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United States Court of Appeals for the Federal Circuit

LARRY G. JUNKER, Plaintiff-Appellee

v.

MEDICAL COMPONENTS, INC., MARTECH MEDICAL PRODUCTS, INC.,

Defendants-Appellants

2021-1649

Appeal from the United States District Court for the Eastern District of Pennsylvania in No. 2:13-cv-04606-MSG, Judge Mitchell S. Goldberg.

Decided: February 10, 2022

JAMES D. PETRUZZI, The Petruzzi Law Firm, Houston, TX, argued for plaintiff-appellee. Also represented by LAURA MAUPIN, Maupin Redman, Livingston, TX.

ALFRED W. ZAHER, I, Montgomery McCracken Walker & Rhoads LLP, Philadelphia, PA, argued for defendants-appellants. Also represented by JOSEPH MONAHAN.

Before Dyk, Reyna, and Stoll, Circuit Judges.

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STOLL, Circuit Judge.

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Larry G. Junker, the named inventor of U.S. Design Patent No. D450,839, sued Medical Components, Inc. and Martech Medical Products, Inc. (collectively, "MedComp") for infringement of the sole claim of the D'839 patent. The parties filed cross-motions for summary judgment, debating whether a letter sent before the critical date was a commercial offer for sale of the claimed design, rendering the claim invalid under the on-sale bar, 35 U.S.C. § 102(b). The district court granted Mr. Junker's motion for summary judgment of no invalidity under the on-sale bar. The district court thereafter held a bench trial on several remaining issues in the case, including MedComp's remaining invalidity challenges, infringement, and damages. The court again ruled in Mr. Junker's favor. The court rejected each of MedComp's invalidity challenges, found that each of the accused products infringed the D'839 patent claim and that the infringement was willful, and awarded Mr. Junker \$1,247,910 in damages under 35 U.S.C. § 289, which allows recovery of an infringer's profits from sale of the infringing products.

MedComp appeals the district court's summary judgment of no invalidity under the on-sale bar, the judgment of infringement, and the damages award. For the reasons below, we agree with MedComp that the pre-critical date letter was a commercial offer for sale. Because there is no dispute that the claimed design was ready for patenting, we reverse the district court's summary judgment of no invalidity. We therefore do not reach the remaining issues on appeal.

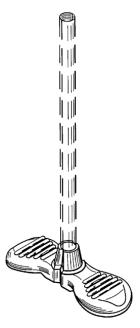
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BACKGROUND

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Ι

The D'839 patent, at the heart of the dispute on appeal, is titled "Handle for Introducer Sheath," and includes a single claim for "[t]he ornamental design for a handle for introducer sheath, as shown and described." D'839 patent, claim. Figure 1 shows a perspective view of the claimed design (represented with solid lines):



Id. Fig. 1. Mr. Junker filed the application that led to the D'839 patent on February 7, 2000. Thus, the critical date for analyzing the on-sale bar under § 102(b)¹ is February 7, 1999, one year before the filing date.

 $^{^1}$ Congress amended § 102 when it enacted the Leahy–Smith America Invents Act (AIA). Pub. L. No. 112–29, § 3(b)(1), 125 Stat. 284, 285–87 (2011). However, because the application that led to the D'839 patent

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Mr. Junker started working in the medical device industry in the 1970s. In the late 1970s, Mr. Junker started his own company for purchasing and reselling catheter kits. These kits typically included a needle, syringe, guidewire, and introducer sheath that were used for inserting a catheter into the vein of a patient. Mr. Junker's company also designed and manufactured some components in the kits, including the introducer sheath. In the mid-1980s, Mr. Junker began developing a new design for the introducer sheath based on his experience observing catheterinsertion procedures. Mr. Junker focused on the design for the introducer sheath's handle, eventually settling on a handle with large, rounded Mickey-Mouse-shaped ears that made it easier for doctors to grasp the introducer sheath during catheter-insertion procedures. The handle was designed such that the sheath could be peeled apart into two pieces when removing the sheath while leaving the catheter in place in the patient's body. These products are referred to as "peelable," "peel-away," or "tearaway" introducer sheaths.

Mr. Junker, however, did not have the proper machinery to manufacture the product. He began reaching out to other companies to handle the actual manufacture of his new design. Eventually, in 1998, Mr. Junker developed a business relationship with James Eddings, the founder of a medical device company called Galt Medical. At their first meeting in August 1998, Mr. Junker and Mr. Eddings entered into a non-disclosure agreement (Mr. Junker on behalf of his company and Mr. Eddings on behalf of Galt), after which Mr. Junker told Mr. Eddings about his new design for the introducer sheath handle. The next month, in September 1998, Mr. Eddings informed Mr. Junker that

was filed before March 16, 2013, the pre-AIA § 102 applies. *See id.* § 3(n)(1), 125 Stat. at 293.

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Galt could manufacture Mr. Junker's product. Around this same time, Mr. Eddings also founded a new company, Xentek Medical, to develop, manufacture, and sell tearaway introducer sheath products.

Over the course of the next several months, Mr. Junker and Mr. Eddings continued to discuss Mr. Junker's new design. Mr. Eddings enlisted the help of an engineer, Richard Gillespie, to sketch out Mr. Junker's proposed design. After some back and forth, Mr. Gillespie provided Mr. Junker with a sketch of the design. This sketch, however, was lacking the handles with Mickey Mouse ears that Mr. Junker had envisioned. In a fax dated December 16, 1998, Mr. Junker relayed his critiques of the sketch to Mr. Eddings, noting the absence of larger, rounded portions on the handle and providing a rough sketch of his design as he had imagined it. Mr. Eddings asked Mr. Gillespie to modify the sketch accordingly. In January 1999, Mr. Eddings' company, Xentek, developed and provided to Mr. Junker a prototype of the product that included all of the features of his design, including (importantly) a handle with Mickey Mouse ears.

В

In early January 1999, Mr. Eddings, through Xentek, began communicating with Boston Scientific Corporation regarding a peelable introducer sheath product. In response to a request from Boston Scientific, on January 8, 1999, Xentek sent Boston Scientific a letter detailing bulk pricing information for variously sized peelable introducer sheath products. The letter stated:

Thank you for the opportunity to provide this quotation for the Medi-Tech Peelable Sheath Set. When we first received this request for quotation we were under the mistaken impression that you wanted the exact configuration as the drawing that was provided which would have required extensive tooling expense. Subsequently, we have learned

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that this is not the case and are pleased to submit this quotation for a product of our design.

. . .

The principals of Xentek Medical have extensive experience in the design, development and manufacture of this type of medical device. If you should have any specific dimensional requirements this product could generally be tailored to your specifications.

J.A. 1572.

The January 8, 1999 letter also included a price chart (shown below), and specified that the "prices are for shipment in bulk, non-sterile, FOB [free on board] Athens, Texas on a net 30-day basis":

Size	ORDER QUANTITIES			
	5,000	10,000	25,000	50,000
4F-6F	\$4.45	\$4.25	\$4.05	\$3.95
7F-8F	4.70	4.50	4.30	4.20
11F	5.05	4.85	4.75	4.70

J.A. 1573. Mr. Eddings concluded the letter by noting his appreciation for "the opportunity to provide this quotation" and that he "look[ed] forward to discussing [Boston Scientific's] requirements in person." *Id*.

Mr. Eddings sent additional letters to Boston Scientific in January and February 1999.

II

In 2013, Mr. Junker sued MedComp, accusing four of MedComp's products of infringing the claimed design. MedComp, in response, raised affirmative defenses of invalidity, unenforceability, and noninfringement and filed counterclaims seeking a declaratory judgment that the claimed design is invalid, unenforceable, and not infringed.

Following several years of discovery, in 2017, the parties filed cross-motions for summary judgment on several issues, including, as relevant here, invalidity under the on-The crux of the parties' disagreement was whether the January 8, 1999 letter from Xentek to Boston Scientific—which was sent before the critical date—was a commercial offer for sale of a product embodying the claimed design. The district court held that it was not as a matter of law. See Junker v. Med. Components, Inc., CIVIL ACTION No. 13-4606, 2019 WL 109385, at *10 (E.D. Pa. Jan. 4, 2019). In so holding, the district court determined that the letter was a preliminary negotiation, not a definite offer. Id. The court specifically focused on the fact that the letter thrice uses the word "quotation" and concludes with an invitation to further discuss specific requirements. Id. at *9-10. The district court acknowledged that the letter included numerous, specific, commercial terms (such as payment terms, shipment terms, and delivery conditions), supporting a conclusion that the letter was a commercial offer for sale. The court ultimately determined, however, that the presence of these terms did not outweigh the other language in the letter suggesting that Xentek and Boston

The case then proceeded to trial on the remaining issues, namely MedComp's remaining invalidity defenses, the questions of infringement and willfulness, and damages. As to invalidity, the district court determined that MedComp had failed to prove, by clear and convincing evidence, invalidity of the claimed design based on any of its various asserted theories. *Junker v. Med. Components, Inc.*, CIVIL ACTION No. 13-4606, 2021 WL 131340, at *1 (E.D. Pa. Jan. 14, 2021). It also found that Mr. Junker had demonstrated, by a preponderance of the evidence, that each of the accused products infringed the claimed design,

Scientific were engaged in preliminary negotiations. *Id.* at *10. The district court accordingly granted Mr. Junker's motion for summary judgment of no invalidity under the

on-sale bar.

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and that the infringement was willful. *Id.* The district court awarded Mr. Junker \$1,247,910 in disgorged profits under 35 U.S.C. § 289. *Id.* No enhanced damages were awarded in connection with the willfulness finding.

MedComp appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

T

We begin and end with MedComp's challenge to the district court's summary judgment of no invalidity under the on-sale bar. We review the district court's summary judgment under the law of the regional circuit, here the Third Circuit. See SRI Int'l, Inc. v. Cisco Sys., Inc., 930 F.3d 1295, 1306 (Fed. Cir. 2019). "The Third Circuit reviews a grant of summary judgment de novo, applying the same standard as the district court." *Id.* (citing *Gonza*lez v. Sec'y of Dep't of Homeland Sec., 678 F.3d 254, 257 (3d Cir. 2012)). Summary judgment is appropriate when, drawing all justifiable inferences in the nonmovant's favor, there exists no genuine issue of material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

II

A patent claim is invalid under § 102(b) 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." Section 102(b)'s on-sale bar is triggered if, before the critical date, the claimed invention was both (1) the subject of a commercial offer for sale and (2) ready for patenting. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67–68 (1998). "Whether the on-sale bar applies is a question of law based on underlying factual findings." *Meds. Co. v. Hospira, Inc.*, 827 F.3d 1363, 1371 (Fed. Cir. 2016) (en

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banc). We review the ultimate determination of whether a claim is invalid under the on-sale bar de novo. *Id.*

The material facts here are not in dispute. The parties agree that the January 8, 1999 letter speaks for itself. They also agree that the products described in the letter embody the claimed design. And they agree that the claimed design was ready for patenting. The question before us is therefore a simple one: Whether the January 8, 1999 letter is a commercial offer for sale of the claimed design, or merely a quotation signaling the parties were engaged in preliminary negotiations. Because the facts are not disputed, we review the question of whether this particular communication constitutes a commercial offer for sale (a question of law) without deference. See In re Kollar, 286 F.3d 1326, 1329 (Fed. Cir. 2002); see also, e.g., Linear Tech. Corp. v. Micrel, Inc., 275 F.3d 1040, 1049-52 (Fed. Cir. 2001). For the reasons below, we hold that the letter is a commercial offer for sale of the claimed design.

In making this determination, we look to the specific facts and circumstances presented in this case, "apply[ing] traditional contract law principles" along the way. Merck & Cie v. Watson Lab'ys, Inc., 822 F.3d 1347, 1351 (Fed. Cir. 2016) (quoting Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1352 (Fed. Cir. 2002)). "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)." Id. at 1351 (quoting Grp. One, Ltd. v. Hallmark Cards, Inc., 254 F.3d 1041, 1048 (Fed. Cir. 2001)). To help guide our determination of whether a given communication rises to the level of a commercial offer for sale, we often rely on resources such as the Uniform Commercial Code, Restatement (Second) of Contracts, and other similar treatises. See, e.g., Meds. Co., 827 F.3d at 1375-76 (discussing Uniform Commercial Code); Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc., 855 F.3d 1356, 1365 & n.5 (Fed. Cir. 2017) (citing favorably

Williston on Contracts (4th ed. 2013), Restatement (Second) of Contracts (1981), and Corbin on Contracts (1999)), aff'd, 139 S. Ct. 628 (2019). "In determining whether an offer [has been] made[,] relevant factors include the terms of any previous inquiry, the completeness of the terms of the suggested bargain, and the number of persons to whom a communication is addressed." Restatement (Second) of Contracts § 26 cmt. c (1981).

With this background in mind, we turn to the language in the January 8, 1999 letter. As stated on the face of the letter, Xentek was directly responding to a "request for quotation" from Boston Scientific, and the letter was addressed to Boston Scientific alone. J.A. 1572. This signals that the letter was not an unsolicited price quotation or invitation to negotiate, but rather a specific offer to Boston Scientific to take further action. See Restatement (Second) of Contracts § 26 cmt. c (explaining that a relevant factor for determining whether an offer is made is "the number of persons to whom a communication is addressed").

The letter also contains a number of necessary terms typical for a commercial contract. For instance, the letter specifies that the prices provided are for "shipment in bulk, non-sterile." J.A. 1573. Thus, the letter provides specific delivery conditions—the product will be shipped in "bulk" and will be "non-sterile." The letter further specifies that shipment will be "FOB Athens, Texas." *Id.* FOB (which stands for free on board) is a standard commercial term used to allocate the risks and responsibilities of the buyer and seller with respect to delivery, payment, and loss of the product. *See Free on Board*, Black's Law Dictionary (11th ed. 2019). The letter also provides a payment term, "net 30-day basis," J.A. 1573, meaning that payment is due in full within 30 days of delivery.

Finally, and importantly, Xentek's letter specifies multiple different purchase options for its peelable sheath products. For example, the letter offers 5,000 sets of size

4F-6F Medi-Tech Peelable Sheath at a price of \$4.45 per set and offers discounted prices if the purchase quantity is increased (e.g., the price per set decreases to \$4.25 for 10,000 sets of the same size sheath, \$4.05 for 25,000, and \$3.95 for 50,000). The letter also offers Boston Scientific the option to purchase two additional sizes of Xentek's Medi-Tech Peelable Sheath Set—7F-8F and 11F—with similarly discounted pricing as the purchase quantity increases.

While the letter concludes with an invitation to further discuss Boston Scientific's specific requirements in person, "expressing a desire to do business in the future does not negate the commercial character of the transaction then under discussion." Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1370 (Fed. Cir. 2007). The completeness of the relevant commercial sale terms in the letter itself signals that this letter was not merely an invitation to further negotiate, but rather multiple offers for sale, any one or more of which Boston Scientific could have simply accepted to bind the parties in a contract.²

We have determined that communications with similarly complete and definite commercial terminology were commercial offers for sale within the meaning of § 102(b). For example, in *Merck*, we disagreed with the district court's determination that a certain fax did not rise to the level of a commercial offer for sale of the claimed invention. The fax specified a product, set forth the price of the product (\$25,000 per kilogram), the location for delivery (the buyer's research and development center), payment terms

We also note that subsequent communications between Xentek and Boston Scientific after the critical date used the exact same commercial terms, providing some indication that these terms were definite, not in flux. *See, e.g.*, J.A. 1577 (February 16, 1999 letter from Xentek to Boston Scientific).

(net 60 days), and the amount to be purchased (two kilograms, with the option to purchase additional product). 822 F.3d at 1349. We explained that this was not just "an unsolicited price quote sent to numerous potential customers." *Id.* at 1351 (citing Restatement (Second) of Contracts § 26 cmt. c). Rather, the "fax was sent in direct response to [the buyer's] request to purchase two kilograms" of the product. *Id.* We also found it highly relevant that the fax "provid[ed] essential price, delivery, and payment terms." *Id.* Because the fax "contained all the required elements to qualify as a commercial offer for sale," we reversed the district court's determination that the claims were not invalid under the on-sale bar. *Id.* at 1351, 1355.

In a similar vein, in *Cargill*, we agreed with the district court that the relevant letter was a commercial offer for sale. That letter was sent to confirm a request for a certain amount of canola oil. 476 F.3d at 1369. The letter "explicitly set[] forth an amount of oil to be delivered . . . , at a specified unit price, and under a standard contract designation, FOB (free on board)." *Id.* We explained that this was "powerful evidence of a sales transaction," *id.*, and accordingly affirmed the district court's summary judgment of invalidity under the on-sale bar.

Here, as in *Merck* and *Cargill*, the letter—which specifies multiple sized products for sale, different bulk pricing options available for each product, payment terms (net 30-day basis), and delivery terms and conditions (bulk shipment, non-sterile, FOB)—contains all the required elements to qualify as a commercial offer for sale. That is sufficient to invoke § 102(b)'s on-sale bar.

Mr. Junker argues that the letter omits essential terms—which size product is being purchased and in what quantity—and, therefore, the letter is not an offer that could be made into a binding contract by simple acceptance. Appellee's Br. 15. We are not persuaded. The standard Mr. Junker proposes—that the offer must specify

the exact amount of product the buyer desires to qualify as an offer for sale—is too stringent. Under § 102(b), the question is merely whether there is an offer for sale. As explained above, the letter here offers for sale multiple sizes of products with tiered pricing depending on the number of sets desired. That there were multiple offers does not mean that there was no offer to be accepted. And that the letter does not specify the exact amount Boston Scientific desires likewise does not mean that there is no offer to be accepted. Rather, the letter comprises multiple different offers that Boston Scientific could have accepted by simply stating, for example, "We'll take 5,000 sets of the 4F-6F Medi-Tech Peelable Sheath" or "10,000 sets of the 11F Medi-Tech Peelable Sheath."

Mr. Junker also argues, as the district court determined, that the January 8, 1999, letter was merely a price quotation inviting further negotiations, not a definite offer. Appellee's Br. 15–16, 19. To be sure, the fact that the letter uses the word "quote" three times is an important fact supporting the district court's conclusion that the letter is a quotation, not a definite offer. See Restatement (Second) of Contracts § 26 cmt. c. ("[T]he word 'quote' is commonly understood as inviting an offer rather than as making one, even when directed to a particular customer."). This fact makes the question before us closer than in either Merck or Cargill. "But just as the word 'offer' does not necessarily mean that an offer is intended, so the word 'quote' may be used in an offer." Restatement (Second) of Contracts § 26 cmt. c. While the precise label used for a given communication is relevant, it is not controlling. Rather, the terms of the communication must be considered in their entirety to determine whether an offer was intended, or if it was merely an invitation for an offer or further negotiations. A quotation typically leaves many terms necessary to a contract—such as place of delivery, payment terms, and the like—unexpressed. Corbin on Contracts § 2.5, at 157 (2018); accord Restatement (Second) of Contracts § 26 Case: 21-1649 Document: 53 Page: 14 Filed: 02/10/2022

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cmt. c (explaining that a quote "may omit the quantity to be sold, time and place of delivery, terms of payment, and other terms"). Where, however, "the quotation . . . contains detailed terms," as is the case here, "it may well be deemed an offer." Corbin on Contracts § 2.5, at 161. For the reasons above, we conclude that the specificity and completeness of the commercial terms in the letter outweigh the three references to "quotation" and mention of possible future discussions. Taken as a whole, the overall language of the letter signals Xentek's intent to make a commitment and invite Boston Scientific to act rather than merely negotiate.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. For the foregoing reasons, we agree with MedComp that the January 8, 1999 letter was a commercial offer for sale of the claimed design. Because the parties do not dispute that the invention was ready for patenting, we reverse the district court's summary judgment of no invalidity. The effect of our determination renders the sole claim of the D'839 patent invalid and we therefore need not reach MedComp's remaining arguments on appeal.

REVERSED