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The Federal Circuit: Actual Sale is Not Required for Triggering the On-Sale Bar under 35 U.S.C. § 102(b)

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On May 13, 2016, the Federal Circuit, in *Merck & Cie v. Watson Laboratories, Inc.,* held that an offer for sale that qualifies as a commercial offer under the law governing contracts, is enough to trigger an on-sale bar under 35 U.S.C. §102(b), even when an actual sale has not been actually consummated.

Merck & Cie and Bayer Pharma (collectively "Merck") sued Watson Laboratories, Inc. ("Watson"), accusing Watson of infringing a patent claim directed to a pharmaceutical ingredient, MTHF, by filing an Abbreviated New Drug Application ("ANDA") with the FDA, seeking approval of Watson's generic versions of the oral contraceptives Safyral® and Beyaz®. Over a year before filing the patent application, Merck explored the possibility of entering into a joint venture with Weider Nutrition International, Inc. ("Weider") to market MTHF. Weider backed out of the joint venture, but was still interested in *purchasing* MTHF. In response, Merck sent a fax detailing terms of the offer such as the price, payment terms, as well as shipping and delivery terms. Shortly thereafter, Weider cancelled what it characterized as its "existing order" and the sale never took place.

Validity of the patent hinged on whether the fax qualified as a commercial offer for sale even though the sale was never completed. Because Merck's patent application was filed in 2000, pre-AIA § 102(b) applied, which states that a patent claim is invalid if "the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States." In *Pfaff v. Wells Electronics, Inc.,* the Supreme Court articulated that the on-sale bar requires proof of two conditions: (1) the product is "ready for patenting," and (2) the invention is "the subject of a commercial offer for sale." Merck agreed that the invention was ready for patenting at the time of the fax. Therefore, the only remaining issue for the court was to determine whether a commercial offer for sale had occurred.

Notwithstanding the language in the fax that Merck would "arrange everything" including insurance once it received a purchase order, the court found that the communication "contained all the required elements to qualify as a commercial offer for sale." The court noted that while Merck had not delivered any MTHF to its customer, this fact was not dispositive of the issue. Rather, the court found that "an offer to sell is sufficient to raise the on-sale bar, regardless of whether the sale is ever consummated."

This is a cautionary tale and the moral of the story here is to consider filing a patent application as soon as the invention is ready for patenting, before engaging in sales negotiations because sales activity, including offers for sale will continue to be important given the uncertainty surrounding the on-sale clause of 35 U.S.C. §102(a)(1) of the Leahy-Smith America Invents Act ("AIA"), enacted in 2011. In addition, under AIA 35 U.S.C. §102(a)(1), offers for sale will qualify as "disclosures," thereby triggering the one-year clock under AIA 35 U.S.C. §102(b)(1).

This decision comes just a week after the Federal Circuit heard oral arguments in another case

involving an on-sale bar, *Medco v Hospira*, where the issue presented was whether an agreement with a third party to manufacture the invention was sufficient to trigger the on sale bar *under AIA*, a decision has not yet been issued in that case.

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