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Federal Circuit Evaluates Import of Factual Statements Made During BPCIA Pre-litigation Patent Dance

Article By:

Joseph D. Rutkowski

In a nonprecedential opinion issued on November 13, 2017, the United States Court of Appeals for the Federal Circuit affirmed a district court finding that Apotex's aBLAs for biosimilar versions of Neulasta® and Neupogen® did not infringe an Amgen protein folding patent. The Federal Circuit affirmed the non-infringement finding despite statements made in Apotex's pre-litigation letters sent during the parties' information exchange (i.e., the "patent dance"), which the district court found were controverted by evidence presented by Apotex at trial.

Background

Amgen makes the biologic drugs Neulasta® (pegfilgrastim) and Neupogen® (filgrastim). Apotex submitted aBLAs ("abbreviated Biologics License Applications") to the FDA seeking approval of biosimilar versions of both drugs under the BPCIA ("Biologics Price Competition and Innovation Act") framework. The parties engaged in the BPCIA's "patent dance" information exchange process, whereby Apotex provided Amgen with copies of Apotex's aBLAs. Amgen ultimately brought suit under 35 U.S.C. § 271(e)(2)(C), (a) and (g), asserting that Apotex's proposed manufacturing processes would infringe, among others, Amgen's U.S. Patent. No. 8,952,138 (the '138 patent).

The '138 patent covers a method of refolding misfolded proteins. This process purportedly allows for large-scale protein refolding using lower reagent volumes than was previously possible. The district court construed (and the Federal Circuit did not reverse) asserted claim 1 of the '138 patent to require "refold mixture" protein concentrations above 1.0 g/L.

Apotex's conflicting pre-litigation statements and trial evidence

During the parties' information exchange, Apotex stated in letters to Amgen that Apotex's aBLA processes practiced an "inclusion body concentration" of 0.9 to 1.4 g/L. At trial, Amgen argued that these statements demonstrated infringement of the claimed concentration range, above 1.0 g/L.

However, Apotex presented evidence at trial that its pre-litigation 0.9-1.4 g/L concentration statements were factually inaccurate. Apotex's fact witness testified that Apotex's maximum possible protein concentration would actually be 0.708 g/L. Amgen chose not to challenge these statements on cross examination or to present any contradictory evidence, besides the pre-litigation

statements themselves. Apotex also presented two batch records (from some 89 times that Apotex ran the process) which showed actual protein concentrations below 0.56 g/L.

On appeal, the Federal Circuit explained that, while not binding, “a district court cannot ignore letters sent during the BPCIA’s information exchange if properly offered into evidence” and that, as party admissions, such statements are entitled to at least “*some* probative weight.” That weight, however, may be overcome by other evidence presented at trial indicating that the prior statements were inaccurate. The Federal Circuit found that Apotex’s fact witness testimony and batch records – which were not challenged at trial – were sufficient to overcome its pre-litigation statement.

Thus, the Federal Circuit explains here that, while the parties’ statements made during the BPCIA patent dance must be considered if relevant to the court’s ultimate infringement analysis, they are not necessarily binding and may be overcome by sufficient contrary factual evidence at trial.

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