JONES DAY

COMMENTARY

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IN SHORT

The Situation: The Biologics Price Competition and Innovation Act was considered in a November 2017 decision by the United States Court of Appeals for the Federal Circuit.

The Result: The court found that the commercial marketing of Apotex's proposed biosimilar versions of Amgen's Neulasta® and Neupogen® would not infringe on a patent held by Amgen.

Looking Ahead: Amgen v. Apotex underscores the importance of fact witness testimony and other factual evidence to support arguments regarding infringement.

The United States Court of Appeals for the Federal Circuit ("Federal Circuit") considered the Biologics Price Competition and Innovation Act ("BPCAI") once again on November 13, 2017. The Federal Circuit issued a nonprecedential decision in *Amgen v. Apotex*, on appeal from the United States District Court for the Southern District of Florida, finding that the commercial marketing of Apotex's proposed biosimilar versions of Amgen's Neulasta® and Neupogen® would not infringe Amgen's United States Patent No. 8952,138 ("'138 patent"). *Amgen v. Apotex*, No. 2017-1010, slip op. at 3 (Fed. Cir. Nov. 13, 2017). The opinion provides guidance on several issues, including:

- **Patent Dance Statements.** Statements made during the information exchange pursuant to 42 U.S. 42 U.S.C. 262(*l*)(3) ("Patent Dance") are party admissions and carry *some* probative weight. As such, these statements cannot be ignored if properly offered into evidence. It was not clear error, however, to weigh the probative value of these statements by interpreting their relative weight in light of other evidence.

- **Application of *Sunovion*.** *Sunovion v. Teva*, a Federal Circuit case that arose in the Hatch-Waxman context, was distinguishable on the facts. In *Sunovian*, internal manufacturing guidelines, and a certification from the defendant that it would not run its process in an infringing manner, were deemed insufficient to avoid infringement where the ANDA, on its face, authorized infringing activity. But where an abbreviated Biologics Application ("aBLA") constrains the accused processes to noninfringing levels, or is silent on the issue, *Sunovian* does not apply.

> The Federal Circuit noted that Amgen had not argued that Apotex was legally bound by its 'pre-litigation letter' statements, but instead argued that the district court erred by disregarding those statements.

The '138 patent explains that recombinant proteins expressed in nonmammalian expression systems can precipitate into misfolded proteins known as "inclusion bodies." (*Amgen*, No. 2017-1010, slip op. at 3 (Fed. Cir. Nov. 13, 2017) The patent is directed to a method for refolding such proteins. The only independent claim of the patent recites a "refold mixture" with particular protein concentrations, which the district court construed as a high protein concentration "at or above 1 g/L." (*Id.* at 5.) As part of the patent dance, in several "pre-litigation letters," Apotex stated that it did not infringe Amgen's '138 patent because the relevant inclusion body concentration in its product was limited to 0.9-1.4 g/L. (*Id.*) Further, Apotex's aBLAs also identified an "inclusion body concentration" of 0.9-1.4 g/L. (*Id.*) At trial, however, Apotex distinguished between the concentration of "inclusion bodies" and the concentration of "proteins" in its aBLAs. (*Id.* at 6.) Apotex's fact witness testified that the "pre-litigation letters" were "factually inaccurate," and Apotex also presented two batch records showing the protein concentration in its "refold mixture" never exceeded 0.56 g/L. (*Id.*) Based on this evidence, the district court found that Amgen had failed to prove direct infringement of the '138 patent.

On appeal, Amgen argued that the district court erred: (i) in finding Apotex's "pre-litigation letters" lacked probative value; (ii) in not treating "protein concentration" as interchangeable with "inclusion body concentration;" and (iii) by reading Apotex's aBLAs and the specifications provided therein too restrictively, particularly in light of other case law from the Federal Circuit. (*Id.* at 7.)

On the first argument, the Federal Circuit noted that Amgen had not argued that Apotex was legally bound by its "pre-litigation letter" statements, but instead argued that the district court erred by disregarding those statements. (*Id.*) The Federal Circuit found that the district court's factual finding was not clearly erroneous—the district court properly considered the statements in the "pre-litigation letters"

and found that they lacked probative value in light of the other evidence. (*Id.* at 8.) The Federal Circuit also noted that Amgen did not present any evidence to contradict the statements from Apotex's fact witness, and did not attempt to challenge the accuracy of the fact witness's testimony. (*Id.* at 9.) In so finding, the Federal Circuit clarified that statements made in the "pre-litigation letters" are party admissions and therefore have *some* probative value. (*Id.*) The Federal Circuit also rejected Amgen's argument regarding claim construction—that "inclusion bodies" is interchangeable with "proteins." (*Id.*) Identifying various statements from the specification, the Federal Circuit found that it "pervasively disproves rather than supports" Amgen's argument. (*Id.* at 9-12.)

Finally, on Amgen's argument that the district court's finding of noninfringement rested on a restrictive reading of the aBLAs, the Federal Circuit distinguished the case from *Sunovian Pharm., Inc., v. Teva Pharm. USA, Inc.*, 731 F.3d 1271 (Fed. Cir. 2013), a case that arose under the Hatch-Waxman context. (*Id.* at 12.) Amgen argued that the district court was required to assess infringement based on the full range of processes that would be consistent with Apotex's aBLAs. (*Id.*) The Federal Circuit found that, unlike *Sunovian*—where a defendant's internal manufacturing guidelines and a certification that it would not run its processes in an infringing way was deemed insufficient proof of noninfringement—here, there was actual evidence in the aBLA in the form of "key process parameters" that would put Apotex's process out of the infringing range. Although Amgen argued that the process parameters were not absolute limits, and that there was no explicit limitations in the aBLAs, Apotex's fact witness testified that Apotex would "throw out" batches that did not fall within the process parameters. (*Id.* at 13.) The Federal Circuit also noted that "Amgen has pointed … to no evidence" that Apotex's aBLAs authorized infringing levels of protein concentrations." (*Id* at 14.) In the court's opinion, at most, the applications were silent on the issue and the batch records pointed towards noninfringement. Finally, the Federal Circuit rejected Amgen's argument that Apotex provided two batch records, but withheld 89 other batch records, stating that "it was not Apotex's burden to prove noninfringement." (*Id.*)

This case underscores the importance of fact witness testimony and other factual evidence to support arguments regarding infringement. Parties should be conscious of statements made during the patent dance exchange, as these statements are party admissions. Parties should also be prepared to rebut or support these statements with witness testimony and other evidence. Further, aBLA applicants should be aware that *Sunovion*'s standard only applies where an application leaves open the possibility of an infringing process.

TWO KEY TAKEAWAYS

1. Parties should be conscious of statements made during the patent dance exchange, as these statements are party admissions.
2. In cases where an abbreviated Biologics Application constrains the accused processes to noninfringing levels, or is silent on the issue, *Sunovion v. Teva* does not apply.

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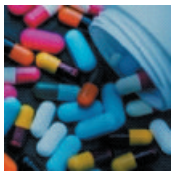
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