21 July 2016

Practice Group(s):

Pharma and BioPharma Litigation

IP Litigation

Biosimilars and Follow on Biologics

Federal Circuit Confirms Post-Licensure Notice of Commercial Marketing Is Mandatory in Biosimilar Litigation

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On July 5, 2016, a unanimous Federal Circuit panel held that Apotex failed to give Amgen proper notice of commercial marketing required by the Biologics Price Competition and Innovation Act ("BPCIA" or "Biologics Act")[1] and must wait 180 days after giving Amgen post-licensure notice before commercially marketing its FDA-licensed biosimilar product.[2] In affirming the district court's preliminary injunction against Apotex until the end of the 180-day period, the Federal Circuit followed its previous holding in *Amgen v. Sandoz*,[3] a split-panel decision. The court reiterated the bright-line rule that a biosimilar applicant must provide notice of commercial marketing to a reference product sponsor *after* the FDA grants licensure of the biosimilar product and cannot launch its product until 180 days following that post-licensure notice.

Background

As we have written previously,[4] the BPCIA was enacted in 2010 to "balanc[e] innovation and consumer interests"[5] by creating a framework and process under which an applicant may bring to market a product "biosimilar" to an FDA-approved reference product. Under the BPCIA, there is a "step-by-step process for exchanging information and channeling litigation about patents relevant to [a biosimilar-product] application."[6] At issue in the present case was 42 U.S.C. § 262(*l*)(8)(A), which requires biosimilar applicants—*after receiving FDA licensure approval*—to provide a "reference product sponsor notice at least 180 days before marketing its 'licensed' product"[7] (the "Notice of Commercial Marketing").

In 2002, Amgen received FDA approval of a biologics license application for its Neulasta® product, which is used to stimulate the production of neutrophils, reducing rates of infection among chemotherapy patients. To obtain approval, Amgen had to show that its product was "safe, pure and potent" under 42 U.S.C. § 262(a)(2)(C)(i)(l). The BPCIA allows a competitor like Apotex to submit an application under § 262(k) four years after a reference product is first licensed by the FDA to market a product "biosimilar" to the reference product using "publically available information about the reference product's safety, purity, and potency."[8] To balance competing interests, a biosimilar-product license "'may not be made effective' until twelve years after the reference product was first licensed."[9] Apotex filed a biosimilar application in October of 2014 naming Neulasta® as its reference product.[10] It has yet to be granted licensure by the FDA to produce its biosimilar product.[11]

The BPCIA contains a detailed, multipart subsection, § 262(*l*), that is designed to provide the framework for inevitable patent disputes between the reference product sponsor and biosimilar-product applicant.[12] Section 262(*l*)(2)(A) calls for a biosimilar applicant to notify the reference product sponsor within twenty days of the FDA stating that its biosimilar application is acceptable for review and to provide a copy of the application (the "Notice of

Filing"). The Notice of Filing begins a series of exchanges under the BPCIA that are intended to resolve patent infringement issues between the companies before the biosimilar product hits the market. In this case, Amgen cited three patents that allegedly would be infringed by Apotex.[13] Apotex responded that it would not market the biosimilar product until after two of the three patents expired and asserted that the third patent was invalid or would not be infringed by the biosimilar product.[14] On the same day, Apotex sent Amgen a letter "stating that it was thereby providing notice of future commercial marketing under [§ 262(*l*)(8)(A)]."[15]

After Apotex and Amgen reached this point, the Federal Circuit decided *Sandoz*, in which it held that the 180-day Notice of Commercial Marketing under § 262(*l*)(8)(A) must be "given after FDA licensure of the biosimilar product, not before."[16] The court explained that "the product, its therapeutic uses, and its manufacturing processes" would be fixed only after licensure, which enables the parties at that point to "fairly assess [their] rights."[17]

District Court Decision

Amgen sued Apotex for infringement of the third patent and moved for a preliminary injunction preventing Apotex from marketing its biosimilar product until 180 days after Apotex provides Amgen the post-licensure Notice of Commercial Marketing. Apotex argued that it was not bound by the *Sandoz* decision because, unlike Sandoz, Apotex had already started the statutory process required and outlined by the BPCIA, which included providing Amgen Notice of Filing, exchanging patent information, and providing a notice of "future commercial marketing," which Apotex argued should satisfy the Notice of Commercial Marketing provision. Apotex's primary contention was the start of the 180-day period, stating that it would be against legislative intent for the courts to add "180 days to § 262(k)(7)'s 12-year exclusivity period for reference product sponsors."[18] The district court followed *Sandoz* and granted a preliminary injunction against Apotex.[19] The district court also ruled against Apotex's secondary contention that § 262(*l*)(9) would exclusively limit Amgen's remedy to a declaratory judgment on the merits of the patent infringement case.[20] Apotex appealed the grant of a preliminary injunction.

Federal Circuit Decision

The Federal Circuit held that Apotex was required to give Amgen Notice of Commercial Marketing and that Amgen giving a Notice of Filing provided "only a factual distinction, not a legally material distinction, between its situation and that of Sandoz in *Amgen v. Sandoz*."[21] The court found that it would not be extending Congress's twelve-year minimum exclusivity period as a rule, because as time passes by, applications for biosimilars will be submitted with enough time for the FDA to grant licensure well before the twelve-year period elapsed.[22] Situations like Apotex faces, caused by the recent enactment of the BPCIA in 2010, will be less and less likely as time goes on because there is "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."[23] The court reiterated that the "statute must be interpreted as it is enacted, not especially in light of particular, untypical facts of a given case."[24]

The Federal Circuit also rejected Apotex's argument that because it had followed the procedures under § 262(*l*), Amgen's exclusive remedy for Apotex's failure to give proper notice under (8)(A) should be an action for declaratory judgment on the patent under §

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262(*l*)(9)(B).[25] The court distinguished the allowance of a remedy from a mandate that such a remedy be the sole remedy available to a plaintiff, finding that "'equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command.'"[26]

Looking Forward

As the law currently stands, all biosimilar applicants with products pending FDA approval under the BPCIA will be required to provide post-licensure Notice of Commercial Marketing 180 days before market entry. However, *Sandoz* is currently subject to a petition for certiorari to the Supreme Court. It is also possible that the parties in *Apotex* may seek a petition for rehearing en banc or also petition the Supreme Court for review. A decision in any of these venues may affect the requirements for biosimilar applicants and should be closely watched by those with, or considering filing, applications under the BPCIA.

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[1] 42 U.S.C. § 262 *et seq.*
[2] *Amgen Inc. v. Apotex Inc.*, No. 2016-1308 (Fed. Cir. July 5, 2016), *available at* http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/16-1308.Opinion.6-30-2016.1.PDF.
[3] *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347 (Fed. Cir. 2015).
[4] *See, e.g.*, BPCIA Statute: Has the Music Stopped or Will the Patent Dance Continue?; *see also* BPCIA Statute: Patent Dance Is Optional, But Opting Out Has Consequences.
[5] *Apotex*, at 5 (quoting Pub. L. No. 111-148, § 7001(b), 124 Stat. at 804).
[6] *Apotex*, at 3.
[7] *Id*. at 7.
[8] *Id*. at 5.
[9] *Id*. (quoting 42 U.S.C. § 262(k)(7)(A), (B)).
[10] *Apotex*, at 11.
[11] *Id*. at 2.
[12] *Id.* at 5.
[13] *Id.* at 11.
[14] *Id.*
[15] *Id.* at 11–12.
[16] *Id.* at 12.
[17] *Id.* at 12–13 (quoting *Sandoz*, 794 F.3d at 1358).
[18] *Apotex*, at 14.
[19] The parties stipulated as to all of the other required elements to grant a preliminary injunction under *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006).
[20] *Apotex*, at 14.
[21] *Id.* at 15.
[22] *Id*. at 17.
[23] *Id*.
[24] *Id*. at 18 (quoting *Sandoz*, 794 F.3d at 1358).
[25] *Apotex*, at 21.
[26] *Id*. (citations omitted).

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