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# Will Biosimilar Applicants Opt Out of Patent Dance?

## Federal court ruling to have impact on future litigation strategies

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On March 6, the federal Food and Drug Administration licensed the first-ever U.S. biosimilar drug, Sandoz's Zarxio, a version of Amgen's Neupogen (filgrastim). Less than two weeks later, the U.S. District Court for the Northern District of California denied Amgen's motion for a preliminary injunction against Sandoz's Zarxio launch, removing the final barrier to consumers being able to obtain the drug.

In its ruling, the court held (1) that the information exchange procedures laid out in §262(l)(2)-(8) of the Biologics Price Competition and Innovation Act (BPCIA), known as the "patent dance," are optional; and (2) that a biosimilar applicant may properly give the 180-day notice of commercial marketing required by §262(l)(8)(A) before obtaining its FDA license to sell its product. This ruling is the first to interpret these two key provisions of the BPCIA and, if upheld on appeal, will have a tremendous impact on the patent litigation strategies of both reference product sponsors and biosimilar applicants going forward.

### Patent Dance Requirements

The court, in ruling in favor of the biosimilar applicant, Sandoz, held that the information exchange procedures laid out in §262(l)(2)-(8) of the BPCIA are optional. In summary, the ruling provides that—for a biosimilar applicant—providing its biosimilar license application (BLA) and engaging in the patent exchange procedure of §262(l) are optional. The court thus held that Sandoz did not violate the BPCIA by refusing to participate. This aspect of the court's holding may be particularly significant for the enforcement of method patents.

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Without the BLA it may be difficult for a reference product sponsor to determine whether one of its method patents is infringed. This is due, in part, to the fact that biosimilar products are not identical products to the reference product but—as is suggested by the name—are merely similar products. Thus, it is not a given that biosimilar products are manufactured using the same methods as the reference product. This can result in a reference product sponsor having imperfect knowledge regarding a biosimilar applicant's manufacturing processes.

That being said, a reference product sponsor can file a declaratory judgment action in order to obtain the manufacturing information contained in the BLA through discovery. This can be done by either bringing an immediate declaratory judgment action on another of its patents that does not cover a method or by bringing a declaratory judgment action directly on the method patents.

The first approach—bringing suit over a nonmethod-of-manufacture patent—suffers as reference product sponsors do not always have another patent to assert. Under

the second approach of bringing suit directly over the method patents, attorneys must be cognizant of their duties under Rule 11 of the Federal Rules of Civil Procedure. That is, the reference drug sponsor attorneys must do a reasonable investigation under the circumstances that the factual contentions (i.e., that the biosimilar's manufacturing processes infringe the method patents) will likely have evidentiary support after a reasonable opportunity for further investigation or discovery. This can be a harrowing ledge to crawl on for attorneys, but a ledge that no doubt will have some company. In either the first or second strategy, however, it is not a given that discovery will provide the information it needs to add its method patents to the suit under the first approach or to maintain their cause of action under the second approach.

Therefore, if upheld on appeal, biosimilar applicants may, as a default strategy, avoid the patent dance provisions of the BPCIA so as to force reference product sponsors to make strategic decisions early in the dance.

## 180-Day Notice Requirements

The second question in front of the court was whether Sandoz's 180-day notice of commercial marketing was sufficient under the BPCIA. The BPCIA requires a §262(k) applicant to provide the reference product sponsor notice at least 180 days before the "date of first commercial marketing of the biological product licensed under [the act]."

It was undisputed by the parties that Sandoz sent a letter to Amgen on July 8, 2014, indicating Sandoz's intent to market its biosimilar product as soon it obtained its FDA license, which Sandoz did in fact receive on March 6, 2015. Amgen, however, contended that notice could only be given after Sandoz obtained its FDA license for its biosimilar filgrastim. This reading of the law would extend a reference product's exclusivity period by six months by barring the biosimilar applicant from giving its 180-day notice before the end of the reference product's 12-year exclusivity period.

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The California court, however, was unpersuaded by Amgen's argument. Instead, the court concluded that the statute referred to the biosimilar product as the "biological product licensed under subsection (k)" in §262(l)(8)(A) simply because it would be nonsensical to refer to it as the subject of a §262(k) application on its first commercial marketing and that if Congress had intended to provide 12 1/2 years of exclusivity rather than 12 years, it would have done so in a less-convoluted manner. The court thus held that the 180-day notice may be given before licensure and that Sandoz had provided adequate notice with its July 2014 letter to Amgen. The impact of this ruling, if upheld, may affect the behavior of both biosimilar applicants and reference product sponsors.

The holding that the 180-day notice of marketing can be given before the licensure of the biosimilar product means that reference products may not know which of its patents may be infringed before the launch of a biosimilar product, even if the §262(k) supplies its BLA. This is due, in part, to the fact that biosimilar applicants can amend their §262(k) application before its approval. For example, Sandoz made numerous changes to its §262(k) application during the approval process and other §262(k) applicants will likely do the same. Thus, the 180-day notice provision, from a reference drug sponsor's perspective, may lack some of its utility as there are likely to be many unanswered questions at the time that the reference drug sponsor receives notice going forward. This reality is likely balanced, however, by other realities that are driven by business demands as well as the reference product sponsor's ability to file for a declaratory judgment early on, either as a result of the patent dance or a lack thereof. Thus, reference product sponsors will often find themselves seeking injunctive relief regardless of when they receive the 180-day notice of a biosimilar's intent to market.

In conclusion, strategies for both biosimilar and reference product sponsors abound within the framework of the BPCIA, and if the district court's ruling holds, numerous strategies abound outside of the BPCIA framework. Given the importance of these issues to the biological products industry, a potential U.S. Court of Appeals for the Federal Circuit opinion is eagerly awaited. ■

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