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Dance or Not, Biosimilar Applicants Must Provide 180-Day Notice of Commercial Marketing Under the BPCIA

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Enacted in 2009, the BPCIA establishes a process by which a biosimilar applicant can obtain regulatory approval for a biological product that is sufficiently similar to a previously approved reference product based on information provided to the FDA by the reference product sponsor. 42 U.S.C. § 262(k). In addition to providing a mechanism for abbreviated regulatory approval of biosimilars, the BPCIA also created a framework for the resolution of patent disputes that might arise between a biosimilar applicant and a reference product sponsor. 42 U.S.C. § 262(l). Pursuant to § 262(l), once a biosimilar applicant receives notice from the FDA that its application has been accepted, a series of exchanges, frequently referred to as the "patent dance," are triggered between the applicant, here Apotex, and the reference product sponsor, here Amgen. First, the biosimilar applicant is to provide its application and manufacturing information to the reference product sponsor. *Id*. at § 262(l)(2)(A). Then the reference product sponsor is to provide a list of patents it could reasonably assert against the biosimilar applicant and identify any such patents it is willing to license. *Id*. at § 262(l)(3)(A). Next, the biosimilar applicant is to provide a substantive response addressing any defenses it may assert against the reference product sponsor's patents, stating whether any patents will expire before it intends to commercially market its product, and optionally identifying any additional patents it believes may be asserted against its product. *Id*. at § 262(l)(3)(B)(i)-(iii). Shortly thereafter, the reference product sponsor is to provide a substantive reply addressing the biosimilar applicant's non-infringement, invalidity or unenforceability positions. *Id*. at § 262(l)(3)(C). The parties then engage in a series of negotiations through which the parties agree on any patents that will be asserted in litigation, and which culminates in litigation filed pursuant to § 262(l)(6)(A).

In addition to providing a procedure for litigation that allows the biosimilar applicant and reference product sponsor to resolve patent disputes during the period of regulatory approval, the BPCIA also provides for a second stage of litigation connected to the first commercial marketing of the biosimilar product. Under § 262(l)(8)(A), a biosimilar applicant is required to provide notice to the reference product sponsor at least 180 days prior to the first commercial marketing of the licensed biosimilar product. At this time, the reference product sponsor has 180 days to seek a preliminary injunction based on any patents that were identified during the patent dance exchanges, but not litigated under § 262(l)(6) and any patents that issued or were exclusively licensed after the reference product sponsor gave its notice of patents under § 262(l)(3)(A). In its *Amgen v. Sandoz* decision, the Federal Circuit held the 180-day clock cannot start ticking until after the FDA approves the applicant's biosimilar product. 794 F.3d at 1357-58. In other words, a notice of commercial marketing that is provided prior to FDA-approval has no legal authority.

The issue raised in this case is whether the 180-day notice requirement of § 262(l)(8)(A) is mandatory and enforceable by injunction against a party who participates in the patent dance procedures and subsequent litigation provided for under §§ 262(l)(2) - 262(l)(6). In *Amgen v. Sandoz*, the Federal Circuit held the notice period under § 262(l)(8)(A) applied to a biosimilar applicant who refused to engage in the patent dance procedures and consequently never provided the reference product sponsor with the notice to launch required under § 262(l)(2)(A). In this case, after Apotex filed an application with the FDA, seeking permission to begin marketing a biosimilar version of Amgen's FDA-approved Neulasta®, it complied with the requirements of § 262(l)(2)(A). Apotex also provided notice to Amgen that it would begin commercially marketing its biosimilar product following the expiration of two patents at issue and provided defenses as to a third. The parties then engaged in the patent dance, and Amgen subsequently filed suit for patent infringement under § 262(l)(6)(A).

Following the Federal Circuit's decision in *Amgen v. Sandoz*, Amgen filed a motion asking the District Court to enforce the 180-day notice provision of § 262(l)(8)(A) by way of a preliminary injunction, which the District Court granted. On appeal, Apotex argued the *Amgen v. Sandoz* decision was inapplicable to the present case because in that case, Sandoz opted to forego the patent dance. According to Apotex, its notice to launch under § 262(l)(2)(A) should suffice to provide adequate notice of commercial marketing, and as a result, Amgen should not be entitled to the 180-day post-licensure notice period provided for in § 262(l)(8)(A).

In affirming the decision of the District Court to enforce the 180-day notice requirement of § 262(l)(8)(A), the Federal Circuit held that the language of § 262(l)(8)(A) is a mandatory standalone provision that is triggered after FDA approval, that covers all applicants regardless of whether they file a (2)(A) notice, and that is properly enforceable though an injunction. In this way, the BPCIA provides all reference-product sponsors with time to review the final FDA-approved product and determine whether it should seek injunctive relief to prevent commercial marketing of a product while yet-to-be-litigated patents are adjudicated.

Amgen Inc. v. Apotex, Inc., Case No. 2016-1308 (Fed. Cir. July 5, 2016).

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