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Pharmaceutical Law & Industry Report®

Biosimilars

Strategy Considerations for Biosimilar Applicants after Sandoz v. Amgen




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In *Sandoz Inc. v. Amgen Inc.*, 137 S.Ct. 1664 (2017) (''*Sandoz*''), the U.S. Supreme Court for the first time interpreted the Biologics Price Competition and Innovation Act of 2009 (''BPCIA''), the federal law that established an abbreviated approval pathway for biological medicines deemed ''biosimilar'' to a previously approved biologic. Although the unanimous decision resolved two important aspects of the BPCIA, it raises important questions about the optimal strategy for biosimilar applicants considering bringing a new product to market.

In a major victory for biosimilar developers, the Court ruled that: 1) a biosimilar applicant cannot be compelled under federal law to provide the reference product sponsor with its biosimilar application and manufacturing information, which is the first step in the BPCIA's mechanism for the pre-market adjudication of patent disputes, commonly known as the ''patent dance;'' and 2) a biosimilar applicant may provide its 180-day advance notice of commercial marketing, which the statute requires, before the FDA grants a license to market the biosimilar product. (*Sandoz*, slip op. at 2) Biosimilar applicants therefore face important strategic decisions about whether to dance and when to give notice of commercial marketing.

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The Rationale for the ''Patent Dance''

Much of the *Sandoz* opinion is devoted to explaining the rationale for and workings of the BPCIA patent dance. The Court described the patent dance as having two phases. In the first phase, the parties work together to identify the patents that will be litigated immediately. The second phase does not begin until the biosimilar applicant provides its notice of commercial marketing. As noted by the Court, ''[t]he BPCIA bars any declaratory judgment action prior to this notice.'' *Sandoz*, 137 S.Ct. at 1672 The second phase involves patents that were not litigated in the first phase. In the second phase, ''*either* party may sue for declaratory relief.'' *Id.* (emphasis in original).

The Court explained that the BPCIA is designed to give biosimilar applicants ''substantial control'' over both phases of the patent dance. *Id.* at 1671-1672. In the first phase, for example, the biosimilar applicant determines the number of patents that will be the subject of immediate litigation and can influence which patents are ultimately litigated. Likewise, because the biosimilar applicant determines when it will launch its biosimilar product, and therefore when it will provide the reference product sponsor with the 180-day notice of commercial marketing, it similarly can influence the timing of the second phase of litigation. By providing the bio-

 ISSN 1542-9547

similar applicant with the ability to largely control both phases of litigation, the BPCIA contains strong incentives for biosimilar applicants to utilize the ''patent dance.''

But the BPCIA also contains a number of consequences for the biosimilar applicant who fails to follow the two-phase pathway. Importantly, if the biosimilar applicant fails to provide the reference product sponsor with its application and manufacturing information, thereby ''effectively pretermitting the entire two-phase litigation process,'' then the reference product sponsor, *but not the biosimilar applicant* can bring an immediate declaratory judgment action for infringement, validity or enforceability of any patent that claims the biological product or use of the biological product. *Id.* at 1672. Thus, by electing to skip the ''patent dance'' altogether, the biosimilar applicant cedes its substantial control over the scope and timing of the pre-approval litigation to the reference product sponsor. Indeed, the sponsor then dictates which of its patents will be litigated and when. As the Court noted:

> Section 262(l)(9)(C) thus vests in the sponsor the control that the applicant would otherwise have exercised over the scope and timing of the patent litigation. *It also deprives the applicant of the certainty that it could have obtained by bringing a declaratory-judgment action prior to marketing its product.*

Id. at 1675 (emphasis added). Thus, while the biosimilar applicant can elect to forgo participating in the patent dance, the BPCIA contains significant penalties for doing so.

Implications of the Decision

To Dance or Not to Dance? The Supreme Court evidently views the BPCIA as putting biosimilar applicants in the driver's seat with respect to the timing and scope of the pre-launch patent adjudication and providing strong incentives for them to do the patent dance. Ultimately, the biosimilar applicant can choose not to dance, but in doing so it will largely cede the control provided to it by the BPCIA to the reference product sponsor. The Court's decision strongly suggests, although the issue was not squarely before the court, that if the biosimilar applicant opts out of the dance, it will forfeit its ability to force adjudication of key sponsor patent rights in a declaratory judgment action prior to launch, thus greatly increasing the likelihood of having to launch at risk.

In deciding whether to dance, the biosimilar applicant must carefully weigh the need to adjudicate key sponsor patents to achieve patent certainty prior to launch. As might be expected, the ultimate conclusion depends a number of factors and will depend very much on the product at issue. In some cases, a biosimilar applicant may have high confidence in its patent positions as a result of its due diligence as well as prior patent disputes with the reference product sponsor in other jurisdictions. This might be a reason why Sandoz decided to forgo the patent dance for its filgrastim biosimilar product, since many of the key filgrastim patents had expired and the foreign counterparts of others had been the subject of proceedings in other jurisdictions.

Conversely, where the biosimilar applicant has less clarity on the patent estate surrounding the reference product, or where the applicant's ultimate commercial decision to launch its biosimilar is more dependent on obtaining pre-approval adjudication of certain key patents, then the applicant might have powerful incentives to participate in the patent dance. For instance, Amgen elected to engage in the patent dance in connection with its biosimilar version of AbbVie's HUMIRA®, a product that AbbVie claimed was covered by well over 100 patents. In that case, AbbVie identified over 60 patents that it could reasonably assert would be infringed by Amgen's biosimilar, but the parties ultimately agreed to litigate only 10 of those in the first phase. *See AbbVie Inc. v. Amgen Inc.*, No. 1:16-cv-00666 (D. Del).

Another set of factors a biosimilar applicant should weigh are the number and stage of competing biosimilar applicants. In the competitive race to be the first to market, a biosimilar applicant will likely wish to minimize any potential delay in market entry that could result from engaging in the patent dance. While this may be less important in those cases where there is still significant regulatory exclusivity remaining for the reference product, if such exclusivity has expired then any delay associated with the patent dance could put a biosimilar applicant at a competitive disadvantage vis-à-vis other such applicants.

When to Provide Notice of Commercial Marketing In light of the *Sandoz* decision, a biosimilar applicant has broad discretion on when to provide its notice of commercial marketing to the reference product sponsor. Notice can be given either before or after FDA approval of the biosimilar, provided it is at least 180-days before the commercial launch date. The decision when to provide notice is potentially very important, as the timing of the notice determines when declaratory judgment actions may be brought with respect to patents that are not being litigated in the first phase of the patent dance. *Sandoz*, 137 S.Ct. at 1675.

This raises additional strategic issues for the biosimilar applicant. If the applicant has initiated the patent dance but delays in providing the 180-day notice, it can effectively limit the patent dispute between the parties to the first-phase litigation. The reference product sponsor will be prevented from bringing a declaratory judgment action on any patent contained on the initial lists but not litigated in the first phase. But the applicant will not be able to file a declaratory judgment action either. *Id.* This may be desirable where the applicant's ultimate decision on whether or when to launch its biosimilar product turns primarily on the outcome of the specific patents being litigated in the first phase.

On the other hand, if the goal of the biosimilar applicant is to litigate as many of the reference product sponsor's patents as possible prior to launch, then providing early notice of commercial marketing (e.g., soon after the Abbreviated Biologics License Application is accepted for review) would be advantageous. Early notice would not only allow the biosimilar applicant to litigate certain patents in the first phase, but also would enable them to file declaratory judgment actions while the first phase litigation is still pending to challenge other patents that were on the lists exchanged by the parties but not subject to the first phase litigation.

Conclusion

The *Sandoz* decision makes clear that the biosimilar applicant has broad discretion to dictate the prelaunch

  PLIR ISSN 1542-9547

patent adjudication. But while the applicant can chose to forgo the patent dance, doing so can have major consequences.