Federal Circuit Rejects Application of the On-Sale Bar to Contract Manufacturers

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Today, in The Medicines Co. v. Hospira, Inc., Appeal Nos. 2014-1469, -1504, the en banc Federal Circuit reversed the panel decision and held that the on-sale bar did not apply to The Medicines Co.’s (“MedCo’s”) use of a contract-manufacturing organization to produce a product or product-by-process invention. In reaching its decision, the Court determined that, “to be ‘on sale’ under § 102(b), a product must be the subject of a commercial sale or offer for sale, and that a commercial sale is one that bears the general hallmarks of a sale pursuant to Section 2-106 of the Uniform Commercial Code.” Op. at 3. According to the Court, the manufacture of a drug product by a contract-manufacturing organization, where title to the drug product never passed between the contracting parties, does not rise to the level of a commercial sale triggering the on-sale bar.

I. Background

MedCo is the maker of Angiomax®, a branded form of the anti-coagulant bivalirudin. Because MedCo is a small pharmaceutical company, it lacks the facilities in-house to manufacture Angiomax®. Instead, since October 2006, it has contracted with Ben Venue Laboratories (“BVL”), a third-party manufacturing organization, to produce commercial quantities of Angiomax® according to the patents-in-suit, U.S. Patent Nos. 7,582,727 and 7,598,343. The patents-in-suit contain product and product-by-process claims for pharmaceutical batches of an improved drug product. Since applications leading to both patents were filed on July 27, 2008, the critical date for an on-sale bar was July 27, 2007.

In relevant part, MedCo contracted with BVL to manufacture three batches of bivalirudin according to the novel process. The first batch of approximately 5,700 commercially-saleable vials was completed on October 31, 2006 for a price of roughly $70,000. Three and six weeks later, BVL completed two additional batches of 27,500 and 27,000 vials, respectively, for $140,000. The three batches were worth over $20 million on the commercial market. The manufacturing protocol covering the transaction specified that the vials were for commercial use—including marking each batch with commercial product codes and customer lot numbers—but that they would be quarantined until fully tested and FDA-approved. MedCo released the batches from quarantine in August 2007.

Hospira, a generic drug manufacturer, filed two Abbreviated New Drug Applications seeking approval to sell generic bivalirudin drug products. MedCo subsequently filed suit against Hospira in the District of Delaware for infringement of the patents-in-suit. Hospira asserted that MedCo’s activities with BVL before the critical date constituted invalidating sales. After a bench trial, the district court in relevant part found that the patents were ready for patenting but not the subject of a commercial offer for sale.
and therefore not invalid. In so holding, the Court construed the transactions between MedCo and BVL as sales of contract manufacturing services in which title to Angiomax® always resided with MedCo and found that such an arrangement did not run counter to the purposes of the on-sale bar.

II. Panel Decision

Hospira appealed the district court’s ruling, arguing that (i) any transaction that provides a commercial benefit to the inventor is enough to trigger the on-sale bar and (ii) the fact that title did not transfer was of no consequence because the immediate financial benefit to MedCo of having a ready supply of product for sale constituted commercialization and triggered the bar.

In an opinion written by Judge Hughes and joined by Judges Dyk and Wallach, the panel reversed the district court’s no on-sale bar holding. The panel found that, even though title did not transfer between Medco and BVL, the invention was commercially exploited before the critical date. According to the panel, there was no distinction between an offer to sell products prepared by a patented method, see D.L. Auld Co. v. Chroma Graphics Corp., 714 F.2d 1144, 1147 (Fed. Cir. 1983), and a commercial sale of services that result in a patented product-by-process. In other words, because MedCo paid BVL for services that resulted in the patented product, the transactions were commercial sales. The panel stated that holding otherwise would conflict with the “no supplier exception” of Special Devices, Inc. v. OEA, Inc., 270 F.3d 1353, 1355 (Fed. Cir. 2001).

III. En Banc Decision

The en banc Court held that the transaction between MedCo and BVL did not constitute a commercial sale sufficient to trigger the bar. After a brief discussion of the history of the on-sale bar, Judge O’Malley, writing for the Court, stated that “the mere sale of manufacturing services by a contract manufacturer to an inventor to create embodiments of a patented product for the inventor does not constitute a ‘commercial sale’ of the invention.” Op. at 19. Rejecting Hospira’s position, the Court held that “commercial benefit—even to both parties in a transaction—is not enough to trigger the on-sale bar of § 102(b); the transaction must be one in which the product is ‘on sale’ in the sense that it is ‘commercially marketed.’” Id. “Applying the on-sale bar to the transaction-at-issue would be: (1) arbitrary, as it treats companies making the same pre-commercial preparations differently; (2) ineffective to discourage stockpiling, as it does not penalize or prevent companies with in-house manufacturing capabilities from stockpiling; (3) and unnecessary, as stockpiling by the purchaser of manufacturing services is not the type of commercial activity with which the on-sale bar is concerned.” Id. at 29.

The Court began its discussion by noting that the patents-in-suit were to product and product-by-process claims, as opposed to method and process claims, a key distinction when applying the on-sale bar. Although Hospira argued that, by manufacturing embodiments of the patented product for MedCo, BVL put the invention “on sale,” the Court has “never espoused the notion that, where the patent is to a product, the performance of the unclaimed process of creating the product, without an accompanying “commercial sale” of the product itself, triggers the on-sale bar.” Id. at 20. In all of the cases relied on by Hospira, the implicated claims covered processes and methods, not products. According to the Court, “[t]he most natural conclusion to draw from all of the evidence presented in this case is that BVL sold contract manufacturing services—not the patented invention—to MedCo [and] acted as a pair of ‘laboratory hands’ to reduce MedCo’s invention to practice.” Id. at 21-22. The Court was also persuaded by the lack of title transfer, which “indicate[d] an absence of commercial marketing of the product by the inventor,” id. at 23, and the confidentiality of the transaction, id. at 24.
The Court also looked to the policy of the on-sale bar in rejecting Hospira’s commercial benefit argument. Those purposes (i.e., to prevent any attempt to use an invention for profit and to prevent an inventor from exploiting his discovery competitively after it is ready for patenting) require a commercial sale or offer for sale, not mere stockpiling. Indeed, the Court found that stockpiling “is, when not accompanied by an actual sale or offer for sale of the invention, mere pre-commercial activity in preparation for future sale. . . . [S]tockpiling by an inventor with the assistance of a contract manufacturer is no more improper than is stockpiling by an inventor in-house,” a preparation for future commercialization. Id. at 26, 28. And while prohibiting stockpiling using the bar may incentivize the early filing of patents, it would go against the plain language and purposes of the statute.

Having disposed of the commercial sale inquiry, the Court turned to the “supplier exception” from Special Devices and decided not to overrule that case. It instead clarified that, “in the face of a concession by the inventor that the transaction between it and its supplier was a commercial sale, . . . the import of Special Devices is simply that the fact that a sale is made by a supplier is not, standing alone, sufficient grounds upon which to characterize a transaction having all of the hallmarks of a commercial sale under the UCC as something other than a commercial sale.” Id. at 30. The Court, however, did note that there was no “blanket ‘supplier exception’ to what would otherwise constitute a commercial sale as we have characterized it today,” since the focus of the inquiry must be on the commercial nature of the transaction, not the participants. Id. at 31.

The Court remanded the case back to the panel to decide, among other things, whether and when the invention was ready for patenting and whether a distribution agreement that MedCo entered into would trigger the on-sale bar.

IV. Implications

The Federal Circuit’s decision paves the way for specialty companies to employ outside vendors to manufacture their inventions. In holding that a contract-manufacturing organization’s production of an invention covered by a product or product-by-process claim does not trigger the on-sale bar, the Court rejected the distinction between companies that have such capabilities in-house and those that require outside assistance for those activities. That decision will allow companies to focus their efforts on research and development, as appropriate, without having to confront potential patentability issues post-invention.

The breadth of the Court’s ruling, however, remains to be decided. While the Court sanctioned the use of contract manufacturers, the panel still needs to address the remanded issue of contract distributors. The Court’s language equating services performed in-house and those performed by contract service providers (as well as its focus on factors such as confidentiality and whether the third party has the ability to freely market the invention before the critical date) should provide guidance to the panel.

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