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Federal Circuit Requires Actual Commercial Marketing of an Invention to Trigger the On-Sale Bar Under § 102(b)

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The case involved two patents owned by the Medicines Company ("MedCo"). The patents include product and product-by-process claims. Defendant Hospira Inc. ("Hospira") sought approval to sell generic drug products covering the drug Angiomax, which is covered by the patents-in-suit. MedCo sued Hospira, claiming patent infringement. Hospira asserted that MedCo had contracted with Ben Venue, a third-party laboratory, to manufacture commercial quantities of the drug more than one year before the filing date of the patents-in-suit, thus triggering the on-sale bar under § 102(b). Hospira claimed that the manufacturing contract allowed MedCo to stockpile products, which constituted a commercial benefit. Hospira also alleged that MedCo's distribution agreement with another third party also triggered the on-sale bar. Although MedCo entered into this distribution agreement before the critical date under § 102(b), no sale took place under the contract before the critical date.

The district court found that the on-sale bar did not apply. It held that under the Supreme Court's *Pfaff v. Wells Elecs, Inc.* decision, the on-sale bar applies only if the claimed invention was (1) the subject of a commercial offer for sale; and (2) ready for patenting. The district court found that the contract manufacturer made the drugs for experimental purposes only so that the on-sale bar did not apply. It also held that the distribution agreement was an agreement to sell and did not constitute an invalidating sale.

The first Federal Circuit panel reversed, finding that MedCo commercially exploited the invention before the critical date. The first panel also found that the district court should not

have applied the experimental use exception to the on-sale bar because the invention had already been reduced to practice.

The Federal Circuit subsequently granted rehearing *en banc*, and reversed the previous panel's decision. Specifically, it held that the transaction between MedCo and Ben Venue did not constitute commercial sales of the patented product. It explained that mere sale of a manufacturing service by a contract manufacturer to create embodiments for the inventor does not constitute a "commercial sale." Here, Ben Venue acted as only a pair of laboratory hands to reduce MedCo's invention to practice. It never had any title or freedom to use or sell the claimed products. Further, the court explained that merely receiving a commercial benefit, such as stockpiling the patented drugs, is not enough to trigger the on-sale bar. According to the court, MedCo's stockpiling was a pre-commercial activity. Instead, a transaction triggering the on-sale bar must be an actual commercial marketing of the invention. Reaching the conclusion that no commercial sale or offer for sale took place, the court affirmed the district court's decision that MedCo's actions did not trigger the on-sale bar. The court did not rule on the remaining issue of whether the experimental use exception to the on-sale bar applies.

The Medicines Co. v. Hospira, Inc., C.A. Nos. 2014-1469, 2014-1504 (July 11, 2016).

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