wiley

ALERT

Federal Circuit Patent Bulletin: *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc., USA*

April 21, 2014

"[P]atentability may consider all of the characteristics possessed by the claimed invention, whenever those characteristics become manifest."

On April 21, 2014, in *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc., USA*, the U.S. Court of Appeals for the Federal Circuit (Newman,* Linn, Wallach) affirmed and remanded the district court's judgment entering the jury verdict that U.S. Patent No. 5,721,244, which related to the antihypertension drug combination of the angiotensin converting enzyme (ACE) inhibitor trandolapril and the calcium channel blocker verapamil hydrochloride marketed by Abbott Laboratories as Tarka®, was not invalid for obviousness under 35 U.S.C. § 103, and awarding $15,200,000 in lost profits and $803,514 in price erosion damages. The Federal Circuit stated:

Patent validity on the ground of obviousness is a question of law based on underlying facts. The factual components include the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of skill in the art, and any objective evidence of nonobviousness. "[O]bvious to try" may apply when "there are a finite number of identified, predictable solutions" to a known problem. [W]hen the path has been identified and "leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." [T]he identified path must "present a finite (and small in the context of the art) number of options easily traversed to show obviousness." [I]t would not be "obvious to try" when "the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful."

Glenmark argues that the inventors' selection of the double-ring ACE inhibitors for testing in combination with calcium antagonists is of itself evidence that it was obvious to try this combination. Patentable invention does not require that inventors work from ignorance. Technologic advance flows from knowledge, experience,

insight—perhaps hunch or curiosity. Patentability does not turn on how the invention was made, but on whether it would have been obvious to a person of ordinary skill in the field. [I]n the medical arts "potential solutions are less likely to be genuinely predictable," as compared with other arts . . . .

Glenmark also argues that later-discovered benefits cannot be considered in an obviousness analysis, here referring to the improved kidney and blood vessel function that were observed after the patent application was filed. That is incorrect; patentability may consider all of the characteristics possessed by the claimed invention, whenever those characteristics become manifest. [T]here was no prior knowledge that the combination of a double-ring ACE inhibitor with calcium antagonists would be longer lasting than the hypertension treatments at the time. The jury could reasonably have relied on the testimony of the Plaintiffs' expert, that persons skilled in the art in 1986 would not have predicted the longer-lasting hypertension control demonstrated by the double-ring structures of quinapril and trandolapril in combination with calcium antagonists, because of the widespread belief that double-ring inhibitors would not fit the pocket structure of the ACE. Although Glenmark disputed every aspect, there was substantial evidence to support findings that in turn support the verdict that obviousness had not been proved by clear and convincing evidence. The district court's review of the evidence and confirmation of the jury verdict manifests no error of law. The judgment that invalidity had not been proved is affirmed. . . .

Glenmark challenges the standing of Abbott Laboratories and Abbott Laboratories, Inc. (ALI) as co-plaintiffs in the instant suit. Glenmark argues that these United States companies do not have exclusive licenses to the'244 patent, as Glenmark states is required for entitlement to damages for their lost profits and price erosion due to infringement. It is not disputed that Sanofi-Aventis as the owner by assignment of the '244 patent, and Aventis Pharma as exclusive licensee of the '244 patent, have standing in this action. Aventis Pharma in turn granted the "irrevocable, sole and exclusive right" to Abbott GmbH to make, use, and sell the trandolapril-verapamil combination product under the '244 patent. Abbott Laboratories has since 2001 been the owner of the FDA-approved NDA for this product, and ALI is the exclusive United States distributor for Abbott Laboratories. . . .

The district court penetrated these complexities. The court's finding that any necessary licenses existed, expressly or impliedly, has not been shown to be incorrect in law or clearly erroneous in fact. . . . Here, Abbott Laboratories and ALI have fully exclusive rights in the United States. Although Glenmark argues that Abbott Laboratories' ownership of the NDA [(New Drug Application)] has no bearing on patent exclusivity, the issue before the district court was whether the Plaintiffs intended to grant exclusive rights to Abbott's United States companies, and did so grant. Abbott Laboratories' exclusive ownership of the NDA conforms to that intent, and is reflected in the entirety of the commercial relationships, as the district court recognized. . . . We affirm

that Abbott Laboratories and ALI have the exclusive rights to the Tarka® product in the United States [and] these United States entities have standing to participate in this suit and to recover damages for their injury due to Glenmark's infringement.