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# The BPCIA "Patent Dance" – Waiting for the Music to Begin

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The Biologics Price Competition and Innovation Act of 2009 (BPCIA) provides an abbreviated pathway for biosimilar products to enter the market by ripening patent disputes prior to FDA approval. Although somewhat analogous to the 1984 Hatch Waxman Act, the BPCIA contains a more complex—and to date, untested—statutory framework for exchanging patent information followed by two possible "waves" of litigation prior to biosimilar launch. The so-called "patent dance" begins when the biosimilar applicant discloses it confidential application and manufacturing trade secrets to the pioneer. When the dance stops, the pioneer will have an opportunity to assert at least one of its patents in a first wave of litigation.

But what if the biosimilar applicant refuses to disclose, as appears to have happened already in at least two instances? Under the BPCIA, if there is no disclosure there can be no patent dance and no first wave litigation opportunity for the pioneer. Believing that this would put the pioneer at a serious disadvantage not intended by Congress, one pioneer has now asked the FDA to make disclosure mandatory and require a biosimilar applicant to share its secrets with a pioneer as part of the approval process.

The BPCIA does not provide for an Orange Book-type listing of pertinent patents, but instead lays out a procedure by which the parties make a series of exchanges—including potentially, the biosimilar application and manufacturing process—to determine which pioneer patents might be at issue. The parties then negotiate the patents that are to be asserted in a first wave of litigation. *See* 42 U.S.C. §§ 262(l)(2)-(6). A second wave of litigation, triggered by the applicant's obligation to provide 180-day notice of intent to launch, may follow. None of the patents litigated in the first wave may be reopened in the second wave. *See* 42 U.S.C. § 262(l)(8).

## Both Sides Challenge BPCIA

Attempts by biosimilar applicants to circumvent the BPCIA approval process have been unsuccessful. Two district courts have dismissed declaratory judgment actions brought by biosimilar applicants, holding that a patent dispute would ripen only after the biosimilar applicant has filed an application with the FDA and complied with the BPCIA's procedures. Now a party asks whether the BPCIA's confidential information disclosure requirements are in fact mandatory. In September 2014, Amgen filed a Citizen Petition asking the FDA to require an applicant to certify that it will share its application and manufacturing data with the pioneer within 20 days after the FDA has accepted it for review, claiming the statute's "shall provide" language makes such disclosures mandatory. Amgen further argues non-disclosure would undermine the exclusivity period given to the first interchangeable product due to linkage in the statute between the termination of this right and the first wave litigation timeline. *See* §262(k)(6)(B)-(C).

But a fair reading of the legislation suggests that a refusal to provide access to a biosimilar application does not undermine the BPCIA or run counter to Congress's intent. Indeed, the statutory language indicates that the first wave of litigation is optional for the biosimilar applicant, and nothing in the BPCIA suggests Congress intended the FDA to play a gatekeeping role. Under §262 (l)(9)(C), if a biosimilar applicant fails to disclose its confidential information, a pioneer can bring a declaratory judgment action on any product or use—but not process—patents that cover its

product. Congress likely limited the remedy because it foresaw the scenario in which the biosimilar applicant might refuse to provide information about its manufacturing process. Yet, no such restriction is imposed on a pioneer who has access to the confidential information—it can assert a product, use, or process patent. Of even greater significance, the BPCIA amended Section 271 of the Patent Act to make a failure to provide the biosimilar application and confidential manufacturing information an act of infringement. *See* §271(e)(2)(C)(ii). This further confirms that Congress intended the disclosure of a biosimilar applicant's confidential information to be discretionary, and not mandatory.

Discretionary disclosure makes practical sense as well: a biosimilar applicant must decide whether to disclose later, under a protective order, or earlier under the BPCIA's statutory protections. Under the BPCIA, a court can provide injunctive relief to a biosimilar applicant whose confidential information has been misused by the pioneer. *See* §262(l)(1)(H). The applicant would have to first seek court intervention, and then show the misuse and get the court to award relief. Under a protective order, misuse of information by the pioneer would expose it to contempt proceedings by a presiding judge almost immediately, who could impose compensatory or coercive fines in addition to injunctive relief. Thus even if the ultimate remedy is the same—courts are often reluctant to award monetary sanctions—a biosimilar applicant would likely have quicker access to injunctive relief under a protective order. More importantly, given the importance of its manufacturing process information, a biosimilar applicant may not want to risk disclosing its "crown jewels" unless required to do so by a court.

### Problems for Pioneers

If access to confidential information is intended to be optional, it does present one potentially thorny problem for the pioneer—knowing when the act of infringement occurs so that it can file a patent suit. The Hatch-Waxman Act and the BPCIA both define an "artificial" act of infringement to occur with the submission of an application for FDA approval. Under Hatch-Waxman, if a generic applicant challenges a pioneer patent the FDA will need to know whether and when to stay approval of the ANDA thus, the statute requires the generic to notify the pioneer of its application. The BPCIA has no similar notice provision. And, thus far, the FDA has given no indication that it plans to publish any notice of biosimilar applications to give pioneers a heads up as to artificial acts of infringement.

In contrast, the FDA may have a role to play in the second wave litigation process because, here, the applicant is required to give the pioneer notice 180 days prior to commercial marketing. The FDA alone determines when commercial marketing of a biosimilar can begin so it may require proof of notice or condition final approval of the biosimilar application on the expiration of 180 day period.

Congress appears to have given biosimilar applicants a choice: whether to disclose confidential information early in the FDA approval process and face two possible waves of litigation or disclose nothing until trial, shortly before its drug is ready for launch. And while non-disclosure may be problematic for pioneers, it is doubtful that courts will force biosimilar applicants to share their vital secrets outside the confines of a judicial proceeding.