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Intellectual Property Alert:

Full Federal Circuit Affirms District Court on Inapplicability of On-Sale Bar to MedCo's Transactions

By Ernest V. Linek

July 12, 2016—Yesterday, the Court of Appeals for the Federal Circuit issued a unanimous *en banc* decision in favor of The Medicines Company (MedCo), holding that use of a contract manufacturer's services does not constitute an invalidating sale under Section 102(b) of the America Invents Act where neither title to the product nor the right to market the same passes to the supplier. Rather, in order for the on-sale bar to apply, the court held that the 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 the Uniform Commercial Code.

This case concerns the circumstances under which a product produced pursuant to the claims of a product-by-process patent is "on sale" under 35 U.S.C. §102(b). This is important because, if an invention is "on sale" more than one year before the filing of an application for a patent on the governing claims, any issued patent is invalid, and the right to exclude others from making, using, and selling the resulting product will be lost.

MedCo owns two patents (US 7,582,727 and US 7,498,343) with claims directed to the preparation of the drug bivalirudin (sold as Angiomax®), a synthetic peptide used as an anti-coagulant.

MedCo purchased batches of Angiomax® from Ben Venue Laboratories between 1997 and 2006. In 2005, one of those batches contained impurities, and MedCo discovered that it could reduce the impurities by adding a pH-adjusting solution. In 2008, MedCo filed patent applications that include product-by-process claims directed to this method. However, more than one year before the filing, MedCo hired Ben Venue Labs to prepare three batches of the drug using the claimed method.

In 2010, MedCo sued Hospira for infringement. The Delaware district court rejected Hospira's on-sale invalidity defense, finding (1) that Ben Venue only sold manufacturing services, and (2) that the batches fell under the experimental use exception.

The district court applied the Supreme Court's two-step on-sale bar analysis from *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998). *Pfaff*'s two-step on-sale bar analysis requires that the claimed invention was both (1) the subject of a commercial offer for sale; and (2) ready for patenting. 525 U.S. at 67-68.

The district court held that the claimed invention was ready for patenting under the second prong of *Pfaff* because MedCo had developed two enabling disclosures prior to the critical date, or, alternatively, reduced the invention to practice before the critical date. However, the district court concluded that the first prong of *Pfaff* was not met, because the claimed invention was not commercially offered for sale prior to the critical date. Accordingly, the district court found that the three batches Ben Venue manufactured for MedCo did not trigger the on-sale bar. The district court also agreed with MedCo that the transactions between MedCo and Ben Venue were sales of contract manufacturing services in which title to the drug Angiomax always resided with MedCo.

The original Federal Circuit panel's decision took a literal approach to the on-sale bar and determined that because MedCo had paid Ben Venue to manufacture the drug, a sale took place and the bar applied. Judge Hughes, writing for the panel, found that it did not matter that Ben Venue provided only services and that title to the batches did not change hands. He said the Court held in *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144 (Fed. Cir. 1983), that the on-sale bar may apply where an inventor, before the critical date, sold products made by a patented method.

In granting the petition for *en banc* review, the Federal Circuit vacated the panel opinion and asked the parties to address whether "the circumstances presented here constitute a commercial sale under the on-sale bar," and whether the court should overrule or revise the principle "that there is no 'supplier exception.'"

The court posed the following questions for *en banc* briefing:

> (a) Do the circumstances presented here constitute a commercial sale under the on-sale bar of 35 U.S.C. 102(b)?
>
> > (i) Was there a sale for the purposes of 102(b) despite the absence of a transfer of title?
> >
> > (ii) Was the sale commercial in nature for the purposes of 102(b) or an experimental use?
>
> (b) Should this court overrule or revise the principle in *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), that there is no "supplier exception"?

The case was argued to the *en banc* court on May 5, 2016. Hospira argued that there was a commercial sale, which benefited MedCo. This sale was before the critical date, and accordingly, the sale met the "on sale bar" test.

MedCo argued that there was no sale of the claimed product. Instead, MedCo simply purchased services from Ben Venue for the manufacture of the drug. Those services were paid for—$347,500 to make over $20 million worth of the drug Angiomax®. Title to the drug did not pass from MedCo to Ben Venue.

The federal government also participated in the *en banc* argument. The government's attorney agreed that there was likely no commercial sale in this case. The manufacturing agreement was confidential. There was no public benefit from the activities of MedCo and Ben Venue. There was no public exploitation of the invention.

The *en banc* Federal Circuit court held 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.

> The absence of title transfer further underscores that the sale was only of Ben Venue's manufacturing services. Because Ben Venue lacked title, it was not free to use or sell the claimed products or to deliver the patented products to anyone other than MedCo, nor did it do so. 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." U.C.C. §2-106(1). The passage of title is a helpful indicator of whether a product is "on sale," as it suggests when the inventor gives up its interest and control over the product. A "sale" under §102(b) occurs when the parties . . . give and pass rights of property for consideration. *Special Devices*, 270 F.3d at 1355 (quoting *Zacharin v. United States*, 213 F.3d 1366, 1370 (Fed. Cir. 2000)); *see also Trading Techs.*, 595 F.3d at 1361 ("The transaction at issue must be a 'sale' in a commercial law sense.").

Because the original Federal Circuit panel held that the two patents in suit were invalid under the on-sale bar as a result of Medco's transactions with Ben Venue, the panel did not address any other issues raised on appeal. The *en banc* court likewise did not address any issues other than the on-sale bar:

> Given our conclusion that there was no "commercial sale" of the inventions in the '727 and '343 patents, we agree that we need not reach the question of experimental use. Since the panel opinion has been vacated, we also decline to parse individual statements therein that are not determinative of the question presented. For the same reason, we do not reach the second prong of *Pfaff*—whether the invention was ready for patenting—despite the fact that MedCo argued at the district court that it was not and challenges the district court's finding to the contrary on appeal. Ultimately, we reach the same conclusion the

> district court did regarding the inapplicability of the on-sale bar to Medco's transactions with Ben Venue, but do so on modified grounds. All other issues are remanded to the merits panel for consideration in the first instance.

The commercial character of the transaction rules. The court addressed the Supplier Exception at page 31 of the opinion:

> We still do not recognize a blanket "supplier exception" to what would otherwise constitute a commercial sale as we have characterized it today. While the fact that a transaction is between a supplier and inventor is an important indicator that the transaction is not a commercial sale, understood as such in the commercial marketplace, it is not alone determinative. Where the supplier has title to the patented product or process, the supplier receives blanket authority to market the product or disclose the process for manufacturing the product to others, or the transaction is a sale of product at full market value, even a transfer of product to the inventor may constitute a commercial sale under § 102(b). The focus must be on the commercial character of the transaction, not solely on the identity of the participants.

This decision supports the practice of using third-party contract manufacturing services by pharmaceutical companies for their drug development programs. As long as the patent owner retains ownership of the invention, there will be no on-sale bar based on such service contracts.

Please click here to view the opinion in *The Medicines Company v. Hospira, Inc.*, No. 14-1469 at the U.S. Court of Appeals for the Federal Circuit.