Keywords: on sale bar, 35 U.S.C. § 102(b)

General: Federal Circuit finds that a 'supply contract' for manufacturing services between a manufacturer and an inventor, more than one year before filing a patent application, does not trigger the on-sale bar of 35 U.S.C. § 102(b) (pre-AIA) as it is not a "commercial sale" under the Uniform Commercial Code.

The Medicines Company v. Hospira, Inc.,
United States Court of Appeals for the Federal Circuit
Nos. 2014-1469, -1504
Decided: July 11, 2016 (en banc)

I. Background

The Medicine Company ("Medco") markets a form of the drug bivalirudin, trade named Angiomax, in the United States. Angiomax is commonly used to prevent blood from clotting and is highly effective during coronary surgery. The active ingredient of Angiomax is too acidic for human injection and must be processed to reduce its pH level, however, processing the drug forms impurities. High levels of such impurities make Angiomax unusable. On July 27, 2008, Medco filed two patent applications, "727" and "343," claiming a new compounding process that produces an improved Angiomax product that does not have randomly high levels of impurities.

Medco does not have its own manufacturing facilities and is not capable of making its product in-house. Medco contracted with Ben Venue Laboratories ("Ben Venue") to manufacture Angiomax. In late 2006, Medco paid Ben Venue $347,500 to manufacture three batches of Angiomax using the new process claimed in the '727' and '343' patents. The first batch was completed on October 31, 2006 and the subsequent batches were complete in November and December of 2016.

The manufacturing protocol under the contract state that "[t]he solution will be filled for commercial use" and that the three batches "will be placed on quality hold until all testing has been successfully completed." In August 2007, Medco released the three batches from quarantine and made them available for sale.

This suit arises out of the submission from Hospira Inc. ("Hospira") to the Food and Drug Administration ("FDA") seeking approval to sell a generic bivalirudin, manufactured using the process of patents '727' and '343' before the expiration those patents. Hospira argues, *inter alia*, that the on-sale bar under 35 U.S.C. § 102(b) (pre-AIA) was triggered when Medco paid Ben Venue to manufacture Angiomax before July 27, 2007.

Under 35 U.S.C. § 102(b), "[A] person shall be entitled to a patent unless - (b) the invention was patented or described in a printed publication in this or a foreign country or in public use **or on sale in this country**, more than one year prior to the date of application for patent in the United States." (Emphasis added.)

II. Issue

Does a third party manufacturer's sale to the inventor of manufacturing services, more than one year before the filing of an application for a patent, where neither title to the embodiments nor the right to market the same passes to the supplier, constitute an invalidating sale under §102(b)(pre-AIA)?

III. Discussion

No. The Federal Circuit applied the two-step framework of *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 119 S. Ct. 304, 142 L. Ed. 2d 261 (1998) in determining whether the on-sale bar had been triggered. *Pfaff*'s two-step framework requires that the claimed invention was (1) the subject of a commercial offer for sale; and (2) ready for patenting. The Court held that the invention was ready for patenting. Therefore, the focus of this en banc appeal was on the first prong of the test: whether the invention was the subject of a commercial sale or offer for sale. For the following reasons, the court held that a commercial sale of the invention did not occur.

First, the court determined that Ben Venue sold manufacturing services, not the patented invention, to Medco. Under Medco's instructions, Ben Venue only acted as a pair of "laboratory hands" to reduce Medco's invention to practice. That is, Ben Venue was paid to manufacture Angiomax for Medco. Thus, the Court reasoned that Ben Venue sold manufacturing services and not the "invention."

Second, the Court held that the transaction was not a "sale" in a commercial law sense (looking to Section 2-106 of the Uniform Commercial Code). The Court defined a sale as 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. Under the contract, Ben Venue was not free to use or sell the claimed products or to deliver the patented products to anyone other than Medco. The title and rights to sell Angiomax did not pass from Medco to Ben Venue. Thus, although the Court declined to create a bright line rule making the passage of title dispositive on the issue, the Court held that under the circumstances of this case, the transaction was not a "sale" in a commercial law sense.

Third, the confidential nature of this transaction weighs against the conclusion that the transactions here were commercial in nature. It is well established that a single sale, even if kept secret, is enough to bar patentability, but the Court found that the scope and nature of the confidentiality imposed on Ben Venue supports the view that the sale was not for commercial marketing purposes.

Fourth, "stockpiling" of an invention does not trigger the on-sale bar. Hospira argued that Medco triggered the on-sale bar by "stockpiling" the invention through its transaction with Ben Venue. However, it is well-settled that mere preparation for commercial sales, stockpiling, are not themselves commercial sales. An actual sale or offer for sale must be proved to trigger the on-sale bar.

IV. Conclusion

A manufacturer's sale to the inventor of manufacturing services, more than one year before the filing of an application for a patent, where neither title to the embodiments nor the right to market the same passes to the supplier does not constitute an invalidating sale under §102(b)(pre-AIA).

V. Post-AIA

The current case applies to patents subject to the pre-AIA rule. However, the post-AIA rule modifies the statutory language of 35 U.S.C. § 102(b), "[a] person shall be entitled to a patent unless- (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." Thus, it is unclear whether courts will follow the same interpretation as the pre-AIA rule or whether the post-AIA language exempts any "secret sale" from the on-sale bar.