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Sandoz v. Amgen: The Supreme Court makes its first decision on biosimilars

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***Sandoz v. Amgen Inc*. is a momentous decision for the Supreme Court,** marking the first time that the court has heard a case regarding biosimilars and the Biologics Price Competition and Innovation Act (BPCIA)[1] . Consequently, the decision may have far reaching implications for drug makers and patent practitioners.

Biosimilars are the generic version of a class of drug called biologics. Biologics are made from organic material —living cells. These cells are typically an engineered bacterium or yeast; because each biologic is created from a unique cell there is no way to guarantee that each dose will be identical.[2] Moreover, the fact that biologics are living makes them extremely dynamic. Biologics have been used in treating conditions from arthritis to cancer. Given their effectiveness, biologics are also immensely profitable and popular--by 2014 six of the ten best-selling medicines globally were biologics, with about $49 billion in combined sales.[3] Consequently, drug makers readily seize on the chance to create their own version of wildly successful biologics like Rituxan® (used to treat cancer and arthritis) and Humira® (used to treat arthritis and skin disorders). After the BPCIA-mandated exclusivity period on a biologic expires, manufacturers are allowed to market their own "generic" versions of biologics—called biosimilars.

The BPCIA contains the laws which govern biosimilars. The main thrust of the BPCIA permits drug manufacturers to produce biosimilars that are "highly similar to a reference product in their active ingredients".[4] The reference product refers to the biologic being copied, and the company that makes the brand name biologic is known as a "reference sponsor."[5] The BPCIA also refers to an "applicant"; the applicant is the company that applies to manufacture the biosimilar.[6] Furthermore, under the BPCIA, the FDA must deem each biosimilar safe for use, pure and sufficiently potent.[7] Finally, a biosimilar must use the same mechanism for action and route of administration as its reference product.[8] In this case, Sandoz is the applicant (seeking to make the biosimilar) and Amgen is the sponsor (attempting to extend its exclusive rights to its biologic).

Biosimilars raise a host of complex issues; however there are three main issues that the Supreme Court addressed in *Sandoz v. Amgen*. First, the court ruled on the BPCIA requirement that an applicant provide the sponsor with its application and manufacturing information.[9] Second, the court ruled on whether applicant's failure to provide the information was a question of state or federal law.[10] Third, the court ruled on whether an

applicant is required to provide notice of commercial marketing to the sponsor until after the FDA licenses its biosimilar.[11]

Acknowledging the complexity of pharmaceutical patent litigation, the Supreme Court made a relatively unusual announcement during oral arguments. Before arguments began on this case of first impression, Chief Justice John Roberts instructed the representing attorneys: "the court has decided to give each of you five extra minutes" of argument time.[12] Critics have noted that the extra time signals to the lawyers, and to the larger biomedical community...that the court understands this litigation to be far more complex than most others and that the justices are willing to put in extra effort to try to resolve the relevant issues in a conscientious manner.[13] After an intensely scrutinized process which began in 2014, the Supreme Court issued its judgment, a unanimous opinion, on July 14th 2017.

Court's Ruling: As mentioned above, the Court's opinion held three prongs. First, the court held that under federal law the BPCIA's provision requiring applicant (Sandoz) to provide sponsor (Amgen) with its application and manufacturing information could not be enforced by injunction.[14] In particular, the Court disagreed with the Federal Circuit's ruling that failure to disclose the required information is an act of artificial infringement under §271(e)(4). Instead, the Court held that a sponsor is entitled to bring a declaratory judgment action for artificial infringement under §271(e)(2)(C)(ii), depriving the applicant of the opportunity to bring a declaratory judgment action prior to marketing.[15] Second, the court held that the legality of an applicant's failure to provide sponsor with its application and manufacturing information, fell under California's unfair competition law; hence, the court deemed it a question of state law and remanded the issue back to California. Finally, the court held that an applicant (Sandoz) is not required to wait until the FDA licenses its biosimilar to provide notice of commercial marketing to the sponsor (Amgen). [16]

The Supreme Court's ruling overturned the Federal Circuit's initial ruling in favor of Amgen.[17] The Federal Circuit ruled that an applicant had to have its drug approved by the FDA, before giving its marketing notice to the sponsor. Marketing notice in this case means that the biosimilars manufacturer alerts the biologic maker (the reference sponsor), that it will be marketing its generic version in short order. The BPCIA requires this notice in order to warn the biologic maker that its reign of exclusivity will end soon. Additionally, after FDA approval, and giving marketing notice, the applicant subsequently had to wait 180 days before it was able to market its biosimilar.[18] The Supreme Court held that only one wait time was necessary under the plain language of the BPCIA: "the applicant may provide notice either before or after receiving FDA approval."[19] The justices ruled that the BPCIA imposes only a "single timing requirement" (180 days before commercial marketing of the biosimilar) not "two timing requirements" (after FDA licensure and 180 days before commercial marketing).[20]

Practically speaking, after the Supreme Court's decision, companies may now be able to market biosimilars immediately after FDA licensing, provided that three stipulations are satisfied. First, the biosimilars company has to give notice at the beginning of the FDA process; second, the FDA process takes more than 180 days; and third, the biosimilar does not infringe any valid patent rights.[21] All three elements are fulfilled in this case.

After the Supreme Court issued its opinion, producers of brand name biologics have lamented that the ruling takes away at least another 180 days of exclusivity, and billions of dollars in additional revenue. Conversely, biosimilars manufacturers and patients needing less-costly drugs are rejoicing at the potential for reduced wait times. Overall, the Supreme Court's decision represents a landmark victory for Sandoz and other biosimilars manufactures. However, the opinion looks to be the first ruling in a potentially robust new frontier for the Supreme Court.

1. Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148 §§7001-7003, 124 Stat. 119, 804-21 (2010).

*2. <**http://www.popsci.com/what-is-biosimilar**>*

3. Steven L. Baron and Michael J. Weil, "Sandoz v. Amgen: Biosimilars arrive at the Supreme Court," Illinois State Bar Association, Intellectual Property Law Newsletter, Volume 56, No. 5 (June 2017)

4. Steven L. Baron and Michael J. Weil, "Sandoz v. Amgen: Biosimilars arrive at the Supreme Court," Illinois State Bar Association, Intellectual Property Law Newsletter, Volume 56, No. 5 (June 2017)

5. Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148 §§7001-7003, 124 Stat. 119, 804-21 (2010).

6. 42 U.S.C. § 262(k)

7. 42 U.S.C. § 262(l)(2)(A)

8. Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148 §§7001-7003, 124 Stat. 119, 804-21 (2010).

*9. Sandoz v. Amgen Inc., **137 S. Ct. 1664** (2017)*

*10. Sandoz v. Amgen Inc., **137 S. Ct. 1664** (2017)*

*11. Sandoz v. Amgen Inc., **137 S. Ct. 1664** (2017)*

*12. <**http://www.scotusblog.com/2017/04/argument-analysis-supreme-court-struggles-acas-patent-provisions**/>*

*13. <**http://www.scotusblog.com/2017/04/argument-analysis-supreme-court-struggles-acas-patent-provisions**/>*

*14. Sandoz v. Amgen Inc., **137 S. Ct. 1664**, at 1667 (2017)*

*15. <**https://www.ipintelligencereport.com/2017/06/28/the-supreme-court-delivers-a-win-for-biosimilar-manufacturers-in-sandoz-v-amgen/**>; Sandoz v. Amgen Inc., **137 S. Ct. 1664**, at 1667-68 (2017)*

*16. Sandoz v. Amgen Inc., **137 S. Ct. 1664** (2017)*

*17. Amgen Inc. v. Sandoz Inc., **794 F.3d 1347**, 1357-58, 1360-61 (Fed. Cir. 2015).*

*18. Amgen Inc. v. Sandoz Inc., **794 F.3d 1347**, 1357-58, 1360-61 (Fed. Cir. 2015).*

*19. Sandoz v. Amgen Inc., **137 S. Ct. 1664** (2017)*

*20. <**http://www.scotusblog.com/2017/06/opinion-analysis-supreme-court-reverses-another-federal-circuit-patent-case/**>*

21. <http://www.scotusblog.com/2017/06/opinion-analysis-supreme-court-reverses-another-federal-circuit-patent-case/>