).

[133] *Id.* (stating that "Myriad's critics charged that its licensing policy, and the high prices demanded for testing under the patented technologies, had the effect of preventing other laboratories in countries where the patent was in force from carrying out diagnostic testing.").

[134] *Id.*

[135] *Id.*

[136] Sorrell, *Tinkering with Patents*, *supra* note 3.

[137] Thomas Pogge, *Health Care Reform That Works for the U.S. and for the World's Poor*, GLOBAL HEALTH GOVERNANCE, Fall 2008/Spring 2009, at 7 (2008–2009).

[138] *Id.*

¶47 While patents are crucial in encouraging future medical progress, there must be a cap on both the breadth and length of patent protection in order to protect the free transfer of information of our most basic scientific building blocks. Evidence suggests that longer time periods of patent protection do not necessarily encourage any reciprocal boost in increased medical innovation.[139] Indeed:

> Temporal limits make sense, because additional years of patent life barely strengthen innovation incentives: At a typical industry discount rate of 12 percent per annum, a 10-year effective patent life generates 72 percent, and a 15-year effective patent life 85 percent, of the profit (discounted to present value) that a permanent patent would generate. It makes no sense to impose monopoly prices on all future generations for the sake of so slight a gain in innovation incentives.[140]

The breadth of patent protection must also be limited to protect the free transfer of medical and scientific information, and the ability of medical practitioners to openly diagnose and treat medical conditions without fear of patent infringement. For example, the Secretary's Advisory Committee on Genetics, Health and Society expressed concern that "patenting and exclusive licensing practices might have limited the availability and quality of [patented genetic] tests."[141] In addition, the committee stated that patents for genetic tests may lead to "hold-outs," where "a single entity holding critical technology may refuse to license or may charge what others regard as unfair or disproportional fees even though it holds only one technology of many needed for a clinically useful test."[142]

¶48 The patenting of medical diagnostic tests and genetic material creates several complications. For example, there is a risk of transforming human life and human tissues into commodity items, which has legal, political, social, and ethical ramifications.[143] Furthermore, there is a risk that granting monopoly patent rights over biotechnological inventions may impede the public access to this important field of research.[144] Indeed, patented biotechnological inventions may not be accessible without the cooperation of the patent holder, or may be required to be purchased rather than copied in a laboratory.[145] Thus, the market price of the invention is artificially inflated above what it would have been in the absence of a monopoly. On a broad scale, this results in increased health care costs to the consumer or patient due to "the monopoly of prices which have to be paid."[146]

¶49 Due to the potential of creating "class health-care," Europe considers medical treatment methods to be unpatentable:

---

[139] *Id.*
[140] *Id.*
[141] Secretary's Advisory Committee on Genetics, Health and Society, *Public Consultation Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, 28 BIOTECHNOLOGY L. REP. 417, 417 (2009).
[142] *Id.* at 418.
[143] S.J.R. Bostyn, *The Prodigal Son: The Relationship Between Patent Law and Health Care*, 11 MED. L. REV. 67, 83 (2003).
[144] *Id.* at 85.
[145] *Id.* at 86.
[146] *Id.* at 87.

> [T]hese treatments were excluded because it was considered almost "unethical" from the point of view of society, to allow patent protection for this type of inventions . . . . If medical treatment methods were patented, they could become more expensive, which excludes part of the population from enjoying the best treatment method for their medical condition.[147]

VIII. CONCLUSION

¶50 The production of biotechnology drugs for the treatment of diseases is becoming increasingly important. Thus, it is crucial that the U.S. analyze the consequences of granting medical diagnostic and therapeutic patents for the future of health care.[148]

¶51 Now that healthcare reform is underway in the U.S., Congress and the Supreme Court would be well advised to set standards for limiting medical process and diagnostic method patents. As scientific knowledge continues to advance in the areas of genetics and personalized medicine, the Supreme Court must clarify the state of method patent law and provide further explanation of potential tests for determining process patent eligibility in order to protect U.S. public interests. Although the *Bilski v. Kappos* court affirmed the ruling in *In re Bilski*, it did so at the cost of the machine-or-transformation test. The Supreme Court's decision to diminish the strength of the machine-or-transformation test could have a potentially devastating and costly impact on the future of U.S. healthcare.

¶52 Healthcare reform in the U.S. under the Patient Protection and Affordable Care Act is centered on reducing costs and providing wide scale access to healthcare. However, this alone may not be enough. Additional Congressional action aimed at tightening the patent eligibility standards for medical diagnostic and therapeutic methods, similar to the restrictions in European Patent Convention, could prove effective in cutting health care costs and providing assurances for health care workers and the greater public.

[147] *Id.* at 101.
[148] *Id.* at 117.