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Supreme Court dismisses LabCorp appeal — personalized medicine, beware

Last month, the U.S. Supreme Court in *Laboratory Corp. of America v. Metabolite Laboratories* decided to dismiss LabCorp's appeal, saying that it should not have been granted review. However, the dissent in that case shows that it has far greater significance for intellectual property rights in the life sciences, particularly in the field of personalized medicine, which, broadly speaking, includes pharmacogenomics, pharmacogenetics, pharmacoproteomics, nutrigenomics, and diagnostics.

The case stems from U.S. Patent No. 4,940,658, based on the discovery that there was a relationship between elevated levels of total homocysteine, an amino acid, and a deficiency in either cobalamin (vitamin B12) or folate (folic acid). The claim at issue in this patent was Claim 13, which specifically related to a method of detecting the deficiency of B12 or folic acid in warm-blooded animals that comprised the steps of assaying a body fluid from a subject for elevated levels of total homocysteine and correlating an elevated level of such levels in the body fluid tested with a deficiency of either vitamin B12 or folic acid.

The patent at issue in this case was assigned to a patent management firm, Competitive Technologies, Inc., with Metabolite Laboratories handling distribution. They, in turn, initially sublicensed the patent to Laboratory Corporation of America (LabCorp), one of the largest diagnostic testing labs in the U.S. In 1998, LabCorp started using a new test developed by Abbott. Thereafter, Competitive Technologies and Metabolite Laboratories filed suit against LabCorp for infringement of the patent. In 2001, LabCorp lost in the trial court and was ordered to pay \$7.8 million in damages and attorney's fees. LabCorp appealed the case to the Court of Appeals for the Federal Circuit, the appellate court that reviews all patent cases from all the district courts in the country. The appeal contained the standard arguments, namely, that Claim 13 in the patent was invalid because it did not comply with 35 U.S.C. § 112 on grounds of indefiniteness, lack of written description, and lack of enablement, and that it was anticipated and/or obvious and, thus, invalid under 35 U.S.C. §§ 102 and 103. The Federal Circuit rejected those arguments and affirmed the trial court decision in 2004.

In requesting that the Supreme Court review this case (grant request for certiorari), LabCorp argued, for the first time, that the case was invalid under 35 U.S.C. § 101 because it was attempting to patent a natural phenomenon, which is not permitted under the patent laws. The Supreme Court initially agreed to hear the case. In June of this year, the majority of the court dismissed the case as "improvidently granted" without providing any further explanation. However, the dissent of three members of the court – Justices Breyer,



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Stevens, and Souter – indicates that the majority dismissed the case because the issue of the patent being in violation of 35 U.S.C. § 101 had not been brought up below.

The significance of the LabCorp case is that, after being routinely granted for years, these types of patents are now being questioned. Namely, these patents relate to the discovery that there is a different level of a molecule in people afflicted with a certain condition, as opposed to people not afflicted with that condition. Sometimes it's an elevated level of an amino acid or protein. In other cases, it can be a lower level. Indeed, there are certain instances where any major change in the level of the protein from the normal population indicates the problem. It is the ability to obtain intellectual property rights for these types of discoveries that has formed the basis for much of the personalized medicine field.

Accordingly, the dissent by three justices arguing that “[t]here can be little doubt that the correlation between homocysteine and vitamin deficiency set forth in Claim 13 is a natural phenomenon” shows an incredible lack of appreciation for the scientific process and for life sciences patents. In one sense, it can be argued that this occurred because there was not a full record developed below that truly explained that such discoveries are not observations of mere natural phenomena, as the dissenters believe. It can also be argued that legal arguments misled the dissenters. Others can take some comfort in the fact that the Supreme Court did nothing and, thus, the Federal Circuit’s decision stands. However, it is clear that the issue of whether a discovery in the life sciences area, particularly in the personalized medicine area, is entitled to IP protection or simply one trying to claim a “natural phenomenon” and, thus, is in violation of 35 U.S.C. § 101, is going to be raised in virtually every case until the Supreme Court ultimately deals with the subject.

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