Pepper Hamilton LLP
Attorneys at Law

Supreme Court Affords Greater Leeway to Biosimilars in the 'Patent Dance'

CLIENT ALERT | June 22, 2017

Pierre E. Queiroz de Oliveira | queirozp@pepperlaw.com
Raymond A. Miller | millerr@pepperlaw.com

In a recent ruling, the U.S. Supreme Court clarified what happens when biosimilar applicants do not follow the regulatory framework for disputes with reference product sponsors — a process known as the "patent dance." Since the Biologics Price Competition and Innovation Act (BPCIA) was enacted in 2009, there have been questions about the consequences of filing a biosimilar application but refusing to comply with the rules of the patent dance under the BPCIA. In *Sandoz Inc. v. Amgen Inc.* (available at https://www.supremecourt.gov/opinions/16pdf/15-1039_1b8e.pdf), the U.S. Supreme Court said that it is *not* an act of "artificial infringement" for a biosimilar applicant to refuse to share its application and manufacturing information and that the reference product sponsor is not entitled to injunctive relief under federal law. The Court also ruled that a biosimilar applicant may provide notice either before or after receiving FDA approval and that the BPCIA contains a *single* timing requirement — 180 days before commercial marketing.

The decision makes two important points:

- Biosimilar applicants can opt out of the patent dance by not disclosing their application and manufacturing information to reference product sponsors.

- If biosimilar applicants opt out, reference product sponsors will have control over any ensuing patent litigation.

Overview of the Patent Dance

The BPCIA governs the approval of biosimilars. It created a mechanism where biosimilars can be approved by showing that they are "highly similar" to a previously licensed biologic, known as a "reference product," and that there are no "clinically meaningful differences" between the two products in terms of safety, purity and potency. The BPCIA also created a regulatory framework where the biosimilar applicant and reference product sponsor engage in a "patent dance" for the purpose of resolving any patent infringement disputes early in the approval process.

The BPCIA allows the reference product sponsor to sue the biosimilar applicant when the biosimilar application is filed with the FDA, even though the biosimilar applicant has not yet committed an actual act of patent infringement on which a patent owner would normally sue, creating an act of "artificial infringement" by the biosimilar applicant.

The patent dance is a carefully choreographed process. Within 20 days of the biosimilar applicant's application being approved by the FDA, the biosimilar applicant will provide a copy of its application and information about the product's manufacturing to the reference product sponsor. This allows the reference product sponsor to evaluate the biosimilar for potential patent infringement.

Within 60 days of receiving this information, the reference product sponsor will provide a list of patents that would be infringed if the biosimilar applicant were to sell its product after obtaining FDA approval. The reference product sponsor must also list any patents that it would be willing to license to the biosimilar applicant.

Within 60 days of receiving the patent list from the reference product sponsor, the biosimilar applicant may provide its own list of patents that it believes are relevant, but that the reference product sponsor omitted from its list. The biosimilar applicant will also provide

reasons why it would not be held liable for infringing the relevant patents. The biosimilar applicant must also respond to reference product sponsor's offer to license particular patents. Within 60 days of receiving this list and arguments, the reference product sponsor will provide its own arguments about the infringement, enforceability and validity of the relevant patents.

Once the parties complete this exchange, two phases of patent litigation become available under the BPCIA. In the first, the parties collaborate to identify patents to litigate immediately. At this point, the biosimilar applicant has substantial control over the scope of litigation because the number of patents in suit is limited to those on its list. The reference product sponsor, however, may list at least one patent. After agreeing on the patents to be litigated, the reference product sponsor must sue within 30 days. This process allows patent litigation to be completed before marketing the biosimilar.

The second phase of litigation is triggered by the biosimilar applicant's notice of commercial marketing. The biosimilar applicant must give notice to the reference product sponsor at least 180 days before marketing the biosimilar. The reference product sponsor can then sue on any patents that were included on the parties' lists, but not litigated in the first phase. The biosimilar applicant also has substantial control over this phase because it controls the date of the commercial marketing notice. A preliminary injunction may be sought by the reference product sponsor while the question of patent infringement is determined by the court.

Sandoz v. Amgen

In the *Sandoz* case, the reference product was Neupogen®, a biologic used to stimulate white blood cell production. Sandoz, the biosimilar applicant, refused to share with Amgen, the reference product sponsor, its application and manufacturing information about its biosimilar product (brand name Zarxio®). Sandoz told Amgen that it would not submit the information and that Amgen could immediately sue for infringement.

Amgen sued and also claimed that Sandoz's conduct violated California's unfair competition laws. Amgen argued that Sandoz violated the BPCIA patent dance rules that required Sandoz to share the biosimilar application and manufacturing information, as well as the requirement that Sandoz provide notice of commercial marketing *before* the FDA licensed its biosimilar *and* 180 days before commercial marketing. Amgen sought injunctions to enforce both BPCIA patent dance requirements.

The Supreme Court ruled that filing a biosimilar application is an act of artificial infringement under the BPCIA, but failing to disclose an application and manufacturing information is not infringement and is not remediable under the BPCIA. This holding reversed the Federal Circuit's interpretation of the BPCIA.

The Supreme Court also said the BPCIA authorizes the reference product sponsor, but not the biosimilar applicant, to bring an immediate declaratory judgment action for artificial infringement when the biosimilar applicant fails to turn over its application and manufacturing information.

This raises an important point for both parties in the patent dance. By refusing to share its application and manufacturing information, the biosimilar applicant cedes control of the patent dance and gives the reference product sponsor control over the ensuing patent litigation. A reference product sponsor can then immediately bring an action for a declaration of infringement, validity or enforceability of any patent that claims the biologic product or its use.

The Supreme Court found that injunctive relief under the BPCIA is limited to a violation, or threatened violation, of the rules governing the confidentiality of information disclosed by the biosimilar applicant or reference product sponsor as part of the patent dance. The Supreme Court did not rule on whether Amgen was entitled to injunctive relief under state law. This question was remanded to the Federal Circuit, which will determine if Sandoz's conduct was unlawful under California law.

The *Sandoz* ruling confirms that a biosimilar applicant can effectively opt out of the patent dance by not disclosing to a reference product sponsor its application and manufacturing information. Opting out of the patent dance, however, shifts control to the reference product sponsor on the substance of ensuing patent litigation. Therefore, a decision to circumvent the patent dance is not without risk and should be considered carefully with counsel.

Pierre Queiroz de Oliveira is an associate and Raymond Miller is a partner in Pepper Hamilton's Health Sciences Department, a team of 110 attorneys who collaborate across disciplines to solve complex legal challenges confronting clients throughout the health sciences spectrum.