Federal Circuit rules distribution agreement may be invalidating 'offer for sale'

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In a February 6, 2018, decision, a Federal Circuit panel reasoned that a pharmaceutical distribution agreement can qualify as an invalidating “offer for sale” under 35 USC section 102(b) when the terms of the agreement demonstrate the commercial character and elements of an offer to sell a patented product.

Background

The Medicines Company (Medicines) asserted two patents covering its Angiomax anti-blood-clot drug product (the Product) against Hospira, a generic drugmaker and Abbreviated New Drug Application (ANDA) filer. Medicines developed a new method of formulating Angiomax that reduced impurities. That formulation was the subject of the asserted patents, which were filed on July 27, 2008. Prior to that filing, Medicines, on February 27, 2007, entered into an agreement with Integrated Commercialization Solutions, Inc. (ICS) to distribute the Angiomax formulation. The agreement stated that Medicines “desire[d] to sell the Product” to ICS and that ICS “desire[d] to purchase and distribute the Product.” The agreement further provided that title passed to ICS upon receipt of the Product at the distribution center. The agreement also included a commercial price list for the Product.

The district court decision

As the Supreme Court has held, a patent for an invention is invalid under the on-sale bar if, before the critical date, (i) a product embodying the invention is the subject of a commercial offer for sale, and (ii) the invention is ready for patenting. *Pfaff v. Wells Elecs., Inc.,* 525 US 55, 67 (1998). In the instant case, the district court found that the invention was ready for patenting at the time of the agreement, but concluded that the patents were not invalid under section 102(b)’s on-sale bar because the distribution agreement between Medicines and ICS did not constitute an offer to sell.

The Federal Circuit's reversal

The Federal Circuit reversed and remanded, finding that the terms of the distribution agreement show that the agreement was an offer for sale.

In its decision, the Court noted that it analyzed the “on-sale bar” issue “under the law of contracts as generally understood,” focusing “on those activities that would be understood to be commercial sales and offers for sale ‘in the commercial community.” *Medicines Co. v. Hospira, Inc.* (*Medicines I*), 827 F.3d 1363 (Fed. Cir. 2016) (*en banc*) (citation omitted). Although the Uniform Commercial Code (UCC) is not dispositive, it is a useful guide for defining whether a transaction is a commercial offer for sale. Accordingly, a commercial sale “is a contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing

bought or sold." *Id.* (citation omitted).

The Federal Circuit noted that the terms of the distribution agreement included statements that Medicines desired to sell the Product and that ICS desired to purchase and distribute the Product. The agreement also forbade Medicines from selling the Product to any other party in the US for the duration of the contract. Although ICS had been distributing for Medicines since 2002, the previous distribution agreement did not have ICS take title to the Product. The new one specifically included the commercial price of the Product, a purchase schedule, and a provision transferring title to ICS upon receipt.

The new agreement also required ICS to place weekly purchase orders "for such quantities of Product as are necessary to maintain an appropriate level of inventory based on customers' historical purchase volumes." Under the agreement, the orders from ICS were deemed accepted unless Medicines rejected them within two business days.

Medicines argued the agreement was not an offer for sale because it was permitted to reject all purchase orders. However the Federal Circuit noted that the agreement required Medicines to use "commercially reasonable efforts" to fill the purchase orders, and that Medicines would be unlikely to reject an order because ICS had exclusive distribution rights under the agreement and Angiomax constituted the majority of Medicines' revenues. In addition, the Court noted that Medicines and ICS "explicitly and purposefully changed their previous distribution services relationship" to let ICS take title to the Product upon receipt at the distribution center. Therefore, the Federal Circuit held, the distribution agreement did not constitute an optional sales arrangement, but instead provided all of the necessary terms and conditions to constitute a commercial offer for sale. The Court remanded the case to the district court to determine whether the offer to sell covered the patented invention.

In the Federal Circuit decision, the Court provided some useful context for its reasoning, distinguishing Medicine's distribution agreement with ICS from an agreement that Medicines had with another contract manufacturer, Ben Venue Laboratories. Medicines' deal with Ben Venue was to manufacture experimental batches of Angiomax to ensure it met US Food and Drug Administration requirements. The Federal Circuit determined that that transaction did not constitute a commercial sale and, therefore, did not invalidate Medicine's patents, because: (i) the invoices issued by Ben Venue covered only manufacturing charges; (ii) Medicines paid Ben Venue only about 1 percent of the market value of the product; and (iii) title to the pharmaceutical batches did not transfer to Ben Venue. As such, Ben Venue only sold Medicines contract manufacturing services, rather than a product embodying the patented invention. In contrast, the terms of the distribution agreement with ICS dictated the sale of a product between Medicines and ICS, including the commercial price of the product and the transfer of title.

The Federal Circuit ended its analysis of the on-sale bar issue with a reminder that "the on-sale bar does not exempt commercial agreements between a patentee and its supplier or distributor." As the Federal Circuit noted:

> 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.

Medicines I, 827 F.3d at 1380.

Conclusion

This latest *Medicines* decision provides both would-be patent applicants and patent holders with useful guidance as they develop, manufacture and commercialize their products. The terms of a manufacturing or distribution agreement may very well be determinative of whether any activities undertaken pursuant to that agreement could constitute

invalidating 102(b) commercial sales or offers for sale.

If you have any questions or concerns regarding your manufacturing or distribution agreements, feel free to contact Dentons to determine whether any modifications are needed to effectively meet regulatory and commercial goals for products while simultaneously preserving patent rights to inventions that may cover those products.

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