

7-12-2016

Full Federal Circuit Curbs On Sale Bar's Threat to Patents

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Recommended Citation

Tian, Zong-Qiang Bill and D'Amore, Matthew, "Full Federal Circuit Curbs On Sale Bar's Threat to Patents," *Morrison Foerster Client Alert*, July 12, 2016

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Client Alert

July 12, 2016

Full Federal Circuit Curbs On Sale Bar's Threat to Patents

By Zong-Qiang Bill Tian and Matthew D'Amore

Biotech and pharmaceutical companies received critical guidance from the Federal Circuit yesterday, when the *en banc* court exempted a broad category of common manufacturing and supply arrangements from the reach of the patent law's "on sale" bar. In *The Medicines Company v. Hospira, Inc.*, App. No. 14-1469 (Fed. Cir. 2016) (*en banc*), the Federal Circuit ruled unanimously 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" and does not create a potential bar to patentability under 35 U.S.C. § 102(b). The decision reduces the IP risk that smaller pharmaceutical companies faced when contracting out for manufacturing services during commercial development, and provides in-house counsel with signposts to craft agreements that will stay clear of the on sale bar.

BACKGROUND

The Medicines Company (MedCo) is a specialty pharmaceutical company that does not have its own manufacturing facilities and is not capable of making its products in-house. MedCo contracted with Ben Venue Laboratories ("Ben Venue") to manufacture its Angiomax® (bivalirudin) drug product. During production, MedCo developed a new process that reduced impurities in the drug product. MedCo paid Ben Venue to manufacture three commercial batches of the drug product in late 2006 for validation testing and ultimately commercial sale. Once manufactured by Ben Venue, the batches were placed in quarantine with MedCo's distributor (ICS) while testing was completed, and they were released from quarantine and made available for sale to consumers in August 2007.

MedCo filed two patent applications on this process in July 27, 2008, more than a year after receiving the commercial batches from Ben Venue but less than a year before the batches were released from quarantine and sold to consumers.

PROCEDURAL HISTORY

In 2010, MedCo sued Hospira in the District Court for the District of Delaware after Hospira filed Abbreviated New Drug Applications (ANDA) to market generic versions of Angiomax®. Hospira argued that the arrangements between MedCo and Ben Venue, and between MedCo and its distributor ICS, both violated the on sale bar and rendered MedCo's patents invalid.

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The district court applied the two-step framework of *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998).¹ The district court found that the three batches Ben Venue manufactured for MedCo did not trigger the on sale bar because the transactions between MedCo and Ben Venue were sales of contract manufacturing services and the claimed invention (the drug product) was not commercially offered for sale prior to the one-year critical date of July 27, 2007. The district court further held that the batches were made for experimental purposes in order to validate the new manufacturing processes. Additionally, the district court held that MedCo's contract with ICS was "a contract to enter a contract" and not an invalidating sale.

On appeal, a three-judge panel at the Federal Circuit reversed the district court's ruling regarding the applicability of the on sale bar, holding that the on sale bar applies because the inventor commercially exploited the invention before the critical date.² The panel also reversed the finding that the experimental use doctrine applied, because the invention had been reduced to practice and known to work for its intended purpose.

In November 2015, the Federal Circuit granted MedCo's petition for rehearing *en banc*.

HOLDINGS

In its July 11, 2016 decision the *en banc* Court held "that a contract manufacturer's sale to the inventor of manufacturing services where neither title to the embodiments nor the right to market the same passes to the supplier does not constitute an invalidating sale under §102(b)." It thus concluded that the transactions between MedCo and Ben Venue in 2006 and 2007 did not constitute commercial sales of the patented product.³

The Court laid out three reasons for its holding:

- (1) Only manufacturing services were sold to the inventor; the invention was not. Ben Venue invoiced MedCo for manufacturing services, not for sale of an article of manufacture.
- (2) The inventor maintained control of the invention. Ben Venue lacked "title" to the products, and "was not free to use or sell the claimed products or to deliver the patented products to anyone other than MedCo." Noting that section 2-106(1) of the Uniform Commercial Code describes a "sale" as "the passing of title from the seller to the buyer for a price," the court held that the absence of the transfer of title is a helpful (but not dispositive) indicator that a sale did not occur.
- (3) "Stockpiling," standing alone, does not trigger the on sale bar. Stockpiling—or building inventory prior to a commercial sale—is, when not accompanied by an actual sale or offer for sale of the invention, mere pre-commercial activity in preparation for future sale. The court found it irrelevant that the manufacturing and "stockpiling" provided commercial benefit to both MedCo and Ben Venue; the important question was whether the transaction was a sale or offer for sale.

¹ Under *Pfaff*, the on sale bar renders a patent invalid if, more than a year before the subject patent applications were filed, the claimed invention was (1) the subject of a commercial offer for sale and (2) ready for patenting.

² *The Medicines Company v. Hospira, Inc.*, 791 F.3d 1368 (Fed. Cir. 2015). Because the three-judge panel concluded that the transactions between MedCo and Ben Venue violated the on sale bar, it did not address the transactions between MedCo and ICS.

³ The Court did not reach the questions of whether the transactions were subject to the experimental use exception, or whether the MedCo-ICS transaction gave rise to an independent on sale bar. These may be addressed by the original panel on remand.

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In reaching these conclusions, the Court gave weight to the real-world consideration that the prior decision would discriminate between companies that relied on outside manufacturers and those that did not. Recognizing that “we have never held that stockpiling by an inventor in-house triggers the on-sale bar,” the full Court found “no reason to treat MedCo differently than we would a company with in-house manufacturing capabilities.”

Notably, unlike some precedent cited by Hospira, the MedCo patents at issue covered the product itself, not the method of making it; the *en banc* Court suggested that the result might be different for patents that claim a method of manufacturing a product. In that situation, the sale of “manufacturing services” that performed the patented manufacturing method may be found to have put the method “on sale.”⁴

CONCLUSION

The *en banc* decision limiting the reach of the on sale bar should be welcome news in the life sciences industry. The Federal Circuit also provides useful guidance to companies that engage contract manufacturers but hope to ensure that their transactions do not trigger the on sale bar. And it provides insight for patent prosecutors and due diligence attorneys reviewing earlier manufacturing agreements to evaluate patentability of later-issued patents.

Note, however, that the Federal Circuit expressly limited the decision to pre-AIA § 102(b). It remains to be seen whether the reasoning in this case will hold under the AIA.

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⁴ The court distinguished *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147 (Fed. Cir. 1983), *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 518 (2d Cir.1946), *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1328-29 (Fed. Cir. 2001), and *Plumtree Software, Inc. v. Datamize, LLC*, 473 F.3d 1152, 1163 (Fed. Cir. 2006), all on the basis that they found the on sale bar triggered by the use, sale, or offer for sale of patented methods.