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Reviewing Colon-Specific Delivery

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ATTORNEY REVIEW

Are Inventions Based on Discoveries of Natural Phenomena Patentable?

By: Clifford M. Davidson, Esq.

INTRODUCTION

Recently, a patent litigation that appeared to mainly involve a dispute over the scope of patent claims for a diagnostic test for detecting vitamin B deficiency spilled over into an apparent dispute over whether the claims (which are based on a naturally occurring relationship between elevated levels of total homocysteine and a deficiency in either cobalamin or folate) are so broad as to cover natural phenomena outside the scope of patentable subject matter as defined in 35 U.S.C. §101. Many patent holders were interested in the future outcome of this case, as it could have implications to broad patent claims in the medical field, where the claims are based on diagnostic tests or treatments that are based on an underlying naturally occurring phenomena.

THE CASE

US Patent No. 4,940,658 (658 patent) is owned by Competitive Technologies and was licensed to Metabolite Laboratories. LabCorp obtained a sublicense from Metabolite, and from 1991 to 1998, LabCorp tested for homocysteine using the specific method encompassed by the claims of the 658 patent and paid royalties to Metabolite and Competitive Technologies. In 1998, LabCorp began utilizing a method developed by Abbott Laboratories and stopped paying the royalties associated with the 658 patent. Metabolite and Competitive Technologies, Inc., sued LabCorp for infringement of the 658 patent. A jury verdict in the US District Court found that LabCorp indirectly infringed the 658 patent and breached its contract with Metabolite, doubled the infringement award based on willful infringement, and issued a permanent injunction. The case was appealed to the Court of Appeals for the Federal Circuit, which reconsidered (i) the proper interpretation of the claims¹; (ii) whether the specification complied with the written description, enablement,² and definiteness³ requirements of 35 U.S.C. §112; (iii) whether the prior art rendered the claims unpatentable; and (iv) whether the claims were infringed; among other things. The Federal Circuit affirmed the lower court's decision.⁴

In November 2004, LabCorp filed a petition for a writ of certiorari with the Supreme Court posing three questions for review. On October 31, 2005, the US Supreme Court granted certiorari to review only the following question in this matter:

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

On March 21, 2006, the Supreme Court heard oral argument in this case. The oral argument went well beyond the issues of indefiniteness, lack of written description and enablement, and ventured into the realm of whether the subject matter of the claim itself is patentable.

A significant part of the oral argument centered around Claim 13 of the 658 patent, which reads as follows:

13. 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.

Petitioner LabCorp argued that the correlation between elevated homocysteine levels and vitamin deficiencies stated in Claim 13 does not qualify as a novel invention, but instead is a basic scientific principle or law of nature that cannot be the basis of a valid patent claim under 35 U.S.C. § 101.⁵ LabCorp argued that neither the activity of assaying nor the activity of thinking about the scientific correlation transforms Claim 13 into a patentable invention, and further notes the absence of any transformative process in the claim that might otherwise allow the claim to qualify as proper patentable subject matter. LabCorp advanced a general policy argument that upholding the validity of Claim 13 will effectively allow for the patenting of any scientific principle or natural correlation by merely including a "test and correlate" claim similar to Claim 13 into a patent.⁶

A central issue brought to bear by LabCorp was that including scientific principles, such as those set forth in Claim 13 within patentable subject matter, would allow any person who discovers a new correlation a means to demand a royalty from any person or entity who thinks or tells others about the correlation. This in effect would discourage additional researchers from developing new methods or practical applications, which are based on the correlation, thus impeding future discovery and scientific research due to fear of incurring patent infringement liability.⁷

Respondent Metabolite argued that the Supreme

Court should dismiss the writ of certiorari on the grounds that the issue of 35 U.S.C. §101, subject matter patentability, was not raised in the lower court proceedings (although it noted that the LabCorp's answer asserted invalidity based on § 102 (novelty), § 103 (nonobviousness), and §112 paragraph 2 (definiteness). This led to a discussion (and possible disagreement among the Justices) as to whether the issue of subject matter patentability was adequately raised (e.g., by construing LabCorp's arguments broadly).

If the Supreme Court did find that this issue was adequately raised by LabCorp in its papers, then this case could have far-reaching implications not only in this case, but with respect to many patents that have been issued throughout recent years where an inherent or natural phenomena is the "heart" of a granted patent claim.

POSITIONS OF THIRD PARTIES

At the request of the Supreme Court, the Solicitor General filed an amicus brief urging the Supreme Court to deny the writ of certiorari. The Solicitor General believed that the 658 patent appeared to inappropriately claim "all substantial practical applications of the natural relationship," and that the record was not sufficiently developed in the lower court proceedings for the Supreme Court to make a determination on that issue.

An amicus brief was filed by Affymetrix, Inc., a supplier of commercial DNA microarrays. Affymetrix took the position that patent rights should not be granted on basic laws of nature because such rights would directly impede scientific progress. Affymetrix's interest in the matter stems from the fact that its business is primarily in the areas of DNA and gene expression analysis. Similar to the positions set forth by Lab Corp, Affymetrix argues that the correlation between a vitamin deficiency and elevated levels of an amino acid in the blood is a natural phenomenon that is not patentable subject matter under current law.

Similarly, in its amicus brief, the Public Patent Foundation took the position that the Federal Circuit had over-reached the current legal defined boundaries of patentable subject matter by allowing claims similar to Claim 13 of the 658 patent. In addition, the American Medical Association and the American Heart Association filed amicus briefs in favor of the petitioner, Lab Corp, arguing that Claim 13 improperly claims patent rights to a scientific principle and is overly broad because the method stated in Claim 13 is not limited to any particular method of testing homocysteine levels. On the other hand, the American Intellectual Property Law Association and the Federal Circuit Bar Association filed amicus briefs in favor of the positions set forth by respondent, Metabolite.

In its amicus brief, the Intellectual Property Owner's Association (IPO) did not align itself with either party in the underlying matter. Instead, the IPO argued that any ruling in this matter by the Supreme Court should not further limit

patentable subject matter under 35 USC § 101. The IPO argues that the requirements of novelty, nonobviousness, and description sufficiently protect against over-reaching patents, thus obviating the need to further restrict the scope of patentable subject matter.

Several members of the financial services industry (including IBM, AMEX, Bear Stearns, and Lehman Brothers) filed amicus briefs arguing that upholding the validity of Claim 13 of the 658 patent allows for the impermissible patenting of abstract ideas and mental thought processes, stemming from their collective concerns regarding the potential impact that affirming the lower court decision in this matter would have on the scope of allowable business method patents. Consequently, these parties advocate that patentable subject matter under 35 USC §101 should be restricted to inventions that involve technological contributions that are both physical and material in nature, thereby excluding abstract ideas from the scope of patentable subject matter.

DISCUSSION

During oral argument, Justice Kennedy noted that the Federal Circuit did not address the subject matter patentability issue, and Justice Scalia noted that it was not mentioned in LabCorp's petition to the Supreme Court. It was pointed out by counsel for LabCorp that this issue was raised in both the district court and Federal Circuit briefs, and that those briefs discussed numerous cases on claiming natural phenomena. On the other hand, Justice Breyer noted that LabCorp thought it obvious from the cases it cited and discussed that it was making a Section 101 subject matter challenge, and both Justice Breyer and Justice Souter noted the intersection between this issue and the definiteness issue (where the claim if construed broadly fails as covering unpatentable subject matter under §101 and if construed narrowly fails because it is indefinite). Under that reasoning, it is possible that Claim 13 could be construed narrowly such that claims are limited by the "assaying" language; it could also possibly be found to be indefinite, e.g., on the basis that the claim is unclear as to what tests outside of the natural phenomena would or wouldn't be covered by the claim.

Is this case similar to previous cases argued to the Supreme Court, such as *O'Reilly v. Morse*, 56 U.S. (15 How.) 62 (1853), where the Supreme Court rejected Samuel Morse's patent claim because it extended a telegraphy invention through the use of electromagnetism to all uses of electromagnetism, or is it more similar to *Dolbear v. Am. Bell Tel. Co.*, 126 U.S. 1 (1888), where a patent claim to voice transmissions using continuous undulating current was held to be not infringed by other uses of that undulating current?

As Justice Alito stated during the oral argument, a finding that Claim 13 was invalid under §101 for covering unpatentable subject matter, would call into question the validity of perhaps "thousands" of other patents. Certainly, one can imagine the

implications to diagnostic claims where a diagnosis is made by assaying a body fluid for the presence or absence of a substance, which indicates, e.g., a disease state. On the other hand, Metabolite was not taking the position that either the homocysteine/vitamin B relationship or the step of “correlating” this natural relationship was independently patentable. Rather, Metabolite took the position that the combination of the two steps (“assaying” and then “correlating”) into a practical application with concrete results was the heart of the patentable invention in that claim. The author notes that despite this argument, there is no “practical application” within the terminology of Claim 13 (the concrete result arguably being the determination of an elevated level of homocysteine). Rather, if that were the case, one would have expected to find additional language concerning the step of treating a patient (or not treating a patient) with a therapeutic agent for that disease state as the “practical result.”

Underlying many issues in the case is the simple fact that the 658 patent discloses only one particular assay method and is directed for the sole use of detecting vitamin deficiencies. For that reason, the Federal Circuit’s holding essentially gave Metabolite a monopoly on all homocysteine testing regardless of intended use of the results or the specific assay employed.

ACTION BY THE SUPREME COURT

On June 22, 2006, without providing any written opinion as to its reasons, the U.S. Supreme Court dismissed the writ as improvidently granted, thereby preserving the decision to uphold the validity of the ‘658 patent. Although having no precedential value, the dissent by Justice Breyer (joined by Justices Stevens and Souter) provides some insight as to the factors considered by three Justices of the Court: that “this case is not at the boundary” between the realm of patentable subject matter and non-patentable “natural phenomenon” subject matter, but rather “claim 13 as invalid no matter how narrowly one reasonable interprets the doctrine. There can be little doubt that the correlation between homocysteine and vitamin deficiency set forth in claim 13 is a natural phenomenon.”

Should the discovery of a single assay method to test for a correlation known in the art prevent others from developing better assay methods for the same test? That is the essence of patent claim draftsmanship, and the eternal fight between the patentee’s right to obtain broad patent claim coverage commensurate in scope with his contribution to that art, versus the desire of others to design around that claim and/or to improve the technology. That fight was not solved in the LabCorp litigation, and is unlikely to be resolved in the near future.

ACKNOWLEDGEMENT

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REFERENCES

1. The proper interpretation of the claims is typically considered in a pre-trial hearing conducted by the court, which is referred to as a “Markman Hearing” and is discussed in an article by this author that appeared in the January ‘06 issue of Drug Delivery Technology.
2. 35 U.S.C. §112, first paragraph, provides that the specification of a patent “...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.
3. 35 U.S.C. §112, first paragraph, provides that the specification of a patent “...shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354 (Fed. Cir. 2004).
5. 35 U.S.C. §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 therefor, subject to the conditions and requirements of this title.”
6. LabCorp also argued that Claim 13 also fails the definiteness, enablement, and written description requirements of 35 U.S.C. §112 paragraph f because neither the claim nor the specification of the 658 patent disclose the specific steps a person of ordinary skill in the art would use to “correlate” a particular homocysteine level to a particular vitamin deficiency.
7. LabCorp made the powerful argument that, according to the Federal Circuit’s interpretation of Claim 13, the Court finds that every doctor who orders a homocysteine test and looks at the result, regardless of how or why the test is done, automatically engages in the patented “correlating” step by merely thinking of the relationship between homocysteine and vitamin deficiency, and thus would infringe the patent.

BIOGRAPHY



Clifford M. Davidson, Esq. is a founding partner at Davidson, Davidson & Kappel, LLC, an Intellectual Property law firm with offices in New York City and Frankfurt, Germany. He counsels pharmaceutical clients in pharmaceutical patent-related matters, including patent prosecution, freedom to operate and infringement opinions, due diligence and tech-transfer, and litigation (including ex parte and inter partes proceedings worldwide). He has assisted specialty pharma and drug development companies to create significant patent portfolios, and the patents he has written and the patent portfolios he has created have been recognized as creating significant value for his clients. He has written patents covering virtually all areas of drug development, and has pioneered strategic patent focus on the pharmacokinetic profiles and the pharmacologic activity of drug/drug formulations. Mr. Davidson earned his BS in Pharmacy and his JD from Rutgers University and is a member of the New York and New Jersey Intellectual Property Law Associations, the American Pharmaceutical Association, and The Controlled Release Society. His area of expertise includes new chemical entities; new pharmaceutical formulations (including controlled-release oral dosage forms, injectables, transdermals, ophthalmics, inhalation, intranasal, sublingual, suppository, and implantation administration); new combinations of previously known drugs; new modes of administration of previously known drugs; method of treatment; pharmaceutical excipients; and methods of preparation.