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***Practice Group:***

***IP Litigation***

# Federal Circuit Holds That an Offer to Sell a Drug Product Was a Patent-Invalidating Offer for Sale under Pre-AIA § 102(b) Even Though the Offer Lacked "Safety and Liability Terms"

***By Trevor M. Gates, Theodore J. Angelis, and Peter Giunta***

On May 13, 2016, the Federal Circuit determined that Merck's crystalline calcium salt of tetrahydrofolic acid ("MTHF") had been the subject of a commercial offer for sale, and held Merck's MTHF claim in U.S. Patent No. 6,441,168 (the "'168 patent") is invalid under the on-sale bar provision of pre-AIA § 102(b).[1] Specifically, the Federal Circuit held that Merck made an invalidating offer to sell MTHF when it sent a fax that included price, quantity, and delivery terms, and rejected the district court's determination that additional, industry standard "safety and liability terms" were required for there to have been an "offer for sale."

## Background

The Patent Act contains traps for the unwary. For instance, under pre-AIA 35 U.S.C. § 102(b), an invention could not be patented if it had been on sale for more than a year prior to the patent filing.[2] In other words, an inventor had only one year from the on-sale date to file a patent application. Accordingly, the question of what it means to be "on sale" has been the subject of numerous cases. Under the case law, an invention is "on sale" when it is the subject of a commercial offer for sale.[3]

In 1997, Merck entered into a joint venture with Weider Nutrition International, Inc. ("Weider") to market MTHF.[4] Merck and Weider signed a confidentiality agreement (the "Confidentiality Agreement") stating that neither would be obligated to a transaction with the other, unless they enter into a written transaction agreement signed by both parties.[5] In 1998, Weider notified Merck that it no longer wanted to form a joint venture, but asked to purchase two kilograms of MTHF on a stand-alone basis.[6] In response, Merck sent Weider a fax (the "Merck fax") offering two kilograms of MTHF for $25,000 per kilogram, delivered "free of charge" to Weider's U.S. facility.[7] The fax did not include "safety and liability" terms, and it was not signed by either party.[8] Two weeks later, Weider sent Merck an email confirming it

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[1] *Merck & Cie, Bayer Pharma AG, Bayer Healthcare Pharm. Inc. v. Watson Labs., Inc.*, No. 1:13-CV-00978-RGA (Fed. Cir. May 13, 2016) [hereinafter *Merck & Cie v. Watson*], http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/15-2063.Opinion.5-11-2016.1.PDF.

[2] The pre-AIA § 102(b) on-sale bar applied to the patent at issue in this case. The AIA § 102(a)(1) on-sale bar is different and is not discussed here.

[3] *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67–68 (1998).

[4] *Merck & Cie v. Watson*, *supra* note 1, at 2-3.

[5] *Id.* at 3.

[6] *Id.*

[7] *Id.* at 3-4.

[8] *See id.*

would order two kilograms, and Merck sent Weider a letter confirming Weider had placed an order.[9] The order was never fulfilled.[10] Merck filed the application that led to the '168 patent on April 17, 2000.[11]

In 2013, Merck sued Watson for filing Abbreviated New Drug Applications seeking to market generic versions of SAFYRAL and BEYAZ branded MTHF-containing drugs before the expiration of the '168 patent. Watson defended by contending that asserted claim 4 of the '168 patent was invalid under the section 102(b) on-sale bar because the Merck fax to Weider in 1998 was a commercial offer for sale.

## District Court Decision

The district court analyzed the on-sale bar issue. After a bench trial, the district court held that claim 4 was not invalid under the on-sale bar.[12] The court determined that MTHF was ready for patenting at the time of the Merck fax, but concluded that the Merck fax was not an invalidating offer for sale because it was missing industry standard terms.[13] Specifically, the district court was persuaded by Merck's expert who testified that, because MTHF was "a potentially dangerous new drug," a standard offer for sale in the pharmaceutical industry for a product like MTHF would include "important safety and liability terms."[14] The court noted, moreover, that there had been no legally binding sale because no agreement was reduced to writing and signed by both parties, as required by the Confidentiality Agreement.[15] Watson appealed the decision.

## Federal Circuit Decision

The sole issue on appeal was whether the Merck fax was an invalidating commercial offer to sell MTHF. The Federal Circuit held that the Merck fax was an unqualified offer for sale because it contained the essential price, quantity, and delivery terms required under general contract law.[16] It rejected the district court's conclusion that the Merck fax was not an offer because it lacked industry standard "safety and liability" terms. The Federal Circuit noted that, aside from the testimony of Merck's expert, there was no evidence showing: (1) that MTHF was a dangerous new drug,[17] or (2) that the alleged "industry standard" "safety and liability terms" were typically included in an *offer* as opposed to a final contract or supply agreement.[18] The Federal Circuit followed its *Cargill v. Canbra Foods* decision and held that the testimony of Merck's expert in 2015 could not override the commercial offer on the face of the 1998 Merck fax, which included price, quantity, and delivery terms.[19]

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[9] *Id.* at 4.
[10] *Id.* at 5.
[11] *Id.* at 2.
[12] *Id.* at 5-6.
[13] *Id.*
[14] *Id.* at 10.
[15] *Id.* at 6.
[16] *Id.* at 8.
[17] MTHF is the crystalline form of the natural isomer of folate produced by the human body.
[18] *Merck & Cie v. Watson*, *supra* note 1, at 10-11.
[19] *Id.* at 11-12; *see also Cargill Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359 (Fed. Cir. 2007).

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The Federal Circuit also rejected Merck's argument that the Confidentiality Agreement prevented the Merck fax from constituting an offer for sale. It held that the Confidentiality Agreement, by its terms, did not apply to a stand-alone product purchase, and, even if it did, nothing in the Confidentiality Agreement required an *offer* to be signed by both parties.[20]

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**Authors:**

**Trevor M. Gates**
trevor.gates@klgates.com
+1 206 370 8090

**Theodore J. Angelis**
theo.angelis@klgates.com
+1 206 370 8101

**Peter Giunta**
peter.giunta@klgates.com
+1 212 536 3910



[20] *Merck & Cie v. Watson*, *supra* note 1, at 13.