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PERSPECTIVE

The biosimilar patent dance: When in doubt, list it

By Limin Zheng

The Biologics Price Competition and Innovation Act (BPCIA) provides for an exchange of information, known as the "patent dance," between the biosimilar applicant and the reference product sponsor intended to resolve potential patent disputes in an orderly fashion. Under Section 262(l)(2)(A) of the act, within 20 days of acceptation of the biosimilar applicant's application, the applicant "*shall* provide to the reference product sponsor a copy of the application ... , and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." In June, in *Sandoz v. Amgen*, the U.S. Supreme Court held that injunction is not available under federal law to force the biosimilar applicant to initiate the patent dance under Section 262(l)(2)(A) (though the court left open the possibility of an injunction under state law).

But if the biosimilar applicant elects to start the dance, then after receiving the application and other information from the biosimilar applicant, the reference product sponsor is required under Section 262(l)(3)(A) to provide to the biosimilar applicant "a list of patents for which the reference product sponsor believes a claim of patent infringement *could reasonably be asserted*." The list may change after negotiations, but the reference product sponsor can only sue on patents included in the final list.

In *Amgen v. Hospira*, issued Aug. 10, the U.S. Court of Appeals for the Federal Circuit opined that the "could reasonably be asserted" language allows a reference product sponsor to include in the patent dance any patent that it believes in good faith "could" reasonably be asserted, even if it is based on a mistaken belief. And if the biosimilar applicant fails to disclose information required under BPCIA pertinent to assessing infringement of a listed patent, the listing of the patent is automatically "reasonable."

During the patent dance, Hospira refused to provide information about the specific composition of its cell culture medium used to make Hospira's biosimilar of Epogen, claiming that it had provided sufficient information about both its product and the manufacture processes in its abbreviated Biologics License Application. Unable to get the information about the cell culture medium, Amgen did not identify any cell culture patents during the patent dance, and did not assert any cell culture patents when it filed suit in the district court. And because no cell culture patent was asserted in the lawsuit, the district court denied Amgen's motion to compel, finding that the information sought by Amgen was not relevant to the case. Amgen appealed.

> Emphasizing the word 'could' in the statute, the Federal Circuit opined that BPCIA only requires that the sponsor list patents that it 'believes ... could reasonably be asserted,' and provides 'no sanction for holding or asserting a mistaken belief in good faith.'

In dismissing Amgen's appeal, the Federal Circuit held that it lacked jurisdiction over the trial court's discovery order, and that Amgen failed to satisfy the prerequisites for mandamus — that it had "no other adequate means to attain the [desired] relief."

Amgen argued that unless discovery of Hospira's process was allowed, its right to sue on its cell-culture patents under BPCIA would be thwarted. According to Amgen, under BPCIA, it could only list patents that it had a goodfaith belief that a claim of patent infringement could reasonably be asserted or else face sanctions under Rule 11. By withholding information, Hospira effectively prevented Amgen from asserting its cell culture patents.

The Federal Circuit disagreed. Noting that an injunction to force a biosimilar applicant to make disclosures under BPCIA is not available under federal law in view of the Supreme Court's decision in *Sandoz*, the Federal Circuit identified four other potential avenues available to a sponsor like Amgen — though one (sue for patent infringement based on failure to disclose information required under BPCIA) was also made unavailable by *Sandoz*, and another (injunctive relief under state law) was somewhat dubious.

Emphasizing the word "could" in the statute, the Federal Circuit opined that BPCIA only requires that the sponsor list patents that it "believes ... *could* reasonably be asserted," and provides "no sanction for holding or asserting a mistaken belief in good faith." According to the Federal Circuit, what Amgen should have done was to list the cell culture patents during the patent dance, which would have required Hospira to respond with "a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the [biosimilar] applicant that such patent is invalid, unenforceable, or will not be infringed." Had Hospira failed to comply with its disclosure obligations under BPCIA, Amgen "would have a reasonable basis for asserting a claim of patent infringement." (The Federal Circuit noted that the statute also allowed Amgen to sue on patents that "*could* be identified" pursuant to the patent dance provisions of the BPCIA — presumably an even lower threshold than "reasonable basis" — but declined to address whether a biosimilar applicant's failure to disclose information required under BPCIA would allow the sponsor to assert a patent on this basis.)

The Federal Circuit also clarified that its previous opinion that a sponsor "can access the required information through discovery" did not "purport to hold that the usual rules governing discovery do not apply in the BPCIA context." And "[n]othing in Sandoz suggests that the BPCIA somehow supplants the preexisting rules of civil procedure." Having not identified the cell culture patents during the patent dance nor asserted them in the lawsuit, Amgen appears to be out of luck in getting the cell culture information from Hospira through discovery.

So for all the reference product sponsors about to enter into a patent dance, until the Supreme Court says otherwise, when in doubt, list your patents.

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