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CLIENT ALERT

Dancing Doesn't Matter – Federal Circuit Said Biosimilar Companies Must Wait 180 Days

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Last Tuesday, the Federal Circuit unanimously held that all biosimilar companies – even companies that participate in the so called "patent dance" – must notify brand-name rivals of their intent to sell a biosimilar drug 180 days before marketing the drug. The case, *Amgen Inc., v. Apotex Inc*. could have major implications for the timing of when biosimilar companies launch their drugs.

In this case, the Court affirmed the lower court's ruling to preliminarily enjoin Apotex from putting its biosimilar version of Amgen's white blood cell-boosting drug, Neulasta® (pegfilgrastim), on the market until the company received a license from the FDA and then gave Amgen 180 days pre-market notice.

Tuesday's ruling is effectively an extension of the Court's decision last year in *Amgen Inc. v. Sandoz Inc*. As we previously reported, the Court in *Sandoz* held that biosimilar companies that *do not* participate in the BPCIA's optional "patent dance" (exchange of product and patent information, pursuant to 42 U.S.C. § 262(l)) must give the 180-day post-licensure notice before commercial marketing. Here, the Court extended *Sandoz* by requiring biosimilar companies that *do* participate in the BPCIA "patent dance" to also give the brand-name rival the 180-day post-licensure notice. The Court relied mostly on the plain language of the statute, holding that "shall" as used in conjunction with "licensed" in the BPCIA means that the 180-day post-licensure notice is mandatory. With regard to timing of the notice, the Court stated "…and we read (8)(A) [42 USC § 262(l)(8)(A)] as allowing the 180-day notice of commercial marketing to be sent as soon as the license issues, even if it is not yet effective, because it is at the time of the license that the product, its therapeutic uses, and its manufacturing processes are fixed."

Perhaps to quell biosimilar companies' fears, the Court pushed back against arguments that would seek to extend brand-name rival exclusivity from 12 years to 12.5 years. Writing for the unanimous Court, Judge Taranto wrote, "we have been pointed to no reason that the FDA may not issue a license before the 11.5-year mark and deem the license to take effect on the 12-year date." Whether the FDA will approve biosimilar drugs before the 12-year exclusivity period expires remains an open question.

As a result of this Federal Circuit decision, biosimilar manufacturers must give brand rivals 180 days' notice of marketing, *after* obtaining a license from the FDA for a biosimilar. This means that biosimilar manufacturers will have to factor this 180-day notice period into their strategy as an additional step of the "patent dance" under the BPCIA.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

Keith J. Harrison
Partner – Washington, D.C.
Phone: +1 202.624.2560
Email: kharrison@crowell.com

James K. Stronski
Partner – New York

Phone: +1 212.895.4217
Email: jstronski@crowell.com

Anne Elise Herold Li
Partner – New York
Phone: +1 212.895.4279
Email: ali@crowell.com

Alex Rosen
Associate – New York
Phone: +1 212.895.4348
Email: arosen@crowell.com