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CASE NOTE

WHAT IS PATENTABLE SUBJECT MATTER? THE SUPREME COURT DISMISSED LABCORP V. METABOLITE LABORATORIES, BUT THE ISSUE IS NOT GOING AWAY

SUE ANN MOTA*

INTRODUCTION

Patent law seeks to strike a balance regarding patentable subject matter between overprotection, which can impede the free exchange of ideas, and underprotection, which can lessen the incentive to invent.¹ Thus, what actually constitutes patentable subject matter under the Patent Act² is an important question and a question that the U.S. Supreme Court avoided in June 2006 by dismissing Laboratory Corp. of America Holdings (LabCorp) v. Metabolite Laboratories, Inc.³

Section 101 of the Patent Act regarding patentable subject matter was not argued in the court below so the Court did not decide LabCorp on the patentable subject matter issue.⁴ Future litigants, however, will not likely neglect to argue this so the Court will no doubt face this issue again. This article will examine the LabCorp case and the issue of patentable subject matter, concluding with recommendations for when the issue is raised by subsequent litigants. It seems probable that the Court will again address the subject of statutory subject matter on a case

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3. LabCorp, 126 S. Ct. at 2921.
4. Id. at 2922–29 (Breyer, J., dissenting).
brought properly before it and will strike the balance that will encourage innovation but will not extend protection to processes or business methods that are merely ideas, phenomena of nature, or laws of nature.

I. PATENTABLE SUBJECT MATTER

“The Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”5 Pursuant to this power, Congress passed several patent acts, starting with the Patent Act of 1790, which allowed one who “invented or discovered any useful art, manufacture, engine, machine, or device, or any improvement” not known or used before to petition for a patent.6 The Patent Act of 1793 allowed an inventor to obtain letters patent for “any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement.”7 The Patent Act of 1836 again protected “any art, machine, manufacture, or composition of matter” and provided the foundation of the modern American system.8 The Patent Act of 1870 again revised patent law.9

Under the current patent law, as originally enacted through the Patent Act of 1952, an inventor may obtain a patent for “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement.”10 Congress replaced the term “art” from prior acts with “process.”11

The Court has interpreted patentable subject matter numerous times. An illustrative and nonexhaustive discussion of key cases follows.

In 1854, the Supreme Court considered one of Samuel Morse’s claims regarding his patent on the electromagnetic telegraph in O’Reilly v. Morse.12 Morse’s eighth claim on the patent for use of the motive

5. U.S. CONST. art. I, § 8, cls. 1, 8.
12. O’Reilly v. Morse, 56 U.S. (15 How.) 62 (1853). The Court stated that “[i]t is difficult to make a fair report of this case without writing a book. The arguments of counsel
power of electric current, or electromagnetism, designed for making or printing letters or characters at a distance, was deemed overbroad by the Court. Generally, the use of natural phenomena cannot be patented.

The Court in 1972 in *Gottschalk v. Benson* held that a method of computer programming to convert binary-coded-decimal numbers into pure numbers, which was not limited to any particular art or technology, was not a patentable process. The Court cited *Morse* when reaching the conclusion that a mathematical formula, like a law of nature, may not be patented. Ideas, phenomena of nature, and algorithms are not patentable, as they are the basic tools of scientific and technical work.

The Court in *Parker v. Flook* in 1978, citing both *Morse* and *Gottschalk*, held that a method for updating alarm limits during a catalytic conversion process was not patentable subject matter under 35 U.S.C. § 101. The Court stated that this case turned on the proper construction of § 101. The plain language of this section does not answer the question, and the line between a patentable process and an unpatentable principle is not always clear. The Court concluded that the patent application contained no claim of a patentable invention, as the processes involved in catalytic conversion were well-known, and the application simply provided for new methods of calculating alarm limit values.

would fill a volume by themselves.” *Id.* at 63.

13. *Id.* at 112.
14. *Id.* at 116.
15. *Id.*
18. *Id.* at 73 (finding that further action by Congress on the patentability of computer programs was needed).
19. *Id.* at 67.
21. *Id.* at 584.
22. *Id.* at 590.
23. 35 U.S.C. § 100(b) (2000) (stating that “‘process’ means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material”).
24. *Parker*, 437 U.S. at 595. The Court stated that it must proceed cautiously when extending patent rights into areas wholly unseen by Congress. *Id.* at 596.
The Court again construed § 101 in 1980 in Diamond v. Chakrabarty and held that a live, human-made, genetically engineered bacterium capable of breaking down crude oil was a patentable subject matter. While Congress has the role of defining patentable subject matter in § 101, the courts must construe Congress’s language. Finding no ambiguity in the statute, the Court found that the language covered Chakrabarty’s invention. This does not mean, however, that § 101 has no limits or embraces every discovery. Citing Morse, Gottschalk, and Parker, the Court found that laws of nature, physical phenomena, and abstract ideas were not patentable. Similarly, a new mineral discovered in the earth or a new plant discovered in the wild could not be patented, just as Einstein’s equation and Newton’s law of gravity could not be patented.

The Court interpreted patentable subject matter again in the 1981 case of Diamond v. Diehr, holding that a physical and chemical process of curing synthetic rubber fell within the statutory subject matter requirements, even though a mathematical equation and computer program were used in several steps of the process. While mathematical formulae and laws of nature are outside the statutory subject matter, the subject matter for which a patent was sought in Diehr was defined as a process. Citing Chakrabarty, which had been decided in the prior Term, the Court examined the statute and reached the conclusion that such industrial processes have historically been eligible for patent protection.

Against this backdrop of Supreme Court statutory jurisprudence, the dissent in the Supreme Court’s dismissal of LabCorp reached its conclusion.

26. Id. at 305 (stating that no naturally occurring bacteria had this property).
27. Id. at 315.
28. Id. at 318. Congress could amend § 101 to exclude organisms produced by genetic engineering or draft a statute specifically covering them, but until it does, the Court interprets the existing statute to include such things as patentable subject matter. Id.
29. Id. at 309.
30. Id.
32. Id. at 184.
33. Id. at 185 (citing Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U.S. 63 (1972)).
34. Id. at 184-85.
35. Id. at 184.
36. Lab. Corp. of Am. Holdings (LabCorp) v. Metabolite Labs., Inc., 126 S. Ct. 2921,
II. LabCorp

In the 1980s, three university doctors conducted medical research on vitamin deficiencies and discovered a correlation between high blood levels of homocysteine and deficiencies of folate (folic acid) and cobalamin (vitamin B₁₂). The researchers developed more accurate homocysteine tests using a gas chromatography and mass spectrometry method; they then published their findings and applied for a patent.

Patent number 4,970,658 (the '658 Patent) was issued to the inventors in 1990 for a method for determining total homocysteine levels, including methods for detecting cobalamin and folic acid deficiencies using an assay for total homocysteine levels and methods for distinguishing cobalamin deficiency from folic acid deficiency using an assay for total homocysteine levels in conjunction with an assay for methylmalonic acid. The claim at issue was claim number thirteen, which contained a method for detecting a cobalamin or folate deficiency using 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.”

The inventors’ universities assigned the '658 Patent to University Patents, Inc., which later became Competitive Technologies, Inc. Competitive Technologies then granted a license of the '658 Patent to Metabolite Laboratories. Metabolite sublicensed the patent to Roche Biomedical Laboratories, which is now LabCorp. In 1998, LabCorp
switched to a total homocysteine assay developed by Abbott Laboratories and stopped paying royalties to Metabolite Laboratories.\textsuperscript{44}

Competitive Technologies sued LabCorp for patent infringement, inducing infringement, and contributory infringement; Metabolite Laboratories sued LabCorp for breach of the license agreement.\textsuperscript{45} The district court held a \textit{Markman} hearing\textsuperscript{46} to construe terms of the patent claims. The term “correlating” in claim thirteen was construed to be one of several “discrete, sequential process steps.”\textsuperscript{47} “Correlating,” according to the court, is a verb that means more than a simple existence of a relationship between a high level of homocysteine and deficiency in cobalamin or folate, and instead it indicates the establishment of a mutual or reciprocal relationship.\textsuperscript{48}

A jury found that LabCorp breached its license agreement with Metabolite Laboratories, that LabCorp willfully infringed the ’658 Patent, and that the claims were not invalid.\textsuperscript{49} The jury determined damages of over $3,650,000 for breach of contract and over $1,000,000 for patent infringement.\textsuperscript{50} The district court doubled the infringement damages for willfulness and permanently enjoined LabCorp from using the Abbott test.\textsuperscript{51} LabCorp appealed.\textsuperscript{52}

\textsuperscript{44} Metabolite, 370 F.3d at 1359.
\textsuperscript{45} Brief for Respondents, supra note 40, at 8.
\textsuperscript{47} Joint Appendix, Volume I at 60, Lab. Corp. of Am. Holdings (LabCorp) v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607).
\textsuperscript{48} \textit{Id}.
\textsuperscript{49} Metabolite, 370 F.3d at 1359.
\textsuperscript{50} \textit{Id}.
\textsuperscript{51} \textit{Id}.
\textsuperscript{52} \textit{Id}. 

The Court of Appeals for the Federal Circuit affirmed. On appeal, the court first reviewed the district court’s claim construction. The claim language, itself, governs, using the understanding of those with ordinary skill in the art at the time of the invention. Similarly, the appeals court found substantial evidence to support the jury’s verdict on infringement. LabCorp also argued on appeal that claim thirteen was invalid, but the appeals court rejected this as well. The appeals court also affirmed the jury’s finding that LabCorp breached the license agreement.

LabCorp did not challenge the jury’s willfulness finding, but rather, appealed contending that the district court did not discuss the factors for enhanced damages. While the Federal Circuit has a strong preference


54. Metabolite, 370 F.3d at 1362. In most cases, the best source for determining the context is the specification. The specification confirms that the claim language does not require as part of the method that the elevated level causes some bad symptoms. Id.

55. Id. at 1364.

56. Id. The jury found LabCorp liable for indirect infringement, which requires a finding of direct infringement to support it. Id. Physicians directly infringed by ordering the assays and carrying out the correlating step after receiving the results from LabCorp. Id. The appeals court affirmed the finding of LabCorp’s indirect infringement and did not consider contributory infringement. Id. at 1364–65.

57. Id. at 1368. LabCorp argued that claim thirteen was invalid on the grounds of indefiniteness, lack of a written description and enablement, anticipation, and obviousness. Id. at 1365. Concerning the argument that the correlating step in claim thirteen was indefinite, the appeals court cited 35 U.S.C. § 112 and stated that it was not indefinite. Id. at 1366. Under § 112, there is both the written description and enablement for sufficiency of the specification. Id. Claim thirteen is not obvious under 35 U.S.C. § 103. Id. at 1368. The prior art also did not anticipate claim thirteen under 35 U.S.C. § 102, according to the appeals court. Id. at 1367.

LabCorp also raised the same issues concerning claim eighteen, but the court of appeals vacated the district court’s advisory opinion on that claim due to lack of subject matter jurisdiction. Id. at 1368–69.

58. Id. at 1369–70. The contract interpretation was governed by state law. Id. at 1369.

59. Id. at 1370; see Read v. Portec, Inc., 970 F.2d 816, 826–27 (Fed. Cir. 1992) (listing factors for enhanced damages). The factors to be weighed for enhancing damages include: whether the infringer deliberately copied another’s ideas or design; whether the infringer knew of the patent holder’s patent protection, investigated the issue, and had a good-faith
for the district court to set forth its rationale, its failure to do so is at most harmless error. Finally, while LabCorp argued that the injunction was overbroad, the injunction simply addressed LabCorp’s specific acts, according to the appeals court. Thus, the district court’s decision was affirmed.

The Supreme Court granted a writ of certiorari to consider the third question in the petition:

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.

On June 22, 2006, the writ of certiorari was dismissed by the Court as improvidently granted. The petitioner, LabCorp, argued in its brief to the Court that the answer to the question for which certiorari was granted was “no.” Citing Morse, LabCorp argued that claim thirteen involved no inventive process or device beyond the natural phenomenon it recited.

The respondents, Metabolite Laboratories and Competitive Technologies, argued in their brief to the Court that LabCorp’s contention that claim thirteen recited only natural phenomena was not pleaded in LabCorp’s answer, tried in or decided by the district court, raised in or addressed by the court of appeals, presented in the

60. Metabolite, 370 F.3d at 1371.
61. Id. at 1372.
62. Id. With respect to the court’s decision, Circuit Judge Schall dissented only regarding the interpretation of claim thirteen. Id. at 1372 (Schall, J., dissenting). He believed the majority improperly expanded the scope of claim thirteen and would have remanded for the recalculation of damages. Id. at 1372–74.
64. LabCorp, 126 S. Ct. at 2921.
65. Brief for Petitioner at 2, LabCorp, 126 S. Ct. 2921 (No. 04-607).
66. Id. at 18.
certiorari petition, nor included in the grant of certiorari. According to Metabolite Laboratories, “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.”

These contentions were also raised at oral argument before the Court, and the reasons for dismissing the case became clear by the questions raised by the Justices. Justice Kennedy asked counsel arguing for the petitioner to find something in the opinion of the U.S. Court of Appeals for the Federal Circuit that was wrong. Justice Kennedy did not receive a specific reply to the question. Arguing for the respondents, Miguel Estrada stated that the judgment should be affirmed because LabCorp never asked the trial judge or the Federal Circuit to declare the patent claim invalid under § 101. The Deputy Solicitor General, as amicus curiae supporting petitioner LabCorp, ironically argued that parties should be held responsible for procedural errors. If the § 101 issue had been addressed by the Court, then defendants would have held this defense for a second trip to court as a way to tire the inventor and start over. According to LabCorp’s amicus, “[t]hat’s no way to run a legal system.”

In June 2006, the Court agreed with Metabolite Laboratories and dismissed the case. Justice Breyer, joined by Justices Stevens and Souter, dissented. The writ should not have been dismissed, according to the dissenters, because the Court had authority to decide it, the Court said that it would decide it, the parties and amici briefed it, the question was not difficult, and the medical field and patients would have benefited from a decision.

67. Brief for Respondents, supra note 40, at 10–11.
68. Id. The respondents further argued that if the Court did consider the § 101 issue, then claim thirteen was “drawn to statutory subject matter.” Id. at 12.
69. Transcript of Oral Argument at 7, 18, LabCorp, 126 S. Ct. 2921 (No. 04-607).
70. Id. at 8–10. When asked by Justice Stevens why § 101 was not quoted, LabCorp’s counsel responded that the Court, itself, never cited § 101 in such cases until 1972. Id. at 49–50.
71. Id. at 30. Further, Estrada contended that “you’re being asked to tell [sic] trial court and three courts of appeals judges that they committed reversible error for failing to address a question that nobody ever asked them.” Id. at 32.
72. Brief for the United States as Amicus Curiae, LabCorp, 126 S. Ct. 2921 (No. 04-607).
73. Transcript of Oral Argument, supra note 69, at 46.
74. LabCorp, 126 S. Ct. at 2921.
75. Id. at 2922–23 (Breyer, J., dissenting).
76. Id. at 2921.
The dissent to the dismissal of the writ acknowledged a technical procedural reason as well as a practical reason for not answering the question for which the writ of certiorari was granted. The dissent, however, found stronger reasons for reaching a decision in the case. The dissent believed the procedural objection was tenuous because LabCorp argued the essence of the claim, and there was no practical reason for refusing to decide the case. It was in the public interest, according to the dissent, to clarify the law sooner rather than later.

Despite the fact that the case was dismissed, the dissent turned to the merits. Citing Morse, Flook, Chakrabarty, and Diehr, the dissent stated that laws of nature, natural phenomena, and abstract ideas, such as a mathematical formula or the motive power of electromagnetism, may not be patented. Although non-patentable phenomena of nature are difficult to define, according to the dissent, the correlation between

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77. Id. at 2925 (finding that LabCorp did not refer to § 101 in the lower courts).
78. Id. (suggesting that there is a “benefit” to be derived from the views of the Federal Circuit, which did not consider the issue).
79. Id. at 2925–26. “Of course, further consideration by the Federal Circuit might help us reach a better decision . . . but the thoroughness of the briefing leads me to conclude that the extra time, cost, and uncertainty that further proceedings would engender are not worth the potential benefit.” Id. at 2926.
80. Id. at 2926.
81. Id. at 2922.
82. Id. at 2926–27 (citing F ED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 3 (2003) [hereinafter FTC REPORT], available at http://www.ftc.gov/os/203/10/innovationrpt.pdf). This study was also cited in Justice Kennedy’s concurrence in eBay Inc. v. MercExchange, L.L.C., which was decided the same Term. 126 S. Ct. 1387, 1842 (2006) (Kennedy, J., concurring). The FTC Report examines the proper balance of competition and patent laws; chapter three examines current innovation in selected industries. FTC REPORT, supra. Justice Kennedy’s concurrence in eBay, joined by Justices Breyer, Souter, and Stevens, cited the FTC Report concerning patent non-practicing entities, which obtain and enforce patents but either have no product or do not create or sell a product vulnerable to infringement countersuit. eBay, 126 S. Ct. 1387 (Kennedy, J., concurring) (citing FTC REPORT, supra). See generally Sue Ann Mota, eBay v. MercExchange: Traditional Focu-Factor Test for Injunctive Relief Applies to Patent Cases, According to the Supreme Court, AKRON L. REV. (forthcoming 2007). The non-practicing entities referred to in the FTC Report have also been called “patent trolls,” a term coined by Intel’s former patent chief Peter Detkin. Nicholas Varchaver, Who’s Afraid of Nathan Myhrvold?, FORTUNE, July 10, 2006, at 110.

Justice Breyer cited the FTC Report on the need for strong patent protection in the pharmaceutical and biotechnology industries to spur innovation. LabCorp, 126 S. Ct. at 2926 (Breyer, J., dissenting) (citing FTC REPORT, supra). Justice Breyer also cited a law review article on the issue of the industry-specific nature of innovation. Id. at 2926–27 (citing Dan L. Burke & Mark A. Lemley, Policy Levers in Patent Law, 89 VA. L. REV. 1575, 1577–89 (2003)).
homocysteine and vitamin deficiency constituted a natural phenomenon.\textsuperscript{83}

The dissent to the dismissal of the writ further stated that even if the dissent was wrong on the merits, there would still have been value in deciding the case to avoid uncertainty in the future\textsuperscript{84} and to contribute to the ongoing discussion of whether patent laws keep the necessary careful balance between overprotection and underprotection.\textsuperscript{85}

CONCLUSION

The Supreme Court dismissed the writ in \textit{LabCorp}\textsuperscript{86} in June 2006 as improvidently granted, but the issue of patentable subject matter is not going away. The Court, in this author’s opinion, properly refused to decide an issue not argued or decided below and for which LabCorp could not point to reversible error in the U.S. Court of Appeals for the Federal Circuit.\textsuperscript{87} Anxious to get to the merits, the dissent from the dismissal would have decided the case despite what the dissent acknowledged to be a “tenuous” procedural roadblock.\textsuperscript{88} On the merits, the three dissenters would have found claim thirteen invalid.\textsuperscript{89}

\textsuperscript{83} \textit{LabCorp}, 126 S. Ct. at 2927 (Breyer, J., dissenting). Claim thirteen’s process is merely for the user to obtain test results and think about them. \textit{Id}. Neither the Supreme Court’s decision in \textit{Gottschalk v. Benson}, 409 U.S. 63 (1972), nor the Federal Circuit’s decision in \textit{State Street Bank & Trust v. Signature Financial Group, Inc.}, 149 F.3d 1368 (Fed. Cir. 1998), help the respondents according to the dissent. \textit{LabCorp}, 126 S. Ct. at 2927–28 (Breyer, J., dissenting). The dissent further states that the statement in \textit{State Street Bank} that a process is patentable if it produces a useful, tangible, concrete result, \textit{State St. Bank}, 149 F.3d at 1373, has never been stated by the Court. \textit{LabCorp}, 126 S. Ct. at 2927–28 (Breyer, J., dissenting).

\textsuperscript{84} \textit{LabCorp}, 126 S. Ct. at 2929 (Breyer, J., dissenting).

\textsuperscript{85} \textit{Id}. at 2922. The dissent cited Justice Kennedy’s concurrence in \textit{eBay}, which all of the dissenters to this dismissal joined. \textit{Id}. at 2929 (citing \textit{eBay}, 126 S. Ct. at 1842). The dissent in \textit{LabCorp} also cited Robert Pitofsky, \textit{Unresolved Issues at the Heart of the New Economy}, 16 BERKELEY TECH. L.J. 535 (2001) (stating that competition policies need to adjust to the new economy and intellectual property policy must also be revisited), and Malla Pollack, \textit{The Multiple Unconstitutionality of Business Method Patents: Common Sense, Congressional Consideration, and Constitutional History}, 28 RUTGERS COMPUTER & TECH. L.J. 61 (2002) (concluding that there are four arguments for the unconstitutionality of business method patents).

\textsuperscript{86} \textit{LabCorp}, 126 S. Ct. at 2921.

\textsuperscript{87} Brief for Petitioner, \textit{supra} note 65, at 13.

\textsuperscript{88} Transcript of Oral Argument, \textit{supra} note 69, at 8–10. This author agrees with the Deputy Solicitor General that such a ruling would result in legal counsel holding arguments in reserve to raise later and that is not how the legal system should be run.

\textsuperscript{89} \textit{LabCorp}, 126 S. Ct. at 2922 (Breyer, J., dissenting).
This outcome leaves LabCorp liable for the damages for infringement and breach of contract, although three members of the Court were willing to aid LabCorp. It seems probable that in a future case, parties will properly plead, argue, and, if necessary, appeal the issue of statutory subject matter under § 101. If the Court grants certiorari on the issue, Justices Breyer, Stevens, and Souter have indicated in LabCorp their concern with the statutory subject matter, and they provided the foundation for a future decision. Justice Kennedy, who was joined by those Justices in a concurrence in another patent case in the same Term, eBay Inc. v. MercExchange, L.L.C., also patiently awaits the issue to appear properly before the Court. If these four can get at least one more member of the Court to agree, the Court will address the subject matter issue and restore the proper balance of patent protection to ensure the continued incentive to innovate. Business methods and processes that are mere ideas or phenomena of nature will likely be addressed by this Court, which may draw the line of statutory subject matter more closely around § 101.

90. See id. at 2921 (majority opinion).
91. Id. at 2921–29 (Breyer, J., dissenting).
93. See LabCorp, 126 S. Ct. at 2922–23 (Breyer, J., dissenting).
94. The Court may also carefully address non-practicing entities as well. Based on his concurrence in eBay, Justice Kennedy seems poised to tackle the technological issues in the new economy. eBay, 126 S. Ct. at 1842–43 (Kennedy, J., concurring).