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Federal Circuit Decision Clarifies When an ANDA Filer May Appeal an Adverse IPR Ruling

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At issue in *Amerigen* was UCB's '650 Patent, which relates to a urinary incontinence drug that UCB's licensee, Pfizer, sells under the brand name Toviaz. The '650 Patent expires in 2022 and is included in the FDA's "Orange Book" entry for Toviaz, which lists all the patents covering the drug. Amerigen filed an ANDA for a competing generic version of Toviaz. In accordance with the requirements of the Hatch-Waxman Act, Amerigen included in its ANDA a "Paragraph IV Certification," i.e., a declaration averring that its new drug would not infringe any of the patents on the Toviaz Orange Book entry, and that those patents are invalid or otherwise unenforceable in any event. UCB and Pfizer subsequently sued Amerigen for infringement in Delaware. The district court eventually held the '650 Patent not invalid and infringed. As a result, Amerigen was barred from obtaining FDA approval, and therefore, could not launch its new drug until after the '650 patent expired in 2022. The decision effectively foreclosed Amerigen from ever infringing the '650 patent

However, Amerigen also petitioned for *inter partes* review of the '650 Patent. The Board, after instituting review on two obviousness grounds, ultimately ruled that the '650 Patent is not invalid as obvious and denied the petition. Amerigen's appeal followed. On appeal, UCB challenged whether Amerigen possessed Article III standing given that the FDA would not approve its product before expiration of the '650 patent. According to UCB, without the possibility of infringement, no justiciable controversy existed between the parties.

The Federal Circuit disagreed. The court highlighted Amerigen's factual representations that the FDA already tentatively approved its ANDA, and that its generic drug product would be

ready for commercial sale in 2019, three years before the '650 Patent expires. Relying on these representations (which it accepted as true for purposes of its standing analysis), the court reasoned that the '650 Patent, unless invalidated, would delay Amerigen's new drug launch by three years. But if the '650 Patent were to be declared invalid before 2022, it would be removed from the Toviaz Orange Book entry, and Amerigen could "launch its competing product substantially earlier than it otherwise could." The court concluded that "Amerigen has a concrete, economic interest in the sales of its tentatively approved drug obstructed by the listing of the '650 Patent [in the Orange Book], and has thereby demonstrated a controversy 'of sufficient immediacy and reality' for Article III standing."

The Court thus held that the threatened harm underpinning Amerigen's standing stemmed not from any risk of incurring infringement liability, but rather from "the mere *listing* of the '650 patent in the Orange Book." As the court explained, Amerigen's inability to launch its new drug because of the Orange Book listing constituted a "concrete commercial injury redressable [in] court."

Practice tip:

Although Amerigen ultimately lost the appeal (since the Federal Circuit upheld the Board's conclusions on obviousness and affirmed the '650 Patent's validity), Amerigen still was able to obtain appellate review of a patent that it could never incur liability for infringing, and that a district court already had held enforceable in a separate case. Going forward, parties should be aware that standing may exist to appeal a decision from the Board even if a prior activity, such as a district court litigation, has removed the possibility of infringement liability. The key is whether a party can demonstrate a controversy of sufficient immediacy that is traceable to the existence of a particular patent and redressable by the court.

Amerigen Pharmaceuticals Limited v. UCB Pharma GMBH, No. 2017-2596 (Fed. Cir. Jan. 11, 2019) (JJ Lourie, Chen, Stoll)

Categories

Federal Circuit | Patent Trial & Appeal Board | Infringement | Obviousness | Pharmaceuticals | Inter Partes Review