Vanderbilt Journal of Entertainment & Technology Law

Volume 10
Issue 1 *Issue 1 - Fall 2007*

Article 2

2007

Patently Wrong: The U.S. Supreme Court Punts in the Case of LabCorp v. Metabolite

John G. New

Patently Wrong: The U.S. Supreme Court Punts in the Case of *LabCorp v. Metabolite*

John G. New[*]

ABSTRACT

In June 2006, after having granted certiorari and hearing oral arguments, the United States Supreme Court dismissed the case of Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc. *as having been improvidently granted a writ of certiorari. Dissenting from this extraordinary step was Justice Breyer, joined by Justices Stevens and Souter. At issue in the case was a patent, the owners of which claimed that a physician's use of any test to infer vitamin deficiency by raised blood serum levels of the chemical homocysteine infringed the patent. This Article argues that the Supreme Court was itself improvident in dismissing the case because the patent at issue claims ownership of a basic scientific fact, a "phenomenon of nature," in violation of 35 U.S.C. § 101. Moreover, the lower courts' construction of the term "correlate" was erroneous in that it was not determined according to the knowledge of biomedical investigators and practitioners skilled in that art. Finally, sound public policy arguments caution against granting such a patent. By failing to act, the Supreme Court essentially affirmed the U.S. Court of Appeals for the Federal Circuit's holding that a patent claiming a scientific fact can be valid, and that practicing physicians who merely think about that fact are liable for patent infringement.*

---

[*] J.D., 2007, Chicago-Kent College of Law. Professor of Biology, Loyola University Chicago; Adjunct Professor of Cell Biology, Neurobiology and Anatomy, Stritch School of Medicine, Loyola University Chicago. The author gratefully acknowledges the constructive criticisms of Professor Lori Andrews and Professor Bradley Hulbert.

TABLE OF CONTENTS

In March of 2006, the U.S. Supreme Court heard oral arguments in the case of *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*[1] This case stirred more than the usual interest that a patent case, even one heard in such an exalted venue, can generally expect to receive. That interest was manifested by an unusually large number of amicus briefs submitted to the Court.[2] But on June 22, the Court dismissed the case as having been improvidently granted a writ of certiorari, which very rarely happens once oral arguments have been heard. Justice Breyer, joined by Justices Stevens and Souter, vigorously dissented from the Court's dismissal of the case.[3]

---

1. 546 U.S. 975, 975 (2005) (per curium) (granting petition for writ of certiorari), *cert. dismissed per curiam*, 126 S. Ct. 2921 (2006) (mem.); *see* Andrew Pollack, *U.S. Court Backs Off Patent Case*, INT'L HERALD TRIB., June 24, 2006, at 15.

2. A total of twenty-one amicus briefs were filed by a wide variety of parties, including the Intellectual Property Owners Association, I.B.M., the Public Patent Foundation, AARP, and the American Heart Association. *See* Pollack, *supra* note 1, at 15; *see, e.g.*, Brief of American Intellectual Property Law Ass'n as Amicus Curiae Supporting Respondent, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607) (mem.), 2006 WL 303907; Brief of American Heart Ass'n as Amicus Curiae Supporting Petitioner, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607) (mem.), 2005 WL 3561169.

3. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2921 (2006) (No. 04-607) (mem.) (Breyer, J., dissenting).

The controversy at the heart of this case is the question of how far the rights protected by a patent may be extended to cover scientific knowledge. Having tacitly affirmed the decision of the United States Court of Appeals for the Federal Circuit,[4] the Supreme Court has radically altered the boundaries prohibiting the patenting of "phenomena of nature." Such a decision will likely have negative and far-ranging consequences for the practice of medicine, essentially rendering the mental processes forming the basis of a diagnostic decision patentable and subject to licensing fees. Such patents will act to the detriment of the practice of medicine in this country at the level of doctor–patient interactions, as well as on the development and advancement of medical research.

Specifically, the language of claim 13 of the patent in dispute, U.S. Patent No. 4,940,658 (the '658 patent), claims in part the correlation of elevated levels of the amino acid homocysteine with decreased levels of folic acid (folate) and vitamin B_{12} (also known as cobalamin).[5] The language of the claim also embraces *any* assay[6] used to detect homocysteine, including those anticipated in the prior art and those not yet developed, if it is used to infer folate or vitamin B_{12} deficiency in a patient.[7] In 2001, the U.S. District Court for the District of Colorado held that this patent was indirectly infringed[8] when Laboratory Corporation of America Holdings (LabCorp), a medical testing laboratory, employed a noninfringing homocysteine assay that allowed physicians to diagnose vitamin deficiency in patients with elevated homocysteine levels.[9]

Metabolite Laboratories, Inc. (Metabolite), the holder of the '658 patent, argued successfully that any homocysteine-only test that permitted physicians to make such an inference between the levels of homocysteine and vitamin deficiency infringed its patent.[10] Moreover, Metabolite also argued successfully that any publication that

---

4. *See generally* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (Fed. Cir. 2004) (affirming a finding of willful infringement of a patent claiming a method for detecting vitamin deficiencies).

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

6. An "assay" is a "laboratory test performed to measure the activity of a substance against a certain target" and "must maintain a certain minimal level of biological activity to be considered for animal or clinical testing." LARRY L. MAI ET AL., THE CAMBRIDGE DICTIONARY OF HUMAN BIOLOGY AND EVOLUTION 41 (2005).

7. '658 Patent col.6 ll.1-4.

8. Metabolite Labs., Inc., 370 F.3d at 1358; *see* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, No. 99-CV-870, 2001 WL 34778749, at *1 (D. Colo. Dec. 3, 2001).

9. Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1365 (Fed. Cir. 2004).

10. *See id.* at 1371-72.

described the relationship between homocysteine levels and vitamin deficiency could be viewed by the courts as an inducement to infringe.[11] Thus, the holders of the '658 patent claim nothing less than the mental process of inferring the relationship between elevated homocysteine levels in the body and decreased levels of folate and vitamin B_{12}. The district court's finding of indirect infringement was subsequently upheld on appeal by the U.S. Court of Appeals for the Federal Circuit.[12]

This Article will examine the history of the *Metabolite* case as well as the arguments made before the Court. Part I will explain the scientific principles underlying the patent in dispute and their relationship to the prior art. Part II will follow the history of the *Metabolite* case in the lower courts and review the arguments made to the Supreme Court in Petitioner's and Respondent's briefs. Part III will argue that, rather than dismiss the case, the Court should have vacated the decision of the U.S. Court of Appeals for the Federal Circuit and held claim 13 of the '658 patent invalid. First, this part will demonstrate that the Federal Circuit relied upon an erroneous construction of the claim language by the district court in its *Markman* hearing, specifically with respect to the construction of the word "correlate."[13] Second, this part will contend, as argued by Justice Breyer's dissent, that the Court could have properly considered the patentability of the subject matter of claim 13 under the Constitution and under 35 U.S.C. § 101. Third, this part will contend that the language of the disputed claim 13 is so overly broad as to render it invalid under 35 U.S.C. § 102. Finally, this part will discuss the potentially catastrophic implications for the practice of medicine in this country following the Supreme Court's failure to overturn the Federal Circuit's decision.

I. THE SCIENCE AND THE '658 PATENT

The *Metabolite* case involves the use of an assay for the amino acid homocysteine as an indicator of potentially deleterious vitamin deficiency in the human body. It may therefore be useful to the reader to briefly review some of the biological concepts that form the basis of the '658 patent and lie at the heart of the dispute in this case.

---

11. *See id.* at 1365 ("[A] reasonable jury could find intent to induce infringement because LabCorp's articles state that elevated total homocysteine correlates to cobalamin/folate deficiency.").

12. *Id.* at 1358.

13. *See id.* at 1361-64 (reviewing and affirming the district court's construction of "correlate" to mean "establish[ing] a mutual or reciprocal relationship between").

Proteins form an important constituent of the chemical makeup of the human body. They may act as structural elements of body tissues, elements in the body's defense mechanisms, chemical signals between various cells in the body, transport elements moving compounds in and out of cells, and as enzymes that catalyze the chemical reactions forming the basis of metabolism.[14] Proteins consist of one or more long, folded chains of chemicals known as amino acids.[15] There are over 300 naturally occurring amino acids present in biological systems; however, only twenty amino acids form all of the proteins found in the body.[16] Chemical interactions resulting in the formation of chemical bonds between the amino acids forming the long polypeptide chains give a protein its distinctive three-dimensional configuration.[17] Such a configuration is essential to the function of proteins; when the bonds formed by the interactions of amino acids are disrupted, the protein's configuration breaks down (denatures) and loses its functional capacity.[18] Of the twenty amino acids used in the synthesis of proteins, eight must be obtained from the diet (the essential amino acids); the remainder can be synthesized in the body from precursor organic molecules.[19]

Vitamins are organic molecules that are vital to the health of the individual, but which are required in only minute amounts.[20] Although they have a variety of functions, one of the most important is to act as coenzymes in concert with protein enzymes to catalyze important metabolic chemical reactions.[21] Two water-soluble vitamins, folate and B_{12}, are of relevance to the *Metabolite* case. Both

---

14. DAVID L. NELSON & MICHAEL M. COX, LEHNINGER PRINCIPLES OF BIOCHEMISTRY 113-14 (3d ed. 2000). Catalysis by enzymes lowers the energy of activation (E_a) of chemical reactions, accelerating the rate at which chemical reactions proceed from reactant to product. *Id.* at 248.

15. *See generally id.* at 152-53 (summarizing the structures of various proteins). Amino acids are so called because they possess at least one basic amino group ($-NH_3$) and one carboxylic acid group (-COOH) attached to a variable group (R), which gives the amino acid its identity. *Id.* Condensation reactions between amino and carboxyl groups of amino acids result in the formation of a highly stable covalent peptide bond, enabling the formation of chains of amino acids of considerable length. *Id.* at 116. Condensation reactions between amino and carboxyl groups of amino acids result in the formation of a highly-stable covalent peptide bond, enabling the formation of chains of amino acids of considerable length. *Id.* at 126.

16. ROGER K. MURRAY ET AL., HARPER'S ILLUSTRATED BIOCHEMISTRY 14 (26th ed. 2003).

17. *See* NELSON & COX, *supra* note 14, at 199.

18. *Id.*

19. *See* MURRAY ET AL., *supra* note 16, at 237.

20. NELSON & COX, *supra* note 14, at app. G-14.

21. *Id.*

of these vitamins act as coenzymes in the synthesis of amino acids and nucleic acids.[22] Deficiencies of folate and B_{12} can result in a number of serious health problems, including anemia, cardiovascular disease, neural tube-related birth defects such as spina bifida, and possibly neuropsychiatric disorders.[23]

Homocysteine is an amino acid occurring in the human body, but it is not one of the twenty amino acids employed in the structure of proteins.[24] Rather, it is an intermediate compound in the synthesis of several of those amino acids occurring in proteins.[25] Although a detailed discussion of the biochemical interactions between folate, B_{12}, and homocysteine is beyond the scope of this paper, both folate and B_{12} are essential cofactors in the conversion of homocysteine to methionine, one of the amino acids used in proteins, and is itself important in the synthesis of other amino acids.[26]

The roles of folate and B_{12} in the synthesis of methionine have been well known for over thirty years. Although the precise mechanisms of how they cause the symptoms presented in cases of folate- or B_{12}-deficiencies are less clear, the metabolic pathways employing folate and B_{12} in the conversion of homocysteine to the amino acid methionine were well understood long before the '658 patent was filed in 1985.[27] Furthermore, elevated homocysteine levels were demonstrated to induce arteriosclerosis in primates prior to the application date of the '658 patent; studies of this sort relied in part on

---

22. *See* MURRAY ET AL., *supra* note 16, at 51.

23. *See id.* at 492, 494; NELSON & COX, *supra* note 14, at 611.

24. N.V. BHAGAVAN, MEDICAL BIOCHEMISTRY 354 (4th ed. 2002).

25. *See id.* at 354-55.

26. *Id.* at 355. Briefly, both B_{12} and folate (in its active form, tetrahydrofolate) are important in the synthesis of the amino acid methionine. NELSON & COX, *supra* note 14, at 642. Homocysteine acts as methyl group donor, forming methionine from 5-methyl-tetrahydrofolate via the activity of the enzyme 5-methyl-tetrahydrofolate-homocysteine transferase. *Id.* at 831. Methylcobalimin, a form of vitamin B_{12}, also plays an important intermediate role in the methylation of 5-methyl-tetrahydrofolate by homocysteine to form methionine. *Id.* at 642. Methionine in turn plays a vital metabolic role as a methyl group donor to a number of other biologically important compounds, including creatine, phosphatidylcholine, epinephrine, cyclic fatty acids, and others. COLLEEN SMITH ET AL., MARK'S BASIC MEDICAL BIOCHEMISTRY: A CLINICAL APPROACH 732 (2d ed. 2005). However, methionine can only be synthesized via the limited reactions described above; thus, methionine synthesis via homocysteine forms a metabolic "choke point" in the formation of a number of important compounds. *See id.* ("This is the only reaction in which methyl-tetrahydrofolate can donate the methyl group. If . . . B_{12} or [folate] levels are insufficient, homocysteine will accumulate.").

27. *See, e.g.*, Jeffrey M. Gawthorne & Richard M. Smith, *Folic Acid Metabolism in Vitamin B_{12}-Deficient Sheep: Effects of Injected Methionine on Methotrexate Transport and the Activity of Enzymes Associated with Folate Metabolism in Liver*, 142 BIOCHEMISTRY J. 119, 125 (1974) (Gr. Brit.) (concluding that a B_{12} deficiency resulted in an impaired transformation of homocysteine to methionine).

well-established assays of serum homocysteine levels.[28] However, the relationship between elevated homocysteine levels in body fluids and tissues and the etiology of diseases associated with folate and B_{12} deficiency are complex and still not entirely understood.[29]

The '658 patent, entitled *Assay for sulfhydryl amino acids and methods for detecting and distinguishing cobalamin and folic acid deficiency*, was filed with the U.S. Patent Office on November 20, 1986.[30] In general, the patent claims a method for determining levels of homocysteine in samples of body fluids from warm-blooded animals. Specifically, the patent claims a method for detecting vitamin B_{12} (cobalamin) and folate deficiencies that employ a specific assay for total homocysteine levels, and a method for distinguishing deficiencies of B_{12} from folate using an assay for total homocysteine in combination with an assay for methylmalonic acid.[31] The inventors named in the patent, Robert H. Allen, Sally P. Stabler, and John Lindenbaum, assigned the patent rights to University Patents, Inc. (UPI) of Westport, Connecticut.[32] The U.S. Patent and Trademarks Office granted the patent on July 10, 1990.[33]

On its face, much of the '658 patent is an unobjectionable method patent describing an assay for total homocysteine levels in animal tissue. It satisfies the established requirements of novelty, utility, and nonobviousness,[34] and it also fulfills the enablement, written description, and best mode requirements of 35 U.S.C. § 112.[35] However, claim 13 stands out as something different—the eye of the

28. *See, e.g.*, Laurence A. Harker et al., *Homocysteine-Induced Arteriosclerosis: The Role of Endothelial Cell Injury and Platelet Response in its Genesis*, 58 J. CLINICAL INVESTIGATION 731, 733 (1976) (citing Darrel H. Spackman et al., *Automatic Recording Apparatus for Use in the Chromatography of Amino Acids*, 30 ANALYTICAL CHEMISTRY 1190, 1190-99 (1958)) (quantifying homocysteine by "column chromatography using a modified procedure of Spackman et al.").

29. *See* COUNCIL ON SCIENTIFIC AFFAIRS, AM. MED. ASS'N, FOLIC ACID RELATIONSHIPS TO SPINAL CLOSURE BIRTH DEFECTS AND ADULT VASCULAR DISEASE (1995), *available at* http://www.ama-assn.org/ama/pub/category/13679.html (recommending increased funding for "basic research, epidemiologic studies, and clinical trials to assess expeditiously the . . . metabolic interrelationships of folate, vitamin B6 and vitamin B12").

30. U.S. Patent No. 4,940,658 at 22 (filed Nov. 20, 1986).

31. *Id.* at [57]. "[T]otal homocysteine" includes homocysteine in "both free and complexed forms." *Id.* col.7 ll.26-29.

32. *Id.* at [75], [73].

33. *Id.* at [45].

34. *See* 35 U.S.C. §§ 101-03 (2000 & Supp. 2003-2004).

35. *See id.* § 112 (2000).

storm swirling about the *Metabolite* case.[36] Claim 13 claims in its entirety:

> 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 homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.[37]

In short, claim 13 claims the use of any method for measuring homocysteine levels (not just those covered in the patent's other claims) and the use of those results to infer cobalamin or folate deficiencies from elevated levels of homocysteine.

UPI's successor to the rights to the '658 patent, Competitive Technologies, Inc., licensed the patent to Metabolite, which in turn sublicensed the patent to Roche Biomedical Laboratories (later LabCorp). LabCorp performed the homocysteine assays under the license.[38] However, in 1998, LabCorp abandoned the total homocysteine assay licensed from Metabolite in favor of one developed by Abbott Laboratories.[39] Consequently, LabCorp ceased paying royalties to Metabolite when it discontinued use of the '658 patent assay.[40] Metabolite brought suit against LabCorp in the U.S. District Court for the District of Colorado alleging breach of contract, patent infringement, and contributory infringement of the '658 patent. [41]

II. *METABOLITE*: THE LITIGATION HISTORY

A. The Decisions in the District and Federal Circuit Courts

Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings went to trial before a jury and Judge Zita L. Weinshienk on November 5, 2001.[42] On November 20, 2001, the jury returned a verdict against LabCorp, awarding Metabolite over three million dollars in damages for breach of contract and an additional one million

---

36. *See* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1361 (Fed. Cir. 2004).

37. '658 Patent col.41 ll.58-65.

38. *Metabolite Labs., Inc.*, 370 F.3d at 1359.

39. *Id.*

40. *Id.*

41. Second Amended Complaint and Jury Demand at 90-94, 107-14, Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, No. 99-CV-870, 2001 WL 34778749 (D. Colo. Jan. 31, 2000).

42. Metabolite Labs. Inc. v. Lab. Corp. of Am. Holdings, No. 99-CV-870, 2001 WL 34778749, at *1 (D. Colo. Jan. 31, 2000).

dollars for the indirect infringement counts.[43] After denying LabCorp's motion for judgment as a matter of law, the district court doubled the infringement award, finding that LabCorp willfully infringed the '658 patent, and issued a permanent injunction against LabCorp, preventing it from using the homocysteine-only test.[44]

LabCorp appealed to the U.S. Court of Appeals for the Federal Circuit, arguing that the district court erred in denying its motion for judgment as a matter of law.[45] Specifically, LabCorp disputed the district court's construction of the term "correlating" in the second part of claim 13.[46] It was upon the construction of this term that the finding of direct and indirect infringement by the jury hinged.[47]

Reviewing the construction of the claim de novo, the court of appeals properly asserted that it would discern the language of the claim—including the term "correlating"—in the context of the "understanding of [such] terms among artisans of ordinary skill in the relevant art at the time of invention."[48] The court noted that intrinsic evidence (the usage of terminology in the patent claims, specifications, and prosecution history) as well as extrinsic evidence (expert testimony, treatises, dictionaries, etc.) could be used in construing the language of the patent claims and the terminology contained therein.[49] In determining the level of ordinary skill in the art, through which the claims should be construed, the court adopted the district court's standard: "'[A] person having a medical degree and experience in researching the amino acid homocysteine and its relationship to diseases.'"[50]

In reviewing the district court's *Markman*[51] hearing for its construction of the term "correlating," as well as the prosecution history,[52] the court of appeals affirmed the district court's

---

43. *Id.*

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

45. *Id.*

46. *See id.* at 1361.

47. *See id.* at 1360.

48. *Id.* at 1360 (citing Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001)).

49. *Id.*

50. *Id.* at 1361 (quoting the jury instructions at the district court level).

51. Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996) (holding that claim construction is a matter of law and that "the construction of a patent, including terms of art within its claim, is exclusively within the province of the court").

52. *See Metabolite Labs., Inc.*, 370 F.3d at 1362. As originally filed, claim 13 lacked the "correlating" step and was rejected by the examiner for failure to comply with 35 U.S.C. § 112 in providing a complete written description of the sequential steps of the process. *Id.* The rejection was later withdrawn, but the claim was again rejected under 35 U.S.C. § 102

interpretation.[53] According to the court of appeals, "correlating" should be construed to mean "relating total homocysteine levels to cobalamin or folate deficiency, a deficiency in both, or a deficiency in neither."[54] Correlating, as thus defined by the circuit court, "includes both a mutual relationship between the presence of an elevated level of homocysteine and a vitamin deficiency and a reciprocal relationship between the absence of an elevated level of homocysteine and no vitamin deficiency."[55] Furthermore, according to the court of appeals, the claim language required no "confirmatory step" linking either condition to diagnosed or apparent symptoms.[56]

The court of appeals then addressed LabCorp's challenge to the validity of claim 13 of the '658 patent.[57] LabCorp argued that the claim was invalid because of its indefiniteness, as well as its failure to meet 35 U.S.C. § 112's requirements of a written description and enablement.[58] The court affirmed the district court's *Markman* finding that there were "no 'material ambiguities' cloud[ing] the meaning of the term 'correlating' to the extent that one of skill in the art would find the claim wholly indefinite," and thus, invalid.[59] Likewise, the court held that the jury's finding that physicians engaged in homocysteine research, who were persons of ordinary skill in the art, "understood from the specification that the '658 patent inventors possessed the 'correlating' step at the time they filed the patent application," was supported by substantial evidence.[60] Finally, the court of appeals held that the language of the claim itself enabled "one of ordinary skill in the art" to practice the method described in the claim.[61] According to the court, "[t]he correlating step is a simple conclusion that a cobalamin/folate deficiency exists *vel non* based on the assaying step," and it noted that the correlation was neither concealed nor undisclosed, but was the "centerpiece of the invention."[62]

Next, the court of appeals rejected LabCorp's argument that claim 13 was obvious and therefore, invalid under 35 U.S.C. §§ 102 or

---

as merely citing an intended use. *Id.* The "correlating" language was then added to overcome this latter rejection. *Id.*

53. *Id.* at 1363-64.
54. *Id.* at 1363.
55. *Id.* at 1364.
56. *Id.*
57. *See id.* at 1365-68.
58. *Id.* at 1366; *see* 35 U.S.C. § 112 (2000).
59. *Metabolite Labs., Inc.*, 370 F.3d at 1366.
60. *Id.*
61. *See id.* at 1366-67.
62. *Id.* at 1367.

103.[63] The court noted that, although the prior art reference, an article by Professor Helga Refsum,[64] did disclose that total homocysteine should be used to investigate "'perturbations of homocysteine metabolism in humans during disease [sic] or pharmacological interventions that affect metabolism of one-carbon compounds,'" the reference did not specifically mention cobalamin or folate deficiencies but merely "invite[d] further experimentation to find such associations."[65] The court held that LabCorp failed to meet its heavy burden of proof of demonstrating that the prior art disclosed enough evidence to show that a person "in the art would have been motivated to combine the various references"; the disputed claim was therefore nonobvious.[66]

Having thus concluded that, under claim 13, any test for homocysteine could be used to infer decreased levels of folate and/or cobalamin, the court found that substantial evidence supported the jury's verdict of indirect infringement.[67] Dr. Peter Wentz, a LabCorp Director, testified at trial that "'the correlating step . . . [is] a separate, distinct step that's performed by the physician who receives . . . our results.'"[68] Dr. Sally Stabler, one of the inventors of the '658 patent, also testified that "it would be malpractice for a doctor to receive [the results of] a total homocysteine assay without determining cobalamin/folate deficiency."[69]

In its finding, the court of appeals extended the definition of "correlating" to mean that any physician who made the logical inference that an assay revealing elevated levels of total homocysteine in a patient and also predictively indicating low levels of folate and/or cobalamin was infringing upon claim 13 of the '658 patent.[70] The

---

63. *See id.* at 1367-68. The court noted that a prior art reference anticipates a patent claim under § 102 "'if the reference discloses, either expressly or inherently, all of the limitations of the claim.'" Id. at 1367 (quoting EMI Group N. Am., Inc. v. Cypress Semiconductor Corp., 268 F.3d 1342, 1350 (Fed. Cir. 2001)).

64. *See* Helga Refsum et al., *Radioenzymic Determination of Homocysteine in Plasma and Urine*, 31 CLINICAL CHEMISTRY 624 (1985).

65. *Metabolite Labs., Inc.*, 370 F.3d at 1367 (quoting Helga Refsum et al., *Radioenzymic Determination of Homocysteine in Plasma and Urine.* 31 CLINICAL CHEMISTRY 624 (1985) ("[P]erturbations of homocysteine metabolism in humans during diseases or pharmacological interventions that affect metabolism of one-carbon compounds.")).

66. *Id.* at 1368 (citing Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1372 (Fed. Cir. 2000)).

67. *See id.* at 1365.

68. *Id.* at 1364 (alteration in original).

69. *Id.* at 1364.

70. *See id.* at 1364-65. Since homocysteine is a precursor of methionine and folate and B_{12} are essential to its conversion, deficiencies of folate and B_{12} will result in an

circuit court also found that, by publishing literature describing the relationship between elevated homocysteine levels and vitamin deficiency and by offering to perform homocysteine assays with Abbott's non-infringing method, LabCorp had actively induced physicians to infringe upon the '658 patent by encouraging them to diagnose a vitamin deficiency based upon increased total homocysteine levels.[71]

LabCorp appealed the Federal Circuit's decision. After a rehearing en banc was denied by the Federal Circuit,[72] an appeal to the Supreme Court was granted certiorari on October 31, 2005.[73] Certiorari was limited to Question 3 of Petitioner's brief:

> 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.[74]

The question of whether a patent could claim even the pondering of a basic scientific relationship would thus be considered by the Supreme Court.

B. The Arguments on Appeal to the Supreme Court

In its petition for certiorari, LabCorp pointed out that the Federal Circuit's opinion posed grave dangers for the practice of medicine. If the Federal Circuit's affirmation of the construction of "correlating" was upheld by the Court, then

> any person—such as an author of a medical textbook—would be guilty of induced infringement if he or she simply published the basic scientific fact that elevated levels of homocysteine correlate to deficiencies of cobalamin or folate. . . . A truthful statement of medical fact—standing alone—cannot under any circumstances constitute a specific intent to infringe a patent.[75]

---

increase in homocysteine levels since the action cannot "go forward." *See* SMITH ET AL., *supra* note 26, at 732.

71. *Metabolite Labs., Inc.*, 370 F.3d at 1365. The circuit court vacated the district court's finding of infringement of another claim in the '658 patent for lack of subject matter jurisdiction, affirmed the jury's finding of breach of contract, and held that the district court did not abuse its discretion in both awarding enhanced damages to Metabolite and issuing the injunction against LabCorp. *Id.* at 1369-72.

72. *See* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, No. 03-1120, 2004 U.S. App. LEXIS 17408, at *1 (Fed. Cir. Aug. 5, 2004).

73. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 546 U.S. 975, 975 (2005) (per curium).

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

75. *Id.* at 18.

Furthermore, LabCorp argued that "[t]o hold otherwise would dramatically transform the patent laws from an engine of discovery into a means of preventing the dissemination of basic scientific information,"[76] and pointed out the Court's longstanding recognition that "laws of nature are outside the scope of patentable inventions."[77]

LabCorp argued that the Federal Circuit improperly construed the '658 patent as conferring a monopoly on the mental processes of doctors.[78] By holding that a physician directly infringes merely by "look[ing] at a homocysteine test result and think[ing] about a possible connection to vitamin deficiencies," without reference to what type of assay is employed or to whether further confirmatory tests are required, LabCorp claimed that the Federal Circuit improperly broadened the scope of patent law.[79] Furthermore, LabCorp argued that the Federal Circuit erred in holding that a third-party such as LabCorp, which did not infringe directly by employing the non-infringing Abbott homocysteine assay, could be held liable for inducing infringement by physicians.[80] According to LabCorp's argument, since no person can patent a scientific fact or principle, it follows that "no person can be guilty of induced infringement merely by stating such a fact" in a publication or by offering to perform a noninfringing test that demonstrates that fact.[81]

LabCorp argued further that the disputed claim 13 was "[i]ndefinite, [i]nsufficiently [d]escribed, [a]nd [n]on-[e]nabling."[82] LabCorp argued that because it embraces all assays for homocysteine, including those claimed in the patent, those described in the prior art, and even those not yet developed, and because it does not describe the method by which an individual is to "correlate" an elevated homocysteine level with a vitamin deficiency, the claim attempts to assert a patent monopoly over a scientific fact and is therefore invalid.[83] A claim that simply directs a practitioner to correlate a test result with a medical condition fails to meet the requisite standard of

76. *Id.*

77. *Id.* (citing Diamond v. Diehr, 450 U.S. 175, 185 (1981); Gottschalk v. Benson, 409 U.S. 63, 67 (1972); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948); Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 94 (1939)).

78. *Id.* at 19.

79. *Id.*

80. *Id.*

81. *Id.*

82. *Id.* at 23.

83. *See id.*

"accuracy, precision, and care" in disclosing the invention.[84] Moreover, LabCorp asserted that claim 13 fails to

> contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.[85]

LabCorp argued that the term "correlate" is impermissibly vague because it fails to set forth any correlating step beyond merely thinking about a simple scientific fact—the relationship between elevated homocysteine levels and vitamin deficiency.[86] Therefore, a physician of ordinary skill in the art "cannot determine [the claim's] scope without speculation."[87] For the same reasons, LabCorp argued, claim 13 must also fail the written description and enablement requirements of 35 U.S.C. § 112.[88]

According to LabCorp, the correlating step as construed by the lower court would not require a doctor to actively perform any discrete step in the patented process, but merely to possess the knowledge of the link between elevated homocysteine levels and cobalamin and folate deficiencies. Thus, anyone might obtain a patent on a scientific correlation such as a link between two sets of facts "merely by drafting a patent claiming no more than 'test for fact A and correlate with fact B,' without any explanation of the testing or correlation processes."[89] Such a construction of an undefined claim cannot constitute a valid patented invention because it merely states a scientific fact and does not define any novel invention.[90]

Finally, LabCorp argued in its brief that there are important policy reasons for overturning the holding of the Federal Circuit.[91] LabCorp maintained that, although a patent may properly protect a test for obtaining information, patent law "cannot, and should not,

---

84. *See* Brief for Petitioner at 34, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607) (mem.), 2005 WL 3543099 (quoting Merrill v. Yeomans, 94 U.S. 568, 573 (1876)).

85. Petition for Writ of Certiorari, *supra* note 74, at 24 (quoting 35 U.S.C. § 112 (2000)).

86. *See id.*

87. *Id.* at 24-25.

88. *See id.* at 25; 35 U.S.C. § 112 ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.").

89. Brief for Petitioner, *supra* note 84, at 14.

90. *See id.*

91. *See* Petition for Writ of Certiorari, *supra* note 74, at 26-27.

protect the medical facts that a test result [or assay] may convey."[92] Such protection may prevent medical professionals from exercising sound professional judgment if the "threat of patent lawsuits pressure doctors to delay or refrain from learning about medical facts that could help provide appropriate care and diagnosis."[93] By holding that a doctor's merely thinking about the relationship between a detected elevation in homocysteine in a patient as an indicator of vitamin deficiency is a direct infringement of the '658 patent, LabCorp argued that the Federal Circuit cast a "pall" over the very nature of patient care.[94]

Furthermore, LabCorp alleged that, should the Supreme Court find claim 13 of the '658 patent valid, then any "test plus correlate" patent would likewise be similarly valid.[95] Such a patent could directly inhibit the free dissemination of scientific information between medical and scientific investigators that is at the very heart of biomedical and scientific research.[96] LabCorp warned that the Federal Circuit's decision would have disastrous consequences for medical care and research in the United States.[97]

In its reply brief, Metabolite attacked LabCorp's arguments at statutory, procedural, and policy levels.[98] First, Metabolite argued that subject matter patentability was not properly brought before the Court.[99] According to Metabolite, LabCorp's argument that claim 13 attempted to patent a basic scientific fact or phenomenon of nature in violation of 35 U.S.C. § 101 was never argued or invoked in the courts below, and was only raised in Petitioner's Brief to the Court.[100] Metabolite quoted the Patent Act of 1952, which states that invalidity of the patent on any ground—including the § 101 ban on patenting phenomena of nature—"'shall be defenses in any action involving the validity or infringement of a patent *and shall be pleaded*.'"[101] According to Metabolite, because LabCorp's underlying suit attacked the '658 patent only on grounds of lack of novelty (§ 102), obviousness

92. *Id.* at 27.
93. *Id.*
94. *Id.*
95. *Id.* at 29.
96. *See id.* at 28-29.
97. *See id.* at 27.
98. *See* Brief for Respondents, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607) (mem.), 2006 WL 303905.
99. *Id.* at 19.
100. *See id.* at 19 ("[W]ith the exception of a single cryptic footnote in its merits brief filed in this Court, petitioner has *never* so much as cited, much less invoked or discussed, Section 101 in the long history of [the] litigation." (internal citation omitted)).
101. *Id.* at 21 (quoting 35 U.S.C. § 282 (2000)).

(§ 103), and indefiniteness (§ 112),[102] LabCorp was now barred from making an attack not pleaded in the lower courts or submitted to a jury on the grounds of patentability based upon § 101.[103]

Moreover, Metabolite contended that LabCorp's attempt to attack the '658 patent on § 101 grounds also offended the Federal Rules of Civil Procedure.[104] By failing to plead an infringement defense based on § 101 in the lower courts, Metabolite claimed that LabCorp violated Federal Rule of Civil Procedure 8(c), which requires defendants to plead "'any . . . matter constituting an avoidance or affirmative defense.'"[105] Furthermore, Metabolite argued that LabCorp's failure to raise the issue at all until the case reached the merits stage at the Supreme Court should also act as a bar against employing the defense now.[106] In essence, Metabolite's "use it or lose it" argument sought to bar the Court from even considering LabCorp's arguments concerning § 101 invalidity, and to restrict the Court to considering only LabCorp's defenses based on §§ 102, 103, and 112.[107]

Although LabCorp argued that the issue was "fairly included in Question 3" of the Grant of Certiorari issued by the Court,[108] Metabolite argued that the Court's own rules prevented consideration.[109] According to Metabolite, the sole issue before the Court was the review of the lower court's decision that claim 13 of the '658 patent met the written description and enablement requirements of 35 U.S.C. § 112.[110] Metabolite maintained that, since the Court did not grant certiorari on the question of whether LabCorp could be held liable for infringing the '658 patent merely for disseminating a scientific fact (the relationship between elevated homocysteine levels and vitamin deficiency), an attack by LabCorp on § 101 grounds was prohibited.[111]

---

102. *Id.*

103. *Id.* at 22 (citing Elec. Storage Battery Co. v. Shimadzu, 307 U.S. 5, 16-17 (1939); Johnson & Johnson v. C. B. Stenvall, Inc., 193 F. Supp. 128, 132 (S.D.N.Y. 1961)).

104. *See id.*

105. *Id.* (quoting FED. R. CIV. P. 8(c)) (alteration in original).

106. *Id.* at 23 (citing Helvering v. Tex-Penn Oil, Co., 300 U.S. 481, 497-98 (1937) (barring defendant from seeking a ruling on an issue that it had not sought in a lower court)).

107. *See id.* at 25.

108. Brief for Petitioner, *supra* note 84, at 17 n.9.

109. Brief for Respondents, *supra* note 98, at 25.

110. *See id.* at 26.

111. *See id.*

Metabolite maintained that claim 13 of the '658 patent claimed patentable subject matter.[112] Metabolite contended that the disputed claim did employ a scientific fact that could be determined using the assay that the patent described.[113] Metabolite argued that the technical application (the homocysteine assay) employed a law of nature, but that useful inventions employing such natural laws fall within the realm of patentable subject matter.[114] Metabolite cited, in support of its contention, *Diamond v. Diehr,* in which the Supreme Court held that a "mathematical equation or a law of nature . . ., when incorporated as part of a process that yields a more efficient or useful end, '. . . is at the very least not barred at the threshold by § 101.'"[115]

Metabolite also argued that claim 13 met the requirements of § 101 because the assay in question entails a physical transformation of matter.[116] Metabolite dismissed LabCorp's argument that the assay was in no way transformative, but merely measures the homocysteine level present.[117] According to Metabolite, the chemical transformation steps required as a part of the assay in order to provide a detectable measure of homocysteine satisfied the transformative requirement.[118] Thus, the chemical reactions required to assay homocysteine satisfied the transformative element required to validate the patent.[119]

Moreover, Metabolite championed the validity of the '658 patent because the correlation, when combined with an assay, is instrumental in producing a "useful, tangible, and concrete result."[120] The patent, argued Metabolite, is clearly useful in that it detects potentially dangerous vitamin deficiencies in patients—deficiencies that can lead to a number of potentially life-threatening health

---

112. *Id.* at 27 (assuming arguendo that the issue of § 101 patentability was even before the Court).

113. *See id.* at 29.

114. *See id.* at 32 ("[A] natural phenomenon 'in the abstract' does not constitute patentable subject matter, but a claimed invention does meet Section 101's subject matter requirements when the phenomenon 'has been reduced to some practical application rendering it useful.'" (citations omitted) (internal quotation marks omitted)).

115. *Id.* (quoting Diamond v. Diehr, 450 U.S. 175, 188 (1981)).

116. *See id.* at 34 ("Because the invention of claim 13 *requires* the transformation of matter (*i.e.*, blood or other body fluid) in order to diagnose vitamin deficiencies, it is patentable under Section 101.").

117. *See id.*

118. *See id.*; *see also* U.S. Patent No. 4,940,658 col.7 ll.12-14 (filed Nov. 20, 1986) ("Reduction is required for release and subsequent assay of protein bound sulfhydryl compounds.").

119. Brief for Respondents, *supra* note 98, at 35.

120. *Id.* at 36 (citing State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1373, 1375 (Fed. Cir. 1998)).

consequences.[121] The results of the method described by the patent are likewise tangible, according to Metabolite, in that the assay provides measurable results that may accurately predict a corresponding deficiency.[122] And because the results of the test are repeatable and predictable, they are "concrete," as defined by the Patent and Trademark Office.[123] Metabolite contended that LabCorp's reliance upon the standard established in *Parker v. Flook*[124] was misplaced because that case had been supplanted by the Supreme Court's subsequent holding in *Diehr* that a process employing a natural phenomenon and resulting in a practical use falls within § 101.[125]

Metabolite further scoffed at LabCorp's prediction of dire consequences for medical practice and research should the Court uphold the validity of the patent.[126] Metabolite maintained that it neither claimed nor sought "a monopoly on the correlation between total homocysteine and vitamin deficiencies."[127] Rather, Metabolite argued that the patent merely claimed a "particular *application* of that correlation, when used as a sequential step in a diagnostic method."[128] Metabolite insisted that the natural process of correlation between homocysteine and vitamin deficiency was not at issue in the claim, merely the means of making such a correlation.[129]

As an example of a non-infringing use of the correlation in claim 13, Metabolite offered a study wherein the authors recommended prophylactic administration of folate and cobalamin in order to reduce homocysteine levels and prevent disease in which no levels of homocysteine were measured in any of the experimental subjects.[130] Metabolite further argued that a failure by the Court to support the validity of the '658 patent would undermine the validity of

---

121. *Id.*

122. *Id.* at 36-37. Metabolite states that "claim 13 does not 'disclose mere abstract ideas, but a practical and potentially life-saving process.'" *Id.* at 37 (quoting Arrhythmia Research Tech., Inc. v. Corazonix Corp., 958 F.2d 1053, 1065-66 (Fed. Cir. 1992) (Rader, J., concurring)).

123. *Id.* at 37 ("The PTO defines 'concrete' as the opposite of 'unrepeatable or unpredictable.'").

124. 437 U.S. 584, 593-95 (1978).

125. Brief for Respondents, *supra* note 98, at 37 (citing Diamond v. Diehr, 450 U.S. 175, 188, 192 (1981)).

126. *See id.* at 38.

127. *Id.* at 39.

128. *Id.*

129. *See id.* at 39.

130. *Id.* at 41 (citing Joint Appendix at 107-08, Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (2005) (No. 04-607)).

"hundreds or thousands of patents on medical diagnostic methods, which frequently recite the sequential steps of assaying (or determining) the amount of a particular substance [in] the body and correlating the determined amount with a disease."[131]

One example of such a threatened patent recited by Metabolite was U.S. Patent No. 6,811,993, which claims a method for evaluating the activity of an enzyme (protein kinase C) in vascular tissues.[132] Claim 1 of that patent requires a three-step diagnostic procedure in which the level of protein kinase C is assayed, optionally compared to a standard, and correlated with the determined level of a disease.[133] Thus, the use of a "marker" as an indicator of the presence or absence of a disease is, according to Metabolite, a common feature of claims in patented diagnostic methods.[134]

Finally, Metabolite argued that the standards established by the Court in *Diamond v. Diehr* provided a workable patent jurisprudence and, furthermore, that it is within Congress's power to alter patent law should Congress find it to be in the public interest to do so.[135] Finally, Metabolite argued that the Federal Circuit, as the "expert court" established by Congress, should be the first body to consider policy issues.[136]

III. WHY THE SUPREME COURT SHOULD HAVE INVALIDATED CLAIM 13 OF THE '658 PATENT

A. Misconstruction of the Term "Correlating" by the District and Federal Circuit Courts

The district court, in its *Markman* hearing, properly determined that the term "correlating" should be construed as it would be understood by a person of ordinary skill in the art; that is "'a person having a medical degree and experience in researching the amino acid homocysteine and its relationship to diseases.'"[137] It then went on to define "correlating" as "relating total homocysteine levels to

131. *Id.* at 45.

132. *See id.* (citing U.S. Patent No. 6,811,993 col.7-8 (filed Dec. 21, 2001)).

133. *Id.* (citing '993 Patent col.7-8).

134. *Id.* ("Markers" are "proteins, enzymes, amino acids, [and] other substances that change . . . in the presence of disease.").

135. *See id.* at 46-47.

136. *Id.* at 47.

137. Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1361 (Fed. Cir. 2004) (quoting the jury instruction from the district court trial and noting that the parties agreed on the level of ordinary skill in the art).

cobalamin or folate deficiency, a deficiency in both, or a deficiency in neither."[138] In other words, the district court and the Federal Circuit construed "correlating" to mean determining the levels of total homocysteine in a patient's body tissues and then *inferring* from those levels whether a corresponding deficiency of folate and/or cobalamin exists.[139]

Such a definition is a misconstruction of the term as it would be understood by a biomedical researcher of ordinary skill in the art (as defined by the courts). "Correlation" is a term of scientific art—a precisely-defined statistical term for inferring a possible relationship between two independent sets of measured variables.[140] Correlation requires more than a strong association between two variables; the variables must be related to appropriate time-order, and a possible causal relationship must be the only explanation for the strong association between the two variable sets.[141] Unlike the district court's construction of the claim, in which correlation is understood to be an inferential relationship between a single datum and a known condition, correlation as understood by biomedical researchers requires ascertaining the relationship between *two sets* of data, each of multiple paired variables.

The calculation of the correlation coefficient between two sets of paired data is thus an indicator of the reliability of the linear association between any two paired variables and also an index of the likelihood of cause and effect between dependent and independent variables.[142] The essential point is that, in order for a researcher of ordinary skill in the art to determine that a correlation exists between variables (for example, total homocysteine levels in a body fluid and

---

138. *Id.* at 1363.

139. *See id.* According to the Federal Circuit, "[i]n essence, 'correlating' means to relate the presence of an elevated total homocysteine level to either a cobalamin or folate deficiency, or both (i.e., a mutual relationship), and also to relate the absence of an elevated total homocysteine level to a deficiency in neither (i.e., a reciprocal relationship)." *Id.*

140. *See* P.V. RAO, STATISTICAL RESEARCH METHODS IN THE LIFE SCIENCES 442 (Alex Kugushev ed., 1998).

141. *Id.* For example, to establish a "significant positive correlation between [two variables] X and Y, where X is the change in the subject's anxiety level (measured on a numerical scale) and Y is the corresponding change in the subject's blood pressure," the investigator must demonstrate that the anxiety was induced before the change in blood pressure was noted and that, for this particular set of data, "only a change in anxiety level can cause a change in blood pressure." *Id.*

142. *See id.* at 435-36. The correlation coefficient is established by letting "(x_1, y_1), (x_2, y_2), . . . [and] (x_n, y_n) denote a random sample of n pairs of observed values of a pair of continuous variables (X, Y)." *Id.* at 434. Next, the correlation coefficient is calculated as: "$r_{xy} = S_{xy}/\sqrt{S_{xx}S_{yy}}$, where $S_{xx} = \sum (x_i - \bar{x})^2$, $S_{yy} = \sum (y_i - \bar{y})^2$ and $S_{xy} = \sum (x_i - \bar{x})(y_i - \bar{y})$." *Id.* at 396, 434.

the level of cobalamin and/or folate), *both variables* need to be observed (measured) *multiple times*, generating two sets of paired variables. A correlation between the relative levels of homocysteine and vitamins may then be determined by calculating the correlation coefficient to determine whether a linear relationship between the two exists, wherein the high levels of the former reliably indicate a causal deficiency of the latter.

This is a far cry from the much more casual definition placed upon the term "correlate" by the district court and affirmed by the Federal Circuit.[143] "Correlate," as defined by those courts, describes an inferential process by which the relative concentration of homocysteine levels is used to predict whether or not there is a vitamin deficiency.[144] This cannot be a correlation, as understood in a scientific context, unless a corresponding measurement of the relative concentrations of folate or cobalamin are made and the values compared to the homocysteine level are applied. Thus, for a physician to infringe by correlating she must measure both homocysteine and vitamin levels in multiple patients and test those levels statistically to determine if a correlation indeed exists.

It is true that the inventor of a patented device or method may choose to define terms in a manner specific to the patent, but such terms must be clearly defined in the specification or prosecution history.[145] However, the '658 patent employs the term "correlate" in its specification in a manner entirely consistent with its common usage in the art.[146] In the study described in Example 1, serum cobalamin and folate levels were measured and correlated with a number of contemporaneously measured hematological criteria, including homocysteine and methylmalonic acid levels.[147] The example clearly demonstrates a usage of the term "correlate" in a manner consistent with the scientific usage of the term.

The misconstruction of the term speaks to the very heart of the case. Claim 13 of the '658 patent should be properly determined to be

---

143. *See Metabolite Labs., Inc.*, 370 F.3d at 1363.

144. *See supra* text accompanying notes 48-56.

145. *See* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). The *Vitronics* court noted that:

> [a]lthough words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.

Id.

146. *See* U.S. Patent No. 4,940,658 col.10-12 (filed Nov. 20, 1986).

147. *See* '658 Patent col.10 l.38-43, col.11 l.46-48.

infringed only when a physician measures both homocysteine and folate and/or cobalamin levels, and then correlates the two values. As the American Clinical Laboratory Association pointed out in its brief as amicus curiae:

> The alleged infringement on the part of doctors is not correlating in its usual sense, because the doctors are not *establishing* the relationship between homocysteine and the B vitamins (each physician is not, for example, performing separate controlled experiments on large numbers of patients) but rather *applying* that relationship in specific instances as part of patient care.[148]

Because the courts below misconstrued the term "correlate," in the absence of an alterative definition supplied by the inventors, the Supreme Court should have vacated the earlier decisions and remanded the case to the district court with instructions to construe the term within its proper meaning as understood by those of ordinary skill in the art. A physician who measures homocysteine levels by a (non-infringing) assay and uses the results to infer that the patient suffers from cobalamin or folate deficiency is not performing any sort of statistical correlation, and does not infringe. Nor did LabCorp induce infringement by performing non-infringing assays or publishing information concerning the relationship between homocysteine levels and vitamin deficiencies because these activities do not fall within the scientific definition of "correlating."

B. The Supreme Court Can Examine the Patentability of the Subject Matter under 35 U.S.C. § 101

In its brief, Metabolite attempted to checkmate LabCorp's argument that the '658 patent is invalid because it claims a basic scientific fact in violation of 35 U.S.C. § 101.[149] According to Metabolite, because LabCorp failed to plead invalidity under § 101 in the lower courts, it was barred from doing so in its argument before the Supreme Court.[150] Metabolite invoked both statutory and

---

148. Brief of the American Clinical Laboratory Ass'n as Amicus Curiae Supporting Petitioner at 6, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607) (mem.), 2005 WL 3543098.

149. *See* Brief for Respondents, *supra* note 98, at 21. Section 101 states that "[w]hoever 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 thereof, subject to the conditions and requirements of this title." 35 U.S.C. § 101 (2000). The statute has been regularly interpreted to forbid the patenting of laws of nature, natural phenomena, and abstract ideas such as mathematical formulae. *See, e.g.*, Diamond v. Diehr, 450 U.S. 175, 185 (1981) ("Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas.").

150. *See* Brief for Respondents, *supra* note 98, at 22.

procedural authority in support of its argument.[151] Metabolite argued that having failed to plead invalidity under § 101, LabCorp had in effect abandoned its right to raise it as an "affirmative defense" and the Court was therefore precluded from considering it under the Patent Act of 1952 and the Federal Rules of Civil Procedure.[152] Metabolite went so far as to invoke the Seventh Amendment, arguing that, because "no jury ha[d] found the *factual* predicates [necessary] to a Section 101 defense," the Court could not find the '658 patent invalid.[153] Implicit in Metabolite's argument was the assumption that without the facts having been tried before a jury, a § 101 "affirmative defense" could not be pleaded before the Supreme Court.

Metabolite's argument, however, is unpersuasive. Failing to mount an attack on the validity of the '658 patent on § 101 grounds in the lower courts was undoubtedly poor legal strategy and a major oversight by LabCorp. However, unlike defenses mounted on issues of fact, which cannot be raised on appeal if they are not pled in the trial court, the validity of a patent based on the patentability of the subject matter under § 101 is a matter of law and may be reviewed sua sponte by the Court.[154] In *Slawson v. Grand Street Railroad Co.*, the Supreme Court established that "the question whether [the] invention is patentable or not, is always open to the consideration of the court, whether the point is raised by the answer or not."[155] The precedents, though old, remain good law, although they have not been relied upon often by courts.

More recently, however, the Federal Circuit itself has raised § 101 concerns sua sponte. In *Titanium Metals Corp. of America v. Banner*, the Federal Circuit held that the issuance of a patent was clearly erroneous based upon § 101 and reversed the decision of the district court, holding a patent invalid.[156] As Judge Garjasa of the Federal Circuit recently pointed out in *SmithKline Beecham Corp v. Apotex, Corp*, although the *Slawson* case is old, the policy behind the decision remains vibrant.[157] Judge Garjasa noted that, less than a

---

151. *See supra* text accompanying notes 98-111.

152. *See* Brief for Respondents, *supra* note 98, at 19-20.

153. *Id.* at 41 n.21 (citing Dimick v. Schiedt, 293 U.S. 474, 486-87 (1935)).

154. *See* SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1352-54 (Fed. Cir. 2005) (Gajarsa, J., concurring) (providing examples of courts independently raising § 101 concerns).

155. 107 U.S. 649, 652 (1883); *see also* Richards v. Chase Elevator Co., 158 U.S. 299, 301 (1895) ("We have repeatedly held that a patent may be declared invalid for want of novelty, though no such defense be set up in the answer.").

156. 778 F.2d 775, 783 (Fed. Cir. 1985).

157. *SmithKline Beecham Corp.*, 403 F.3d at 1353 (Gajarsa, J., concurring).

decade after *Slawson*, the Supreme Court, in the context of a patent interference, emphasized that: "[T]he parties to the present suit . . . have litigated merely the question of priority of invention, on the assumption that the invention was patentable. But neither the Circuit Court nor this court can overlook the question of patentability."[158] Judge Gajarsa further observed that the Supreme Court has "recognized that there is a significant public policy interest in removing invalid patents from the public arena."[159] In *United States v. Glaxo Group, Ltd.*, the Court cited numerous cases as "sufficient authority" to support its statement that "'[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.'"[160]

Another policy consideration supporting the Supreme Court's ability to review the subject matter eligibility of a patent sua sponte is that in the United States, unlike in Europe, there is no right of third-party opposition to the validity of a patent's subject matter.[161] Therefore, the Supreme Court is the ultimate protector of the public from "bad patents" attempting to monopolize ineligible subject matter. As such, the power of the Court to examine any patent for § 101 eligibility is an important power protecting society.

These arguments are reflected in Justice Breyer's dissent in *Metabolite*.[162] Justice Breyer argued that the technical procedural objection to hearing the case was too tenuous to stand, citing prior Supreme Court precedent for the proposition that the failure to make a § 101 argument in itself was an insufficient reason for denying review.[163] Moreover, Justice Breyer could see "no good practical

158. *Id.* (quoting Hill v. Wooster, 132 U.S. 693, 698 (1890)) (alteration in original).

159. *Id.* at 1354 (citing Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 100 (1993); Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313 (1971); United States v. Glaxo Group Ltd., 410 U.S. 52, 57-58 (1973)).

160. 410 U.S. 52, 57-58 (1973) (quoting Pope Mfg. Co. v. Gormully, 144 U.S. 224, 234 (1892)). The issue before the Court was whether the United States could set aside a patent in the context of antitrust litigation. *Id.* at 57.

161. *See* Syntex (U.S.A.) Inc. v. U.S. Patent & Trademark Office, 882 F.2d 1570, 1574-75 (1989) (noting that, while statutory provisions grant third-parties the right to request reexamination by the PTO, those provisions "do not provide for judicial review . . . for any party other than the patent owner"). The grant of a European patent can be opposed by a third-party within nine months of the date of grant. A successful opposition can result in the complete revocation of the European patent in all of the designated states. Convention on the Grant of European Patents arts. 99-102, Oct. 5, 1973, 13 I.L.M. 268, 294-95.

162. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607) (mem.) (Breyer, J., dissenting).

163. *See id.* at 2925-26 (citing United States v. Williams, 504 U.S. 36, 40 (1992)).

reason" not to decide the case: the arguments had been fully briefed and argued, and there were no gaps in the factual record or any prejudice identified by either party in answering the question.[164]

Thus, the Court had ample precedent and scope to review the patentability of the subject matter of claim 13 of the '658 patent under § 101. Furthermore, neither statute nor the Federal Rules of Civil Procedure barred it from doing so. It is likely that LabCorp did not endear itself much to the Justices on the Court by raising the issue of § 101 at this stage of the case; however, to argue, as Metabolite did, that LabCorp was barred from doing so ignored the Court's own latent power to examine the patentability of subject matter at any time. The public policy reasons alone support the contention that, if claim 13 is indeed "invalid" under § 101, the public interest is well-served in removing it from the public arena.[165]

Metabolite further argued that the Court's own rules prevented LabCorp from presenting the issue of the validity of claim 13's subject matter.[166] Metabolite contended that the question of subject matter patentability was not "fairly included in Question 3,"[167] which was the only question upon which the Court had granted certiorari. Question 3 asks:

> 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.[168]

Metabolite maintained that the language of Question 3 restricted the Court to reviewing only the lower court's holding of validity on grounds that claim 13 meets the written description and best mode requirements of 35 U.S.C. § 112.[169] But the plain language of the question brought the validity of the subject matter itself into sharp focus. In short, the real question before the Court was whether patenting a test that requires a physician to simply correlate test results can allow the inventor to obtain a monopoly over a basic scientific fact. By centering the question squarely upon the "monopoly

---

164. *Id.* at 2926.

165. *See* SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1354 (Fed. Cir. 2005) (Gajarsa, J., concurring) (citing 35 U.S.C. § 101).

166. *See* Brief for Respondents, *supra* note 98, at 25-26; *supra* text accompanying notes 100-103.

167. Brief for Respondents, *supra* note 98, at 25.

168. Petition for Writ of Certiorari, *supra* note 74, at i.

169. *See* Brief for Respondents, *supra* note 98, at 25-26.

over a scientific fact," the issue of subject matter patentability came before the Court's consideration.

C. The '658 Patent is Invalid Under 35 U.S.C. § 101

Claim 13 of the '658 patent claims a method for using any assay (including those claimed in the '658 patent, those in the prior art, and, presumably, those not yet invented or developed) for total homocysteine in body tissues to "correlate" elevated homocysteine levels with folate or vitamin B_{12} (cobalamin) deficiencies.[170] The biochemical relationship between elevated levels of homocysteine and vitamin deficiencies is a basic scientific principle, grounded in the biochemistry of homeothermic ("warm-blooded") animals, including humans.[171] Homocysteine levels were raised in humans suffering from vitamin deficiencies long before the very existence of homocysteine or folate and cobalamin were even imagined. Such basic scientific relationships are "manifestations of nature" and are expressly precluded from being patentable;[172] a biochemical reaction occurring naturally in animals and resulting in the production of methionine from 5-methyl tetrahydrofolate via the actions of homocysteine and folate/cobalamin is no different in its essence than is the relationship between energy, matter, and the speed of light in $E=mc^2$. It is well-established that such natural phenomena may not be patented under 35 U.S.C. § 101.[173]

However, it is equally well-established that a new invention that employs a "manifestation of nature" is patentable under § 101.[174] Those portions of the '658 patent that claim a novel technique for determining total homocysteine measured from body tissues of a warm-blooded animal[175] are perfectly valid insofar as they describe a

---

170. *See* U.S. Patent No. 4,940,658 col.6 ll.1-4 (filed Nov. 20, 1986).

171. *See* SMITH ET AL., *supra* note 26, at 732.

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

173. *See id.* For example,

> a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none."

Id. (quoting Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (alteration in original)).

174. *See, e.g.*, Diamond v. Diehr, 450 U.S. 175, 192 (1981) ("[W]hen a claim containing a mathematical formula implements or applies that formula in a structure or process which . . . is performing a function which patent laws were designed to protect . . . then the claim satisfies the requirements of § 101.").

175. *See* '658 Patent cols.41-44 (filed Nov. 20, 1986).

technique that is useful, novel, and nonobvious when viewed in light of the prior art.[176] However, claim 13 of the '658 patent goes beyond those limits and claims the use of all assays for homocysteine, including those found in the prior art, those claimed in the patent, and even those not yet developed, when used to predict or infer a folate or cobalamin deficiency from increased homocysteine levels.[177] By so claiming every possible assay for homocysteine, Metabolite attempts to corner the market on the entire genus of homocysteine tests when applied to the determination of a law of nature.

The problem with such a claim is that it attempts to include all possible homocysteine tests, including those not yet anticipated by those of ordinary skill in the art, such as the later-developed and non-infringing Abbott Laboratories' assay.[178] Such a claim to an entire genus (i.e. all past, present, and future assays for homocysteine levels in warm-blooded animals) by claiming one or two species is impermissible.[179] Metabolite may prevent competitors from infringing upon the claims described with definiteness under the claims of its patent, but it may not lay claim to all possible methods, including those not yet invented or anticipated, of describing a phenomenon of nature.

Metabolite's argument thus resembled a house of cards. Claim 13 of the '658 patent impermissibly claims an entire genus from a limited number of species. But, even if such a claim was permissible, the patent impermissibly claims a phenomenon of nature, inherent in the biochemistry of living systems, and attempts to establish a monopoly over any inference or conclusion arising from knowledge of that inherent biochemical relationship.

Justice Breyer's dissent addressed this argument eloquently, arguing that, no matter how narrowly one constructs the "phenomena of nature" argument, claim 13 is invalid.[180] According to Justice Breyer, "[t]here can be little doubt that the correlation between homocysteine and vitamin deficiency set forth in claim 13 is a 'natural

176. 35 U.S.C. §§ 101-03 (2000 & Supp. 2003-2004).

177. *See supra* text accompanying notes 48-56, 138-139.

178. Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1359 (Fed. Cir. 2004); *see also supra* text accompanying notes 48-56, 138-139.

179. *See Metabolite Labs., Inc.*, 370 F.3d at 1367 ("A prior art reference that discloses a genus still does not inherently disclose all species within that broad category."); *accord* Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1262 (Fed. Cir. 1989) ("[A] claim to a genus would inherently disclose all species. We find [this] argument wholly meritless whether considered under [35 U.S.C. §] 102(b) or under 35 U.S.C. § 103.").

180. *See* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2926-27 (2006) (No. 04-607) (mem.) (Breyer, J., dissenting).

phenomenon.'"[181] Claim 13, as Breyer noted, "is *not* a process for transforming blood or any other matter."[182] Instead, claim 13's process "instructs the user to (1) obtain test results and (2) think about them."[183] Moreover, claim 13 instructs the user to "use any test at all."[184] No precedent cited by Metabolite suggests that such a claim concerning natural phenomena might be patentable.[185] Despite Metabolite's attempts to couch claim 13 in "the abstract patent language of a 'process,'" it "cannot avoid the fact that the process is no more than an instruction to read some numbers in light of medical knowledge."[186] As such, according to Breyer, the "correlation is an unpatentable 'natural phenomenon,'" and there is "nothing in claim 13 that adds anything more of significance."[187]

D. Sound Policy Reasons Militate Against the Validity of the '658 Patent

Numerous amicus briefs were filed with the Supreme Court on behalf of LabCorp arguing that granting validity to a patent that claims a basic scientific fact will stifle innovation and basic biomedical research and will directly conflict with patient care.[188] These concerns were also acknowledged by Justice Breyer in his dissent.[189] Despite

---

181. *Id.* at 2927.

182. *Id.*

183. *Id.*

184. *Id.*

185. *See id.* (citing Gottschalk v. Benson, 409 U.S. 63, 71-73 (1972); Cochrane v. Deener, 94 U.S. 780, 785 (1877)).

186. *Id.* at 2928.

187. *Id.*

188. *See, e.g.*, Brief of AARP as Amicus Curiae Supporting Petitioner at 2, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607) (mem.), 2005 WL 3597809; Brief of the American Clinical Laboratory Ass'n as Amicus Curiae Supporting Petitioner, *supra* note 148, at 8-13; Brief for the American Medical Ass'n et al. as Amici Curiae Supporting Petitioner at 23-26, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607) (mem.), 2005 WL 3597812; Brief of Financial Services Industry as Amici Curiae Supporting Reversal at 1, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607) (mem.), 2005 WL 3543097; Brief of People's Medical Society as Amicus Curiae Supporting Petitioner at 21-26, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607) (mem.), 2005 WL 3597702.

189. *See Metabolite Labs., Inc.*, 126 S. Ct. at 2928-29 (Breyer, J., dissenting) (expressing concern that a failure to decide the case leaves restrictions in place that "may inhibit doctors from using their best medical judgment; . . . may divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations; [and] may raise the cost of healthcare while inhibiting its effective delivery").

Metabolite's assertions to the contrary, such policy concerns have real merit and should have been addressed by the Court in an opinion.

One argument is that if an individual claiming a basic scientific fact, such as a relationship between elevated homocysteine levels and vitamin deficiency, is "permitted to patent any means of testing for [that relationship,] then that patentee may 'shut the door' to the development or use of such new tests, and discourage further research and development."[190] Indeed, the Federal Circuit holding arguably subjects laboratories to damages and penalties for inducing infringement of a patent "simply by informing physicians, in an article for continuing medical education, that high levels of an amino acid signal a risk to patient health."[191] Such a ruling undoubtedly inhibits the dissemination of basic scientific facts essential to medical research and education.[192] In its amicus brief, the American Medical Association (the A.M.A.) illustrated by way of example how overreaching Metabolite's argument was.[193] It noted that, under the Federal Circuit's logic, if a researcher "discover[ed] a previously unknown correlation between obesity and illness, . . . [he] could obtain a patent on the process of stepping on a scale and thinking of that illness."[194] Any entities manufacturing scales or publishing information (including in a medical textbook) concerning the relationship between obesity and the illness would then be liable for willfully inducing infringement.[195] According to the A.M.A., "[s]uch a result is unthinkable."[196]

Similarly, the A.M.A. argued that any physician who knows of the relationship between elevated homocysteine levels and vitamin deficiency would be practically unable to avoid infringing claim 13 of the '658 patent.[197] A physician or scientist who learns of the relationship "cannot put that knowledge out of mind"; such knowledge is "essential to the practice of medicine" and, once learned, cannot be intentionally forgotten.[198] In the practice of medicine, a physician is "ethically obligated" to consider the results of diagnostic tests "in light,

190. Brief for the American Medical Ass'n et al. as Amici Curiae Supporting Petitioner, *supra* note 188, at 24 (quoting O'Reilly v. Morse, 56 U.S. 62, 113 (1853) (internal alteration omitted)).

191. *See id.*

192. *See id.*

193. *See id.* at 25.

194. *Id.*

195. *See id.*

196. *Id.*

197. *See id.*

198. *Id.*

among other things, of current medical knowledge."[199] Scientific facts, once known, must be considered and should not be constrained by the claims of a patent to their consideration in diagnosis.[200] For this reason, facts are not, and ought not to be, patentable.

Furthermore, if a patent can prevent dissemination of scientific fact by making publishers liable for inducing infringement, it might well be found to chill protected First Amendment speech.[201] The Supreme Court has previously held that "the state may not, consistently with the spirit of the First Amendment, contract the spectrum of available knowledge."[202] By enforcing as valid a patent that claims basic scientific knowledge concerning a natural phenomenon, the state is in fact contracting the spectrum of such knowledge available to be freely used by medical practitioners and investigators.

IV. CONCLUSION

In *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, the U.S. Supreme Court had the opportunity to prevent the claiming of basic scientific knowledge as patently valid subject matter. It is undeniable that LabCorp was not well-served by the legal strategy it employed in the lower courts, and the Supreme Court likely looked unfavorably upon LabCorp's raising the subject of invalidity on § 101 grounds at such a late date in the proceedings. Nevertheless, as Justice Breyer noted in his dissent, neither precedent nor the question raised before the Court on certiorari precluded the Court from examining the validity of the '658 patent on those grounds.[203] Furthermore, it is self-evident that claim 13 of the '658 patent claims a phenomenon of nature in violation of 35 U.S.C. § 101. Moreover, there is solid legal ground upon which to argue that both the district court and the Federal Circuit erroneously construed the term "correlating" as it would be understood by one of ordinary skill in the art. Finally, there are compelling policy arguments militating in favor of invalidating claim 13.

In a time when the increased liberality of American courts concerning the patenting of genes and other biological material has

---

199. *Id.* at 26.

200. *See id.*

201. *See* Brief of People's Medical Society as Amicus Curiae Supporting Petitioner, *supra* note 188, at 19-21.

202. *Id.* (quoting Griswold v. Conn., 381 U.S. 479, 482 (1965)).

203. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2925-26 (2006) (No. 04-607) (mem.) (Breyer, J., dissenting).

become a matter of widespread debate, the implied upholding of the validity of the '658 patent, particularly claim 13, by the Supreme Court represents a further and troubling erosion of the long-held bar on the patenting of natural or scientific phenomena. Moreover, it poses a significant threat to the modern practice of medicine and physicians' ability to provide the best possible care to their patients. If, by merely considering the relationship between a clinical indication and the possibility of a disease, a physician is potentially infringing a patent, then diagnosis becomes a thickly-strewn minefield of potential patent liability. Such a threat, if vigorously pursued, is likely to exert a chilling effect on the ability of physicians to best care for their patients. Indeed, if the diagnosis of a disease by clinical indicators is protectable, and if every textbook and diagnostic handbook's description of biological relationships is patentable, then even basic medical education and clinical training pose a risk of giving rise to litigation.

Regrettably, the Supreme Court gave no reason for why it dismissed *Metabolite* after the case had been thoroughly briefed and argued. Given the potential consequences of letting the Federal Circuit's decision stand, some explanation of why the Court dismissed the case as having been improvidently granted a writ of certiorari would be welcome. Better yet, the Court should have decided the case correctly and delivered an opinion invalidating claim 13 of the '658 patent.