FDA APPLICANT NOT SUBJECT TO INJUNCTION UNDER BPCIA

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Artificial patent infringement occurs when certain types of approval applications are submitted to the U.S. Food And Drug Administration (the "FDA"). The U.S. Supreme Court recently considered a situation in which an allegation of artificial patent infringement was made against an entity desiring the approval of the FDA to market a biologic. On June 12, 2017, the Supreme Court acknowledged in *Sandoz Inc. v. Amgen Inc.* that it is possible to infringe a patent merely by submitting certain types of approval applications to the FDA (a.k.a. "artificial infringement"), and acknowledged the "patent dance" that may result under the *Biologics Price Competition and Innovation Act of 2009* ("BPCIA") following submission of such FDA applications. The Court's June 12 decision clarifies rules surrounding that "patent dance" in favor of FDA-applicants seeking to protect sensitive and valuable information about biosimilar products.

The BPCIA prohibits the introduction of a "biological product" (defined at 42 USC 262(i)) into interstate commerce unless a license has been obtained from the FDA, and the packaging bears certain information. One means by which such a license may be obtained involves submitting an application to the FDA that demonstrates the biological product is "biosimilar" to a reference product. Such an application for an FDA license of the biosimilar product can not be submitted until 4 years after the reference product was first licensed, and the FDA's approval can not be made effective until 12 years after the date the reference product was first licensed. As such, the reference product enjoys a period of exclusivity in the marketplace.

A U.S. patent can also provide marketplace exclusivity, and that exclusivity period can be longer than that arising from the BPCIA. For a particular biological product, these two types of exclusivity may run in tandem for some period of time, with the exclusivity afforded by a U.S. patent often continuing to run after expiration of the BPCIA's 12 year exclusivity period. Interestingly, U.S. patent law makes it an infringement to submit certain types of applications to the FDA, including applications seeking FDA approval of a biological product, if the purpose of such submission is to obtain approval from the FDA to engage in the commercial manufacture, use, or sale of a … biological product claimed in a patent or the use of which is claimed in a patent before the patent expires. *See* 35 USC 271(e)(2)(C). Consequently, the mere filing of an FDA-application for a biological product may and often does bring scrutiny for patent infringement to an FDA-applicant that may

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be years away from being able to make, use, offer to sell, sell, or import a biological product. Complicating the situation is the fact that reference sponsors owning a patent and seeking to protect their market exclusivity may lack information needed to evaluate whether an FDA-applicant has or will infringe its patent rights. For example, it would be difficult for a reference sponsor to know that an FDA-applicant had the requisite purpose without first bringing the patent infringement suit. And, it may be difficult for the reference sponsor to know, without first bringing the patent infringement suit, whether the FDA-applicant's biosimilar achieves its biosimilar status by a means other than infringement of the reference sponsor's patent. As such, it is often the case that the reference sponsor is operating in an information-vacuum with regard to whether infringement of its patent is occurring, and the FDA-applicant may be subjected to scrutiny (or worse) with regard to a groundless infringement allegation.

To somewhat mitigate these unknowns, the BPCIA affords provisions that encourage applicants using the abbreviated approval process of 42 USC 262(a)(2)C(i)(I) to turn over information to the attorneys for the reference product sponsor ("reference sponsor"), including a copy of the biosimilar application and other information that describes the biosimilar's manufacturing process. *See* 42 USC 262(l)(2). Clearly, such information is likely to be very sensitive, and so an FDA-applicant may be reluctant to turn over that information, even though the BPCIA attempts to guard against misuse of that information. If the applicant fails to turn over such information, the BPCIA allows the reference sponsor to bring a declaratory judgement action on the issue of infringement, and bars the applicant from doing so.

In the June 12 decision, the U.S. Supreme Court considered a situation in which a biosimilar applicant refused to turn over to the attorneys for the reference sponsor the information identified by the BPCIA. Following the biosimilar applicant's refusal, the reference sponsor sued the applicant for (a) patent infringement, and (b) violation of a State unfair competition law that prohibits unlawful business acts or practices. In its ruling, the U.S. Supreme Court held that the applicant's failure to turn over the information was not an element of patent infringement, but instead merely resulted in identifying which of the sponsor's patents could be asserted in the patent infringement action. The Court noted that the relevant act for purposes of determining whether patent infringement occurred was the filing of the FDA application, and not the refusal to turn over information pursuant to the BPCIA. The Court also held that the exclusive remedy under the BPCIA for the applicant's refusal to turn over the information was that the reference sponsor could bring a declaratory-judgement action seeking a decision on the issue of infringement, validity, or enforceability of a patent. In doing so, the Court refused to allow an injunction to arise from the BPCIA for the FDA-applicant's breach of the BPCIA's disclosure provisions. In addition, the Court did not decide whether a violation of the State unfair competition law occurred when the applicant refused to comply with the turn over requirements, but the Court seemed to caution lower courts to carefully consider that issue going forward.

The Supreme Court's decision provides additional clarity to those engaged in the activities outlined in the BPCIA, and may afford biosimilar applicants a better opportunity under the BPCIA to evaluate a sponsor's ability to assert a patent infringement suit without prematurely disclosing sensitive and valuable information. However, FDA-applicants operating under the BPCIA should not overlook the fact that the Supreme Court left open the possibility that an injunction is available under State unfair competition law. In addition, efforts by patent owners to obtain such information from FDA-applicants will not stop as a result of the Court's decision, and prospectively we should expect to see different and more creative arguments asserted against FDA-applicants under both Federal and State laws. Therefore, FDA-applicants are not yet free to assume that they can withhold information once they begin the BPCIA's "patent dance", and at the very least

FDA-applicants should assume it will be expensive to do so.