A Fractured Federal Circuit Panel Interprets The Biosimilars Patent Resolution Procedures

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On July 21, the Federal Circuit interpreted the patent litigation procedures and requirements of the Biologics Price Competition and Innovation Act (BPCIA), including whether a company submitting an abbreviated BLA ("k applicant") is required to comply with the BPCIA's detailed patent challenge process. In a fractured decision, Judges Lourie and Chen joined in holding that a (k) applicant does not violate the BPCIA when it fails to disclose its application and manufacturing information by the statutory deadline. Judge Newman dissented. Then, Judges Lourie and Newman, with Judge Chen dissenting, joined in holding that the (k) applicant is nevertheless required to give a 180-day notice of commercial marketing after FDA approval of its biosimilar product, giving the reference product sponsor six months to seek a preliminary injunction to block launch of the product until resolution of any patent disputes.

The BPCIA established procedures to define and narrow disputes between biosimilar applicants and reference product sponsors after the (k) application is filed. That procedure contemplated that the (k) applicant would share the contents of its application with the reference product sponsor so that the parties could determine which patents may cover the biosimilar product or its manufacture or use. Although the statute provides that the (k) applicant "shall provide" the contents of its (k) application, Judges Lourie and Chen reasoned that "shall" does not mean "must" when the statute is read as a whole, because when the application is not provided, the statute provides the reference product sponsor with specified remedies. In particular, they noted that when the (k) application is not provided, the reference product sponsor can immediately sue for infringement or file a declaratory judgment action asserting any patents that cover the biosimilar product, including process patents covering its manufacturing. In their view, the statute made these remedies exclusive. Judge Newman's dissent warns that the majority's interpretation of the BPCIA information exchange process as "optional" eviscerates the purpose of the BPCIA, which "requires the statutorily identified disclosures at the threshold, in order to both avert and to expedite litigation."

Judge Newman joined Judge Lourie, however, in a second part of the decision holding that the BPCIA's requirement of a 180-day notice of commercial marketing prior to biosimilar launch is mandatory when the applicant has failed to disclose its application by the statutory deadline. Importantly, they ruled that the requisite notice cannot be given until after the FDA has *approved* the biosimilar product, thereby allowing the reference product sponsor a six-month period in which to seek a preliminary injunction prohibiting launch of the product as approved. In his dissent, Judge Chen interpreted the notice of commercial marketing as part of the larger BPCIA litigation procedures, not a standalone provision, and argued that a (k) applicant who opts out of the early information exchange is opting out of the entire BPCIA process, including the notice requirement.

The outcome of this case is surprising to many who participated in the development of the BPCIA patent procedures. As Judge Chen acknowledged, Congress created the BPCIA as a "comprehensive, integrated litigation management system." Congress had prior experience with the Hatch-Waxman Act, which provided a means for generics manufacturers to challenge innovator companies' patents on small molecule drugs, and led to the FDA's creation of the familiar "Orange Book" as the means to identify relevant patents. During the debate on the proposed biosimilars legislation, however, stakeholders urged Congress not to create an Orange Book for patents covering biologics and biologics manufacturing processes. The information exchange procedures in the BPCIA, including the requirement that the (k) applicant disclose its application and manufacturing information, and the requirement that the reference product sponsor thereafter identify relevant patents that could be asserted, were intended as a way to replace the Orange Book and allow for the orderly resolution of patent challenges prior to approval and launch of biosimilar products. If these procedures are not mandatory, a reference product sponsor has no way to know in advance of litigation the range of patents that may apply to a biosimilar product, and a (k) applicant has no

way to identify all the patents the reference product sponsor believes will cover the product or its manufacture. This will lead to more at-risk launches and make it harder to achieve Congress's goal of creating an efficient process for clearing patent disputes in advance.

It remains to be seen whether (k) applicants will take advantage of the panel's decision and choose to opt out of the BPCIA procedures. Participating in the BPCIA "patent dance" offers many advantages to a biosimilar applicant, including the ability to manage the scope and timing of patent infringement litigation and to force the reference product sponsor to identify relevant patents and provide pre-litigation infringement and validity contentions. To be sure, following the BPCIA procedures may lengthen the time to patent resolution, but in future cases, where the (k) application can be filed prior to expiration of the reference product's 12-year data exclusivity period, the advantages to a (k) applicant would seem to outweigh the disadvantages. If so, the *Amgen* decision may turn out to be simply an anomaly, a transitional set of patent rules applied mainly to reference products that no longer enjoy data exclusivity, as was the case here.

In the meantime, we can expect to see reference product sponsors closely monitoring the activities of biosimilar applicants and preparing for infringement and declaratory judgment actions as soon as they become aware of the filing of a (k) application. Where the (k) applicant opts out of the BPCIA and litigation results, early discovery will be important to identify all of the manufacturing process patents that may be asserted against the biosimilar product.

With respect to the 180-day notice of commercial marketing, biosimilar applicants will be disappointed that the reference product's 12 years of exclusivity has effectively been extended by six months, at least when the applicant fails to participate in the initial information exchange. The decision leaves the door open, however, to the possibility that, where the FDA gives tentative approval to a biosimilar product prior to the expiration of the 12-year period, that itself may be a sufficient trigger to allow the (k) applicant to give notice of commercial marketing and start the clock running. Judge Lourie seemed to think so, noting that "the extra 180 days will not likely be the usual case, as aBLA's will often be filed during the 12-year exclusivity period."

This decision may not be the last word. The importance of this first interpretation of BPCIA, the need for certainty in this area as more and more biosimilar products are submitted for FDA approval, and the conflicting interpretations offered by the three judges who made up the panel suggest the prospect of an *en banc* rehearing by the full Court before these issues are finally resolved. Stay tuned.

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