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Fed. Circ. Backs Sanofi, Regeneron PTAB Win Over Amgen

By **Ryan Davis**

Law360 (October 13, 2020, 7:33 PM EDT) -- The Federal Circuit on Tuesday upheld a Patent Trial and Appeal Board decision invalidating an Amgen unit's patent on treating inflammatory disorders, in a win for Sanofi and Regeneron, whose eczema and asthma treatment Dupixent was accused of infringement.

The appeals court rejected an argument by Amgen's Immunex subsidiary that the PTAB's inter partes review decision was based on an incorrect holding that in the context of the patent, the phrase "human antibodies" can refer to those that are only partially human. The Federal Circuit said the evidence shows the board got it right.

The court said in its precedential opinion that among other evidence, the written description of Immunex's patent "makes clear that 'human antibodies' is a broad category encompassing both partially and completely human antibodies."

The board therefore did not err in finding that every claim of Immunex's patent was obvious in view of prior art that describes "humanized" antibodies that are partially human and partially derived from mice, the court concluded.

The court used a canine analogy to illustrate its conclusion: "'brown dogs' plainly include 'partially brown' dogs, such as a mostly brown dog with a white spot."

Sanofi and Regeneron said in a joint statement Tuesday that they are pleased with the court's decision. The companies collaborated to develop and commercialize Dupixent, which had global sales of $2.3 billion in 2019, according to Regeneron's annual report.

"It has been our longstanding belief that Immunex's asserted patent claims are invalid, and the decision by the Federal Circuit confirms that the law and facts support our position," they said.

A representative of Amgen said the company had no comment on the decision.

Immunex sued Sanofi and Regeneron in the Central District of California in 2017, alleging that Dupixent infringes a single patent. The defendants challenged that patent in an inter partes review, and the infringement case was stayed pending the outcome of the PTAB case.

Immunex's patent is directed to antibodies that can treat inflammatory disorders like arthritis, asthma and dermatitis, and describes an "isolated human antibody."

The Federal Circuit's opinion explained that early therapeutic antibody development used antibodies generated by mice, but they caused harmful immune reactions in humans. Antibodies were therefore developed that were either fully human or "humanized," mostly human with some nonhuman components.

The case hinged on whether the PTAB was correct to construe the phrase "human antibody" in the patent to include humanized antibodies, and to conclude that Immunex's patent is obvious in view of them.

While Immunex said at arguments in August that the phase can only mean antibodies that are fully human, the Federal Circuit said that evidence from the patent itself "supports the correctness of the board's construction."

For instance, the patent's written description "repeatedly clarifies" that some "human antibodies" are "fully human," and that would not be necessary if "human antibodies" were understood to be fully human, the court said.

Immunex had also argued that the board did not adequately consult so-called extrinsic evidence it submitted, like expert testimony and journal articles, that it said showed "human antibodies" refers to those that are fully human.

The Federal Circuit said such evidence can be useful if the patent itself is equivocal, but in this case, the patent is clear that human antibodies can include those that are partially human, and that trumps any conflicting extrinsic evidence.

While such evidence "may sometimes illuminate a well-understood technical meaning, that does not mean that litigants can introduce ambiguity in a way that disregards language usage in the patent itself," the court said.

The Federal Circuit also said that the PTAB did not err by reaching a different claim construction than the district court in the underlying case, which held that "human antibodies" refers only to those that are fully human.

The appeals court rejected Immunex's argument that the PTAB had to give a thorough explanation of why it interpreted the claims differently, saying that the board "is not generally bound by a previous judicial construction."

"The board's opinion was sufficiently detailed to permit meaningful appellate review," the court said. "We conclude that the board did not err by not saying more."

Finally, the Federal Circuit rejected Immunex's argument that the claims of the patent should be construed under the same narrow claim construction standard as the district court because the patent expired in May.

The Federal Circuit noted that the expiration occurred only because Immunex "abruptly" gave up the remainder of the patent term after the appeal was briefed. It said it would thus refuse to consider the impact of that move.

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, David Holman, David Roadcap and Jon Wright of Sterne Kessler Goldstein & Fox PLLC.

Sanofi-Aventis, Genzyme and Regeneron are represented by Lauren Fornarotto, Mike McKool, Eric Hansen, John Garvish, Joel Thollander, Geoffrey Smith and Matthew Cameron of McKool Smith PC, and George Hicks, Nathan Mammen and Noah Frank of Kirkland & Ellis LLP.

The U.S. Patent and Trademark Office is represented by Frances Lynch, Sarah Craven, Thomas Krause and Farheena Rasheed of the agency's solicitor's office.

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

The underlying infringement case is Immunex Corp. v. Sanofi, case number 2:17-cv-02613, in the U.S. District Court for the Southern District of California.

-- Additional reporting by Britain Eakin. Editing by Abbie Sarfo.