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Federal Circuit Patent Bulletin: *The Medicines Co. v. Hospira, Inc.*

July 11, 2016

"[T]he 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 [under 35 U.S.C. § 102(b), and] "stockpiling" by the purchaser of manufacturing services is not improper commercialization under § 102(b)."

On July 11, 2016, in *The Medicines Co. v. Hospira, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Prost, Newman, Lourie, Dyk, Moore, O'Malley,* Reyna, Wallach, Taranto, Chen, Hughes, Stoll) affirmed-in-part the district court's judgment, *inter alia*, that U.S. Patents No. 7,582,727 and No. 7,598,343, which related to pH-adjusted pharmaceutical compositions of bivalirudin and a synthetic anticoagulant for use in coronary surgery (marketed by MedCo as Angiomax®), were not invalid as on-sale under 35 U.S.C. § 102(b). The Federal Circuit *en banc* stated:

Unlike *Pfaff* itself, the focus of this en banc appeal is on the first prong of the *Pfaff* test: whether the invention was the subject of a commercial sale or offer for sale. We have held that "the question of whether an invention is the subject of a commercial offer for sale is a matter of Federal Circuit law, to be analyzed under the law of contracts as generally understood." We also have held that, to be true to *Pfaff* when assessing prong one of § 102(b), we must focus on those activities that would be understood to be commercial sales and offers for sale "in the commercial community." We have also indicated that, "[a]s a general proposition, we will look to the Uniform Commercial Code (UCC) to define whether . . . a communication or series of communications rises to the level of a commercial offer for sale." And we have made clear that, post-*Pfaff*, "[t]he transaction at issue must be a 'sale' in a commercial law sense," and that "[a] 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."

Applying § 102(b) in light of *Pfaff*, we conclude that the transactions between MedCo and Ben Venue in 2006 and 2007 did not constitute commercial sales of the patented product. We, thus, affirm the district court's conclusion that those transactions were not invalidating under § 102(b). In the discussion that follows, we first clarify 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. We then address the issue of "stockpiling" by an inventor and clarify that "stockpiling" by the purchaser of

manufacturing services is not improper commercialization under § 102(b). We explain that commercial benefit —even to both parties in a transaction—is not enough to trigger the on-sale bar of § 102(b); the transaction must be one in which the product is "on sale" in the sense that it is "commercially marketed." There are, broadly speaking, three reasons for our judgment in this case: (1) only manufacturing services were sold to the inventor—the invention was not; (2) the inventor maintained control of the invention, as shown by the retention of title to the embodiments and the absence of any authorization to BenVenue to sell the product to others; and (3) "stockpiling," standing alone, does not trigger the on-sale bar. . . .

Hospira argues that, by manufacturing embodiments of the patented product for MedCo, Ben Venue put the invention "on sale." But we have never espoused the notion that, where the patent is to a product, the performance of the unclaimed process of creating the product, without an accompanying "commercial sale" of the product itself, triggers the on-sale bar. . . . The most natural conclusion to draw from all of the evidence presented in this case is that Ben Venue sold contract manufacturing services—not the patented invention—to MedCo. Under MedCo's instructions and using an API supplied by MedCo, Ben Venue acted as a pair of "laboratory hands" to reduce MedCo's invention to practice. The invoices for the manufacturing service stated, "Charge to manufacture Bivalirudin lot." In addition, MedCo paid Ben Venue only about 1% of the ultimate market value of the product Ben Venue manufactured. As described above, MedCo paid Ben Venue a total of $347,500 to make the three batches, even though these batches were commercially valued at well over $20 million. Unsurprisingly, therefore, the district court chose MedCo's description of the transaction as one in which "Ben Venue was paid to manufacture Angiomax for [MedCo]," over Hospira's description of the transaction as a "sale of the validation batches." As the original panel of this court stated, "the district court is correct that Ben Venue invoiced the sale as manufacturing services and title to the pharmaceutical batches did not change hands." Thus, under the plain text of § 102(b), there was no sale of the "invention."

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." 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." . . . Like the absence of title transfer, the confidential nature of the transactions is a factor which weighs against the conclusion that the transactions were commercial in nature. Again, this factor is not disqualifying in all instances—it too is not of talismanic significance. . . .

Hospira argues that finding the bar inapplicable here "would improperly permit an inventor to commercially stockpile his invention," in order to "restock its long-depleted commercial pipeline." But commercial benefit generally is not what triggers§ 102(b); there must be a commercial sale or offer for sale. The statute itself says the invention must be "on sale," or that there must be an offer for sale of the invention. *Pfaff* made this distinction clear and explained that we are not to look to broad policy rationales in assessing whether the on-sale bar applies; we are to apply a straightforward two-step process—one which permits an inventor to "both understand and control the first commercial marketing of his invention." For this reason, we find that the mere

stockpiling of a patented invention by the purchaser of manufacturing services does not constitute a "commercial sale" under § 102(b). Stockpiling—or building inventory—is, when not accompanied by an actual sale or offer for sale of the invention, mere pre-commercial activity in preparation for future sale. This is true regardless of how the stockpiled material is packaged. The on-sale bar is triggered by actual commercial marketing of the invention, not preparation for potential or eventual marketing. Contrary to Hospira's assertions, not every activity that inures some commercial benefit to the inventor can be considered a commercial sale. Instead, stockpiling by an inventor with the assistance of a contract manufacturer is no more improper than is stockpiling by an inventor in-house.

It is well-settled that mere preparations for commercial sales are not themselves "commercial sales" or "commercial offers for sale" under the on-sale bar. . . . Expanding the on-sale bar to encompass stockpiling by inventors that outsource manufacturing might encourage earlier filing of patents. But we cannot endorse any blunt instrument that rewards earlier patent applications when so doing ignores the wording Congress chose when enacting the on-sale bar. . . .

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. . . .

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.