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LABCORP V. METABOLITE: PROVIDENTLY DISMISSED

*Robert Kent**

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I. INTRODUCTION

In 1990, Metabolite's corporate predecessor obtained a patent on methods of measuring certain vitamin deficiencies. In several patent claims, it described its blood test in detail; in another claim, it asserted the exclusive right to any method that involves measuring the level of a particular chemical and "correlating" any elevation with a vitamin deficiency. The Supreme Court initially granted certiorari on the question of whether this claim could be construed so broadly that a doctor's mental correlation of one number with another would constitute infringement. However, after the question was completely briefed — including the filing of twenty-one amicus briefs[1] — and oral arguments had been heard, the Court dismissed certiorari as having been improvidently granted.

In dismissing certiorari, the Court likely made the right decision for patent doctrine as a whole. The underlying facts of the case arguably presented a solid basis for a reexamination of the patentable subject matter doctrine due to the clarity and breadth of the claim language. Furthermore, through amicus briefs, many constituencies were represented in this litigation that are not ordinarily parties to pat-

* Harvard Law School, candidate for J.D., 2007.

1. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2926 (2006) (citing briefs submitted by "the Government, and 20 *amici*").

ent validity disputes. The petitioner, however, had waived its right to challenge the patent under 35 U.S.C. § 101[2] through failure to plead, and the substance of the question on which certiorari was granted is plainly § 101 material.[3]

While it may seem a technicality, this defect plagued all of the trial and appellate pleadings of Laboratory Corporation of America ("LabCorp"), up to and including its petition to the Court, throughout which it strained to present the issue through various 35 U.S.C. § 112[4] rubrics, all of which were unavailing. While it may have been possible for the Court to read a more stringent patentable subject matter standard into the distinctness, written description, or enablement requirements of § 112, such a move would unnecessarily muddle patent law doctrines that have been deliberately separated through statutory revisions and Federal Circuit precedent. If the Court were to reconsider patentable subject matter doctrine, it should base such reconsideration on a conflict involving parties who have fully and directly argued the issue. Though the regulatory deck is stacked against plaintiffs looking to challenge the current § 101 doctrine, the Court's manifest interest in the topic might embolden such challenges in the near future.

II. FACTUAL AND TECHNOLOGICAL BACKGROUND

The core technology of U.S. Patent No. 4,940,658 ("'658 Patent") is an improved test for certain vitamin deficiencies. Abnormally low levels of cobalamin (vitamin B_{12}) and folate (folic acid) can lead to life-threatening neuropsychiatric problems[5] as well as increased risk for cardiovascular disease.[6] The problems caused by such vitamin deficiencies can almost always be easily treated in their early stages by the administration of supplements of the deficient vitamin.[7] It is, therefore, crucial to accurately detect such vitamin deficiencies as early as possible. In the early 1980s, it was the belief of the medical community that deficiencies in cobalamin and folate could only be associated with anemia[8] or assayed directly.[9] Because these tests were

2. *See* 35 U.S.C. § 101 (2000) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.").

3. *See* Petition for a Writ of Certiorari at i, *LabCorp*, 126 S. Ct. 2921 (No. 04-607), 2004 WL 2505526.

4. *See* 35 U.S.C. § 112 (2000) (describing the specification and claims required to obtain a patent).

5. U.S. Patent No. 4,940,658 col.1 ll.32–40 (filed Nov. 20, 1986).

6. Am. Heart Ass'n, Homocysteine, Folic Acid and Cardiovascular Disease, http://www.americanheart.org/presenter.jhtml?identifier=4677 (last visited Nov. 15, 2006).

7. '658 Patent col.1 ll.32–44.

8. *Id.* col.2 ll.7–45.

9. *Id.* col.2 ll.46–55.

not very accurate, a better alternative was needed.[10] Around this time, three doctors associated with University Patents, Inc. ("UPI") discovered that cobalamin and folate deficiencies were correlated with high levels of homocysteine in the blood.[11] They developed improved blood tests for homocysteine and published their findings in 1985.[12] In 1986, they applied for a patent on the new homocysteine tests.[13]

Claim 1 of the '658 Patent describes the homocysteine assay in general terms.[14] Claims 2 through 12 depend on claim 1 and describe several slightly narrower variations on the test.[15] Claim 13, however, describes a method for detecting cobalamin or folate deficiency that merely calls for "assaying a body fluid for an elevated level of total homocysteine" and "correlating an elevated level of total homocysteine . . . with a deficiency of cobalamin or folate."[16] Claim 13 is an independent claim and does not rely on any of the specific tests described in claims 1 through 12.[17]

As originally filed, claim 13 did not include a "correlating" step.[18] The patent examiner rejected the claim because, without such a step, "[t]he claim lack[ed] a positive limitation for correlating to a particular condition," among other reasons.[19] In response to this rejection, UPI added the correlating step to create the version of claim 13 which eventually issued in 1990 as part of the '658 Patent.[20]

III. THE LITIGATION

A. Licensing Transaction and District Court Litigation

After the patent's issuance, Competitive Technologies, Inc. ("CTI") succeeded UPI in ownership of the '658 Patent and licensed it to Metabolite.[21] Metabolite sublicensed the patent to Roche Biomedi-

10. *Id.* col.3 ll.6–47.

11. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2923 (2006).

12. *Id.*; *see also* Paul D. Marcell et al., *Quantitation of Methylmalonic Acid and Other Dicarboxylic Acids in Normal Serum and Urine Using Capillary Gas Chromatography-Mass Spectrometry*, 150 ANALYTICAL BIOCHEMISTRY 58 (1985).

13. '658 Patent, at [22].

14. *Id.* col.41 ll.1–19.

15. *Id.* col.41 ll.20–57.

16. *Id.*

17. *Id.*

18. Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1362 (Fed. Cir. 2004).

19. *Id*. The examiner also objected to the method claim because it did not "recite discrete, sequential process steps," but this objection was dropped without an amendment. *Id*.

20. *Id.*; *see also* '658 Patent, at [45]. The issued version of claim 13 reads: "A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate." '658 Patent col.41 ll.58–65.

21. *LabCorp*, 370 F.3d at 1359.

cal Laboratories, which later became LabCorp.[22] LabCorp used the patented homocysteine assay to perform blood tests for homocysteine levels.[23] However, in 1998, in an effort to cut costs, LabCorp stopped paying royalties on the patent license[24] and switched to a different homocysteine assay developed by Abbott Labs.[25] After LabCorp stopped paying royalties, Metabolite sued in the United States District Court for the District of Colorado for direct, contributory, and induced infringement of the '658 Patent and for breach of the licensing agreement.[26]

At a pretrial claim construction hearing, the district court partially adopted LabCorp's suggested construction of the term "correlating," holding that "correlate" meant "to establish a mutual or reciprocal relation of."[27] The district court granted LabCorp's motion for summary judgment on the direct infringement claim,[28] finding that LabCorp itself had not performed the "correlating" step of claim 13 simply by performing the homocysteine assays.[29] However, the contributory and induced infringement and breach of contract claims were sent to the jury, which found LabCorp liable for both indirect patent infringement and breach of contract and awarded damages to Metabolite on both counts.[30] The district court doubled the portion of the award attributed to patent infringement, since it found the infringement to be willful, and ordered a permanent injunction against LabCorp.[31]

In its answer to Metabolite's patent-related claims, LabCorp raised fourteen affirmative defenses, including two related to the invalidity of the '658 Patent.[32] At no point during the district court proceedings did LabCorp plead that claim 13 of the '658 Patent was

22. *Id.*

23. *Id.*

24. *See* Brief for Respondents in Opposition at 8, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607), 2004 WL 2803464.

25. *LabCorp*, 370 F.3d at 1359.

26. *See* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, No. 99-CV-870, 2001 WL 34778749 (D. Colo. Dec. 3, 2001); *see also* Corrected Brief for Appellant Lab. Corp. of Am. Holdings at 5, *LabCorp.*, 370 F.3d 1354 (Fed. Cir. 2004) (No. 03-1120), 2003 WL 24305314.

27. *LabCorp*, 370 F.3d at 1361. LabCorp further urged the district court to include the requirement that the correlation show "a hematologic abnormality" caused by a cobalamin or folate shortage in order to be covered by the patent, a restriction that the district court declined to read into the claim. *Id*.

28. *See* Corrected Brief for Appellant Lab. Corp. of Am. Holdings, *supra* note 26, at 5.

29. Petition for a Writ of Certiorari, *supra* note 3, at 7.

30. *LabCorp*, 370 F.3d at 1358.

31. *Id*.

32. *See* Joint Appendix Vol. 1 at 65–71, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2005) (No. 04-607), 2005 WL 3939545.

invalid as falling outside of patentable subject matter in violation of 35 U.S.C. § 101.[33]

B. Appeal Before the Federal Circuit

In its appeal before the Federal Circuit, LabCorp contested the indirect infringement, claim construction, and breach of contract rulings.[34] It also argued invalidity based on indefiniteness, lack of written description, and lack of enablement.[35] The crux of LabCorp's argument on indefiniteness was that "[i]f the Court were to uphold this vague claim [13], anyone could obtain a patent on any scientific correlation — that there is a link between fact A and fact B . . . . CTI would improperly gain a monopoly over a basic scientific fact."[36] In support of this argument, LabCorp cited *Diamond v. Diehr*, a landmark Supreme Court decision stating that "laws of nature, natural phenomena, and abstract ideas" are excluded from patent protection by 35 U.S.C. § 101.[37] However, claim definiteness is a requirement of 35 U.S.C. § 112,[38] which LabCorp duly cited in its brief.[39] LabCorp did not cite § 101. Its arguments that the patent lacked proper written description and enablement both centered on that the patent nowhere described how the "correlation" should be performed.[40]

In response to LabCorp's argument on claim definiteness, the Federal Circuit held that the district court's claim construction had "produced a discernable and clear meaning" for the term "correlating" and that the claim was therefore not indefinite.[41] The Federal Circuit also rebuffed LabCorp's written description and enablement arguments.[42] Nowhere did the Federal Circuit cite *Diehr* or 35 U.S.C. § 101, and indeed, it affirmed the district court's judgment in all respects.[43]

Judge Schall filed a partial dissent to the panel opinion, disagreeing with the majority as to the construction of claim 13.[44] The patent's

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33. *See id.*; *see also* Brief for Respondents at 19–24, *LabCorp*, 126 S. Ct. 2921 (No. 04-607), 2006 WL 303905.

34. *See* Corrected Brief for Appellant Lab. Corp. of Am. Holdings, *supra* note 26, at iii.

35. *See id.* at 38–52.

36. *Id.* at 41.

37. Diamond v. Diehr, 450 U.S. 175, 185 (1981).

38. 35 U.S.C. § 112 para. 2 (2000) ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."); *see also* Union Pac. Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 692 (Fed. Cir. 2001) (construing the definiteness requirement to be met when "those skilled in the art would understand the scope of the claim").

39. *See* Corrected Brief for Appellant Lab. Corp. of Am. Holdings, *supra* note 26, at ix.

40. *See id.* at 42–50.

41. Metabolite Labs., Inc., v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1366 (Fed. Cir. 2004).

42. *See id.* at 1366–67.

43. *See id.* at 1358.

44. *Id.* at 1372–74 (Schall, J., dissenting).

literal language claims only "correlating an *elevated* level of total homocysteine . . . with a deficiency of cobalamin or folate."[45] Therefore, Judge Schall reasoned, the claim scope was limited to situations where an elevated homocysteine level was present, and could not be infringed if the homocysteine level was found to be normal.[46] Judge Schall concurred with the panel in all other aspects of the case.[47]

C. Supreme Court Proceedings

LabCorp submitted a three-question petition for certiorari to the Supreme Court on November 3, 2004.[48] Question one was directed to the Federal Circuit's standard for finding willful inducement of infringement, and question two was directed to claim construction.[49] Question three was:

> Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to "correlat[e]" test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.[50]

Nowhere did the petition for certiorari refer to 35 U.S.C. § 101. The argument section in support of question three closely tracked the mode of argument used in LabCorp's Federal Circuit briefs. It urged that claim 13 must be indistinct because, as written, the claim encompassed the use of any assay method and a simple correlation of the assay results and argued that "[s]uch a vague claim cannot be valid; for if it could be, parties could claim patent monopolies over basic scientific facts."[51] LabCorp's arguments regarding written description and enablement were also similar to those pressed below.[52]

Chief Justice Roberts recused himself from consideration of the petition, and the remainder of the court granted a limited writ directed to question three only.[53] The Court then took the unusual step of inviting comments from the Solicitor General on the question of whether "the ['658] patent [is] invalid because one cannot patent 'laws of na-

45. '658 Patent col.41 ll.63–65 (emphasis added).
46. *See LabCorp*, 370 F.3d at 1373–74 (Schall, J., dissenting).
47. *Id.* at 1372.
48. Petition for a Writ of Certiorari, *supra* note 3.
49. *Id.* at i.
50. *Id*.
51. *Id.* at 23.
52. *See id.* at 24–25.
53. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 601 (2005) (mem.) (granting certiorari).

ture, natural phenomena, and abstract ideas.'"[54] This request seemed obviously directed at the question of patentable subject matter under 35 U.S.C. § 101, the core of the *Diehr* case quoted in the Court's request,[55] even though § 101 was not addressed by the petition for certiorari. The Solicitor General responded with an amicus curiae brief stating that "[t]he record is not sufficiently developed" to address the § 101 question because the petitioner had not addressed it below.[56] Twenty other amicus briefs were submitted to the Court.[57]

The Supreme Court heard oral arguments for the case on March 21, 2006.[58] At oral argument, LabCorp again focused on the § 112 doctrines of definiteness, enablement, and written description,[59] but five justices asked LabCorp's counsel about patentable subject matter and two of them mentioned § 101 specifically.[60] The Justices went on to discuss patentable subject matter almost exclusively with the representative from the Department of Justice, who was forced to concede that "there appears to be prima facie evidence of invalidity"[61] under *Gottschalk v. Benson*, a case which held that bare mathematical algorithms are not patentable on subject matter grounds and formed the basis for the *Diehr* holding. [62]

On June 22, 2006, the Court issued a single-sentence per curiam order dismissing certiorari as having been improvidently granted.[63] The Court issued no opinion in support of the dismissal, but Justice Breyer entered a dissenting opinion that was joined by Justices Souter and Stevens.[64] Justice Breyer argued that the Court could legitimately reach the § 101 patentability issue, that claim 13 of the '658 Patent should be invalidated on that basis, and that a ruling either way on the § 101 issue would better serve the public interest than no ruling at all.

After setting forth the facts of the case and relevant § 101 decisions, Justice Breyer argued that the Court could have defensibly reached the § 101 issue. He wrote that LabCorp's district court and Federal Circuit filings had raised "the essence" of the § 101 claim by

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54. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 543 U.S. 1185 (2005) (mem.) (quoting Diamond v. Diehr, 450 U.S. 175, 185 (1981)) (inviting the Acting Solicitor General to file a brief in this case).

55. *Diehr*, 450 U.S. at 177.

56. Brief for the United States as Amicus Curiae at 9, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 2072283.

57. *LabCorp*, 126 S. Ct. 2921.

58. Transcript of Oral Argument, *LabCorp*, 126 S. Ct. 2921 (No. 04-607), *available at* http://www.supremecourtus.gov/oral_arguments/argument_transcripts/04-607.pdf.

59. *See id.* at 3–20.

60. *See id.* at 5 (Justice Ginsburg, mentioning § 101); *id.* at 9 (Justice Kennedy); *id.* at 10 (Justice Souter); *id.* at 10–11 (Justice Breyer, mentioning *Diehr*); *id.* at 14 (Justice Scalia, mentioning § 101).

61. *Id.* at 23.

62. Gottschalk v. Benson, 409 U.S. 63, 72–73 (1972); *see also infra* Part IV.B.

63. *LabCorp*, 126 S. Ct. 2921.

64. *Id*. at 2921 (Breyer, J., dissenting).

suggesting that the asserted vagueness of the patent terms amounted to an improper monopoly over a scientific fact.[65] He further argued that, in seeking the opinion of the Solicitor General on whether the § 101 question should be addressed and continuing to hear the case after being advised against it, the Court "necessarily consider[ed] and reject[ed] that contention as a basis for denying review."[66]

On the merits of the § 101 question, Justice Breyer argued that claim 13 should be invalidated. After conceding that the line between natural phenomena and patentable processes might not always be clear, he wrote that "this case is not at the boundary."[67] This is true, according to Justice Breyer, because the mere existence of the correlation is, in itself, a natural fact and the steps added in Metabolite's process are not enough to grant patent protection.[68] Breyer then fired a shot across the Federal Circuit's bow, dismissing Metabolite's reliance on *State Street Bank*[69] by saying that "if taken literally, the [holding] would cover instances where this Court has held to the contrary."[70]

If Justice Breyer was correct on the merits, he maintained, then the public interest would naturally be better served by invalidating the patent than by letting it stand.[71] But even if he were incorrect, a Supreme Court holding would, in his view, be useful in reducing the legal uncertainty clouding process patents of this nature, which would be of interest both to patentees and to doctors who might be infringing.[72] A holding on the merits would also "help Congress determine whether legislation is needed."[73]

IV. ANALYSIS

Although Justice Breyer made a compelling argument that the public interest would be served by a Supreme Court ruling on patentable subject matter, patent doctrine was best served by dismissing certiorari. The underlying facts may have lent themselves to a clear ruling on the breadth of § 101, but LabCorp's early waiver of this issue forced it to reframe this argument in terms of § 112 provisions. It might be possible to approach patentable subject matter in this way, but to do so would recall the muddled patent doctrine of the nine-

65. *Id.* at 2925.

66. *Id.* at 2926 (quoting United States v. Williams, 504 U.S. 36, 40 (1992)) (internal quotation marks omitted).

67. *Id.* at 2927.

68. *Id.* at 2927–28.

69. State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368 (Fed. Cir. 1998)*; see also infra* Part IV.B.

70. *LabCorp*, 126 S. Ct. at 2928 (Breyer, J., dissenting).

71. *Id.*

72. *See id.* at 2929.

73. *Id.*

teenth century. The patent code has undergone revolutionary changes since that time, not least of which was the separation of concepts such as patentable subject matter and written description into distinct statutory sections in order to facilitate the development of sophisticated case law for each individual section.

Arguably, the Supreme Court should revisit the doctrine of patentable subject matter, especially since it has not commented on the issue since the Federal Circuit was created. It should, however, do so in a way that will not threaten the conceptual divisions that have characterized sophisticated reasoning about patents in recent decades. Deciding this case would have forced the Court to make a muddled decision because LabCorp's procedural problems prevented it from making a strong argument addressing patentable subject matter.

A. Evolution and Conceptual Separation of Patent Law

The doctrines of patentable subject matter, enablement, and written description have not always been clearly distinct. In fact, all of these doctrines were applied in an overlapping manner by the Supreme Court in a famous early patent decision, *O'Reilly v. Morse*.[74] In that case, Samuel Morse brought an infringement suit under his patent for the telegraph. Claims 1 through 7 described Morse's particular telegraph device in some detail,[75] but claim 8 was problematically broad:

> I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electromagnetism, however developed for marking or printing intelligible characters, signs, or letters, at any distances, being a new application of that power of which I claim to be the first inventor or discoverer.[76]

The patent statute in effect at the time distinctly enumerated a "process" as patentable subject matter, from which a mere "idea" or "law of nature" should be distinguished. Nonetheless, the Court struck claim 8 as being too broad: "the patent embraces nothing more than the improvement *described* and *claimed* as new . . . . Is there any reason why the inventor's patent should cover broader ground?"[77] In

74. O'Reilly v. Morse, 56 U.S. 62 (1854).
75. *See id.* at 85–87.
76. *Id.* at 112.
77. *Id.* at 119 (emphases added).

other words, Morse's patent extended only to the bounds of his specification and not to any ideas or principles outside of those bounds — an analysis that evokes, in the contemporary context, written description and claim definiteness requirements. However, it is now commonly taught that "*Morse* provides the foundation for the prohibition on patenting natural principles,"[78] an issue that today seems more properly cognizable under patentable subject matter, not written description or claim definiteness.

The section of the Patent Act of 1836 cited by the court in *Morse* reveals the likely cause of the confusion. That section contains, in a single paragraph, language directed to patentable subject matter, the written description and enablement requirements, claim definiteness, and anticipation, among other issues. [79]

The clarity of the Patent Act was improved significantly in 1870 with major structural changes to both the copyright and patent statutes of the time.[80] The contents of the old section 6 were divided into many different provisions of the new code; in relevant part, section 24 enumerated patentable subject matter as well as anticipation and statutory bars,[81] and section 26 described the written description, enablement, best mode, and claim definiteness requirements that would later be found in 35 U.S.C. § 112.[82] The Patent Act of 1952 further subdivided the statute, separating the old section 24 concerns into the new 35 U.S.C. § 101 (patentable subject matter) and 35 U.S.C. § 102 (anticipation and statutory bars) and adding paragraph lettering to 35 U.S.C. § 102 to make that section even more granular. [83]

Cases analyzing patents under the 1952 Act are careful to treat the various statutory sections as conceptually separate. In *Diamond v. Diehr*, the Court granted certiorari on the question of whether an industrial process involving computer calculations at several of its steps was patentable subject matter under § 101.[84] Nevertheless, the Patent Commissioner argued that the respondent's invention lacked novelty, on the premise that § 101 required novelty because it contained the word "new."[85] The Supreme Court quickly dispatched this argument, citing the legislative history highlighting the separation of novelty into

78. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 85 (3d ed. 2002); *see also id.* at 78–84; DONALD S. CHISUM, CHISUM ON PATENTS § 1.03(2)(b) (2006).

79. *See Morse*, 56 U.S. at 118–19; Patent Act of 1836, ch. 357, § 6, 5 Stat. 117, 119 (1836), *reprinted in* CHISUM, *supra* note 78, app. 11.

80. *See* Patent Act of 1870, ch. 230, 16 Stat. 198 (1870), *reprinted in* CHISUM, *supra* note 78, app.14.

81. *See id.* § 24, at 201; *cf.* 35 U.S.C. §§ 101, 102 (2000).

82. *See* Patent Act of 1870, ch. 230, § 26, 16 Stat. 198, 201; *cf.* 35 U.S.C. § 112.

83. *See* Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792 (1952).

84. Diamond v. Diehr, 450 U.S. 175, 177 (1981).

85. *Id.* at 189.

its own section of the code.[86] The Court went on to hint at one justification for considering the different provisions as analytically distinct: they could be treated at discrete stages in the litigation, facilitating more efficient conflict resolution if only one provision was genuinely at issue at any given procedural stage. [87]

Just as *Diehr* recognized the analytic utility of considering subject matter issues separately from novelty and nonobviousness issues, so too was the Court right to keep subject matter problems distinct from § 112 matters in the present case. While a reexamination of § 101 case law might be proper,[88] the doctrines surrounding § 112 are relatively well-settled, or at least not currently subject to the same degree of controversy as the patentable subject matter doctrine.[89] In any case, the underlying purposes of the various § 112 requirements are clear and distinct and would not benefit from the addition of subject matter considerations to their analyses.

The written description requirement specifies that a patent must include "a written description of the invention, and of the manner and process of making and using it."[90] The purpose of the requirement is to "guard against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation,"[91] and the fulfillment of this requirement is generally at issue when an accused infringer contends that a claim amendment is not supported by the specification.[92]

The enablement requirement further demands that the written description must be set forth "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same."[93] The purpose of this requirement is to ensure that the public receives something in exchange for the patentee's exclusive right: the knowledge of how to make and use the

86. *Id.* at 189–91.

87. *Id.* at 191 ("In this case, it may later be determined that the respondents' process is not deserving of patent protection because it fails to satisfy the statutory conditions of novelty under § 102 or nonobviousness under § 103.").

88. *See infra* Part IV.B.

89. There is admittedly some irony in holding out the § 112 doctrines as a model of Federal Circuit jurisprudence, as written description and enablement are perhaps the most often confused doctrines in patent law. *See, e.g.*, Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991) ("There appears to be some confusion in our decisions concerning the extent to which the 'written description' requirement is separate and distinct from the enablement requirement.").

90. 35 U.S.C. § 112 (2000).

91. *Vas-Cath*, 935 F.2d at 1561 (Fed. Cir. 1991) (quoting Rengo Co. v. Molins Mach. Co., 657 F.2d 535, 551 (3d Cir. 1981)).

92. *See* MERGES & DUFFY, *supra* note 78, at 262.

93. 35 U.S.C. § 112.

patented item.[94] The requirement is met when the description includes enough information that one skilled in the art can make or use the invention "without undue experimentation."[95]

The claim definiteness requirement derives from the second paragraph of § 112, stating that claims must "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention."[96] Courts have long held that this requirement is met when the claims "reasonably apprise those skilled in the [relevant] art" of the invention's scope.[97] This standard highlights the primary purpose of the requirement, which is to put other parties on notice of the precise boundaries of the invention claimed in a patent.[98]

B. Current Confusions in the Patentable Subject Matter Doctrine

If a well-pleaded case were brought before the Supreme Court, the state of the patentable subject matter doctrine would be ripe for review. When the Court last addressed the doctrine, it applied the well-established bar on patenting abstract ideas to hold essentially that software algorithms, standing alone, could not be patented, but that industrial processes involving some computational steps would not be barred for this reason.[99] When the Federal Circuit began analyzing patentable subject matter, this distinction seemed to disappear, ushering in a deluge of software patent applications and grants.[100] The Federal Circuit doctrine arguably conflicts with Supreme Court precedent, rendering review by the higher court appropriate.

The principle that laws of nature and abstract ideas could not be patented began with *Morse*[101] and was well-entrenched when the Supreme Court applied this doctrine in the software context in *Gottschalk v. Benson*.[102] The patent in question in *Benson* concerned a process of converting numerical data from one format to another in a general-purpose computer; no new computer circuitry was included in the patent, only a computer program.[103] The Court invalidated the

94. *See* Michael Delmas Plimier, *Genentech, Inc. v. Novo Nordisk & University of California v. Eli Lilly and Co.*, 13 BERKELEY TECH. L. J. 149, 149–50 (1998).

95. Amgen v. Chugai Pharm. Co*.,* 927 F.2d 1200, 1212 (Fed. Cir. 1991).

96. 35 U.S.C. § 112.

97. Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624 (Fed. Cir. 1985) (quoting Georgia-Pacific Corp. v. U.S. Plywood Corp., 258 F.2d 124, 136 (2d Cir. 1958)).

98. CHISUM, *supra* note 78, at § 8.03.

99. *See* Diamond v. Diehr, 450 U.S. 175 (1981); Parker v. Flook, 437 U.S. 584 (1978).

100. In 1998 (the year of the *State Street Bank* decision), the "data processing" technology classes (classes 700 through 707) all saw a spike in patent grants, and most have seen a continuing increase since then. *See* U.S. Patent and Trademark Office, Patent Counts by Class by Year, http://www.uspto.gov/go/taf/cbcby.htm (last visited Nov. 15, 2006).

101. *See supra* Part IV.A.

102. Gottschalk v. Benson, 409 U.S. 63 (1972).

103. *Id.* at 64.

patent on the basis that the mathematical formula at issue had "no substantial practical application" outside of digital computing,[104] and therefore, to allow the patent to stand would "in practical effect . . . be a patent on the algorithm itself."[105] This analysis relied on the Court's identification of the algorithm itself, apart from any particular application of it, with an abstract mathematical concept akin to a law of nature,[106] which therefore could not be patented.

Benson established that algorithms themselves could not be patented, but it left unclear to what extent an otherwise patentable process could be "infected" by inclusion of an algorithm and thereby become unpatentable. The Court began to address this question in *Parker v. Flook*, which applied *Benson* to a patent concerning the automatic recalculation of "alarm limits" for conditions such as temperature and pressure in engines.[107] The patentee in that case argued that his process was not an abstract algorithm because it had "post-solution" applications such as alteration of the alarm limit and thus the engine operation.[108] The Court pointed out that the algorithm in *Benson* would also have had post-solution applications, and that, for this reason, allowing the activities specified in the *Flook* patent to convert the algorithm into patentable subject matter would "exalt[] form over substance."[109]

The Court further refined its approach to algorithm patentability in *Diamond v. Diehr*,[110] which concerned a patent on a rubber curing process that included computer calculations at several steps to constantly monitor the mold temperature and end the curing process at the appropriate time.[111] The Court came to the conclusion that an otherwise patentable industrial process would not be excluded from patentable subject matter simply because it involved some algorithmic, computational steps.[112] In reaching this conclusion, the Court made much of the fact that the computations were part of a process that would certainly be patentable in their absence[113] and that the algorithm was used in the "transformation of an article . . . to a different state or thing."[114] Far from overruling *Benson* or *Flook*, the Court viewed this result as entirely consistent with the earlier cases, and

104. *Id.* at 71.
105. *Id.* at 72.
106. *See id.* at 67.
107. Parker v. Flook, 437 U.S. 584, 585 (1978).
108. *Id.* at 590.
109. *Id.*
110. Diamond v. Diehr, 450 U.S. 175 (1981).
111. *See id.* at 177–78.
112. *See id.* at 187.
113. *See id.* at 184, 187–88.
114. *Id.* at 184 (quoting *Benson,* 409 U.S. at 70 (1972)) (internal quotation marks omitted).

indeed, founded in the *Benson* reasoning.[115] After *Diehr*, it seemed clear that, without overruling its previous precedent on algorithm patentability, the Court had established the patentability of physical processes involving some computational steps on the basis that they involved the transformation of some article into a different state or thing — which the Patent Act was plainly meant to cover.

Diehr was the last Supreme Court holding on patentable subject matter regarding algorithms or software. It was not the end of the evolution of that doctrine, however, as the Court of Appeals for the Federal Circuit was created to hear all patent appeals barely a year later.[116] Accordingly, the Federal Circuit assumed the task of interpreting patentability doctrines. The Federal Circuit showed its tolerance for computer algorithm patents in *In re Alappat*, concerning a technique for reducing the jaggedness of computer displays.[117] The Federal Circuit reasoned that, because the pertinent calculations led to an improved display, a computer using the improved technique amounted to "a specific machine to produce a useful, concrete, and tangible result."[118] The dissent pointed out that the inventor regarded the algorithm itself to be "the 'substance' of the claimed invention" and thus no machine parts were meaningfully included in the patent.[119] Rather, the patent was directed solely to software.

The Federal Circuit dropped any pretense that an invention must constitute a "specific machine" in order to be patentable in its famous decision in *State Street Bank*. State Street Bank challenged the validity of a patent held by Signature Financial on a method of combining several mutual funds into a single investment portfolio to reduce administrative costs.[120] The Federal Circuit interpreted § 101 to allow a patent on this system since "the transformation of data, representing discrete dollar amounts . . . constitutes a practical application of a mathematical algorithm . . . because it produces a 'useful, concrete and tangible result.'"[121] Though it was true that the portfolio management system would need to use a computer because of the complexity of the calculations involved,[122] the Federal Circuit found it to be "of little relevance"[123] whether the claims were drafted to machines or processes.

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115. *See id.* at 191–93.

116. *See* Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982).

117. *In re* Alappat, 33 F.3d 1526 (Fed. Cir. 1994) (en banc).

118. *Id*. at 1544.

119. *Id.* at 1563.

120. State St. Bank & Trust Co. v. Signature Fin. Group, Inc.,149 F.3d 1368, 1371 (Fed. Cir. 1998).

121. *Id*. at 1373 (quoting *In re Alappat*, 33 F.3d at 1544).

122. *Id.* at 1371.

123. *Id.* at 1372.

State Street Bank raises several questions. First, is the holding in *State Street Bank* truly compatible with those of *Benson*, *Flook*, and *Diehr*, all of which are binding precedent on the Federal Circuit and none of which have been overruled? In some ways, the temperature and pressure alarm limits in the *Flook* application seem at least as concrete and tangible as the transient dollar amounts calculated in *State Street Bank*. How would the Federal Circuit treat the *Flook* patent if it were litigated today? Second, in directing that an algorithm application will be patentable if the application is *useful*, concrete, and tangible, has the Federal Circuit improperly imported utility considerations into the patentable subject matter doctrine?[124] The Supreme Court has very clearly held that patentable subject matter under § 101 is to be analyzed separately from concerns, such as utility, that are addressed in other statutory sections.[125]

C. LabCorp*: The Wrong Vehicle for § 101 Review*

Although it would be appropriate for the Supreme Court to revisit the patentable subject matter doctrine in a future case, and there are compelling arguments that it could have done so in this case, ultimately *LabCorp* would have made a poor vehicle for review. LabCorp waived the § 101 issue in the district court, although it never expressly conceded this point, and the waiver had a substantial effect on its pleadings. It caused LabCorp to frame every issue in § 112 language, which resulted in a muddled argument that ran contrary to the clear statutory divisions of the modern patent code. In its answer to the substance of Metabolite's patent allegations in the trial court, LabCorp said nothing about patentable subject matter, despite the requirement in the Federal Rules of Civil Procedure that affirmative defenses be set forth in a responsive pleading.[126] The Supreme Court recently reiterated that "under the Civil Rules, a defense is lost if it is not included in the answer or amended answer."[127] Metabolite specifically noted the waiver of this issue in its Federal Circuit brief,[128] and LabCorp did not contest the issue in any of its replies. Instead, LabCorp consistently raised § 112 provisions and cases in arguing that Metabolite had improperly obtained a monopoly over a basic scientific fact.

Justice Breyer suggested that this mere "technical procedural" problem could easily be overcome in order to facilitate reaching a

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124. *Cf.* MERGES & DUFFY, *supra* note 78, at 155–56 ("In other words, the [USPTO] Guidelines collapse patentable subject matter into the utility requirement.").

125. *See supra* Part IV.A.

126. Fed. R. Civ. Proc. 8(c); *see also supra* Part III.A.

127. Kontrick v. Ryan, 540 U.S. 443, 459 (2004).

128. *See* Brief for Appellees at 71, Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (Fed Cir. 2004) (No. 03-1120), 2003 WL 24305315.

decision on the merits,[129] and there were several aspects of this case that would have made it a good opportunity to develop § 101 doctrine. The underlying facts were clear and straightforward, and several constituencies that do not typically participate in patent litigation were represented via amicus curiae briefs. However, Labcorp's waiver of the patentable subject matter issue undermined its ability to make the strongest case for a change to that doctrine. In our adversarial litigation system, it would be unfortunate to base Supreme Court precedent on anything less than a robustly argued case squarely on point, and even the inclusion of a uniquely diverse constituency could not overcome this flaw.

The inclusion of a broad constituency was admittedly an important aspect of *LabCorp* because, even when a patent is litigated, there are obstacles to meaningful review of its patentability. In any given case, the alleged infringer will marshal every available weapon to prevail in court, including invalidity arguments. But in many cases it might be strategic to instead prevail on the basis of non-infringement — then, the alleged infringer has received what amounts to a free license to a valid patent and, accordingly, is at a competitive advantage. Furthermore, patent litigation tends to take place between large intellectual-property-owning corporations.[130] Any argument that a defendant makes against the patentability of its opponent's inventions could later be asserted against that defendant's own patents. Indeed, the groups submitting amicus briefs in *LabCorp* indicated this strategic preference in favor of non-infringement. Among the amicus briefs, three of the five in support of Metabolite (and thus in support of the current subject matter standard) were submitted by the American Intellectual Property Law Association, the Federal Circuit Bar Association, and the Boston Patent Law Association.[131] Critically, LabCorp might have availed itself of any of those same organizations during different litigation. The advantage of addressing § 101 in this case would have been that other perspectives were also represented in the eight amicus briefs submitted in favor of reexamining the subject matter standard, including briefs from the American Medical Associa-

129. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2925 (2006) (Breyer, J., dissenting).

130. The economics of patent litigation keep all but the richest corporations out of the game. For large-stakes litigation, with over $25 million in controversy, each side typically spends up to $4.5 million on litigation. ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS 68 (2004). Even in smaller cases, with under $1 million at stake, each side typically spends between $300,000 and $750,000. *Id.*

131. *See* Amicus Curiae Brief of Am. Intellectual Prop. Law Ass'n in Support of Respondent, *LabCorp*, 126 S.Ct 2921 (No. 04-607), 2006 WL 303907; Amicus Curiae Brief of the Fed. Cir. Bar Ass'n in Support of Respondents, *LabCorp*, 126 S.Ct 2921 (No. 04-607), 2006 WL 303906; Brief of Boston Patent Law Ass'n in Support of Respondents, *LabCorp*, 126 S.Ct 2921 (No. 04-607), 2006 WL 303909.

tion, the AARP, and the American Heart Association,[132] who are not typically parties to patent litigation but clearly have a stake in the patentability of medical diagnostic techniques.

However, to decide this case, the Court would have had to issue either an essentially sua sponte ruling on the § 101 issues based on weak arguments from the parties, or a ruling that approached patentable subject matter through § 112 provisions. The former would have been a less than optimal use of the adversarial judicial system and would have done a disservice to an important patent law doctrine. The latter would have gone too far in blending patent doctrines that have been meticulously differentiated through statutory reforms and case law over the last 150 years.

V. CONCLUSION

It may seem disappointing that the Court avoided ruling on *LabCorp* after the case was fully briefed — by both parties, twenty amici, and the United States government — and argued before a Court clearly interested in the substance of the case. Despite the extensive preparation and the inclusion of such diverse amici, however, the issue of patentable subject matter under § 101 was not adequately argued, and the Court was wise to avoid blending the concerns of disparate statutory sections.

The silver lining for LabCorp's amici, if not for LabCorp itself, may be that the Supreme Court has finally manifested an interest in reviewing the Federal Circuit's interpretation of § 101. The Court granted certiorari on a question directed, however circuitously, to patentable subject matter, expressly asked for the Solicitor General's advice on the § 101 issue, and spent a good deal of time during oral argument discussing patentable subject matter. Furthermore, three Justices (out of eight) would have decided the case on the merits and invalidated the patent. Perhaps, then, *LabCorp* will soon inspire an accused patent infringer to bring a better-crafted patentable subject matter attack on the patent in question.

132. *See* Brief for the Am. Med. Ass'n et al. as Amici Curiae in Support of Petitioner, *LabCorp*, 126 S.Ct 2921 (No. 04-607), 2005 WL 3597812; Brief Amicus Curiae of AARP in Support of Petitioner, *LabCorp*, 126 S.Ct 2921 (No. 04-607), 2005 WL 3597809; Brief of the Am. Heart Ass'n. as Amicus Curiae in Support of Petitioner, *LabCorp*, 126 S.Ct 2921 (No. 04-607), 2005 WL 3561169.