

PTAB Nixes Patent Claims UPenn Said Erbitux Infringed

By **Matthew Bultman**

Law360, New York (July 14, 2017, 3:27 PM EDT) -- The Patent Trial and Appeal Board invalidated claims in a University of Pennsylvania patent on a tumor treatment Thursday, handing a win to Eli Lilly Co., which faced allegations that its cancer drug Erbitux infringed the patent.

The board, in a final decision, said Lilly persuasively showed each of the challenged claims in the UPenn patent were invalid because they would have been obvious based on earlier scientific articles. Lilly challenged the patent after it was sued in 2015 for infringement.

Erbitux, which is used to treat cancer in the colon, head and neck, is among the world's best-selling cancer drugs, generating more than \$687 million in revenue in 2016. Bristol-Myers Squibb Co. sold Erbitux in the U.S. for more than a decade but turned its North American rights over to Lilly in 2015.

Representatives for UPenn and Lilly could not immediately be reached for comment.

UPenn filed a lawsuit against Bristol-Myers and Lilly, along with Lilly's ImClone unit, which initially developed Erbitux, in Pennsylvania federal court in November 2015. The Ivy League university claimed the drug infringed a patent it owns that covers a method of treating tumors.

The lawsuit was put on hold last year after the PTAB agreed to examine the patent in inter partes review. According to the district court's order, the review encompassed all the claims involved in the infringement case, save for a handful the court had already found were invalid.

As part of its defense at the PTAB, UPenn went after the experts Lilly used to support its invalidity arguments, contending they "lack both the knowledge required to opine as a skilled artisan" and lacked "the candor mandated by these proceedings."

It noted, for example, that one expert admitted to not understanding "inherency" as used in patent law.

As explained in a 2013 Biotechnology Law Report article, the term "refers to a determination of whether a characteristic, property, or feature recited in a claim that is not explicitly taught by the prior art, would have necessarily been present in the teachings of the prior art."

But the PTAB seemed unbothered by this disclosure, saying UPenn "does not cite any legal authority indicating that understanding patent law terms of art is a requirement for qualifying a scientific or technical expert."

Agreeing with Lilly that the challenged claims were obvious, the board also rejected UPenn's argument that the patented tumor treatment produced "unexpected results." It said, in part, that this wasn't supported by evidence, like expert testimony, and amounted to "attorney argument."

"[W]e find that the secondary considerations do not weigh in favor of a finding of nonobviousness of the challenged claims," the board wrote.

UPenn had filed a motion seeking to amend certain patent claims in the event the board ruled against it in the review. In order to secure a claim amendment, a patent owner must show that the substitute claims are patentable.

The board said UPenn had not done so.

"We agree with petitioner that the proposed substitute claims are unpatentable as having been obvious over the prior art cited in the petition," it wrote.

The patent at issue is U.S. Patent No. 7,625,558.

Lilly is represented by Andrea Reister and Enrique Longton of Covington & Burling LLP.

UPenn is represented by Bonnie McLeod, Fraser Brown and Michael Tuscan of Cooley LLP.

The case is Eli Lilly & Co. v. The Trustees of the University of Pennsylvania, case number IPR2016-00458, before the Patent Trial and Appeal Board.

--Editing by Jack Karp.