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Federal Circuit Reverses PTAB Finding Tarceva® Method of Treatment Claims Invalid for Lack of Reasonable Expectation of Success Based on over 99.5% Failure Rate among Treatment Candidates

Article By
Peter J. Cuomo
Joseph D. Rutkowski
Mintz
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In a precedential opinion on October 4, 2019, the United States Court of Appeals for the Federal Circuit, in *OSI Pharmaceuticals v. Apotex*, No. 2018-1925, reversed the Board's Final Written Decision in an *inter partes* review ("IPR") finding that claims of United States Patent No. 6,900,221 (the "'221 patent") were invalid as obvious. The Federal Circuit panel held on appeal that the prior art relied upon by the Patent Trial and Appeal Board ("PTAB") failed to sufficiently support its finding that a person of

ordinary skill in the art would have had a reasonable likelihood of success of achieving the claimed invention – a method of using erlotinib (marketed by OSI under the name Tarceva®) to treat non-small cell lung cancer ("NSCLC") in a mammal. In so ruling, the court relied on the highly unpredictable nature of NSCLC cancer treatment and a failure rate of over 99.5% for NSCLC treatments entering Phase II clinical trials at the time of invention.

On September 2, 2015, OSI had filed a Hatch-Waxman patent infringement suit against Apotex, alleging that Apotex's generic version of Tarceva® will infringe one or more claims of the '221 patent. *OSI Pharmaceuticals v. Apotex*, No. 15-cv-00772 (D. Del.). On June 28, 2016, Apotex filed a petition for IPR (IPR2016-01284) asserting that claims 44-47 and 53 of the '221 patent are invalid as being obvious or anticipated by the prior art. The Delaware action was stayed pending resolution of the IPR proceeding. The PTAB instituted review and, in January 2018, the Board found the challenged claims invalid as obvious over a prior art combination of a patent for treatment of hyperproliferative diseases, such as cancers ("Schnur"), a review article on anticancer drugs and growth factor signaling ("Gibbs"), and OSI's 1998 10-K filing. The PTAB based its finding on Schnur disclosing all claimed elements except the treatment of NSCLC and that Gibbs and the 10-K filing provided a reasonable expectation of success in using erlotinib to treat NSCLC.

First, the Court found that the PTAB erroneously read the Gibbs reference as supporting erlotinib's anti-cancer activity. As a review article, Gibbs did not include first-hand research and instead relied on previously cited references to frame its conclusions. But the two references cited in the portion of Gibbs that the PTAB relied on made no reference to using erlotinib to treat NSCLC. Moreover, the PTAB improperly disregarded a declaration submitted by the author, Dr. Gibbs, stating that he was unaware of any publication demonstrating erlotinib's effect on NSCLC at the time he wrote the article. Thus, the Court found that the PTAB erred by failing to consider both Dr. Gibbs' declaration and the lack of support within the references Gibbs relied on.

Second, the Federal Circuit held that the PTAB's finding of a reasonable expectation of success was not supported by substantial evidence in light of the highly unpredictable field of NSCLC treatment. None of the cited references contained any data or promising information regarding erlotinib's efficacy in treating NSCLC. The Court found the lack of any efficacy data critical in light of the unpredictable nature of treating NSCLC. Specifically, the Court relied on the fact that over 99.5% of drugs for treatment of NSCLC failed Phase II clinical trials between 1990 and 2005, a period including the time of '221 patent invention. And that failure rate did not even include the drug candidates that failed before or during preclinical or Phase I testing. Based on these data, the Court concluded that "the only reasonable expectation at the time of the invention was failure, not success."

While the Federal Circuit made clear that efficacy data is not always required to establish a reasonable expectation of success nor is an "absolute predictability of success," the opinion provides a reminder against applying hindsight to frame a reasonable expectation of success in a highly unpredictable field with a high failure rate, like the NSCLC treatment at issue.

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