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Patents

AbbVie's Patents Asserted Against Centocor's Stelara Psoriasis Treatment Ruled Invalid

A patent interference decision at the Patent and Trademark Office is not final when the loser there files a civil action contesting the decision, the U.S. Court of Appeals for the Federal Circuit ruled on July 1 (*AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, Fed. Cir., No. 2013-1338, 7/1/14).

That decision allowed Centocor Biologics LLC to add in district court arguments for the invalidity of patents owned by AbbVie Deutschland GmbH, ones that Centocor did not present before the PTO. The appeals court now affirmed a jury finding of invalidity for lack of adequate written description under 35 U.S.C. § 112, ¶1.

The court's written description analysis was particularly relevant to patents in the life sciences industries, building on the en banc Federal Circuit's 2010 *Ariad* decision.

Interference Loss Leads to Infringement Charge. AbbVie holds patents (U.S. Patent 6,914,128 and 7,504,485) directed to fully human antibodies that bind to and neutralize the activity of human interleukin 12 (IL-12). Overproduction of IL-12 can cause psoriasis and rheumatoid arthritis.

Centocor markets the Stelara IL-12 antibody as a psoriasis treatment. It filed a patent application (U.S. Patent Application 10/912,994) intended to provoke an interference with the '128 patent. The Board of Patent Appeals and Interferences awarded priority to AbbVie and rejected Centocor's contention that claims of the '128 patent were invalid for obviousness.

Four days later, AbbVie sued Centocor—related subsidiary Centocor Ortho Biotech changed its name to Janssen Biotech Inc.—in the U.S. District Court for the District of Massachusetts, alleging patent infringement by Stelara. Centocor's district court action appealing the BPAI decision, under 35 U.S.C. § 146, was transferred to Massachusetts and the cases were consolidated.

Judge F. Dennis Saylor IV denied AbbVie's motion that Centocor was collaterally estopped from challenging validity after the interference proceeding.

However, a jury found each of the asserted claims invalid for inadequate written description, lack of enablement and obviousness. Saylor denied AbbVie's post-trial motions and also entered judgment of invalidity in the appeal of the interference result. AbbVie appealed.

No Collateral Estoppel. Judge Alan D. Lourie wrote the court's opinion, addressing the collateral estoppel question first. It agreed with Centocor that the BPAI's decision was not final based on the text of Section 146.

The civil action path is an alternative to contesting the board's decision by appeal to the Federal Circuit, under Section 141. An appellant relies on the record before the board in the latter, but Section 146 allows "the further cross-examination of the witnesses as the court imposes, without prejudice to the right of the parties to take further testimony."

The court thus said, "Because a district court can make a *de novo* determination of facts upon the submission of new evidence, a Board decision that is reviewed under § 146 is not a 'binding final judgment' to preclude a losing party from litigating the same or related issues in a parallel proceeding."

Patent interferences expert Charles L. Gholz of Oblon, Spivak, McClelland, Maier & Neustadt LLP, Alexandria, Va., commented to Bloomberg BNA on two interesting aspects of this part of the court's decision.

First, Gholz said, "It is black-letter law that a plaintiff in a Section 146 action cannot raise in that action an issue that it didn't raise in the administrative phase of the interference." Centocor only pursued the obviousness challenge in the interference, so Gholz said, "It could be argued that Centocor's failure to go through with motions for judgments of unpatentability based on written description, enablement, and definiteness meant that the board's judgment was indeed final on those issues."

Gholz also questioned why the Federal Circuit specifically left open the question of whether estoppel would apply had Centocor taken the Section 141 route instead. He said, ''There is a great deal of law (unmentioned by either the majority or the concurrence) on the subject of whether a decision at the trial level in a first action is entitled to collateral estoppel effect in a second action during the pendency of an appeal from the decision in the first action.''

***Ariad* Written Description Requirement Enhanced.** The issue related to the written description requirement derived from the nature of the asserted claims to IL-12, in terms of its ''binding and neutralizing characteristics, rather than by structure.''

The court distinguished between species ''representing the genus throughout its scope'' and those that ''only abide in a corner of the genus,'' analogizing the genus to a plot of land.

The patent specification disclosed a family of structurally similar antibodies derived from a lead composition AbbVie had discovered after considerable narrowing of a wide range of human DNA fragments. Centocor's written description challenge was thus that the functional claiming would cover an entire genus of which the lead composition was not representative.

The court agreed with Centocor, relying heavily on its decision in *Ariad Pharm. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 2010 BL 62410, 94 U.S.P.Q.2d 1161 (Fed. Cir. 2010) (en banc) (56 PTD, 3/25/10).

After quoting several passages from that case and noting AbbVie's concession that structural features of the genus were not disclosed, the court here said that the question reduced to ''whether the patents sufficiently otherwise describe representative species to support the entire genus.''

The court distinguished between species ''representing the genus throughout its scope'' and those that ''only abide in a corner of the genus,'' analogizing the genus to a plot of land. Here, the court said, the latter was true, as ''the jury heard ample evidence that AbbVie's patents only describe one type of structurally similar antibodies and that those antibodies are not representative of the full variety or scope of the genus.''

In particular, the court noted, Stelara falls within the scope of the claim, and even AbbVie acknowledged that Stelara's structure was significantly different from AbbVie's lead structure.

The court summed up its holding here with a paraphrase of another holding in *Ariad*:

> Functionally defined genus claims can be inherently vulnerable to invalidity challenge for lack of written description support, especially in technology fields that are highly unpredictable, where it is difficult to establish a correlation between structure and function for the whole genus or to predict what would be covered by the functionally claimed genus.

The court thus affirmed the judgment of invalidity on written description grounds.

Questions on Evidence, Jury Instructions. Evidentiary rulings and jury instructions were also at issue on appeal.

AbbVie contested the district court's decision to exclude the interference file history from evidence. But since the court's affirmance related to the written description challenge, and that was not at issue before the BPAI, the court ruled that AbbVie's substantive rights were not affected.

Finally, AbbVie objected to a jury instruction that ''new information presented at trial that was not considered by the PTO would make it easier for Centocor to carry its burden of proving invalidity by clear and convincing evidence.''

The court acknowledged that its prior jurisprudence allowing a similar instruction applied to anticipation and obviousness challenges, where new prior art was added at trial. However, it cited *Microsoft Corp. v. i4i LP*, 131 S. Ct. 2238, 2011 BL 151820, 98 U.S.P.Q.2d 1857 (2011) (112 PTD, 6/10/11), for language that appeared to give a broader leeway to phrasing the burden standard in that way.

And the court in any case again concluded that the instruction was not ''sufficiently prejudicial to warrant a new trial.''

Judge Raymond T. Chen joined the opinion in full.

Concurrence: Obviousness Result Was Enough. Judge Kathleen M. O'Malley concurred in the judgment but argued that the appeal was resolved so long as the jury instruction was proper. AbbVie had not appealed the obviousness finding under that instruction.

In the court's opinion, Lourie acknowledged in a footnote that ''we could affirm [the district] court's obviousness holding and proceed no further.'' However, he said, ''as an 'inferior' court, we are well-advised to review more than one issue raised before us on appeal, lest higher authority find error in any basis for a more limited review.''

He further justified the attention given the written description issue because it ''constituted the principal basis of AbbVie's appeal to this court.''

William F. Lee of Wilmer Cutler Pickering Hale and Dorr LLP, Boston, Massachusetts, represented AbbVie. Dianne B. Elderkin of Akin Gump Strauss Hauer & Feld LLP, Philadelphia, represented Centocor.

BY TONY DUTRA

Text is available at http://www.bloomberglaw.com/public/document/AbbVie_Deutschland_GmbH__Co_v_Janssen_Biotech_Inc_Docket_No_13013.

Gholz is a member of this journal's advisory board.

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