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**LESSONS FROM LABORATORY CORP. OF
AMERICA HOLDINGS V. METABOLITE
LABORATORIES, INC.**

Cynthia M. Ho[†]

Abstract

This article provides reflections on the scope of patentable subject matter, using the Supreme Court's recent consideration of Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc. as a springboard for discussion. A brief introduction to the case and the current standard of patentable subject matter are provided as a backdrop for discussion of the role of patentable subject matter in the overall scheme of patentability and patent enforcement. In addition, this article addresses potential repercussions of the case within the judicial and legislative arenas. This article concludes by offering some broad-based issues for consideration, including both domestic and international implications.

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I. INTRODUCTION

The world of patentable subject matter may soon be subject to a seismic shift. Initial rumblings were heard when the Supreme Court granted certiorari on the issue of patentable subject matter in *Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings* – an issue seemingly crafted out of whole cloth since neither party had litigated the issue. Expectations of a clear metric in this area where dashed when the Court ultimately dismissed certiorari as improvidently granted. However the dissenting opinion to the dismissal directly challenged the standard of patentable subject matter¹ that the Federal Circuit, the court with exclusive jurisdiction over appeals in patent cases, has been applying for the last decade.²

Although the dismissal of certiorari in *Metabolite* leaves patent lawyers waiting for a final conclusion from the Court on the proper scope of patentable subject matter, other institutional bodies continue to struggle with this issue. Until the Court declares a new standard of patentability, the Federal Circuit will likely continue to apply its standard of looking at whether an invention produces a “useful, concrete and tangible result,” which has undeniably opened the patentable subject matter door to new categories of inventions, such as business methods.³ Whether the Federal Circuit will allow further categories of inventions, such as electrical signals disembodied from a standard storage medium, to be patentable remains open to question as the Federal Circuit currently considers the case *In re Nuijten*.⁴ In addition, the U.S. Patent and Trademark Office (“USPTO”) Board of Appeals has taken different positions on whether the scope of patentable subject matter should be limited by engraving a

1. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921, 2926 (2006) (Breyer, J., dissenting). There were twenty amicus briefs filed in this case, which the dissenting Justices suggested as being adequately thorough, such that further proceedings were likely to provide only diminishing returns. *See id.* at 2926.

2. *Id.* at 2928 (noting that the Supreme Court has never approved the Federal Circuit test of patentable subject matter that focuses on whether an invention “produces ‘a useful, concrete, and tangible result’”) (quoting *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998)).

3. *AT&T Corp. v. Excel Comms., Inc.*, 172 F.3d 1352 (Fed. Cir. 1999); *State St. Bank*, 149 F.3d 1368.

4. *In re Nuijten*, No. 2006-1371 (Fed. Cir. filed Mar. 17, 2006) (appealing the decision of the Board of Patent Appeals and Interferences of the U.S. Patent and Trademark Office that “signals” are not patentable subject matter).

technological arts requirement on inventions.⁵ Moreover, public perceptions of an unduly broad scope of patentable subject matter are again percolating, with the latest result being embodied in a bill to limit patentability on methods of achieving tax avoidance.⁶

The appropriate scope of patentable subject matter is a prime topic for consideration by courts and commentators alike. This article focuses on the impact and import of the dissent from the dismissal of certiorari in *Metabolite* as a possible predictor of Supreme Court clarification on the issue. At a minimum, this article hopes to provide some lessons from the Court's consideration of the case that may be useful for both pending and future cases.

This article begins in Section II with a review of the procedural history of *Metabolite*, including the subject matter of the invention. A brief review of the claim at issue provides context to discussing future directions in the area. Section III considers the implications of *Metabolite* with respect to future Supreme Court cases. Section IV outlines potential repercussions of *Metabolite* beyond the Supreme Court. Section V considers implications of the case for consideration by other institutional actors involved in patentable subject matter. Finally, Section V concludes with some remaining questions for consideration by policy-makers at all levels.

II. BACKGROUND

To help set the stage for discussion of the future of patentable subject matter, this section begins with the case that captured the attention of the Supreme Court. In addition, the prevailing standard for evaluating patentable subject matter, as articulated by both the Supreme Court and the Federal Circuit are presented.

A. *Metabolite*

The patentable subject matter issue that intrigued at least four Justices of the Supreme Court – the requirement for granting

5. *Ex parte* Bilski, App. No. 2002-2257 (B.P.A.I. 2006) (holding that there is a technological arts requirement); *Ex parte* Lundgren, 76 U.S.P.Q.2d 1385, 1388 (B.P.A.I. 2005) (holding that there is no “technological arts” requirement for patentable subject matter, but with strong dissents from two of the five judges).

6. *See* Stop Tax Haven Abuse Act, S. 681, 110th Cong. § 303 (2007) (proposing to amend the patent act to bar patenting of “invention[s] . . . designed to minimize, avoid, defer, or otherwise affect liability for Federal, State, local, or foreign tax” in context of the broader tax bill); *see also* Press Release, Carl Levin, U.S. Sen., Levin, Coleman, Obama Introduce Stop Tax Haven Abuse Act (Feb. 17, 2007), <http://levin.senate.gov/newsroom/release.cfm?id=269479>.

certiorari – began in a seemingly unlikely case.⁷ Laboratory Corp. of America Holdings (“LabCorp”) was sued for contributory patent infringement because it sold a test to doctors that allegedly used the plaintiff’s patented method to evaluate patient blood for certain key vitamin deficiency levels without authorization.⁸ However, despite the fact that LabCorp was ultimately found liable for willfully infringing, there are facts that indicate LabCorp had in fact taken affirmative actions to respect the rights of the patent holder. For example, LabCorp had accepted a license under the patent-in-suit and duly made payments to the patentee for years.⁹ The patent infringement dispute arose when LabCorp believed that it was permitted to terminate the license agreement in accordance with the contract terms.¹⁰

Metabolite brought suit against LabCorp based on a single claim that encompassed a far broader scope of subject matter than the narrower claims originally licensed.¹¹ LabCorp raised a number of defenses, including that the claim was invalid for being overbroad and indefinite.¹² Despite mounting a vigorous defense against the patent, LabCorp never explicitly raised patentable subject matter as an

7. In addition, although it is true that a plurality of the Justices agree to hear the case, the agreement may be even less uniform given that eight of the nine Justices use a “pool” system whereby their clerks take turns writing up summaries of cert petitions upon which the Justices decide whether to grant certiorari. *See, e.g.*, Wikipedia, Cert Pool, http://en.wikipedia.org/wiki/Cert_pool.

8. Although not party to the lawsuit, doctors who used LabCorp’s test were found to be directly infringing the patented method by “correlating” the patient’s vitamin levels with known standards. *See, e.g.*, *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1364 (Fed. Cir. 2004), *cert. dismissed*, 126 S. Ct. 2921 (2006) (noting substantial evidence to support the jury verdict that doctors using assays from LabCorp carried out the correlating step of the patent).

9. *See id.* at 1359.

10. The license permitted LabCorp “to terminate the agreement if ‘a more cost effective commercial alternative is available that does not infringe a valid and enforceable claim of’ the patent.” *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921, 2923 (2006) (Breyer, J., dissenting). When LabCorp in good faith began using a procedure from Abbott Laboratories that LabCorp believed to be far superior, it ceased paying royalties. *Id.*

11. *Id.* at 2923-24.

12. *Id.* at 2924. Although LabCorp challenged the patent claim on grounds of indefiniteness, lack of written description, enablement, anticipation and obviousness, it was unable to establish invalidity of the claim based on any of these defenses – at least not by the clear and convincing evidence necessary to overcome the statutory presumption of validity for all issued patents. *See Metabolite*, 370 F.3d at 1367-68 (affirming district court rejection of invalidity defenses); *see also* 35 U.S.C. § 282 (2000) (presumption of validity).

issue.¹³ As a matter of basic pleading rules, affirmative defenses are waived and precluded from consideration at trial when they are not timely included in initial pleadings.¹⁴ Indeed, lack of patentable subject matter was not expressly mentioned in any of the three questions LabCorp posed to the Court in its petition for certiorari.¹⁵

The Court divined a subject matter issue from a question that seemed to raise ambiguous issues of patent scope. In particular, the Court focused on the question of

[w]hether 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.¹⁶

Unlike the other two questions posed in the original certiorari grant, this omnibus question suggests a relationship between patent infringement and different bases of invalidity. While it is true that an invalid patent cannot be infringed, this question, as posed, seems to try to revisit validity issues that are not explicitly presented for certiorari. In addition, the question suggests that whether a claim is invalid under the three different bases of invalidity under section

13. Indeed, the Solicitor General argued against the grant of certiorari, in part, based on the fact that LabCorp had failed to raise the issue. Brief for the United States as Amicus Curiae at 15, *Metabolite*, 126 S. Ct. 2921 (No. 04-607), 2005 WL 3533248.

14. FED. R. CIV. P. 8(c); 5 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE & PROCEDURE § 1278 (3d ed. 2004) (noting that lower courts “virtually universal[ly]” hold that failure to plead an affirmative defense results in waiver of the defense and exclusion from the case); see also Brief for Respondents at 11, *Metabolite*, 126 S. Ct. 2921 (No. 04-607), 2006 WL 303905 (noting that “it is unlikely that there has ever been another case in the annals of this Court in which a party so clearly embraced every avenue for forfeiting a right, in every court along the way.”).

15. The precise questions posed were as follows:

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.

Petition for Writ of Certiorari, *Metabolite*, 126 S. Ct. 2921 (No. 04-607), 2004 WL 2505526.

16. *Id.*

112,¹⁷ might be tied to the proper scope of a patent right. While it is unclear what the precise strategic rationale was for this question, the petitioner was clearly successful in obtaining the attention of the Court. The inclusion of the phrase “basic scientific relationship” seemed to pique the Court’s interest that this was a case involving a question of patentable subject matter and, in particular, whether the claim was invalid because it attempted to claim a natural phenomena or scientific relationship in violation of prior Court precedent.¹⁸

An initial puzzle is why the Court was interested in addressing patentable subject matter issue when it was neither squarely raised in the petition, nor considered below. Indeed, lack of lower court consideration is often sound justification to deny consideration of an issue. However, some members of the Court seemed to believe that the “essence” of the patentable subject matter objection was argued below in the context of some of the invalidity arguments.¹⁹ In addition, the Court has inherent discretion to overlook petitioner’s failure to raise an issue in lower courts.²⁰ If the opinion of the dissenting Justices is any indication of the views of the full Court, some Justices may have strong feelings both about whether the Federal Circuit is misapplying the standard for patentable subject matter, as well as the policy implications of an erroneous scope of patentable subject matter. For example, the dissenting Justices noted that an overly expansive breadth of patentable subject matter might actually undermine public health as well as scientific progress.²¹

17. 35 U.S.C. § 112 (2000).

18. An unanswered question is why the Court chose to ignore the stated question regarding whether the claim was indefinite, undescribed and non-enabling – all legitimate grounds for challenging the validity of a patent and all defenses properly raised below. A cynical perspective might be that these technical defenses are difficult to understand, or, at a minimum, less interesting than revisiting patentable subject matter in light of the seemingly over-expansive scope of patentable subject matter.

19. *Metabolite*, 126 S. Ct. at 2925 (Breyer, J., dissenting) (suggesting that because LabCorp argued that the claim was so vague that it would permit an improper monopoly over a basic scientific fact, it must be invalid). Moreover, sidestepping the fact that the only prior discussion related to § 112, rather than § 101, 35 U.S.C. § 101 (2000), the dissenting Justices believed that the procedural argument was necessarily rejected by reading into the fact that the Court granted certiorari despite advice to the contrary by the Solicitor General. *Id.* at 2926 (noting that “after considering the Solicitor General’s advice not to hear the case (primarily based upon LabCorp’s failure to refer to 35 U.S.C. § 101), we rejected that advice, thereby ‘necessarily consider[ing] and reject[ing] that contention as basis for denying review.’”) (citation omitted).

20. See SUP. CT. R. 15.2; see also *Metabolite*, 126 S. Ct. at 2922 (Breyer, J., dissenting).

21. *Metabolite*, 126 S. Ct. at 2927-29 (Breyer, J., dissenting).

This article does not linger on a definitive interpretation of the claim at issue. A wide perspective of interpretations is already reflected in amici briefs and the interpretation is essentially a moot point.²² Nonetheless, a brief review is helpful to see both why the defendant originally assumed that there was no issue of patentable subject matter, as well as why many amici viewed the case as a vehicle for their perspectives on the scope of patentable subject matter.

The sole claim at issue, claim 13, begins by stating “[a] method for detecting a deficiency of cobalamin or folate in warm-blooded animals” comprised of two steps.²³ The steps are stated as comprising “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.”²⁴ In other words, the patented method comprised a method of correlating the bodily level of a protein with a vitamin B deficiency.

While methods may be patentable subject matter, the issue here was whether the method was barred by a common law doctrine precluding the patenting of a natural phenomenon.²⁵ In particular, the question was whether the patented method was tantamount to simply observing natural phenomena.²⁶ One brief suggested a doctor would infringe by merely using his medical judgment in correlating the blood protein level with the vitamin deficiency.²⁷ However, infringement is only possible when every element of the claimed invention is performed²⁸ – a full reading of the claim suggests that merely thinking about the numbers would not constitute infringement since the doctor would not perform the assay step in his or her head.

22. Some briefs suggested that the invention covered the thought processes of a physician thinking about a basic scientific relationship, or that upholding the validity of the claim would infringe on free speech. *See, e.g.*, Brief for Petitioner at 14, *Metabolite*, 126 S. Ct. 2921 (No. 04-607), 2005 WL 3543099; *see also* Brief of the Public Patent Foundation as Amicus Curiae in Support of Petitioner at 15, *Metabolite*, 126 S. Ct. 2921 (No. 04-607), 2005 WL 3597813 (suggesting that upholding the claim would “in effect, prevent the patent from generating or communicating *any* information that could help other would-be inventors” because all inferences would result in infringement).

23. U.S. Patent No. 4,940,658 col.41, l. 58-65 (filed Nov. 20, 1986).

24. *Id.*

25. *Metabolite*, 126 S. Ct. at 2922 (Breyer, J., dissenting).

26. *See id.* at 2923.

27. Reply Brief for Petitioner at 1, *Metabolite*, 126 S. Ct. 2921 (No. 04-607), 2005 WL 598181.

28. *See, e.g.*, *Lairam Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991).

B. *The Standard(s) of Patentable Subject Matter*

One lingering issue after *Metabolite* lies in the two potentially different standards enunciated by the Supreme Court and the Federal Circuit. In particular, the Federal Circuit has found business method patents to be patentable under a standard that looks at whether an invention “transforms” an object, or whether the invention produces a useful, concrete or tangible result.²⁹ The Supreme Court, on the other hand, has never embraced such a standard.³⁰ As the Justices dissenting from the dismissal of certiorari in *Metabolite* noted: “this Court has never made such a statement and, if taken literally, the statement would cover instances where the Court has held the contrary.”³¹ Rather, the dissenting Justices observed that the relevant test is whether patentable subject matter is barred because the claim covers a law of nature, natural phenomena or abstract ideas, which are all excluded as a matter of principle.³²

Interestingly, the patent act itself – which would be the typical starting place for considering the scope of patentable subject matter – does not directly support either position. The applicable statutory language here is relatively sparse; the federal patent act provides that “[w]hoever invents or discovers any new and useful process,³³ . . . or any new and useful improvement thereof, may obtain a patent”³⁴ No explicit exclusions follow this broad language. Although there are some exclusions from patentability,³⁵ Congress has declined to follow the practice of many other countries that expressly exclude medical procedures, mathematical methods, plant or animal varieties, and inventions that are contrary to morality.³⁶

29. See, e.g., *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998).

30. *Metabolite*, 126 S. Ct. at 2928 (Breyer, J., dissenting).

31. *Id.*

32. *Id.* at 2922.

33. The invention at here seems to clearly be a process. The Patent Act simply defines a process as a “process, art or method, and includes a new use of a known process” 35 U.S.C. § 100(b) (2000).

34. 35 U.S.C. § 101 (2000).

35. One clear exclusion is for inventions that are “useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon.” 42 U.S.C. § 2181(a) (2000). However, this exclusion is notably not within the patent act itself. One bar to patentability that is located within the patent act – although not as an express limit to patentable subject matter – is a bar on inventions whose publication or disclosure might be detrimental to national security. 35 U.S.C. § 181 (2000).

36. See, e.g. European Patent Convention art. 52(4)-53, Oct. 5, 1973, 13 I.L.M. 268, available at <http://www.european-patent-office.org/legal/epc/index.html> (twelfth revision as of Apr. 2006); see also Agreement on Trade-Related Aspects of Intellectual Property Rights art.

Although the general statutory framework does not include any explicit exclusion from patentability, courts have nonetheless interpreted the minimalist language to have some prohibitions. Although most prohibitions have evolved to extinction over time, there still seems to be a bar on patenting abstract concepts, mathematical algorithms and scientific principles.³⁷ The Court's own decisions have crafted a more nuanced distinction between attempts to patent algorithms per se (unpatentable under *Parker v. Flook*³⁸) versus methods that utilize a mathematical formula or algorithm in one step of a multi-step process (patentable process under *Diamond v. Diehr*³⁹). However, the Court has admitted that determining when the exclusion applies "is not easy to define."⁴⁰

Without explicitly jettisoning the bar to patentability for natural phenomena, the Federal Circuit has created an alternative framework for evaluating patentable subject matter. In particular, for method claims since the 1998 case of *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, the Federal Circuit has found patentable subject matter where an invention "produces 'a useful, concrete and tangible result.'"⁴¹ Based upon this standard, the Federal

27.2-3, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex IC, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125 (1994), available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf [hereinafter TRIPS].

37. See, e.g., *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). See also Thomas F. Cotter, *A Burkean Perspective on Patent Eligibility 8* (Univ. of Minn. Law Sch. Legal Studies Research Paper Series, Paper No. 06-68, 2006), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=951800 (noting that courts and commentators have traditionally agreed that laws of nature, abstract ideas and naturally-occurring physical phenomena are unpatentable). On the other hand, the Federal Circuit has dispensed with any perceptions of a per se bar to either computer-related art, or business methods. See *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1375 (Fed. Cir. 1998); *In re Alappat*, 33 F.3d 1526, 1543-44 (Fed. Cir. 1994). Similarly, the mental steps doctrine has been largely disposed of since *In re Musgrave*. See *In re Musgrave*, 431 F.2d 882, 890 (C.C.P.A. 1970); see also Kevin Emerson Collins, *Propertizing Thought, Syllogistic and Other 36-37* (Aug. 31, 2006) (unpublished manuscript, on file with the Intellectual Prop. Scholars Conference), available at <http://www.law.berkeley.edu/institutes/bclt/ipsc/papers2/Collins.doc>.

38. *Parker v. Flook*, 437 U.S. 584 (1978).

39. *Diehr*, 450 U.S. 175.

40. Although the opinion quotes from legendary cases concerning some examples that are clearly excluded, it also admits that such categories are "not easy to define." *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921, 2926 (2006) (Breyer, J., dissenting). The Supreme Court quotes from *Flook* that "[t]he line between a patentable 'process' and an unpatentable 'principle' is not always clear," as well as from a federal appellate court decision on the scope of copyrightable subject matter. *Id.* (quoting *Flook*, 437 U.S. at 589).

41. *State St. Bank*, 149 F.3d at 1373; see also *AT&T Corp. v. Excel Comms., Inc.*, 172 F.3d 1352, 1357 (Fed. Cir. 1999).

Circuit has opened the door for business method patents and the USPTO has followed suit by issuing patents in this area.⁴² In addition, the USPTO has revised its guidelines for evaluating patentable subject matter to not only address this standard, but also to clarify that there is no requirement that the invention be within a technical art.⁴³

III. FUTURE DIRECTIONS FOR THE SUPREME COURT

At a minimum, *Metabolite* seems to signal that some Justices are ready to revisit the scope of patentable subject matter despite the fact that a 7-2 majority of the Court affirmed a broad scope of patentable subject matter just five years ago in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*⁴⁴ In *J.E.M.* the Court strongly affirmed the

42. Indeed, there is a dedicated web page within the USPTO site directed to business method patents. U.S. Patent and Trademark Office, Patent Business Methods, <http://www.uspto.gov/web/menu/pbmethod/> (last visited Apr. 4, 2007) (providing statistics, as well, as guidelines for successfully preparing and prosecuting business method applications). See also COMM. ON INTELLECTUAL PROP. RIGHTS IN THE KNOWLEDGE-BASED ECON. BOARD ON SCI., TECH., AND ECON. POLICY, NAT'L ACAD. OF SCI., A PATENT SYSTEM FOR THE 21ST CENTURY 55-57 (Stephen A. Merrill, Richard C. Levin & Mark B. Myers eds., 2004), available at <http://books.nap.edu/html/patentsystem/0309089107.pdf> [hereinafter NAS REPORT] (describing growth in business method patent applications in the wake of the *State Street Bank* decision, as well as the results of the USPTO's initiative for extra review of class 705 – often synonymous with business method applications – that indicated a distinct decline in the number of issued business method patents). Whether business methods as a class should be patentable or reviewed differently than other classes of inventions is a separate question for which there is ample scholarly attention. See, e.g., John R. Allison & Starling D. Hunter, *On the Feasibility of Improving Patent Quality One Technology at a Time: The Case of Business Methods*, 21 BERKELEY TECH. L.J. 729 (2006); John R. Allison & Emerson H. Tiller, *The Business Method Patent Myth*, 18 BERKELEY TECH. L.J. 987 (2003) (presenting evidence to suggest that business method patents are no less valid than other types of patents); Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577 (1999) (providing an early perspective on the emergence on business method patents).

43. U.S. PATENT AND TRADEMARK OFFICE, INTERIM GUIDELINES FOR EXAMINATION OF PATENT APPLICATIONS FOR SUBJECT MATTER ELIGIBILITY 42 (2005), http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf; see also U.S. Patent and Trademark Office, Overview of Interim Guidelines for Subject Matter Eligibility, http://www.uspto.gov/web/offices/pac/compexam/interim_guide_subj_matter_eligibility.html (last visited Apr. 4, 2007) (clarifying that an invention no longer need not be within a “technological art” to qualify as patentable subject matter).

44. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001). In an interesting parallel to *Metabolite*, at the time certiorari was granted for *J.E.M.*, some speculated that the Court's decision might set a new path for patentable subject matter because the issue of whether plants were patentable was thought to have been a long-settled issue by most patent practitioners. However, unlike *Metabolite*, where the Court injected the issue of patentable subject matter for the first time, one of the parties to *J.E.M.* did affirmatively raise the issue of patentable subject matter as an affirmative defense, such that the issue was thoroughly discussed and considered by lower courts.

broad scope of patentability set forth in *Diamond v. Chakrabarty* in holding plants within the scope of patent law despite the fact that other types of protection were available.⁴⁵ The Court gave weight not only to its prior precedent in *Chakrabarty*, but also the views of the USPTO.⁴⁶ This deference is in sharp contrast to the suggestion of the dissenting *Metabolite* Justices that directly challenge the Federal Circuit standard.

Moreover, the comments of the dissenting *Metabolite* Justices suggest a possibly important shift in focus for policy considerations underlying patentable subject matter.⁴⁷ These three Justices seem concerned with the impact of patentable subject matter on a variety of issues, including health care costs, as well as scientific research.⁴⁸ The opinion freely admits that “monetary incentives may matter” to scientific research, but that exclusion is nevertheless appropriate in some instances because of a necessary balance.⁴⁹ The opinion boldly states that “the reason for the exclusion is that sometimes *too much* patent protection can impede rather than ‘promote the Progress of Science and useful Arts,’ . . . by impeding the free exchange of information”⁵⁰ While the impact of patent rights on scientific research and norms is not a new concept among academic realms, it has not typically been discussed as an independent factor in cases involving patentable subject matter.

This is in contrast to the presumptive need for patent incentives that played a heavy role in *Chakrabarty*.⁵¹ The *Chakrabarty* Court – at least the five Justices in the majority opinion – placed a clear emphasis on providing a patent incentive to accelerate research

45. *Id.* at 124.

46. The opinion further noted that since *Chakrabarty*, the USPTO Board of Patent Appeals and Interferences explicitly found plants to be included within the scope of patentable subject matter and that “the [USPTO] has had an unbroken practice of conferring utility patents for plants.” *Id.* at 125.

47. Moreover, in contrast to some prior Court decisions that seemed to distance patent policy from the proper realm of judicial oversight, the dissenting opinion suggests that the judiciary not only explicitly consider policy implications, but possibly lead the way for Congress.

48. Within the introductory paragraphs of the opinion, Justice Breyer noted that “those who engage in medical research, who practice medicine, and who as patients depend upon proper health care, might well benefit from this Court’s authoritative answer.” *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921, 2922 (2006) (Breyer, J., dissenting).

49. *Id.*

50. *Id.* (quoting U.S. CONST. art. I, § 8, cl. 8).

51. See *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980) (“Whether respondent’s claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.”).

without concern for possible risk in the then-fledgling area of genetic research.⁵² Moreover, the majority in *Chakrabarty* paid no heed to the dissent's call for balance and caution in the area of patentable subject matter, or the idea that Congress was better situated to address policy issues.⁵³ Rather, the majority blithely remarked that pregnant policy issues were simply beyond the realm of judicial interpretation and not necessary to consider unless and until Congress amended what it perceived to be a broad scope of patentable subject matter.⁵⁴

The *Chakrabarty* opinion is particularly interesting in a broader historical context since the Court had previously taken a more cautious approach to patentable subject matter cases. The two Supreme Court cases on patentable subject matter immediately preceding *Chakrabarty* both found the inventions at issue unpatentable and also articulated a conservative approach to new technology.⁵⁵ Only two years before *Chakrabarty*, the majority in *Parker v. Flook*, noted that the Court should "proceed cautiously" in the area of computer programs.⁵⁶ The Court specifically noted that its decision was not intended to suggest that patent protection should be barred from computer programs, but suggested instead that since the area was wholly unforeseen by Congress, Congress would be in a better position as a matter of policy to decide whether to grant protection, and, if so, the extent of such protection.⁵⁷ Similarly, in *Gottschalk v. Benson*, the Court was sympathetic to "considerable problems" that would be raised for the USPTO examination process, such that Congress would be in the best position to decide.⁵⁸

IV. MOVING BEYOND THE SUPREME COURT

This section examines the possible implications of *Metabolite* beyond the Supreme Court. Although the Supreme Court clearly has the power to declare the law of the land, it does not retain sole authority in creating laws. Rather, Congress can clearly pass laws⁵⁹

52. *Id.* at 316-17.

53. *Id.* at 319 n.2 (Brennan, J., dissenting).

54. *Id.* at 317 (majority opinion).

55. *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 64 (1972).

56. *Flook*, 437 U.S. at 596.

57. *Id.* at 595-96.

58. *Gottschalk*, 409 U.S. at 73.

59. For example, Congress has passed legislation to explicitly overrule judicial decisions. See, e.g., 35 U.S.C. § 271(f) (2000) (overruling U.S. Supreme Court decision in *Deepsouth Packing Co., Inc. v. Laitram Corp.*, 406 U.S. 518 (1972)).

and even the Federal Circuit can – and has – created new laws,⁶⁰ subject to possible review by the Court. This section focuses on the impact of *Metabolite* for modification of patent laws by actors beyond the Court.

A. Patent Reform – Federal Circuit Reconsideration?

Perhaps the most immediate impact of *Metabolite* will be on Federal Circuit jurisprudence. The Federal Circuit is uniquely poised to revisit the standard of patentable subject matter as the single Court of Appeals to hear patent cases decided by both federal district courts, as well as appeals from the USPTO.⁶¹ Moreover, the *Metabolite* dissent clearly puts the Federal Circuit on notice that at least three Justices disagree with its standard of patentable subject matter.⁶² While the Federal Circuit is under no obligation to revisit its jurisprudence on the issue, let alone defend its standard, recent history suggests that the Federal Circuit is in fact sensitive and responsive to criticism. For example, since the Court granted certiorari in *Teleflex, Inc. v. KSR International Co.* to evaluate the nonobviousness standard,⁶³ the Federal Circuit has issued a series of opinions on the same issue that go to great lengths in defending its standard.⁶⁴ Indeed, since *Metabolite*, the Federal Circuit has already heard oral arguments regarding the scope of patentable subject matter with another case possibly pending.⁶⁵ Whether the Federal Circuit will take this

60. While the Federal Circuit probably considers itself to interpret, rather than create new law wholesale, most consider the Federal Circuit to have indisputably expanded the scope of patentable subject matter since the *State Street Bank* decision. See, e.g., NAS REPORT, *supra* note 42, at 43-44 (explaining how the Federal Circuit moved beyond the Supreme Court jurisprudence in *In re Alappat*, as well as with *State Street Bank* and *AT&T Corp. v. Excel Communications, Inc.*).

61. 28 U.S.C. § 1295(a)(2), (4)(A)-(C) (2000).

62. Thomas B. Lindgren, *The Sanctity of the Design Patent: Illusion or Reality? Twenty Years of Design Patent Litigation Since Comco v. Day-Brite Lighting, Inc., and Sears, Roebuck & Co. v. Stiffel Co.*, 10 OKLA. CITY U. L. REV. 195, 199 (1985).

63. *Teleflex, Inc. v. KSR Int'l Co.*, 119 Fed. App'x 282 (Fed. Cir. 2005), *cert. granted*, 126 S. Ct. 2965 (June 26, 2006) (No. 04-1350).

64. See, e.g., *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006) (holding patent obvious and reversing district court decision to the contrary); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006) (holding patents obvious); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299 (Fed. Cir. 2006) (holding patent obvious in reversal of district court decision); *In re Kahn*, 441 F.3d 977 (Fed. Cir. 2006) (affirming rejection of patent application as obvious).

65. The Federal Circuit has already heard oral arguments in the case of *In re Nuijten*. As of the time of publication, no opinion was yet available. In addition, *Ex parte Bilski* is a case that has been appealed to the Federal Circuit from the USPTO Board of Patent Appeals. See *supra* notes 4-5.

opportunity to defend its current standard, or modify it, remains to be seen.

B. Patent Reform – Congressional Action?

In addition to possible re-evaluation of the scope of patentable subject matter by the Federal Circuit, *Metabolite* may also impact the broader movement for congressional patent reform. There has long been a call for reform of the U.S. patent system, with extensive bills proposed in the last session of Congress.⁶⁶ On the other hand, to date, the extensive proposals do *not* include suggestions for amending patentable subject matter; rather, the proposals suggest changes to what is considered prior art, as well as opportunities for post-grant opposition as methods to minimize weak, or even invalid, patents.⁶⁷ *Metabolite* may help challenge the long-prevailing assumption that the scope of patentable subject matter is proper. Many have previously assumed that a broad scope of patentable subject matter is important to promote innovation without citing any evidence, or decline to suggest any changes because of an assumption that modification is politically impossible.⁶⁸

Metabolite may already be having an impact on congressional discussions of patentable subject matter. In the short time since the decision, two bills have been introduced in Congress to limit patentable subject matter – one involving controversial tax avoidance

66. See, e.g., Patent Reform Act of 2006, S. 3818, 109th Cong. (2006); Patents Depend on Quality Act of 2006, H.R. 5096, 109th Cong. (2006); Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005). In addition, legislative proposals for patent reform are anticipated shortly in the current Congress. See, e.g., Susan Decker, *US Businesses Laud ‘Season for Patent Reform,’* INT’L HERALD TRIB., Mar. 13, 2007,

<http://www.iht.com/articles/2007/03/13/business/patents.php>; *Legislation/Intellectual Property: House IP Panel’s Priorities Include PTO Oversight, Patent Reform, Music Licensing, 73 BUREAU OF NAT’L AFFAIR’S PATENT, TRADEMARK & COPYRIGHT J. 554 (2007).*

67. Patent Reform Act of 2006, S. 3818, 109th Cong. § 6 (2006) (detailing post-grant review proceedings).

68. See, e.g., FTC, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 4, at 43 (2003), *available at*

<http://www.ftc.gov/os/2003/10/innovationrpt.pdf> [hereinafter INNOVATION REPORT] (suggesting that promotion of innovation should be “presumed unless empirical evidence to the contrary exists”); ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 115, 126 (2004); NAS REPORT, *supra* note 42, at 44; *but see* Peter S. Menell, *A Method for Reforming the Patent System* 9-12 (Univ. of Cal., Berkeley, Pub. Law and Legal Theory Research Paper Series, Paper No. 958089, 2007), *available at* <http://ssrn.com/abstract=958089> (criticizing the National Academy of Sciences report, as well as the Jaffe and Lerner report for failing to provide a careful analysis of the appropriate scope of patentable subject matter).

schemes, and another involving gene patents.⁶⁹ While tax avoidance patents (typically business patents) are a recent genre, gene patenting is not new. Indeed, in the initial remarks accompanying the legislation, Representative Becerra noted that many gene patents have been issued and indicated a desire to halt further patenting in this area, although the bill would not implicate existing patents.⁷⁰ Whether further evaluation of the issue will ultimately alter the patent landscape is unclear. After all, recent attempts to amend the scope of patentable subject matter have failed despite the passage of some legislation. For example, although repeated attempts to exclude medical procedures from the scope of patentable subject matter have failed,⁷¹ the last attempt resulted in an amendment to the patent act that limits liability of medical doctors.⁷² Another recent example involved a failed attempt to bar human-like inventions from the scope of patentable subject matter⁷³ that was more successful upon reincarnation as a limit to USPTO funding for examination of applications involving the same subject matter.⁷⁴ In both of these examples, while *some* legislation passed, rhetoric concerning the importance of the patent incentive steered action away from modifying the scope of patentable subject matter.⁷⁵ Moreover, groups that strongly protested prior attempts to modify the standard, such as biotechnology and pharmaceutical companies, would likely oppose similar efforts in the future.

69. See Stop Tax Haven Abuse Act, S. 681, 110th Cong. § 303 (2007); Genomic Research and Accessibility Act, H.R. 977, 110th Cong. (2007).

70. 153 CONG. REC. E315 (daily ed. Feb. 9, 2007) (statement of Rep. Becerra).

71. Medical Procedures Innovation and Affordability Act, H.R. 1127, 104th Cong. (1995) (proposing to amend the scope of subject matter to exclude certain medical procedures).

72. 35 U.S.C. § 287(c) (2000). In effect the amendment produces the same result as a limit on patentable subject matter from the perspective of medical doctors since they are not liable; however, for the patent holder, there is an important distinction since secondary actors may be sued for infringement under the current system.

73. In particular, Senator Brownback had proposed an amendment to a terrorism bill (providing for federal funding to insurance companies) that included an amendment to narrow the scope of patentable subject matter. 148 CONG. REC. S5556 (2002).

74. Consolidated Appropriations Act, 2004, Pub. L. No. 108-199, § 634, 118 Stat. 3, 101 (2004).

75. See, e.g., Rick Weiss, *Funding Bill Gets Clause on Embryo Patents*, WASH. POST, Nov. 17, 2003, at A04 (noting concern of biotechnology industry that legislation would prematurely limit incentives on a promising area of research); Julie Kimbrough, *CAMR: Anti-Patent Legislation Could Cripple Medical Research; Patient Groups, Researchers, Universities Voice Opposition*, SCIENCE BLOG, Nov. 19, 2003,

<http://www.scienceblog.com/community/older/archives/K/4/pub4765.html> (arguing against an overly broad ban on patentable subject matter for fear that it will reduce research incentives and negatively impact the competitive position of the United States in the global economy).

Beyond past history, the substantive content of both of the pending proposals for amending patentable subject matter are also questionable: Both proposals provide short, yet vague, bars from patentability.⁷⁶ The proposed bar on human material is particularly likely to elicit objections from the same biotechnology interests that objected to other recent proposals. In addition, the genesis for the bill seems to reflect less of the nuanced concerns of the dissenting *Metabolite* Justices in balancing patent incentives against health policy, and more of a misunderstanding of fundamental patent law, or at least some of its nuances. For example, the introductory remarks to the gene patent bill erroneously suggest that patents on gene sequences result in natural human genetic material being owned; however, only isolated gene sequences can be patented.⁷⁷ In addition, while some statements regarding the negative impact of gene patents on research scientists have validity, there is no reflection concerning whether limiting patentable subject matter is the *best* way to provide a balance that maintains the incentive for innovation.⁷⁸

V. ISSUES FOR CONSIDERATION

This section provides some continuing issues for consideration that stem from the original discussion of *Metabolite*. Although a full discussion of these issues is beyond the scope of this article, this section aims to outline issues for future consideration by all institutional actors involved with the scope of patentable subject matter.

A. *What Is the Proper Role of Patentable Subject Matter?*

In evaluating what courts or Congress should strive for in addressing patentable subject matter, a fundamental question is the purpose of this requirement in the context of patentability generally. As every student of patent law is well aware, patentable subject

76. See Stop Tax Haven Abuse Act, S. 681, 110th Cong. § 303 (2007) (proposing to bar patents where “the invention is designed to minimize, avoid, defer, or otherwise affect the liability for Federal, State, local, or foreign tax”); see also Genomic Research and Accessibility Act, H.R. 977, 110th Cong. § 2 (2007) (proposing to amend the patent act to state that “[n]otwithstanding any other provision of law, no patent may be obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies.”).

77. See 153 CONG. REC. E315, E316 (daily ed. Feb. 9, 2007) (statement of Rep. Becerra) (asserting that “who we are is owned by someone else.”).

78. See generally *id.* (providing no discussion of a need to balance patent incentives with policy, other than a conclusory and unsupported statement that the act “does not hamper invention . . . Medical innovation and economic advancement will occur if the study of genes is allowed to happen unabated.”).

matter is merely one requirement of patentability.⁷⁹ Even if an invention is deemed within the scope of patentable subject matter, it must still be considered new, useful and nonobvious to be patentable.⁸⁰ However, there is sometimes a tendency to conflate consideration of the appropriate scope of patentable subject matter with other requirements of patentability, without considering whether each requirement should be serving independent purposes.⁸¹

An important question is whether patentable subject matter should intentionally serve an independent or duplicative function to the doctrines of novelty and nonobviousness? In particular, given recent criticisms that the bar for novelty and, especially, nonobviousness are too low, or at least difficult to apply rigorously, should patentable subject matter be used to police the proper scope of patents?⁸² Or, should such criticisms be addressed directly by improving application of novelty and nonobviousness standards, rather than indirectly by invoking patentable subject matter? Alternatively, what harm is there from having patentable subject matter serve as a gatekeeper to patentability?⁸³ A possible harm is that narrowing the standard of patentable subject matter may result in a complete bar to patents of inventions that might in fact benefit society. While it is true that issued patents may be impacted by either a more narrow scope of subject matter or more rigorous application of other standards, this does not address the policy question of whether

79. See, e.g., JAFFE & LERNER, *supra* note 68, at 27-28 (noting in a book written by economists for the general public, that while "U.S. courts have become progressively more generous in determining what subject matter is indeed patentable," that "is not the end of the story" since there are three other tests – utility, novelty and nonobviousness).

80. See 35 U.S.C. §§ 101-103 (2000). Moreover the patent application must provide an adequate description of the invention that enables someone of skill in the art to make and use the invention. *Id.* § 112.

81. This was aptly noted by the dissent in *Parker v. Flook*. *Parker v. Flook*, 437 U.S. 584, 600 (1978) (Stewart, J., dissenting) (noting that the majority confuses patentable subject matter with the standard of patentability under the doctrines of novelty and nonobviousness). Similarly, the current Federal Circuit standard of patentability incorporates utility, even though that is a separate requirement. See *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1375 (Fed. Cir. 1998).

82. Indeed, recent studies of U.S. patent laws have in fact suggested that, at least for some types of technologies, these standards have not been applied in a sufficiently rigorous manner. See, e.g., NAS REPORT, *supra* note 42, at 95.

83. Indeed, there has been a suggestion that courts have abdicated the gate-keeping function of patentable subject matter through the unduly weak standard. See, e.g., David S. Olson, Patentable Subject Matter: The Problem of the Absent Gatekeeper 1 (Sept. 27, 2006) (unpublished manuscript, on file with the Stanford Law Sch. Ctr. for Internet and Soc'y), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=933167.

patentable subject matter should perform a duplicative gate-keeping role.

In considering the role of patentable subject matter, courts and Congress should be conscious of the tendency of some to use patentable subject matter as a solution for other problems. For example, the Supreme Court has been repeatedly asked to utilize patentable subject matter to bar certain technologies from patentability on questionable policy grounds. For example, during the infancy of the computer software era, the USPTO requested – and obtained – Court approval for denying computer software from the scope of patentable subject matter when the USPTO had logistical problems in applying *other* requirements of patentability.⁸⁴ In particular, the USPTO was concerned that it had an inadequate library of prior art, such that too many invalid patents might issue.⁸⁵ While the USPTO's concern may have been valid, other methods of addressing the prior art problem such as allowing patents to be opposed, or bolstering the prior art collection would seem to be more direct solutions than contorting the doctrine of patentable subject matter.

B. Patent Rights

In addition to the relationship amongst various patentability requirements, the scope of patent rights may also need to be revisited. After all, a broad scope of patentable subject matter and even patents need not result in an impediment to research if there is a broader scope of exceptions to the enforcement of patent rights. Accordingly, the fears of the dissenting opinion in *Metabolite* could be addressed by modifying patent standards to provide some exceptions from patent infringement. Indeed, domestic patent laws provide far more exclusivity to the patent owner than most other countries. For example, there is no general experimental use exception to patentability – even for academic researchers.⁸⁶ Accordingly, recent

84. See *Gottschalk v. Benson*, 409 U.S. 63, 72 (1972) (noting that the USPTO was concerned about an inability to examine computer software applications because of a lack of relevant prior art); see also *Flook*, 437 U.S. at 587-88 (majority opinion) (noting that the USPTO Commissioner petition for certiorari suggested that Court intervention was needed to reverse the lower court finding of patentability for fear of a flood of USPTO applications).

85. *Gottschalk*, 409 U.S. at 72 (suggesting the Court was sensitive to an indirect attempt to patent computer programs in light of the USPTO's assertion of difficulty in examining computer programs due to limited prior art available to the USPTO).

86. See *Madey v. Duke Univ.*, 307 F.3d 1351, 1360 (Fed. Cir. 2002).

policy reports have argued for an explicit statutory exception for scientific research.⁸⁷

The impact of patent rights is particularly an issue for health care, as noted by the dissenting *Metabolite* Justices.⁸⁸ These Justices, as well as amici briefs, highlight a critical need to revisit the current balance of patent rights to assess whether they promote innovation at too great a cost to other values, such as health care access.⁸⁹ The rising costs of health care further support consideration of whether patents unduly contribute to such costs – either through an overly broad scope of patentable subject matter, or the lack of exceptions to patent rights. While pharmaceutical companies repeatedly insist that patents are crucial to promoting necessary research that benefits the public overall, there is a clear tension between providing maximal patent rights and maximum health care. The conflict is most extreme in less developed countries, but the same issues exist in the United States where patients may be precluded from necessary medical care because patented drugs or tests are cost-prohibitive.⁹⁰ The need to address this policy concern has been noted in policy studies⁹¹ and

87. See, e.g., NAS REPORT, *supra* note 42, at 110-11. Indeed, even before *Madey v. Duke University*, there have been repeated proposals to embrace a more explicit experimental use provision. See, e.g., Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000).

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

89. Brief of the American Heart Association as Amicus Curiae in Support of Petitioner at 27-28, *Metabolite*, 126 S. Ct. 2921 (No. 04-607), 2005 WL 3561169; Brief for the American Medical Association et al. as Amici Curiae in Support of Petitioner at 23-24, *Metabolite*, 126 S. Ct. 2921 (No. 04-607), 2005 WL 3597812.

90. In fact, some might suggest that the “working poor” in the United States suffer the most since the United States does not provide universal health care, such that patented medical treatment is often completely out of reach for the many Americans without health insurance.

91. See generally AUSTL. ADVISORY COUNCIL ON INTELLECTUAL PROP., PATENTS AND EXPERIMENTAL USE OPTIONS PAPER (2004), available at <http://www.acip.gov.au/library/Experimental%20Use%20Options%20Paper%20A.pdf>; SVEN J.R. BOSTYN, EUROPEAN COMM'N, PATENTING DNA SEQUENCES AND SCOPE OF PROTECTION IN THE EUROPEAN UNION: AN EVALUATION, BACKGROUND STUDY FOR THE EUROPEAN COMMISSION WITHIN THE FRAMEWORK OF THE EXPERT GROUP ON BIOTECHNOLOGICAL INVENTIONS (2004), available at http://bookshop.europa.eu/eubookshop/FileCache/PUBPDF/KINA21122ENC/KINA21122ENC_002.pdf; W.R. CORNISH ET AL., INTELLECTUAL PROPERTY RIGHTS (IPRS) AND GENETICS: A STUDY INTO THE IMPACT AND MANAGEMENT OF INTELLECTUAL PROPERTY RIGHTS WITHIN THE HEALTHCARE SECTOR (2003), available at <http://www.phgu.org.uk/pages/work/IP.htm>; INNOVATION REPORT, *supra* note 68; NAS REPORT, *supra* note 42; NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA (2002), available at <http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf>;

even been subject to legislative proposal, but, so far, Congress has not yet enacted any legislation to balance patent rights and public health, other than a very minor exception from liability for doctors using some types of patented medical procedures. However, the *Metabolite* opinion may help provide momentum for such efforts.

In reconsidering the role of patentable subject matter, as well as the intersection between patents and public health, a more critical consideration of whether patents truly promote innovation, as well as whether a broad scope of patentable subject matter is important, needs to be closely examined. After all, despite strong rhetoric from lobbying groups and some judicial opinions, the empirical evidence is more mixed. Patents have been traditionally viewed as important in some industries, such as health care and chemical industries.⁹² However, some have suggested that patents merely promote copying of popular drugs,⁹³ as well as searches for “blockbuster” drugs that will be commercially successful, even if not truly novel.⁹⁴ Moreover, whether patents are necessary to promote development of new medical procedures is even more controversial. For example, when Congress last considered whether to bar medical procedures from the scope of patentable subject matter, some suggested that, in contrast to pharmaceuticals, medical procedures are typically developed during the course of medical practice and are inexpensive to develop, such that a patent incentive may not be necessary.⁹⁵ However, even the medical profession admitted that if such procedures were barred from

THE ROYAL SOC'Y, KEEPING SCIENCE OPEN: THE EFFECTS OF INTELLECTUAL PROPERTY POLICY ON THE CONDUCT OF SCIENCE (2003), *available at* <http://www.royalsoc.ac.uk/displaypagedoc.asp?id=11403>.

92. See, e.g., NAS REPORT, *supra* note 42, at 35-36. Additionally, in industries that are new to patent protection, such as software and business methods, the relevance of a patent incentive is even more questionable since they have clearly succeeded before patents were granted.

93. Worse yet, some contend that the exclusivity tied to patent rights is associated with bad faith attempts to extend patent exclusivity with minor modifications. Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. Rev. 63, 80 (2004).

94. See MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 52-58 (2004) (asserting that from 1998-2002 only 14% of the total amount of new drugs reviewed by FDA were “innovative,” and that most of them originated from publicly-supported research).

95. See COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, AM. MED. ASS'N, ETHICAL ISSUES IN THE PATENTING OF MEDICAL PROCEDURES 1-2 (1995), *available at* http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja_1a95.pdf. In addition to questioning the need for a patent incentive, the same report noted that the existence of such patents had negative ramifications for the practice of medicine since doctors would often be unaware of the existence of such patents until they were sued. *Id.*

patentability, the lack of a patent incentive might result in some procedures being underdeveloped.⁹⁶

When the impacts of patents are considered on a national or global scale, the import of strong patents or broad patentable subject matter is even less clear. Part of the problem may be that it is impossible to do true scientific research with control groups since any country that does not provide patents could be seen as necessarily free-riding on the innovative efforts of countries that do provide patent systems. On the other hand, researchers have not conclusively found that introduction or strengthening of a patent system necessarily spurs innovation.⁹⁷ In addition, the *type* of innovation that is promoted may also differ. For example, India successfully promoted innovation in new methods as well as development of a generic drug industry when it consciously made the decision to only grant process patents for pharmaceuticals. Although the scope of patentable subject matter was intentionally restricted, it had the intended effect of promoting innovation in new processes while simultaneously allowing competition to reduce the price of necessary drugs.⁹⁸ Also, while innovative firms may have patents, there is not necessarily a correlation between extensive patenting and extensive innovation. Although patent protection may generally promote innovation, it may more fundamentally promote strategic behavior.⁹⁹

C. *Can Policy Goals Trump Clever Claim Drafting?*

A final consideration is whether patent policy goals or standards may nonetheless be circumvented through clever claim drafting. Although claim-drafting considerations do not answer fundamental policy questions, claims are crucial in determining an invention's

96. *Id.* at 5.

97. See, e.g., MICHELE BOLDRIN & DAVID K. LEVINE, AGAINST INTELLECTUAL PROPERTY ch. 8, at 7-13 (2005), <http://www.dklevine.com/papers/ip.ch.8.m1004.pdf>; NAS REPORT, *supra* note 42, at 40.

98. See, e.g., Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation* 25-30 (Aug. 16, 2006) (unpublished manuscript, on file with the Univ. of Pittsburgh Sch. of Law), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=923538; Dwijen Rangnekar, *No Pills for Poor People? Understanding the Disembowelment of India's Patent Regime* 6-8 (Centre for the Study of Globalisation and Regionalisation, Univ. of Warwick, Working Paper No. 176/05, 2005), available at <http://www2.warwick.ac.uk/fac/soc/csgr/research/workingpapers/2005/wp17605.pdf>.

99. See KEVIN G. RIVETTE & DAVID KLINE, REMBRANDTS IN THE ATTIC: UNLOCKING THE HIDDEN VALUE OF PATENTS 43-48, 53-55 (2000) (illustrating with real world examples that patents are indeed important in today's corporate strategic decision-making).

patentability and the scope of any issued patent.¹⁰⁰ Moreover, claim drafting is an art that sometimes permits patents to issue that seem inconsistent with intended policies. For example, with respect to the issue of whether computer software should be patentable, for many years the rule was that software per se was unpatentable, but, when combined with hardware, patent protection was available.¹⁰¹ Accordingly, able claim drafters always included some hardware in claims to obtain patent protection.

In addition, Canada's recent experience with bright line bars against patentability for living organisms suggest that claim drafting, together with claim construction, may have interesting results. The Canadian Supreme Court took a bold step in finding higher life forms unpatentable in *Harvard College v. Canada*, despite contrary rulings in all other industrialized countries.¹⁰² In doing so, the Canadian Supreme Court rejected the arguments of the biotechnology industry that such patents were essential. However, a few years later, the Canadian Supreme Court (albeit with a slightly different group of judges) held a genetically modified plant to be patentable.¹⁰³ More precisely, the court rejected defendant Schmeiser's contention that the claims should be unpatentable based on *Harvard*.¹⁰⁴ Rather, the court found that because the claims were directed to the cellular level, rather than to the entire plant, they were valid – despite the fact that both claims would have the same result in prohibiting others from making, using, or selling the genetically altered plant.¹⁰⁵ While it is possible to consider the two Canadian Supreme Court decisions to merely reflect the positions of different judges, it is also possible to

100. See, e.g., *Autogiro Co. of Am. v. U.S.*, 384 F.2d 391 (Ct. Cl. 1967) (focusing on meaning of claims as critical to determining the scope of patent rights); U.S. PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2106 (8th ed. 2006) (noting that each claim should be reviewed to determine whether it constitutes patentable subject matter).

101. See, e.g., *In re Alappat*, 33 F.3d 1526, 1543 (Fed. Cir. 1994); Examination Guidelines for Computer-Related Inventions, 61 Fed. Reg. 7,478 (Feb. 28, 1996). See also European Patent Convention, *supra* note 36, art. 52(2) (excluding from the scope of patentable invention not only discoveries and scientific theories, but also methods of doing business, computer programs, and presentations of information); Andreas Grosche, *Software Patents – Boon or Bane for Europe?*, 14 INT'L J.L. & INFO. TECH. 257, 271, 275 (2006) (noting test cases, T1173/97, T935/97, and T258/03, the latter of which held that a method of conducting Dutch auction using a computer program was patentable since it comprised technical features).

102. *Harvard College v. Canada*, [2002] 4 S.C.R. 45 (Can.).

103. *Monsanto v. Schmeiser*, [2004] 1 S.C.R. 902 (Can.).

104. *Id.*

105. *Id.*

consider the cases as emblematic of the power of careful claim drafting to elude whatever current judicial or legislative bars exist.

D. What Is at Stake – International Implications?

International implications pose a final consideration in a comprehensive view of the scope of patentable subject matter. The international context is important not just because of the typical comparative lessons that can be learned, but because the United States has often led the development of patent law worldwide. *Diamond v. Chakrabarty* was the first judicial decision to declare living matter patentable and prompted other countries to modify their patent laws in hopes of emulating the success of the U.S. biotechnology industry.¹⁰⁶ Moreover, the United States has played an active role in global patent laws through its role in development of international agreements. For example, the United States played a leading role in creating the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”),¹⁰⁷ a landmark international agreement, which established the first-ever minimum levels of patent rights on a global scale.¹⁰⁸ After TRIPS, most countries can no longer decide whether or not to grant patents as a matter of purely domestic policy – at least not without fear of being in violation of TRIPS and being subject to either trade sanctions under the World Trade Organization’s (“WTO”) highly effective dispute settlement procedures,¹⁰⁹ or subject to unilateral trade sanctions by the United States.¹¹⁰

106. See, e.g., Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13; see also Commission of the European Communities, *Biotechnology in the Community*, at 34, COM (1983) 672 final/2-Annex (noting the necessity of taking actions “for the promotion of competitiveness in modern biotechnology” in Europe). But see *Harvard College v. Canada*, [2002] 4 S.C.R. 45 (declining to interpret a similarly-worded scope of patentable subject matter to permit patenting of higher life forms in a narrow 5-4 decision).

107. See TRIPS, *supra* note 36. The new patent requirements are binding on all member states of the comprehensive World Trade Organization (“WTO”). Because of the breadth of the WTO membership, TRIPS effectively established near universal requirements of patent rights. See *Understanding the WTO: The Organization, Members and Observers*, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (providing list of 150 member states).

108. See, e.g., SUSAN K. SELL, *PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 1-2* (2003) (describing the impact of a dozen U.S.-based executives in building multilateral support for TRIPS).

109. All agreements under the WTO are enforceable under the Dispute Settlement Understanding, which is generally understood as one of the most effective international methods of ensuring compliance. See, e.g., Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J.

Ironically, if the scope of patentable subject matter is ultimately determined to be overly broad in the United States, it will be in the odd position of having exported requirements that are unsound from a policy perspective. The problem is more than a theoretical one since the United States has been aggressively entering into bilateral and regional agreements with ever-increasing standards of patent rights, including heightened requirements for patentable subject matter.¹¹¹ For example, whereas some countries would prefer not to permit patents on new methods of using pre-existing compositions, the United States has required such patents by decree in certain bilateral agreements.¹¹² Moreover, even if a broad scope of patentable subject matter is sound policy in the United States, the lack of empirical evidence showing that patent policy necessarily results in economic prosperity suggests that applying a “one-size-fits-all” patent standard is questionable. While a complete discussion of the international implications of exporting U.S. patent standards is beyond the scope of this article, international repercussions should nonetheless be considered at all times given the current policy of imposing ever-increasing levels of patent protection.¹¹³ In addition, even for countries not subject to trade pressures, since U.S. patent laws are often

INT’L L. 275, 303-04 (1997); Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of Intellectual Property Lawmaking*, 29 YALE J. INT’L L. 1, 23 (2004).

110. OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2006 TRADE POLICY AGENDA AND 2005 ANNUAL REPORT OF THE PRESIDENT OF THE UNITED STATES ON THE TRADE AGREEMENTS PROGRAM pt. V, at 226 (2006), *available at* http://www.ustr.gov/assets/Document_Library/Reports_Publications/2006/2006_Trade_Policy_Agenda/asset_upload_file922_9075.pdf.

111. For a list of existing and pending trade agreements entered into by the United States, *see* Office of the U.S. Trade Representative: Trade Agreements, http://www.ustr.gov/Trade_Agreements/Section_Index.html.

112. *See, e.g.*, Agreement Between the Government of the United States of America and the Government of the Sultanate of Oman on the Establishment of a Free Trade Area, U.S.-Oman, art. 15.8.1, Jan. 19, 2006, http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Oman_FTA/Final_Text/asset_upload_file715_8809.pdf (“confirm[ing]” that patents are available for known products for treatment of medical conditions).

113. The Office of the U.S. Trade Representative has a strong mandate to continue to negotiate and implement trade agreements with ever-stronger terms for intellectual property laws. *See, e.g.*, Trade Act of 2002, Pub. L. No. 107-210, § 2102(b)(4)(A)(i)(II), 116 Stat. 933, 995-96 (2002) (codified at 19 U.S.C. § 3802(b)(4)(A)(i)(II) (Supp. III 2005)) (noting that a primary objective of the United States regarding trade-related intellectual property rights is to ensure that “provisions of any multilateral or bilateral trade agreement . . . entered into by the United States reflect a standard of protection similar to that found in United States law”). For a further discussion of the patent policy and health issues involved with trade agreements, *see* Cynthia M. Ho, *A New World Order For Addressing Patent Rights and Public Health*, 82 CHL.-KENT L. REV. (forthcoming 2007).

influential for economically similar nations, a heightened consideration of patentable subject matter policy and related implications seems reasonable.

VI. CONCLUSION

Even though *Metabolite* did not provide the immediate satisfaction of a decisive standard of patentable subject matter, the dissenting opinion provides some important lessons for the near future. At a minimum, it highlights some policy considerations for discussion by other institutional actors. Hopefully, *Metabolite* will help promote greater consideration of not only the proper scope of patentable subject matter, but also the overall patent system – in both the domestic and international arenas.

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