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Client Alert

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Recent Supreme Court Ruling Favors Biosimilar Applicants

In a highly anticipated decision, the US Supreme Court on Monday reversed the Federal Circuit in a case involving the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which provides a complicated procedure for resolving patent disputes between biosimilar applicants and reference-product manufacturers. This procedure, known as the "patent dance," begins with the filing of a biosimilar application, which under the BPCIA constitutes an act of infringement against a reference product manufacturer's patents covering the biosimilar product. Within 20 days of being notified by the FDA of the acceptance of its biosimilar application, the biosimilar applicant "shall" provide the reference product manufacturer with a copy of its application and a description of the process(es) used to manufacture the proposed biosimilar product. 42 U.S.C. § 262(l)(2). The parties then negotiate a list of relevant patents to be litigated in a first phase of litigation. The BPCIA also provides that the applicant "shall" notify the reference product manufacturer of its intent to market its product at least 180 days before such marketing, which triggers a second phase of litigation wherein the reference product manufacturer can sue on certain patents not litigated in the first phase. 42 U.S.C. § 262(l)(8)(A).

In *Amgen Inc. v. Sandoz Inc.* (Fed. Cir. 2015), the Federal Circuit gave different interpretations of the term "shall" in the different sections of the BPCIA. The court held that the term "shall" in Section 262(l)(2) (notice of the biosimilar application) indicated that participation in the "patent dance" was optional, whereas that the term "shall" in Section 262(l)(8)(A) indicated that the provision of the 180-day pre-marketing notice was mandatory. The court reasoned that, in the case of the 180-day pre-marketing notice, the reference product manufacturer has no recourse should the applicant fail to provide the notice, whereas, should the applicant opt out of the "patent dance," the BPCIA permits the reference product manufacturer to immediately seek declaratory judgment against the applicant on any patent claiming the biological product or use thereof. The Federal Circuit also held that the applicant may provide the pre-marketing notice only after it obtains approval of its application, as it is unclear, before approval, what the approved product will be or whether marketing of the product is even imminent. Many in the biosimilar industry had argued that this ruling amounted to providing the reference product manufacturer with a 180-day extension on its 12-year marketing exclusivity.

In Monday's ruling, the Supreme Court unanimously reversed the Federal Circuit and held that the 180-day pre-marketing notice may be given at any time 180 days or more before commercial marketing ***regardless*** of whether the biosimilar application had been approved at the time of the notice. The Court's ruling is seen as favorable to biosimilar applicants because it effectively allows the marketing of a biosimilar immediately after the reference product manufacturer's 12-year exclusivity period expires and the biosimilar product is approved, instead of requiring that the biosimilar applicant wait an additional 180 days. Another advantage for biosimilar applicants is that the reference product manufacturer may no longer have a clear idea as to when the biosimilar will launch (though such may be a matter of required disclosures if the biosimilar company is a public entity).

The Supreme Court notably declined to address whether participation in the "patent dance" was mandatory—an issue closely watched by the industry. But, the Court stated that the only federal remedy for a biosimilar applicant's failure to participate in the "patent dance" is that the reference product manufacturer may immediately bring a declaratory judgment action. Therefore, the Court held that the reference product manufacturer could not use a federal injunction to compel the applicant to participate in

the “patent dance.” The Court remanded to the Federal Circuit, however, the issue of whether the reference product manufacturer may avail itself of any remedies under state law.

The Court’s holding effectively gives biosimilar applicants the option, at least at the federal level, of avoiding having to participate in the “patent dance.” That said, one drawback in opting out is that the applicant may face uncertainty as to potential infringement before commercial launch as it will now be up to the reference product manufacturer to decide when and whether to bring a declaratory judgment action, thus creating the specter of a preliminary injunction’s being imposed to prevent a timely launch.

Notably, however, while a reference product manufacturer may immediately bring a declaratory judgment action in situations in which the biosimilar applicant has opted out of the “patent dance,” this right does not extend to patents directed to methods of making a product. Therefore, the reference product manufacturer arguably has no proper recourse with respect to a biosimilar applicant’s infringement of methods of manufacture patents should the applicant refuse to dance.

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