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Amgen, Sandoz Both Winners And Losers At Federal Circuit

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The Court of Appeals for the Federal Circuit on July 21 rendered its decision on the applicability and interpretation of two key provisions of the Biologics Price Competition and Innovation Act. The court ruled that: (1) the BPCIA does not require biosimilar applicants to turn over their application and manufacturing information to the reference product sponsor (RPS), making it "optional" to take part in the so-called patent dance; and (2) biosimilar applicants can only comply with the obligation to give notice of commercial marketing by giving "notice" once the U.S. Food and Drug Administration has licensed the biosimilar product for commercial marketing. The decision was not unanimous, however, with Judge Alan Lourie the only member in the majority on both issues and Judges Pauline Newman and Raymond Chen dissenting on issues one and two, respectively.

On issue one, the court focused on how to reconcile section 42 USC 262(l)(2), which provides that a biosimilar applicant shall provide a copy of their abbreviated biologics license application (aBLA) to the RPS, with 262(l)(9)(C), which specifically provides a remedy for when the applicant does not provide that information to the RPS. The court held that although section 262(l)(2) states that the biosimilar applicant "shall" provide the application and manufacturing information to the RPS, and that use of the term "shall" is generally construed as mandatory, the fact that 262(l)(9)(C) provides for a remedy when this procedure is not followed, indicates that biosimilar applicants can elect to not choose that disclosure route. The court reasoned that mandating compliance with paragraph 262(l)(2)(a) in all circumstances would render sections 262(l)(9)(C) and 35 USC 271(e)(2)(C)(ii) superfluous.

In dissent, Judge Newman focused on the intent of the BPCIA, and the balance of obligations and benefits provided to both biosimilar applicants and RPSs. She stated that since Sandoz obtained the benefit of Amgen's data in filing a biosimilar application, they should be required to respect its obligations. She argued that 262(l)(9)(C) "does not ratify non-compliance," rather it "prevents a non-compliant party from obtaining relief through a declaratory judgment action, while that prohibition is lifted as to the aggrieved party."

On issue two, the court ruled in Amgen's favor, holding that the 180-day notice of commercial marketing required by section (l)(8)(A) can only be effective after the FDA has licensed the biosimilar product. The court pointed out that section (l)(8)(A) refers to "the biological product licensed under

subsection k," while all of the other provisions of subsection (k) refer to "the biological product that is the subject of" the application. The court concluded that if Congress had intended to permit effective notice before the biosimilar product is licensed, it would have used the "subject of" language. Moreover, the court reasoned that providing for notice after licensure of the biosimilar product ensures that the product's therapeutic uses and manufacturing processes are fixed and the controversy regarding the need for injunctive relief is "fully crystallized." Thus, the court concluded that the notice of commercial marketing given by Sandoz in July 2014, prior to FDA approval of its product, was "premature and ineffective," but the supplemental notice given to Amgen on the day the biosimilar product was approved was operative and effective. Accordingly, Sandoz will not be able to market its biosimilar until Sept. 2 of this year.

While the court acknowledged that this interpretation of the statute would in effect provide Amgen with an additional 180-days of market exclusivity for its Neupogen product, it suggested that the additional 180-day exclusivity "will not likely be the usual case" since many abbreviated BLAs will be filed during the 12-year exclusivity period for other products.

The court considered a separate question to be whether the notice provision of (l)(8)(A) is mandatory. In the context of this litigation at least, the court concluded that it is. In contrast to the application and process information provision of (l)(C)(2), which the court concluded was optional, the court could not find any provision in the BPCIA that contemplated or specified the consequence for a failure to provide the 180-day notice of commercial marketing. The court refused to read (l)(9)(B) as providing the consequence for failure of the biosimilar applicant to provide such notice. While the court acknowledged that section (l)(9)(B) provided the consequence for failure to provide notice of commercial marketing after the biosimilar applicant has turned over its application and process information, that section does not apply where, as here, the biosimilar applicant elects not to provide that information. The court held that since Sandoz had failed to provide its aBLA and manufacturing information to Amgen, the requirement to give 180-day notice of commercial marketing is mandatory. The court's reasoning suggests then that this provision may not be mandatory in instances where the application and process information are turned over at the outset.

In his dissent, Judge Chen asserts that the "context-based" interpretation of the BPCIA that the majority used in finding the aBLA and process information provision to be optional applies equally to the interpretation of the notice requirement of (l)(C)(8). According to Judge Chen, the 180-day notice provision is not mandatory, and section (l)(C)(9) provides the reference product sponsor with the sole course of action for failure of the biosimilar applicant to provide such notice, i.e., the right to pursue immediate patent infringement litigation. The majority opinion, he contends, gives Amgen an extra-statutory exclusivity windfall.

The lack of unanimity, combined with the exceptional importance of this decision to the biopharmaceutical industry suggests that one or both litigants may seek en banc rehearing.

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