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Sandoz v. Amgen: Supreme Court Nixes Post-Approval Waiting Period for Biosimilars

By Jamaica Szeliga

Seyfarth Synopsis: *In its first opinion relating to the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), the Supreme Court in Sandoz Inc. v. Amgen Inc. provided a win to biosimilar companies, eliminating the Federal Circuit's requirement that the company wait to launch its product until 180 days after FDA approval. The Sandoz decision also keeps alive, however, the possibility that the brand biologic company could compel biosimilar applicants to produce their application and manufacturing information under state law. The Federal Circuit must address that concern on remand.*

Finding against the Federal Circuit once again on a patent case, the Supreme Court this week issued a unanimous decision in *Sandoz v. Amgen* relating to the interpretation of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). The BPCIA provides the mechanism by which companies can bring to market "biosimilar" compounds, i.e., products that can compete with biological drugs much the same way as generic drugs compete with traditional "brand" pharmaceutical products.

The Supreme Court considered two issues. First, the biosimilar applicant, Sandoz, challenged the Federal Circuit's interpretation of the BPCIA as requiring an applicant to wait until after the FDA approved its biosimilar application before providing the requisite 180-day notice of commercial marketing to the brand company. This meant that a biosimilar applicant had to wait an additional 180 days after its application was granted before it could launch a competing product. The FDA cannot approve ("license") a biosimilar product until twelve years after the biologic was first approved by the agency. Thus, the Federal Circuit's decision effectively provided the brand manufacturer with 12½ years rather than 12 years of market exclusivity.

The Supreme Court reversed the Federal Circuit and explicitly determined that applicants can provide notice before or after FDA approval. According to the Supreme Court, the pertinent statutory language in the BPCIA has two separate requirements: (1) that the biosimilar application is "licensed" before it is marketed; and (2) that the biosimilar applicant gives notice 180 days before marketing occurs. The Federal Circuit thus erred in requiring licensure before notice could be given.

The second issue tackled by the Supreme Court relates to the "patent dance" provisions of the BPCIA. The "patent dance" is a statutory scheme through which the biosimilar applicant and the brand manufacturer exchange information and legal theories until deciding upon which patents to litigate first. Sandoz refused to provide the biosimilar application and manufacturing information contemplated in the dance, leading Amgen to seek an injunction under federal and state law to compel participation. The district court and Federal Circuit determined that an injunction was not available.

On cross-appeal, the Supreme Court agreed with the Federal Circuit that injunctions under federal law are not permitted, but remanded the case to review state law remedies. According to the Court, the BPCIA allows the brand company immediately to bring a declaratory judgment action against the biosimilar applicant if they do not provide their application and manufacturing information. This remedy deprives the applicant of the ability to control the scope of the litigation (i.e., which patents to litigate) and the timing of the suit. The Supreme Court determined that the remedy of immediate suit was the only federal remedy contemplated for an applicant's failure to dance. The Supreme Court remanded the case to address whether non-compliance with the BPCIA can be considered a violation of California law entitling Amgen to an injunction and/or whether the BPCIA's remedy pre-empts any state law remedies.

Seyfarth will be closely monitoring the remand of *Sandoz* in the coming months.

Takeaways:

- Biosimilar applicants can submit notice of intent to market before or after FDA approval of their biosimilar products.
- Under federal law, failing to comply with the "patent dance" provisions of the Biologics Price Competition and Innovation Act of 2009 cannot be enforced by an injunction. Whether state law could compel the dancing remains to be determined on remand.

If you have any questions, please contact Jamaica Szeliga at *jszeliga@seyfarth.com*.

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