CLIENT ALERTS & INSIGHTS

Court Kills Patent For Failing to Enable Full Claim Scope

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Authors: Manish K. Mehta

On February 16, 2018, Judge Stark of the District of Delaware overturned the largest patent verdict in history. This extremely contentious patent infringement suit between Idenix Pharmaceuticals LLC ("Idenix"), a subsidiary of Merck & Co., and Gilead Sciences, Inc. ("Gilead") was stripped of its landmark status when Judge Stark granted-in-part Gilead's renewed motion for judgement as a matter of law ("JMOL"), overthrowing Idenix's jury verdict of $2.54 billion and finding Idenix's U.S. Patent No. 7,608,597 (the "'597 patent") invalid for lack of enablement under 35 U.S.C. § 112, first paragraph.[1]

This lawsuit began in 2013, when Idenix sued Gilead for infringement of U.S. Patent No. 6,914,054 (the "'054 patent") and the '597 patent in the United States District Court for the District of Massachusetts. Later, the case was transferred to the District of Delaware.

In 2003, Idenix filed the application that matured into the '597 patent, which was directed to a noteworthy modification of nucleosides, namely placement of a methyl group at the nucleoside's 2' up position, targeted to cure the Hepatitis C virus ("HCV").[2] NS5B polymerase was the key to its compound demonstrating effectiveness in the treatment of HCV.

Around the same time, Gilead likewise was developing nucleosides to treat HCV, which were sold under the brand names Sovaldi® and Harvoni®. Gilead's formulation included a methyl group at the 2' up position, however, and importantly, the compound also included a fluorine atom at the 2' down position. This formulation acted on HCV's NS5B polymerase.

The Court overturned the $2.54 billion jury award on February 16, 2018. As an initial matter, before addressing invalidity, the Court resolved multiple claim construction disputes. At trial, Idenix asserted infringement of, *inter alia*, independent claim 1 of the '597 patent, which read as follows:

A method for the treatment of a hepatitis C virus infection, comprising administering an effective amount of a purine or pyrimidine β-D-2'-methyl-ribofuranosyl nucleoside or a phosphate thereof, or a pharmaceutically acceptable salt or ester thereof.

The Court construed claim 1 to require both a structural limitation and a functional limitation, namely, "β-D-2'-methyl-ribofuranosyl nucleoside" (the "Structural Limitations"), and claim 1's preamble and its "effective amount" term (the "Functional Limitations"). In view of these two limitations, the Court found that the claims covered *only* a subset of nucleosides that met both the Structural Limitations *and* the Functional Limitations. The Court concluded that the accused compound fell within the scope of the claims. However, Gilead's specific compound, 2' methyl up 2' fluoro down, was not expressly disclosed in the specification of the '597 patent.

The Court next addressed whether the specification satisfied the enablement requirement under 35 U.S.C. § 112, first paragraph. The full scope of the claims (i.e., all of the compounds that fall within

the ambit of the claims) must be enabled from the perspective of a person of ordinary skill in the art ("POSA"). The Court, here, found that this statutory requirement was not met.

The Court concluded that the scope of the claims, even when narrowly construed, encompassed "millions or at least many, many thousands" of potential compounds. This would leave "a POSA with a very large (and unspecified) number of compounds, measured at least in the thousands. Both numbers - the billions and the at least many thousands - are relevant to the enablement analysis."[3] With the specification of the '597 patent offering "only a little bit of guidance" as to how to identify the compounds that met *both* Limitations, the Court concluded that no reasonable factfinder would have found that the '597 patent enabled all of the embodiments that were encompassed by the scope of the claims. *Idenix Pharm. LLC,* 2018 WL 922125, at *25 n.13. Without more guidance from the specification, "a POSA [would be left] asking herself the crucial question: which of the compounds meeting the [] Structural Limitations also satisfy the Functional Limitations? A reasonable factfinder could only conclude that the patent fails to provide this necessary information." *Id.* at *21.[4]

This was true notwithstanding the sophistication of a POSA, who would be fully capable of identifying subsets of potentially interesting arrangements from countless compound variations. Further, the Court held that a reasonable factfinder would have found that a great deal of time and effort would have been required if a POSA wanted to synthesize each and every compound that met the Structural Limitations, including the 2' methyl up 2' fluoro down embodiment. Similarly, the Court discussed that a reasonable jury would have found it necessary to screen compounds meeting the Structural Limitations to determine if they also met the Functional Limitations. The screening would have taken time and effort, above and beyond the time and effort required to synthesize the compounds.

Accordingly, for the foregoing reasons, the court found the '597 patent invalid for lack of enablement and granted Gilead's renewed JMOL.

For more information on this topic, please contact a member of Benesch's Intellectual Property/3iP Practice Group.

Manish Mehta at mmehta@beneschlaw.com or 312.212.4953.

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[1] *Idenix Pharm. LLC v. Gilead Scis., Inc.,* No. CV 14-846-LPS, 2018 WL 922125, at *1 (D. Del. 2018).

[2] The '597 patent claims priority to U.S. provisional application no. 60/206,585 filed on May 23, 2000. Further, the '597 patent is a continuation of U.S. Pat. No. 6,914,054 (the "'054 patent") filed on May 23, 2001.

[3] The Court mentions, here, "Refined Structural Limitations." Throughout the Opinion, this refers to the "at least many thousands" of compounds, among the billions, on which a POSA, relying on her experience and "common sense," would focus in attempting to practice the patent. For simplicity's sake, this summary refers to the compounds as "Structural Limitations."

[4] The citation relates to the Jury Instruction on Enablement, including: "A patent specification must contain a sufficiently full and clear description of how to make and use the full scope of the claimed

invention. . . . In order to be enabling, the patent must permit persons having ordinary skill in the field of technology to make and use the full scope of the claimed invention at the time of original filing without having to conduct undue experimentation."