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Federal Circuit Clarifies the "Commercial Offer for Sale" Prong of the On-Sale Bar

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On July 11, 2016, a unanimous Federal Circuit *en banc* affirmed that The Medicines Company's ("TMC") use of third-party contract manufacturing services did not invalidate U.S. Patent Nos. 7,582,727 and 7,598,343 (the "patents-in-suit") under the on-sale bar, reverting back to the district court's original ruling but on modified grounds. *The Medicines Company v. Hospira, Inc.*, No. 2014-1469 ("*Hospira*"). The Court provided useful guidance for companies and patentees that have third-party agreements to ensure they do not run afoul of the bar.

The on-sale bar under pre-AIA 35 U.S.C. § 102(b) prohibits patentability if "the invention" was "on sale" more than one year before the effective filing date of the invention. Here, TMC contracted with a batch manufacturer, Ben Venue Laboratories ("BV"), to produce Angiomax®, a blockbuster blood thinning drug covered by the patents-in-suit. More than a year before the effective filing dates of the patents-in-suit, TMC contracted with BV to manufacture a new formula of Angiomax® that met FDA requirements. In a decision penned by Judge O'Malley, the Federal Circuit reached the opposite conclusion from last year's 3-judge panel decision holding that the patents-in-suit were not invalid under the on-sale bar.

The Federal Circuit addressed the first prong of the U.S. Supreme Court's two-prong *Pfaff* test, which holds that a "claimed invention" is "on sale" when it is: 1) the subject of a commercial offer for sale; and 2) ready for patenting. Because the Federal Circuit dispensed with the issue on the first prong, it did not reach either the second prong or experimental use. The Court held that a "commercial sale or offer for sale" must bear the "general hallmarks of a sale pursuant to Section 2-106 of the Uniform Commercial Code," *i.e.*, when parties, intending to be legally bound, agree to give and pass property rights for consideration. An offer for sale can also trigger the bar when the offer rises to a "commercial" level—that is, an offer that another party could make into a binding contract by simple acceptance (assuming consideration).

Here, the Federal Circuit held that the transactions between TMC and BV did not rise to a commercial level. The Court reasoned that § 102 requires the claimed invention to be "on sale," in the sense that it is "commercially marketed." The product and product-by-process claims of the patents-in-suit covered a product. But, the contract between TMC and BV was a manufacturing service contract for the claimed product, not a contract for the sale of the product. The Court identified four factors in reaching its decision:

1. ***Manufacturing Service-Style Terms and Conditions:*** The Federal Circuit indicated that the invoice between TMC and BV was "to manufacture" the product, and the amount paid to BV was only about 1% of the ultimate market value of the manufactured product—indicating a service, not a sales, contract.

2. ***No Title Transfer:*** After clarifying that title transfer is a "helpful indicator" and not dispositive, the Court found that BV lacked title in the claimed products as it was not free to use or sell the products or to deliver the products to anyone other than TMC—reflecting a lack of commercial nature to the transaction ("[T]he inventor maintained control of the invention, as shown by the retention of title to the embodiments and the absence of any authorization to [the manufacturing service provider] to sell the product to others.")

3. ***Confidentiality:*** After noting that the confidential nature of the transaction is an important factor but not one of "talismanic significance," the Court held that the "scope and nature of the confidentiality" imposed on BV supported the view that the sale was not a commercial sale of the patented invention.

4. ***Stockpiling:*** "'[S]tockpiling,' standing alone, does not trigger the on-sale bar." The Court clarified that mere "commercial benefit" does not trigger the on-sale bar. *E.g.*, mere stockpiling of a patented invention by a purchaser of manufacturing services—irrespective of how the stockpiled material is packaged—does not constitute a "commercial sale" as it is "a pre-commercial activity in preparation for future sale." Instead, the Federal Circuit focused on "those characteristics that make a sale 'commercial' in the most well-understood sense of that term and on what constitutes commercial marketing of a product, as distinct from merely obtaining some commercial benefit from a transaction...."

The Court also refused to create a blanket "supplier exception," upholding its prior precedent and noting that the focus must be on the commercial character of the transaction and not solely on the identity of the parties.

Takeaways after Hospira

- Now that contract manufacturing does not *per se* trigger the on-sale bar, drugmakers and others that cannot make products in-house can rest assured that their patents are free from challenge ("We see no reason to treat [TMC] differently than we would a company with in-house manufacturing capabilities" as "there is no room in the statute and no principled reason . . . to apply a different set of on-sale bar rules to inventors depending on whether their business model is to outsource manufacturing or to manufacture in-house."). Yet, careful attention should be paid to the type of contractual terms between patent owners (and/or their exclusive licensees) and third parties.

- Structure supplier agreements as service manufacturing agreements, not product purchase/requirement contracts, and retain rights with title-retention clauses. The role of confidentiality and non-disclosure agreements over sales or offers for sale, as well as trade secrets, may expand to potentially avoid triggering the on-sale bar.

- Pre-commercial activities, such as stockpiling and publicizing upcoming availability of a product for sale, should not trigger the on-sale bar. Nonetheless, active steps should be taken to not create an "offer" in the commercial sense, which another party could merely accept to create a contract.

For practice-based tips for practitioners which still apply despite *Hospira's* holding, please click here and scroll down to Section IV. To view the Court's opinion, please click here.

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