

Immunex Faces Skeptical Fed. Circ. In Antibody Patent Fight

By Britain Eakin

Law360 (August 5, 2020, 8:46 PM EDT) -- A Federal Circuit panel appeared skeptical Wednesday that the Patent Trial and Appeal Board ignored vital evidence in construing a key claim term to invalidate an Immunex antibody patent at the behest of Sanofi-Aventis, suggesting that evidence supports the board's claim construction.

U.S. Circuit Judge Richard G. Taranto said there is material in the patent's written description that "very strongly suggests" the board's claim construction of the term, "human antibodies," was not wrong.

Immunex Corp. attorney Eldora Ellison of Sterne Kessler Goldstein & Fox PLLC countered that the board erred by disregarding how a skilled artisan would understand the term along with an amendment narrowing the patent to human-only antibodies, and so wrongly determined that the term encompasses partially human antibodies.

But Judge Taranto suggested the record is ambiguous. In the absence of anything "quite clear to the contrary," substantial evidence seems to support the board's determination that the term includes partially human antibodies, he said.

"Neither the prosecution history nor the extrinsic evidence is clear," Judge Taranto said.

U.S. Circuit Judge Jimmie V. Reyna also chimed in, suggesting the board found nothing in the amendment of the patent that clearly intended to limit the claims to only human antibodies.

Ellison said the board's error rested on a misunderstanding that there was overlap among terms in the patent's written description — partially human, humanized and chimeric antibodies — and so the board determined they might describe the same antibody. But Ellison said that conclusion was wrong because even if they overlap, there is no overlap with fully human antibodies. To support that argument, Ellison noted that during amendment, Immunex canceled a dependent claim that encompassed the non-fully human antibody terms.

During Wednesday's hearing, Sanofi-Aventis U.S. LLC attorney Lauren Fornarotto of McKool Smith PC told the panel that Immunex's cancellation of the dependent claim didn't rise "to the level of a clear and unambiguous disclaimer" of partially human antibodies. Even after the amendment, Fornarotto said, the patent examiner stated the claims still include "humanized antibodies," which she said are partially human.

"It's important to note that the only scope that Immunex gave up here was nonhuman antibodies," Fornarotto said.

Immunex's patent covers methods for treating inflammatory disorders like arthritis, dermatitis and asthma. Amgen unit Immunex sued Sanofi for infringement in April 2017, several weeks after Sanofi — in anticipation of Immunex's suit — sued for a declaratory judgment that its eczema drug Dupixent doesn't infringe. The board agreed to review the patent the following year, invalidating it in February last year, with the appeal following.

The board also grappled Wednesday with what claim construction standard to use. The PTAB applied the broadest reasonable interpretation standard, which it used prior to a rule change in 2018 that switched over to the so-called Phillips standard used in district court.

In April, Immunex informed the appeals court that the U.S. Patent and Trademark Office had accepted a terminal disclaimer surrendering the remaining term of the patent. Since the patent expired during the appeal, Immunex argued that the appeals court is now required to use the Phillips standard for claim construction.

In the parallel litigation, which has been paused pending resolution of the appeal, the district court construed the term in Immunex's favor to mean fully human.

But Sanofi attorney Fornarotto urged the board to reject Immunex's belated attempt at a claim construction do-over, an argument that got backing from the USPTO, which intervened in the case. USPTO in-house counsel Frances Lynch told the panel it should apply the broadest reasonable interpretation standard since Immunex forced expiration of the patent after the PTAB reached its decision.

"Because Immunex's terminal disclaimer is not part of the record on appeal, this court shouldn't give it any effect," Lynch said.

The patent-at-issue is U.S. Patent No. 8,679,487.

U.S. Circuit Judges Sharon Prost, Jimmie V. Reyna and Richard G. Taranto sat on the panel for the Federal Circuit.

Immunex is represented by Eldora Ellison of Sterne Kessler Goldstein & Fox PLLC.

Sanofi-Aventis is represented by Lauren Fornarotto of McKool Smith PC.

The U.S. Patent and Trademark Office is represented in-house by Frances Lynch.

The cases are Immunex Corporation v. Sanofi-Aventis U.S. LLC, case numbers 19-1749 and 19-1777, before the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Dorothy Atkins and Dani Kass. Editing by Aaron Pelc.