Janssen v. Celltrion: A Misstep in the BPCIA Patent Dance

Written by Donald R. Ware, Barbara A. Fiacco, Emma S. Winer

March 8, 2017

Last week, a federal judge in Boston answered a question of first impression arising under the patent dispute resolution provisions of the Biological Price Competition and Innovation Act ("BPCIA"), a process commonly known as the "patent dance." The BPCIA limits a patentee's damages to a reasonable royalty if an infringement suit was filed more than 30 days after the end of the information-exchange process. Does this limitation apply when the applicant has chosen not to complete the various steps in the dance?

In *Janssen v. Celltrion*, Celltrion had moved for summary judgment alleging that Janssen lacked standing due to a failure to join all the owners of the patent. The patent is directed to a manufacturing process that allegedly covers the manufacture of the biosimilar product. In its decision, the court provided guidance on whether, if the pending cases were dismissed without prejudice for lack of standing and a new case were thereafter brought, Janssen would be limited to a reasonable royalty for any proven infringement.

In this case, the court ruled that Janssen could seek lost profits, in addition to a reasonable royalty, because Celltrion did not engage in the required "good-faith" negotiation to develop a list of patents to be asserted in the first phase of BPCIA litigation. The court's order emphasizes the importance of complying with the BPCIA's patent dance, noting that "the Biologics Act lays out a step-by-step process for exchanging information and channeling litigation about patents relevant to the application." The BPCIA further states that the parties "shall" engage in "good-faith negotiations" and "shall" engage in the specified dispute resolution procedure if those negotiations fail. The court construed "shall" to mean that "the alleged infringer must comply with each step in the BPCIA process in order to limit the patentee to a reasonable royalty if it does not sue within 30 days of the end of that process." As the court explained, it is only the patents that emerge from the prescribed negotiation that "are subject to the reasonable royalty damages limitation."

The interpretation of "shall" in other provisions of the BPCIA is currently the subject of separate litigation and much debate. On April 26, 2017, the Supreme Court will hear arguments in *Amgen v. Sandoz* on whether the term "shall provide" is mandatory or optional in another BPCIA information-exchange provision. Sandoz has argued that a biosimilar applicant can choose to engage in the BPCIA's patent dispute resolution procedures, but cannot be compelled to do so. The Supreme Court will also construe a related provision of the BPCIA to determine whether a biosimilar applicant is required, under all circumstances, to give the sponsor a "notice of commercial marketing" not later than 180 days before the applicant begins commercial marketing.

RELATED PRACTICES

- Intellectual Property Litigation
- Patent Prosecution, Strategy and Management
- Patent, Trade Secrets and Related Rights Litigation
