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Patenting the Diagnosis of a Disease: The Scope of Patentable Subject Matter Based on Labcorp v. Metabolite Labs

Timothy J. Ohara

NOTE

PATENTING THE DIAGNOSIS OF A DISEASE: THE SCOPE OF PATENTABLE SUBJECT MATTER BASED ON *LABCORP V. METABOLITE LABS*

INTRODUCTION: THE STRUGGLE TO DEFINE THE SCOPE OF PATENTABLE SUBJECT MATTER

Determining the limits of what should be patentable subject matter is a fundamental issue of patent law. Congress defined patentable subject matter in 35 U.S.C. § 101 as a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[1] The United States Supreme Court in *Diamond v. Chakrabarty* noted that 35 U.S.C. § 101 should be construed broadly to promote innovation and account for unforeseeable changes in technology.[2] However, the Court also noted that 35 U.S.C. § 101 cannot be construed so broadly as to allow patenting of "[t]he laws of nature, physical phenomena, and abstract ideas."[3]

Currently, a method of diagnosing a disease can be broadly claimed in a patent.[4] In *Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings*, the United States Court of Appeals for the Federal

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[1] 35 U.S.C.A. § 101 (Westlaw 2007).

[2] *See* Diamond v. Chakrabarty, 447 U.S. 303, 316 (1980). The Court construed § 101 to encompass microorganisms. *Id.* at 318.

[3] *Id.* at 309.

[4] Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1361-65 (Fed. Cir. 2004).

Circuit recently upheld the patentability of a method-of-diagnosis claim for a vitamin B deficiency.[5] The method claim correlated an elevated level of total homocysteine to a vitamin B deficiency.[6] This method claim was not limited to a particular procedure for performing the measurement.[7] In fact, the method claim was arguably construed to cover all future improvements to the measurement method so long as the resulting measurement was used for the determination of a vitamin B deficiency.[8]

The United States Supreme Court initially granted certiorari in *Metabolite Labs* to decide whether the method-of-diagnosis claim was patentable.[9] Later, the Court dismissed certiorari as improvidently granted.[10] This Note asserts that the Court should have adjudicated the case because there is a great need to clarify what is patentable subject matter for method claims that do not entail a physical transformation of matter, particularly in view of the seeming inconsistency between *Diamond v. Diehr* and *State Street Bank & Trust Co. v. Signature Financial Group.*[11] There is strong public interest in clarifying 35 U.S.C. § 101, as evidenced by an unusually large number of amici briefs in *LabCorp.*[12] Twenty amici briefs were submitted from a diverse group of entities such as the American Association of Retired People,[13] American Medical Association,[14] American Express,[15] IBM,[16] Bear Stearns &

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[5] *Id.* at 1368.

[6] *Id.* at 1358-59.

[7] *See id.*

[8] *See* Brief of the American Clinical Laboratory Association as Amicus Curiae in Support of Petitioner at 13, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[9] Petition for a Writ of Certiorari, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2004 WL 2505526; Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc. (*LabCorp*), 126 S. Ct. 543 (2005) (limiting grant of certiorari to issue three only).

[10] Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc. (*LabCorp*), 126 S. Ct. 2921, 2922 (2006).

[11] *See id.* at 2928 (Breyer, J., dissenting). *Compare* Diamond v. Diehr, 450 U.S. 175, 192 (1980) (holding that a method claim that includes a physical transformation of matter is patentable) *with* State Street Bank & Trust Co. v. Signature Fin. Group, 149 F.3d 1368, 1373 (Fed. Cir. 1998) (holding that a method claim that produces "'a useful, concrete, and tangible result'" is patentable).

[12] *LabCorp*, 126 S. Ct. at 2926 (Breyer, J., dissenting).

[13] Brief Amicus Curiae of AARP in Support of Petitioner, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[14] Brief for the American Medical Association, the American College of Medical Genetics, the American College of Obstetricians and Gynecologists, the Association for Molecular Pathology, the Association of American Medical Colleges, and the College of American Pathologists as Amici Curiae in Support of Petitioner, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

Lehman Brothers,[17] Affymetrix,[18] Perlegen,[19] American Clinical Laboratory Association,[20] and the Computer & Communications Industry Association.[21]

This Note additionally asserts that a patent claiming a method of diagnosing a disease that consists of essentially two steps—(1) a medical measurement that is not specific to a particular method, and (2) a correlation step that uses the medical measurement for identifying a disease state—should not be patentable subject matter under 35 U.S.C. § 101.[22] As currently construed by the court of appeals in *Metabolite Labs*, a method-of-diagnosis claim can cover *all* improvements to the measurement method that will likely be invented in the future.[23] The method claim in *Metabolite Labs* essentially grants a monopoly over a natural phenomenon, and allowing such monopolies will impede progress in developing improved medical measurements and thus deprive the public of potential advancements in healthcare.[24]

Part I will provide a brief background in patent law, describe the

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[15] Brief of Amicus Curiae American Express Company in Support of Neither Party, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[16] Brief of International Business Machines Corporation as Amicus Curiae in Support of Neither Party, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[17] Brief of Financial Services Industry Amici Curiae in Support of Reversal, 126 S. Ct. 2921 (2006) (No. 04-067).

[18] Brief Amicus Curiae of Affymetrix, Inc. and Professor John H. Barton in Support of Petitioner, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[19] Brief for Amicus Curiae Perlegen Sciences, Inc. and Mohr, David Ventures in Support of Respondents, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[20] Brief of the American Clinical Laboratory Association as Amicus Curiae in Support of Petitioner, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[21] Brief for Amicus Curiae Computer & Communications Industry Association in Support of Petitioner, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[22] *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc. (*LabCorp*), 126 S. Ct. 2921, 2927 (2006) (Breyer, J., dissenting).

[23] *See* Brief of the American Clinical Laboratory Association as Amicus Curiae in Support of Petitioner at 13, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067); Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1362-64 (Fed. Cir. 2004). Abbott Laboratories later developed an improved assay that was held to be an infringing assay. Brief for Respondents at 7, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2006 WL 303905.

[24] *See* Michael Meehan, *The Handiwork of Nature: Patentable Subject Matter and Laboratory Corporation v. Metabolite Labs*, 16 ALB. L.J. SCI. & TECH 311, 317 (2006); *see also* Brooks Gifford, Paper, *Oh, Diehr: The CAFC'S Troubling Patent Eligibility Jurisprudence as Applied in Metabolite Laboratories v. LabCorp*, 25 BIOTECHNOLOGY L. REP. 129, 129 (2006).

current interpretation of 35 U.S.C. § 101 for method claims, and summarize the facts and procedural history of the suit against LabCorp.[25] Part II will analyze why the Federal Circuit's interpretation of a method of diagnosing a vitamin B deficiency was too broad and will inhibit future research needed for better healthcare.[26] Part III will conclude that the Supreme Court should have reversed the Federal Circuit's decision in *Metabolite Labs*.[27]

I. BACKGROUND

To enhance the discussion of *LabCorp*, *infra*, a review of basic patent law will be provided. Next, the current interpretation of 35 U.S.C. § 101 for software method claims will be summarized. Issues that the biotech industry is facing due to the current application of 35 U.S.C. § 101 also will be presented. Finally, the facts regarding the discovery of the method of diagnosing a vitamin B deficiency and the procedural history of the infringement suit against LabCorp will be set forth.

A. PATENT LAW BASICS

Article I, section 8, clause 8, of the United States Constitution gave Congress the right to regulate patents for promoting "the Progress of Science and the useful Arts."[28] A person who invents a "new and useful process, machine, manufacture, or composition of matter" may apply for and obtain a patent.[29] An inventor may apply for a patent by submitting an application to the United States Patent and Trademark Office (USPTO).[30] If a patent examiner at the USPTO finds that the invention is novel and non-obvious based on the prior art,[31] a patent will be granted.[32] The inventor will then receive a limited monopoly on his or her invention for a term beginning on the date on which the patent issues

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[25] *See infra* notes 28-161 and accompanying text.

[26] *See infra* notes 162-312 and accompanying text

[27] *See infra* notes 313-317 and accompanying text.

[28] U.S. CONST art. I, § 8, cl. 8.

[29] 35 U.S.C.A. § 101 (Westlaw 2007).

[30] 35 U.S.C.A. § 111 (Westlaw 2007); *see also* U.S. Patent & Trademark Office, Patent, How to Get a, http://www.uspto.gov/web/patents/howtopat.htm (last visited Mar. 18, 2007).

[31] "Prior art" a body of knowledge from the beginning of time that may include public knowledge, public use, a patent, a printed publication, or a public sale. *See* 35 U.S.C. § 102 (Westlaw 2007); Walter J. Blenko, Jr., *Considering What Constitutes Prior Art in the United States*, 43 JOM 45 (1991), *available at* http://www.tms.org/pubs/journals/JOM/matters/matters-9106.html.

[32] 35 U.S.C.A. §§ 102, 103 (Westlaw 2007).

and ending twenty years from the date the application was filed.[33] In exchange for the limited monopoly, the invention will be free for the public to use once the patent expires.[34] Further, the invention will usually be published eighteen months after filing of the application so that the public can improve upon the invention or design around the invention.[35] Thus, patent law must provide "'a careful balance'" between the benefits to the inventor in the form of a limited monopoly, and the utility to the public in the form of public disclosure, because the patent system is the "very lifeblood of a competitive economy."[36]

A patent provides a patentee the right to exclude others from infringing the patent.[37] There are two types of infringement, direct and indirect.[38] Direct infringement occurs when one makes, uses, offers to sell, or sells any patented invention within the United States and without authority.[39] To directly infringe a patent, the accused infringer must perform each and every element of a patent claim.[40] The intent of the infringer does not matter when evaluating direct infringement,[41] in contrast to indirect infringement.[42]

One form of indirect infringement is inducement to infringe, which

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[33] 35 U.S.C.A. § 154(a)(2) (Westlaw 2007).

[34] *See* Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 152 (1989).

[35] 35 U.S.C.A. § 122 (Westlaw 2007).

[36] *See* Brief for Amicus Curiae Affymetrix, Inc. and Professor John H. Barton in Support of Petitioner at 12, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067) (citing *Bonito Boats*, 489 U.S. at 146).

[37] "[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C.A. § 271(a) (Westlaw 2007) (direct infringement). "Whoever actively induces infringement of a patent shall be liable as an infringer." U.S.C. § 271(b) (Westlaw 2007) (inducement to infringe). "Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer." 35 U.S.C.A.. 271(c) (Westlaw 2007) (contributory infringement). A further discussion of 35 U.S.C.A. § 271(c) is beyond the scope of this Note.

[38] 35 U.S.C.A. § 271(a),(b) (Westlaw 2007).

[39] 35 U.S.C.A. § 271(a) (Westlaw 2007).

[40] Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co., 520 U.S.17, 29 (1997); *see also* Prouty v. Ruggles, 41 U.S. 336, 341 (1842); Kristin E. Gerdelman, Comment, *Subsequent Performance of Process Steps by Different Entities: Time to Close Another Loophole in U.S. Patent Law*, 53 EMORY L.J. 1987, 1994-95 (2004).

[41] *Warner-Jenkinson*, 520 U.S. at 35.

[42] Kristin E. Gerdelman, Comment, *Subsequent Performance of Process Steps by Different Entities: Time to Close Another Loophole in U.S. Patent Law*, 53 EMORY L.J. 1987, 1994 (2004) (citing Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988)).

occurs when a party actively induces or encourages infringement by another party.[43] As a threshold consideration, it must be determined whether someone directly infringed the patent.[44] Next, there must be evidence that the alleged indirectly infringing party encouraged another to perform the infringing act.[45] Either direct or circumstantial evidence may be used for establishing liability for inducement to infringe.[46] An example of circumstantial evidence could be an advertising document that encourages one to infringe a patent.[47] Lastly, unlike direct infringement, the party allegedly actively inducing another to infringe must intend to do so.[48]

B. HISTORY OF UNITED STATES SUPREME COURT DECISIONS DEFINING PATENTABLE SUBJECT MATTER UNDER 35 U.S.C. § 101 FOR SOFTWARE-RELATED METHOD CLAIMS

Starting around the 1970s, there was an explosion in the development of computers and software technology that continues to this day.[49] There are "[c]lose to one hundred thousand software or software-related patents [that] are now in force in the United States, and several thousand more are being issued every year."[50] In a trio of cases, the United States Supreme Court defined the patentability requirements for software-related method[51] claims under 35 U.S.C. § 101.[52] The most recent of these decisions for defining patentable subject matter was decided over 25 years ago.[53] In *Diamond v. Diehr*, the Court held that a method claim that includes a physical transformation of matter is patentable subject matter under 35 U.S.C. § 101.[54] However, the Court indicated that a method claim not involving a physical transformation of

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[43] 35 U.S.C.A. § 271(b) (Westlaw 2007).

[44] *See* Joy Techs., Inc. v. Flakt, Inc., 6 F.3d 770, 774 (Fed. Cir. 1993).

[45] *Id.*

[46] Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1272 (Fed. Cir. 1986) (citing Michalic v. Cleveland Tankers, Inc., 364 U.S. 325, 330 (1960)).

[47] Kristin E. Gerdelman, *supra* note 42, at 2001.

[48] *Water Techs. Corp.*, 850 F.2d at 660; Gerdelman, *supra* note 42, at 2000.

[49] *See* Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 11-14 (2001).

[50] *Id.* at 11.

[51] A method claim and a process claim have the same meaning and are used interchangeably. 35 U.S.C.A. § 100(b) (Westlaw 2007).

[52] Diamond v. Diehr, 450 U.S. 175, 192 (1980); Parker v. Flook, 437 U.S. 584, 590-94 (1978); Gottschalk v. Benson, 409 U.S. 63, 70-71 (1972).

[53] *Diehr*, 450 U.S. at 192.

[54] *See id.*

matter *may* still be patentable.[55] The Court broadly stated that a method claim is patentable subject matter if it "perform[ed] a function which the patent laws were designed to protect."[56] After the holding in *Diehr*, there remained substantial uncertainty in defining patentable subject matter under 35 U.S.C. § 101 for process claims that do not entail a physical transformation of matter.[57]

There were several cases in the 1980s and 1990s in which the Federal Circuit and its predecessor, the United States Court of Customs and Patent Appeals, struggled to apply the holding of *Diehr* to determine whether software process claims should be patentable subject matter 35 U.S.C. § 101.[58] In an attempt to clarify the United States Supreme Court holding in *Diehr*,[59] the Federal Circuit in *State Street Bank* seemingly eliminated the physical-transformation requirement.[60] The Federal Circuit held that a method claim would be patentable subject matter so long as it provided "a useful, concrete, and tangible result."[61] The rule in *State Street Bank* has arguably increased the scope of patentable subject matter to include abstract ideas or mental thoughts.[62] As a result, since *State Street Bank*, the United States Patent and Trademark Office has issued an increasing number of software-method patents, especially business-method patents.[63] The rapid increase in issued method patents has generated harsh criticism of the rule developed in *State Street Bank*.[64]

C. ISSUES FACING THE BIOTECH INDUSTRY UNDER THE CURRENT INTERPRETATION OF 35 U.S.C. § 101

Similar to the computer software industry, the biotechnology

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[55] *See id.*

[56] *Id.*

[57] *See* Cathy E. Cretsinger, *I. Intellectual Property: B. Patent: 4. Patentability: a) Computer Software: AT&T Corp. v. Excel Communications, Inc.*, 15 BERKELEY TECH. L.J. 165, 168 (2000).

[58] *See In re* Alappat, 33 F.3d 1526, 1542-44 (Fed. Cir. 1994); Arrhythmia Research Tech., Inc. v. Corazonix Corp., 958 F.2d 1053, 1056-60 (Fed. Cir. 1992); *In re* Meyer, 688 F.2d 789, 794-96 (C.C.P.A. 1982); *In re* Abele, 684 F.2d 902, 907-908 (C.C.P.A. 1982).

[59] *Diehr*, 450 U.S. at 192.

[60] *See* State Street Bank & Trust Co. v. Signature Fin. Group, 149 F.3d 1368, 1373 (Fed. Cir. 1998).

[61] *Id.*

[62] *See* Cretsinger, *supra* note 57 at 177-80.

[63] Brief for Amicus Curiae Computer & Communications Industry Association in Support of Petitioner at 14-15, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* http://www.ccianet.org/modules/patentPDFs/CCIALabCorpMeritsAmicus[04-607].pdf.

[64] *See* Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 587 (1999).

industry has experienced explosive growth and technological advancement over the last thirty years.[65] One area of recent growth in biotechnology has been in the medical diagnostic field, involving the development of new blood tests (i.e., assays) for diagnosing a disease or predicting the likelihood of developing a disease in the future.[66] For example, such a test can measure a concentration of a particular chemical or the presence of a genetic marker.[67]

The medical diagnostics industry is very important to the United States economy in regard to sales and the creation of jobs,[68] and thus significant benefits would flow from a clarification of 35 U.S.C. § 101. The diagnostic portion of the biotech industry generated approximately forty-six billion dollars in revenue and 187,500 jobs in the year 2004 alone.[69] The United States government has a significant interest in tailoring patent law to provide an incentive for innovation, by promoting commerce through the award of limited monopolies.[70] However, to promote innovation through patents, the United States government must exercise the right balance by granting a limited monopoly only when the inventor provides the public a substantive advance in science and the useful arts.[71]

Broad-based method patents can be used to enjoin the performance of diagnosing a disease.[72] In essence, allowing a broad-based method

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[65] *See* John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 113 (2001).

[66] *See* Genetics: The Future of Medicine, NIH Publication No. 00-4873, at 9, *available at* http://www.genome.gov/Pages/EducationKit/images/nhgri.pdf (last visited Dec. 16, 2006); Brief for Amicus Curiae Perlegen Sciences, Inc. and Mohr, David Ventures in Support of Respondents at 21, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067); Brief for Amicus Curiae Affymetrix, Inc. and Professor John H. Barton in Support of Petitioner at 12, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067) (noting growth in genome analysis).

[67] *See* Genetics: The Future of Medicine, NIH Publication No. 00-4873, at 9, *available at* http://www.genome.gov/Pages/EducationKit/images/nhgri.pdf (last visited Mar. 18, 2007); Brief for Amicus Curiae Perlegen Sciences, Inc. and Mohr, David Ventures in Support of Respondents at 12-14, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067) (describing diagnostic tests for prostate cancer, AIDS, ovarian cancer, and neoplastic tissue).

[68] Biotechnology Industry Organization (2005). Biotechnology Industry Facts; and Burrill and Company (2005). Biotech 2006: *What's Really Going to Happen.* Gene Acres, Sept. 25, *available at* http://www.cccbiotech.org/pdf/trainingneeds21stcentury.pdf.

[69] *Id.*

[70] *See* Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 146 (1989).

[71] *See id.*

[72] *See* Brief of the American Clinical Laboratory Association as Amicus Curiae in Support of Petitioner at 8-13, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

claim amounts to granting a patent on the practice of medicine.[73] Examples of diseases covered by method claims are prostate cancer,[74] HIV/AIDS,[75] breast cancer,[76] ovarian cancer,[77] and vitamin B deficiency.[78] In the practice of medicine, a physician will routinely order a blood test to measure particular chemical or genetic information, correlate the results to the presence or absence of a disease, and inform the patient of the result.[79] Thus, the standard practice of medicine for diagnosing a disease may be enjoined through broad-based method patents.

Under one interpretation, the medical measurement step in *Metabolite Labs* does not include a physical transformation of matter, and thus it should not be patentable subject matter based on the U.S. Supreme Court holding in *Diehr*.[80] However, the method-of-diagnosis claim can be construed to provide a useful, concrete, and tangible result and therefore could be patentable subject matter based on the Federal Circuit holding in *State Street Bank*.[81] This inconsistency illustrates the apparent dichotomy in standards for defining patentable subject matter for process claims that has existed since the ruling in *State Street Bank*.[82]

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[73] *See* Brief Amicus Curiae of AARP In Support of Petitioner at 17, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[74] U.S. Patent No. 5,840,501 (issued Nov. 24, 1998) (quoted in Brief for Amicus Curiae Perlegen Sciences, Inc. and Mohr, David Ventures in Support of Respondents at 12, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067)).

[75] U.S. Patent No. RE38,352 (issued Dec. 16, 2003) (quoted in Brief for Amicus Curiae Perlegen Sciences, Inc. and Mohr, David Ventures in Support of Respondents at 12, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067)).

[76] U.S. Patent No. 5,709,999 (issued Jan. 20, 1998) (quoted in Brief for Amicus Curiae Affymetrix, Inc. and Professor John H. Barton in Support of Petitioner at 19, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[77] U.S. Patent No. 4,968,603 (issued Nov. 6, 1990) (quoted in Brief for Amicus Curiae Perlegen Sciences, Inc. and Mohr, David Ventures in Support of Respondents at 13, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067)).

[78] U.S. Patent No. 4,940,658 (issued July 10, 1990).

[79] *See* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1364 (Fed. Cir. 2004).

[80] *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc. (*LabCorp*), 126 S. Ct. 2921, 2927 (2006) (Breyer, J., dissenting).

[81] *See* State Street Bank & Trust Co. v. Signature Fin. Group, 149 F.3d 1368, 1373 (Fed. Cir. 1998).

[82] *Compare* Diamond v. Diehr, 450 U.S. 175, 192 (1980) *with State Street Bank*, 149 F.3d at 1373.

D. FACTS AND PROCEDURAL HISTORY OF *LABCORP*

1. Discovery of the Method

In *Metabolite Labs*, a trio of medical-school professors from the University of Colorado and Columbia University discovered a method of diagnosing a vitamin B deficiency.[83] The discovered method involved a correlation between the concentration of total homocysteine in blood and a vitamin B deficiency.[84] The term "total homocysteine" represents the aggregate concentration of four different forms of homocysteine.[85] Homocysteine is an amino acid that can be found in the human body.[86] Amino acids may be used to build proteins that exist in nature.[87] Vitamin B is an essential chemical necessary for the health and development of humans.[88] Vitamin B complex is a group of vitamins including B_1 (thiamin), B_2 (riboflavin), B_6 (pyridoxine), niacin, pantothenic acid, folate, and B_{12} (cobalamin).[89] Although there are several different vitamin B complexes, the specific type of vitamin B deficiency referred to in this Note concerns only cobalamin (vitamin B_{12}) and folate. Thus, all references to vitamin B hereinafter will refer only to cobalamin and folate.

A vitamin B deficiency may cause one or more serious illnesses including those that relate to cognitive dysfunction, birth defects, and cancer.[90] If the vitamin B deficiency is detected early, a physician can prescribe a vitamin supplement to improve the patient's health and overcome the vitamin B deficiency.[91] However, if the diagnosis is not timely, a patient can suffer serious illness or death.[92] Thus, although the

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[83] Brief for Respondents at 1-2, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2006 WL 303905.

[84] *Id.* at 2. For more information on homocysteine, see generally American Heart Association, What is Homocysteine?, http://www.americanheart.org/presenter.jhtml?identifier=535 (last visited Sept. 16, 2006).

[85] Brief for Respondents at 3, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2006 WL 303905.

[86] Brief for Petitioner at 2, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2005 WL 3543099.

[87] FUNDAMENTALS OF CLINICAL CHEMISTRY, 291 (Norbert W. Tietz ed., 3d ed. 1987).

[88] *Id.* at 497.

[89] *Id.* at 497-512, 815-18.

[90] Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1358 (Fed. Cir. 2004).

[91] *Id.*

[92] *See* Brief for Respondents at 1, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2006 WL 303905.

new method was initially repudiated by the medical community, it provided physicians with a useful and previously unknown way of detecting a vitamin B deficiency that eventually became well-accepted and frequently referenced.[93]

Traditionally, a vitamin B deficiency was initially diagnosed by observing anemia and enlarged red blood cells in a patient's blood.[94] After the initial diagnosis, the deficiency was verified by measuring a low concentration of vitamin B in the patient's blood.[95] Research studies had demonstrated that a vitamin B deficiency was not detected in a significant number of people using the traditional test.[96] Thus, a large number of patients in need of immediate treatment were left untreated because they were not diagnosed by the traditional test.[97]

In contrast, the new total homocysteine test was much more effective because of a much lower percentage of false negative results (i.e., the proportion of patients with a vitamin B deficiency that were not diagnosed).[98] Therefore, the total homocysteine measurement was a major breakthrough enabling the early diagnosis of a vitamin B deficiency. Without the new test, millions of people with a vitamin B deficiency would not be properly diagnosed, causing them to potentially suffer a serious illness.[99]

2. *Licensing of the Idea*

In addition to discovering the correlation between the total homocysteine concentration and a deficiency in vitamin B, the medical-school professors invented new and better assays for measuring total homocysteine in blood.[100] Through their research, the universities that employed the professors were able to obtain U.S. Patent No. 4,940,658 ("'658 patent"). The '658 patent claimed a method of measuring the total homocysteine concentration and a method of diagnosing a patient

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[93] *Id.* at 4-5.

[94] *Id.* at 2. Anemia is a condition that consists of a relatively low concentration of red cells in blood. FUNDAMENTALS OF CLINICAL CHEMISTRY, 789 (Norbert W. Tietz ed., 3d ed. 1987).

[95] Brief for Respondents at 2, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2006 WL 303905.

[96] *See id.* at 4.

[97] *Id.*

[98] *See id.* at 2 n.2.

[99] *See id.* at 4.

[100] Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1358 (Fed. Cir. 2004). An assay is an analysis is to determine the presence, absence, or quantity of one or more components. Merriam-Webster Online Dictionary, http://www.m-w.com/dictionary/assay (last visited Feb. 25, 2007).

with a vitamin B deficiency.[101] Both Columbia University and the University of Colorado assigned the patent to a predecessor of Competitive Technologies, Inc.[102] In turn, Competitive Technologies granted a patent license to Metabolite Laboratories, Inc. ("Metabolite Labs").[103] Metabolite Labs sublicensed the patent to Roche Biomedical Laboratories to perform the total homocysteine assay.[104] Later, Roche Biomedical Laboratories became Laboratory Corporation of America ("LabCorp").[105]

LabCorp performed the assay and paid royalties to both Metabolite Labs and Competitive Technologies for six years.[106] In 1998, Abbott Laboratories developed an improved total homocysteine assay.[107] LabCorp adopted the Abbott assay but did not pay royalties to Metabolite Labs and Competitive Technologies when using the Abbott assay.[108] However, LabCorp did continue to pay royalties when it used the Metabolite Labs version.[109] LabCorp thought that royalty payments were not necessary when using the Abbott version of the total homocysteine assay.[110] However, Metabolite Labs and Competitive Technologies sued LabCorp for patent infringement and breach of license because they asserted that the '658 patent covered *any* assay for measuring total homocysteine, including the Abbott assay.[111]

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[101] *Metabolite Labs*, 370 F.3d at 1358.

[102] Brief for Respondents at 6, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2006 WL 303905. Competitive Technologies is a company that specializes in licensing technological developments to industry from universities. *Id.*

[103] Brief for Respondents at 6, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2006 WL 303905. The University of Colorado established Metabolite Labs so that the inventors could develop the total homocysteine assay into a format available to physicians. *Id.*

[104] *Metabolite Labs*, 370 F.3d at 1359.

[105] *Id.*

[106] Brief for Respondents at 7, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2006 WL 303905. A physician would order the assay and arrange to have the blood sample sent to LabCorp for performing the measurement of total homocysteine. *Id.* at 7 n.3.

[107] Brief for Respondents at 7, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2006 WL 303905.

[108] *Id.* at 8.

[109] Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc. (*LabCorp*), 126 S. Ct. 2921, 2923 (2006) (Breyer, J., dissenting).

[110] *See* Brief for Respondents at 8, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2006 WL 303905.

[111] Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1358-59 (Fed. Cir. 2004).

3. District Court Decision

At the district-court level, the jury found that LabCorp had infringed the patent and breached the license agreement.[112] LabCorp was ordered to pay nearly 3.7 million dollars in damages for breach of contract and 2 million dollars for willful infringement of the patent.[113]

One of the main issues argued in the district court was whether LabCorp infringed Claim 13 of the '658 patent.[114] Whether LabCorp infringed rested on how the district court construed Claim 13.[115] Claim 13 describes "a method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: *assaying* a body fluid for an elevated level of total homocysteine; and *correlating* an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate."[116]

During the *Markman* claim-construction hearing,[117] LabCorp wanted the court to construe "correlating" as establishing a mutual or reciprocal relationship with "an elevated level of homocysteine."[118] LabCorp also asserted that the correlating step must include a vitamin B deficiency that causes either a hematologic or neuropsychotic abnormality.[119] The district court adopted only the initial portion of LabCorp's construction, holding that "correlate" means "'to establish a mutual or reciprocal relation of' an elevated level of homocysteine," "but declined to 'include a[ny] reference to [a] hematologic or neuropsychotic abnormality.'"[120] The trial judge found that construing the correlation step to include evidence of a hematologic or neuropsychotic disorder would "impermissibly import[] a limitation from the specification" into the claim.[121] LabCorp appealed to the Federal Circuit.[122]

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[112] *Id.* Interestingly, Abbott Laboratories, who manufactured and sold the total homocysteine assay kit used by LabCorp, was not charged with infringement in this suit. There are no facts discussed in the case on whether Abbott Laboratories induced infringement.

[113] *Metabolite Labs*, 370 F.3d at 1359.

[114] *Id.* at 1361.

[115] *See id.* at 1360.

[116] U.S. Patent No. 4,940,658 (issued July 10, 1990) (emphasis added).

[117] A *Markman* hearing is where the judge can construe the meaning of the language used in a patent claim. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 987 (Fed. Cir. 1995).

[118] *Metabolite Labs*, 370 F.3d at 1361.

[119] *Id.*

[120] *Id.* (quoting LabCorp's *Markman* brief).

[121] Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1361 (Fed. Cir. 2004) (finding a hematologic or neuropsychotic disorder that is described in the written description of the patent should not be required as a necessary result of the correlation step described in the claim). A specification is a written description of the invention. 35 U.S.C. § 112 (Westlaw 2007).

[122] *Metabolite Labs*, 370 F.3d at 1358.

4. Federal Circuit's Affirmance of District Court

On appeal, LabCorp argued that the district court erred in construing the term "correlating" too broadly.[123] LabCorp argued again that the term "correlating" should be limited to a vitamin B deficiency that "'causes a hematologic or neuropsychiatric abnormality.'"[124] However, the Federal Circuit affirmed the district court's construction.[125]

The court then turned to the issue of direct infringement.[126] Based on the district court's claim interpretation, the jury verdict had held LabCorp liable for indirect infringement, but the jury also found that physicians directly infringed the patent because they ordered the assay and correlated the results.[127]

As evidence to support the direct infringement, LabCorp's Discipline Director testified at trial that physicians performed the correlation step after receiving the results from LabCorp.[128] As further evidence that physicians performed this step, an inventor of the '658 patent "testified that it would be malpractice for a [physician] to receive a total homocysteine assay without determining cobalamin/folate deficiency."[129] The court noted that "'[c]ircumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence.'"[130] Therefore, the Federal Circuit found sufficient evidence to support the jury finding that physicians directly infringed because they would *always* be ethically compelled to think about the correlation after ordering a total homocysteine assay.[131]

After physicians were established as direct infringers, the Federal Circuit went on to analyze whether LabCorp had induced physicians to infringe Claim 13.[132] LabCorp had published articles targeted to physicians to inform them that elevated concentrations of total homocysteine could be correlated to a vitamin B deficiency.[133] In addition, the articles stated that such a deficiency could be treated

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[123] *See id.* at 1361.

[124] *Id.*

[125] *Id.* at 1364.

[126] *Id.*

[127] *Id.*

[128] *Id.*

[129] *Id.*

[130] *Id.* at 1365 (citing Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1272 (Fed. Cir. 1986)).

[131] *See Metabolite Labs*, 370 F.3d at 1365.

[132] *Id.*

[133] *Id.*

through vitamin supplements.[134] The Federal Circuit interpreted the publications as evidence that LabCorp promoted the use of total homocysteine assays for detecting a vitamin B deficiency.[135] The Federal Circuit therefore affirmed the jury's finding that LabCorp had induced infringement of Claim 13.[136]

5. Denial of Certiorari by the United States Supreme Court

After losing on appeal, LabCorp filed a petition for a writ ofcertiorari to the United States Supreme Court.[137] The Court initially granted certiorari on only one issue: whether a method patent that directs a party to simply correlate test results can validly "claim a monopoly over a basic" scientific principle such that any physician necessarily infringes the patent by merely thinking about the relationship after looking at test results.[138] Although certiorari was initially granted, it was subsequently dismissed as having been improvidently granted.[139]

In dissenting from the dismissal of the petition for the writ of certiorari, Justice Breyer acknowledged that there was a procedural problem with the writ in that "LabCorp did not refer in the lower courts to" an issue with 35 U.S.C. § 101.[140] Although the Court "might benefit from the views of the Federal Circuit" [141] on the 35 U.S.C. § 101 issue, Justice Breyer asserted that the Court nevertheless had the power to adjudicate an issue that was not properly raised in the lower court, citing *United States v. Williams*.[142]

Because the issue was "fully briefed and argued by the parties, the Government, and the [twenty] *amici*," he argued that the case could be fairly adjudicated by the Supreme Court despite the absence of rulings by

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[134] *Id.*

[135] *Id.*

[136] *Id.*

[137] Petition for a Writ of Certiorari, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2004 WL 2505526.

[138] *Id.*; Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc. (*LabCorp*), 126 S. Ct. 543 (2005) (limiting grant of certiorari to issue three only).

[139] Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc. (*LabCorp*), 126 S. Ct. 2921, 2921 (2006).

[140] *Id.* at 2925 (Breyer, J., dissenting).

[141] *Id.* at 2925 (Breyer, J., dissenting) (citing United States v. Bestfoods, 524 U.S. 51, 72-73 (1998)).

[142] *Id.* at 2925-26 (Breyer, J., dissenting) (citing United States v. Williams, 504 U.S. 36, 40 (1992)). The traditional rule is that the Supreme Court should not grant *certiorari* when the argument was not pressed by the litigant or passed on by the court below. *Williams*, 504 U.S. at 41. The *Williams* Court noted that the rule "operate[d] in the disjunctive, permitting review of an issue not pressed so long as it has been passed upon." *Id.*

the lower courts.[143] Justice Breyer conceded that it would have been better for the issue to have been considered by the Federal Circuit, but found "the extra time, cost, and uncertainty that further proceedings would engender [were] not worth the potential benefit."[144]

Justice Breyer emphasized that a timely clarification of 35 U.S.C § 101 was important because it would benefit medical researchers, physicians, and the patients who depend on proper healthcare.[145] He noted that the Federal Circuit's current interpretation for method-of-diagnosis claims, such as Claim 13 of the '658 patent, "may inhibit [physicians] from using their best medical judgment."[146] As a potentially undesirable result of the Federal Circuit's interpretation, Justice Breyer noted that physicians may be forced to spend time licensing patents and searching for potentially infringing patents instead of focusing their efforts on helping the public through the practice of medicine.[147]

Additionally, Justice Breyer discussed whether Claim 13 was patentable subject matter under 35 U.S.C. § 101.[148] He stated that "the correlation between homocysteine and vitamin deficiency set forth in Claim 13 is a 'natural phenomenon.'"[149] As support, he noted that Metabolite Labs had practically conceded that the correlation step between total homocysteine and a deficiency in vitamin B standing alone is a natural phenomenon.[150]

Metabolite Labs, however, had asserted that Claim 13 was valid because considered as a whole, it "entails a physical transformation of matter" (the alteration of a blood sample) and "produces a useful, concrete, and tangible result" (the diagnosis of a vitamin B deficiency).[151] Justice Breyer rejected the first argument because Claim 13 does not describe an assay that transforms blood.[152] Claim 13 simply describes the use of any assay for measuring total homocysteine, which includes unpatented methods of measuring homocysteine.[153] He interpreted Claim 13 to "instruct[] [a] user to (1) obtain test results and

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[143] *LabCorp*, 126 S. Ct. at 2926 (Breyer, J., dissenting).

[144] *Id.*

[145] *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc. (*LabCorp*), 126 S. Ct. 2921, 2928 (2006) (Breyer, J., dissenting).

[146] *Id.*

[147] *Id.* at 2928-29.

[148] *Id.* at 2927.

[149] *Id.*

[150] *Id.*

[151] *Id.* (quoting Brief for Respondent at 33, 36, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067)).

[152] *LabCorp*, 126 S. Ct. at 2927 (Breyer, J., dissenting).

[153] *Id.*

(2) think about them."[154] He rejected Metabolite Labs' argument as not persuasive, because virtually any law of nature applied to "any useful purpose could involve the use of empirical information obtained through an unpatented means that might have involved transforming matter."[155]

Justice Breyer also rejected Metabolite Labs' second argument that a process is patentable if it produces a "'useful, concrete, and tangible result.'"[156] He noted that the Court itself had not held that *all* processes that have a useful, concrete, and tangible result were patentable subject matter, and "if taken literally [that] statement would cover instances where [the] Court ha[d] held the contrary."[157] Justice Breyer cited several cases in which the Court had held process claims unpatentable, even though they produced a useful, concrete, and tangible result.[158]

Justice Breyer emphasized that he would reject Claim 13 as outside the scope of patentable subject matter under 35 U.S.C. § 101, because it "amount[ed] to a simple natural correlation, *i.e.,* a 'natural phenomenon.'"[159] In this case, he interpreted the process claim as "an instruction to read some numbers in light of medical knowledge."[160] Justice Breyer concluded that Claim 13 was unpatentable because the correlation step was a "natural phenomenon" and there was nothing in Claim 13 that "add[ed] anything more of significance."[161]

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[154] *Id.*

[155] *Id.*

[156] *Id.* at 2928.

[157] *Id.*

[158] *Id.* (citations omitted). In *O'Reilly v. Morse* , the Court invalidated a process claim that transmitted messages over long distances, which was certainly a useful, concrete, and tangible result. *See* O'Reilly v. Morse, 56 U.S. 62, 112-13 (1854). In *Flook*, the Court invalidated a process claim that triggered alarm limits for a catalytic converter, which was also a useful, concrete, and tangible result. Parker v. Flook, 437 U.S. 584, 594 (1978). In *Gottschalk*, the Court invalidated a process claim that converted decimal figures into binary figures, which would arguably be a useful, concrete, and tangible result for improving the wiring system of a computer. Gottschalk v. Benson, 409 U.S. 63, 73 (1972).

[159] Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc. (*LabCorp*), 126 S. Ct. 2921, 2928 (2006) (Breyer, J., dissenting) (citing *Flook*, 437 U.S. at 588 n.9).

[160] *Id.*

[161] *Id.*

II. ANALYSIS

A. THE METHOD IN CLAIM 13 IS NOT PATENTABLE UNDER UNITED STATES SUPREME COURT PRECEDENT

1. Claim 13 Can Be Construed as a Mathematical Formula that Wholly Preempts the Field for Measuring Total Homocysteine

"[O]ne may not patent an idea."[162] The United States Supreme Court held in *Gottschalk v. Benson* that a process claim directed to a mathematical formula would in effect be a patent on an idea if the process claim wholly preempts the use of the mathematical formula.[163] In *Gottschalk*, the mathematical formula converted binary-coded decimal numerals into pure binary numerals.[164] The alleged invention in *Gottschalk* was that a binary number can be transformed into a different state using a mathematical formula.[165] The claim was broadly drafted such that all unknown and future uses of the mathematical formula would infringe the patent.[166]

The correlation step in *Metabolite Labs* is analogous to the mathematical formula in *Gottschalk*. Claim 13 of the '658 patent may be construed to have a mathematical formula in the correlation step.[167] The correlation step essentially consists of a physician comparing a total homocysteine concentration to a threshold value.[168] If the total homocysteine concentration is greater than the threshold, then the patient is diagnosed with a vitamin B deficiency.[169] The correlation step can be translated to the following mathematical formula: if $H > E$, then there is a vitamin B deficiency, where H = total homocysteine concentration, and E = elevated level of total homocysteine. Construing the correlation step as a mathematical formula does not change the meaning of the claim in any

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[162] *Gottschalk*, 409 U.S. at 71; *accord* Diamond v. Diehr, 450 U.S. 175, 185 (1980).

[163] *Gottschalk*, 409 U.S. at 71-72.

[164] *Id.* at 64

[165] *Id.* Conversion of decimal numbers to binary numbers may be useful "within a computer's wiring system." Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc. (*LabCorp*), 126 S. Ct. 2921, 2928 (2006) (Breyer, J., dissenting).

[166] *See Gottschalk*, 409 U.S. at 68.

[167] *See In re* Application of Richman, 563 F.2d 1026, 1030 (C.C.P.A. 1977) (noting that words can essentially mean the same thing as a mathematical formula).

[168] *See* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1364, 1367 (Fed. Cir. 2004) (citing the '658 patent at col. 9, ll 26-29).

[169] *See id.*

way, but it does illustrate the application to the holding in *Gottschalk*.[170]

The mathematical formula is a compulsory step that is performed in the physician's mind after ordering a total homocysteine assay, because "it would be malpractice for a [physician] to receive a total homocysteine assay without determining a vitamin B deficiency."[171] Therefore, a physician necessarily uses the mathematical formula when ordering a total homocysteine assay and infringes Claim 13. Conversely, the mathematical formula cannot be used without performing an assay for total homocysteine concentration because the concentration (i.e., *H*) is part of the mathematical formula. Accordingly, all uses of the mathematical formula would infringe Claim 13 of the '658 patent.[172] Claim 13 of '658 patent should be invalidated because it wholly preempts the use of the mathematical formula as defined here in the correlation step, which violates the rule in *Gottschalk*.[173]

2. *The Mathematical Formula in Claim 13 Patents a Law of Nature*

"[T]he discovery of a law of nature cannot be patented."[174] The United States Supreme Court, in *Parker v. Flook*, noted that "natural phenomena . . . are not the kind of 'discoveries'" that were meant to be patented under 35 U.S.C. § 101.[175] The Court defined a scientific principle or a natural phenomenon to be a relationship that has always existed even before its discovery.[176] The Court used Newton's law of gravity between two bodies as an example of a natural phenomenon that has always existed, even before its discovery by Newton.[177] The Court emphasized that mere recognition of an existing phenomenon does not

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[170] *Gottschalk*, 409 U.S. at 71-72.

[171] *Metabolite Labs*, 370 F.3d at 1364.

[172] *See* Brief for Amicus Curiae Affymetrix, Inc. and Professor John H. Barton in Support of Petitioner at 11-12, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067) ("[T]he natural relationship between elevated amino acid levels and vitamin deficiency has been 'pre-empted' by the patent claim."); *Gottschalk*, 409 U.S. at 71-72.

[173] *See* Brief for Amicus Curiae Affymetrix, Inc. and Professor John H. Barton in Support of Petitioner at 11-12, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067); *Gottschalk*, 409 U.S. at 71-72. One may argue that Claim 13 does not have a mathematical formula. However, to interpret the correlation step as being different from the mathematical formula would allow a competent drafter to avoid the limitations of *Gottschalk* by translating the mathematical formula into a series of steps in plain English. *See In re* Application of Richman, 563 F.2d 1026, 1030 (C.C.P.A. 1977); Diamond v. Diehr, 450 U.S. 175, 192 (1980).

[174] Parker v. Flook, 437 U.S. 584, 593 (1978).

[175] *Id.*

[176] *Id.* at 593 n.15.

[177] *Id.* at 593.

allow one to exclude others from its enjoyment.[178] The Court also emphasized that "patentable subject matter must be new[] [and] not merely heretofore unknown."[179]

The correlation of an elevated total homocysteine concentration with a vitamin B deficiency is a law of nature.[180] The relationship between total homocysteine and a vitamin B deficiency has always existed in human beings, long before LabCorp's important discovery.[181] The process of regulating the production of homocysteine based on the amount of vitamin B is part of a natural process in mammals.[182] Thus, LabCorp should not have the right to exclude others from using the natural phenomenon of an elevated total homocysteine concentration correlating to a vitamin B deficiency merely because its patent assignors were the first to discover such a relationship in nature.[183]

3. *Claim 13 Does Not Entail a Physical Transformation of Matter Necessary to Satisfy 35 U.S.C. § 101*

The Court in *Diehr* held that if "a claim containing a mathematical formula . . . perform[s] a function which the patent laws were designed to protect (*e. g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101."[184] In *Diehr*, the patentee claimed an improved process for molding rubber that used a mathematical equation known as the Arrhenius equation.[185]The Court found that the process claim comprised several steps for molding rubber and thus did not wholly preempt all uses of the Arrhenius equation.[186]

The Court found that the Arrhenius equation was applied as a tool for improving the process of molding rubber.[187] The Court noted that the claim described a complete and detailed step-by-step process "beginning with the loading of a mold with raw, uncured rubber and ending with the

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[178] *Id.* (citing P. Rosenberg, Patent Law Fundamentals, § 4, p. 13 (1975)).

[179] *Flook*, 437 U.S. at 593.

[180] *See* Brief for Petitioner at 21, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2005 WL 3543099.

[181] *See id.*; *Flook*, 437 U.S. at 593.

[182] *See* Brief for Petitioner at 21, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2005 WL 3543099.

[183] *See id.*

[184] Diamond v. Diehr, 450 U.S. 175, 192 (1980).

[185] *Id.* at 177-179.

[186] *Id.* at 187. The opinion suggests that the Arrhenius equation could still be used in the process of curing rubber, but not in the same way as claimed by the patentee. *Id.*

[187] *Diehr*, 450 U.S. at 177-178.

eventual opening of the press at the conclusion of the cure."[188] The Court justified the patentability of the claim because the process was an industrial process for physically producing an article that had historically been eligible to receive patent protection.[189] Because the process claim described the physical transformation of raw, uncured rubber to a different state, the Court held that the claim satisfied the requirement of 35 U.S.C. § 101.[190]

The Court accepted the petitioner's definition of a mathematical formula, which is "a set of rules that leads [to] and assures development of a desired output from a given input."[191] In *Diehr*, the input was a physical article, the raw, uncured rubber that goes into the mold, and the output was a precision-molded rubber part.[192] Analogously, for Claim 13, the input is the total homocysteine concentration, and the output is the knowledge of whether there is a presence or absence of a vitamin B deficiency. The total homocysteine concentration is a *number* and not a physical article.[193] Therefore, Claim 13 does not have a transformation or reduction of a physical article for satisfying 35 U.S.C. § 101 as construed by *Diehr*.[194]

Metabolite Labs argued that Claim 13 does include a physical transformation of homocysteine in blood and should therefore be patentable subject matter based on *Diehr*.[195] Metabolite Labs supported the argument by noting that the written description of the '658 patent described a chemical process for transforming homocysteine into a different state for enabling the measurement with an instrument.[196] The chemical homocysteine may be construed as a physical article because it is a tangible matter.[197] However, the express language of Claim 13 does not include any limitations that describe a transformation of homocysteine itself.[198] Claim 13 merely states "assaying a body fluid" without stating any limitations for describing *how* to perform the

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[188] *Id.* at 184.

[189] *Id.*

[190] *Id.* at 184, 192-93.

[191] *See id.*

[192] *See id.* at 177.

[193] *Cf. id.* at 186 (discussing how the "alarm limit [was] simply a number" in *Flook*); *see also* Parker v. Flook, 437 U.S. 584, 586 (1978).

[194] *Diehr*, 450 U.S. at 192.

[195] Brief for Respondent at 33-35, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[196] *See id.*

[197] *Id.*

[198] Brief for Petitioner at 27, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2005 WL 3543099.

assay.[199] Because the Federal Circuit construed Claim 13 broadly to include *any* method of measuring total homocysteine, the measuring step should cover an assay that is either transformative or non-transformative.[200] For there to be a finding that Claim 13 included a transformation of blood, the claim must impermissibly read in a limitation from the specification.[201] Therefore, Claim 13 should not be construed to include a physical transformation of homocysteine, and thus it cannot satisfy 35 U.S.C. § 101 based on the holding of *Diehr*.[202]

4. *Claim 13 Does Not Contain a Process the Patent Laws Were Designed to Protect*

In a subsequent case, the Federal Circuit interpreted the use of "e.g." in *Diehr* to mean that the process does not necessarily have to be a transformation or reduction of an article to a different state or thing.[203] Thus, the court of appeals concluded that a method claim that does not include a physical transformation can still be patentable under certain circumstances.[204] In *Diehr*, the Court vaguely deemed a process to be patentable if it is "performing a function which the patent laws were designed to protect."[205] Because the transformation or reduction of a physical article is absent in Claim 13, the process claim must next be analyzed to determine whether it is a process that "patent laws were designed to protect" for qualifying as statutory subject matter under 35 U.S.C. § 101.[206]

A method of detecting a disease, such as a vitamin B deficiency, is the practice of medicine.[207] Patents that exclude physicians from performing new and useful medical methods for treating sick patients, independent of a particular type of instrument, have long been

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[199] *Id.*

[200] If a future inventor were to discover a new method of measuring total homocysteine in blood without adding reagent chemicals, Claim 13 would still cover the new measuring method. *See* Brief for Petitioner at 27, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2005 WL 3543099.

[201] *See* Brief for Petitioner at 27, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2005 WL 3543099.

[202] *See* Diamond v. Diehr, 450 U.S. 175, 192 (1980).

[203] AT&T Corp. v. Excel Commc'ns, Inc., 172 F.3d 1352, 1358-59 (Fed. Cir. 1999).

[204] *Id.*

[205] *Diehr*, 450 U.S. at 192; *Excel*, 172 F.3d at 1358-59.

[206] *Excel*, 172 F.3d at 1358-59.

[207] *See* Brief Amicus Curiae of AARP In Support of Petitioner at 9-10, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

controversial.[208] In 1996, Congress enacted 35 U.S.C. § 287(c) to protect physicians from being liable for patent infringement that occurs during the performance of a medical activity.[209] Thus, a physician who is a direct infringer of a method-of-diagnosis patent would not be liable to the patentee.[210] In such a situation, the patent law (i.e., 35 U.S.C. § 287(c)) was designed to protect the physician from liability for direct infringement of the process claim.[211] Extrapolating Congress's reasoning in enacting 35 U.S.C. § 287(c), a medical diagnostic claim would not be a traditional type of claim that "patent laws were designed to protect."[212]

5. *Claim 13 Does Have a Useful, Tangible, and Concrete Result But Still Does Not Satisfy 35 U.S.C. § 101*

Metabolite Labs argued that the process in Claim 13 produced a useful, tangible, and concrete result and should therefore be patentable subject matter under 35 U.S.C. § 101.[213] Metabolite Labs noted that Claim 13 can be used to diagnose a person with a vitamin B deficiency, making it possible to prevent a potentially dangerous medical condition,[214] the output of which is a useful, tangible, and concrete result.[215]

As noted above, in *State Street Bank*, the Federal Circuit held that a process claim without a physical transformation of matter could still be patentable subject matter so long as the result was useful, tangible, and concrete.[216] However, a process claim still cannot be used to patent a

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[208] Morton v. N.Y. Eye Infirmary, 17 F. Cas. 879 (C.C.S.D.N.Y. 1862)DONALD S. CHISUM, 1-1 CHISUM ON PATENTS § 1.03[3] (2007).

[209] H.R. CONF. REP. NO. 104-863, at 852-55 (1996); Brief Amicus Curiae of AARP In Support of Petitioner at 9-10, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067); Todd Martin, *Patentability of Methods of Medical Treatment: A Comparative Study*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 381 (2000).

[210] This assumes that a physician's order of an assay would constitute a "performance of a medical ... procedure on a body" under 35 U.S.C. § 287(c). Brief Amicus Curiae of AARP In Support of Petitioner at 9-10, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067). As a side note, 35 U.S.C. § 287(c) does not apply to *LabCorp* because the '658 patent was filed on November 20, 1986, before the enactment of the statute. *Id.* at 9.

[211] Brief Amicus Curiae of AARP In Support of Petitioner at 9-10, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[212] *See id.*; Act of Sept. 30, 1996, Pub. L. No. 104-208, 110 Stat. 3009-67-68.

[213] Brief for Respondents at 36, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2006 WL 303905 (citing State Street Bank & Trust Co. v. Signature Fin. Group, 149 F.3d 1368, 1373, 1375 (Fed. Cir. 1998)).

[214] *Id.*

[215] *Id.*

[216] *State Street Bank*, 149 F.3d at 1373. Justice Breyer's dissenting opinion in *LabCorp* could be interpreted as a hint that he and at least two other Justices would overrule *State Street Bank*.

law of nature, according to the Court in *Diehr*.[217] Thus, assuming that the Federal Circuit's holding in *State Street Bank* does not conflict with the Supreme Court's holding in *Diehr*, a process claim can be patentable if (1) the claim does not constitute an attempt to patent a law of nature *and* (2) the process provides a useful, concrete, and tangible result.[218]

However, as discussed above, Claim 13 of the '658 patent is a law of nature.[219] Therefore, Claim 13 cannot be patentable subject matter under 35 U.S.C. § 101, even though the process provides a useful, tangible, and concrete result.[220]

B. THE FEDERAL CIRCUIT'S INTERPRETATION OF CLAIM 13'S SCOPE WAS TOO BROAD

In *Metabolite Labs*, the Federal Circuit broadly construed Claim 13 so that both physicians and the reference laboratory (i.e., LabCorp) infringed.[221] The court affirmed the jury's finding that LabCorp had induced infringement and that physicians had directly infringed.[222] A negative consequence of the Federal Circuit's holding is that a physician can now directly infringe a patent while simply practicing medicine.[223] Further, a reference laboratory's publication that generally describes the best practices in healthcare for detecting a deficiency in vitamin B can now be construed as an inducement to infringe.[224]

Justice Breyer noted that *State Street Bank* does say that "a process is patentable if it produces a 'useful, concrete, and tangible result.' But this Court has never made such a statement and, if taken literally, the statement would cover instances where this Court has held the contrary." Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc. (*LabCorp*), 126 S. Ct. 2921, 2928 (2006) (Breyer, J., dissenting).

[217] Diamond v. Diehr, 450 U.S. 175, 185 (1980).

[218] *See State Street Bank*, 149 F.3d at 1373; *see also* Diehr, 450 U.S. at 185.

[219] *See supra* notes 174-183 and accompanying text.

[220] *See State Street Bank*, 149 F.3d at 1373; *see also Diehr*, 450 U.S. at 185.

[221] Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1361-65 (Fed. Cir. 2004).

[222] *Id.* at 1364-65.

[223] Brief for the American Medical Association, the American College of Medical Genetics, the American College of Obstetricians and Gynecologists, the Association for Molecular Pathology, the Association of American Medical Colleges, and the College of American Pathologists as Amici Curiae in Support of Petitioner at 13-15, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[224] Brief of the American Clinical Laboratory Association as Amicus Curiae in Support of Petitioner at 12-14, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

1. *Direct Infringement by Physicians*

The Federal Circuit's holding that physicians directly infringed was a surprising result.[225] Traditionally, direct infringement of a method claim requires that a single entity perform all of the steps.[226] Thus, a physician would have to perform the assaying step and the correlating step to support a finding of direct infringement.[227] Technically, physicians did not perform the assay step, which should have prevented a finding of direct infringement.[228] The assaying step was performed at LabCorp, where the blood sample was mixed with reagent chemicals and processed with a laboratory instrument to obtain a total homocysteine concentration.[229]

The Federal Circuit inexplicably broadened the assaying step to also include the *ordering* of an assay by a physician.[230] Based on the plain language of Claim 13, the Federal Circuit has therefore appeared to establish an agency relationship between the physician and LabCorp to find that the physician effectively *performed* the assaying step.[231] This was not altogether unprecedented. Some courts have held that direct infringement can be found when an independent contractor or agent is used to perform at least one of the steps of a method patent for manufacturing an article.[232] More recently, some courts have loosened the rule for direct infringement so long as there is "some connection" between the two parties performing the method claim.[233]

The Federal Circuit found that physicians performed the correlation

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[225] *See* DONALD S. CHISUM, 5-16 CHISUM ON PATENTS SUPP. to § 16.02[6][a] (2007).

[226] *See* Mark A. Lemley, *Inducing Patent Infringement*, 39 U.C. DAVIS L. REV. 225, 226 (2005).

[227] *See id.*

[228] *See* Mobil Oil Corp. v. Filtrol Corp., 501 F.2d 282, 291-92 (9th Cir. 1974) (noting that it was questionable "whether a method claim can be infringed when two separate entities perform different operations and neither has control of the other's activities"); CHISUM, *supra* note 208, § 16.02[6][a] ("A thorny problem arises when different persons successfully perform the steps of a patented process.").

[229] *See* Brief for Amicus Curiae Perlegen Sciences, Inc. and Mohr, David Ventures in Support of Respondents at 8, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[230] Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1364 (Fed. Cir. 2004).

[231] *See* CHISUM, *supra* note 225.

[232] *E.g.*, Crowell v. Baker Oil Tools, Inc., 143 F.2d 1003, 1004 (9th Cir. 1944).

[233] Faroudja Labs., Inc. v. Dwin Electronics, Inc., No. 97-20010 SW, 1999 WL 111788, at *5 (N.D. Cal. Feb. 24, 1999) (citations omitted); E.I. DuPont De Nemours & Co. v. Monsanto Co., 903 F. Supp. 680, 735 (D. Del.1995), *aff'd*, 92 F.3d 1208 (Fed. Cir. 1996).

step, based on indirect evidence.[234] For this case, direct evidence would probably not be available unless physicians admitted to performing the correlation step in their minds. As one inventor testified, "[I]t would be malpractice for a [physician] to receive a total homocysteine assay without determining a [vitamin B] deficiency."[235] The court found that this supported the theory that physicians had performed the correlation step when merely ordering an assay.[236]

Thus, a physician must now elect either to perform the mental step of correlating a total homocysteine concentration with a vitamin B deficiency or to commit malpractice. This leads to the absurd outcome that a physician should have an irresistible impulse to think about a vitamin B deficiency every time a total homocysteine assay is ordered and therefore infringe Claim 13 of the '658 patent. Using this logic, the mere ordering of a total homocysteine test by a physician will necessarily result in a direct infringement.[237] Even if a physician intends to correlate the total homocysteine concentration with a cardiac disease, the physician must additionally perform a correlation to a vitamin B deficiency too, and therefore infringe the Claim 13 of the '658 patent.[238] Therefore, based on the broad construction, a physician cannot avoid performing the correlation step and thus infringes Claim 13 of the '658 patent when ordering a total homocysteine assay for the purpose of diagnosing a cardiac disease.[239]

In summary, based on the holding of *Metabolite Labs*, physicians can directly infringe a method-of-diagnosis claim by merely ordering an assay and thinking about it.[240] Such a broad interpretation will inhibit both the practice of medicine and research into new or improved medical assays.[241] Therefore, the rate of innovation in discovering new and better medical assays will likely decrease because of the increased possibility of patent infringement based on the holding of *Metabolite Labs*.

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[234] *Metabolite Labs*, 370 F.3d at 1364-65.

[235] *Id.* at 1364.

[236] *See id.*

[237] Brief for Petitioner at 29, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2005 WL 3543099.

[238] *Id.* at 26; *see* Brief of the American Heart Association as Amicus Curiae in Support of Petitioner at 24, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067). It should be noted that there is strong interest in using the total homocysteine assay for diagnosing and treating cardiovascular disease. *Id.* at 18-19.

[239] *See* Brief of the American Heart Association as Amicus Curiae in Support of Petitioner at 24, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[240] *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc. (*LabCorp*), 126 S. Ct. 2921, 2927 (2006) (Breyer, J., dissenting).

[241] *See id.* at 2922.

2. *LabCorp's Liability for Inducement to Infringe*

The Federal Circuit affirmed the jury's finding that LabCorp induced infringement because of its published article, which taught that elevated concentrations of total homocysteine can be correlated to a deficiency of vitamin B.[242] In other words, LabCorp was found liable for infringement by publishing sound medical advice for helping patients and saving their lives.[243] LabCorp had merely published information regarding the diagnosis and treatment of a vitamin B deficiency,[244] which was already published in a medical journal[245] and in a patent specification.[246] With the Federal Circuit's decision, the '658 patent essentially enjoins people from communicating information needed to enable better medical treatment.[247]

Under the Federal Circuit's reasoning, *anyone*, not just a medical reference laboratory like LabCorp, who publishes information stating the relationship between total homocysteine and a deficiency of vitamin B may be found liable for inducement to infringe Claim 13. Such a broad reading of medical diagnostic patents could have a chilling effect on free speech in terms of communicating good medical advice or the practice of medicine.[248] In general, a decrease in the free exchange of information will also have an effect on innovation in the area of developing new and improved medical assays.[249] Free communication of ideas generally promotes research and the development of inventions.[250] "[T]he ultimate goal of the patent system is to bring new designs and technologies into

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[242] *See* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1365 (Fed. Cir. 2004).

[243] *See* Brief Amicus Curiae of AARP In Support of Petitioner at 12-14, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[244] *See Metabolite Labs*, 370 F.3d at 1365.

[245] John Lindenbaum, M.D., Edward B. Healton, M.D., David G. Savage, M.D., John C.M. Brust, M.D., Thomas J. Garrett, M.D., Elaine R. Podell, B.A., Paul D. Marcell, B.S., Sally P. Stabler, M.D., & Robert H. Allen, M.D., *Neuropsychiatric Disorders Caused by Cobalamin Deficiency in the Absence of Anemia or Macrocytosis*, 318 NEW ENGLAND JOURNAL OF MEDICINE 1720-28 (June 30, 1988), *available at* 2005 WL 3939546, at *211.

[246] U.S. Patent No. 4,940,658 (issued July 10, 1990).

[247] *See* Brief Amicus Curiae of AARP In Support of Petitioner at 12-14, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[248] *Cf.* Washington Legal Found. v. Henney, 202 F.3d 331, 335-336 (D.C. Cir. 2000) (noting that a First Amendment right existed to provide published articles to physicians about a drug's benefits without violating the Food and Drug Administration Modernization Act (FDAMA)). Later, the FDA asserted that an amended version of the FDAMA did not prohibit the dissemination of published articles causing the constitutional issue to be moot. *Id.* at 334.

[249] *See* W. Fritz Fasse, *The Muddy Metaphysics of Joint Inventorship: Cleaning Up After the 1984 Amendments to 35 U.S.C. § 116*, 5 HARV. J. LAW & TECH. 153, 159-60 & n.37 (1992).

[250] *See id.*

the public domain through [publication]."[251]

Medical researchers must now be careful about their research activities and their publications. Based on *Madey v. Duke University*, even academic researchers can be liable for infringement of patents when performing basic research with a potential profit motive.[252] Any publication that can be construed as sound medical advice in diagnosing a disease can now be potentially used as a basis for inducement to infringe a patent.[253] In view of *Metabolite Labs*, a patent can be a prior restraint that inhibits publication of scientific information. Moving forward, a researcher will now have to contemplate searching prior patents before publishing because the researcher could potentially be liable for inducement to infringe if the publication happens to teach a process that infringes a patent.[254]

Ironically, LabCorp would likely have been better off not publishing the article and waiting for physicians to learn about the beneficial use of the assay through other means. For example, an academic researcher or a medical professional society[255] could have published the benefits of the '658 patent to educate physicians about total homocysteine measurements causing physicians to order the assay from LabCorp. Based on the holding of *Warner-Lambert v. Apotex*, LabCorp's mere knowledge alone that physicians would likely infringe the '658 patent was not enough for a finding of inducement to infringe.[256] Therefore, LabCorp could have avoided an inducement to infringe by not publishing the article and simply selling the assay to physicians who learned about the benefits through other means.[257]

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[251] Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 151 (1989).

[252] Madey v. Duke Univ., 307 F.3d 1351, 1362 & n.7 (Fed. Cir. 2002) ("[N]on-profit status of the user is not determinative" for determining if experimental use exception applies because non-profit institutions can have "an aggressive patent licensing program from which it derives a not insubstantial revenue stream").

[253] *See* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1365 (Fed. Cir. 2004).

[254] *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc. (*LabCorp*), 126 S. Ct. 2921, 2928-29 (2006) (Breyer, J., dissenting).

[255] Examples of medical professional societies are the American Medical Association, American Association of Clinical Chemistry, and American Heart Association.

[256] Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1363 (Fed. Cir. 2003) (citing Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 553 (Fed.Cir.1990)). Apotex sought to market a generic drug that could be used to infringe a new method-of-use patent owned by Warner-Lambert. *Id.* at 1352. However, the Federal Circuit found no inducement to infringe by Apotex because it did not seek to market the drug for the patented use. *See id.* at 1365. The fact that Apotex probably knew that the majority of the generic drug sales would be used for the infringing use was not enough to establish liability. *Id.*

[257] *See Warner-Lambert*, 316 F.3d at 1363.

C. PUBLIC POLICY CONSIDERATIONS

1. Claim 13 Stifles Future Development

In the past, the United States Supreme Court has used public policy to invalidate a broad patent claim that essentially preempts the field.[258] It is instructive to examine an early patent law case. Samuel Morse, who invented the telegraph, had obtained a broad claim directed to *any* method of using electromagnetism, independent of his device, for transmitting messages over any distance.[259] The Court found that the broad claim would preempt any use of the natural phenomenon known as electromagnetism for transmitting messages.[260] Because the claim gave an exclusive right to *every* improvement in which electromagnetism was used for transmitting a message, the Court invalidated this claim as being too broad.[261]

The Court noted that allowing Morse's broad claim would inhibit improvements in the field of using electromagnetism for transmitting messages and that the public would be deprived of the potential benefit.[262] The Court speculated that a future inventor might invent an improved method for transmitting messages using electromagnetism without using any part of the process or combination set forth in the Morse patent.[263] According to the Court, such improvements could be an improved machine that is less complicated, more robust, less expensive to build, and less expensive to operate.[264] The Court wanted to prevent Morse from having patent rights to all future improvements if he did not contribute to them.[265] The Court noted that allowing Morse's broad claim would prevent a future inventor from using the improved machine unless Morse provided his permission.[266] In summary, the Court held Morse's broad generic claim invalid so that the public could benefit from improvements by entities other than Morse.[267]

Morse's claim covering *any* use of electromagnetism is analogous

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[258] *See* O'Reilly v. Morse, 56 U.S. 62, 113 (1854).

[259] *See id.* at 112.

[260] *Id.* at 112-113.

[261] *Id.* at 113.

[262] *Id.*

[263] *Id.*

[264] *Id.*

[265] CHISUM, *supra* note 208, § 1.03[2][c]; *see Morse*, 56 U.S. at 113.

[266] *Morse*, 56 U.S. at 113.

[267] *Id.*

to Metabolite's claim covering *any* method of measuring total homocysteine.[268] The *use* of electromagnetism for transmitting a message necessarily included a step for *measuring* electromagnetism.[269] Additionally, Claim 13 covers unpatented methods and future methods for measuring total homocysteine concentration that is analogous to Morse's broad claim that preempted the use of electromagnetism.[270] Thus, Claim 13 would cover every improvement to the method of measuring total homocysteine even if Metabolite Labs does not contribute to the improvements, which is exactly the same situation that existed in *Morse*.[271]

The '658 patent has already prevented the public from benefiting from improvements to the total homocysteine assay. Not surprisingly, one inventor did improve the method of measuring total homocysteine after the original discovery cited in the '658 patent.[272] Abbott Laboratories commercialized an improved assay, which required only a few minutes as opposed to upwards of eighteen hours with the Metabolite method.[273] Additionally, the Abbott assay was less labor-intensive and therefore less expensive than the Metabolite assay.[274] The public could potentially benefit from the Abbott assay in the form of reduced assay cost and a reduced turnaround time.[275] However, the jury's finding that a physician's use of Abbott's improved assay infringed Claim 13 was upheld by the Federal Circuit.[276] Thus, Metabolite Labs can block the use of the improved assay even though it did not contribute to the improvement. In summary, Claim 13 should be invalidated based on the public policy reasons described in *Morse*; otherwise the public cannot benefit from improvements to the assay.[277]

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[268] *Compare* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1358-59 (Fed. Cir. 2004) *with Morse*, 56 U.S. at 112.

[269] *See Morse*, 56 U.S. at 112-13. The measurement step occurred when the armature moved in response to the presence or absence of a sufficient amount of electromagnetism to form a dot or a dash.

[270] *Compare Metabolite Labs*, 370 F.3d at 1358-59, *with Morse*, 56 U.S. at 112.

[271] *Morse*, 56 U.S. at 112-13.

[272] Brief for Petitioner at 9, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067), *available at* 2005 WL 3543099.

[273] *Id.*

[274] *Id.*

[275] In general, a short test time has a big advantage because a physician can communicate the results to the patient faster. Additionally, the physician can start treatment for the vitamin B deficiency much sooner.

[276] *See* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1365 (Fed. Cir. 2004).

[277] *See* O'Reilly v. Morse, 56 U.S. 62, 112-13 (1854).

2. *Broad Method Claims Will Inhibit Future Research Needed by the Public—An Example Is a Genetic Test for Breast Cancer*

There is a great need to develop new and improved medical assays to help identify diseases and to provide better treatment options to the patient.[278] In particular, there has been an explosion in research activity for genetic tests.[279] New and better genetic tests may allow earlier and more accurate diagnosis of diseases, better prediction of whether a patient will be diagnosed with a particular disease in the future, personalized drugs that are adapted for maximal efficacy based on a person's genetic sequence, and faster development cycles for drug development.[280] Allowing broad diagnostic claims, as did the court of appeals in *Metabolite Labs*,[281] will have a chilling effect on the development of better laboratory assays.[282] The following illustrates the chilling effect on future research by describing an example of a genetic test that has a need for improvement but is limited because of broad method claims.

Myriad Genetics offers a genetic test that predicts whether a person has a strong likelihood of getting breast cancer.[283] If a person has a mutated BRCA1 or BRCA2 gene, then the person has a thirty-six to eighty-five percent chance of getting breast cancer.[284] In comparison, about thirteen percent of the general population will be diagnosed with breast cancer.[285] The discovery of a gene that predicts an increased likelihood of getting breast cancer was a pioneering breakthrough.[286] From the patient's viewpoint, however, the BRCA1 and BRCA2 test

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[278] *See* Brief of the American Clinical Laboratory Association as Amicus Curiae in Support of Petitioner at 8-13, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[279] *See* Brief for Amicus Curiae Affymetrix, Inc. and Professor John H. Barton in Support of Petitioner at 15-20, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[280] *See id.*

[281] *Metabolite Labs*, 370 F.3d at 1363-64.

[282] *See* Brief for Amicus Curiae Affymetrix, Inc. and Professor John H. Barton in Support of Petitioner at 20, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[283] Melissa E. Horn, Note, *DNA Patenting and Access to Healthcare: Achieving the Balance Among Competing Interests*, 50 CLEV. ST. L. REV. 253, 269 (2002).

[284] National Cancer Institute: U.S. National Institute of Health, Genetic Testing for BRCA1 and BRCA2, http://www.nci.nih.gov/cancertopics/factsheet/Risk/BRCA (last visited Sept. 25, 2006).

[285] *Id.*

[286] *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 699 (1998).

may cause more confusion than it is worth.[287] For instance, even if the mutation is detected, there is up to a sixty-four percent chance that the patient will not get breast cancer.[288] In other words, a patient who was diagnosed as having the BRCA1 or BRCA2 gene will have to deal with the stress of *possibly* getting breast cancer for the rest of his or her life, even though there is still a significant chance (up to sixty-four percent) that breast cancer will not occur.[289]

A person who has a mutated BRCA1 or BRCA2 gene will struggle with whether to take preemptive action to improve his or her outcome.[290] Although the person may be a prime candidate for considering an experimental drug[291] or procedure[292] to prevent the onset of breast cancer, there will be a risk of serious side effects.[293] To further complicate matters, as many as sixty-four out of a hundred people with the gene mutation will not get the disease and will thus be treated unnecessarily.[294] Therefore, although the BRCA1 and BRCA2 test for breast cancer shows great promise, there is a clear need to improve the test's predictive power.[295]

For entities other than Myriad Genetics, there is little incentive to develop a better multiple gene test that uses BRCA1 or BRCA2, because such a test will infringe one of Myriad Genetics' patents.[296] Myriad

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[287] *See* David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 BERKELEY TECH. L.J. 985, 1005-06 (2005).

[288] National Cancer Institute: U.S. National Institute of Health, Genetic Testing for BRCA1 and BRCA2, http://www.nci.nih.gov/cancertopics/factsheet/Risk/BRCA (last visited Sept. 25, 2006).

[289] *Id.*

[290] *See id.*

[291] An example of an experimental drug for preventing breast cancer is tamoxifen. National Cancer Institute: U.S. National Institute of Health, Genetic Testing for BRCA1 and BRCA2, http://www.nci.nih.gov/cancertopics/factsheet/Risk/BRCA (last visited Sept. 25, 2006).

[292] As an extreme example of an experimental procedure, some women with the gene mutation have elected to remove their breast tissue (i.e., mastectomy) to prevent the *possible* occurrence of breast cancer. National Cancer Institute: U.S. National Institute of Health, Genetic Testing for BRCA1 and BRCA2, http://www.nci.nih.gov/cancertopics/factsheet/Risk/BRCA (last visited Sept. 25, 2006).

[293] An example of an experimental drug that caused serious side-effects was Prempro (hormone replacement therapy). Biospace.com, http://www.biospace.com/news_story.aspx?StoryID=8486 (last visited Dec. 31, 2006). A large scale NIH study showed that Prempro actually increased the risk of breast cancer as well as the risk of other diseases such as heart disease, stroke, and dementia. *Id.* Unfortunately, a significant number of women used Prempro and, in the process, helped Wyeth generate about one billion dollars in sales for the year 2001. *Id.*

[294] National Cancer Institute: U.S. National Institute of Health, Genetic Testing for BRCA1 and BRCA2, http://www.nci.nih.gov/cancertopics/factsheet/Risk/BRCA (last visited Sept. 25, 2006).

[295] *See* David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 BERKELEY TECH. L.J. 985, 1005-06 (2005).

[296] *See* Melissa E. Horn, Note, *DNA Patenting and Access to Healthcare: Achieving the*

Genetics has a broad method claim that essentially patents a law of nature similar to Claim 13 of the '658 patent.[297] Any improved test that uses BRCA1 or BRCA2 will require a license from Myriad Genetics.[298] Assuming that Myriad Genetics would grant a reasonable license,[299] the researcher would then be burdened with increased costs for developing the improved assay or risk being sued for patent infringement.[300] Because research is a high-risk and costly investment, researchers will tend to avoid developing better assays that require a licensing agreement and look to develop new assays that are unencumbered by existing patents.[301]

Discovering a better breast-cancer-prediction assay in an expedited manner that uses multiple genes[302] including either BRCA1, BRCA2, or a combination thereof is a very complicated problem that would likely require a large-scale effort using the world's best and brightest

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Balance Among Competing Interests, 50 CLEV. ST. L. REV. 253, 264-267 (2002).

[297] *Compare* U.S. Patent No. 4,940,658 (issued July 10, 1990) (correlating an elevated level of total homocysteine with diagnosing a vitamin B deficiency) *with* U.S. Patent No. 5,709,999 (issued Jan. 20, 1998) (correlating the presence of a particular gene mutation with the likelihood of developing breast cancer); Brief for Amicus Curiae Affymetrix, Inc. and Professor John H. Barton in Support of Petitioner at 18-20, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[298] *See* Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133, 149 (2004).

[299] Myriad Genetics has not granted an exclusive license to anyone for the breast cancer patents. Shanshan Zhang, Comment, *High Tech Law Institute Publications: Proposing Resolutions to the Insufficient Gene Patent System*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1139, 1159 (2004).

[300] *See* Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133, 149-50 (2004). The risk of being sued for patent infringement appears to be significant. Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services, Journal of Molecular Diagnostics*, 25 JOURNAL OF MOLECULAR DIAGNOSTICS 3, 5 (2003), *available at* http://www.bioethics.upenn.edu/prog/ethicsgenes/pdf/cho_etal_2003.pdf. A survey of laboratories performing genetic tests showed that sixty-five percent of the laboratories have been contacted by a patent holder regarding potential infringement. *Id.* In addition, about fifty percent of the survey participants decided not to develop or perform a genetic test specifically because of intellectual-property considerations. *Id. at 7.*

[301] *See* Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133, 149-150 (2004).

[302] *See* Melissa E. Horn, Note, *DNA Patenting and Access to Healthcare: Achieving the Balance Among Competing Interests*, 50 CLEV. ST. L. REV. 253, 272-273 (2002). One logical possibility for improving the test's predictive power is to discover one or more genes that can be combined with either the BRCA1 or BRCA2 gene. *Id.* The theory is that two genes (or more) are better than one for predicting a complicated disease such as breast cancer. *See id.*

researchers.[303] Because Myriad Genetics is only one company, it does not have sufficient resources to try all possible combinations of genes and strategies to improve the assay. As a result, Myriad Genetics may have an underutilized monopoly on a natural phenomenon that is an important piece for solving the breast-cancer-prediction puzzle.[304] Thus, Myriad Genetics is likely slowing down the progress of improving the assay because of its broad patent position.[305]

Myriad Genetics may have little financial incentive to incrementally improve its assay for breast cancer. Because Myriad Genetics can charge a relatively high fee for its test,[306] it may not want to bother taking on the financial risk to incrementally improve its technology. Thus, Myriad Genetics may be able to make more money by simply selling the BRCA1 and BRCA2 test until its patents expire, because of its broad patent position. To further complicate matters, Myriad Genetics may not be able to recoup its investment costs through increased sales by improving its test, because the current test may be too profitable.[307]

In summary, there is a need to incrementally improve diagnostic assays such as the BRCA1 and BRCA2 test, but allowing patents with broad method claims will inhibit such improvements.[308] With the breast-cancer test, for example, more reliable laboratory tests will enable better treatments or at least enable more rational decisions about electing experimental treatments.[309] The public has a need for better laboratory

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[303] *See* David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 BERKELEY TECH. L.J. 985, 1006-1024 (2005). "[T]he dichotomy between genetic-data production and invention creates an environment in which research opportunities are, as a practical matter, unbounded because they far exceed the capacities of the scientific community." *Id.* at 1017.

[304] *See* Melissa E. Horn, Note, *DNA Patenting and Access to Healthcare: Achieving the Balance Among Competing Interests*, 50 CLEV. ST. L. REV. 253, 270 (2002).

[305] *See id.* at 266. This situation has been referred to as a "tragedy of the anticommons," where a resource is underused "because too many people are excluded from using the resource," as is the case when a natural phenomenon is patented. *See id.*

[306] *See* Shanshan Zhang, Comment, *High Tech Law Institute Publications: Proposing Resolutions to the Insufficient Gene Patent System*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1139, 1159 (2004). Myriad Genetics charges about $2700 per test that is performed exclusively at Myriad Genetics' laboratory in Utah. *Id.* at 1159-60. Therefore, all blood samples from around the world must be sent to only one laboratory in Utah to have a BRCA1 or BRCA2 test performed. *Id.*

[307] *See* Shanshan Zhang, Comment, *High Tech Law Institute Publications: Proposing Resolutions to the Insufficient Gene Patent System*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1139, 1159 (2004).

[308] Melissa E. Horn, Note, *DNA Patenting and Access to Healthcare: Achieving the Balance Among Competing Interests*, 50 CLEV. ST. L. REV. 253, 268 (2002).

[309] *See* National Cancer Institute: U.S. National Institute of Health, Genetic Testing for BRCA1 and BRCA2, http://www.nci.nih.gov/cancertopics/factsheet/Risk/BRCA (last visited Sept. 25, 2006).

tests that can be used as a tool for improving healthcare.[310] There is a large number of diseases that could be potentially diagnosed and treated more effectively through improved diagnostic testing, such as Alzheimer's disease, rheumatoid arthritis, cardiovascular disease, diabetes, osteoporosis, schizophrenia, and autism.[311] However, researchers will not have an incentive to take on the risk of incrementally improving an assay if broad diagnostic claims are allowed to remain valid, even when there is a market-driven, unmet need for such an improvement.[312]

III. CONCLUSION

The United States Supreme Court should have reversed the Federal Circuit's holding in *Metabolite Labs*.[313] The method-of-diagnosis claim in *Metabolite Labs* is the equivalent of a mathematical formula that wholly preempts a law of nature.[314] Further, the method-of-diagnosis claim in *Metabolite Labs* does not entail a physical transformation of matter to satisfy 35 U.S.C. § 101 based on *Diehr*.[315] Claim 13 of the '658 patent does provide a useful, tangible, and concrete result for diagnosing a medical disease, satisfying the requirements of *State Street Bank*,[316] but it still does not satisfy 35 U.S.C. § 101, because Claim 13 is an attempt to patent a law of nature. The Federal Circuit affirmed a construction of the method-of-diagnosis claim that is so broad that improvements to medical assays and healthcare will now be stifled.[317]

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[310] Brief for Amicus Curiae Affymetrix, Inc. and Professor John H. Barton in Support of Petitioner at 12-20, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[311] Brief for Amicus Curiae Perlegen Sciences, Inc. and Mohr, David Ventures in Support of Respondents at 21, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-067).

[312] *See* Melissa E. Horn, Note, *DNA Patenting and Access to Healthcare: Achieving the Balance Among Competing Interests*, 50 CLEV. ST. L. REV. 253, 269 (2002).

[313] Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc. (*LabCorp*), 126 S. Ct. 2921 (2006); Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (Fed. Cir. 2004).

[314] *See supra* notes 174-183 and accompanying text.

[315] *LabCorp*, 126 S. Ct. at 2927 (Breyer, J., dissenting); Diamond v. Diehr, 450 U.S. 175, 192 (1980).

[316] State Street Bank & Trust Co. v. Signature Fin. Group, 149 F.3d 1368, 1373 (Fed. Cir. 1998).

[317] *Metabolite Labs*, 370 F.3d at 1358.

*TIMOTHY J. OHARA**

*J.D., Candidate, 2008, Golden Gate University School of Law, San Francisco, CA; B.S. Chemistry, 1988, University of California, Berkeley; Ph.D. Chemistry, 1994, University of Texas at Austin. Dr. Ohara is registered with the U.S. Patent and Trademark Office and currently works in the medical diagnostic field as a Principal Scientist at LifeScan Inc., A Johnson & Johnson Company. All opinions stated herein are solely those of the author and do not necessarily reflect the views of LifeScan Inc. or Johnson & Johnson. I would like to thank my editors, Josh Shey, Dije Ndreu, and Gwynneth F. Smith, and my advisor, William T. Gallagher, for their help in reviewing this work. Lastly, I would also like to thank my family, Carol, Lillian, and Matthew, for their moral support in completing this work