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MOST VALUABLE PATENT: THE USE OF NATURAL PHENOMENA IN PATENTS

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The power of patents has always struck a tenuous balance between encouraging innovation and sanctioning monopolies. Justice Bradley's much-referenced quote explains this tension:

> The design of the patent laws is to reward those who make some substantial discovery or invention, which adds to our knowledge and makes a step in advance in the useful arts. Such inventors are worthy of all favor. It was never the object of those laws to grant a monopoly for every trifling device, every shadow of a shade of an idea, which would naturally and spontaneously occur to any skilled mechanic or operator in the ordinary progress of manufactures. Such an indiscriminate creation of exclusive privileges tends rather to obstruct than to stimulate invention.[1]

The tension becomes particularly poignant when the invention incorporates a judicial exception. The three judicial exceptions to

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[1] Atl. Works v. Brady, 107 U.S. 192, 200 (1883).

what constitutes patentable material are laws of nature, abstract ideas, and natural phenomena. This article will highlight the natural phenomena judicial exception. Phenomena of nature are facts of nature or elements that exist in nature which are merely objects of discovery and not invention.[2] As the Supreme Court has noted, Newton could not have patented gravity nor could Einstein have patented $E=mc^2$.[3] But in *Diamond v. Diehr*, the Court conceded that incorporating such phenomena in a *process* or using phenomena in an *application* does not render an invention unpatentable.[4] The multitude of patents and applications that use genetic and biological elements in process and method patents have many practitioners questioning the wisdom of the Court's decision. The recent decision by the Court to address these patents in *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.* ("*LabCorp*"),[5] followed by a sharp pivot and dismissal of the original grant of certiorari,[6] has left the issue in flux.

This article will discuss the use of phenomena of nature in patents. Part I will give an overview of the *LabCorp* case. Part II will highlight the issues and concerns the public, academics, and practitioners have regarding patents that use phenomena of nature as part of a process or method. Part III will discuss the current Supreme Court test and provide an analysis of an alternative test. Part IV will conclude with a summary of why natural phenomena are still important elements in the patent system and the author's opinion on how concern over their use should be addressed.

I. LABCORP: THE SUPREME COURT PUNTS

This part will first outline the facts of the underlying Federal Circuit case, and then move to the analysis the court used in its determination. This part will conclude with an overview of the dissent in the Supreme Court's dismissal of the original grant of certiorari.

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[2] Diamond v. Diehr, 450 U.S. 175, 188 n.11 (1981). Justice Douglas described phenomena of nature as follows: "[t]hey are manifestations of laws of Nature, free to all men and reserved exclusively to none." *See* Funk Bros. Seed Co. v. Kalo Inoculant, 333 U.S. 127, 130 (1948). The author notes that *Diamond v. Diehr* is generally referred to as *Diehr* and will be for the remainder of the article.

[3] *Diehr*, 450 U.S. at 185 (citing Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

[4] *Id.* at 187 (emphasis added).

[5] Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 601 (2005).

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

The Federal Circuit case of *Metabolite Laboratories, Inc. v. Laboratory Corporation of America Holdings*[7] started as many patent litigations start: one company accused the other of infringing one or more patent claims in one or more patents. The patent at issue in this case was patent 4,940,658 ('658) that had been licensed to Metabolite.[8] The '658 patent claimed the use of a total homocysteine test and a total homocysteine-methylmalonic acid test.[9] These tests are used by doctors to determine if their patients are suffering from cobalamin (B_{12}) or folate (folic acid) vitamin deficiencies.[10] A deficiency of either cobalamin or folate can lead to various diseases, but both are easily treated with vitamin supplements.[11] The patent characterizes the tests disclosed in the claims as more efficient than the previous diagnostic devices that were in use.[12] Metabolite and LabCorp had entered into a contract that sub-licensed the use of Metabolite's total homocysteine test to LabCorp.[13] LabCorp however, began to use Abbott Laboratories' total homocysteine test and stopped paying royalty fees to Metabolite.[14] Metabolite then accused LabCorp of both indirectly infringing Metabolite's patent and violating the contract between the two companies.[15] Both the District Court and the Federal Circuit agreed with Metabolite and found LabCorp guilty of infringement.[16]

In its decision, the Federal Circuit interpreted Claim 13[17] as encompassing "a method for detecting a vitamin deficiency."[18] Additionally, the court interpreted the term "correlating" to refer to the doctor's comparison of the total elevated homocysteine levels against

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

[8] *Id.* at 1358.

[9] *Id.* at 1358. The total homocysteine test became the point of litigation in *LabCorp*. Claim 13 encompasses the total homocysteine test. *Id.* at 1358-59.

[10] *Id.* at 1358.

[11] *Id.*

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

[13] Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1359 (Fed. Cir. 2004).

[14] *Id.*

[15] *Id.*

[16] *Id.* at 1358.

[17] The text of Claim 13 is as follows: "A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate." U.S. Patent No. 4,940,658, *supra* note 12.

[18] *Metabolite Labs., Inc.*, 370 F.3d at 1362.

the normal homocysteine levels.[19] As "correlating" is part of Claim 13, this comparison is part of the method claimed in the patent. Therefore, infringement occurred when the assay of homocysteine levels was completed and the results were sent to doctors who compared the homocysteine levels from the assay to normal homocysteine levels to determine if their patients were suffering from cobalamin or folate deficiencies.[20]

The Federal Circuit did not address whether the inclusion of homocysteine in this method allowed unpatentable subject matter to be patented in violation of 35 U.S.C. § 101. Although LabCorp did not expressly press the Federal Circuit to include that question in its analysis,[21] LabCorp did argue that if the court found Claim 13 was valid, then any scientific concept could be patented in a "vague, two step 'test-plus-correlate' claim."[22] The Federal Circuit refused to address the issue. However, the Supreme Court originally did grant a writ of certiorari to address whether the use of homocysteine in the method was unpatentable.[23] The question presented 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 relationship after looking at a test result.[24]

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[19] *Id.* at 1363-64.

[20] *Id.* at 1364. *See also* Brief for the United States as amicus curiae at 22, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2005 WL 3533248, at *22 [hereinafter U.S. Brief].

[21] *Metabolite Labs., Inc.*, 370 F.3d at 1365-66. LabCorp argued that the '658 patent was invalid on different grounds, including "indefiniteness, lack of written description and enablement, anticipation, and obviousness" but it did not assert that the subject matter was unpatentable under 35 U.S.C. § 101 (2006). *Id.*

[22] Corrected Brief for Appellant Laboratory Corp. of America Holdings at 38, Metobolite Labs. Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (Fed. Cir. 2004) (No. 03-1120), 2003 WL 24305314, at *38.

[23] Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 601 (2005).

[24] Petition for a Writ of Certiorari at i, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (Nov. 3, 2004) (No. 04-607), 2004 WL 2505526, at *i (alteration in original).

Three of the Justices believed the original question warranted an answer and would have kept the grant of certiorari in place.[25]

The dissent in the Supreme Court's dismissal of the grant of certiorari makes clear that the Court will have to address the issue of the inclusion of phenomena of nature in method or process patents soon. From the dissent's point of view, not reaching a decision in *LabCorp* "threatens to leave the medical profession subject to the restrictions imposed" on these method patents using phenomena of nature.[26]

The dissent begins its argument by outlining the precedent and justifications for the phenomena of nature patent exclusion. Justice Breyer first points to the *Diamond v. Diehr*[27] principle of law that "laws of nature, natural phenomena, and abstract ideas" are all excluded from patent protection.[28] The dissent notes that the justification for excluding "laws of nature" is that "sometimes *too much* patent protection can impede . . . the constitutional objective of patent and copyright protection."[29] The dissent goes on to commend the Court's decision to exclude phenomena of nature as "reflect[ing] a basic judgment" that allowing such patents would "interfere with . . . development and the further spread of useful knowledge itself."[30] In reviewing past decisions, the dissent appears to highlight the strength of the phenomena of nature patent exclusion as justification for hearing the *LabCorp* case, even in the face of several procedural problems.[31] Justice Breyer gives three distinct reasons why the Court should have heard the *LabCorp* case.[32] First, the effect of patents that include natural phenomena could hinder the "special public interest"

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[25] *Lab. Corp. of Am. Holdings*, 126 S.Ct. at 2921 (2006) (Breyer, J., dissenting).

[26] *Id.* at 2928. The dissent goes on to predict that the patents will "inhibit doctors from using their best medical judgment; . . . force doctors to spend unnecessary time and energy to enter into license agreements; . . . divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations; . . . [and] raise the cost of healthcare while inhibiting its effective delivery." *Id.* at 2928-29.

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

[28] *Id.* at 185.

[29] *Lab. Corp. of Am. Holdings*, 126 S.Ct. at 2922 (Breyer, J., dissenting) (emphasis in original).

[30] *Id.* at 2923.

[31] *Id.* at 2925-26. The dissent acknowledges that there are two valid, procedural reasons for not deciding the *LabCorp* case. First, the petitioner did not argue 35 U.S.C. § 101 in the lower courts. *Id.* at 2925. Second, the Federal Circuit has not been given a chance to consider and make a decision on these types of patents. *Id.*

[32] DONALD S. CHISUM, 1-1 CHISUM ON PATENTS § 1.03 (2006).

of the medical profession to provide the highest standard of care.[33] Therefore, a decision is needed to protect the standard of care. Second, a decision is also needed to alleviate "legal uncertainty in the area."[34] Third, the debate between specialist courts and generalist courts regarding the balance of the patent system would benefit from a decision from the highest generalist court, the Supreme Court.[35]

One specific issue the dissent has regarding the *LabCorp* decision is the Federal Circuit's interpretation of the '658 patent's Claim 13 which makes the claim so broad that it encompasses "every homocysteine test that a doctor reviewed"[36] simply because every doctor will look at a total homocysteine assay and, in his or her mind, compare the results against the normal levels of homocysteine.[37] Even without this expansion, the dissent would invalidate the claim because Justice Breyer, with "little doubt," considered the correlation between total homocysteine and cobalamin or folate deficiencies a natural phenomenon.[38] The inclusion of this phenomenon of nature in the midst of a method does not validate the claim because it is still "no more than an instruction to read some numbers in light of medical knowledge."[39]

II. WHY IS THIS PLAY IMPORTANT?

To impress why the issue of patenting natural phenomena is important, this part will discuss concerns identified in different segments of society. Specifically, this part will discuss the concerns of the public, academic commentators, and the participants in *LabCorp*. This part will begin with the concerns of the public person

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[33] *Lab. Corp. of Am. Holdings*, 126 S. Ct. at 2928-29 (Breyer, J., dissenting).

[34] *Id.* at 2929. Justice Breyer goes on to cite the United States' amicus brief assertion that there will be a "substantial number of patent claims" affected by a decision regarding these types of patents. *Id.* These issues are not central to the topic of this article and will not be discussed by the author.

[35] *Id.*

[36] *Id.* at 2924.

[37] *Id.* The Federal Circuit in its decision even noted the testimony of Dr. Sally Stabler when she stated that "it would be malpractice for a doctor to receive a total homocysteine assay without determining cobalamin/folate deficiency." *Metabolite Labs.*, 370 F.3d at 1364.

[38] *Lab. Corp. of Am. Holdings*, 126 S. Ct. at 2927 (Breyer, J., dissenting). Justice Breyer also refers to the Brief for the United States as Amicus Curiae as supporting the contention that the correlation between homocysteine levels and vitamin deficiencies is a phenomenon of nature. *Id.*

[39] *Id.* at 2928.

over patents that include natural phenomena incorporating the paradigm example of a natural phenomenon, DNA. The part will then discuss other issues that commentators have identified that are important when considering these types of patents. Lastly, the part will deal with the issues raised in the briefs filed in *LabCorp*.

One commentator has divided the concerns of the public into two overriding issues: the subject matter itself and social justice.[40] The concern over the subject matter of the patent is primarily the idea that pieces of nature were not invented by man and thus man should not be able to patent nature.[41] If, for example, a man were allowed to patent DNA, then that patent would allow him to own, or have dominion over, a living organism, since DNA is the building block of life.[42] Cases such as *Ex Parte Allen*[43] and the Harvard mouse patent[44] only heightened fear that life can be owned. George Annas identifies this fear of "commodifying life" as the underlying fear surrounding DNA patents.[45] The social justice concern is rooted instead in the fear that those who are attempting to patent DNA will exploit people groups.[46] Annas uses the example of the Human Genome Diversity Project collecting DNA from "vanishing tribes" where the tribes were given no royalties or consideration for the products created from the tribes' DNA.[47] The social justice concern also applies to the idea found above; it is not fair to society for one patent owner to "own" a living organism or some other part of nature.

The public's perception of patents issued on a genetic sequence make those patents the paradigm of the phenomenon of nature problem. Genes exist in nature and are therefore "free to all men."[48] However, the isolated and purified sequence is patentable because the

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[40] George Annas, *Molecules vs. Information: Should Patents Protect Both?, Address at the Symposium on Bioinformatics and Intellectual Property Law* (Apr. 27, 2001), 8 B.U. J. SCI. & TECH. L. 190, 207 (2002).

[41] *Id*.

[42] *Id.*

[43] *Ex Parte* Allen, 2 U.S.P.Q.2d (BNA) 1425 (1987). The patent at issue in *Ex Parte Allen* was an attempt to patent polyploidy oysters. *Id.* at 1425-26. The U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences found that "Section 101 [of the Patent Act] includes man-made life forms." *Id.* at 1426.

[44] U.S. Patent No. 4,736,866 (filed June 22, 1984).

[45] Annas, *supra* note 40, at 208.

[46] *Id.* at 209.

[47] *Id.*

[48] Michael J. Malinowski & Radhika Rao, *Legal Limitations on Genetic Research and the Commercialization of its Results*, 54 AM. J. COMP. L. (SUPP.) 45, 49 (2006).

inventor has in some way manipulated the natural phenomenon[49] so that it is no longer a phenomenon of nature but a "product of human ingenuity."[50] This product can be the subject of a patent and therefore can be owned by a patent holder. The fear of humans being owned is constantly reinforced in the public arena. For example, the highly recognizable author Michael Crichton wrote an Op-Ed piece for the *New York Times* in which he stated that "[twenty] percent of the genome is now privately owned."[51] With these types of statements, the fears of social justice and commodifying life continue to grow.

In the face of the public's fears of social injustice associated with the ownership of life, the Patent and Trademark Office ("PTO") has been unresponsive. Its position is that "[f]rom a patent law standpoint, genes are treated just like any other chemical found in nature."[52] This statement is indicative of the PTO's attitude concerning natural phenomena outside of the genetic context. If the invention falls under a mandate from Congress and does not fall under a judicial exception to the Patent Act, then the invention is patentable. According to academics, there are both monetary and developmental problems with this approach.[53] These two elements are intertwined, encouraging each other and making the larger problem more pressing. However, in this article the author will discuss each problem separately.

Patent protection, as discussed earlier,[54] must walk a fine line between encouraging development and granting monopolies. The fear is that patents that use natural phenomena are cutting off future avenues of development while granting larger monopolies than the patent-bargain ever anticipated. Future development and innovation is tied to a constant source of public domain information that Peter Lee has categorized in his article as "upstream" knowledge.[55] This

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[49] *Id.* at 48-49. *See also* M. Scott McBride, *Bioinformatics and Intellectual Property Protection*, 17 BERKELEY TECH. L.J. 1331, 1341 (2002).

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

[51] Michael Crichton, *This Essay Breaks the Law*, N.Y. TIMES, Mar. 19, 2006, at 13. To emphasize the amount of information available to the public concerning patents on the genome, the author conducted several LexisNexis searches of news articles from the last year that contained either the terms "patent" and "genome" or "patent" and "DNA." Each search yielded over 3,000 results.

[52] Andrew Pollack, *Patenting a Human Gene As if It Were an Invention*, N.Y. TIMES, June 28, 2000, at C1.

[53] *Infra*, text p. 260-62 and accompanying notes.

[54] *Supra* text p. 253.

[55] Peter Yun-hyoung Lee, *Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine to Constrain Patents on*

upstream knowledge is essential because it is the foundational knowledge that is used to create the patentable "downstream" inventions.[56] One way that upstream knowledge can be monopolized is by patenting research tools.[57] These tools produce basic, or upstream, knowledge that is necessary for new innovations.[58] In the case of *LabCorp*, the total homocysteine assay is a research tool producing upstream knowledge that has been monopolized by Metabolite, and therefore stifles downstream innovation. Lee suggests that the hindrance on innovation occurs because patents on research tools create patents on the fundamental inputs into new tools.[59] In the context of *LabCorp*, the problem is that the patent covers an assay *of* homocysteine. Therefore, according to Lee's characterization of these patents, homocysteine would be the input that has essentially been covered by the patent on the research tool (i.e., the assay).

In the same vein, the monopolies created through patent rights give patent holders the power to demand royalties from any new developments that may use the method or process. While the ability to stop others from using or making one's invention is an essential element of the patent-bargain, the effect is to stifle new developments by driving up the costs of innovations such that they are prohibitively expensive. The patents on isolated genes, assays, and other tools used in research and patient care allow fees to be tacked on to the new product even when the new product has no actual relation to the gene or assay.[60] In *LabCorp*, the patent on the assay for total homocysteine could theoretically allow Metabolite to extract a royalty payment from every laboratory that completes a homocysteine assay because the results could be used to determine a vitamin deficiency. According to Christopher Hazuka, that is exactly what has happened to embryonic stem cell research.[61]

The Wisconsin Alumni Research Foundation owns the two patents that cover significant areas of embryonic cell lines.[62]

Biotechnology Research Tools, 19 HARV. J.L. & TECH. 79, 81 (2005).

[56] *Id.*

[57] *Id.*

[58] *Id.*

[59] *Id.*

[60] Andrew Marks, *Molecules vs. Information: Should Patents Protect Both?, Address at the Symposium on Bioinformatics and Intellectual Property Law* (Apr. 27, 2001), 8 B.U. J. SCI. & TECH. L. 190, 205-06 (2002).

[61] Christopher D. Hazuka, *Supporting the Work of Lesser Geniuses: An Argument for Removing Obstructions to Human Embryonic Stem Cell Research*, 57 U. MIAMI L. REV. 157 (2002).

[62] *See* U.S. Patent No. 5,843,780 (filed Jan. 18, 1996) (issued Dec. 1, 1998);

Therefore, any research into the use of human embryonic cells must have approval from, and pay money to, the Wisconsin Alumni Research Foundation.[63] While not research tools as Lee envisioned them, these cell lines are still upstream tools necessary for creating downstream innovation. For the innovation to take place, money must change hands. If it does not, research stops thereby stifling innovation. This is how the two parts of the problem, development and money, encourage one another.

Players in the current market, whatever that market is, must adapt to the power of patents over development and profit in order to survive. For example, the fear and respect for the power of the patent has become a driving force in the pharmaceutical industry with every company trying to patent as much as it can so that the next company cannot.[64] Another interesting example of an industry responding to the power of the patent is the Motion Picture Association of America, Inc. ("MPAA"). According to its website, the MPAA has its roots as a trade organization that now acts as an advocate for the companies involved in theatrical film and lobbies for "strong protection of creative works."[65] The MPAA has recently responded to the PTO's request for comments regarding its interim guidelines. The MPAA called upon the PTO to address "issues specific to patents involving creative and artistic works."[66] The MPAA is concerned that the PTO might begin granting patents on claims that cover "artistic content" without fully considering the implications of such claims.[67] The MPAA's interest in the possibility of patents being issued on some forms of creative works, which usually fall under copyright law, demonstrates how strong the power of the patent is regarded.

In every argument, there must be two sides. One side, as stated above, is that using natural phenomena in patents stifles development. The other logical side of the argument is that the patents Lee calls upstream patents, or simply patents that incorporate phenomena of

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U.S. Patent No. 6,200,806 (filed June 26, 1998) (issued Mar. 13, 2001).

[63] Hazuka, *supra* note 61, at 158-59.

[64] Marks, *supra* note 60, at 212.

[65] Motion Picture Association of America, About Us, http://www.mpaa.org/AboutUs.asp (last visited Mar. 21, 2007).

[66] Comment from the Motion Picture Association of America, Inc. to the U. S. Patent and Trademark Office regarding Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 Fed. Reg. 75, 451 (Dec. 20, 2005), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab98/mpaa.pdf.

[67] *Id.*

nature, will actually "accelerate research and development."[68] Unfortunately, the author has not found any law review or journal articles that take this position. Even Metabolite's Brief for Respondents does not take this position. Instead, almost all participants in *LabCorp*, either as parties or as amici curiae, focused on other issues.

The foundation for Metabolite's arguments is that (1) the issue of subject matter patentability was never brought as a defense at the lower court level, (2) the '658 patent follows all the correct forms, and (3) that the Supreme Court would have to overturn precedent allowing patents of this type in order to overturn the Federal Circuit's decision.[69] Likewise, the briefs filed in support of the respondents rest first on the procedural grounds for not reaching subject matter patentability and second on the contention that Claim 13 is in the form required by *Diehr*.[70]

One *amicus* brief does come close to arguing that patents on processes or methods that include phenomena of nature are a positive development in patent law.[71] The Boston Patent Law Association ("Boston Law") notes in its brief that without the patent, the information that elevated levels of homocysteine correlate to vitamin deficiencies would not be known to the public.[72] However, the majority of the brief defends the correlation as patentable subject matter.[73] Boston Law directs the Court to two criteria that the PTO

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[68] Lee, *supra* note 55, at 81-82.

[69] Brief for Respondents at 43-44, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2006 WL 303905, at *43-44 [hereinafter Brief for Respondents].

[70] *See, e.g.*, Brief for Perlegan Sciences, Inc. and Mohr, Davidow Ventures as Amicus Curiae Supporting Respondents at 5, 126 S.Ct. 2921 (2006) (No. 04-607) 2006 WL 303908, at *5 [hereinafter Perlegan Brief]. The brief outlines the Supreme Court precedent concerning process patents that contain a law of nature or phenomenon of nature. The brief then goes on to compare Claim 13 to the facts of those Supreme Court precedent cases to show that Claim 13 is only doing what the Court has already allowed. *Id.* at *6-7. The brief also counsels the Court to look at the transformation language found in Diamond v. Diehr, 450 U.S. 175, 183 (1981), to support Claim 13. *Id.* at *8-9.

[71] Brief for Boston Patent Law Association et al. as Amicus Curiae Supporting Respondents at 14, Lab. Corp. of Am. Holdings v. Metabolite Labs. Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2006 WL 303909, at *14 [hereinafter Boston Brief]. The Boston Brief also outlines that the affirmation of Claim 13 "will not hinder innovation, and the public will continue to be served by scientific and technological progress." *Id.* at *16.

[72] *Id.* at *14.

[73] *Id.* at *3.

recently put forth in its Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility[74] ("Interim Guidelines") to bolster the claim that the subject matter is patentable. These criteria refer to the two ways the PTO suggests that a claim can be identified to determine if the claim falls under an excluded subject matter.[75] Boston Law directs the Court to the "transformation" and "useful, concrete and tangible result" criteria found in the Interim Guidelines through the *Diehr* holding to support Boston's contention that Claim 13 is patentable.[76]

Boston Law's brief also attempts to draw a comparison between Claim 13 and claims to medical devices because those devices "are also premised on scientific principles."[77] The brief asserts that the "[e]xclusivity conferred on a patented medical process should be treated no differently from the exclusivity conferred on patented medical devices" because medical devices are "also premised on scientific principles" just as are medical processes.[78] However, the author notes that medical devices that use scientific principles are more like the downstream innovations Lee identified[79] than the upstream knowledge Claim 13 appears to encompass.[80] Generally, Metabolite and its supporters treat the question of whether phenomena of nature should be allowed in patents as moot. Instead, the threshold question is whether a phenomenon of nature has been applied correctly in a process that performs a function.[81]

The amicus curiae briefs in support of the petitioner LabCorp have taken a more aggressive approach by confronting the issue of natural phenomena in patents directly.[82] In confronting the issue, the

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[74] Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 1300 OFF. GAZ. PAT. & TRADEMARK OFFICE 142 (Nov. 22, 2005), *available at* http://www.uspto.gov/web/offices/com/sol/og/2005/week47/patgupa.htm [hereinafter *Interim Guidelines*].

[75] *Id.* A more exhaustive discussion concerning the Interim Guidelines can be found *infra* pp. 272-273.

[76] Boston Brief, *supra* note 71, at *5-6. Note that Boston Law does not refer to the Interim Guidelines until after it has directed the Court's attention to *Diehr*, 450 U.S. 175 (1981).

[77] Boston Brief, *supra* note 71, at *15.

[78] *Id.*

[79] *See* Lee, *supra* note 55, at 81-82.

[80] *Id.*

[81] *See, e.g.*, Perlegan Brief, *supra* note 70, at *9.

[82] *See, e.g.*, Brief for American Clinical Laboratory Association as Amicus Curiae Supporting Petitioner at i, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (Dec. 23, 2005) (No. 04-607), 2005 WL 3543098, at *i ("The Disputed Patent Claim Is Invalid Because It Seeks To Protect Nothing More Than A

individual briefs raise different concerns regarding the inclusion of natural phenomena in patents.

The American Medical Association's ("AMA") brief argues that the construction of Claim 13 is so broad that it covers the natural phenomena of elevated levels of homocysteine in relation to vitamin deficiencies with none of the necessary limitations.[83] One of the AMA's concerns is that patents on "basic scientific principles . . . erode the quality of patient care by limiting the knowledge" available to physicians when treating their patients.[84] In addition to the threat to patients, the AMA also identifies a threat to a physician's professional obligation to disseminate knowledge.[85] The AMA accuses the patent system of having created a system that rewards physicians for sharing "medical knowledge, skills and techniques [with] colleagues for reasons of personal gain" instead of for the general good of health care and the patient's well-being.[86]

Similarly, the American Clinical Laboratory Association ("Clinical Laboratory") argues that the elevated levels of homocysteine and its relation to vitamin deficiencies is a natural phenomenon that the two-step assay claim is taking out of the public domain.[87] The problem Clinical Laboratory identifies is that once a correlation between a naturally occurring condition and the source of that condition is patented, future clinical testing will be significantly curtailed, even if the test had not been developed at the time of the patent.[88] Clinical Laboratory's concern is that any new or improved test related to some sort of correlation "would be entirely at the

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Naturally Occurring Biochemical Relationship - A Quintessentially Unpatentable Discovery") [hereinafter Clinical Lab. Brief]; Brief for AARP as Amicus Curiae Supporting Petitioner at iii, *id.* (Dec. 23, 2005), 2005 WL 3597809, at *iii ("The Court Should Invalidate Claim 13 Because It Improperly Claims a Mental Process of Recognizing a Phenomenon of Nature") [hereinafter AARP Brief]; Brief for American Medical Association, et al. as Amici Curiae Supporting Petitioner at iii, *id*. (Dec. 23, 2005), 2005 WL 3597812, at *iii ("Claim 13 Improperly Claims Non-Patentable Subject Matter") [hereinafter AMA Brief].

[83] AMA Brief, *supra* note 82, at 18-20, 2005 WL 3597812, at *18-20.

[84] *Id.* at 13, 2005 WL 3597812, at *13.

[85] *Id.* at 13-14, 2005 WL 3597812, at *13-14.

[86] *Id.* at 14, 2005 WL 3597812, at *14.

[87] Clinical Lab. Brief, *supra* note 82, at 4-7, 2005 WL 3543098, at *4-7.

[88] *Id.* at 8, 2005 WL 3543098, at *8. The AMA refers to over 1,100 clinical test codes that correspond to even more actual tests all of which can be categorized as testing correlations such as the correlation found in *LabCorp*. *Id.* at 8-9, 2005 WL 3543098, at *8-9.

mercy" of the owner of the patent for that correlation.[89] As the AMA identified in its brief, this would affect patient care.[90]

Attacking from a different angle, the AARP Brief argued that Claim 13 was a patent on the *mental process* of recognizing a natural phenomenon and correlating that information with the possibility of a vitamin deficiency.[91] AARP reached this conclusion by noting that the correlation step of Claim 13 is carried out by a physician who looks at the test results and establishes a relationship between the results and the patient's condition.[92] In addition to the concern that mental processes are not patentable subject matter, the AARP was also concerned with the same issues as the AMA and Clinical Laboratory: a patent on a mental process used in diagnosis and patient treatment "threatens public health and interferes with the practice of medicine."[93]

LabCorp picked up on this threat and argued that the lower court's interpretation of Claim 13 will mean that "merely thinking about a scientific correlation is enough to infringe" the patent.[94] LabCorp went further and attempted to draw a connection between the "correlation" in Claim 13 and "equations" such as $E=mc^2$ and the Pythagorean theorem, which academics and jurists agree are not patentable.[95] The only concern or issue that LabCorp brought to the attention of the Court is the simple, but effective, public policy argument that a "monopoly over a basic tool of science hinders . . . innovation."[96] According to LabCorp, the dissemination of scientific principles among academics and physicians will be adversely affected by patents on correlations that use medical facts and mental process, much to the detriment of the medical community and the patients.[97]

The playbooks of the amici curiae briefs are fairly predictable. The respondents and their supporters cite form and predictability over concerns of patenting natural phenomena. The petitioner and its supporters cite the need for medical innovation and putting the

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[89] *Id.* at 9, 2005 WL 3543098, at *9.

[90] *See supra* notes 83-86 and accompanying text.

[91] AARP Brief, *supra* note 82, at 26-27, 2005 WL 3597809, at *26-27.

[92] *Id.* at 6, 2005 WL 3597809, at *6 (citations omitted). The brief also references the original trial where the correlation is referred to as being "all done in the mind." *Id.* at 6, 2005 WL 3597809, at *6 (internal citations omitted).

[93] *Id.* at 17, 2005 WL 3597809, at *17.

[94] Brief for Petitioner at 24, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3543099, at *24.

[95] *Id.* at 25, 2005 WL 3543099, at *25.

[96] *Id.* at 43, 2005 WL 3543099, at *43.

[97] *Id.* at 45-47, 2005 WL 3543099, at *45-47.

patients' needs over exclusive patent rights on a scientific principle. The announcers are the academics that are concerned with the self-fulfilling cycle of development and money. While on the sidelines, the public is concerned that it will one day be the subject of a patent. The Supreme Court has been primed for the next play.

III. THE SUPREME COURT HAS THE BALL: WILL IT RUN?

The Supreme Court signaled to the PTO that phenomena of nature are patentable when included in a process or method patent claim.[98] Therefore, it is up to either Congress to referee this game or the Supreme Court to give a new play to the PTO, and to set the boundaries on these patents. This part will present the current test the Supreme Court uses then will discuss the proposed approach from the United States Brief and the support this approach has received from the PTO. Finally, this part will analyze the proposed test and discuss why this is the test the Supreme Court should use when it again has control of the ball.

The Supreme Court itself has blurred the boundary between what is patentable and what is unpatentable in the realm of natural phenomena. In *Parker v. Flook*, the Court stated that "a process is not unpatentable simply because it contains a law of nature."[99] But the Court then clarifies that the idea that "post-solution activity . . . can transform an unpatentable principle into a patentable process that exalts form over substance."[100] Likewise, the Court again noted, three years later, that "insignificant post-solution activity will not transform an unpatentable principle into a patentable process."[101] The Court in *Diehr* stipulated that claims must be read as a whole to prevent courts from dissecting claims and eliminating known steps such as natural phenomena.[102] The Court's most definite statement concerning natural phenomena and patents was made in *Diehr*: "[i]t is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."[103] The current test centers on the need for the patentable innovation within the invention to overcome the

[98] Parker v. Flook, 437 U.S. 584, 590 (1978). This case is generally referred to as *Flook* and will be referred to as such for the remainder of this article.

[99] *Id.*

[100] *Id.*

[101] Diamond v. Diehr, 450 U.S. 175, 191-92 (1981).

[102] *Id.* at 188.

[103] *Id.* at 187 (emphasis in original).

unpatentable natural phenomenon within the invention. The Supreme Court's decisions have allowed the PTO to escort a patent into the "end-zone" when the invention has applied a natural phenomenon to create something more then a mere discovery of a natural phenomenon.[104]

The United States proposed a new game plan for patents that include a natural phenomenon or any judicial exception to subject matter patentability. The amicus curiae brief filed by the United States agreed with the respondents and their supporters insomuch as the petitioner failed to raise a 35 U.S.C. § 101 defense at the lower court level.[105] However, the United States recommended that the Court remand the case to the Federal Circuit for a factual determination of whether Claim 13 "encompass[ed] all 'substantial practical application[s]' of the natural relationship."[106] The Solicitor General contended that if Claim 13 is interpreted to include all the practical applications of the relationship between homocysteine and vitamin deficiencies then the claim would create "a monopoly over a basic scientific relationship"[107] in violation of the Supreme Court's holding in *Gottschalk v. Benson*.[108]

The Court in *Benson* considered a patent application that attempted to patent an invention for a "method for converting binary-coded decimal ("BCD") numerals into pure binary numerals."[109] This method had not been limited to a specific result or machinery, but instead could be applied to any "general-purpose digital computer of

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[104] Julian David Forman, Comment, *A Timing Perspective on the Utility Requirement in Biotechnology Patent Applications*, 12 ALB. L.J. SCI. & TECH. 647, 659 (2002).

[105] U.S. Brief, *supra* note 20, at 6, 2005 WL 3533248, at *6.

[106] *Id.*

[107] *Id.* at 17, 2005 WL 3533248, at *17.

[108] 409 U.S. 63 (1972). This case is generally referred to as the *Benson* decision and will be referred to as such in the remainder of the article. The United States amicus curiae brief also references the Interim Guidelines from the PTO that were referenced by Boston Law. U.S. Brief, *supra* note 20, at 20, 2005 WL 3533248, at *20. *See also* Boston Brief, *supra* note 71, at 5-6, 2006 WL 303909, at *5-6. However, the Solicitor General is citing the pre-emption portion of the Interim Guidelines, not the "transformation" and "useful, concrete and tangible result" portion cited by Boston Law. *Compare* U.S. Brief, *supra* note 20, at 20, at 2005 WL 3533248, *20 *and* Boston Brief, *supra* note 71, at 5-6, 2006 WL 303909, at *5-6. In a footnote, the Solicitor General takes note that the issue that would raise a "transformation" analysis is not before the Court. U.S. Brief, *supra* note 20, at 21 n.4, 2005 WL 3533248, at *21 n.4.

[109] *Benson*, 409 U.S. at 64.

any type."[110] The Court took note that although this was a process or method claim that used a natural phenomenon as part of the process or method, the claim was still "so abstract and sweeping" that it would cover any use of the binary decimals converted to numerals.[111] According to the Court, the "practical effect" of such a patent would "wholly pre-empt" the field and "would be a patent on the algorithm itself."[112] The Court found that the patent application was directed to the judicial exception of abstract ideas.[113] This decision though has since been broadened to apply to all the judicial exceptions, including phenomena of nature.[114]

The Court's decision in *Benson* made clear that while patents could include a process that *used* a natural phenomenon, if the patent was essentially a patent *on* the natural phenomenon, then the patent would be invalid.[115] For the Solicitor General, that decision is the real test Claim 13 must pass: Is the patent on Claim 13 a "monopoly over a basic scientific relationship?"[116] The Solicitor General appears to respond to that question in the affirmative.[117]

The United States brief concluded that Claim 13 was interpreted to be a monopoly over the correlation through its analysis of the prior decisions. The Solicitor General first focused on the Federal Circuit's claim construction.[118] The United States concluded that the Federal Circuit's interpretation of "correlate" held that "anyone who thinks about the relationship between elevated total homocysteine and cobalamin or folate deficiency after obtaining the results of a total homocysteine assay infringes the patent claim."[119] The Solicitor General then pointed out that the jury awarded damages for all the homocysteine tests LabCorp performed, regardless of the doctors' reasons for ordering the tests.[120] According to the United States, this award indicated that the "jury necessarily concluded that no substantial non-infringing uses of the total homocysteine assays"

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[110] *Id.*

[111] *Id.* at 68.

[112] *Id.* at 71-72.

[113] *Id.*

[114] *See generally*, *Interim Guidelines*, *supra* note 74, at IV.C.3.

[115] Gottschalk v. Benson, 409 U.S. 63, 71-72 (1972) (emphasis added).

[116] U.S. Brief, *supra* note 20, at 20-21, 2005 WL 3533248, at * 20-21 (contending that if the Court does hear *LabCorp*, the section 101 issue will be whether Claim 13 "asserts 'a monopoly over a basic scientific relationship'").

[117] *Id.* at 22-23, 2005 WL 3533248, at *22-23.

[118] *Id.* at 22-24, 2005 WL 3533248, at *22-24.

[119] *Id.* at 22, 2005 WL 3533248, at *22.

[120] *Id.*

existed.[121] The Solicitor General also noted that the Federal Circuit affirmed the district court's permanent injunction against LabCorp from performing any homocysteine tests.[122] In making this decision, the Federal Circuit "concluded that *any* assay for total homocysteine would infringe [C]laim 13, regardless of the reason a doctor ordered it."[123] The Solicitor General's conclusions are significant because they demonstrate that Claim 13 does create a monopoly over the scientific principle that homocysteine levels correlate to vitamin deficiencies. Therefore the claim is invalid under *Benson*.[124]

The United States was not the only amicus curiae that supported this test on judicial exceptions found in patents. In its brief, the American Heart Association counseled the Court to use a test similar to the Solicitor General's test: whether the claim "would confer a private exclusionary right on all, or a substantial part of, a natural phenomenon or law of nature."[125] This test again implicates the Court's decision in *Benson*.[126] The pre-emption approach espoused by the United States and American Heart Association is a significantly different play than tests other participants, amici curiae and parties alike, have encouraged the Supreme Court to use. This play may be the game winner.

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[121] U.S. Brief, *supra* note 20, at 23, 2005 WL 3533248, at *23.

[122] *Id.* at 23-24, 2005 WL 3533248, at *23-24.

[123] *Id.* at 24, 2005 WL 3533248, at *24 (emphasis in original).

[124] The respondents have strongly denied that Claim 13 has pre-empted the use of homocysteine levels. The respondents have stated that the natural phenomenon, i.e, the correlation between the vitamin deficiency and the homocysteine level, is safely within the public domain because "[t]he act of assaying body fluids for total homocysteine for reasons other than diagnosing vitamin deficiencies would not infringe." Brief for Respondents, *supra* note 69, at 38. Respondents also asserted that they "[did] not claim a monopoly to the correlation." *Id.* at 31.

[125] Brief of the American Heart Association as Amicus Curiae in Support of Petitioner at 11, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S.Ct. 2921 (2006) (No. 04-607), 2005 WL 3561169, at *11 [hereinafter Heart Association Brief].

[126] The Heart Association Brief does not cite *Benson* directly for this principle but highlights several Court decisions. *Id.* at 12-15, 2005 WL 3561169, at *12-15. The Heart Association Brief does cite a Court of Customs and Patent Appeals judge who consolidated the decisions of the Supreme Court prior to 1979 into one statement: "The common thread throughout [this Court's] cases is that [patent] claims which *directly or indirectly preempt* natural laws or phenomena are proscribed, whereas claims which merely *utilize* natural phenomena via explicitly recited manufactures, compositions of matter or processes to accomplish new and useful end results define statutory inventions." *Id.* at 16, 2005 WL 3561169, at *16 (citing *In re Bergy*, 596 F.2d 952, 988 (C.C.P.A. 1979) (Baldwin, J., concurring)) (alterations in Heart Association Brief).

The concept of pre-emption to help determine if an invention that includes a natural phenomenon is patentable did not start with *Benson*.[127] The pedigree of the pre-emption test reaches back to the Telegraph Case of 1853 when the Supreme Court denied Morse the broad patent he was attempting to validate.[128] However, the actual use of a pre-emption analysis in *Benson* has been called "nonsense."[129] Even if the pre-emption analysis should not have been used in *Benson*, the effect of the analysis is still felt in other Supreme Court cases and Federal Circuit cases. The Federal Circuit's analysis in 1994 was "to see whether the claimed subject matter as a whole is a disembodied mathematical concept . . . which in essence represents nothing more than a 'law of nature,' 'natural phenomenon,' or 'abstract idea.'"[130] The court went on to cite *Diehr*, explaining that if the claimed subject matter did represent an unpatentable subject matter then "*Diehr* precludes the patenting of that subject matter."[131] The Supreme Court distinguished *Diehr* from *Benson* and *Flook* when it pointed out that the respondents in *Diehr* did "not seek to pre-empt the use of [the natural phenomenon]."[132] The United States in its *amicus* brief noted that neither *Diehr* nor *Flook* focused on questions about pre-emption.[133] However, the fact that both cases addressed the pre-emption analysis signifies that pre-emption has at least been accepted in part as grounds for refusing to grant a patent on an invention including a natural phenomenon. The degree to which the pre-emption analysis has been accepted can be inferred by its inclusion in the PTO Interim Guidelines of November 22, 2005.[134]

According to the PTO, the "principal objective [of the Interim Guidelines] is to assist examiners in determining . . . whether a claimed invention falls within a judicial exception to statutory subject matter."[135] The Interim Guidelines assist the patent examiners by providing them with the PTO's "current understanding of the law"

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[127] *See, e.g.*, Heart Association Brief, *supra* note 125, at 12-15, 2005 WL 3561169, at *12-15. (highlighting Supreme Court cases).

[128] O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853). *See also*, Heart Association Brief, *supra* note 125, at 12, 2005 WL 3561169, at *12.

[129] CHISUM, *supra* note 32, at § 1.03[6][c].

[130] *In re* Alappat, 33 F.3d 1526, 1544 (Fed. Cir. 1994).

[131] *Id.*

[132] Diamond v. Diehr, 450 U.S. 175, 187 (1981).

[133] U.S. Brief, *supra* note 20, at 21 n.4, 2005 WL 3533248, at *21 n.4 (citing *Diehr*, *Flook*, and *Benson*).

[134] *Interim Guidelines*, *supra* note 74.

[135] *Id.*

regarding subject matter patentability.[136] It is important to note that the Interim Guidelines do not have the force of law and do not *have* to be followed by the patent examiners.[137] However, the Interim Guidelines are considered the official view of the PTO.[138]

Under the Interim Guidelines, when an examiner considers the subject matter of the invention under § 101, he or she should determine whether the subject matter falls within the judicial exceptions to patentability (laws of nature, natural phenomena, and abstract ideas).[139] The examiner is to first consider whether the invention falls into one of these judicial exceptions or is a practical application of the laws of nature, natural phenomena, or abstract idea which has been incorporated in the claims.[140] The examiner can identify a practical application of a judicial exception to subject matter if the invention "'transforms an article or physical object to a different state or thing" or if it "otherwise produces a useful, concrete and tangible result."[141] The examiner should also consider whether the invention pre-empts one of the judicial exceptions to § 101.[142] The PTO cites to *Diehr* and *Benson* to explain to the examiners what to consider.[143] Specifically, the examiners "must ensure that [the invention] does not in reality 'seek[] patent protection for that formula in the abstract.'"[144] The PTO also informs examiners that "[o]ne may not patent a process that comprises every 'substantial practical application' of an abstract idea, because such a patent 'in practical

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[136] *Id.* at I.

[137] *Id.* ("These Guidelines…do not have the force and effect of law…[A]ny failure by USPTO personnel to follow the Guidelines is neither appealable nor petitionable."). To clarify, the Manual of Patent Examining Procedure (MPEP) also does not have the force of law even though it does "outline[] the current procedures which the examiners are required or authorized to follow." U.S. PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE Foreword (8th ed. 2001), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r5_Foreword.pdf.

[138] *See generally*, *Interim Guidelines*, *supra* note 74 (discussing in Foreword and Introduction that the examiners should use the Interim Guidelines when they examine patent applications).

[139] *Id.* at IV.C.

[140] *Id.* at IV.C.1.

[141] *Id.* at IV.C.2. The Interim Guidelines also provide guidance on what is a "useful result," "tangible result," and a "concrete result."

[142] *Id.* at IV.C.3.

[143] *Id.*

[144] *Interim Guidelines*, *supra* note 74, IV.C.3 (citing Diamond v. Diehr, 450 U.S. 175, 191 (1981) (second alteration in original).

effect would be a patent on the [abstract idea].'"[145] The PTO's interpretation of the pre-emption analysis and its inclusion in the Interim Guidelines is another indication that the pre-emption test is a legitimate play.

The pre-emption test appears to be supported by Supreme Court precedent, the PTO, and the Solicitor General. However, it is not supported by all the players. The PTO requested comments from the public concerning these Interim Guidelines and even extended the comment time to take into account the decision from the Supreme Court in *LabCorp*.[146] Some who responded voiced concerns over the pre-emption approach and its place in the examiners' patentable subject matter determinations under § 101. Intellectual Ventures, a business based on "creat[ing] and invest[ing] in new inventions,"[147] considered the pre-emption test more of a subjective "final check" than a condition to patentability as it is used in the Interim Guidelines.[148] Similarly, Rick Nydegger, a patent attorney, considered the pre-emption test to be a "final, separate inquiry" in the § 101 analysis.[149] The American Intellectual Property Law Association ("AIPLA") also disagreed with the PTO including the pre-emption test as part of the § 101 analysis.[150] In AIPLA's view, *Flook* had already overruled the pre-emption test, therefore the test had no place in any section of the code governing patents.[151] Brian Hickman, a registered

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[145] *Id.* (citing *Benson*, 409 U.S. at 64) (second alteration in original).

[146] Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 71 Fed. Reg. 34,307, 34,308 (Jun. 14, 2006).

[147] Comment from Intellectual Ventures, LLC, to the U.S. Patent and Trademark Office regarding Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 Fed. Reg. 75,451 (Dec. 20, 2005), 1 (July 31, 2006), http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab98/iv.pdf [hereinafter Intellectual Ventures Comment]

[148] *Id.* at 6.

[149] Comment from Rick Nydegger to the U.S. Patent and Trademark Office regarding Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 Fed. Reg. 75,451 (Dec. 20, 2005), II (Aug. 4, 2006), http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab98/nydegger.pdf.

[150] Comment from the American Intellectual Property Law Association to the U.S. Patent and Trademark Office regarding Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 Fed. Reg. 75,451 (Dec. 20, 2005), 4 (July 28, 2006), http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab98/aipla.pdf.

[151] *Id.* However, Chisum has interpreted *Flook* as following *Benson*'s treatment of abstract ideas which has been extended to all judicial exceptions of § 101.

patent agent, was somewhat more lenient in his comments on the pre-emption test.[152] Hickman demoted the pre-emption test to a "theoretical requirement" that possibly deserved "a paragraph, or a footnote" in the Interim Guidelines.[153]

Not all of the comments the PTO received were negative. While the National Institutes of Health ("NIH") expressed concern over the pre-emption test as it applies to "diagnostic methods and assays,"[154] it did not attempt to completely discredit the pre-emption test. The NIH did not believe the Interim Guidelines' current pre-emption test provided enough guidance for examiners when the invention contains diagnostic or assay methods like the patent in *LabCorp*[155] and recommended instead that the framework of the test be changed. [156] On the other hand, the Association of American Medical Colleges ("AAMC") strongly supported the pre-emption test.[157] The AAMC even recommended that the test "play a decisive role" in any § 101 analysis.[158]

There will be disagreement over using the pre-emption test more aggressively when there are valuable patents at stake. However, the Supreme Court should use the pre-emption test to determine if subject matter that falls under a judicial exception to § 101, such as phenomena of nature, is being removed from the public domain. The current test, focusing on the overall process or method instead of the

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CHISUM, *supra* note 32, at § 1.03.

[152] Comment from Brian Hickman to the U.S. Patent and Trademark Office regarding Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 Fed. Reg. 75,451 (Dec. 20, 2005), (May 19, 2006), http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab98/hickman.pdf.

[153] *Id.*

[154] Comment from the National Institutes of Health to the U.S. Patent and Trademark Office regarding Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 Fed. Reg. 75,451 (Dec. 20, 2005), 2 (Jul. 31, 2006), http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab98/nih.pdf. This concern arises from the possible tension between *Diehr* (consider the claims as a whole) and *Flook* (a pre-existing relationship is never patentable). *Id.* at 2-3 (internal citations omitted).

[155] *Id.*

[156] *Id.* at 4-6.

[157] Comment from the Association of American Medical Colleges to the U. S. Patent and Trademark Office regarding Request for Comments on Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 70 Fed. Reg. 75,451 (Dec. 20, 2005), 3 (July 31, 2006), http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab98/aamc.pdf.

[158] *Id.*

natural phenomenon included in the process, works well to exclude patents that truly are patents on laws of nature, natural phenomena, and abstract ideas. True to the innovative spirit the patent system fosters and encourages, inventors and patent attorneys have found ways to circumvent the current test. The pre-emption test will cut off one of those avenues of circumvention.

Another important factor, as the United States Brief pointed out, is that the Supreme Court has already accepted and affirmed the pre-emption analysis.[159] There are four different teams deciding how the patent system is run: Congress, the Supreme Court, the Federal Circuit Court of Appeals, and the PTO. The Supreme Court will be more likely to endorse a test that the Federal Circuit currently uses, the PTO has incorporated into its Interim Guidelines, and Congress has not legislated away, than a new or different test that has not garnered as much support from the other teams. While this may be a general observation concerning the balance between Congress, the Supreme Court, the lower courts, and administrative agencies, tension between the branches of government is more pronounced in the field of patent law where there is the ongoing discussion between generalists and specialists that Justice Breyer referred to in *LabCorp*.[160]

Although there may be problems with the implementation of the pre-emption test by the PTO, the test itself is a necessary defense to patents that may be taking scientific principles out of the public domain. The pre-emption test requires the examiners to think beyond the four corners of the patent application and consider the further implications of the claims. This may make the test more subjective, as Intellectual Ventures suggested.[161] Subjectivity in the patent system will negatively influence the predictability of patent applications and therefore may affect the willingness of companies to devote resources to innovation. The respect companies have for the power of the patent should overcome any hesitancy over researching a new drug, medical device, or diagnostic tool.[162] Just as innovation has continued to flourish under the current test, innovation will continue to flourish under the pre-emption test.

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[159] U.S. Brief, *supra* note 20, at 20, 2005 WL 3533248, at *20 (citing *Benson*, *Diehr*, and *Flook* as well as the Interim Guidelines to support the pre-emption test).

[160] *Lab. Corp. of Am. Holdings*, 126 S.Ct. at 2929 (Breyer, J., dissenting).

[161] Intellectual Ventures Comment, *supra* note 147, at 6.

[162] *See supra* notes 64-67 and accompanying text.

IV. CONCLUSION

One commentator believes that simple reliance on the "common law prohibition against patenting natural laws, natural phenomena, and abstract principles" as well as the "policy interest in keeping knowledge and other foundational elements of research freely available in the public domain" will be enough to reverse the trend of phenomena of nature found in patents.[163] As demonstrated above, all players believe that the common law prohibition is to their benefit. They also all agree that none of the judicial exceptions, including natural phenomena, should be directly patented. The current test, simply allowing a method or process to be patented as long as the natural phenomenon found within the steps is an application that produces a "new and useful end,"[164] has not been able to keep necessary information in the public domain. Therefore, either the Supreme Court or Congress must step up to the line. The ideal course of events would be for the Federal Circuit to take this issue out of the hands of either team and begin making decisions based on *Benson* and guided by the Interim Guidelines. The more likely course of events is that the Supreme Court will be asked to grant the petition for a writ of certiorari in a case where the petitioner has argued that the subject matter was unpatentable under § 101 because it pre-empted the use of a phenomenon of nature or some other judicial exception. When this occurs, the Supreme Court should look to its precedent and applies the pre-emption test. The Supreme Court should be able to leave in place the protections that the patent system affords inventors to encourage research while at the same time make the standard for using natural phenomena in inventions harder to meet. The pre-emption test is the game-winning play that will provide incentives for inventors and protection for natural phenomena.

[163] Lee, *supra* note 55, at 82.
[164] *Benson*, 409 U.S. at 67 (internal citations omitted).