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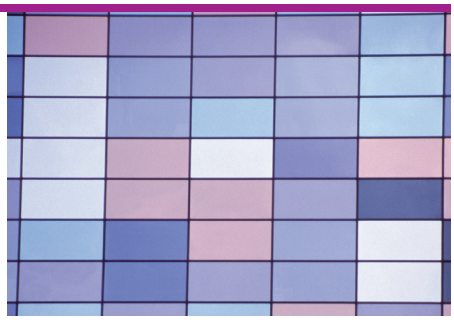

Amgen Inc. v. Sandoz Inc.

On March 19, 2015, the United States District Court for the Northern District of California issued its decision in *Amgen Inc. v. Sandoz Inc.*, construing the patent negotiation provisions of the Biologics Price Competition and Innovation Act ("BPCIA"). The court ruled that the BPCIA's patent negotiation provisions are not mandatory and therefore denied Amgen's request for an injunction against Sandoz, which had not complied with the provisions. If upheld on appeal, the decision will have significant implications for the timing and posture of biosimilar patent litigation.

Background: The BPCIA

The BPICA provides a streamlined regulatory pathway for "biosimilars," biologic drugs that use active substances that the FDA has already approved in an earlier application (a "reference product"). At issue in Amgen was the BPCIA's detailed process and schedule for the exchange of technical and patent information between the biosimilar applicant and the reference product's sponsor.[1] In general terms, the exchange begins when the biosimilar applicant provides the sponsor with a copy of its application.[2] The parties then engage in several rounds of exchanges and negotiations regarding the patents that should be the scope of an infringement suit, which is the expected outcome of the process.[3] While the process is ongoing, neither party may file a declaratory judgment action on any of the patents that are included in the regulations.[4] If the applicant does not provide a copy of its application or fails to complete the process, the sponsor may file suit, but the applicant may not.

Also at issue in Amgen was the BPCIA's provision requiring applicants to notify the reference product sponsor at least 180 days before the applicant markets its product.[5] After receiving that notice, the sponsor may seek an injunction on grounds of patent infringement, and may include in the case any patents that were the subject of the parties' exchanges and negotiations.

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1 42 U.S.C. § 262(l).

2 *Id.* §§ 262(l)(1)(B), 262(l)(2).

3 *Id.* §§ 262(l)(3)-(6).

4 *Id.* § 262(l)(9).

5 *Id.* § 262(l)(8).

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Amgen v. Sandoz (Neupogen®): The BPCIA's Patent Provisions Are Optional

Since 1991, Amgen has marketed the biologic filgrastim under the trade name Neupogen®. On July 7, 2014, the FDA notified Sandoz that it had accepted Sandoz's application for a filgrastim biosimilar, which Sandoz calls Zarxio®. Sandoz notified Amgen the next day, explaining that it expected the FDA to approve Zarxio® in the second quarter of 2015, at which time Sandoz planned to begin marketing its drug. The parties did not engage in any of the BPCIA's patent exchanges or negotiations regarding the scope of a patent infringement action.

On October 24, 2014, Amgen sued Sandoz in the Northern District of California, seeking a preliminary injunction barring the FDA from approving Sandoz's application.[6] According to Amgen, Sandoz had failed to complete the BPCIA's patent negotiation process, which Amgen argued was mandatory. Sandoz disagreed, arguing that applicants may forego the process, thus exposing themselves to the consequences prescribed in the statute for not doing so (i.e., a patent infringement suit). The parties cross-moved for judgment on the pleadings regarding their respective statutory interpretations.

The court agreed with Sandoz that biosimilar applicants need not participate in the BPCIA's patent negotiation process. The BPCIA offers applicants benefits for participating in the negotiations—including a temporary safe harbor from litigation—which persuaded the court that applicants may opt out, foregoing those benefits and potentially being subject to an immediate lawsuit. The court reasoned that Sandoz had "traded in the chance to narrow the scope of potential litigation . . . [through the BPCIA's process] in exchange for the expediency of an immediate lawsuit," an approach the court found to be consistent with the BPCIA's "overall statutory scheme."[7] Had Sandoz opted to follow the statutory negotiation process, it could have forced the parties to wait 230 days before beginning litigation, which the court saw as potentially "needless communications and delay."[8]

Amgen also argued that Sandoz had not complied with the BPCIA's 180-day notice provision. The provision refers to the "product *licensed under*" the BPCIA, which, according to Amgen, requires the applicant to provide 180 days' notice *after* the FDA licenses (i.e., approves) the product. The court disagreed, holding that the provision's use of the term "licensed" simply reflects the reality that an applicant cannot sell an un-licensed product, not Congressional intent to require notice after approval, which would automatically extend the statutory 12-year "data exclusivity" period by another six months.[9] The court found Sandoz's notice adequate, but noted that even if Sandoz had provided no notice at all, Amgen's only remedy would have been to file a declaratory judgment action for patent infringement.[10] Because it rejected Amgen's arguments on the BPCIA, and because Amgen had "yet to proceed on its remaining claim for patent infringement," the court denied Amgen's request for an injunction.[11] Amgen has appealed the decision to the Federal Circuit, which granted Amgen's motion to expedite briefing and oral argument. Briefing will be completed by the end of April, although argument has not yet been scheduled.

Considerations for Biologic Sponsors and Biosimilar Applicants

The *Amgen* decision essentially commits the patent negotiation process to the applicant's discretion. If upheld, the decision will have significant implications, particularly for drugs that were approved long ago and are not protected by the BPCIA's 12-year "data exclusivity" period.[12] The decision also raises several important questions, including:

- Would an evaluation of the legislative history of the BPCIA, which the *Amgen* court did not cite or discuss, change the analysis?
- How will courts reconcile the *Amgen* court's conclusion that patent negotiations are unnecessary with the BPCIA's 180-day notice provision, which depends in part upon prior patent negotiations?
- How will courts interpret *Amgen's* suggestion that 180 days' notice is not mandatory, particularly in light of the court's statement elsewhere in the opinion that the notice provision will prevent applicants from keeping sponsors "in the dark"?[13]

6 *Amgen Inc. v. Sandoz Inc.*, No. 14-CV-04741-RS, 2015 WL 1264756, at *3-4 (N.D. Cal. Mar. 19, 2015).

7 *Id.* at *5-7.

8 *Id.* at *7.

9 *Id.* at *7-8.

10 *Id.* at *8 & n.8.

11 *Id.* at *9-10.

12 42 U.S.C. § 262(k)(7).

13 *Amgen*, 2015 WL 1264756, at n.6.