

COLUMN

## Biotech patents under fire

What Supreme Court decisions say about threats to the progress of personalized medicine.

By Ronald I. Eisenstein and David S. Resnick

ON THE FACE OF IT, THE RECENT DECISION BY THE US SUPREME COURT

in *Laboratory Corp. of America v. Metabolite Laboratories* seems like a footnote. LabCorp was sued for patent infringement and lost. Upon appeal, the Supreme Court dismissed the case, saying that it should not have granted review. Open and shut, except that the dissent justices opened a can of worms that will be wiggling their way through the field of personalized medicine for years to come.

The case stems from US Patent No. 4,940,658, which is based on the discovery that there is a relationship between elevated levels of total homocysteine and a deficiency in either cobalamin (vitamin B12) or folate (folic acid). The claim focused on a method of detecting the deficiency of B12 or folic acid in warm-blooded animals, and using this in an assay for B12 or folic acid deficiency. The patent was assigned to the patent management firm Competitive Technologies, and to Metabolite Laboratories for distribution. They sublicensed the patent to LabCorp.

In 1998, LabCorp started using a new test, developed by Abbott, to measure the same deficiency. Competitive Technologies and Metabolite Laboratories filed suit for patent infringement. In 2001, LabCorp lost in trial court and was ordered to pay \$7.8 million in damages and attorney's fees. They appealed the case to the Court of Appeals for the Federal Circuit. Their appeal contained the standard arguments, namely that the patent was invalid because of indefiniteness, lack of written description, lack of enablement and was anticipated and/or obvious. The Federal Circuit rejected these arguments and in 2004 affirmed the trial court decision.

But when LabCorp requested that the Supreme Court review the case, they introduced a new argument: They said the patent was invalid because it was attempting to patent a natural phenomenon. The Supreme Court agreed to hear the case.

This past June, 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, Stevens, and Souter, indicates that the majority dismissed the case for a technicality – that the issue of the patent being for a natural phenomenon had not been brought up before. The three dissenting justices argued "[t]here can be little doubt that the correlation between homocysteine and vitamin deficiency set forth in claim 13 is a natural phenomenon."

This shows an incredible lack of appreciation for the scientific process and life science patents. In one sense, it can be argued that this occurred because there was not a full record developed by the patent owner in the district court trial that truly explained that such discoveries are not observations of mere natural phenomenon as the dissent believe. It is clear, however, that the natural-phenomenon argument will now be an issue raised when considering if a discovery in the life sciences, and particularly in the personalized medicine area, is entitled to IP protection. This will be brought up in virtually every case until the Supreme Court ultimately deals with the subject. Indeed, LabCorp might find itself defending the validity of a patent against someone making such an argument.

While courts are supposed to dispassionately rule on cases, judges, to some extent, reflect the world they live in. On one side, there are right-leaning antiscience groups arguing against certain technologies, and on the other, there are politically left groups arguing that patenting anything to do with living things is immoral. Biotech companies need to realize that the public relations battle may affect future court decisions. And as such, companies should be planning and implementing their public outreach now to decrease the risk of legal decisions that will be bad for the biotech business. ■

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Both the left and right of the Supreme Court are leading an assault on biotech IP.