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Federal Circuit Patent Bulletin: *Merck & Cie v. Watson Labs., Inc.*

May 13, 2016

"An offer to sell is sufficient to raise the on-sale bar, regardless of whether that sale is ever consummated."

On May 13, 2016, in *Merck & Cie v. Watson Labs., Inc.*, the U.S. Court of Appeals for the Federal Circuit (Dyk, Mayer,* Hughes) reversed the district court's judgment that U.S. Patent No. 6,441,168, which related to a crystalline calcium salt of a tetrahydrofolic acid (MTHF), was not invalid under the on-sale bar of 35 U.S.C. § 102(b). The Federal Circuit stated:

"Our patent laws deny a patent to an inventor who applies for a patent more than one year after making an attempt to profit from his invention by putting it on sale." Section 102(b)'s on-sale bar is triggered when a claimed invention is: (1) ready for patenting; and (2) the subject of a commercial offer for sale prior to the critical date. Here, because Merck does not challenge the district court's determination that "MTHF was . . . ready for patenting by September 1998," our focus is on whether there was an invalidating commercial offer to sell the product prior to the critical date—April 17, 1999. In making this determination, we "apply[] traditional contract law principles." "Only an offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance (assuming consideration), constitutes an offer for sale under § 102(b)."

By August 1998, Weider had decided that it did not wish to enter into a partnership with Merck to market MTHF in the United States. Weider informed Merck, however, that it wanted to purchase two kilograms of MTHF on a stand-alone basis. In response, on September 9, 1998, Martin, a Merck manager, sent Weider a signed fax directing it to send its order for the purchase of MTHF to him directly, explaining that he would "arrange everything." Martin stated that the price for the MTHF would be $25,000 per kilogram, that payment terms were "60 days net," and that the product would be delivered, free of charge, to Weider's U.S. facility. Martin assured Weider, moreover, that if it needed more than two kilograms of MTHF, Merck had "no problem . . . immediately" delivering additional quantities. . . .

Martin did not qualify his offer to sell MTHF. To the contrary, he expressly invited Weider to send its purchase order to his attention and assured it that he would "arrange everything." . . . Although Merck ultimately failed to deliver any MTHF to Weider— possibly because it subsequently decided to pursue a more lucrative exclusive licensing arrangement with one of Weider's competitors—this is not dispositive. An offer to sell is

sufficient to raise the on-sale bar, regardless of whether that sale is ever consummated.

The district court concluded that Merck's September 9, 1998, fax did not qualify as an invalidating commercial offer because MTHF was "a potentially dangerous new drug," and "important safety and liability terms, which Dr. Buchholz testified were standard in the industry, were missing." We do not find this reasoning persuasive. First, the record provides no credible support for the conclusion that MTHF—which is simply a crystalline form of the natural isomer of folate produced by the human body—is a "dangerous new drug." To the contrary, as Merck represented to the district court, MTHF "is sold as a folate supplement, similar to folic acid in most people's common understanding."

Second, Buchholz's testimony failed to establish that any "industry standard" terms were missing from Martin's September 9, 1998, fax. Buchholz asserted that certain safety and apportionment of liability provisions would likely be included in a standard industry contractor supply agreement. Buchholz's testimony was insufficient, however, to demonstrate that it was standard practice in the industry to include such provisions in an offer to sell a particular product on a standalone basis. The record is likewise devoid of any documentary evidence showing that it was standard practice in the industry to include safety and liability apportionment provisions in a product sales offer.

Finally, and most importantly, Buchholz's conclusory testimony cannot trump the unambiguous documentary record. While Buchholz testified that Merck would not have sold MTHF to Weider without first resolving safety and liability issues, his testimony was squarely contradicted by Martin's September 9, 1998, fax in which he agreed to "arrange everything" and "immediately" supply Weider with two or more kilograms of MTHF. . . .

Merck further contends that Martin's September 9, 1998, fax was not an invalidating offer to sell MTHF because the Confidentiality Agreement, which Weider and Merck executed in February 1998, required any "definitive agreement" to be "signed by both parties." This argument is unavailing. . . . Nothing in the Confidentiality Agreement suggests that an offer for sale and a completed sales agreement must be contained in the same document. Thus, Martin's September 9, 1998, fax qualifies as a commercial offer to sell MTHF notwithstanding the fact that it did not invite Weider to accept that offer by signing the fax and returning it to Merck.

Merck does not contend that it offered to supply Weider with MTHF for experimental purposes. Indeed, Merck acknowledges that two kilograms of MTHF "was an enormous amount of material, representing 62,500,000 doses." Because Merck's September 9, 1998, offer to sell MTHF was a premature commercial exploitation of its invention, claim 4 of the '168 patent is invalid under the on-sale bar.