United States Court of Appeals for the Federal Circuit

MERCK & CIE, BAYER PHARMA AG, BAYER HEALTHCARE PHARMACEUTICALS INC.,
Plaintiffs-Appellees

v.

WATSON LABORATORIES, INC.,
Defendant-Appellant

2015-2063, 2015-2064

Appeals from the United States District Court for the District of Delaware in Nos. 1:13-cv-00978-RGA, 1:13-cv-01272-RGA, Judge Richard G. Andrews.

Decided: May 13, 2016

JOHN SCOTT MCBRIDE, Bartlit Beck Herman Palenchar & Scott LLP, Chicago, IL, argued for plaintiffs-appellees. Also represented by ADAM MORTARA, REBECCA HORWITZ, FAYE PAUL.

STEVEN ARTHUR MADDOX, Maddox Edwards, PLLC, Washington, DC, argued for defendant-appellant. Also represented by JEREMY J. EDWARDS, MATTHEW C. RUEDY, KAVEH SABA.

Before DYK, MAYER, and HUGHES, *Circuit Judges.*

MAYER, *Circuit Judge.*

Watson Laboratories, Inc. ("Watson") appeals the final judgment of the United States District Court for the District of Delaware holding that claim 4 of U.S. Patent No. 6,441,168 (the "'168 patent") is not invalid under the on-sale bar of 35 U.S.C. § 102(b) (2006).[1] *See Merck & Cie v. Watson Labs., Inc.*, 125 F. Supp. 3d 503 (D. Del. 2015) ("*District Court Decision*"). For the reasons discussed below, we reverse.

BACKGROUND

A. The '168 Patent

Claim 4, the sole asserted claim of the '168 patent, is directed to a crystalline calcium salt of a tetrahydrofolic acid ("MTHF"). Claim 4 recites: "A crystalline calcium salt of 5-methyl-(6S)-tetrahydrofolic acid with 2 theta values of 6.5, 13.3, 16.8 and 20.1 (Type I) said crystalline salt having a water of crystallization of at least one equivalent per equivalent of 5-methyltetrahydrofolic acid." '168 patent, col. 10 ll. 57–61. The application for the '168 patent was filed on April 17, 2000, and it issued on August 27, 2002. *See* Joint Appendix ("J.A.") 8, 22.

In 1997, Merck KGaA ("Merck") and Weider Nutrition International, Inc. ("Weider") began "exploring a strategic partnership to introduce dietary supplements with Merck ingredients into the United States." *District Court Decision*, 125 F. Supp. 3d at 508. The first major project

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[1] Section 102(b) was amended by the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, § 3(b)(1), 125 Stat. 284, 285–86 (2011). Because the application for the '168 patent was filed in 2000, however, we apply the pre-AIA version of the statute. *See In re Giannelli*, 739 F.3d 1375, 1376 n.1 (Fed. Cir. 2014).

considered by the parties was a joint venture to market and distribute MTHF. J.A. 1287–90, 1434. In February 1998, Merck and Weider executed a Confidentiality and Noncompetition Agreement (the "Confidentiality Agreement"). J.A. 1368–73. Section 5.2 of the Confidentiality Agreement provided: "Unless and until such definitive agreement regarding a transaction between Weider and Merck has been signed by both parties, neither party will be under any legal obligation of any kind with respect to such a transaction." J.A. 1371.

In August 1998, Weider notified Merck that it was no longer interested in forming a joint venture to market MTHF in the United States, explaining that the advertising expenses associated with such a "large-scale" project were too high. J.A. 1419. Weider stated, however, that it would like to purchase two kilograms of MTHF on a stand-alone basis. J.A. 1419, 1446–48. Weider explained that "[i]n order to complete the transaction," it needed information on the price for the product. J.A. 1446. Weider also informed Merck that it would like to handle the purchase of MTHF in a way that was "simplest . . . for both companies." J.A. 1446.

In response, on September 9, 1998, Dr. Roland Martin, a manager in Merck's Health, Cosmetic and Nutrition Business Unit, sent Weider a signed fax stating:

> [W]e would like to handle your purchase of [MTHF] very simpl[y].
>
> Therefore please send the order to my attention and I will arrange everything. In addition we need the exact delivery address/person.
>
> The price is 25,000 US$ per kg [of MTHF] free delivered to your R&D center in the U.S. Payment terms are 60 days net. With Rick Blair and Richard Bizzaro we discussed a purchase of 2 kg [of MTHF]. If you need more, we have no problem for

> an immediate[] delivery. After receiving your order you will get the official confirmation of the order.

J.A. 1386.

On September 16, 1998, Gary Jepson, Weider's purchasing manager, responded to Martin, stating that Weider would order two kilograms of MTHF for delivery to its Salt Lake City, Utah facility. J.A. 1352. Jepson asked Martin to provide the information he needed to complete Weider's purchase order, including the "[s]pecification sheet for the raw material outlining physical, analytical, and microbial characteristics" of the MTHF product as well as the "material safety data sheets." J.A. 1352. In addition, Jepson asked for a certificate of insurance naming Weider as an additional insured. J.A. 1352.

Shortly thereafter, on September 25, 1998, Martin sent Jepson a specification and analytical data sheet for the MTHF product. J.A. 1355. Martin informed Jepson that Weider would receive a certificate of insurance naming it as an additional insured "after dispatch of [the] product." J.A. 1354. Martin reiterated, moreover, that the purchase price for the MTHF would be $25,000 per kilogram and that it would be delivered, free of charge, to Weider's Utah facility. J.A. 1354. On October 8, 1998, Merck sent Weider a letter confirming that it had placed a "first order" for two kilograms of MTHF. J.A. 1455.

Merck subsequently met with Whitehall Robins ("Whitehall"), a Weider competitor. J.A. 1398, 1461–62. Whitehall informed Merck that it was interested in obtaining exclusive rights to market MTHF in the United States and Canada. J.A. 1461–62.

In a November 1998 internal memorandum, Weider noted that it needed to "track" its MTHF order and "determine [a] delivery date." J.A. 1438. In December 1998,

Merck agreed to try to locate Weider's MTHF order. J.A. 1388. Merck contacted Weider in January 1999, inquiring about whether its purchase order for MTHF was still "active." J.A. 1428. On January 6, 1999, Preston Zoller, a Weider employee, noted in an internal Weider email that "Merck wasn't expecting us to buy any [MTHF] immediately." J.A. 1428. Zoller further stated that it was his "understanding that there wouldn't be any dire consequences to cancelling [Weider's purchase order] (if one exists) until such time as a new [MTHF] product is actually approved for launch." J.A. 1428. On January 9, 1999, Weider sent Merck an email noting that the parties had made a "mutual decision" to cancel Weider's "existing order for [MTHF]." J.A. 1463.

B. The District Court Litigation

In 2013, Bayer Pharma AG, Bayer Healthcare Pharmaceuticals Inc., and Merck & Cie, a Merck subsidiary, brought suit against Watson. They accused Watson of infringing claim 4 of the '168 patent by filing Abbreviated New Drug Applications seeking approval to manufacture and market generic versions of the Safyral® and Beyaz® oral contraceptive products. *See District Court Decision*, 125 F. Supp. 3d at 506. Because Watson stipulated to infringement if claim 4 was valid, the only issue for trial was validity. *Id.* at 507.

Following a bench trial, the district court held that claim 4 of the '168 patent was not anticipated, obvious, or invalid for lack of adequate written description. *Id.* at 511–15. It further held that claim 4 was not invalid under the on-sale bar. *Id.* at 507–10. Although the court determined that MTHF was ready for patenting by September 1998, *id.* at 508, it concluded that there had been no invalidating commercial offer for sale or sale of the product, *id.* at 509–10. In the court's view, the fax Merck sent to Weider on September 9, 1998, was not sufficiently definite to qualify as a commercial offer because it did not

include "important safety and liability terms." *Id.* at 510. The court noted, moreover, that under section 5.2 of the Confidentiality Agreement any "definitive agreement" between Merck and Weider had to be signed by both parties. *Id.* at 509. According to the court, because any agreement for the sale of MTHF was not "reduced to writing and signed by both parties," there had been no legally binding sale. *Id.* at 510.

Watson then filed a timely appeal with this court. Watson limits its appeal to the issue of whether the district court correctly held that claim 4 of the '168 patent is not invalid due to the on-sale bar. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

A. Standard of Review

Invalidity under the on-sale bar is a question of law based on underlying questions of fact. *Robotic Vision Sys., Inc. v. View Eng'g, Inc.*, 249 F.3d 1307, 1310 (Fed. Cir. 2001). "[T]he 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." *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047 (Fed. Cir. 2001).

B. The On-Sale Bar

"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." *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1365 (Fed. Cir. 2008); *see City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 137 (1877) ("[A]n inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law."). 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.[2] *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67–68 (1998); *see Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1347 (Fed. Cir. 2003).

Here, because Merck does not challenge the district court's determination that "MTHF was . . . ready for patenting by September 1998," *District Court Decision*, 125 F. Supp. 3d at 508, 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." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1352 (Fed. Cir. 2002); *see also Grp. One*, 254 F.3d at 1047 (explaining that "the offer must meet the level of an offer for sale in the contract sense, one that would be understood as such in the commercial community"). "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)." *Grp. One*, 254 F.3d at 1048.

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. J.A. 1419. Weider informed Merck, however, that it wanted to purchase two kilograms of MTHF on a stand-alone basis. J.A. 1419. 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

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[2] "The date exactly one year prior to the date of application for the patent is known as the critical date." *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1327 (Fed. Cir. 2001).

he would "arrange everything." J.A. 1386. 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. J.A. 1386. Martin assured Weider, moreover, that if it needed more than two kilograms of MTHF, Merck had "no problem . . . immediately" delivering additional quantities. J.A. 1386.

Martin's September 9, 1998, fax was not an unsolicited price quote sent to numerous potential customers. *See* Restatement (Second) of Contracts § 26, cmt. c (1981) (explaining that a "relevant factor[]" in determining whether an offer has been made is "the number of persons to whom a communication is addressed"); *see also Grp. One*, 254 F.3d at 1048 (noting that "mere advertising" may not rise to the level of a commercial offer). To the contrary, that fax was sent in direct response to Weider's request to purchase two kilograms of MTHF. J.A. 1419. Martin's detailed fax—providing essential price, delivery, and payment terms—contained all the required elements to qualify as a commercial offer for sale. *See Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1369 (Fed. Cir. 2007) (concluding that a letter which specified the price per unit of a product and the terms for delivery qualified as an invalidating offer for sale); *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1052 (Fed. Cir. 2001) (explaining that purchase orders were "offers to buy" because "they included quantity terms and clearly identified the requested product," notwithstanding the fact that they did not specify a price); *Scaltech*, 269 F.3d at 1329 (concluding that proposals to process refinery waste were commercial offers because they contained "sufficiently definite offer language"). Notably, 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." J.A. 1386.

Merck argues that Martin's September 9, 1998, fax was not an invalidating commercial offer because "neither Weider nor Merck ever acted as if Merck had made . . . a binding offer to sell [MTHF]." Br. of Plaintiffs-Appellees at 10. This contention is belied by the record, which shows that in the weeks following Martin's fax both Merck and Weider proceeded on the understanding that Merck had made an unequivocal offer to sell MTHF. A week after receiving Martin's fax, Weider sent Merck an email confirming that it would "order 2 KG of [MTHF]" for delivery to its Utah facility. J.A. 1352. It also asked for the "[MTHF] safety data sheets" and the "certificate of analysis" it needed to complete its purchase order, as well as a certificate of insurance naming Weider as an additional insured. J.A. 1352. On September 25, 1998, Merck provided Weider with technical and safety information on the MTHF product. J.A. 1353–57; *see also* J.A. 1465. Merck further stated that it would provide a certificate of insurance naming Weider as an additional insured after the MTHF was "dispatch[ed]." J.A. 1354. Soon thereafter, on October 8, 1998, Merck sent Weider a letter confirming that Weider had placed a "first order" for two kilograms of MTHF. J.A. 1455. Regardless of whether the communications between Merck and Weider in the fall of 1998 were sufficient to establish a binding contract for the sale of MTHF, they confirm that, at a minimum, both parties understood that Martin's September 9, 1998, fax was an offer to sell the product. 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, J.A. 1462—this is not dispositive. An offer to sell is sufficient to raise the on-sale bar, regardless of whether that sale is ever consummated. *See Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc.*, 726 F.3d 1370, 1374–76 (Fed. Cir. 2013) (explaining that the on-sale bar applies to a commercial offer regardless of whether the parties execute a binding contract); *Cargill*,

476 F.3d at 1370 ("[E]vidence of an offer to sell is sufficient to trigger the on-sale bar under 35 U.S.C. § 102(b). There is no requirement that the sale be completed.").

C. The District Court's Analysis

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." *District Court Decision*, 125 F. Supp. 3d at 510. 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." J.A. 1035, 1089, 1540. 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." J.A. 1035.

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 contract or supply agreement. J.A. 1291–95. 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. *See Lacks*, 322 F.3d at 1348 (concluding that the issue of whether there had been an invaliding offer could not be resolved based on conclusory testimony as to "how business [was] done in the automotive industry" (internal quotation marks omitted)); *see also H & W Indus., Inc. v. Occidental Chem.*

Corp., 911 F.2d 1118, 1122 (5th Cir. 1990) ("To establish 'regularity of observance,' the proffering party must demonstrate a dominant pattern of use within the industry. The testimony of one officer as to that company's practices is generally insufficient to establish such a pattern.").

Finally, and most importantly, Buchholz's conclusory testimony cannot trump the unambiguous documentary record. *See Cucuras v. Sec'y of Dep't of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) ("[O]ral testimony in conflict with contemporaneous documentary evidence deserves little weight."). While Buchholz testified that Merck would not have sold MTHF to Weider without first resolving safety and liability issues, J.A. 1291–99; *see also* J.A. 1057, 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, J.A. 1386.[3]

The situation here parallels that presented in *Cargill*. There, Procter & Gamble Co. ("P&G") made a verbal request to purchase a particular type of canola oil from DNA Plant Technology Corporation ("DNAP"). *See Cargill*, 476 F.3d at 1369. In response, DNAP sent a letter to P&G which contained the price, quantity, and shipping

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[3] Significantly, moreover, the record shows that Merck had, in fact, addressed certain safety and liability apportionment issues related to MTHF prior to the time Martin sent his September 9, 1998, fax. In an internal Merck memorandum, dated September 4, 1998, Martin stated that Merck had no supply agreement in place with Weider and that a note should be attached to the confirmation of Weider's MTHF purchase order stating that "with respect to patent infringement and toxicology the [MTHF] will be used at Weider's risk." J.A. 1421.

terms for the oil. *Id.* Subsequently, however, DNAP's successor-in-interest attempted to establish that DNAP's letter was not an invalidating commercial offer by relying on a declaration from a DNAP employee who stated that DNAP "did not view the . . . letter as an offer for a sale." *Id.* at 1370. We rejected this attempt to evade the on-sale bar, concluding that the testimony of the DNAP employee was insufficient to override "what [was] abundantly plain from the price, quantity, and delivery terms on the face of [DNAP's] letter." *Id.* We explained that because the language of DNAP's letter was "unambiguous . . . the subsequent testimony of [the DNAP employee] about the intended purpose of the letter [was], for practical purposes, irrelevant." *Id.*

A similar analysis applies here. Although Buchholz testified that Merck would not have sold MTHF to Weider without first resolving certain safety and liability issues, J.A. 1291–95, his post hoc testimony cannot override what was "abundantly plain from the price, quantity, and delivery terms," *Cargill*, 476 F.3d at 1370, on the face of Martin's September 9, 1998, fax. Simply put, Buchholz's testimony—which he gave in May 2015 about events occurring nearly seventeen years before—does not supersede the contemporaneous documentary evidence. *See Linear Tech.*, 275 F.3d at 1053 (explaining that under "general principle[s] of contract law . . . the parties' objective, expressed intent—not their secret, subjective intent—controls whether a bargain has been struck"); *Sinskey v. Pharmacia Ophthalmics, Inc.*, 982 F.2d 496, 498–99 (Fed. Cir. 1992) (concluding that an inventor's affidavit regarding events occurring many years before was entitled to little weight in the on-sale bar analysis).

D. The Confidentiality Agreement

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." J.A. 1371. This argument is unavailing. As a preliminary matter, Merck and Weider executed the Confidentiality Agreement during a period when they were contemplating entering into a broad-ranging joint venture relationship. Merck points to nothing in that agreement indicating that it was intended to have any applicability to a stand-alone product purchase.

Even assuming *arguendo*, however, that the Confidentiality Agreement can be stretched to cover a stand-alone purchase of MTHF, it does not help Merck. Section 5.2 of that agreement states: "Unless and until such definitive agreement regarding a transaction between Weider and Merck has been signed by both parties, neither party will be under any legal obligation of any kind with respect to such a transaction." J.A. 1371. By its plain terms, section 5.2 requires any "definitive agreement" to be reduced to writing and signed by both Weider and Merck. J.A. 1371. Nothing in the Confidentiality Agreement suggests that an *offer* is valid only if it is signed by both parties.

Merck contends, however, that because section 5.2 requires any agreement to be signed by both parties, "no fax or other communication could be a legally binding offer to sell unless it invited the other party to counter-sign it and such counter-signature would create the required 'definitive agreement.'" Br. of Plaintiffs-Appellees at 17. Thus, in Merck's view, Martin's September 9, 1998, fax was not a valid offer to sell MTHF because it did not contain a signature line or otherwise "invite" Weider's signature. We disagree. 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. *See Pfaff*, 525 U.S. at 64 ("[A]n inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention . . . . The law has long recognized the distinction between inventions put to experimental use and products sold commercially."). Indeed, Merck acknowledges that two kilograms of MTHF "was an enormous amount of material, representing 62,500,000 doses." Br. of Plaintiffs-Appellees at 7; *see also* J.A. 1075; *Atlanta Attachment*, 516 F.3d at 1366 (concluding that the on-sale bar applied where a patent holder "presented a commercial offer for sale of [its] invention en masse"). 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.[4]

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[4] While this court is currently considering whether an inventor's agreement with another party to manufacture the inventor's product is sufficient to trigger the on-sale bar, *see The Medicines Co. v. Hospira, Inc.*, 805 F.3d 1357, 1358 (Fed. Cir. 2015) (order granting en banc review), there is no dispute that the bar arises when a product is marketed to the public prior to the critical date. *See Pfaff*, 525 U.S. at 67; *see also Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148–49 (1989) ("From the Patent Act of 1790 to the present day, the public sale of an unpatented article has acted as a complete bar to federal protection of the idea embodied in the article thus placed in public commerce."); *Abbott Labs. v. Geneva Pharm., Inc.*, 182 F.3d 1315, 1319 (Fed. Cir. 1999) ("One of the primary purposes of the on-sale bar is to prohibit the withdrawal of inventions that have been

CONCLUSION

Accordingly, the judgment of the United States District Court for the District of Delaware is reversed.

REVERSED

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placed into the public domain through commercialization.").