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BPCIA Questions Continue To Arise For Biosimilar Applicants

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On June 12, 2017, the U.S. Supreme Court decided its first case under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Sandoz Inc. v. Amgen Inc. (No. 15-1039, 15-1195). The court considered two key provisions of the statute: (1) 42 U.S.C. §262(l)(2)(A), which sets forth that the biosimilar applicant (hereafter "applicant") "shall" provide its application and information that describes the process or processes used to manufacture the biosimilar ("manufacturing information") to a reference product sponsor (hereafter "sponsor") and starts the prelitigation exchange of information commonly known as the "patent dance," and (2) 42 U.S.C. §262(l)(8)(A), which sets forth that the applicant must provide notice of commercial marketing to the sponsor 180 days prior to market launch of the biosimilar.


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In a unanimous decision, the court held that: (1) the failure of the applicant to provide its application and other information to the sponsor is not enforceable by injunction under federal law, and (2) the applicant's 180-day notice of commercial marketing may be given prior to U.S. Food and Drug Administration approval of the biosimilar application. See Sandoz, slip op. at 2. The court remanded to the Federal Circuit to consider whether remedies were available under California state law. Id.

The Supreme Court's decision raises a number of questions, including whether the applicant can avoid the bar on its ability to bring a declaratory judgment action under the BPCIA by providing its notice of commercial marketing at the same time or shortly after it provides its application and manufacturing information to the sponsor.

Declaratory Judgment and the BPCIA Patent Dance

Filing a biosimilar application is an act of infringement under 35 U.S.C. § 271(e)(2)(C). The patent dance begins when the applicant, within 20 days of receiving notice of acceptance of its application from the FDA, provides a copy of its application and manufacturing information to the sponsor pursuant to 42 U.S.C. §262(l)(2)(A). After that exchange, the parties go through a sequenced information exchange, including exchange of a patent list citing patents that could be asserted by the sponsor, and contentions regarding the infringement, validity and enforceability of the patents identified on the patent list. 42 U.S.C.

§262(l)(3). After exchange of the contentions, the parties negotiate which patents may be brought in an immediate patent infringement action, leaving the other patents for later litigation. 42 U.S.C. §262(l)(4),(5). Once negotiations conclude, the sponsor may sue only on patents eligible for the immediate infringement action. 42 U.S.C. §262(l)(6),(9).

The statute also contains a "Limitation on Declaratory Judgment Action" that sets forth when a sponsor or applicant, respectively, may bring a declaratory judgment action under 28 U.S.C. § 2201 regarding infringement, validity or enforceability of certain patents. 42 U.S.C. §262(l)(9). For example, if the applicant fails to provide the sponsor its application (thereby skipping the patent dance) the sponsor may bring suit on any patent that claims the biological product or its use, but the applicant is barred from any such suit. See §(9)(C).

However, once the applicant starts the patent dance by providing its application and manufacturing information pursuant §(2)(A), the BPCIA bars either party from bringing a declaratory judgment action unless certain events happen. See § (9). Thus, if the applicant fails to perform its information exchange obligations, the bar to declaratory judgment action is lifted for the sponsor. See §(9)(B). Once the applicant provides its notice of commercial marketing under §(8)(A), the declaratory judgment bar is lifted and either party may bring suit on the patents that were set for later litigation, i.e., patents that are on the initial patent list but not eligible for the immediate infringement action. See 42 U.S.C. §(9)(B), § (8)(B). Further, §(8)(B) provides that for the "later-litigation" patents, the sponsor may seek a preliminary injunction upon notice of commercial marketing, but prior to launch.

In light of the Supreme Court's decision, the applicant can theoretically provide both its application and notice of commercial marketing on the same day. Thus, the question arises, does the applicant have the right to bring a declaratory judgment under §(8)(B) once the notice of commercial marketing is provided to the sponsor? Or, alternatively, does the BPCIA's limitation on declaratory judgment action apply even if notice of commercial marketing is given because the requisite steps of the patent dance (i.e., the exchange of the patent list and negotiations of patents eligible for the immediate infringement action) have not yet taken place?

Legal Analysis

Analysis of the right to bring a claim under the Declaratory Judgment Act begins with the Supreme Court's guidance in MedImmune. See MedImmune Inc. v. Genentech Inc., 549 U.S. 118, 127 (2007). MedImmune established that subject-matter jurisdiction under the Declaratory Judgment Act requires an analysis of "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Id.

Post-MedImmune Federal Circuit cases in the Hatch-Waxman space, such as Novartis and Caraco, are potentially instructive for the BPCIA, because under both statutes, the act of infringement is "artificial," that is, it is a statutory act of infringement. Teva Pharms. USA Inc. v. Novartis Pharms. Corp., 482 F.3d 1330 (Fed.Cir.2007) ("Novartis "); Caraco Pharmaceutical Laboratories Ltd. v. Forest Labs. Inc., 527 F.3d 1278 (Fed. Cir. 2008)("Caraco"). Those cases generally acknowledge that the NDA holder's listing of patents in the FDA's Orange Book acts as a bar to approval of the ANDA or 505(b)(2) application, thus supporting the existence of a case or controversy of sufficient immediacy and reality to meet the MedImmune test. For example, the Novartis court stated that, by listing patents in the Orange Book, Novartis was affirmatively representing that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale," pursuant to 21

U.S.C. § 355(b)(1). Novartis, 482 F.3d at 1341.

The BPCIA does not contain an Orange Book equivalent in which the sponsor must notify applicants of the existence of patents in order to bring prelaunch patent infringement action. Assuming there has been no other assertion by the sponsor, prior to the patent dance's exchange of the initial patent list under §3(A), there is arguably no affirmative representation that could give rise to a case or controversy that meets the Medimmune standard for a declaratory judgment action by the applicant. Whether the statute itself provides the applicant with the right to bring a declaratory judgment action once the notice of commercial marketing is given has yet to be litigated. Any such argument would necessitate a review of the statutory language and purpose.

A literal reading of the statute is consistent with Medimmune and the post-MedImmune Hatch-Waxman cases. Section 9(A) lifts the bar on the applicant's ability to bring a declaratory judgment action with respect to the patents set forth in §(8)(B). This category of patents exists only after the sponsor makes an affirmative representation that a claim of patent infringement could reasonably be asserted by providing the patent list, and the parties engage in the statutory negotiations regarding which patents may be brought in the immediate infringement action. Thus, despite providing an early notice of commercial marketing, the applicant, once it provides its application under §(2)(A), is barred from bringing a declaratory judgment action at least until the sponsor provides the initial patent list and the parties negotiate the patents eligible for the immediate infringement action. Under this statutory reading, the sponsor would also be barred from bringing a declaratory judgment action until after the initial patent list is provided and the applicant fails to take an action required by the statute (e.g., fails to provide its contentions under §(3)(B)). Such a literal reading of the statute means that once the application is provided, the parties are forced through at least §(3)(A) of the patent dance, even if notice of commercial marketing has already been provided.

It could, however, be argued that the notice of commercial marketing was intended to "start the clock" to launch, such that either party should be able to bring a declaratory judgment action in order to expedite prelaunch patent litigation. That is, because the statute was intended to promote resolution of patent litigation prior to launch of the biosimilar, the notice of commercial marketing may arguably satisfy the "sufficient immediacy and reality" prong of the Medimmune test, regardless of any affirmative representation by the sponsor of patents it may assert. This will likely also depend upon when within the 12-year exclusivity period the notice of commercial marketing is provided to the sponsor. This argument could characterize the §(8)(B) reference in §(9)(A) as not intended to force the parties to go through §(3)(A) of the patent dance if that step has not yet been reached. Rather, §(8)(B) could arguably be meant merely to preclude suit on those patents that were eligible for, but were not asserted in, the immediate infringement action in those cases where the parties had already reached that stage of the patent dance. This argument may also be consistent with MedImmune, as it would permit declaratory judgment where infringement is imminent, but bar it as to those patents that the sponsor failed to assert in immediate infringement action despite its ability to do so.

Conclusion

This is only one of the many questions that has arisen in the wake of the Supreme Court's decision in Sandoz v. Amgen. The lack of clarity in the statute gives rise to multiple possible interpretations that will undoubtedly await litigation to be resolved by the courts. Whether and when an early notice of commercial marketing lifts the bar to declaratory judgment actions set forth in the BPICA is one of the many issues likely to be litigated in follow-up to the Supreme Court's decision that notice of commercial marketing may be given prior to FDA approval of the biosimilar application.

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