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CLIENT ALERT

Mere Possibility of Delay by First ANDA Filer Does Not Support Declaratory Judgment Jurisdiction

Sep.12.2008

In *Janssen Pharmaceutica, N.V. et al. v. Apotex, Inc*. (No. 2008-1062; September 4, 2008), the Federal Circuit affirms a district court's dismissal of a generic drug manufacturer's (Apotex's) declaratory judgment counterclaims of non-infringement based on the filing of Apotex's Abbreviated New Drug Application ("ANDA"). At issue are patents for the anti-psychotic drug risperidone (Janssen's U.S. Patent Nos. 4,804,663; 5,453,425; and 5,616,587).

Under the Hatch-Waxman Act, a Paragraph IV certification (filed in conjunction with an ANDA) is an act of patent infringement. A second generic drug manufacturer, Teva Pharmaceuticals USA, Inc. ("Teva"), was the first to file a Paragraph IV certification challenging the '425 and '587 patents, which thus entitled it to a 180-day period of market exclusivity for its generic risperidone product, but Teva did not challenge the validity or infringement of the '663 patent. Apotex was the second to file a Paragraph IV certification on the '425 and '587 patents, but, unlike Teva, Apotex later amended its ANDA to challenge the '663 patent. Janssen sued Apotex for infringement of the '663 patent but not for infringement of the '425 and '587 patents. Apotex responded by bringing declaratory judgment counterclaims of noninfringement for the two non-asserted patents. However, because Janssen then provided Apotex with a covenant-not-to-sue with respect to the '425 and '587 patents, the district court found "no case or controversy" with respect to these patents, and granted Janssen's motion to dismiss for lack of subject matter jurisdiction.

Apotex argued that there was a case or controversy based on "three actual and continuing injuries": (i) its asserted inability "to promptly launch its generic risperidone product and compete in the market immediately upon the expiration of the '663 patent;" (ii) that the approval of Apotex's generic risperidone product was "being indefinitely delayed;" and (iii) "its affiliates, suppliers, and downstream customers face patent uncertainty because Janssen's covenant-not-to-sue does not cover them." The Federal Circuit rejects all three arguments. First, the Court concludes that "Apotex's inability to promptly launch its generic risperidone product because of Teva's 180-day exclusivity period is not a cognizable Article III controversy." In reaching this conclusion, the Court distinguished case law cited by Apotex on the basis that Apotex had stipulated to the validity, infringement, and enforceability of the '663 patent. With respect to the indefinite delay argument, the Court rejects it as too speculative to create an actual controversy. Finally, the Federal Circuit determines that the covenant-not-to-sue does in fact protect Apotex's affiliates, suppliers and downstream customers.

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