Alexander Lutzky in IP Litigator: Practice Areas: Patent Litigation

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PRACTICES Intellectual Property, Patent Litigation

Did the Federal Circuit Just Raise the Evidentiary Bar for Establishing Obviousness?

According to the panel in *OSI Pharmaceuticals, LLC v. Apotex, Inc.*, Slip Op. No. 2018-1925 (Fed. Cir. Oct. 4, 2019), the answer to the question posed in this article's title is a solid no. Considering the opinion's precedential nature and the facts in the case, the Federal Circuit, however, may have just given patentees extra ammunition to defeat an obviousness challenge on evidentiary grounds.

The Federal Circuit analyzed whether certain pharmaceutical method claims related to a treatment for lung cancer were obvious and concluded that the lack of efficacy data in asserted prior art showed a person of ordinary skill would not have a reasonable expectation of success in applying their teachings. This holding reversed an obviousness determination by the PTAB in a preceding IPR of the patent at issue, and shows that for challengers mounting an obviousness challenge, prior art containing data-based evidence may be needed to be successful, particularly if the patent being targeted is in the pharmaceutical or chemical arts.

Technical and Procedural Background

Patentee OSI Pharmaceuticals, LLC (OSI) owns U.S. Patent 6,900,221 (the '221 patent), which it filed in November of 2000. Claims 44-46 and 53 of the '221 patent are directed to methods of treating Non-Small Cell Lung Cancer (NSCLC) with a chemical compound known as "erlotinib." By the end of the late 1990s, NSCLC was the leading cause of cancer deaths in the U.S., and existing therapies, particularly chemotherapy, were inadequate.

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