Courts Reject Attempts to Sidestep Patent Dance

Last month’s article, titled “BPCIA Litigation Provisions Get No Respect,” reported on several cases in which a biosimilar applicant has attempted to avoid using the litigation provisions of the Biosimilars Price Competition and Innovation Act (BPCIA), sometimes called the “patent dance.” In a less than one week span this month, three of those efforts were rejected by the courts and one was withdrawn voluntarily.

First, in a closely-watched case, the Federal Circuit affirmed the district court’s dismissal of Sandoz’s Complaint seeking a declaratory judgment that its proposed biosimilar of Amgen’s Enbrel® product (etanercept) would not infringe two relatively recent U.S. patents. Sandoz v. Amgen, Appeal No. 2014-1693 (Fed. Cir. Dec. 5, 2014). The gist of the Court’s rationale is set forth in the following paragraph:

Any dispute about patent infringement is at present subject to significant uncertainties—concerning whether it will actually arise and if so what specific issues will require decision. Sandoz’s Phase III trial may fail in material ways. If so, perhaps Sandoz will not file for approval, thereby eliminating altogether the patent dispute it has asked the district court to adjudicate. Perhaps, if the trial materially fails, i.e., uncovers significant problems, Sandoz will instead modify its proposed product and ultimately file for FDA approval of the modified product. At a minimum, that scenario could alter the content of any patent dispute: notably, infringement of the specific claims of the specific patents—which cover, e.g., particular proteins, pharmaceutical compositions, polynucleotides, and methods—could present different questions depending on the precise product. In fact, modifying the product now being tested might even eliminate a genuine patent dispute.

Slip op. at 11-12. The court was careful to state that it was not adopting a categorical rule. Id. at 10. Also, to at least the author’s disappointment, the Federal Circuit expressly declined to address the district court’s alternative holding that Sandoz had to follow the litigation provisions of the BPCIA. Id. at 2, 8, and 15.
Second, on December 1, the U.S. District Court for the Southern District of New York (SDNY) dismissed Celltrion’s Complaint against the Kennedy Trust seeking a declaration that certain patents are invalid, among other reasons, for obviousness-type double patenting. Celltrion wanted to invalidate the Kennedy Trust’s patents to facilitate the marketing of Remsima, a biosimilar to Janssen Biotech’s Remicade®, in the US after its approval by the FDA. Celltrion Healthcare Co., Ltd. v. Kennedy Trust for Rheumatology Research, Case No. 14 Civ. 2256 (PAC) (S.D.N.Y. Dec. 1, 2014). The court found that Celltrion was not close enough to receiving FDA approval to market Remsima and that Kennedy Trust had not done enough to prove that it intended to sue Celltrion for infringement. The court also exercised its discretion not to accept the case because Celltrion had not complied with the litigation provisions of the BPCIA. The court also stated it was “improper” for Celltrion not to follow those procedures.

Finally, also on December 1, the SDNY also dismissed Hospira’s Complaint against Janssen Biotech, the Kennedy Trust, and others. Hospira, Inc. v. Janssen Biotech, Inc., Case No. 14 Civ. 7049 (PAC). Hospira will be the U.S. distributor for Celltrion’s Remsima biosimilar, and also sought a declaratory judgment to clear the way for U.S. marketing of the product. Although the Court dismissed the case for the same reasons it dismissed Celltrion’s case against Kennedy Trust, this opinion is noteworthy for at least two reasons. First, the Court would not allow a biosimilar applicant to avoid the BPCIA litigation provisions by appointing a distributor: “As defendants argue, adjudicating this case would enable any biosimilar developer to partner with another distributor and thereby skirt the dispute resolution procedures Congress purposefully enacted for use in such situations.” Slip op. at 3. Second, the Court noted that “Celltrion has voluntarily dismissed its identical suit against Janssen in the District of Massachusetts and has begun engaging in the information exchange procedures of the BPCIA.” Id.

For anyone keeping score, the current tally is: Reference product sponsors 4, biosimilar applicants attempting to sidestep the patent dance 0.

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