

Recent Development

***Metabolite Labs* and Patentable Subject Matter: A Review of Federal Circuit and PTO Precedent was Narrowly Averted, but for How Long?**

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One cannot patent “laws of nature, natural phenomena, and abstract ideas.”¹ On October 31, 2005, the United States Supreme Court granted certiorari, in the case of *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, to determine whether claim thirteen of Competitive Technologies, Inc.’s (CTI) U.S. Patent No. 4,940,658 (“the ‘658 patent”) was invalid because it recited nothing more than a natural phenomenon.² On June 22, 2006, after hearing oral arguments, the Court dismissed the writ as “improvidently granted”.³ Despite ultimate dismissal of the writ, the question remains whether the Federal Circuit and the United States Patent and Trademark Office’s (PTO) interpretation of Supreme Court precedent and 35 U.S.C. § 101 on subject matter patentability will be reexamined and possibly limited or altered by the Supreme Court in the near future.

PATENTABLE SUBJECT MATTER

Section 101 identifies what subject matter may be entitled

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1. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).
2. *Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 126 S. Ct. 543 (2005) (granting the petition for writ of certiorari).
3. *Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 126 S. Ct. 2921, 2921 (2006) (dismissing the writ of certiorari as improvidently granted).

to a patent.⁴ In *Diamond v. Diehr*, the leading case on patentable subject matter and the last case on this topic the Supreme Court has decided, the Court recognized that “Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’”⁵ The Court, however, also reiterated its long-standing determination that despite the broad scope of patentable subject matter “laws of nature, natural phenomena, and abstract ideas” are not patentable, but rather free for all to use.⁶ Therefore, as is often noted, Newton could not have patented the law of gravity and Einstein could not have patented $E = mc^2$.⁷ Drawing clear distinctions between what constitutes permissible subject matter considered broadly, as Congress intended, and what constitutes impermissible subject matter because the claim involves a natural law, natural phenomenon, or abstract idea has proven challenging for the Court.⁸ Despite the difficulty

4. 35 U.S.C.A. § 101 (2006). “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.” *Id.*

5. *Diehr*, 450 U.S. at 182 (quoting S. Rep. No. 82-1979, at 5 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2399).

6. *Id.* at 185.

7. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

8. *O’Reilly v. Morse*, 56 U.S. 62 (1853) (holding Morse’s claim eight invalid as too broad because it attempted to claim any machinery that used electromagnetism for making or printing intelligible characters, signs, or letters, at any distance. The claim was too broad because it precluded others from using any process or machine, including ones that Morse had not invented or described, to accomplish the result. Further, the claim was too broad because Morse had not discovered that the form of machinery did not matter because electric current would *always* print at a distance). *C.f.* *Dolbear v. Am. Bell Tel. Co.*, 126 U.S. 1 (1887) (finding claim five valid and distinguishing it from claim eight in *Morse* because Bell only claimed the transmission of vocal sounds by means of undulations in continuous current. Further, the Court noted that at the time, for all anyone knew, that change in current was required for the current to serve as a medium for speech transmission. Because Bell was the first to discover how to change the current, and he claimed changing the current in the way described in the claim to transmit sound, he was entitled to the patent.). *Gottschalk v. Benson*, 409 U.S. 63 (1972) (holding a method for converting binary coded decimal numerals into pure binary numerals unpatentable subject matter because it was merely a mathematical formula without practical application except in connection with a digital computer.). *Parker v. Flook*, 437 U.S. 584 (1978) (holding the claim at issue, which recited a new method for calculating alarm limit values, invalid because the only novel thing in the method was the mathematical formula or algorithm, and was therefore not patentable subject matter). *Diehr*, 450 U.S.

the Court has had in determining when to apply the judicial exceptions to § 101, the standard for meeting the requirement of § 101 is quite low, and the issue is rarely litigated.⁹

THE CASE

Researchers at University Patents Inc. (UPI) discovered a relationship between an elevated level of total homocysteine and a deficiency in B vitamins, specifically B12 (cobalamin) and folic acid (folate).¹⁰ Serious health risks, including vascular disease, cognitive dysfunction, birth defects and cancer, can result from a deficiency in these vitamins.¹¹ If, however, the deficiency is caught early enough, vitamin supplements can easily treat the deficiency.¹² UPI inventors developed a method of assaying for total homocysteine along with other metabolites that could indicate which vitamin may be deficient.¹³ In general, the '658 patent was directed to the developed diagnostic method for determining whether deficiencies in B12 and folic acid existed.¹⁴ Independent claim thirteen, the sole claim at issue in the case, recited:

“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.”¹⁵

CTI, UPI's successor, acquired the rights to the patent before it issued.¹⁶ CTI granted a non-exclusive license to the patent to Metabolite Laboratories, Inc. (Metabolite).¹⁷ Under

at 175-76 (holding that while a mathematical formula by itself is not patentable subject matter, if a claim containing a mathematical formula implements it in a process that when considered as a whole performs a useful function, the claim is then patentable. Further the Court found that it was irrelevant if each step in a process was itself unpatentable, if the process taken as a whole constituted patentable subject matter).

9. PRATISING LAW INSTITUTE, *Overview of Patent Litigation*, 798 PLI/PAT 281, 325 (2004).

10. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1358 (Fed. Cir. 2004).

11. *Id.*

12. *Id.*

13. *Id.*

14. U.S. Patent No. 4,940,658 (filed Nov. 20, 1986).

15. *Metabolite*, 370 F.3d at 1358–59.

16. Brief for Petitioner at 6, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3543099.

17. *Id.*

the licensing agreement Metabolite was permitted to sublicense the patent to other parties, which Metabolite did.¹⁸ Metabolite sublicensed the patent to Laboratory Corporation of America Holdings (LabCorp, formerly Roche Biomedical Laboratories).¹⁹ In 1992, LabCorp began using the assaying method covered by the '658 patent and paying the required royalties to Metabolite.²⁰ In 1998, however, LabCorp also began using a method developed by Abbott Laboratories (Abbott) for testing for homocysteine alone (without the other metabolites), which was useful in diagnosing heart disease.²¹ LabCorp continued to pay royalties to Metabolite whenever it used the assaying method claimed in the '658 patent, but LabCorp did not pay royalties when it used the Abbott test.²²

In May 1999, CTI, the patent holder, sued LabCorp for infringement, inducing infringement and contributory infringement of claim thirteen.²³ Metabolite sued LabCorp for breach of the licensing agreement,²⁴ arguing that the agreement only permitted LabCorp to use other methods for assaying for homocysteine levels if the other tests did not infringe *any* valid claim of the '658 patent.²⁵ The district court granted LabCorp's summary judgment motion on direct infringement because LabCorp itself did not perform the correlating step required by claim thirteen.²⁶ The contributory infringement charge remained, however, because LabCorp allegedly induced physicians to infringe claim thirteen whenever physicians viewed total homocysteine test results and concluded the patient either did or did not have a vitamin deficiency.²⁷ The jury found claim thirteen valid and also

18. *Id.*

19. *Id.* at 7. LabCorp is a large clinical reference laboratory that conducts tests ordered by health care professionals used in diagnosing and treating patients. *Id.* at 6.

20. *Id.* at 7.

21. *Metabolite*, 370 F.3d at 1359; *see also* Brief for Petitioner, *supra* note 16, at 8. The correlation between elevated levels of homocysteine and an elevated risk of heart disease had been known since 1969 or earlier. *Id.*

22. Brief for Petitioner, *supra* note 16, at 9.

23. Brief for Respondents at 8, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2006 WL 303905.

24. *Id.* at 8.

25. Brief for Petitioner, *supra* note 16, at 7.

26. *Id.*

27. *See Metabolite*, 370 F.3d at 1364.

found that LabCorp willfully induced infringement of the claim.²⁸ LabCorp was ordered to pay nearly \$5.7 million in damages.²⁹ LabCorp's motion for judgment as a matter of law was denied and the district court enjoined LabCorp from using the Abbott test.³⁰ LabCorp appealed.³¹ On appeal, the Federal Circuit affirmed the district court's ruling.³²

LabCorp petitioned the Supreme Court of the United States for writ of certiorari.³³ The Court granted cert only as to question three of Petitioner's Petition for Writ of Certiorari:³⁴

Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to 'correlate' 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.³⁵

After the parties filed their briefs, the Court invited the Solicitor General, on behalf of the government, to express its views on whether the patent was invalid because one cannot patent laws of nature, natural phenomena, and abstract ideas.³⁶

After hearing oral arguments on the case from the parties, as well as the Solicitor General, the Court dismissed the writ as improvidently granted on June 22, 2006.³⁷ Justice Breyer, joined by Justices Stevens and Souter, wrote a vehement dissent.³⁸

THE DISMISSAL

While the Court did not provide a reason for dismissing the writ as improvidently granted, it is likely that the Court was

28. *Id.* at 1359.

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.* at 1372.

33. Petition for Writ of Certiorari at *i, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2004 WL 2505526.

34. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. at 543.

35. Petition for a Writ of Certiorari, *supra* note 33, at *i.

36. Brief for United States as Amicus Curiae, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3533248.

37. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. at 2921.

38. *Id.*

heavily influenced by the arguments made in the briefs of the Respondent (collectively Metabolite), and the Solicitor General, which strenuously requested that the Court dismiss the writ on procedural grounds.³⁹ They argued that the writ was granted to decide a question which was never addressed in either of the lower courts, namely § 101 subject matter patentability.⁴⁰ LabCorp never specifically cited § 101 in its briefs or oral arguments in the lower courts, nor did it ever state that claim thirteen covered unpatentable subject matter.⁴¹ The jury was not instructed to reach a verdict on whether claim thirteen recited patentable subject matter.⁴² The Federal Circuit did not consider whether claim thirteen recited patentable subject matter.⁴³ In Metabolite's Supreme Court brief it recited a panoply of authority from the Federal Rules of Civil Procedure, to the Patent Act, to the Supreme Court's own precedent in order to demonstrate the inappropriateness of reviewing an issue which was not pleaded, argued, or considered in the lower courts.⁴⁴

The Solicitor General, in its requested brief, also vigorously argued that the validity of claim thirteen under § 101 should not be considered by the Court because the issue was "neither pressed nor passed upon below."⁴⁵ Specifically, the Solicitor General argued that failure to bring up a § 101 defense potentially limited the district court's claim construction of claim thirteen so as to make the record incomplete for purposes of assessing whether claim thirteen recited patentable subject

39. Transcript of Oral Argument, *Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 126 S. Ct. 2921 (2006) (No. 04-607), *available at* http://www.supremecourtus.gov/oral_arguments/argument_transcripts/04-607.pdf. The Supreme Court spent a significant amount of time at oral arguments trying to determine whether Petitioner's § 112 arguments, which were pled and argued in the lower courts, legitimately incorporated the issue before the Court, namely whether claim thirteen recited patentable subject matter. *Id.*

40. Brief for the United States as Amicus Curiae, *supra* note 36; Brief for the Respondents, *supra* note 23, at 19. LabCorp argued, as affirmative defenses, that claim thirteen was invalid, unenforceable and/or void for lacking novelty, nonobviousness, definiteness, lacking an adequate written description and being insufficiently enabling. *Id.* at 8.

41. *Id.*

42. *Id.* at 8–9.

43. *Id.* at 10.

44. Brief for Respondents, *supra* note 23, at 20–26.

45. Brief for the United States as Amicus Curiae, *supra* note 40, at 5.

matter.⁴⁶

Further, the Solicitor General noted that the Federal Circuit has interpreted the Court's holding in *Diehr* to substantially limit its holding in *Flook*, so that what would have been unpatentable subject matter under *Flook* because all that was recited was a mathematical formula, is now patentable under *Diehr* as long as the claim containing the formula implements a process that taken as a whole performs a useful function. The Solicitor General stated that the PTO had issued "numerous" patents based on the Federal Circuit's interpretation of those cases.⁴⁷ The Solicitor General cautioned that overturning the PTO's approach to patentable subject matter could "call into question a substantial number of patent claims and undermine the settled expectations of numerous participants in technology-based industries."⁴⁸ The Solicitor General argued that this was an inappropriate case for "examining such a fundamentally important issue," because the issue was not litigated below, and consequently the record was incomplete on the issue.⁴⁹

THE DISSENT

Justice Breyer, joined by Justices Stevens and Souter, dissented from the Court's dismissal of the writ.⁵⁰ Justice Breyer would have found claim thirteen invalid because it does not claim patentable subject matter, but rather attempts to claim a natural phenomenon, which is impermissible.⁵¹ He argued that the Court should have decided the case because the Court had the authority to decide the issue, which was not "unusually difficult", and 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

46. *Id.* at 9–16. The district court, had it known § 101 was at issue, may have required that the parties provide more information so it could determine whether or not the claim term "assay" could mean that assaying bodily fluid *necessarily* involves the transformation of matter from one state to a different state, and if "assay" could be so construed, that would weigh heavily in favor of claim thirteen reciting patentable subject matter under the Federal Circuit's interpretation of *Benson*, 409 U.S. 63, and *Diehr*, 450 U.S. 175.

47. *Id.* at 13–14.

48. *Id.* at 14.

49. *Id.* at 14–15.

50. *Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 126 S. Ct. at 2921.

51. *Id.* at 2927.

authoritative answer.”⁵²

The dissent agreed with LabCorp’s argument that LabCorp did present the issue of subject matter to the Federal Circuit, because subject matter was necessarily incorporated in its § 112 invalidity arguments.⁵³ Because the heart of the argument was presented below he found the procedural reason for dismissing the result “tenuous.”⁵⁴ Justice Breyer acknowledged that the Federal Circuit’s specific review of the issue would have been helpful but that the case should have been decided anyway because it was fully briefed by the parties and many amici, and the record was thorough and complete.⁵⁵ Finally, he argued that he believed the “important considerations of the public interest – including that of clarifying the law in this area sooner rather than later” was a significant reason to decide the issue and not dismiss the writ.⁵⁶

While admitting that the law surrounding the exceptions to patentable subject matter “is not easy to define,” he concluded that the process described in claim thirteen was an easy case, and did not require a complex interpretation of the natural phenomenon line of cases.⁵⁷ Clearly, he argued, the correlation between elevated homocysteine levels and a deficiency in one or both of the B vitamins (folic acid and B12) was a natural phenomenon.⁵⁸ He rejected Metabolite’s argument that it patented a process that included transforming matter from one state to another, because claim thirteen did not claim the assaying step.⁵⁹ In fact, claim thirteen claimed *any* method of assaying for total homocysteine levels, whether that method was patented, unpatented, or not yet invented.⁶⁰ Claim thirteen did not cover the method for testing itself, thus, the fact that the method for testing might transform bodily fluid from one state to another cannot save claim thirteen from

52. *Id.* at 2922.

53. *Id.* at 2925–6.

54. *Id.* at 2925.

55. *Id.* at 2926.

56. *Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 126 S. Ct. at 2926.

57. *Id.* at 2926–27.

58. *Id.* at 2927.

59. *Id.*

60. *Id.*

reciting unpatentable subject matter.⁶¹

Justice Breyer also rejected Metabolite's argument that claim thirteen recited a useful, concrete and tangible result, which the Federal Circuit held adequate to save a claim from subject matter invalidity in *State Street Bank & Trust v. Signature Financial Group, Inc.*⁶² Significantly, Justice Breyer acknowledged that the case stood for that proposition, but that "this Court has never made such a statement and, if taken literally, the statement would cover instances where this Court has held the contrary."⁶³

Even so, assuming *arguendo* that claim thirteen met general requirements for process patentability, Justice Breyer stated that the claim would still be invalid because it is simply nothing more than "the natural law at issue in the abstract patent language of a 'process.'"⁶⁴ Justice Breyer concluded the dissent by stating that if he was correct in finding claim thirteen unpatentable, then the medical community and patients are threatened by permitting the claim to stand.⁶⁵ He continued to state that if he was not correct that claim thirteen is unpatentable, then the medical community would still be aided by clarifying confusion in this area of law, "diminish[ing] legal uncertainty in the area" that could potentially affect a significant number of existing patents, and providing Congress with the knowledge needed to determine whether further legislation would be required.⁶⁶

SOME OF THE CONCERNS

The Supreme Court's grant of certiorari to consider subject matter patentability in this case had some anxious and others optimistic. For instance in the amicus brief filed by the Federal Circuit Bar Association (FCBA) in support of respondents, FCBA argued that according to the Federal Circuit few cases fall into the judicially created exceptions to § 101 (laws of nature, natural phenomena, and abstract ideas) largely because those exceptions have been difficult to apply to specific

61. *Lab. Corp. of Am. Holdings v. Metabolite Labs*, 126 S. Ct. at 2927–8.

62. *Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 126 S. Ct. at 2928 (citing to *State St. Bank & Trust v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998)).

63. *Id.*

64. *Id.*

65. *Id.* at 2928–9.

66. *Id.* at 2929.

cases.⁶⁷ The FCBA argued that “history shows that judicial exceptions to § 101 tend to create more problems than they solve.⁶⁸ If “Congress deemed it necessary, it could amend § 101, but it has left the scope of § 101 unaltered notwithstanding a debate that is far older than the statute itself.”⁶⁹ The FCBA believes the Federal Circuit’s holding in this case should stand, and further that the Federal Circuit’s precedent in this area should not be disturbed.⁷⁰

Conversely, in an amicus brief filed by Financial Services Industry (FSI) in support of reversal, FSI argued that the Federal Circuit had “effectively nullified” the Supreme Court’s “reservation of abstract ideas to the public domain – and attracted significant academic criticism in the process.”⁷¹ FSI argued that clearly unpatentable claims under a “common-sense” reading of the Court’s holding in *Diehr* could now be easily patented under the Federal Circuit’s current interpretation of § 101.⁷² FSI argued that allowing claim thirteen to stand would mean “the free-for-all in the patenting of abstract business methods would continue and undoubtedly hinder innovation and efficiency in the financial services industry for decades.”⁷³ More generally, it warned that the Court’s decision in this case could have “significant economic repercussions.”⁷⁴

American Clinical Laboratory Association (ACLA) argued in its amicus brief in support of petitioner that if the Court found claim thirteen valid it would mean “any researcher who discovers a chemical association in the human body will be able to claim a monopoly over any future diagnostic test based on that association.”⁷⁵ ACLA stated that this prohibition would

67. Amicus Curiae Brief of the Federal Circuit Bar Association in Support of Respondents at 15, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2006 WL 303906.

68. *Id.*

69. *Id.*

70. *Id.*

71. Brief of Financial Services Industry Amici Curiae in Support of Reversal at 9, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3543097.

72. *Id.*

73. *Id.* at 1.

74. *Id.*

75. Brief of the American Clinical Laboratory Association as Amicus Curiae in Support of Petitioner at 1-2, *Lab. Corp. of Am. Holdings v.*

either entirely preclude further innovation and improvements in diagnostic tests that are based upon a patented correlation, or that further innovation and improvement, if they do occur at all, will only occur at a “higher price and on a limited basis.” It continued that “either way, laboratories’ ability to provide new lifesaving tests and patients’ access to those tests would suffer.”⁷⁶

On the other hand, Perlegen Sciences, Inc.⁷⁷ (Perlegen) and Mohr, Davidow Ventures⁷⁸ (MDV) argued in their amicus brief in support of respondents that economic and scientific considerations argue in favor of upholding the Federal Circuit and PTO’s current subject matter interpretation, and that claim thirteen should be held to recite patentable subject matter.⁷⁹ It argued that a holding that claim thirteen did not recite patentable subject matter “could significantly diminish Perlegen’s incentive to engage in research and to develop diagnostic methods for determining the patient population for which particular drugs are safe and effective.”⁸⁰ MDV argued that it provided funding to diagnostic start-ups knowing that processes such as those recited in claim thirteen “have been consistently granted patent protection over an extended period of time.”⁸¹ MDV stated that if claim thirteen, and those like it, is found invalid it “could limit the economic viability of companies seeking to research and develop diagnostic methods like that identified in Claim 13”⁸² MDV concluded that venture capitalists “would have significantly diminished incentives to invest in the very companies that are on the forefront of research and development in personalized medicine

Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607), 2005 WL 3543098.

76. *Id.* at 2.

77. Perlegen is “a leader in personalized medicine, working to provide safe and effective medications to patients worldwide.” Brief for Amici Curiae Perlegen Sciences, Inc., and Mohr Davidow Ventures in Support of Respondents at 1, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (No. 04-607), 2006 WL 303908.

78. MVD is a “leading Silicon Valley-based venture capital firm specializing in predictive diagnostics and personalized medicine.” *Id.* at 2. MDV works with academic institutions that invent and commercialize novel technologies and business models helping to build start-ups. *Id.*

79. Brief for Amici Curiae Perlegen Sciences, Inc., and Mohr, Davidow Ventures in Support of Respondents, *supra* note 77, at 1.

80. *Id.* at 1–2.

81. *Id.*

82. Brief for Amici Curiae Perlegen Sciences, Inc., and Mohr, Davidow Ventures in Support of Respondents, *supra* note 77, at 2.

and diagnostics.”⁸³

CONCLUSION

There are many concerns about the doctrine of patentable subject matter, with the above concerns only presenting a sample of the potential issues that will face the Court should it decide to take up this issue in the near future. The mere fact that the Court granted cert on this issue after a quarter century of silence on the matter would seem to indicate the Court believes the issue needs to be altered, or at least clarified. The fervent dissent of three Justices, the only ones to discuss the issue on its merits, is also telling of where the Court may go with the issue.

The evolution of science and technology has forced the Court to look at subject matter anew in the past. More than twenty-five years have passed since the doctrine has been revisited by the Court, and we find ourselves facing dramatically different scientific and technological advancements, which could not have been appreciated when *Diehr* was decided. Regardless of what the Court decides when it takes the matter up again, all will benefit from more certainty in the area of what constitutes patentable subject matter.

83. *Id.* at 3.