
**The Supreme Court’s
Missed Opportunity to
Settle the Handiwork of
Nature Exception to
Patentable Subject Matter
in *Laboratory Corporation
of America v. Metabolite
Laboratories,*
126 S. Ct. 2921 (2006)**

Daniel T. Marvin*

I. INTRODUCTION

The laws of nature, abstract ideas, and natural phenomena are not patentable subject matter, and thus cannot be patented, because such discoveries and creations “are manifestations . . . of nature, free to all men and reserved exclusively to none.”¹ In *Laboratory Corporation of America v. Metabolite Laboratories, Inc.*

* J.D. candidate, May 2008, Temple University James E. Beasley School of Law. Bachelor of Science in Political Science and Philosophy, 2005, University of Scranton. The author would like to thank

(*Metabolite II*),² the Supreme Court of the United States of America initially granted a writ of certiorari, only to dismiss the case as improvidently granted.³ In so doing, the Court let stand a patent claim⁴ that included a medical professional's mental process—interpreting a nonproprietary test result and applying well-known medical knowledge of a natural correlation—to determine whether a patient had a vitamin deficiency.⁵ By dismissing this writ of certiorari, the Court dismissed an opportunity to clarify the process patent jurisprudence of the United States Court of Appeals for the Federal Circuit [Federal Circuit].⁶

Although the Patent Act⁷ permits processes to be patented, by including them in the subject matter eligible for patent protection,⁸ the Federal Circuit has struggled to decide which processes qualify as statutory subject matter.⁹ The Supreme Court has long held that laws of nature, natural phenomenon, and abstract ideas are excluded from subject matter eligible for patent protection.¹⁰ However, the *State Street*¹¹ test currently utilized by the Federal Circuit to determine if an invention is patentable subject matter requires that the invention produce only a “useful, concrete and tangible result.”¹² This *State Street* test led to the result in *Metabolite*, in which the Federal Circuit upheld a patent claim on a medical thought process.¹³

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¹ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)) (omission in original).

² 126 S. Ct. 2921 (2006) (mem.) (per curiam).

³ *Id.*

⁴ A patent claim is “a formal statement describing the novel features of an invention and defining the scope of the patent’s protection.” BLACK’S LAW DICTIONARY 1160 (8th ed. 2004).

⁵ See *infra* Part IV (arguing that the Court should have definitively decided *Metabolite*).

⁶ See *infra* Part III (detailing background, procedural history, and the Circuit Court’s decision in *Metabolite*). See also *infra* Part IV.A (noting that the Court’s dismissal of the writ of certiorari leaves the law on patentable subject matter uncertain).

⁷ 35 U.S.C. § 101 (2000) (establishing process as a patentable subject matter).

⁸ *Id.*

⁹ See Michael Meehan, *The Handiwork of Nature Patentable Subject Matter and Laboratory Corporation v. Metabolite Labs*, 16 ALB. L.J. SCI. & TECH. 311, 337 (2006) (discussing different tests the Federal Circuit employed to analyze process patent claims). The Court of Claims and Patent Appeals, predecessor to the Federal Circuit, developed a two-step *Parker-Walter-Abele* test for determining if a claim including a mathematical algorithm was unpatentable subject matter. *Id.*

¹⁰ See, e.g., *Diamond v. Diehr*, 450 U.S. 175, 191 (1981) (holding that a patent on a new process for molding rubber, albeit based on a mathematical formula, was patentable subject matter because the natural law was put to new and useful ends); *Chakrabarty*, 447 U.S. at 309-10 (allowing a patent on artificially created bacterium because the bacterium is not a work of nature); *Parker v. Flook*, 437 U.S. 584, 594-95 (1978) (invalidating a patent claim for utilizing a computer to calculate the alarm limit for a catalytic conversion process as non-patentable subject matter because the claim only covered a mathematical formula); *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972) (ruling that a method for converting binary coded decimal numerals into pure binary numerals, for general use in a computer, was not patentable subject matter); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948) (invalidating a patent on an inoculant for root nodule bacteria in plants because such a discovery is merely “the discovery of some of the handiwork of nature and hence is not patentable”).

¹¹ *State St. Bank & Trust Co. v. Signature Fin. Group*, 149 F.3d 1368 (Fed. Cir. 1998).

¹² *Id.* at 1375 (quoting *In re Alappat*, 33 F.3d 1526, 1544 (Fed. Cir. 1994) (en banc)).

¹³ See Brooks Gifford, Paper, *Oh, Diehr: the CAFC’s Troubling Patent Eligibility Jurisprudence as Applied in Metabolite Laboratories v. Labcorp*, 25 BIOTECHNOLOGY L. REP. 129, 134, 138 (2006) (arguing that the Federal Circuit’s current jurisprudence on process patent eligibility is too broad, and led

As Justice Breyer's dissent from the certiorari dismissal in *Metabolite* correctly notes, the *State Street* test currently utilized by the Federal Circuit is broader than the Supreme Court's own precedent.¹⁴ Thus, the Court should have decided *Metabolite* to clarify the Federal Circuit's patentable subject matter jurisprudence, which this Comment will suggest is in need of clarification, if not correction.¹⁵

Additionally, by leaving the Federal Circuit's decision undisturbed, the Court ignored the consequences of such broad patentability on the free dissemination of information, medical practice, and research into public health.¹⁶ The precedent of allowing Claim 13, in *Metabolite*, may permit patenting of natural correlations, the discoveries of which are essential to progress in both laboratory sciences and genetic testing.¹⁷ Furthermore, although the specific issue of patentable subject matter was not raised in the lower courts, the Court could have readily decided *Metabolite* based on the record before it.¹⁸ The issue of patentable subject matter had been "fully briefed and argued by the parties, the Government and 20 amici."¹⁹

Finally, deciding *Metabolite* would have been consistent with the Court's recent pattern of clarifying the Federal Circuit's patent jurisprudence.²⁰ For example, the Court intervened in the Federal Circuit's jurisprudence by replacing the Federal Circuit's practice of granting automatic injunctions against patent infringers with the traditional balancing test of equity law.²¹ The Court abolished the market power presumption that an arrangement tying an unpatented product to a patented product creates a monopoly for the unpatented patent.²² The Court ruled that a licensor

that court to uphold Metabolite's patent claim improperly).

¹⁴ *Laboratory Corp. of Am. v. Metabolite Labs., Inc.*, 126 S. Ct. 2921, 2928 (2006) (mem.) (Breyer, J., dissenting) (observing that the *State Street* test "if taken literally . . . would cover instances where this Court has held the contrary").

¹⁵ See *infra* Part IV.A (arguing that the Court should have decided *Metabolite* to correct the Federal Circuit's patentable subject matter jurisprudence to the Court's own precedent).

¹⁶ See *infra* Part IV.B (discussing the negative impact of *Metabolite*'s patent, and the resulting precedent, on the free flow of important medical information, the practice of medicine, laboratory science, public health research, and genetics research).

¹⁷ See *infra* Part IV.B (observing potential negative impact of *Metabolite* precedent on the development of new tests in laboratory sciences and genetic testing if natural correlations underlying those tests were patentable subject matter).

¹⁸ See *infra* Part IV.C (noting that the Court's failure to determine the validity of *Metabolite*'s patent creates uncertainty in, and will likely limit progress in, medical practice).

¹⁹ *Laboratory Corp. of Am. v. Metabolite Labs., Inc.*, 126 S. Ct. 2921, 2926 (2006) (mem.) (Breyer, J., dissenting).

²⁰ See, e.g., *KSR Int'l Co. v. Teleflex, Inc. (KSR II)*, 2007 WL 1237837, at *12 (U.S. Apr. 30, 2007), *rev'g* *Teleflex, Inc. v. KSR Int'l Co. (KSR I)*, 119 Fed. App'x 282 (Fed. Cir. 2005) (nonprecedential) (rejecting the Federal Circuit's approach to obviousness as being too rigid); *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 774 (2007), *rev'g* 427 F.3d 958 (Fed. Cir. 2005) (reversing Federal Circuit decision that required party to stop paying royalties on patent before seeking declaratory judgment to declare patent invalid); *eBay, Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837, 1839 (2006) (replacing longstanding presumption in favor of issuing injunctions against patent infringers with traditional equity test for injunctions); *Ill. Tools Works, Inc. v. Indep. Ink, Inc.*, 126 S. Ct. 1281, 1292 (2006) (abolishing market power presumption that tying unpatented product causes an antitrust violation because of the market power of the patented product).

²¹ *eBay, Inc.*, 126 S. Ct. at 1839 (ruling that "well established principles of equity" also "apply with equal force to disputes arising under the Patent Act").

²² *Ill. Tool*, 126 S. Ct. at 1293 ("Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee. Today, we reach the same conclusion, and therefore hold that, in all cases involving a tying arrangement, the plaintiff must prove that the defendant has market power in the tying product.").

under a patent does not have to cease paying royalties on the patent before a court will have subject matter jurisdiction over the licensor's declaratory judgment regarding the patent's validity, and in so doing reversed the Federal Circuit.²³ Furthermore, the Court has granted certiorari to evaluate the Federal Circuit's test for determining if a patent should be invalidated for obviousness.²⁴ The Court should have similarly decided *Metabolite* to address and clarify another area of Federal Circuit jurisprudence.²⁵

Because the patent claim at issue in *Metabolite* may preempt a natural law, natural phenomena, or abstract idea,²⁶ Part II of this comment will review the exclusion of natural laws, natural phenomena, and abstract ideas from patentable subject matter, as established by the Supreme Court, and recently developed by the Federal Circuit. Part III of this comment will focus on the history of the *Metabolite* case itself, from the background of the patent to the Court's dismissal of the writ of certiorari. Part IV will explain why the Supreme Court should have issued a definitive decision in *Metabolite*.

II. OVERVIEW OF PROCESS PATENT JURISPRUDENCE

Congress has declared that "any new and useful process, machine, manufacture, or composition of matter"²⁷ is subject matter eligible for a patent, provided that the patent satisfies the other requirements of the Patent Act.²⁸ The United States Supreme Court construed patentable subject matter extremely broadly, including "anything under the sun that is made by man."²⁹ The Court has, however, tempered this broad scope by recognizing that laws of nature, natural phenomena, and abstract ideas are excluded from patent protection.³⁰ The United States Court of Appeals for the Federal Circuit has had considerable difficulty in developing a consistent patentable subject matter jurisprudence since the Supreme Court's last decision on patent subject matter eligibility in 1981.³¹

In applying the statute and Supreme Court precedent, the Federal Circuit originally applied the *Freeman-Walter-Abele*³² test to determine whether the subject

²³ *MedImmune, Inc.*, 127 S.Ct. at 777 (finding that a licensee under a patent need not violate the license before seeking a declaratory judgment challenging the validity of that patent).

²⁴ *KSR II*, 2007 WL 1237837, at *14 (determining that the Federal Circuit erred by transforming "a general principle into a rigid rule that limits the obviousness inquiry").

²⁵ See *infra* Part IV.D (noting Supreme Court's recent involvement in patent issues).

²⁶ Numerous authorities argue that the *Metabolite*'s patent claim preempts a natural phenomena or a law or nature. See, e.g., *Lab. Corp. of Am. v. Metabolite Labs., Inc. (Metabolite II)*, 126 S. Ct. 2921, 2927 (2006) (mem.) (per curiam) (Breyer, J., dissenting) (noting that the claim is likely an unpatentable natural phenomenon); Meehan, *supra* note 9, at 323 (arguing that "Claim 13 of the '658 patent is unpatentable because it is drawn to a law of nature").

²⁷ Patent Act, 35 U.S.C. § 101 (2000).

²⁸ *Id.* (requiring that the applicant for such an invention "may obtain a patent therefor, subject to the conditions and requirements of this title," such requirements including novelty and nonobviousness).

²⁹ *Diamond v. Diehr*, 450 U.S. 175, 182 (quoting S. REP. NO. 82-1979, at 5 (1952)).

³⁰ *Diehr*, 450 U.S. at 185 (citing *Parker v. Flook*, 437 U.S. 584 (1978)).

³¹ See Meehan, *supra* note 9, at 337-38 (discussing two different tests the Federal Circuit and its predecessor court employed to determine if a claim was drawn to patentable subject matter since the Supreme Court decided *Diehr*).

³² *In re Freeman*, 573 F.2d 1237, 1245 (C.C.P.A. 1978), modified by *In re Walter*, 618 F.2d 758, 767 (C.C.P.A. 1980), clarified by *In re Abele*, 684 F.2d 902, 907 (C.C.P.A. 1982).

matter of a patent was eligible for patent protection.³³ The *Freeman-Walter-Abele* test was a two-step test that first required analyzing a patent claim to see if the claim directly or indirectly contained a mathematical algorithm.³⁴ If the claim contained a mathematical algorithm, the claim as a whole would be analyzed to see if the claim was drawn to new and inventive means, in which case the claim would be valid subject matter.³⁵ Starting with *In re Alappat*,³⁶ the Federal Circuit began to limit, and eventually discard, the *Freeman-Walter-Abele* test in favor of the *State Street*³⁷ test focusing solely on whether the invention produced a “useful, concrete, and tangible result.”³⁸ This newer test, however, did not prove effective when it allowed the Federal Circuit to validate the questionable subject matter covered by the patent in *Metabolite*.³⁹

A. Statutory Basis for Patentable Subject Matter

The statutory language that specifies the scope of subject matter eligible for patent protection is extremely broad.⁴⁰ Section 101 of the Patent Act provides that: “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”⁴¹ The Supreme Court construed the scope of § 101 to encompass “anything under the sun made by man.”⁴² Section 101 describes, generally, which inventions and discoveries are eligible for patent protection, although such inventions still must satisfy other requirements of the code, including novelty⁴³ and non-obviousness.⁴⁴

B. The Supreme Court’s “Handiwork of Nature” Exception to Patentable Subject Matter

The Supreme Court, despite the broad literal scope of statutory subject matter under § 101, excluded certain types of discoveries and creations from patentable subject matter.⁴⁵ The Court acknowledged that it is improper to believe that “§ 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable.”⁴⁶ The Court provided

³³ Meehan, *supra* note 9, at 337.

³⁴ *Abele*, 684 F.2d at 907.

³⁵ *Id.*

³⁶ 33 F.3d 1526 (Fed. Cir. 1994) (en banc) (Part I plurality).

³⁷ *State St. Bank & Trust Co. v. Signature Fin. Group*, 149 F.3d 1368 (Fed. Cir. 1998).

³⁸ *Id.* at 1375 (quoting *In re Alappat*, 33 F.3d 1526, 1544 (Fed. Cir. 1994) (en banc)).

³⁹ *Metabolite Labs., Inc. v. Lab. Corp. of Am. (Metabolite I)*, 370 F.3d 1354, 1368 (Fed. Cir. 2004) (“[T]his court rejects LabCorp’s various attempts to invalidate claim 13.”).

⁴⁰ *See Diehr*, 450 U.S. at 182 (stating that patenting subject matter includes “anything under the sun made by man”).

⁴¹ 35 U.S.C. § 101 (2000).

⁴² *Diehr*, 450 U.S. at 182 (quoting S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952)). The Court based its analysis of the scope of § 101 largely on the Congressional intent and legislative history. *Id.*

⁴³ 35 U.S.C. § 102 (2000).

⁴⁴ *Id.* § 103 (2000).

⁴⁵ *Parker v. Flook*, 437 U.S. 584, 589 (1978) (quoting *Gottchalk v. Benson*, 409 U.S. 63, 67 (1972)).

⁴⁶ *Chakrabarty*, 447 U.S. 303, 309 (1980) (citing *Flook*, 437 U.S. 584 (1978)). *See also* *Gottschalk v.*

examples, such as “a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity.”⁴⁷ The Court explained that these exclusions are “manifestations of . . . nature, free to all men and reserved exclusively to none.”⁴⁸

The Court enforced its exclusion of natural law, natural phenomena, and abstract ideas from patentable subject matter when it invalidated patent claims in *Gottschalk v. Benson*,⁴⁹ and *Parker v. Flook*.⁵⁰ In *Benson*, the Court invalidated a patent claim on a means to convert binary coded decimal numbers into pure binary numbers for use in digital computers.⁵¹ The Court observed that Benson’s process claim covered a process that could be done mentally.⁵² The Court also noted that the breadth of the patent was “so abstract and sweeping as to cover both known and unknown uses.”⁵³ After examining its past process patent jurisprudence, the Court recognized that “one may not patent an idea.”⁵⁴ Because Benson’s patent lacked practical application outside of digital computing, and would preempt others from utilizing the mathematical formula, effectively patenting a mathematical algorithm, the Court invalidated Benson’s patent.⁵⁵

In *Parker v. Flook*, the Court invalidated a patent on a formula for calculating and updating the alarm limit in a catalytic conversion process.⁵⁶ The patent contained only a mathematical formula for computing and updating an alarm limit using a computer, although such calculations could be done manually.⁵⁷ The Court observed that “scientific truth, or the mathematical expression of [it], is not a patentable

Benson, 409 U.S. 63, 67 (1972) (“Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”). This exemption of the handiwork of nature from patentable subject matter does not apply to normally natural phenomena that were created artificially, as illustrated in *Chakrabarty*. 447 U.S. 303. In *Chakrabarty*, the Court upheld a patent on an artificially created bacterium that was effective in breaking down oil, and thus effective in treating oil spills. *Id.* at 305. The Court reasoned that the patented bacterium did not fall within the handiwork of nature exception to patentable subject matter because the bacteria was artificially designed, i.e. created by humanity and not by nature. *Id.* at 309-10.

⁴⁷ *Chakrabarty*, 447 U.S. at 309.

⁴⁸ *Id.* (quoting *Funk Bros.*, 333 U.S. at 130). It has been suggested that this exclusion is necessary to preserve a public domain of natural laws, abstract ideas, and natural phenomena available to all of science and society for future research and development. Eileen M. Kane, Patent Ineligibility: Maintaining a Scientific Public Domain, 80 ST. JOHN’S L. REV. 519, 545 (2006).

⁴⁹ 409 U.S. 63 (1972).

⁵⁰ 437 U.S. 584 (1978).

⁵¹ *Benson*, 409 U.S. at 64. Although humans utilize decimal base ten numbers (0, 1, 2, 3, 4, 5, 6, 7, 8, and 9), digital computers process information in binary numbers (0 and 1). *Id.* at 66. Thus, for computer operation, it is necessary to convert decimal numbers understandable by humans into binary numbers understandable by computers. *Id.* at 65. Benson claimed a patent on a mathematical process to convert decimal numbers into binary numbers. *Id.*

⁵² *Id.* at 67 (“The mathematical procedures can be carried out in existing computers long in use, no new machinery being necessary. And, as noted, they can also be performed without a computer.”).

⁵³ *Id.* at 68 (“The end use may vary from the operation of a train to verification of drivers; licenses to researching the law books.”).

⁵⁴ *Benson*, 409 U.S. at 71.

⁵⁵ *Id.* at 71-72.

⁵⁶ *Flook*, 437 U.S. at 594. During a catalytic conversion process, when any “process variable (including temperature, pressure or flow rate), exceeds the predetermined “alarm limit,” it indicates an abnormality in the conversion process, and a possible inefficiency or unsafe condition.” *Id.* at 585.

⁵⁷ *Id.* at 586.

invention.”⁵⁸ Although the claim included activity of updating the alarm limit, the Court refused to uphold the patent claim because any competent drafter could transform an unpatentable mathematical formula into potentially patentable subject matter by attaching a valid process to the formula.⁵⁹ The Court reasoned that the patent only covered the mathematical formula for calculating the alarm limit, and was thus an impermissible attempt to patent a law of nature.⁶⁰

The *Flook* Court observed that a discovery of the handiwork of nature, while itself inherently unpatentable, may serve as the basis for a patentable process or device when put to some useful end.⁶¹ Such was the case in *Diamond v. Diehr*,⁶² where the Court upheld a patent on a computerized system for both calculating the optimal curing time for a rubber press, and opening the press at the appropriate time.⁶³ The patented process in *Diehr* offered a new process of curing rubber in a press, including a new means of measuring the temperature of rubber while it was curing.⁶⁴ The process relied upon Arrhenius’s law, a well-established mathematical formula specifying the curing time for rubber.⁶⁵ The Court held that although the invention incorporated a natural law, Diehr utilized the natural law to the useful end of a more efficient and effective process for implementing the equation, and therefore, the Court upheld the patent.⁶⁶

Thus, the handiwork of nature exception requires patents to be invalidated for lack of subject matter when the patents preempt laws of nature, mathematical formula, or abstract ideas.⁶⁷ However, the Court has upheld patents as valid subject matter when abstract ideas, mathematical formulas, or laws of nature are merely part of an invention.⁶⁸ The Court, summarized this principle in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*,⁶⁹ nearly sixty years ago: “he who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such discovery, it must come from the application of the law of nature to a new and useful end.”⁷⁰

⁵⁸ *Id.* at 591 (quoting *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939)).

⁵⁹ *Id.* at 590. See also Gifford, *supra* note 13, at 132 (“The principle advantage of the *Flook* rule is that a ‘competent draftsman’ is unable to evade it merely by appending novel and nonobvious non-statutory matter to a prior art invention.”).

⁶⁰ *Flook*, 437 U.S. at 594.

⁶¹ *Id.* at 591 (quoting *Funk Bros.*, 333 U.S. at 130).

⁶² 450 U.S. 175 (1981).

⁶³ See *Diehr*, 450 U.S. at 177-79 (discussing the details of Diehr’s patent).

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.* at 188 (quoting *Funk Bros.*, 333 U.S. at 130).

⁶⁷ See, e.g., *Flook*, 437 U.S. at 594 (invalidating patent claim on formula for calculating alarm limits in catalytic conversions); *Benson*, 409 U.S. at 71-72 (ruling that patent claim on computer program to convert binary coded decimal numbers into binary numbers was improper subject matter for patent protection).

⁶⁸ See *Diehr*, 450 U.S. at 179 (holding that patent on a new rubber molding process that incorporated a mathematical formula was valid subject matter eligible for patent protection).

⁶⁹ 333 U.S. 127 (1948).

⁷⁰ *Id.* at 130.

C. The Federal Circuit and the “Handiwork of Nature”

The Supreme Court has never fully explained or provided a rationale for these judicially created exclusions of the laws of nature, natural phenomena, and abstract ideas from patentable subject matter.⁷¹ Because Congress has charged the Federal Circuit with deciding appeals in all patent cases, it has fallen to the Federal Circuit to interpret the exact scope of this subject matter exclusion.⁷² The Court of Claims and Patent Appeals [CCPA], the predecessor court to the Federal Circuit,⁷³ originally developed the *Freeman-Walter-Abele*⁷⁴ test to determine whether patents involving mathematical algorithms qualified as patentable subject matter or were subject to the handiwork of nature exception from patentable subject matter.⁷⁵ The CCPA developed this test because mathematical algorithms as abstract ideas are not by themselves patentable subject matter.⁷⁶

The *Freeman-Walter-Abele* test involves two steps.⁷⁷ First, the court determines if the patent claim recites, either directly or indirectly, a mathematical algorithm.⁷⁸ If the claim includes a mathematical algorithm, the second step is to analyze the whole claim.⁷⁹ The claim is drawn to valid statutory subject matter if “the mathematical algorithm is implemented in a specific manner to define structural relationships between the physical elements of the claim (in apparatus claims) or to refine or limit claim steps (in process claims).”⁸⁰ If the claim merely attempts to present and solve the algorithm, the claim is not subject matter eligible for patent protection.⁸¹ If the claim is an application of an algorithm, then the patent claim is valid subject matter.⁸²

In 1982, the CCPA ratified the *Freeman-Walter-Abele* test when it utilized the test to determine the validity of a patent possibly involving a mathematical algorithm.⁸³ The court also acknowledged that the *Freeman-Walter-Abele* test “conformed to the opinion of the Supreme Court in *Diamond v. Diehr*.”⁸⁴ The Federal Circuit last applied the *Freeman-Walter-Abele* test in 1994.⁸⁵

⁷¹ See Kane, *supra* note 48, at 545 (“Rationales for the exclusion of the laws of nature, natural phenomena and abstract ideas cannot be described with precision. . . . The absence of extensive justifications by the Court may speak for itself.”).

⁷² See 28 U.S.C. § 1296(a)(1)-(4) (2000) (granting the United States Court of Appeals for the Federal Circuit jurisdiction over cases arising under patent law).

⁷³ Meehan, *supra* note 9, at 337.

⁷⁴ *In re Freeman*, 573 F.2d 1237, 1245 (C.C.P.A. 1978), *modified by In re Walter*, 618 F.2d 758, 767 (C.C.P.A. 1980), clarified by *In re Abele*, 684 F.2d 902, 907 (C.C.P.A. 1982).

⁷⁵ See generally Meehan, *supra* note 9, at 337 (discussing *Freeman-Walter-Abele* test).

⁷⁶ *Walter*, 618 F.2d at 765.

⁷⁷ *In re Pardo*, 684 F.2d 912, 915 (C.C.P.A. 1982).

⁷⁸ *Id.*

⁷⁹ *Walter*, 618 F.2d at 767.

⁸⁰ *Id.* (“Once a mathematical algorithm has been found, the claim as a whole must be further analyzed.”).

⁸¹ *Pardo*, 684 F.2d at 915.

⁸² *In re Abele*, 684 F.2d 902, 906 (C.C.P.A. 1982) (summarizing the test as determining “what did the applicants invent?” If the claimed invention is a mathematical algorithm, it is improper subject matter for patent protection, whereas if the claimed invention is an application of the algorithm, § 101 will not bar the grant of the patent.”).

⁸³ *Pardo*, 684 F.2d at 915.

⁸⁴ *Id.*

⁸⁵ *In re Warmerdam*, 33 F.3d 1354, 1359 (Fed. Cir. 1994) (applying *Freeman-Walter-Abele* test and

The Federal Circuit began moving away from the *Freeman-Walter-Abele* test in *In re Alappat*.⁸⁶ Alappat developed a machine—utilizing a mathematical formula, arithmetic logic circuit, and anti-aliasing techniques—to produce a smooth waveform display on the screen of an oscilloscope.⁸⁷ The Federal Circuit upheld the claim as valid and patentable subject matter because the invention was “a specific machine to produce a useful, concrete, and tangible result.”⁸⁸ Despite the use of a mathematical formula, the Federal Circuit distinguished it from cases applying the *Freeman-Walter-Abele* test as involving only “process claims in the guise of apparatus claims.”⁸⁹ The Federal Circuit based its decision on its interpretation of the Supreme Court’s decision in *Diehr*, requiring an examination of the patent claim as a whole to determine if the claim is drawn to patentable subject matter.⁹⁰ The Federal Circuit relied on the Supreme Court’s statement in *Diehr* that a patent claim “drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula.”⁹¹ The court then questioned the *Freeman-Walter-Abele* test, stating that “the dispositive inquiry is whether the claim as a whole is directed to statutory subject matter.”⁹² The court further stated that “it is irrelevant that a claim may contain, as part of the whole, subject matter which would not be patentable by itself.”⁹³ The court attempted to reconcile the *Freeman-Walter-Abele* test with its emphasis on analyzing the patent claim as a whole by suggesting that the *Freeman-Walter-Abele* test was always focused on examining the claim as a whole.⁹⁴

After the Federal Circuit’s *en banc* decision in *Alappat*, the court began to develop a new test for evaluating whether a process claim was patentable subject matter or an unpatentable manifestation of nature.⁹⁵ In *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*,⁹⁶ the court considered Signature Financial Group’s machine patent on a computerized accounting system utilized to manage mutual funds in investment portfolios organized as a partnership.⁹⁷ In *State Street*,

rejecting five of six claims in a patent for a “bubble hierarchies” system for collision avoidance because the invalidated claims merely covered abstract ideas).

⁸⁶ 33 F.3d 1526 (Fed. Cir. 1994) (en banc).

⁸⁷ *Id.* at 1537-38 (discussing Alappat’s patent application).

⁸⁸ *Id.* at 1544.

⁸⁹ *Id.* at 1540.

⁹⁰ Compare *id.* (citing *Diehr*, 450 U.S. at 192) (indicating that *Diehr* requires a test for patentable subject matter to examine the claim as a whole) with *Pardo*, 684 F.2d at 915 (stating that “the second part of this [*Freeman-Walter-Abele*] test conforms to the opinion of the Supreme Court in *Diamond v. Diehr*”).

⁹¹ *Alappat*, 33 F.3d at 1543-44 (quoting *Diehr*, 450 U.S. at 187).

⁹² *Id.* at 1543 (emphasis in original).

⁹³ *Id.* The court did leave open the possibility that the *Freeman-Walter-Abele* test may have some vitality. *Id.* at 1543 n.21 (“[A]n analysis [like the *Freeman-Walter-Abele* test] wherein one attempts to identify whether any part of a claim recites mathematical subject matter which would not by itself be patentable is not improper analysis. Such a dissection of a claim may be helpful under some circumstances to more fully understand the claimed subject matter.”).

⁹⁴ *Id.* (“[E]ven in those cases wherein courts applied a variant of the [*Freeman-Walter-Abele*] analysis . . . the ultimate issue always had been whether the claim as a whole is drawn to statutory subject matter.”)

⁹⁵ See Meehan, *supra* note 9, at 337 (reviewing transition from *Freeman-Walter-Abele* test following *In re Alappat*); Gifford, *supra* note 13, at 134 (discussing the current approach of the Federal Circuit in examining the subject matter eligibility of process patents).

⁹⁶ 149 F.3d 1368 (Fed. Cir. 1998).

⁹⁷ *State St.*, 149 F.3d at 1370-71 (explaining background of U.S. Patent No. 5,193,056 (filed March 11,

the district court granted summary judgment in favor of State Street Bank, holding that the patent was invalid because it lacked valid statutory subject matter.⁹⁸ A panel of the Federal Circuit reversed, ruling that the broad nature of § 101 indicated Congress' intent to include computer software as eligible subject matter for patent protection.⁹⁹

The *State Street* court departed from the *Freeman-Walter-Abele* test, stating that “[a]fter *Diehr* and *Chakrabarty*, the *Freeman-Walter-Abele* test has little, if any applicability to determining the presence of statutory subject matter.”¹⁰⁰ The court noted that although many inventions involve mathematical processes, such inventions are not invalid merely because they include mathematical computations.¹⁰¹ Instead, the court declared that the presence of mathematical algorithms in a patent claim will not render the claim invalid unless the operation of the algorithm “does not produce a ‘useful, concrete and tangible result.’”¹⁰² Applying this new test, the court found that the software, when used on a computer, produced a “useful, concrete, and tangible result,” even though the useful result was expressed numerically and involved mathematics.¹⁰³ Although the patent in *State Street* was a machine patent,¹⁰⁴ the court stressed that it treated all categories of

1911)). The parties managed mutual funds as partnerships to combine the tax advantages of a partnership with the administrative and economies of scale realizable by mutual funds. *Id.*

⁹⁸ *Id.* (discussing procedural history). The district court reviewed the Supreme Court's handiwork of nature jurisprudence and Federal Circuit cases applying the *Freeman-Walter-Abele* test. *State St. Bank & Trust Co. v. Signature Fin. Group*, 927 F. Supp. 502, 507-511 (D. Mass. 1996). The district court applied the *Freeman-Walter-Abele* test, as the best available guidepost, and ruled that the computer program lacked patentable subject matter because it recited a mathematical algorithm but had no physical steps and did not reduce any physical “subject matter to a different state or thing.” *Id.* at 513.

⁹⁹ *State St.*, 149 F.3d at 1373 (“The repetitive use of the expansive term ‘any’ in § 101 shows Congress's [sic] intent not to place any restrictions on the subject matter for which a patent may be obtained beyond those specifically recited in § 101.”). The court did take care to note that manifestations of nature, including laws of nature, natural phenomena and abstract ideas, are excluded from patentable subject matter. *Id.*

¹⁰⁰ *Id.* at 1374. A machine patent is a “device or apparatus consisting of fixed and moving parts that work together to perform some function. Machines are one of the statutory categories of invention that can be patented.” BLACK'S LAW DICTIONARY 969 (8th ed. 2004). The court indicated that a machine patent claim was valid because it utilized the physical electronic structures of the computer as a means to produce the function of managing the mutual funds. *State St.*, 149 F.3d at 1372.

¹⁰¹ *State St.*, 149 F.3d at 1374 (“[A]fter *Diehr* and *Alappat*, the mere fact that a claimed invention involves inputting numbers, calculating numbers, outputting numbers, and storing numbers, in and of itself, would not render it nonstatutory subject matter.”).

¹⁰² *Id.* (quoting *Alappat*, 33 F.3d at 1544). In *Alappat*, the court was simply noting that *Alappat*'s patent produced a “useful, concrete, and tangible result” in an attempt to distinguish it from an “abstract idea,” which is unpatentable subject matter not eligible for patent protection. *See Alappat*, 33 F.3d at 1544 (“This [invention] is not a disembodied mathematical concept which may be characterized as an “abstract idea,” but rather a specific machine to produce a useful, concrete, and tangible result.”). It is not clear that the *en banc* Federal Circuit sought to establish “useful, concrete, and tangible” result as a new standard for judging the statutory subject matter eligibility of claims that include mathematical algorithms. *See id.* (noting that *Alappat*'s invention was a machine that produced a useful, concrete, and tangible result).

¹⁰³ *State St.*, 149 F.3d at 1375. In *Diehr*, the Supreme Court held that using a natural law, manifestation of nature, or abstract idea in a new and useful practical application is patentable subject matter. 450 U.S. at 188; *see supra* Part II.B (discussing the Supreme Court's decision in *Diehr*). In *Chakrabarty*, the Court held that an artificially created bacteria was not a natural law, manifestation of nature, or abstract idea. 447 U.S. at 309-10; *see supra* note 46 (explaining the Supreme Court decision in *Chakrabarty*).

¹⁰⁴ *State St.*, 149 F.3d at 1371.

patents, including process and machine claims, the same.¹⁰⁵

In *AT&T Corp. v. Excel Communications, Inc.*,¹⁰⁶ the Federal Circuit subsequently applied the *State Street* test to process patents.¹⁰⁷ AT&T patented a method (process) for managing and logging in long-distance telephone calls.¹⁰⁸ In granting Excel's motion for summary judgment, the district court ruled that the patent's process claims were invalid for failing to qualify as statutory subject matter.¹⁰⁹ Relying upon *State Street* and *In re Alappat*, a panel of the Federal Circuit reversed and remanded, instructing that "the focus is understood to be not on whether there is a mathematical algorithm at work, but on whether the algorithm-containing invention, as a whole, produces a tangible, useful, result."¹¹⁰ The Federal Circuit stressed that reliance on the *Freeman-Walter-Abele* test was inappropriate.¹¹¹ The Federal Circuit narrowly construed the Supreme Court's subject matter exclusion of laws of nature, natural phenomena, and abstract ideas from patentable subject matter.¹¹² It reasoned that any mathematical algorithm need only be applied in a useful manner if it is to qualify as patentable subject matter.¹¹³ Thus, the Federal Circuit interpreted the *State Street* test, with its focus on the utility of the results of a claimed invention, as the means of determining if a claim was drawn to the handiwork of nature, and thus unpatentable subject matter.¹¹⁴

¹⁰⁵ *Id.* ("The question whether a claim encompasses statutory subject matter should not focus on which of the four categories a claim is directed to—process, machine, manufacture, or composition of matter, but rather on the essential characteristics of the subject matter, in particular, its practical utility.")

¹⁰⁶ 172 F.3d 1352 (Fed. Cir. 1999).

¹⁰⁷ *Id.* at 1374.

¹⁰⁸ *Id.* at 1353-54. The patent enhanced the record keeping of phone companies by allowing for the addition of a primary interexchange carrier [PIC] indicator to records of telephone calls. *Id.* at 1353. The PIC indicator itself is derived from a mathematical formula. *Id.* at 1357. The PIC indicator helped local telephone carriers to provide differential billing to their subscribers, depending on whether a customer called someone with the same long-distance carrier or a different long-distance carrier. *Id.* at 1353.

¹⁰⁹ *AT&T Corp. v. Excel Commc'ns*, 1998 WL 175878, at *7 (D. Del. Mar. 27, 1998). The United States District Court for the District of Delaware reasoned that the patent recited a mathematical algorithm, and the use of computers, telephone switches, and telephone facilities constituted an insufficient change to the data to convert it into patentable subject matter. *Id.* at *6. The district court reasoned that changing the format of telephone data was an insufficient transformation to qualify as a substantive and useful application of the mathematical algorithm that determined the PIC. *Id.* at *7.

¹¹⁰ *AT&T*, 172 F.3d at 1361.

¹¹¹ *Id.* at 1359 (quoting *State St.*, 149 F.3d at 1374) ("Whatever may be left of the earlier test, if anything, this type of physical limitations analysis is of little value because 'after *Diehr* and *Alappat*, the mere fact a claimed invention involves [mathematical processes] . . . would not render it nonstatutory subject matter."). Interestingly, for its mathematical algorithm analysis, the Federal Circuit purported to allay the concerns raised by Justice Stevens' dissent in *Diehr*. See *id.* at 1357, 1360 (quoting *Diehr*, 450 U.S. at 219 (Stevens, J. dissenting)).

¹¹² *Id.* at 1356 (quoting *Diehr*, 450 U.S. at 185) ("In *Diehr*, the Court expressly limited its two earlier decisions in *Flook* and *Benson* by emphasizing that these cases did no more than confirm the 'long-established principle' that laws of nature, natural phenomena, and abstract ideas are excluded from patent protection.")

¹¹³ *Id.* at 1357. The court noted that claims that are unpatentable because they cover the handiwork of nature "are identifiable by showing they are merely abstract ideas constituting disembodied concepts or truths that are not 'useful' [T]o be patentable an algorithm must be applied in a 'useful' way." *Id.* (quoting *State St.*, 149 F.3d at 1373).

¹¹⁴ See *id.* at 1357-58. The Federal Circuit interpreted its *en banc* decision in *In re Alappat* to require "an examination of the contested claims to see if the claimed subject matter as a whole is a disembodied mathematical concept representing nothing more than a 'law of nature' or an 'abstract idea,' or if the

The *State Street* test is now the accepted patent subject matter eligibility test.¹¹⁵ The Patent and Trademark Office [PTO] subsequently adopted the “useful, concrete, and tangible result” standard in its patent examination guidelines.¹¹⁶ In so doing, the Federal Circuit and the PTO have left the applicability of the *Freeman-Walter-Abele* test uncertain¹¹⁷ because the Federal Circuit, in both *State Street* and *AT&T*, severely criticized yet did not overrule the *Freeman-Walter-Abele* test.¹¹⁸ Thus, under the jurisprudence the Federal Circuit developed, to pass muster under § 101, and be considered subject matter eligible for patent protection, the claimed invention must produce a “useful, concrete, and tangible result.”¹¹⁹ The Federal Circuit’s broad approach to patentable subject matter jurisprudence ultimately led to the questionable decision in *Metabolite*, in which the Federal Circuit upheld a patent on the act of correlating a test result.¹²⁰

III. APPLICATION OF SUBJECT MATTER ELIGIBILITY IN *METABOLITE*.

Factual Background of the Patent

To best understand the *Metabolite* case,¹²¹ it is important to understand the patent at issue, the ‘658 patent¹²² which primarily recites a new process for accurately measuring the total level of the amino acid homocysteine in tissues of warm blooded animals, humans.¹²³ The patentees¹²⁴ also discovered that an excess of homocysteine correlates to a deficiency of the vitamins cobalamin (commonly known as vitamin B₁₂), folate (also known as folic acid), or a deficiency of both

mathematical concept has been reduced to some practical application rendering it ‘useful.’” *Id.* at 1358 (quoting *Alappat*, 33 F.3d at 1544). More explicitly, echoing the *State Street* test, the Federal Circuit declared that the claim in *Alappat* was upheld because it was “more than an abstract idea . . . because the claimed invention as a whole was directed toward forming a specific machine that produced [a] useful, concrete and tangible result . . .” *Id.* (citing *Alappat*, 33 F.3d at 1544).

¹¹⁵ See Gifford, *supra* note 13, at 134 (discussing the acceptance of the *State Street* test by the PTO).

¹¹⁶ PATENT AND TRADEMARK OFFICE, INTERIM GUIDELINE FOR EXAMINATION OF PATENT APPLICATION FOR PATENT MATTER ELIGIBILITY 1 (Oct. 26, 2005), available at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf.

¹¹⁷ See generally Meehan, *supra* note 9, at 336-38 (noting that the Federal Circuit has utilized both the *Freeman-Walter-Abele* test and *State Street* test to determine if a claim had patentable subject matter).

¹¹⁸ See *AT&T*, 172 F.3d at 1359-61 (holding that *State Street*’s “useful, concrete, and tangible” test, and not the *Freeman-Walter-Abele* test, is the proper standard to determine if a process patent is patentable subject matter under § 101); *State St.*, 149 F.3d at 1374 (stating that the *Freeman-Walter-Abele* test has scant applicability to determining statutory subject matter).

¹¹⁹ *State St.*, 149 F.3d at 1375. *Accord AT&T*, 172 F.3d at 1361 (holding that *State Street*’s “useful, concrete, and tangible result” is the proper standard to determine if a process patent is patentable subject matter under § 101).

¹²⁰ See *infra* Part III (discussing the background and decisions in *Metabolite*).

¹²¹ *Metabolite Labs., Inc. v. Lab. Corp. of Am. (Metabolite I)*, 370 F.3d 1354 (Fed. Cir. 2004), *cert. dismissed as improvidently granted sub nom.*, *Lab. Corp. of Am. v. Metabolite Labs., Inc. (Metabolite II)*, 126 S. Ct. 2921 (2006) (mem.) (per curiam).

¹²² Assay for Sulfhydryl Amino Acids and Methods for Detecting and Distinguishing Cobalimin and Folic Acid Deficiency, U.S. Patent No. 4,940,658 (filed Nov. 20, 1986) (issued July 10, 1990). This patent is the patent in question in the *Metabolite* case. *Metabolite I*, 370 F.3d at 1358.

¹²³ *Metabolite I*, 370 F.3d at 1358 (“The ‘658 Patent claims both the total homocysteine test and the total homocysteine-methylmalonic acid test.”).

¹²⁴ The patent lists the inventors as Robert H. Allen, Sally P. Satbler, and John Lindenbaum. ‘658 Patent at [75].

vitamins.¹²⁵ Additionally, the patentees discovered that a person who is cobalamin deficient but not folate deficient exhibits elevated levels of methylmalonic acid, a byproduct of homocysteine metabolism.¹²⁶ For example, a patient with elevated homocysteine levels, but with normal levels of methylmalonic acid would logically have a folate deficiency but not a cobalamin deficiency.¹²⁷ A patient with elevated levels of both homocysteine and methylmalonic acid will have a cobalamin deficiency.¹²⁸ Therefore, a medical practitioner can, by testing for homocysteine and methylmalonic acid, determine whether a patient has a cobalamin deficiency, a folate deficiency, or both.¹²⁹

The inventors' discoveries, and the test they developed, are unquestionably useful.¹³⁰ It is crucial for physicians to be able to diagnose and treat cobalamin and folate deficiencies, because a deficiency of either vitamin can cause a life threatening hematologic abnormality, such as anemia.¹³¹ Deficiencies of these vitamins can cause "vascular disease, cognitive dysfunction, birth defects and cancer."¹³² A cobalamin deficiency can also cause potentially life-threatening neuropsychiatric problems.¹³³ These deficiencies can usually be treated by administration of vitamin supplements for the deficient vitamin, but an accurate test is needed to determine which vitamin is deficient.¹³⁴ With the invention of an accurate assay¹³⁵ for total homocysteine, it became possible to directly measure the total level of homocysteine.¹³⁶ The patentees' discovery also enabled medical professionals to accurately detect and distinguish between a folate deficiency and a cobalamin deficiency.¹³⁷ Adding to the utility of this discovery was the reality that, previously, such testing was limited to patients already displaying symptoms of a deficiency, because the then-existing means of testing for cobalamin deficiencies and total

¹²⁵ See '658 Patent col.4 (discussing discovery correlation between total homocysteine level and either cobalamin deficiency or folic acid deficiency or both).

¹²⁶ '658 Patent col.5.

¹²⁷ See *id.* (describing combining assays for total homocysteine and methylmalonic acids to test for folic acid deficiency and cobalamin deficiency).

¹²⁸ Gifford, *supra* note 13, at 136. See also '658 Patent col.5 ll.40-63 (describing correlation between total homocysteine, methylmalonic acids, and cobalamin).

¹²⁹ '658 Patent col.5 ll.40-63.

¹³⁰ See Gifford, *supra* note 13, at 136 (describing medical utility of the correlation and noting that "this discovery is undoubtedly useful").

¹³¹ '658 Patent col.1.

¹³² *Metabolite*, 370 F.3d at 1358-59.

¹³³ *Id.* at 1361.

¹³⁴ *Id.* at 1358-59. At the time of patent filing, it was difficult to treat both deficiencies because cobalamin came only in injection form while folate came in a tablet. *Id.* at 1358. Thus, failure to distinguish between vitamin deficiencies meant possibly subjecting the patient to needless injections of cobalamin. *Id.* After cobalamin and folate became available in a combined tablet, the injections became unnecessary, and medical professionals only had to test the total homocysteine level, and then treat with both vitamins. *Id.*

¹³⁵ In the medical context, "assaying" is defined as "the quantitative analysis of a substance to determine the proportion of some valuable or potent constituent." Meehan, *supra* note 9, at 325. The term "assay" can thus mean "measured; or 'determined.'" *Id.*

¹³⁶ Gifford, *supra* note 13, at 136.

¹³⁷ *Id.* ("Thus, the patentees discovered it is possible to distinguish between cobalamin deficiency and folate deficiency by comparing a patient's total homocysteine and methylmalonic acid concentrations with normal values.").

homocysteine excesses tended to yield false positives.¹³⁸ Thus, the patentee's test enabled medical professionals to better differentiate between cobalamin and folate and treat such deficiencies earlier.¹³⁹

In 1990, the PTO issued the '658 Patent to University Patents, Inc., whose successor in turn licensed the patent to Metabolite Laboratories [Metabolite].¹⁴⁰ Metabolite sublicensed the patent to Roche Laboratories.¹⁴¹ Laboratory Corporation of America [LabCorp] conducted total homocysteine tests under Roche's sublicense until 1998, using the test specified in claims 1-12 of the '658 Patent.¹⁴² By this time, tablets containing both cobalamin and folate existed, making it possible to treat for either deficiency without having to identify which vitamin was deficient.¹⁴³ In 1998, LabCorp switched to a different test for homocysteine, which was developed by Abbott Laboratories, discontinuing the royalties it paid to Metabolite.¹⁴⁴

Procedural History

After LabCorp switched to the Abbott test for testing homocysteine levels, Metabolite sued LabCorp for patent infringement in the United States District Court for the District of Colorado.¹⁴⁵ Metabolite largely based its case on Claim 13 of the Patent, because LabCorp was no longer using Metabolite's test for assaying total homocysteine levels.¹⁴⁶ Claim 13 asserts a claim over:

[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 fluid.¹⁴⁷

In 2001, the case went to a jury trial; the jury entered a verdict in favor of Metabolite, awarding damages of \$1,019,365.01 for patent infringement.¹⁴⁸ The

¹³⁸ '658 Patent col.3. Such symptoms include anemia and neuropsychiatric abnormalities. *Id.*

¹³⁹ Gifford, *supra* note 13, at 136.

¹⁴⁰ *Metabolite I*, 370 F.3d at 1358-59.

¹⁴¹ *Id.* at 1359.

¹⁴² *Id.* Claims 1-12 recite Metabolite's actual test for total homocysteine. U.S. Patent No. 4,940,648 Patent col.41 ll.1-57.

¹⁴³ *Metabolite I*, 370 F.3d at 1358.

¹⁴⁴ *Id.* at 1359.

¹⁴⁵ *Id.* Metabolite also sued for breach of contract, but those claims are not covered by this Comment.

¹⁴⁶ *Id.* at 1358-59. The litigation also involved Claim 18 of the patent, which recited:

[a] method for detecting a deficiency of cobalamin, folate, or both in warm-blooded animals and distinguishing there between comprising assaying body fluids for the presence of elevated levels of total homocysteine and methylmalonic acid, wherein the total homocysteine indicate no cobalamin or folic acid deficiency, elevated levels of total homocysteine and methylmalonic acids indicate cobalamin deficiency, and elevated levels of total homocysteine combined with normal levels of methylmalonic acid indicate folic acid deficiency.

U.S. Patent. No. 4,940,658 col.41, ll.57-65 (filed Nov. 20, 1986). The court did not decide the validity of Claim 18 because it held that it did not have Article III subject matter jurisdiction over the Claim 18 issue because LabCorp continued to pay royalties to Metabolite on Claim 18, and thus there was no "real case or controversy regarding" Claim 18. *Metabolite I*, 370 F.3d at 1369.

¹⁴⁷ '658 Patent. col.41, ll.57-65.

¹⁴⁸ *Metabolite I*, 370 F.3d at 1359.

jury, accepting Metabolite's argument, found that LabCorp indirectly infringed Claim 13 of Metabolite's patent by inducing medical professionals to order the total homocysteine assay that it performed under license from Abbott.¹⁴⁹ The district court entered a judgment on the verdict, and LabCorp moved for judgment as a matter of law.¹⁵⁰ After hearing the postjudgment motions, the district court denied LabCorp's motion for judgment as a matter of law, found that LabCorp willfully infringed upon Metabolite's patents, doubled the jury's infringement award to \$2,038,730.02, and issued a permanent injunction against further infringement by LabCorp.¹⁵¹ LabCorp then appealed to the Federal Circuit.¹⁵²

The Federal Circuit, in a panel decision written by Judge Rader, affirmed the district court's judgment.¹⁵³ Specifically, the Federal Circuit found substantial evidence for the jury's verdict that LabCorp induced infringement, and thus indirectly infringed Metabolite's patent.¹⁵⁴ The court, to support the contention that LabCorp induced infringement, pointed to LabCorp's publication of Continuing Medical Education articles and a Directory of Services informing doctors of the natural correlation between elevated homocysteine levels and cobalamin and folate deficiencies, and that these deficiencies could readily be treated by vitamin supplements.¹⁵⁵ These materials promoted the total homocysteine tests, including the test LabCorp performed under license from Abbott.¹⁵⁶

The Federal Circuit also affirmed the jury verdict finding that LabCorp had indirectly infringed upon Metabolite's patent.¹⁵⁷ However, the court acknowledged that any verdict of indirect infringement is necessarily predicated upon "the presence of direct infringement."¹⁵⁸ The court found that when physicians "order assays and correlate the results of those assays, they thereby directly infring[e]" the patent.¹⁵⁹ The court found that the doctors actually infringed the second, "correlating," step of Claim 13, because they performed the actual correlation between an elevated level of homocysteine and the deficiency in either cobalamin or folate.¹⁶⁰ Thus, under the Federal Circuit's decision, a physician directly infringes Claim 13 of the '658 Patent when she or he orders the test for homocysteine, and, using knowledge that elevated levels of homocysteine indicates a deficiency of the vitamins cobalamin or folate, correlates the result of the test to a deficiency of cobalamin or folate in the patient.¹⁶¹

¹⁴⁹ *Id.* at 1358.

¹⁵⁰ *Id.* at 1359.

¹⁵¹ *Id.*

¹⁵² *Id.* at 1354.

¹⁵³ *Id.* at 1358 ("Because the record supports the jury's verdicts and the trial court's decisions, this court affirms.").

¹⁵⁴ *Id.* at 1365.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.* at 1364.

¹⁵⁸ *Id.* (citing *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 774 (Fed. Cir. 1993)).

¹⁵⁹ *Id.* at 1364.

¹⁶⁰ *Id.* The correlating step exactly reads: "correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate." '658 Patent col.41 ll.63-65.

¹⁶¹ See *Metabolite I*, 370 F.3d at 1364 (holding that substantial evidence supports verdict because there was evidence in the record indicating that doctors directly infringed upon Metabolite's patent).

The Federal Circuit rejected LabCorp's challenge to the validity of Claim 13.¹⁶² LabCorp attacked Claim 13 on the grounds that the correlating step in Claim 13 was indefinite.¹⁶³ The court also rejected LabCorp's challenges to Claim 13 on the basis of prior art¹⁶⁴ and obviousness.¹⁶⁵ The Federal Circuit did not directly consider subject matter because LabCorp did not challenge the patent for lack of statutory subject matter under § 101 either before the district court or at the Federal Circuit.¹⁶⁶

In the Supreme Court

1. *Certiorari Process*

After the Federal Circuit rejected all of LabCorp's arguments, LabCorp filed a petition for a writ of certiorari in the Supreme Court on November 3, 2004.¹⁶⁷ In its petition, LabCorp presented three questions, only the third of which challenged the subject matter of Metabolite's patent.¹⁶⁸ Thus, the only question before the Court was:

Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to "correlat[e]" test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the

¹⁶² *Id.* at 1368 ("[T]his court rejects LabCorp's various attempts to invalidate claim 13. Accordingly, this court affirms the district court denial of LabCorp's JMOL.")

¹⁶³ *Id.* at 1366. Patent claims must be written "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make use of the same." Patent Act, 35 U.S.C. § 112 (2000). The court rejected this challenge because LabCorp's experts, as well as physicians (who are people skilled in the art), fully understood the language of Claim 13. *Metabolite I*, 370 F.3d at 1366-67.

¹⁶⁴ *Metabolite I*, 370 F.3d at 1367 (discussing LabCorp's obviousness challenge to Claim 13). Under 35 U.S.C. § 102, a patent claim must not be anticipated by prior art. The court found that prior research on homocysteine did not recite all of Claim 13, and only invited more research. *Metabolite I*, 370 F.3d at 1367.

¹⁶⁵ *Metabolite I*, 370 F.3d at 1368. A claimed invention must not be obvious from the prior art available at the time of invention. 35 U.S.C. § 103. The Federal Circuit found insufficient references to support LabCorp's argument of obviousness, and concluded that because multiple corporations had licensed the patent, the claim was likely nonobvious. *Metabolite I*, 370 F.3d at 1368.

¹⁶⁶ Brief for the United States as Amicus Curiae at 6, *Lab. Corp. of Am. v. Metabolite Labs.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3533248 [hereinafter Solicitor General's December Brief]. This is the Brief the Solicitor General filed after the Court granted Certiorari, and is not to be confused with the brief the Solicitor General filed in August 2005 before the court granted Certiorari.

¹⁶⁷ Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit at i, *Lab. Corp. of Am. v. Metabolite Labs.*, 126 S.Ct. 2921 (2006) (No. 04-607), 2004 WL 2505526.

¹⁶⁸ *Id.* The three questions LabCorp presented in its Petition for Certiorari were:

1. Whether liability can be imposed for willfully inducing patent infringement under 35 U.S.C. § 271(b) based solely on evidence that a party has disseminated a basic scientific fact to others.
2. Whether an express limitation in a patent claim can be ignored so as to allow the patent to cover the exact opposite of what was claimed.
3. Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to "correlat[e]" test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result. *Id.*

relationship after looking at a test result.¹⁶⁹

On February 28, 2005, the Court asked the Solicitor General to file a brief expressing the views of the United States on the issue of whether the claim was valid subject matter.¹⁷⁰ Nearly a year later, on October 31, 2005, the Supreme Court granted certiorari, but only on the question whether Claim 13 was valid patentable subject matter.¹⁷¹ Three days later, the Court vacated the writ of certiorari after Chief Justice Roberts recused himself from the case.¹⁷² Accordingly, the Court, without the Chief Justice, reconsidered the petition and again granted the writ of certiorari, limited again to the validity of the subject matter of Claim 13.¹⁷³ The Solicitor General remained involved in the case, filing an additional brief in December,¹⁷⁴ and was permitted to participate in the oral argument of the case.¹⁷⁵

2. *The (Non) Decision and the Dissent*

On June 22, 2006, the Court dismissed the writ of certiorari as improvidently granted in a per curiam decision without further explanation from the Court.¹⁷⁶ Justice Breyer, joined by Justices Stevens and Souter, dissented from the dismissal of certiorari.¹⁷⁷ Justice Breyer responded to concerns that the record was insufficiently developed on the issue of patentable subject matter by noting that the case was briefed and argued by the parties, the Solicitor General,¹⁷⁸ and twenty

¹⁶⁹ *Id.*

¹⁷⁰ *Lab. Corp. of Am. v. Metabolite Labs., Inc.*, 543 U.S. 1185 (2005) (mem.). The Court invited the Acting Solicitor General to “file a brief in this case expressing the views of the United States limited to” “[i]s the patent invalid because one cannot patent ‘laws of nature, natural phenomena, and abstract ideas?’” *Id.* (quoting *Diehr*, 450 U.S. at 185). The Solicitor General filed its first brief on August 26, 2005. Brief for the United States as Amicus Curiae, *Lab. Corp. of Am. v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 2072283 [hereinafter Solicitor General’s August Brief]. In that brief, the Solicitor General concluded that the petition for certiorari should be denied because LabCorp did not develop a sufficient record on the issue of patentable subject matter because it did not raise the issue in the lower courts. *Id.* at 15. The Solicitor General also warned that reversing the Federal Circuit may endanger numerous patents on medical and diagnostic procedures. *Id.* at 14-15.

¹⁷¹ *Lab. Corp. of Am. v. Metabolite Labs., Inc.*, 126 S. Ct. 543 (2005) (mem.), *vacated*, 126 S. Ct. 601 (2006) (“Petition for writ of certiorari to the United States Court of Appeals for the Federal Circuit granted limited to Question 3 presented by the petition.”).

¹⁷² *Lab. Corp. of Am. v. Metabolite Labs., Inc.*, 126 S. Ct. 601 (2005) (mem.) (“Having been advised by THE CHIEF JUSTICE that he now realizes that he should have recused himself from participation in this case, and does now recuse himself, the Court vacates its order of Monday, October 31, 2005.”). It is likely that Chief Justice Roberts recused himself because one of his former law firms was representing a party in the case. “*If I am Correct . . . That the Patent is Invalid . . . Special Public Interest Considerations Reinforce My View that We Should Decide This Case*”, 25 BIOTECHNOLOGY L. REP. 404, 404 (2006).

¹⁷³ *Lab. Corp. of Am. v. Metabolite Labs., Inc.*, 126 S. Ct. 601 (2005) (mem.) (“The Court has reconsidered the petition for certiorari, which is granted but limited to question three as presented in the petition. THE CHIEF JUSTICE has not participated in the vote to withdraw the order of October 31, 2005, or in the instant reconsideration of the petition for certiorari.”).

¹⁷⁴ Solicitor General’s December Brief, *supra* note 166. The Solicitor General’s December Brief argued that petitioner’s question was actually a challenge for vagueness, and alternatively, the case should be remanded to better develop the record on the issue of patentable subject matter. *Id.* at 5-6.

¹⁷⁵ *Lab. Corp. of Am. v. Metabolite Labs., Inc.*, 126 S. Ct. 1317 (2006) (mem.) (“Motion of the Solicitor General for leave to participate in oral argument as *amicus curiae* and for divided argument is granted.”).

¹⁷⁶ *Lab. Corp. of Am. v. Metabolite Labs., Inc. (Metabolite II)*, 126 S. Ct. 2921, 2921 (2006) (mem.) (per curiam).

¹⁷⁷ *Id.* (Breyer, J., dissenting).

¹⁷⁸ *Id.* at 2926 (Breyer, J. dissenting). Answering claims that LabCorp did not raise subject matter in the

amici.¹⁷⁹ The dissenters further argued that public interest factors, including the negative impact Claim 13 would have on the medical community and healthcare cost, strongly weighed in favor of deciding the case.¹⁸⁰

District Court or the Federal Circuit, Justice Breyer noted that LabCorp, citing *Diehr*, did argue before the Federal Circuit that the patent “would permit the respondents ‘improperly [to] gain a monopoly over a basic scientific fact.’” *Id.* at 2925-26 (Breyer, J., dissenting) (quoting Brief for Appellant at 41, Lab. Corp. of Am. v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006)). Breyer further noted that the Solicitor General’s argument to deny certiorari was “primarily based upon LabCorp’s failure to specifically refer to 35 U.S.C. § 101.” *Id.* at 2926 (Breyer, J., dissenting). Finally, Justice Breyer noted that the Solicitor General raised LabCorp’s failure to raise the issue of subject matter prior to the Court’s grant of certiorari, and the Court implicitly rejected that argument by granting certiorari. *Id.* (Breyer, J., dissenting).

¹⁷⁹ *Metabolite II*, 126 S. Ct. at 2926 (Breyer, J., dissenting). Five amicus briefs were filed in favor of Metabolite. See Brief Amicus Curiae Franklin Pierce Law Center in Support of the Respondents at 3, Lab. Corp. of Am. v. Metabolite Labs., 126 S. Ct. 2921 (2006) (No. 04-607), 2006 WL 304571 (“This Court should discard the prohibition against patent claims directed to so-called laws of nature. The prohibition arose from dicta contained in old, English, common law decisions. It has no statutory support in our law. It is unnecessary and nearly impossible to apply because it is error-prone, redundant, and obsolete.”); Brief of Amicus Curiae Boston Patent Law Association in Support of Respondents at 17, Lab. Corp. of Am. v. Metabolite Labs., 126 S. Ct. 2921 (2006) (No. 04-607), 2006 WL 303909 (contending that Claim 13 is patentable subject matter because it is not different than a medical device and the patent would not hinder medical innovation); Brief for Amicus Curiae Perlegen Sciences, Inc. and Mohr, Davidow Ventures in Support of Respondents at 3, Lab. Corp. of Am. v. Metabolite Labs., 126 S. Ct. 2921 (2006) (No. 04-607), 2006 WL 303908 (“Claim 13 recites patentable subject matter under 35 U.S.C. § 101.”); Amicus Curiae Brief of American Intellectual Property Association in Support of Respondent at 3, Lab. Corp. of Am. v. Metabolite Labs., 126 S. Ct. 2921 (2006) (No. 04-607), 2006 WL 303907 (arguing that the Court should decline to address whether Claim 13 is valid subject matter because the record was not properly developed below); Amicus Curiae Brief of the Federal Circuit Bar Association in Support of Respondents at 3, Lab. Corp. of Am. v. Metabolite Labs., 126 S. Ct. 2921 (2006) (No. 04-607), 2006 WL 303906 (“The petition for certiorari should be dismissed as improvidently granted.”). Four amici were ostensibly neutral. See Brief of International Business Machines as Amicus Curiae in Support of Neither Party at 4, Lab. Corp. of Am. v. Metabolite Labs. at 3, 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3597815 (observing that the scope of patentable subject matter is too broad, but contending that *Metabolite* was not the appropriate case to announce a new standard for patentable subject matter); Brief of Amicus Curiae American Express Company in Support of Neither Party at 4, Lab. Corp. of Am. v. Metabolite Labs. at 3-4, 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3597810 (stressing that *Metabolite* only concerned the handiwork of nature exception to patentable subject matter, and not business methods patents); Amicus Curiae Brief of the Association of the Bar of the City of New York in Support of Neither Party at 4, Lab. Corp. of Am. v. Metabolite Labs. at 34, 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3597808 (advising against conflation of § 101 with other statutory standards); Brief of Amicus Curiae Intellectual Property Owners Association in Support of Neither Party at 13, Lab. Corp. of Am. v. Metabolite Labs., 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3476621 (arguing that the proper scope of patentable subject matter is already defined by Court precedent, and thus the Court should not further restrict patentable subject matter in *Metabolite*). Multiple amici wrote briefs in support of LabCorp, and advocating the invalidation of Claim 13. See, e.g., Brief of Financial Services Industry Amici Curiae in Support of Reversal at 3-4, Lab. Corp. of Am. v. Metabolite Labs., 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3543097 (recommending that the court should require patents to be physical and material, and thus not allow patents for abstract business methods); Brief Amicus Curiae of AARP in Support of Petitioner at 30, Lab. Corp. of Am. v. Metabolite Labs., 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3597810 (“In order to best promote progress, protect public health, and prevent unwarranted liability, this Court should invalidate Claim 13 and clarify indirect liability standards.”); Brief of the Public Patent Foundation as Amicus Curiae in Support of Petitioner at 2-3, Lab. Corp. of Am. v. Metabolite Labs., 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3597813 (arguing that the Federal Circuit has veered from the Supreme Court precedent on patentable subject matter, and the Court should reaffirm its precedent). Part IV.B discusses the remainder of the amici who favored invalidating Claim 13.

¹⁸⁰ *Metabolite II*, 126 S. Ct. at 2928 (Breyer, J., dissenting). Because the Federal Circuit’s interpretation of the claim construed physicians as directly infringing whenever they correlate between a homocysteine test result and a vitamin deficiency, the dissenters noted that Claim 13 of the Metabolite patent may

inhibit doctors from using their best medical judgment; they may force doctors to

Justice Breyer's dissent from the dismissal of the writ of certiorari also argued that Claim 13 appeared to be invalid for lack of statutory subject matter.¹⁸¹ Justice Breyer concluded "that the correlation between homocysteine and vitamin deficiency set forth in claim 13 is a 'natural phenomenon.'"¹⁸² He rejected Metabolite's contention that Claim 13 deserved patent protection because it was an application of a law of nature involving the physical transformation of matter, in this instance, the blood of the patient.¹⁸³ In addition, the dissent found the *State Street* test to be insufficient, noting that the Supreme Court never adopted the test, and employing the *State Street* test would contradict the established precedent of the Court.¹⁸⁴

Interestingly, for the first time, members of the Supreme Court¹⁸⁵ attempted to provide a rationale for the handiwork of nature exclusion.¹⁸⁶ Justice Breyer admitted that discovering laws of nature or other manifestations of nature may actually require a considerable amount of work on the part of the discoverer, and prove useful to society.¹⁸⁷ However, Justice Breyer argued that manifestations of nature are excluded from patent protection because "sometimes too much patent protection can impede rather than 'promote the Progress of Science and useful Arts,' the Constitutional objective of patent and copyright protection."¹⁸⁸ The dissent noted that patents can inhibit research because they limit the free exchange of information,

spend unnecessary time and energy to enter into license agreements; they may divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations; they may raise the cost of effective health care delivery.

Id. at 2928-29 (Breyer, J., dissenting) (citing Brief for the American Clinical Laboratory Association as Amicus Curiae in Support of Petitioner at 8-13, *Lab. Corp. of Am. v. Metabolite Labs.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3543098).

¹⁸¹ *Metabolite II*, 126 S. Ct. at 2927 (Breyer, J., dissenting).

¹⁸² *Id.* (Breyer, J., dissenting). The dissent noted that both LabCorp and the Solicitor General admitted that Claim 13 was a natural phenomenon, and that Metabolite almost conceded that Claim 13 was a natural phenomenon. *Id.* (Breyer, J., dissenting).

¹⁸³ *Metabolite II*, 126 S. Ct. at 2927 (Breyer, J., dissenting). The dissent found that the transformation of blood in the test was an insufficient application of the manifestation of nature to qualify as statutory subject matter because the actual transformation of blood occurred through an unpatented test. *Id.* (Breyer, J., dissenting). Although Justice Breyer conceded that "manifestations of nature," like abstract ideas and laws of nature, was a difficult category to define, he concluded that Claim 13 covered a natural phenomenon because it was an observable reaction in human biochemistry. *Id.* at 2925-26 (Breyer, J., dissenting).

¹⁸⁴ *Id.* at 2928 (Breyer, J., dissenting). Justice Breyer noted that

[n]either does the Federal Circuit's decision in *State Street Bank* help [Metabolite]. That case 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.

Id. (Breyer, J., dissenting) (citation omitted).

¹⁸⁵ See Kane, *supra* note 48, at 545 ("Rationales for the exclusion of the laws of nature, natural phenomena and abstract ideas cannot be described with precision. . . . The absence of extensive justifications by the Court may speak for itself.").

¹⁸⁶ *Metabolite II*, 126 S. Ct. at 2922-23 (Breyer, J., dissenting) (proffering rationale for exclusion of manifestations of nature from patent protection).

¹⁸⁷ *Id.* at 2922 (Breyer, J., dissenting) ("The justification . . . does not lie in any claim that 'laws of nature' are obvious, or that their discovery is easy, or that they are not useful. To the contrary, research into such matters may be costly and time-consuming; monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race.").

¹⁸⁸ *Id.* (Breyer, J., dissenting) (quoting U.S. CONST. art. I, § 8, cl. 8).

and force researchers to be cautious about avoiding the use of patented ideas.¹⁸⁹ Thus, exclusion of the laws of nature, natural phenomena, and abstract ideas from patent protection serves to avoid stifling overprotection.¹⁹⁰

IV. ANALYSIS

Multiple commentators have already argued that Claim 13 is unpatentable subject matter because it claims to patent a law of nature, natural phenomenon, or abstract ideas.¹⁹¹ However, this Comment is not focused on the validity of Claim 13, but will argue instead that the Court should have issued a definitive decision in *Metabolite*. Because Federal Circuit jurisprudence on patentable subject matter strayed from the Supreme Court's precedent, the Court should have decided *Metabolite*, and the validity of Claim 13, and thus clarified the Federal Circuit jurisprudence.¹⁹² The Court also endangered medicine and science by allowing the Federal Circuit's decision to stand.¹⁹³ Furthermore, the record in *Metabolite* was sufficiently developed to allow the Court to decide the case.¹⁹⁴ Finally, the Court's refusal to decide *Metabolite* is inconsistent with its current pattern of clarifying other issues in patent law.¹⁹⁵

A. The Supreme Court Should Clarify Patentable Subject Matter Jurisprudence.

In dismissing the writ of certiorari, the Supreme Court failed to reassert its own precedent in the law of statutory subject matter for patents, which has been muddled by the Federal Circuit in the twenty-six years since the Supreme Court last weighed in on the handiwork of nature exclusion in *Diamond v. Diehr*.¹⁹⁶ The *State Street*

¹⁸⁹ *Id.* (Breyer, J., dissenting) (noting that patents "can discourage research by impeding the free exchange of information, for example by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented information sometimes prohibitively so.").

¹⁹⁰ *Id.* (Breyer, J., dissenting). The dissenters noted that the handiwork of nature exclusion balances the need to provide incentives for new developments which patent law provides, with the need to limit the danger of overprotection by patent. *Id.* (Breyer, J., dissenting).

¹⁹¹ Numerous authorities agree that Claim 13 of *Metabolite*'s patent, U.S. Patent No. 4,940,658 col.41, ll.57-65 (filed Nov. 20, 1986), covers unpatentable subject matter. *See, e.g., Metabolite II* at 2927 (Breyer, J., dissenting) (noting that Claim 13 is likely an unpatentable natural phenomenon); Meehan, *supra* note 9, at 323 (arguing that "Claim 13 of the '658 patent is unpatentable because it is drawn to a law of nature," and the Claim precludes all use of that law of nature although the process includes minimal use of any post-process physical activity or transformation); Gifford, *supra* note 13, at 139 (contending that Claim 13 is simply a claim on a natural correlation, and thus not patentable subject matter).

¹⁹² *See infra* Part IV.A (demonstrating incompatibility between *State Street* test as the ultimate standard for patentable subject matter and Supreme Court precedent on the exclusion of laws of nature, natural phenomena, and abstract ideas from patentable subject matter).

¹⁹³ *See infra* Part IV.B (explaining the chilling effect of the Federal Circuit's decision may have on the free exchange of information, the practice of medicine, public health research, laboratory science, genetics research).

¹⁹⁴ *See infra* Part IV.C (detailing how the record was sufficiently developed, despite LabCorp not explicitly raising the issue of patentable subject matter in the lower courts).

¹⁹⁵ *See infra* Part IV.D (noting that the Court's refusal to decide *Metabolite* is inconsistent with the Court's recent practice of engaging and clarifying patent issues).

¹⁹⁶ 450 U.S. 175 (1981). Since *Diehr*, the Federal Circuit has moved to the *State Street* test, requiring only that a claim as a whole produces a "tangible, useful and concrete" result. *State St. Bank & Trust*

test does not, by itself, provide for a means of excluding a claim to a law of nature, natural phenomenon, or abstract idea, unless such a claim is also useless, intangible, or non-concrete.¹⁹⁷ In addition, the *State Street* test is overbroad, and its application could allow the patenting of claims that previously fell outside the subject matter eligibility requirements of § 101 as interpreted by the Supreme Court.¹⁹⁸

Although the Federal Circuit, in *Metabolite*, did not directly address the patentable subject matter of Claim 13, the claim would almost certainly pass the scrutiny of the Federal Circuit's *State Street* test.¹⁹⁹ The *State Street* test only requires that a claim taken as a whole produces a "tangible, useful and concrete result" in order to be subject matter eligible for patent protection.²⁰⁰ The ability to determine whether a patient has a potentially dangerous vitamin deficiency is useful, the knowledge of whether or not there is such a deficiency is a tangible result, and the test results involved in the claim are concrete.²⁰¹

Despite its acceptance by the Federal Circuit and PTO,²⁰² the mere application of the *State Street* test is far too lenient and overbroad because it fails to provide a means to exclude from patentable subject matter the laws of nature, abstract ideas, and natural phenomena.²⁰³ Under the Federal Circuit's *State Street* test, any claim that, as a whole, yields a "useful, concrete, and tangible" result will be deemed subject matter eligible for patent protection under § 101.²⁰⁴ The *State Street* test, however, does not provide any explicit means to ensure that a patent claim does not cover or preempt a handiwork of nature, therefore, a useful claim covering a law of nature would pass scrutiny under the *State Street* test.²⁰⁵ Indeed, Newton's Law of Universal Gravitation provides the very useful, concrete, tangible result of being able to predict the results of objects falling to the ground, and Einstein's famous equation $E=mc^2$ provides the useful result of enabling one to predict the amount of energy

Co. v. Signature Fin. Group, 149 F.3d 1368, 1375 (Fed. Cir. 1998) (quoting *In re Alappat*, 33 F.3d 1526, 1544 (Fed. Cir. 1994) (en banc)). See also *AT&T Corp. v. Excel Commc'ns, Inc.*, 172 F.3d 1352, 1361 (Fed. Cir. 1999) (extending the *State Street* test to process patent claims).

¹⁹⁷ See Gifford, *supra* note 13, at 134 (arguing that the *State Street* test does not integrate the requirements for the exclusion of the handiwork of nature).

¹⁹⁸ See *id.* (stating that claim 13 would satisfy the *State Street* test).

¹⁹⁹ See *id.* (noting that claim 13 would satisfy the Federal Circuit's current eligibility requirement of producing a "useful, concrete, and tangible" result).

²⁰⁰ *State St.* 149 F.3d 1368, 1375 (Fed. Cir. 1998) (quoting *In re Alappat*, 33 F.3d 1526, 1544 (Fed. Cir. 1994) (en banc)). See also *AT&T*, 172 F.3d at 1361 (extending *State Street* test to process patent claims). The Federal Circuit also construed the *State Street* test with its emphasis on the utility of the claimed invention to be sufficient to determine whether a claim includes an unpatentable handiwork of nature. See *AT&T*, 172 F.3d at 1357-58 (noting that the Federal Circuit previously upheld a patent claim because the claim produced a "useful, concrete, and tangible result" (citing *Alappat*, 33 F.3d at 1544)).

²⁰¹ Gifford, *supra* note 13, at 137-38 ("It is also indisputable that claims 13 and 18 produce useful, concrete, and tangible results.").

²⁰² See *supra* Part II.C (detailing impact and acceptance of the *State Street* test).

²⁰³ See Meehan, *supra* note 9, at 338 ("The Federal Circuit's test may not exclude from patentable subject matter that for which the Supreme Court has mandated exclusion."). See also Gifford, *supra* note 13, at 134. ("[T]he *State Street* test is too broad to be the ultimate test of eligibility because it completely fails to account for these exceptions that are required by Supreme Court precedent.").

²⁰⁴ *AT&T*, 172 F.3d at 1361.

²⁰⁵ Gifford, *supra* note 13, at 134. See also Meehan, *supra* note 9, at 339 ("The operative question may not be whether the claimed invention produces a useful, concrete, and tangible result, but instead whether the subject matter in question is the kind of discovery that the patent laws are designed to protect, as detailed by the related Supreme Court precedent.").

contained in any given mass of matter.²⁰⁶ Thus, the *State Street* test could permit claims for these natural correlations, although the Supreme Court clearly indicated that neither Newton's Law of Universal Gravitation nor Einstein's equation are subject matter eligible for patent protection.²⁰⁷ Although the Supreme Court invalidated a patent on a formula for converting binary-coded decimal numbers into binary numbers,²⁰⁸ as Justice Breyer argued in his dissent, that patent likely would have been upheld under the *State Street* test because the ability to convert decimal numbers into binary numbers is a useful, tangible, and concrete process.²⁰⁹ Similarly, although a formula for calculating the alarm limits in a catalytic conversion reaction would produce a tangible, useful, and concrete result, by facilitating more efficient catalytic conversion processes,²¹⁰ the Court invalidated a patent on the formula for lack of patentable subject matter.²¹¹ Thus, if the *State Street* test were the ultimate test for patentable subject matter, "*Benson* and *Flook* would have come out the other way and *Diehr* would have been a very short opinion."²¹²

Although the *State Street* test is inconsistent with Supreme Court precedent on the exclusion of the handiwork of nature from patentable subject matter, the Court declined the opportunity to reassert its own precedents,²¹³ despite numerous authorities urging the Court to clarify and reform the Federal Circuit's patentable

²⁰⁶ See Meehan, *supra* note 9, at 338 (noting that the *State Street* test may allow inventions incompatible with the Supreme Court precedent of *Benson* and *Diehr*); Gifford, *supra* note 13, at 134, 140 (criticizing the scope of *State Street* test because it encompasses manifestations of nature that are not patentable subject matter according to Supreme Court precedent).

²⁰⁷ *Chakrabarty*, 447 U.S. at 309 (dicta) (citing *Parker v. Flook*, 437 U.S. 584 (1978)). See also *Metabolite II*, 126 S. Ct. at 2928 (Breyer, J., dissenting) (noting that the Supreme Court has invalidated inventions producing "useful, concrete, and tangible" results). Justice Breyer stated that the *State Street* test would include "instances where this Court has held the contrary." *Metabolite II*, 126 S. Ct. at 2928 (2006) (mem.) (Breyer, J., dissenting).

²⁰⁸ *Benson*, 409 U.S. at 68. The Court found that this formula was an abstract idea, and thus an unpatentable subject matter. *Id.*

²⁰⁹ The ability to convert human-usable decimal numbers into computer-usable binary numbers is certainly useful, the formula would produce a concrete output of binary numbers, and a tangible result because it affects the computer's microcircuits. See *Metabolite II*, 126 S. Ct. at 2928 (Breyer, J., dissenting) ("[T]he Court has invalidated a patent setting forth a process that transforms, for computer-programming purposes, decimal figures into binary figures—even though the result would seem useful, concrete and at least arguably (within the computer's wiring system) tangible."). Despite Justice Breyer's doubts, Gottschalk's formula likely would be tangible under the Federal Circuit jurisprudence because transforming electrical signals from one form into another was a sufficient physical transformation. See *AT&T*, 172 F.3d at 1359 (noting that the Federal Circuit had upheld a patent claim involving a mathematical formula because the claim involved the transformation of data).

²¹⁰ The ability to calculate, in real time, the current alarm limits for a given catalytic conversion process is no doubt useful, and the current alarm limit itself is a concrete and tangible number. *Metabolite II*, 126 S. Ct. 2928 ("[T]he Court has invalidated a patent setting forth a system for triggering alarm limits in connection with catalytic conversion despite a similar utility, concreteness, and tangibility.").

²¹¹ *Flook*, 437 U.S. at 594. The Court found that the claim would preclude the use of the mathematical formula for calculating an alarm limit, and thus was an unpatentable claim on a scientific truth. *Id.*

²¹² *Alappat*, 33 F.3d at 1557 (Archer, C.J., concurring in part and dissenting in part). Accord Meehan, *supra* note 9, at 338-39 (noting that the *State Street* test ignores whether the patent is drawn to valid statutory subject matter).

²¹³ See *infra* Part IV.B (discussing the inconsistency between the *State Street* test and Supreme Court precedent). The Supreme Court precedent on patentable subject matter is also explored elsewhere in this Comment. See *supra* Part II.B.

subject matter jurisprudence.²¹⁴

B. The Court, in allowing Claim 13 to Stand, Disregarded the Consequences for Medicine and Related Sciences.

In dismissing *Metabolite*, the majority of the Court, ignored the possibility that the precedent set by the Federal Circuit in *Metabolite* would have serious negative consequence for medicine and science.²¹⁵ Allowing Claim 13 to stand discourages the free exchange of scientific facts.²¹⁶ Claim 13, and the uncertainty it creates, also has the potential to damage personal medical care,²¹⁷ public health research,²¹⁸ and laboratory science.²¹⁹

²¹⁴ See, e.g., *Metabolite II*, 126 S. Ct. at 2928 (Breyer, J., dissenting) (arguing that special public interest considerations, combined with the likely invalidity of Claim 13, weighed in favor of deciding the case despite the *State Street* test); Meehan, *supra* note 9, at 341 (concluding that the Federal Circuit decision in *Metabolite* should be reversed because the Federal Circuit's approach to patentable subject matter was too broad, and inconsistent with the Supreme Court precedent); Gifford, *supra* note 13, 141-43 (recommending that the Supreme Court should adopt a new test for patentable subject matter, at least in medical diagnostic patents). See also Kane, *supra* note 48, at 555 (recommending codification of the exclusion of laws of nature, natural phenomena, and abstract ideas from patentable subject matter to bolster this exclusion).

²¹⁵ See Meehan, *supra* note 9, at 316-17 (noting that under the Federal Circuit's decision, anyone who discovers a law of nature can patent the process of collecting data related to that law of nature and thinking about the law of nature).

²¹⁶ See 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 24, *Lab. Corp. of Am. v. Metabolite Labs.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3597812 [hereinafter AMA Brief] (noting that the Federal Circuit's "ruling obviously chills the dissemination of basic facts"). Six medical professional associations signed this amicus brief, including the American Medical Association, which is a general professional association for physicians in all fields of medicine. *Id.* at 3. Also joining this brief were the American College of Medical Genetics, an association of clinical and laboratory geneticists, including physicians, and the American College of Obstetricians and Gynecologists, which includes 45,000 OB/GYNs. *Id.* at 3-4. Amicus Association for Molecular Pathology includes physicians, scientists, and technologists who perform molecular diagnostic testing, and the College of American Pathologists, which signed the brief, claims 16,000 pathologists as members, who examine and interpret data from tissues, blood, and other bodily fluids. *Id.* at 5-6. Amicus Association of American Medical Colleges represents all 125 allopathic medical schools and 400 teaching hospitals in the United States, and professional societies representing medical education faculty. *Id.* at 5.

²¹⁷ See Brief of the American Heart Association as Amicus Curiae in Support of Petitioner at 6-7, *Lab. Corp. of Am. v. Metabolite Labs.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3561169 [hereinafter AHA Brief] (arguing that upholding Claim 13 would "open the floodgates to a spate of similar patent applications in other areas of medical diagnosis and treatment"). Amicus American Heart Association is a non-profit organization with the stated purpose of reducing cardiovascular diseases and strokes. *Id.* at 1.

²¹⁸ Brief of Patients not Patents, Inc., as Amicus Curiae in Support of Petitioner at 6, *Lab. Corp. of Am. v. Metabolite Labs.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3597811 [hereinafter PNP Brief]. Amicus Patients not Patents, Inc., describes itself as a non-profit organization dedicated to employing litigation, advocacy, and education to facilitate access to healthcare, and believes that patents and other intellectual property should not restrict access to health care. *Id.* at 1.

²¹⁹ See Brief of the American Clinical Laboratory Association as Amicus Curiae in Support of Petitioner at 8, *Lab. Corp. of Am. v. Metabolite Labs.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3543098 [hereinafter ACLA Brief] ("If respondents succeed in their effort to monopolize the natural statistical relationship . . . the harm to clinical laboratory services in this country would be immeasurable."). Amicus American Clinical Laboratory Association [ACLA], is a non-profit trade association representing twenty-four clinical laboratories, which provide medical testing services for patients across the United States. *Id.* at 1. ACLA estimates its members provided approximately sixty percent of the laboratory testing provided by laboratories not affiliated with hospitals or physician's offices. *Id.*

Because Claim 13 covers a manifestation of nature,²²⁰ or the mental steps involved in contemplating a law of nature,²²¹ permitting Claim 13 to remain valid stifles the free exchange of scientific information.²²² This harmful effect is vividly illustrated by the fact that the defendant was held liable, not for copying a mechanical invention or process, but merely for sharing scientific knowledge.²²³ Specifically, the Federal Circuit found evidence for LabCorp's inducement of infringement of Claim 13 in publishing Continuing Medical Education materials about the correlation between elevated homocysteine levels and vitamin deficiency.²²⁴ Thus, although the Federal Circuit found evidence of indirect infringement in disseminating a medically useful scientific fact, the dissemination of medical information, including this correlation, remains "central to sound medical practice."²²⁵

The Court's action in allowing Claim 13 to stand, along with the Federal Circuit's *State Street* test, damages the practice of medicine.²²⁶ Homocysteine tests are useful to medical practice because high levels of homocysteine indicate an increased risk of numerous diseases, including cardiovascular conditions such as stroke and heart attack.²²⁷ It would be impractical for a physician, who knows about the correlation between an elevated total homocysteine level and a vitamin deficiency from his or her training, to resist considering the correlation upon reading a total homocysteine level test result.²²⁸ However, any physician who considers the correlation would risk breaching Claim 13 of the patent.²²⁹ Claim 13's assertion of a monopoly over use of scientific knowledge discourages physicians from interpreting, or even reading, homocysteine test results, for fear of making the correlation and thus incurring liability for infringing upon Claim 13.²³⁰ A physician wishing to avoid infringement,

²²⁰ See AHA Brief, *supra* note 217, at 18 (contending that Claim 13 contains nothing inventive and only is a recitation of a law of nature); AMA Brief, *supra* note 216, at 18 (arguing that Claim 13 "is indistinguishable from a scientific principle" which is unpatentable subject matter.); *supra* note 191 (noting some authorities contending that Claim 13 recites unpatentable subject matter).

²²¹ PNP Brief, *supra* note 218, at 1-2 ("[Claim 13] is directed to a mental process for recognizing that a natural phenomenon has occurred.").

²²² See AHA Brief, *supra* note 217, at 18 (observing that Claim 13 gives LabCorp "an exclusionary right that would prevent doctors from properly diagnosing their patients"); AMA Brief, *supra* note 216, at 24 (noting that upholding Claim 13 "obviously chills the dissemination of basic facts").

²²³ See *Metabolite Labs., Inc. v. Lab. Corp. of Am. (Metabolite I)*, 370 F.3d 1354, 1365 (Fed. Cir. 2004), *cert. dismissed as improvidently granted sub nom.*, *Lab. Corp. of Am. v. Metabolite Labs., Inc. (Metabolite II)*, 126 S. Ct. 2921 (2006) (mem.) (per curiam) (ruling that LabCorp's dissemination of Continuing Medical Education materials that discussed the correlation between elevated homocysteine levels and vitamin deficiency, constituted evidence of inducement of infringement).

²²⁴ *Id.*

²²⁵ AMA Brief, *supra* note 216, at 24.

²²⁶ See *id.* (noting that Claim 13 chills the free dissemination of medical information crucial to medical practice).

²²⁷ AHA Brief, *supra* note 217, at 20. Because of the utility of homocysteine assays in detecting cardiovascular risks, the American Heart Association issued an advisory to physicians addressing the use of homocysteine testing. *Id.* at 19.

²²⁸ AMA Brief, *supra* note 216, at 25 (arguing that it would be impossible for any medical practitioner "who knows of the association between homocysteine and vitamin deficiency to avoid practicing claim 13" because a "physician who learns—from the medical literature, colleagues, continuing medical education, or other public sources—of [the correlation] . . . can not put that knowledge out of mind.").

²²⁹ *Id.*

²³⁰ PNP Brief, *supra* note 218, at 4. Federal statute, U.S.C. § 287(c) (2000), limits the liability of

while attempting to keep her or his patient informed as to the patient's health status, may pass test results on to the patient, in hopes that the patient can and will determine, through the patient's own research, if she or he has a vitamin deficiency.²³¹ Free communication between physician and patient is hampered because a physician may be afraid to discuss the correlation with the patient, for fear of infringing upon Claim 13.²³² It would be burdensome for a physician to avoid liability for infringement by obtaining a license, because the physician would have to spend resources and energy searching for patents on similar medical correlations, and then expend further resources obtaining licenses under those patents.²³³

Claim 13 adversely affects not just individual patients but public health, because epidemiology²³⁴ studies utilized homocysteine tests to identify increased incidences of vitamin deficiencies among certain sectors of the population.²³⁵ However, because the act of ordering a homocysteine assay and correlating between homocysteine and vitamin deficiency is patented by Claim 13, such epidemiological studies would infringe Metabolite's patent.²³⁶ Thus, public health researchers would be hindered in performing research involving homocysteine if they had to fear infringing Claim 13 of Metabolite's patent, or waste sparse public health resources and research funds to obtain a license for Claim 13.²³⁷

By declining to examine the validity of Claim 13, the Supreme Court caused severe uncertainty and damage to medical laboratory services throughout the United

medical practitioners for infringing patents when performing medical activity. However, this statute would not be applicable because the statute only applies to patents filed after September 30, 1996, and Metabolite's patent was filed before then. *See* PNP Brief, *supra* note 218, at 5 (noting probable inapplicability of U.S.C. § 287(c) to Claim 13). Furthermore, it is not certain that correlating a test result to a well-know natural relationship is a "medical activity." *See id.* (discussing scope of "medical activity" under 35 U.S.C. § 287(c)).

²³¹ PNP Brief, *supra* note 218, at 4. Allowing the patient to make the correlation would not be sufficient because a patient may not be able to obtain accurate medical information about the correlation between homocysteine and cobalamin or folate deficiency on her or his own, and may misconstrue any information she or he does obtain. *Id.*

²³² *Id.* at 4-5 ("The patient's physician may be reluctant to discuss the matter with the patient for fear of creating evidence that he or she correlated the test results with a deficiency of vitamin B 12 or folate, thereby infringing upon the patent. Thus, Claim 13 harms patients by inhibiting honest communication with their physician.").

²³³ *See* Lab. Corp. of Am. v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2928-29 (2006) (mem.) (Breyer, J., dissenting) (noting that Claim 13 "may force doctors to spend unnecessary time and energy to enter into license agreements . . . diverting resources from the medical task of health care to the legal task of searching patent files for similar correlations").

²³⁴ Epidemiology is "the scientific study of factors affecting the health and illness of populations, and serves as the foundation and logic of interventions made in the interest of public health and preventive medicine. It is considered a cornerstone methodology of public health research . . ." Epidemiology, <http://en.wikipedia.org/w/index.php?title=Epidemiology&oldid=103416929> (last visited Apr. 24, 2007).

²³⁵ PNP Brief, *supra* note 218, at 6-7. One such study, for example, found a higher prevalence of folate deficiency among elderly African-American women than elderly Caucasian women. *Id.* at 6. Accordingly, these epidemiological studies enable a better understanding of vitamin deficiencies and disease, and allow the directing of public health interventions towards those populations with higher incidence of vitamin deficiencies. *See id.* at 7 (noting use of homocysteine testing in epidemiological studies).

²³⁶ *Id.* at 7 ("[E]ach newly identified risk factor would inhibit, rather than enhance, research conducted through standard analytic tools such as multivariate regression models.").

²³⁷ *See id.* at 6 (stating that "the cost and availability of licenses for the patented method would also affect the ability of researchers to perform population-based studies").

States.²³⁸ Claim 13 would allow Metabolite to prevent physicians or laboratories from utilizing any homocysteine assay to determine if a patient has a vitamin deficiency.²³⁹ The danger is not limited to Metabolite's Claim 13, because almost all medical laboratory tests are useful because they are premised upon a natural correlation, requiring a medical professional to interpret the test results in light of the knowledge about the correlation.²⁴⁰ However, if the act of reading test results and correlating those test results based on a natural correlation is patentable subject matter, as the Federal Circuit opinion in *Metabolite* holds, medical testing would "be at the mercy of the person who first discovered the natural correlation."²⁴¹ Progress in developing new, safer, and more effective testing methods would be inhibited because any such test depends upon that underlying correlation, and medical professionals would thus have to license the correlation from whoever first discovered and patented the underlying correlation.²⁴² Clinical laboratories would be deterred from expending resources in developing new and better tests if they would be forced to obtain licenses from, and pay royalties to, the original discoverer of the correlation underlying those tests.²⁴³

The Court, by failing to address the Federal Circuit's precedent upholding Claim 13, creates uncertainty as to whether one could patent the correlation between genes in the human genome and the increased risk of disease caused by variations in those genes.²⁴⁴ This will inhibit genetic research and testing.²⁴⁵ For example, if the discoverers of a correlation between a gene mutation and a hereditary disease were able to patent that correlation, as suggested by the decision in *Metabolite*, it would be more costly to test people for that mutation.²⁴⁶ The patentee, exercising its rights of patent exclusivity, could create a testing monopoly for the genetic mutation, preventing the development of any competing test for the genetic mutation and

²³⁸ See ACLA Brief, *supra* note 219, at 8 (noting that upholding Claim 13 would irreparably harm clinical laboratory services in the United States).

²³⁹ *Id.* Indeed, this litigation began only after LabCorp switched from Metabolite's test for homocysteine to another's test. See discussion *infra* Part III.A (exploring scientific background and procedural history of the *Metabolite* case).

²⁴⁰ ACLA Brief, *supra* note 219, at 9.

²⁴¹ *Id.* An example of such a natural correlation is the correlation between low-density lipoprotein ("bad" cholesterol) and an increased risk of heart diseases. *Id.* at 10.

²⁴² See *id.* at 9 (noting that the new and superior tests are "inventive applications of previously discovered laws of nature" that would "be entirely at the mercy of whoever first discovered the natural correlation that makes the test useful").

²⁴³ See *id.* at 13 ("[M]edical science has been able to advance to its current state without the payment of royalties and subsequent discouragement of research that such patent claims would have brought about. . . . [U]pholding claim 13, however, would permit those who make medical advances in the future to patent every potential application of the natural phenomena that underlie their inventions.").

²⁴⁴ See Brief for Amici Curiae Affymetrix, Inc., and Professor John H. Barton in Support of Petitioner at 16, *Lab. Corp. of Am. v. Metabolite Labs.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3597814 [hereinafter *Affymetrix Brief*] (arguing that upholding Claim 13 could allow for the correlation between genes and the effects of those genes to be patented). Amicus Affymetrix, Inc. manufactures DNA microassays, equipment which is used in genetic research. *Id.* at 1. Amicus Professor John H. Barton is a Professor of Law Emeritus at Stanford University, and is an expert on the impact of patents on medicine and biotechnology. *Id.* at 2.

²⁴⁵ *Id.* at 16.

²⁴⁶ *Id.* ("[A] claim like claim 13 might thus preclude a person from testing her own genetic code. Yet testing for a relationship between a single gene mutation and a physical condition has demonstrated medical value and may even be life saving.").

refusing to allow a patient to obtain a second opinion of the test result.²⁴⁷ Furthermore, genetic research would be impeded if such correlations were patentable subject matter because the complex and interrelated nature of genetics would make it difficult to conduct research into genetics without infringing a patent on such a correlation involving gene mutation.²⁴⁸

By allowing Claim 13 to remain valid, the Supreme Court majority ignored the reality that Claim 13, and the precedent it sets, would discourage the free flow of scientific information,²⁴⁹ inhibit individual medical practice,²⁵⁰ complicate epidemiological studies vital to furthering public health,²⁵¹ curtail the development of the medical laboratory sciences,²⁵² and limit research into genetics.²⁵³

C. The Record was Adequately Developed for the Court to Decide the Case

The record was adequately developed for the Court to render a decision on whether Claim 13 was patentable subject matter.²⁵⁴ One possible explanation for the “improvidently granted” dismissal is procedural: that the issue of patentable subject matter was not sufficiently preserved or developed in the lower courts.²⁵⁵ The Solicitor General argued that LabCorp never directly raised the issue of whether Claim 13 was valid patentable subject matter in the lower courts, and thus there was not a fully developed record.²⁵⁶ The Solicitor General’s argument fails to realize the historical lack of success of such challenges, and the likely effect that history had on LabCorp’s decision not to raise a challenge to the validity of the subject matter of

²⁴⁷ See *id.* at 18-19 (discussing the BRCA patent controversy, where three patents claimed to cover any method for detecting certain genetic mutations that contributed to susceptibility for breast cancer. The U.S. holder of the patents has “exercised its exclusivity by prohibiting others from providing the tests, [and] making it impossible for a patient to obtain a second opinion on the result.”).

²⁴⁸ *Id.* at 17 (“Impediments to genetic research if natural genetic phenomena were allowed to be patented are compounded by the fact that modern [sic] genomic research has moved past such one mutation/one function examples to explore much more complex interrelationships among genes and genetic functions.”).

²⁴⁹ See AMA Brief, *supra* note 216, at 24 (noting the importance of free dissemination of information).

²⁵⁰ See AHA Brief, *supra* note 217, at 26 (noting that “if the Federal Circuit’s judgment is not reversed, physicians will not legally be able to follow the AHA advisory set forth above”).

²⁵¹ See PNP Brief, *supra* note 218, at 6 (arguing that Claim 13 would deter public health researchers from performing epidemiological studies involving homocysteine).

²⁵² See ACLA Brief, *supra* note 219, at 9 (observing that Claim 13 would devastate the medical laboratory testing industry).

²⁵³ See Affymetrix Brief, *supra* note 244, at 16 (discussing potential harm to genetic research and genetic testing that could result if the discoverer of a gene mutation could patent all testing of that gene mutation).

²⁵⁴ See discussion *infra* Part IV.C (arguing that the record was fully developed for the Supreme Court to decide whether Claim 13 of Metabolite’s patent was valid patentable subject matter).

²⁵⁵ Several amici, lead by the Solicitor General, argued that certiorari should be denied because LabCorp failed to properly develop the issue below. See Solicitor General’s August Brief, *supra* note 170, at 19 (arguing that the writ of certiorari should be denied because the record was not properly developed due to LabCorp’s failure to raise the issue of subject matter of Claim 13 below). See also Amicus Curiae Brief of American Intellectual Property Law Association in Support of Respondent at 4, *Lab. Corp. of Am. v. Metabolite Labs.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2006 WL 303907 (arguing that the Court should decline to address whether Claim 13 is valid subject matter because the record was not properly developed below); Amicus Curiae Brief of the Federal Circuit Bar Association in Support of Respondents at 3, *Lab. Corp. of Am. v. Metabolite Labs.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2006 WL 303906 (“The petition for certiorari should be dismissed as improvidently granted.”).

²⁵⁶ Solicitor General’s August Brief, *supra* note 170, at 19.

Claim 13.²⁵⁷

In his dissent, Justice Breyer presented several convincing arguments that certiorari was properly granted.²⁵⁸ First, Justice Breyer noted that LabCorp did indirectly argue the validity of the subject matter of Claim 13 to the Federal Circuit.²⁵⁹ Further, Justice Breyer noted that when the Court granted certiorari, it implicitly rejected the Solicitor General's argument that the record was inadequately developed because of LabCorp's failure to challenge the subject matter of Claim 13 in the lower courts.²⁶⁰ Most importantly, briefs by both of the parties, the Solicitor General, and all of the amici could provide a sufficient record on which the Court could decide the case, and further consideration by lower courts would likely prove inefficient.²⁶¹

The Solicitor General also argued that the Court should not decide *Metabolite* because the PTO and the Federal Circuit have allowed numerous patents on medical

²⁵⁷ See Kane, *supra* note 48, at 526-29 (discussing the dearth, in modern patent cases, of challenges to patents on the basis of statutory subject matter). Patent examiners at the PTO and the administrative appeal level of the PTO tend to deny a patent for lack of patentable subject matter only as indicating the PTO's larger resistance to patenting a certain technology. *Id.* at 526-27. For example, the landmark Supreme Court cases on patentable subject matter, from *Parker v. Flook* to *Diamond v. Diehr*, came about because of the PTO's resistance to patents on computer programs. *Id.* at 526-27. Patent contests between adversarial parties are unlikely to include attacks on the claim's subject matter, as indicated by a study of litigated patent cases that showed that only 0.7% of invalidated patents were invalidated because of invalid subject matter. *Id.* at 527 (noting that 42.0% of invalidated patents were invalidated on the basis of obviousness and 31.1% of invalid patents were invalidated because of prior art). Accordingly, many handbooks for patent law practitioners, including the ABA's *Patent Litigation Strategies Handbook* and the Practising Law Institute's *Patent Litigation* briefly review the doctrine of patentable subject matter, while providing thorough and complete coverage of the other grounds for challenging patent claims. *Id.* at 528. Thus, most parties who challenge patents, especially technology and science related patents, have an additional incentive not to challenge patent claims based on subject matter because

[m]any patent disputes are decided between similarly situated competitors, who may be in conflict over a particular patent, but in agreement regarding the general eligibility of subject matter in a particular field. The consequences of a determination that patentable subject matter does not exist might extend beyond the particular patent in suit, resulting in hesitation on the part of either party (or the courts) to raise the issue for fear of sector-wide consequences.

Id. at 528-29. Therefore, it is of little surprise that the issue of subject matter of patent claims rarely comes up in patent litigation, and that LabCorp did not attack Claim 13 on the basis of subject matter in the lower courts. See *id.* at 528 (detailing lack of successful challenges based on invalid subject matter).

²⁵⁸ *Metabolite II*, 126 S. Ct. at 2925-26 (Breyer, J., dissenting).

²⁵⁹ *Id.*, 126 S. Ct. at 2925-26 (Breyer, J., dissenting). See *supra* note 178 for a fuller explanation of Justice Breyer's critique of the Solicitor General's argument.

²⁶⁰ *Metabolite II*, 126 S. Ct. at 2926 (Breyer, J., dissenting) (stating that when the Court granted certiorari the Court "rejected [the Solicitor General's] advice, thereby 'necessaril[y] consider[ing] and reject[ing] that contention as a basis for denying review'" (quoting *United States v. Williams*, 504 U.S. 36, 40 (1992))). Not even the Solicitor General questioned the ability of the Court to accept the case and reach the issue, even when it was not decided below. See Solicitor General's August Brief, *supra* note 170, at 16 ("To be sure, this Court has inherent discretion to overlook petitioner's failure to raise the issue in the lower courts, particularly in light of the fact that the brief for the opposition does not call the Court's attentions to the waiver.").

²⁶¹ *Metabolite II*, 126 S. Ct. at 2926 (Breyer, J., dissenting). Justice Breyer declared outright that "The record is comprehensive, allowing us to learn the precise nature of the patent claim." *Id.* (Breyer, J., dissenting). He went on to note that remanding to require the Federal Circuit or District Court to hear the subject matter challenge would likely be wasteful because "the thoroughness of the briefing leads me to conclude that the extra time, cost, and uncertainty that further proceedings would engender are not worth the potential benefit." *Id.* (Breyer, J., dissenting).

diagnostic procedures and “[a] decision overturning [the] PTO’s approach could call into question a substantial number of patent claims and undermine the settled expectations of numerous participants in technology based industries.”²⁶² The Solicitor General, however, did not name any specific patents, or Federal Circuit decisions upholding patents, on medical diagnosis processes which would be cast into doubt if the Supreme Court invalidated Claim 13.²⁶³ Furthermore, even though the PTO has issued a patent, and the PTO has issued similar patents, patent claims can always be invalidated through litigation.²⁶⁴ As Dr. Michael Meehan²⁶⁵ concluded, “the issuance by the PTO of claims to what appear to be diagnostic methods similar to that of claim 13 does not guarantee that the claims will be held valid, nor should it settle expectations for patentees.”²⁶⁶

D. The Supreme Court Should have Decided *Metabolite*, Consistent with its Recent Pattern of Clarifying Patent Issues.

The Supreme Court engaged in a recent pattern of clarifying patent jurisprudence,²⁶⁷ and, consistent with that pattern, should have decided *Metabolite*, and thus settled the confusing and misguided jurisprudence the Federal Circuit currently utilizes.²⁶⁸

In *eBay, Inc. v. MercExchange, L.L.C.*,²⁶⁹ the Court intervened in Federal Circuit jurisprudence and overturned the Federal Circuit’s longstanding practice of automatically granting injunctions against those who infringe a patent.²⁷⁰ The Court held that the traditional equity balancing test should apply in patent cases as in other

²⁶² Solicitor General’s August Brief, *supra* note 170, at 14. The Solicitor General went on to argue that “[t]he number of patent claims that would be invalidated by a reversal of the Federal Circuit’s understanding of *Flook* and *Diehr* is difficult to predict At a minimum, however, a paradigm shift in the way PTO and the lower courts have viewed *Diehr* would engender substantial uncertainty.” *Id.* at 15 n.*.

²⁶³ Meehan, *supra* note 9, at 339.

²⁶⁴ *Id.* (“[E]ven though there is a presumption that claims allowed by the PTO are valid, patent claims can [be] and are invalidated during trial.” (citation omitted)).

²⁶⁵ Michael Meehan, who previously worked as a patent agent, earned a Ph.D. in computer science and completed his postdoctoral studies at Stanford University, where he is currently earning a J.D. *Id.* at 311, n.a1.

²⁶⁶ *Id.* at 339.

²⁶⁷ *See, e.g.*, *KSR Int’l Co. v. Teleflex, Inc. (KSR II)*, 2007 WL 1237837, at *12 (U.S. Apr. 30, 2007), *rev’g* *Teleflex, Inc. v. KSR Int’l Co. (KSR I)*, 119 Fed. App’x 282 (Fed. Cir. 2005) (nonprecedential) (rejecting the Federal Circuit’s Teaching-Suggestion-Motivation test for obviousness was too rigid); *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 777 (2007), *rev’g* 427 F.3d 958 (Fed. Cir. 2005) (holding that licensee under patent does not have to breach license agreement for a federal court to have Article III subject matter jurisdiction over a licensee’s petition for a declaratory judgement against the patent); *eBay, Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837, 1839 (2006) (abolishing practice of issuing injunctions against patent infringers with traditional equity factors); *Ill. Tools Works, Inc. v. Indep. Ink, Inc.*, 126 S. Ct. 1281, 1292 (2006) (ending market power presumption that tying unpatented product to a patented product allows tying party to leverage the market power of the patent to the unpatented product).

²⁶⁸ *See, e.g.*, Gifford, *supra* note 13, at 134 (criticizing Federal Circuit’s current patent eligibility standard); *supra* Part III.C (arguing that the *State Street* test is inconsistent with Supreme Court precedent).

²⁶⁹ 126 S. Ct. 1837 (2006).

²⁷⁰ *See eBay*, 126 S. Ct. at 1839 (noting that “[n]othing in the Patent Act authorizes” a departure from the traditional norms of equity).

cases.²⁷¹ In *eBay*, MercExchange sued Internet auction site eBay²⁷² for infringing MercExchange's business method patent "designed to facilitate the sale of goods between private individuals by establishing a central authority to promote trust among participants."²⁷³ Although the jury in the United States District Court for the Eastern District of Virginia found that eBay infringed the patent and awarded damages, the district court denied MercExchange's petition for permanent injunctive relief.²⁷⁴ The Federal Circuit reversed, relying upon the "general rule that courts will issue permanent injunctions against patent infringers absent exceptional circumstances."²⁷⁵

The Supreme Court granted certiorari to "determine the appropriateness of this general rule."²⁷⁶ The Court observed that traditional equity principles required the plaintiff seeking a permanent injunction to satisfy a four-factor test before a court may grant such an injunction.²⁷⁷ The Court determined that nothing in the Patent Act authorized a departure from the traditional equity principles for permanent injunctions, and thus the traditional equity test for permanent injunctions applied equally in patent cases.²⁷⁸ The Court thus upended the Federal Circuit's longstanding general rule of favoring permanent injunctions against patent infringers in favor of the traditional equity factors, without expressing any reservation of upsetting any settled expectations.²⁷⁹

The Court in *Illinois Tool Works, Inc. v. Independent Ink, Inc.*²⁸⁰ overruled its own precedent to eliminate the market power²⁸¹ presumption that an arrangement tying an unpatented product to a patented product creates a monopoly for the unpatented product.²⁸² *Illinois Tool* was an antitrust claim arising out of a patent

²⁷¹ *Id.* (ruling that "well established principles of equity" also "apply with equal force to disputes arising under the Patent Act").

²⁷² MercExchange also brought suit against Half.com, an Internet site that allows people to sell goods to each other, which was a wholly-owned subsidiary of eBay by the time the Supreme Court made its decision. *Id.*

²⁷³ *Id.* (citing U.S. Patent No. 5,845,265 (filed Nov. 7, 1995)).

²⁷⁴ MercExchange, L.L.C. v. eBay, Inc., 275 F. Supp. 2d 695, 711 (E.D. Va. 2003).

²⁷⁵ MercExchange, L.L.C. v. eBay, Inc., 401 F.3d 1323, 1339 (Fed. Cir. 2005).

²⁷⁶ *eBay*, 126 S. Ct. at 1839 (citing *eBay, Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 733 (2005) (mem)).

²⁷⁷ *Id.* The four factors a plaintiff must prove before obtaining a permanent injunction are: (1) the plaintiff suffered irreparable harm; (2) no remedy available at law, including monetary damages, is adequate to compensate the plaintiff for that irreparable harm; (3) considering the balance of hardships between plaintiff and defendant, an equitable remedy is appropriate; and (4) the public interest would not be disserved by the permanent injunction. *Id.*

²⁷⁸ *Id.* ("The familiar principles [of equity] apply with equal force to disputes arising under the Patent Act. As this Court has long recognized, 'a major departure from the long tradition of equity practice should not be lightly implied.'" (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 320 (1982))). Further supporting the application of the traditional principles of equity, the Court noted that the Patent Act authorized injunctions "in accordance with the principles of equity." *Id.* (quoting 35 U.S.C. § 283).

²⁷⁹ See *eBay*, 126 S. Ct. at 1839 (abolishing Federal Circuit's longstanding tradition of issuing injunctions against patent infringers).

²⁸⁰ 126 S. Ct. 1281 (2006).

²⁸¹ "Market power" is the "ability to reduce output and raise prices above the competitive level—specifically, above marginal cost—for a sustained period, and to make a profit by doing so. In antitrust law, a large amount may constitute monopoly power." BLACK'S LAW DICTIONARY 991 (8th ed. 2004).

²⁸² See *Ill. Tool*, 126 S. Ct. at 1293 ("Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee.

case,²⁸³ where the Federal Circuit followed Supreme Court precedent and applied the market power presumption.²⁸⁴ Thus, applying the market power presumption, the Federal Circuit presumed that Illinois Tool had market power because of its patent, despite the lack of any evidence that Illinois Tool had actual market power.²⁸⁵

The Supreme Court reversed the Federal Circuit decision in *Illinois Tool*.²⁸⁶ The Supreme Court noted that it had long disapproved of tying arrangements²⁸⁷ between a patented product and an unpatented product, going so far as to create a presumption that such a tying arrangement creates a presumption of market power in the unpatented product.²⁸⁸ The market power presumption created a *per se* presumption that the mere patent gives the patentee market power over the market in which the patented product competes.²⁸⁹ This presumption, although it originated in the judicially created patent misuse doctrine, was applicable to antitrust claims.²⁹⁰ The Court examined its own past treatment of tying arrangements involving patents,²⁹¹ the Congressional abolition of the market power presumption in the patent misuse doctrine,²⁹² and academic literature indicating that a patent does not

Today, we reach the same conclusion, and therefore hold that, in all cases involving a tying arrangement, the plaintiff must prove that the defendant has market power in the tying product.”)

²⁸³ The facts and procedural history of *Illinois Tool* are, briefly, this: Trident Inc, which is now a subsidiary of Illinois Tool Works, produced a patented ink container and patented printhead, and specially formulated ink that was unpatented. *Id.* at 1284. Independent Ink produced identically formulated and competing ink, and Illinois Tool brought an infringement claim which was dismissed for lack of personal jurisdiction. *Id.* at 1285. After the dismissal, Independent Ink responded by filing suit, seeking a judgment of noninfringement, challenging the validity of the patents, and claiming illegal tying and monopolization in violation of antitrust statutes. *Id.* The District Court granted summary judgment in favor of Illinois Tool, noting that Independent Ink did not present any evidence that the patents provided Illinois Tool with any market power. *Indep. Ink, Inc. v. Trident, Inc.*, 210 F. Supp. 2d 1155, 1177 (C.D. Cal. 2002).

²⁸⁴ *Indep. Ink, Inc. v. Ill. Tool Works, Inc.*, 396 F.3d 1342, 1351 (Fed. Cir. 2005). The Federal Circuit reluctantly applied the market power presumption, noting academic criticism of the presumption, but ultimately observed that it was “the duty of a court of appeals to follow the precedents of the Supreme Court until the Court itself chooses to expressly overrule them.” *Id.* The Supreme Court noted that the Federal Circuit relied heavily on several of its decisions. *Ill. Tool*, 126 S. Ct. at 1285 (citing *Int’l Salt Co. v. United States*, 332 U.S. 392 (1947); *United States v. Loew’s*, 371 U.S. 38 (1962); *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2 (1984)).

²⁸⁵ *Indep. Ink.*, 396 F.3d at 1352-53 (finding that the Illinois Ink’s patent create a presumption of market power, although Independent Ink did not present evidence of Illinois Ink’s market power).

²⁸⁶ 126 S. Ct. at 1293 (“[T]he judgment of the Court of Appeals is vacated”).

²⁸⁷ A “tying arrangement” is “[a] seller’s agreement to sell one product or service only if the buyer also buys a different product or service Tying arrangements may be illegal under the Sherman or Clayton Acts if their effect is too anticompetitive.” BLACK’S LAW DICTIONARY 1557 (8th Ed. 2004).

²⁸⁸ *See Ill. Tool*, 126 S. Ct. at 1284 (noting that the Court had previously declared that “if the Government has granted the seller a patent or similar monopoly over a product, it is fair to presume that the inability to buy the product elsewhere gives the seller market power” (quoting *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 16 (1984))).

²⁸⁹ *See Ill. Tool*, 126 S. Ct. at 1287-88 (describing background of market power presumption).

²⁹⁰ *Id.* at 1284. The Court noted that Congress eliminated the use of the market power presumption in patent misuse claims. *Id.* (citing 102 Stat. 4674 (codified as amended at 35 U.S.C. § 271(d) (2000))). Nonetheless, the market power presumption survived in antitrust law. *Id.*

²⁹¹ *Ill. Tool*, 126 S. Ct. at 1286. The Court, reviewing its decisions, concluded that “[o]ver the years, however, this Court’s strong disapproval of tying agreements has substantially diminished. Rather than relying on assumptions, in its more recent opinions, the Court has required a showing of market power in the tying product.” *Id.*

²⁹² *Id.* at 1290. The Court noted that Congress’s elimination of the market power presumption in the patent misuse defense invited reconsideration of the appropriateness of the market power presumption in

necessarily confer market power.²⁹³ After so doing, the Court held that the market power presumption should be abolished because “a patent does not necessarily confer market power upon the patentee.”²⁹⁴ Instead, the Court required a party alleging that a tying arrangement constitutes an antitrust violation to present evidence that the patent gives the patentee market power in the tying product.²⁹⁵

The Supreme Court has maintained its trend of engagement in patent cases, recently reversing the Federal Circuit in *MedImmune, Inc. v. Genentech, Inc.*²⁹⁶ Although MedImmune was a licensee in good standing under the patent, it sought a declaratory judgment that Genentech’s patent was invalid and unenforceable.²⁹⁷ Because of MedImmune’s licensee status, the Federal Circuit determined that “there is no controversy of immediacy or reality because there is no reasonable apprehension of suit.”²⁹⁸ Thus, the Federal Circuit held that the federal courts lacked subject matter jurisdiction over MedImmune’s action for declaratory judgment as long as MedImmune continued to be a licensee in good standing under its license.²⁹⁹

The Supreme Court, reversing the Federal Circuit, held that a licensee under a patent need not cease paying royalties on a patent before seeking a declaratory judgment challenging the patent’s validity.³⁰⁰ The Court began by observing that when a government is threatening action against the plaintiff, the plaintiff is not required to expose him or herself to liability before challenging the threatened governmental action.³⁰¹ The Court noted that in its sole on-point precedent, *Altvater v. Freeman*,³⁰² the Court held that a licensee’s failure to pay royalties did not deprive the federal courts of their Article III subject matter jurisdiction over declaratory judgment claims by the licensee.³⁰³ The Court rejected the Federal Circuit’s attempt

antitrust cases. *Id.* at 1290-91.

²⁹³ *Id.* at 1291 n.4, 1292.

²⁹⁴ *Id.* at 1293.

²⁹⁵ *Id.* The Court observed that a conclusion of market power “must be supported by proof of power in the relevant market rather more by than a mere presumption thereof.” *Id.* at 1291.

²⁹⁶ (*MedImmune II*), 127 S. Ct. 764, 777 (2007), *rev’g* *MedImmune, Inc. v. Genentech, Inc. (MedImmune I)*, 427 F.3d 958 (Fed. Cir. 2005).

²⁹⁷ *MedImmune I*, 427 F.3d at 962. The patent itself, U.S. Patent No. 4,816,567 (filed June 10, 1988), was related “to the use of cell cultures to manufacture human antibodies.” *MedImmune I*, 427 F.3d at 961. MedImmune sought a declaratory judgment to invalidate the patent, in addition to antitrust and unfair competition claims. *Id.* at 963, 965. MedImmune brought its claim after being informed that MedImmune would have to pay royalties for a new product it developed. *Id.* at 962.

²⁹⁸ *MedImmune I*, 427 F.3d at 965. The Federal Circuit noted that the inherent adverse interests between licensor and licensee are insufficient to create a justiciable controversy, instead there must be a “definitive and concrete controversy.” *Id.* at 964 (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 277, 241 (1937)). The controversy must also be of “sufficient immediacy and reality.” *Id.* (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

²⁹⁹ *Id.* at 963-64 (“[T]he jurisdictional requirements of a declaratory action are not met when royalties are fully paid to the licensor and there is no ground on which the licensor can cancel the license or sue for infringement.”).

³⁰⁰ *MedImmune II*, 127 S. Ct. at 777 (“We hold that the petitioner was not required, insofar as Article III is concerned, to break or terminate its 1997 license agreement before seeking a declaratory judgment in federal court that the underlying patent is invalid, unenforceable, or not infringed. The Court of Appeals erred in affirming the dismissal of this action for lack of subject-matter jurisdiction.”).

³⁰¹ *MedImmune II*, 127 S. Ct. at 772 (citing *Terrace v. Thompson*, 263 U.S. 197 (1923)).

³⁰² 319 U.S. 359 (1943).

³⁰³ *MedImmune II*, 127 S. Ct. at 773. In *Altvater*, the Court held that there was a justiciable case or controversy where the licensee was paying royalties “under protest” because of a previous injunction

to distinguish the *Alvater* decision on the basis that *Alvater* involved an injunction.³⁰⁴ Further, the Court found that the Federal Circuit's "reasonable apprehension of suit" standard was inconsistent with *Alvater* because the licensee in *Alvater*, begrudgingly paying royalties only because of an injunction, also did not fear a lawsuit as long as he continued to pay royalties.³⁰⁵ Thus, the Supreme Court held that a licensee under a patent need not breach the licensing agreement before a federal court will have subject matter jurisdiction over the licensee's declaratory judgment action attacking the patent.³⁰⁶

Most recently, the Court, in *KSR International Co. v. Teleflex, Inc.*,³⁰⁷ rejected the rigid approach the Federal Circuit took toward obviousness analysis.³⁰⁸ In *KSR*, Teleflex sued for patent infringement on its patent for a position-adjustable pedal assembly used in electronic throttle control for automobiles.³⁰⁹ The United States District Court for the Eastern District of Michigan granted KSR's motion for summary judgment, concluding based on the prior art referenced in the patent that the patent claim was invalid because the patent was an obvious invention.³¹⁰ In a nonprecedential opinion, the Federal Circuit applied its obviousness precedent and held that a patent claim can be held invalid because of obviousness "only if there was a reason, suggestion, or motivation to combine" the prior art references³¹¹ in the particular manner claimed.³¹² The Federal Circuit noted that it had consistently

that required the licensee to pay the royalties. *Id.* at 773 (quoting *Alvater*, 319 U.S. at 364).

³⁰⁴ *MedImmune II*, 127 S. Ct. at 774. The Supreme Court noted that licensing contracts, and the damages available for the breach of such contracts, can be just as persuasive and threatening as injunctions, and breach of such contracts can, "imperil a man's livelihood, his business enterprises, or his solvency." *Id.* (quoting F. WOODWARD, THE LAW OF QUASI CONTRACTS § 218 (1913)).

³⁰⁵ *MedImmune II*, 127 S. Ct. at 774 ("A licensee who pays royalties under compulsion of an injunction has no more apprehension of imminent harm than a licensee who pays royalties for fear of treble damages and an injunction fatal to his business.")

³⁰⁶ *Id.* at 777.

³⁰⁷ (*KSR II*) 2007 WL 1237837 (2007), *rev'g* Teleflex, Inc. v. KSR Int'l Co. (*KSR I*), 119 Fed. App'x 282 (Fed. Cir. 2005) (nonprecedential). Certiorari was granted on June 26, 2006. *KSR Int'l Co. v. Teleflex Inc.*, 126 S. Ct. 2965, 2966 (2006) (mem.). The Court dismissed the writ of certiorari in *Metabolite* as improvidently granted on June 26, 2006. *Metabolite II*, 126 S. Ct. at 2921.

³⁰⁸ *KSR II*, 2007 WL 1237837, at *12.

³⁰⁹ *KSR I*, 119 Fed. App'x 282, 283-84.

³¹⁰ *Id.* at 284 (discussing procedural history). 35 U.S.C. § 103(a) requires all patent claims to be nonobvious. Obviousness is defined as the "quality of state of being easily apparent to a person with ordinary skill in a given art, considering the scope and content of the prior art, so that the person could reasonably believe that, at the time it was conceived, the invention was to be expected." BLACK'S LAW DICTIONARY 1108 (8th Ed. 2004).

³¹¹ *KSR I*, 119 Fed. App'x at 285 (quoting *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 665 (Fed. Cir. 2000)). Such a reason, suggestion, or motivation can be

"found explicitly or implicitly: 1) in the prior art references themselves; 2) in the knowledge of those of ordinary skill in the art that certain references, or disclosures in those references, are of special interest or import to the field; or 3) from the nature of the problem to be solved, 'leading inventors to look to references relating to possible solutions to the problem.'"

Id. (quoting *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 665 (Fed. Cir. 2000) (quoting *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1572 (Fed. Cir. 1996))).

³¹² *KSR I*, 119 Fed. App'x at 286 (citing *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000)) ("We have consistently held that a person of ordinary skill in the art must not only have some motivation to combine the prior art teachings, but some motivation to combine the prior art teachings in the particular manner claimed.").

applied the teaching-suggestion-motivation test.³¹³ The Federal Circuit, remanding to the district court, found that the district court incorrectly applied the teaching-suggestion-motivation test, and failed to recognize that genuine issues of material fact still existed.³¹⁴ The Supreme Court reversed the Federal Circuit, rejecting the Federal Circuit's teaching-suggestion-motivation test as too rigid.³¹⁵ The Court reviewed its obviousness precedents, established a flexible approach to the obviousness analysis.³¹⁶ The Supreme Court, in rejecting the Federal Circuit's teaching-suggestion-motivation test, found that the test inappropriately narrowed the obviousness analysis.³¹⁷

The Supreme Court has recently involved itself in clarifying issues of patent law, from ending longstanding Federal Circuit traditions of automatically issuing injunctions upon finding infringement,³¹⁸ to overruling its own precedent on the market power presumption.³¹⁹ The Court has also rejected the Federal Circuit's approach to jurisdictional subject matter for declaratory judgments,³²⁰ and the Federal Circuit's teaching-suggestion-motivation test for obviousness.³²¹ This pattern of involvement with patent issues makes the Court's dismissal of *Metabolite* even more inexplicable.³²²

³¹³ *KSR I*, 119 Fed. App'x at 286 (citing *Kotzab*, 217 F.3d at 1371). The court explained that such a standard is necessary to avoid the temptation to employ an obviousness analysis based on hindsight. *See KSR I*, 119 Fed. App'x at 285 (quoting *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1998)) (“[C]ombining prior art references without a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight.”).

³¹⁴ *KSR I*, 119 Fed. App'x at 286. The court found that none of the prior art references addressed the same problem as addressed in Teleflex's patent, and thus there was not a clear motivation or suggestion to employ the prior art reference to solve the problem solved by Teleflex's patent. *Id.* at 288. The court also identified the patent's commercial success and the PTO's patentability determination as issues of material fact that precluded summary judgment on the issue of obviousness. *Id.* at 289.

³¹⁵ *KSR II*, 2007 WL 1237837, at *12. Justice Kennedy, for a unanimous Court, observed that “[w]e begin by rejecting the rigid approach of the Court of Appeals. Throughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its [teaching-suggestion-motivation] test here.” *Id.*

³¹⁶ *Id.* at *13. The Court observed that “a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* (citing *Sakraida v. Ag Pro, Inc.* 425 U.S. 27, 282 (1976)).

³¹⁷ *Id.* at *15 (“The flaws of the analysis of the Court of Appeals relate for the most part to the narrow conception of the obviousness inquiry reflected in its application of the [teaching-suggestion-motivation] test.”). The Court observed that: “our precedents make clear, however, the [obviousness] analysis need not seek out the precise teaching directed to the specific subject matter of the challenged claim, for a court can not take into account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at *13.

³¹⁸ *See eBay, Inc.*, 126 S. Ct. at 1839 (holding that the traditional equity factors for issuing injunctions must apply in patent cases because the Patent Act does not authorize a deviation from traditional equity practice).

³¹⁹ *See Ill. Tool*, 126 S. Ct. at 1293 (overruling market power presumption that a tying agreement to a patented product creates market power in the market of the unpatented product).

³²⁰ *See MedImmune II*, 127 S. Ct. at 777 (ruling that a federal court does have Article III subject matter over an attempt by a licensee in good standing, who continues to pay royalties under the patent, to seek a declaratory judgment invalidating the patent).

³²¹ *See KSR II*, 2007 WL 1237837, at *12 (determining that the Federal Circuit's rigid application of the teaching-suggestion-motivation test for obviousness improperly narrowed the flexible approach to obviousness established by the Court's precedent).

³²² *Compare Lab. Corp. of Am. v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (mem.) (per curiam) (dismissing writ of certiorari to case concerning patentable subject matter) with *supra* Part IV.D

V. CONCLUSION

The Supreme Court should have decided whether Claim 13 was patentable subject matter in *Laboratory Corporation of America v. Metabolite Laboratories, Inc.*³²³ instead of dismissing the writ of certiorari as improvidently granted.³²⁴ Despite the broad scope of statutory patentable subject matter,³²⁵ the Supreme Court has established an exception to patentable subject matter for laws of nature, natural phenomena, and abstract ideas.³²⁶ However, recently, the Federal Circuit has, in its subject matter analysis, focused primarily on the utility of the invention,³²⁷ muddling the exclusion of manifestations of nature from patentable subject matter.³²⁸ In light of this trend, the Federal Circuit held that Claim 13 of Metabolite's patent³²⁹ was valid, although the Claim merely recited the mental steps involved when considering a natural correlation.³³⁰ The Court granted the writ of certiorari to review whether Claim 13 was an unpatentable law of nature, natural phenomena, or abstract idea, only to subsequently dismiss the writ of certiorari as improvidently granted, over the dissent of three Justices.³³¹

By dismissing the writ of certiorari, the Court missed an opportunity to clarify the Federal Circuit's wayward and confused patentable subject matter jurisprudence, especially that concerning the exception of laws of nature, natural phenomena, and abstract ideas from patentable subject matter.³³² Allowing Claim 13 to remain valid may cause considerable harm and uncertainty to the free dissemination of information, medical practice, epidemiological research for public health, medical laboratory science, and genetics testing and research.³³³ The Court also had a sufficiently developed record to determine if Claim 13 was a law of nature, natural phenomena, or abstract idea, and thus unpatentable subject matter.³³⁴ The Court's refusal to clarify patentable subject matter law in *Metabolite* is inconsistent with its recent trend of clarifying issues in patent law.³³⁵ Thus, the Supreme Court should

(discussing Court's recent trend of deciding various patent issues).

³²³ 126 S. Ct. 2921 (2006).

³²⁴ *Id.* at 2921.

³²⁵ *See supra* Part II.A (noting the statutory basis of patentable subject matter).

³²⁶ *See supra* Part II.B (detailing Supreme Court precedents on the exclusion of the natural laws, natural phenomena, and abstract ideas from patentable subject matter).

³²⁷ *See supra* Part II.C (discussing the development and current status of Federal Circuit jurisprudence on patentable subject matter).

³²⁸ *See supra* Part IV.A (arguing that Federal Circuit patentable subject matter jurisprudence is broader than permitted by Supreme Court precedent).

³²⁹ *See supra* Part III.A (noting the scientific and factual background of Metabolite's patent).

³³⁰ *See supra* Part III.B (describing the procedural history of *Metabolite* and the Federal Circuit opinion).

³³¹ *See supra* Part III.C (detailing the history of *Metabolite* in the Supreme Court, including the dismissal of the writ of certiorari as improvidently granted and Justice Breyer's dissent therefrom).

³³² *See supra* Part IV.A (arguing that the Supreme Court should have decided the validity of Claim 13 to clarify the muddled and wayward patentable subject matter jurisprudence of the Federal Circuit).

³³³ *See supra* Part IV.B (contending that the failure to definitively decide the validity of Claim 13 harms medical practice, public health research, clinical laboratory science, and genetics research).

³³⁴ *See supra* Part IV.C (noting that the record in *Metabolite* was sufficiently developed for the Supreme Court to determine if claim 13 was drawn to patentable subject matter, although the issue was never explicitly decided below).

³³⁵ *See supra* Part IV.D (observing that the Supreme Court has been active in patent law, recently deciding, and granted certiorari to, other patent cases).

have decided *Metabolite*, and determined whether or not Claim 13 was drawn to patentable subject matter, thereby bringing clarity to both the law of patentable subject matter and settling the expectations of the entire medical profession.³³⁶

³³⁶ See *supra* Part IV (arguing that the Supreme Court should have made a decision regarding whether Claim 13 preempted a natural law, natural phenomenon, or abstract idea, and therefore excluded from patentable subject matter).