WINSTON & STRAWN LLP

What Is the Patent Dance?

Patent Dance

Colloquially referred to as the "**patent dance**," the BPCIA provides a framework that includes certain steps and a schedule during which the applicant and reference product sponsor exchange confidential information disclosed in the aBLA. During the patent dance, the applicant and sponsor identify the patents that could be litigated in the future during two potential phases of litigation. In the first phase, the sponsor can allege infringement of a subset of the patents identified during the patent dance. The second phase begins after the sponsor receives the Notice of Commercial Marketing from the applicant. During this second phase, the sponsor can assert any remaining patents that were not asserted in the first phase.

How Long Does the Patent Dance Take?

If both the applicant and the sponsor engage in all of the steps set forth in the BPCIA and take the maximum allotted time, the patent dance can take up to 250 days (approximately eight months) to complete.

Is the Patent Dance Mandatory?

No, the patent dance is not mandatory. In *Amgen v. Sandoz*, Nos. 15-1039, 15-1195, the Supreme Court held that the patent dance is not mandatory. Although the BPCIA requires that an applicant "must" provide its application and manufacturing information, the statute also "provides a remedy for an applicant's failure to turn over its application and manufacturing information."

What Are the Consequences for Not Engaging in the Patent Dance?

There are consequences for an applicant that opts out of the patent dance. If the applicant engages in the dance, the applicant preserves the right to file a declaratory judgment action to challenge the validity of the identified patents. If, however, the applicant eschews the dance, the decision of when and which patents to litigate shifts to the

sponsor, who retains the right to immediately seek "a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product." 42 U.S.C. § 262(l)(9)(C). In addition, for example, opting out of the patent dance foregoes certain possible restrictions on damages recovery. (*See* 35 U.S.C. § 271(e)(6).)

Is an Applicant Required to File a Notice of Commercial Marketing?

Yes, an applicant is required to file a Notice of Commercial Marketing. The BPCIA requires that a biosimilar applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." (42 U.S.C. § 262(l)(8)(A).) But according to the Supreme Court, "the applicant may provide notice either before or after receiving FDA approval." Sandoz Slip Op. at 16.

In other words, the applicant need not wait until after it receives FDA approval (or licensure) to provide the sponsor with notice of the applicant's intent to commercially market its biosimilar.

Related Capabilities

Patent Litigation