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Declaratory Judgment of Non-Infringement of a Disclaimed Patent Warranted in Hatch-Waxman

Article By:

Mandy H. Kim

Addressing the issue of subject matter jurisdiction in Hatch-Waxman litigation, the U.S. Court of Appeals for the Federal Circuit reversed a district court's dismissal for lack of case or controversy of an action seeking declaratory judgment of non-infringement with respect to a disclaimed patent. The Federal Circuit also reversed the district court's denial of the first *Abbreviated New Drug Application (ANDA)* filer's motion to intervene. ***Apotex Inc. v. Daiichi Sankyo, Inc***., Case Nos. 14-1282, -1291 (Fed. Cir., Mar. 31, 2015) (Taranto, J.).

Daiichi listed two patents in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* publication (Orange Book) in seeking FDA approval of its New Drug Application (NDA) for ***Benicar®***, a treatment for hypertension. One of the patents covered the active ingredient of the drug, olmesartan medoxomil, and another covered methods of treatment. Mylan was the first to file an ANDA with the FDA to market generic olmesartan medoxomil. In 2006, after receiving notice of Mylan's paragraph IV certification, Daiichi disclaimed the method of treatment patent and sued Mylan for infringing the drug patent. After a full trial, the district court upheld validity of the Daiichi's patent and entered judgment of infringement against Mylan. The Federal Circuit affirmed, thereby presenting Mylan with an earliest date of market entry of October 2016, six months after the expiration date of the Daiichi patent.

In June 2012, Apotex filed its own ANDA for *generic olmesartan medoxomil,* including a paragraph III certification stating that the Daiichi patent is valid and that Apotex's product would infringe, and a paragraph IV certification that Apotex's product would not infringe the method patent. Apotex also brought a declaratory judgment action against Daiichi seeking a declaration that it would not infringe the method patent. Mylan moved to intervene, and both it and Daiichi moved to dismiss for lack of a case or controversy because non-infringement of the method patent would be indisputable as a matter of law in view of the Daiichi patent disclaimer. The district court granted Daiichi's motion and denied Mylan's motion to intervene as moot. Apotex appealed, and Mylan cross-appealed the denial of its motion to intervene.

In reversing the district court, the Federal Circuit explained that the case presented a "substantial controversy, between parties having adverse legal interests, of a sufficient immediacy and reality to warrant the issuance of a declaratory judgment." According to the Federal Circuit, the patent disclaimer did not resolve adversity between the parties because the "patent disclaimer eliminates

one, but only one, potential barrier to Apotex's ability to make sales. The *listing* of the patent, with its current consequence of preventing FDA approval during Mylan's presumptive exclusivity period, is another [barrier], and the parties have adverse concrete interests in the truncation or preservation of that period." The Court also rejected Daiichi's argument that any delayed entry of Apotex would not be "fairly traceable to Daiichi," given that Daiichi's act of listing the method patent in the Orange Book created the entry barrier that Apotex sought to eliminate through a declaratory judgment.

After analyzing the legislative history of the *Hatch-Waxman Act*, the Federal Circuit also disagreed with Mylan's argument that without at least a "tentative approval" of Apotex's ANDA, Apotex's injury is too speculative to create a case or controversy for purposes of a declaratory judgment action. Indeed, the Federal Circuit explained that Apotex could trigger forfeiture of Mylan's exclusivity period under the governing statute by obtaining the non-infringement judgment sought in this case.

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