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Amgen v. Apotex – what is the outcome when biosimilar applicants actually dance?

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On August 6, 2015, Amgen sued Apotex in the US District Court for the Southern District of Florida for patent infringement related to Apotex's pegfilgrastim product, which is purported to be biosimilar to Neulasta®. What is unique about this suit, in view of previous biosimlars litigations, is that Amgen brought suit after they and Apotex actually participated in the "patent dance" as set forth in 42 USC §§ 262(l)(2)-(5) of the Biologics Price Competition and Innovation Act (BPCIA).

Apotex announced that the US FDA had accepted its application for biosimilar Neulasta® for review on December 17, 2014. According to the complaint, beginning in December 2014, the parties engaged in the exchange of information and statements as required by the BPCIA. As a result of the patent exchanges, the parties agreed to the inclusion of two U.S. patents in the infringement action: U.S. Pat. Nos. 5,824,784 and 8,952,138.

The '784 patent relates, in part, to compositions of N-terminally chemically modified G-CSF, and to preparations of the same compositions. Thus, the '784 patent relates to the pegfilgrastim product itself. Interestingly though, the '138 patent relates to methods to overcome the limitations of recombinant expression of proteins at commercially viable levels in bacteria, namely obtaining correctly folded proteins from bacterial inclusion bodies. The '138 patent describes redox chemistry-based methods for efficiently refolding cysteine-containing proteins at high protein concentrations that are expressed in non-mammalian cells and does not specify pegfilgrastim as a claimed product. Therefore, inclusion of the '138 patent in the suit is likely a result of Apotex providing manufacturing information for its biosimilar product.

Amgen is also asserting that Apotex's Notice of Commercial Marketing was not sufficient when it was given because Apotex's product is not yet licensed. In view of the Federal Circuit decision in *Amgen v. Sandoz*, this Notice would appear to be defective on that basis. However, perhaps a bigger issue is whether Notice of Commercial Marketing is even mandatory here. In the *Amgen v. Sandoz* decision, the Court hinted that the Notice of Commercial Marketing may not be mandatory in instances where the biosimilar applicant participated in the patent dance, which appears to be the case here. Thus, even if the Notice was defective, Apotex may be able to defend against Amgen's claim by asserting the Notice is not mandatory in this case.

But if other biosimilar manufacturers, such as Celltrion and Sandoz, are bypassing the patent dance, why would Apotex participate in the process? In ruling that the dance was optional in the Neupogen® case, Judge Seeborg of the U.S. District Court for the Northern District of California offered five reasons why an applicant might participate including: (1) to preview which patents the reference product sponsor believes are valid and infringed, (2) to assess related factual and legal support, (3) to exercise some control over which patents are litigated and when, (4) to undergo the information exchange while protected by the statute's safe harbor from litigation, and (5) to have an opportunity to delay its product launch to protect the investment it made in developing its biosimilar.

Whatever the reasons, it will be interesting to follow this case in parallel with other disputes where biosimilar applicants have bypassed the patent dance to learn more about why applicants pick their particular paths to market.

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