No. 16-

IN THE

Supreme Court of the United States

MERCK & CIE, BAYER PHARMA AG, AND BAYER HEALTHCARE PHARMACEUTICALS INC.,
Petitioners,

v.

WATSON LABORATORIES, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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October 12, 2016

QUESTION PRESENTED

The Patent Act provides that a "person shall be entitled to a patent unless … the invention was … in public use or on sale in this country, more than one year prior to the date of the application" for the patent. 35 U.S.C. § 102(b) (2006).

The question presented is:

Whether the "on sale" bar found in § 102(b) applies only to sales or offers of sale made available to the public, as Congress, this Court, and the United States have all made clear, or whether it also applies to non-public sales or offers of sale, as the Federal Circuit has held.

PARTIES TO THE PROCEEDINGS

The parties to the proceedings are Merck & Cie, Bayer Pharma AG, Bayer HealthCare Pharmaceuticals Inc., and Watson Laboratories, Inc.

RULE 29.6 STATEMENT

Bayer Pharma AG and Bayer HealthCare Pharmaceuticals Inc. are wholly owned subsidiaries of Bayer AG, a publicly held company.

Merck KGaA is a publicly held company that owns more than 10% of Merck & Cie.

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PETITION FOR A WRIT OF CERTIORARI

Merck & Cie, Bayer Pharma AG, and Bayer HealthCare Pharmaceuticals Inc. (collectively, Merck) respectfully petition for a writ of certiorari to review the decision of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The Federal Circuit's opinion is reported at 822 F.3d 1347 and is reproduced at Pet. App. 1a–15a. The Federal Circuit's order denying rehearing en banc is reproduced at Pet. App. 41a–42a. The district court's decision is reported at 125 F. Supp. 3d 503 and is reproduced at Pet. App. 22a–40a. The district court's final judgment is reproduced at Pet App. 16a–21a.

JURISDICTION

The court of appeals filed its decision on May 13, 2016, and denied the petition for rehearing and rehearing en banc on July 15, 2016. This Court has jurisdiction under 28 U.S.C. § 1254.

RELEVANT STATUTORY PROVISION

35 U.S.C. § 102 (2006) provides:[1]

> A person shall be entitled to a patent unless– …
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more

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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, 285–87 (2011); *see infra* at 11. Because Merck applied for its patent in 2000, the pre-AIA law governs this case. Citations are to the pre-AIA statute unless otherwise noted.

than one year prior to the date of the application for patent in the United States, ….

INTRODUCTION

This case presents an all-too-familiar basis for certiorari: Once again, the Federal Circuit has reached a conclusion that contradicts the Patent Act, this Court's precedents, and the considered views of the United States. See also, *e.g.*, *Limelight Networks, Inc.* v. *Akamai Techs., Inc.*, 134 S. Ct. 2111 (2014) (induced infringement); *Octane Fitness, LLC* v. *ICON Health & Fitness, Inc.*, 134 S. Ct. 1749 (2014) (attorney's fees). This time, the subject is the Patent Act's "on sale" bar, which precludes anyone from seeking to patent an invention that has been "on sale" for more than one year prior to the patent application. 35 U.S.C. § 102(b). Because only this Court can correct the Federal Circuit's erroneous standard—which casts doubt on the validity of countless patents—the Court should grant certiorari and reverse.

Outside of the Federal Circuit, the reach of § 102(b) has long been clear. Both Congress and this Court have consistently confirmed that the on-sale bar applies only to sales or offers for sale made available *to the public*. Non-public transactions or discussions, typically conducted in preparation for launching a product, do not place an invention "on sale" within the meaning of the statute. In short, as this Court recently stated, "[f]rom 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." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 148–49 (1989) (emphases added).

The United States agrees. In an en banc case decided contemporaneously with this one, the Department of Justice urged the Federal Circuit to "overrule its decisions interpreting the on-sale bar to reach non-public sales" and to "clarify that, consistent with longstanding Supreme Court precedent and congressional intent, the on-sale bar is trigged only by sales or offers for sale that make the invention available to the public." En Banc Brief for the United States as *Amicus Curiae*, at 17, 19, *Medicines Co.* v. *Hospira, Inc.*, Nos. 2014-1469, -1504 (Fed. Cir. filed Mar. 2, 2016) (en banc) (ECF No. 132) (U.S. Amicus Br.).

The Federal Circuit, however, rejected the United States' request to correct course, and adhered to its incorrect view that non-public communications can trigger the on-sale bar and invalidate a patent. The Federal Circuit reaffirmed its belief that "confidential transactions [can] be patent invalidating sales under § 102(b)" and that confidentiality is merely a "factor" to be considered. *Medicines Co.* v. *Hospira, Inc.*, 827 F.3d 1363, 1376 (Fed. Cir. 2016) (en banc) (citing cases). In line with that view, the court held in this case that confidential, non-public discussions between Merck and a third party during preparations to launch a product triggered the on-sale bar and wiped out Merck's patent entirely. Pet. App. 14a–15a.

This case warrants this Court's review to correct the Federal Circuit's errant view of § 102(b)'s on-sale bar. The Federal Circuit's incorrect approach to the on-sale bar is inconsistent with the Patent Act, this Court's precedent, and the position of the United States. This is the only Court that can correct those wrongs. And because the Federal Circuit held that the on-sale bar was not triggered in *Medicines Co.*, this is the proper case to address the issue.

The issue is also extremely important. Many inventors, out of necessity or efficiency, rely on non-public dealings with manufacturers, wholesalers, and others to launch and bring inventions to the public market in anticipation of receiving patents on their inventions. The Federal Circuit's willingness to invalidate patents for inventors who engage in such a collaborative process, and to reduce the non-public nature of pre-launch transactions to a mere "factor" to be considered, unsettles the fate of many patents, creates perverse incentives for inventors to file prematurely, and favors certain inventors over others.

Nearly 20 years ago, this Court discarded the Federal Circuit's "unnecessarily vague" "totality of the circumstances" approach to the on-sale bar, emphasizing the need for "certainty" and the "interest in providing inventors with a definite standard for determining when a patent application must be filed." *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 65–68 & n.11 (1998). That message has been lost through the Federal Circuit's insistence on a "factor"-based analysis of non-public transactions. The Court should grant the petition or, at a minimum, call for the views of the Solicitor General.

STATEMENT OF THE CASE

A. Factual Background

This case concerns Merck's invention of and patent on a chemical compound used in certain popular contraceptives. In 1997, Merck scientists invented a unique crystalline calcium salt of 5-methyl-(6S)-tetrahydrofolic acid (MTHF). Pet. App. 2a. MTHF is marketed under the trade-name Metafolin® and is used to manufacture oral contraceptives sold as Safyral® and Beyaz®. *Id.* at 22a–23a. Shortly after inventing Metafolin®, Merck realized it needed a lo-

cal partner to help prepare Metafolin® for launch and delivery to the U.S. market. As a result, Merck began "exploring a strategic partnership" with Weider Nutrition International, Inc., to develop and launch commercial uses for Metafolin® in the United States. *Id.* at 2a.

Initial discussions were promising, and the parties signed a confidential disclosure agreement (CDA) in February 1998 to govern their exploration of a partnership. Pet. App. 2a. Protected by the CDA, Merck and Weider continued to discuss the possibility of an exclusive supply arrangement or a joint venture to market and distribute Metafolin®-based products in the United States. *Id.*

By August 1998, Weider was no longer interested in a joint venture, but the parties continued to discuss alternative arrangements—still confidentially, under the cloak of the CDA. Pet. App. 2a–3a. In that context, Weider floated the idea of possibly purchasing 2 kilograms of Metafolin®. *Id.* at 3a. Merck then sent Weider a fax with product details, including a potential price and payment and delivery terms. *Id.* Weider responded that it needed more information and would send a purchase order after receiving that information. *Id.* at 3a–4a.

The likelihood of Weider's possible purchase of Metafolin® faded over the ensuing months. At first, the parties tried to sort out details of the possible transaction, like insurance coverage and safety requirements. Pet. App. 4a. But Weider lost interest, and, by January 1999, both sides had come to the conclusion that any potential undertaking would not be fruitful. *Id.* at 4a–5a. They parted ways, without Weider ever purchasing Metafolin®. *Id.* at 5a.

More than a year later, in April 2000, Merck filed an application for a patent on Metafolin®. Pet. App. 2a. The patent, No. 6,441,168, issued in August 2002. *Id.*

B. Procedural Background

1. Almost a decade after Merck secured its patent, in December 2011, Watson Laboratories, Inc., took the position that the patent was never valid. Watson filed two Abbreviated New Drug Applications (ANDAs) seeking to manufacture generic versions of Safyral® and Beyaz®. Pet. App. 5a, 22a–23a. Once Merck sued Watson for patent infringement, *id.* at 5a, 22a, Watson conceded infringement but argued that Merck's patent was invalid, contending among other things that the on-sale bar nullified Merck's patent from the get-go. *Id.* at 24a. In particular, Watson claimed that Merck's confidential discussions with Weider in late 1998 triggered the bar and, because Merck's patent application was filed more than one year later, wiped out the '168 patent. *Id.* at 26a–29a.

The district court held that Watson failed to prove invalidity and agreed with Merck that the invention had not been "on sale" in 1998. First of all, it was "undisputed" that the CDA remained in effect throughout the fall 1998 discussions and, accordingly, those discussions were non-public. Pet. App. 29a. Against that backdrop, the district court held that the parties' indefinite discussions did not constitute a sale or an offer to sell within the meaning of 35 U.S.C. § 102(b). *Id.* at 29a–30a.

2. The Federal Circuit reversed. Pet. App. 1a–15a. Watson did not challenge the district court's finding that the CDA covered the parties' fall 1998 discussions, and so the Federal Circuit assumed that it did. *Id.* at 13a. Nevertheless, and notwithstanding the

fact that the discussions were not public, the Federal Circuit erased Merck's 14-year-old patent based on the confidential communications made in preparation for launching a potential commercial product. *Id.* at 13a–15a. According to the Federal Circuit, Merck's discussions with Weider constituted a "premature commercial exploitation of its invention" sufficient to invalidate the patent under the on-sale bar. *Id.* at 15a.

3. While this case was pending, the Federal Circuit granted en banc review in *Medicines Co.* v. *Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016), to reconsider the scope of the "on sale" bar. And in that en banc proceeding, the United States submitted an amicus brief explaining why, under this Court's precedent, the on-sale bar does not apply when an "invention was never made available for sale to the public." U.S. Amicus Br. at 2. The United States urged the Federal Circuit to hold that the on-sale bar does not apply when transactions are "confidential and exclusive, such that no member of the public could have purchased the product," and to "overrule its decisions interpreting the on-sale bar to reach non-public sales." *Id.* at 2, 17.

Prior to this en banc proceeding, it obviously would have been futile for Merck to argue that the non-public nature of its discussions with Weider precluded application of the on-sale bar, because a three-judge panel "had no authority to overrule" the Federal Circuit's long line of cases rejecting precisely that argument. See *Medimmune, Inc.* v. *Genentech, Inc.,* 549 U.S. 118, 125 (2007). But, because en banc proceedings are not so limited, Merck asked the panel in this case to defer a decision until after the en banc court decided *Medicines Co.* See Fed. R. App. P. 28(j) Letter, *Merck & Cie* v. *Watson Labs., Inc.*, Nos. 2015-

2063, -2064 (Fed. Cir. filed Mar. 7, 2016) (ECF No. 50). Nonetheless, the panel rejected Merck's request and forged ahead, alluding to the *Medicines* case only in a footnote that said "there is no dispute that the [on-sale] bar arises when a product is marketed to the public prior to the critical date," even though the panel had earlier "assum[ed]" that the Merck-Weider discussions were *not* public. Pet. App. 13a, 15a n.4.

4. Merck filed its own petition for rehearing en banc. ECF No. 53. Merck explained that the panel decision holding that the confidential, non-public discussions triggered the on-sale bar conflicted with the Patent Act, with this Court's precedent, and with the views of the United States. *Id.* at 9–11.

Shortly thereafter, the Federal Circuit issued its decision in *Medicines Co.*, 827 F.3d 1363, and later that same week denied Merck's rehearing petition, Pet. App. 41a–42a. In *Medicines*, the en banc court rejected the United States' plea to realign the on-sale bar with the statute and with centuries of this Court's precedent. Instead, the Federal Circuit reaffirmed its earlier decisions holding that "confidential transactions [can] be patent invalidating sales under § 102(b)" and concluded that the non-public nature of a transaction is merely a "factor" to be considered. *Medicines*, 827 F.3d at 1376 (citing cases).

REASONS FOR GRANTING THE PETITION

The Court should grant certiorari for at least two reasons. *First*, the Federal Circuit's decision is inconsistent with the text of the Patent Act, this Court's precedent, and the considered views of the United States. The Federal Circuit has refused several opportunities to reconcile its precedent with these authorities, making plain that this Court's review is the only way to correct course.

Second, the ramifications of the Federal Circuit's refusal to adhere to the Patent Act and this Court's precedents are severe. This refusal affects millions of patents, presents confusing and uncertain standards for inventors, and is harmful to innovation. The Court's intervention is sorely needed.

I. THE FEDERAL CIRCUIT'S ON-SALE BAR CASE LAW IS INCONSISTENT WITH THE PATENT ACT, THIS COURT'S PRECEDENT, AND THE VIEWS OF THE UNITED STATES.

The Federal Circuit invalidated Merck's 14-year-old patent based on misguided precedent that erroneously applies the on-sale bar to confidential, non-public discussions. This position conflicts with the Patent Act's text, with this Court's precedent, and with the views of the United States. Certiorari is warranted.

A. The Patent Act, This Court's Precedent, And The United States All Demonstrate That The On-Sale Bar Does Not Apply To Non-Public Sales Or Offers Of Sale.

1. The Patent Act provides that "[a] person shall be entitled to a patent unless," among other things, "the invention was … in public use or on sale in this country, more than one year prior to the date of the application" for the patent. 35 U.S.C. § 102(b). The text and history of that provision make clear that an invention must be available for sale *to the public* in order to be considered "on sale" and subject to § 102's bar.

The operative phrase "on sale" has an established ordinary meaning—namely, that a member of the interested public can buy whatever it is that is "on sale." See, *e.g.*, *American Heritage Dictionary* (rev. 5th ed. 2016) (defining "on sale" to mean "[a]vailable

to customers"). An object can of course be *sold* privately or secretly, but saying that something is "on sale" naturally conveys that the item is available more widely and to more than one potential counterparty. See also 26 U.S.C. § 6802(1) (using "on sale" in a way that clearly means accessible to the public).

The Patent Act's long history confirms this commonsense understanding. The earliest iterations did not include the term "on sale"; instead, they barred a patent on any invention that was already "known or used." Act of April 10, 1790, ch. 7, § 1, 1 Stat. 109, 110; Act of Feb. 21, 1793, ch. 11, § 1, 1 Stat. 318, 319. But even then, the Act had a public-facing design: it sought to prohibit patenting any idea "already disclosed to the public" because doing so would "obstruct[] others in the use of what they possessed before." *Bonito Boats*, 489 U.S. at 147 (quoting 13 *Writings of Thomas Jefferson* 326–27 (memorial ed. 1904)). This Court subsequently concluded as much when the provision came before it in *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1 (1829). "[T]he true construction of the act," the Court held, is that an inventor cannot obtain a patent "if he suffers the thing invented to go into public use, or to be *publicly sold for use*, before he makes application for a patent," because his "voluntary act or acquiescence in the *public sale* and use is an abandonment of his right." *Id.* at 23–24 (emphases added).

Congress made that explicit when it amended the statute a few years later to codify *Pennock*'s pronouncement and to prohibit the patenting of any invention that was, at the time of filing, "in public use or on sale." Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119; see *Cannon* v. *Univ. of Chi.*, 441 U.S. 677, 698–99 (1979) ("evaluation of congressional action … must take into account its contemporary legal con-

text"). That language largely stuck for nearly two centuries. See, *e.g.*, Act of July 8, 1870, ch. 230, § 24, 16 Stat. 198, 201; Act of July 19, 1952, ch. 950, § 102(b), 66 Stat. 792, 797 (codified at 35 U.S.C. § 102(b) (2006)). The "on sale" phrase thus arose out of this Court's statements about *public* sales and never wavered from that origin.

Just a few years ago, Congress amended § 102 and in the process confirmed the long-established understanding that an invention is not "on sale" when it is not available to the public. The amended provision states that an inventor cannot acquire a patent if the invention was "in public use, on sale, *or otherwise available to the public*" before filing. 35 U.S.C. § 102(a)(1) (2012) (emphasis added). The broad residual clause clarifies that "the preceding clauses describe things that are of the same quality or nature as the final clause—that is, although different categories of prior art are listed, all of them are limited to that which makes the invention 'available to the public.'" 157 Cong. Rec. S1368, S1370 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl), *cited in* final Committee Report, H.R. Rep. No. 112-98, at 43 n.20 (2011). And, by continuing to use the phrase "on sale" without any direct modifier (like "publicly" or "to the public"), Congress confirmed that it has always covered only sales or offers of sale that are available to the public.

2. Like Congress, this Court has consistently maintained the view, set out in *Pennock*, that non-public transactions do not make an invention "on sale." In *Elizabeth* v. *Pavement Co.*, 97 U.S. 126 (1878), for example, the Court spelled out the distinction between what does and does not trigger the statutory bar. On the one hand, experimental use does not come within the statute's reach so long as the inventor controls

the invention and "does not voluntarily allow others to make [the invention] and use it, and so long as it is not *on sale for general use*." *Id.* at 135 (emphasis added). On the other hand, once the inventor allows the invention "to be used by other persons *generally* [or] put on sale for such use," then the invention would "be in public use *and on public sale*, within the meaning of the law." *Id.* (emphasis added).

Numerous other decisions similarly reflect the need for public accessibility and the fact that the on-sale bar does not cover *non-public* transactions or confidential, pre-launch dealings needed to bring a product to market. See, *e.g.*, *Bonito*, 489 U.S. at 148–49 ("[f]rom the Patent Act of 1790 to the present day, the *public sale* of an unpatented article has acted as a complete bar" to patenting) (emphasis added); *Consol. Fruit-Jar Co.* v. *Wright*, 94 U.S. 92, 93–95 (1877) (sale of more than a dozen fruit jars to members of the public triggered the on-sale bar); *Planing-Mach. Co.* v. *Keith*, 101 U.S. 479, 485 (1880) (invention must not be in public use or on sale or else it could trample the "intervening rights of the public"); *Egbert* v. *Lippmann*, 104 U.S. 333, 337 (1881) (lack of an "obligation of secrecy" during invention's distribution and later widespread use and sale precluded patent); *Muncie Gear Works, Inc.* v. *Outboard, Marine & Mfg. Co.*, 315 U.S. 759, 766–68 (1942) (invention that was widely "popularized" before the patent application barred). Unless an invention is "placed in *public* commerce," *Bonito Boats*, 489 U.S. at 149 (emphasis added), and available for sale *to the public*, it is not "on sale" under § 102. The confidential transactions that patentees typically have with manufacturers, marketers, and other members of the supply chain in order to bring a product to market do not trigger the "on sale" bar.

3. The United States shares this Court's view about the correct scope of the on-sale bar. Citing many of the same authorities noted above, the United States told the en banc Federal Circuit that, "[o]ver the nearly two centuries during which Congress has reenacted the on-sale bar without changing the 'on sale' language, th[is] Court has repeatedly described the statute as addressed to *public* sales." U.S. Amicus Br. at 8–15. When it was "undisputed that the transactions [in that case] were confidential and exclusive," therefore, the government maintained that "section 102(b) would not apply because the invention was never made available for sale to the public." *Id.* at 2. And, the United States explained, such an approach dovetails with Congress's more general "determination to 'exclude from consideration for patent protection knowledge that is already available to the public' because 'the creation of a monopoly in such information would not only serve no socially useful purpose, but would in fact injure the public by removing existing knowledge from public use.'" *Id.* at 9 (quoting *Bonito Boats*, 489 U.S. at 148).

Accordingly, the United States urged the Federal Circuit to "overrule its decisions interpreting the on-sale bar to reach non-public sales, including confidential supplier agreements." *Id.* at 17–19. The path forward, the United States said, was to "hold that the on-sale bar is triggered only by sales or offers for sale that make the invention available to the public." *Id.* at 18.

B. The Federal Circuit's Decision Conflicts With These Authorities.

The Federal Circuit's decision in this case is inconsistent with this body of authority. The discussions between Merck and Weider in preparation for a potential product launch were *not* public. The district

court found that the parties' confidentiality agreement covered these discussions, Pet. App. 27a–30a, and Watson did not challenge that finding in the Federal Circuit. The record is thus clear, as the Federal Circuit "assum[ed]," *id.* at 13a, that the public did not know about Metafolin® and that the '168 patent's invention was *not* available for sale to the public. These undisputed facts mean that the parties' pre-launch discussions about Metafolin® fall squarely outside the scope of § 102(b)'s on-sale bar.

Contrary to the statute and this Court's case law, however, the Federal Circuit held that the parties' non-public discussions in preparation for a potential launch triggered the statutory bar and invalidated Merck's patent. The Federal Circuit's only attempt to reconcile that judgment with this Court's precedent comes in a footnote at the end of the opinion. There, the Federal Circuit alluded to the pending en banc case in *Medicines* but stated that "there is no dispute that the [on-sale] bar arises when a product is marketed to the public prior to the critical date." Pet. App. 15a n.4. That is true, but it is entirely irrelevant to this case, particularly after the Federal Circuit accepted the undisputed fact that Merck's discussions with Weider about the invention were confidential and *not* public. Merck did not market Metafolin® or otherwise make it available for public consumption. It merely explored a possible partnership to facilitate launch of the drug after it became patented and ready for mass sale.

Moreover, there is no doubt about where the Federal Circuit stands on the scope of § 102. For years, it has held that secret and non-public transactions can place an invention "on sale" and preclude patentability. See, *e.g.*, *Special Devices, Inc.* v. *OEA, Inc.*, 270 F.3d 1353, 1357 (Fed. Cir. 2001) (the on-sale bar

would apply "even if a patentee's commercial activities took place in secret"). And when the Federal Circuit's wayward doctrine was presented for reconsideration en banc, with the United States asking the Federal Circuit to correct and overrule its decisions, the court of appeals declined to do so. Indeed, the Federal Circuit did the opposite, citing with approval earlier decisions finding "confidential transactions to be patent invalidating sales under § 102(b)" and declaring that the non-public nature of negotiations or transactions is just one "factor" to be considered in deciding whether the on-sale bar applies. *Medicines*, 827 F.3d at 1367. Although this Court has previously rejected the Federal Circuit's "totality of the circumstances" approach to the on-sale bar as "unnecessarily vague," *Pfaff*, 525 U.S. at 66 n.11, the Federal Circuit's "factor"-based analysis has returned the doctrine to precisely that point of inherent ambiguity. The Court should grant certiorari to bring the Federal Circuit back into line with the Patent Act, this Court's precedent, and the views of the United States.

II. THE QUESTION PRESENTED IS EXCEPTIONALLY IMPORTANT.

Certiorari is also warranted because the question presented is exceptionally important.

1. The on-sale bar issue touches virtually every corner of the economy, from the lone innovator working in his garage, to companies with multimillion dollar research budgets, to everyone in between. Between 2005 and 2010 alone, nearly three million patent applications were filed with the PTO and over one million patents were granted. U.S. Patent & Trademark Office, *U.S. Patent Statistics Chart: Calendar Years 1963-2015*, http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last modified June 15, 2016). That staggering level of innovation de-

serves a clear and correct standard for navigating the potential ramifications of non-public dealings—particularly those conducted in the ordinary course with manufacturers, marketers, and other members of the supply chain in preparation for a commercial launch.

2. In addition to the sheer magnitude of the problem, the Federal Circuit's rule creates all the wrong incentives for inventors and entrepreneurs. The fundamental policy behind the on-sale bar (and much of patent law) is that inventors should not be "allow[ed] to remove existing knowledge from *public* use." *Pfaff*, 525 U.S. at 64 (emphasis added). But, by telling inventors that pre-launch activities and discussions conducted confidentially and non-publicly may *also* prohibit a patent, Pet. App. 13a–15a, the Federal Circuit does violence to the purpose behind the statute and casts doubt on countless patents.

This nebulous state of affairs pushes inventors and the patent system as a whole away from the careful balance that Congress struck. On one end of the spectrum, for example, an inventor confronted with the possibility that the final stages of its inventive process and pre-launch activities could trigger the on-sale bar may easily make the rational choice to "err on the side of filing" for patent protection. Dmitry Karshtedt, *Did Learned Hand Get It Wrong?: The Questionable Patent Forfeiture Rule of* Metallizing Engineering, 57 Vill. L. Rev. 261, 312–13 (2012) (quoting Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 Hastings L.J. 65, 96 (2009)). But that is not a desirable outcome, because too many such early filings in the aggregate risk flooding the PTO with poor-quality applications and flooding the system with poor-quality patents. Cotropia, *supra*, at 103–05. That tends to "drag down the development of

other technologies," *id.* at 112, which is far from fulfilling the constitutional goal of "promot[ing] the Progress of Science and useful Arts." U.S. Const. art. I, § 8, cl. 8.

At the other end of the spectrum, by contrast, the broader economy and the public could lose out on valuable inventions that inventors are pressed to keep secret under the Federal Circuit's approach. An inventor that wisely waits to confirm that its invention is in fact patentable, for instance, may well "'blow[]' the one-year bar and thereafter come[] to see an attorney" who thinks the inventor "can never get [a] patent" and should accordingly "keep the invention a secret in perpetuity." Karshtedt, *supra*, at 311. After all, "[t]here can be no turning back to the patent system" once § 102's year-long period has passed. *Id.* at 311 n.317. But that result is no good either, as it has the obvious and "perverse consequence of potentially *retarding* progress in the useful arts." *Id.*

Apart from these competing concerns in this country, the Federal Circuit's current doctrine puts inventors planning to seek patent rights worldwide in a bind. Most foreign patent regimes reject the proposition that confidential dealings in preparation for launch constitute prior art that can invalidate a patent. Toshiko Takenaka, *Rethinking the United States First-to-Invent Principle from a Comparative Law Perspective: A Proposal to Restructure § 102 Novelty and Priority Provisions*, 39 Hous. L. Rev. 621, 625 (2002). Because the Federal Circuit takes a contrary view, an inventor may be forced to act differently in this country than she would everywhere else. This is so despite the fact that Congress recently made clear its desire to "promote harmonization of the United States patent system with the patent systems commonly used in nearly all other countries" and to "pro-

vide inventors with greater certainty." Pub. L. No. 112–29, sec. 3, § 146(o)–(p), 125 Stat. 284, 293 (2011).

The far better approach, dictated by the statute and this Court's precedent, is one that recognizes the strong "interest in providing inventors with a definite standard for determining when a patent application must be filed" and the overwhelming need for "certainty." *Pfaff*, 525 U.S. at 65–68. Inventors are entitled to at least that much when it comes to the complex and often necessary non-public discussions to prepare an invention for market.

3. Finally, the Federal Circuit's rule jeopardizes critical supply-chain transactions and threatens disparate treatment among market participants. Product development is frequently a long and intricate process during which inventors may need to deal with quality-control organizations, consultants, product-development teams, distributers, marketers, wholesalers, retailers, and others. According to the Federal Circuit, however, even non-public interactions with such entities might come back to terminate a later-issued patent.

In particular, the Federal Circuit's rule "disadvantages small inventors." Leah C. Fletcher, *Equal Treatment Under Patent Law: A Proposed Exception to the On-Sale Bar*, 13 Tex. Intell. Prop. L.J. 209, 230 (2005). Large vertically integrated organizations are often able to both create their invention and prepare it for market without allowing their idea to spread beyond the parking lot. *Id.* Others do not have that luxury. To bring their inventions to the public, for example, they may need to outsource testing, manufacturing, or marketing to a third party. *Id.* at 231. And yet at every turn, even if the inventor takes precautions to keep the invention confidential and non-public, there remains the distinct possibility that a

court will later label certain actions as the "premature commercial exploitation of [the] invention," Pet. App. 15a, that starts the on-sale bar's one-year clock. There is no sound reason, and certainly no reason in the statute, for a rule that risks favoring some inventors over others. See, *e.g.*, Brief of *Amicus Curiae* American Intellectual Property Law Association in Support of Neither Party at 21–22, *Medicines*, Nos. 2014-1469, -1504 (Fed. Cir. filed Jan. 19, 2016) (en banc) (ECF No. 80) ("Application of the on-sale bar should not turn on whether activities are performed in house or through a transaction with a third party."); Brief of *Amicus Curiae* Pharmaceutical Research and Manufacturers of America in Support of The Medicines Company at 5, *Medicines*, Nos. 2014-1469, -1504 (Fed. Cir. filed Mar. 2, 2016) (en banc) (ECF No. 143) ("The on-sale bar is not meant to interfere with manufacturing efficiency, or to discriminate between different classes of patentees.").

The Federal Circuit's en banc decision in *Medicines Co.* does nothing to stabilize these inequities. Rather, it reaffirms the inherent risks for different market participants while signaling a return to a hard-to-predict, multi-factored test like the one rejected in *Pfaff*. Any inventor with a good idea but who needs some help bringing that idea to the public remains at risk that, no matter how careful he or she is, confidential and non-public transactions might cancel out any patent rights associated with that idea down the road.

* * *

The rule underlying the Federal Circuit's decision in this case misapprehends the language of the Patent Act, contradicts this Court's precedents, contravenes the view of the Unites States, frustrates innovation, and breeds uncertainty. The Court should

grant the petition or, at the very least, call for the views of the Solicitor General.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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October 12, 2016

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APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS,
FEDERAL CIRCUIT

Nos. 2015-2063, 2015-2064

MERCK & CIE, BAYER PHARMA AG,
BAYER HEALTHCARE PHARMACEUTICALS INC.,

Plaintiffs-Appellees,

v.

WATSON LABORATORIES, INC.,

Defendant-Appellant.

May 13, 2016

OPINION

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*

[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).

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 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, 24 L.Ed. 1000 (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, 119 S.Ct. 304, 142 L.Ed.2d 261 (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

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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).

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." 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 stand-alone 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 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

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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.

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 494, 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, 119 S.Ct. 304 ("[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]

CONCLUSION

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

REVERSED

[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, 119 S.Ct. 304; *see also Bonito Boats, Inc. v. Thunder Craft Boats, Inc.,* 489 U.S. 141, 148-49, 109 S.Ct. 971, 103 L.Ed.2d 118 (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 placed into the public domain through commercialization.").

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C.A. No. 13-978 (RGA)

MERCK & CIE, BAYER PHARMA AG AND BAYER HEALTHCARE PHARMACEUTICALS INC.,

Plaintiffs,

v.

WATSON LABORATORIES, INC.,

Defendant.

FINAL JUDGMENT

This action, having come to trial before the Court from May 18 through May 21, 2015, Honorable Richard G. Andrews, District Judge presiding, the evidence and testimony of witnesses of each side having been heard and a decision having been rendered:

IT IS HEREBY ORDERED AND ADJUDGED this 14 day of September, 2015, for the reasons set forth in the Order Regarding Infringement and Claim Construction of U.S. Patent No. 6,441,168 dated February 19, 2014 (D.I. 38) and the Court's Trial Opinion dated August 31, 2015 (D.I. 115) that:

1. Judgment is entered in favor of Plaintiffs Merck & Cie, Bayer Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (collectively "Plaintiffs") and against Defendant Watson Laboratories, Inc.

("Watson") on the claim in Plaintiffs' Complaint for Patent Infringement dated June 4, 2013 (D.I. 1), that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic version of Bayer HealthCare's Safyral® combined oral contraceptive that is the subject of Watson's Abbreviated New Drug Application ("ANDA") No. 203594 would infringe Claim 4 of U.S. Patent No. 6,441,168 ("the '168 patent").

2. Judgment is entered in favor of Plaintiffs and against Watson on the counterclaim of invalidity in Watson's Answer to Complaint, Defenses, and Counterclaims dated August 2, 2013 (D.I. 11). Specifically, that Claim 4 of the '168 patent is not invalid for having been on sale in this country, more than one year prior to the date of application for the patent under 35 U.S.C. § 102(b), not invalid as anticipated under 35 U.S.C. § 102, not invalid for obviousness under 35 U.S.C. § 103, and not invalid for lack of written description under 35 U.S.C. § 112.

3. Pursuant to 35 U.S.C. § 271(e)(4)(A), the Food and Drug Administration ("FDA") is ordered to make the effective date of any final approval of Watson's ANDA No. 203594 to be a date that is not earlier than the date of expiration of the '168 patent (April 17, 2020).

4. Pursuant to 35 U.S.C. § 271(e)(4)(B), Watson and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise, are hereby permanently enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Watson's proposed generic version of Bayer HealthCare's

Safyral® combined oral contraceptive that is the subject of Watson's ANDA No. 203594 during the term of the '168 patent.

Sept 14, 2015 /s/ Richard G. Andrews
DATED UNITED STATES DISTRICT JUDGE

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C.A. No. 13-1272 (RGA)

MERCK & CIE, BAYER PHARMA AG AND BAYER HEALTHCARE PHARMACEUTICALS INC.,

Plaintiffs,

v.

WATSON LABORATORIES, INC.,

Defendant.

FINAL JUDGMENT

This action, having come to trial before the Court from May 18 through May 21, 2015, Honorable Richard G. Andrews, District Judge presiding, the evidence and testimony of witnesses of each side having been heard and a decision having been rendered:

IT IS HEREBY ORDERED AND ADJUDGED this 14 day of September, 2015, for the reasons set forth in the Order Regarding Infringement and Claim Construction of U.S. Patent No. 6,441,168 dated February 19, 2014 (D.I. 38) and the Court's Trial Opinion dated August 31, 2015 (D.I. 114) that:

1. Judgment is entered in favor of Plaintiffs Merck & Cie, Bayer Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (collectively "Plaintiffs") and against Defendant Watson Laboratories, Inc.

("Watson") on the claim in Plaintiffs' Complaint for Patent Infringement dated July 23, 2013 (D.I. 1), that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic version of Bayer HealthCare's Beyaz® combined oral contraceptive that is the subject of Watson's Abbreviated New Drug Application ("ANDA") No. 203593 would infringe Claim 4 of U.S. Patent No. 6,441,168 ("the '168 patent").

2. Judgment is entered in favor of Plaintiffs and against Watson on the counterclaim of invalidity in Watson's Answer to Complaint, Defenses, and Counterclaims dated August 19, 2013 (D.I. 11). Specifically, that Claim 4 of the '168 patent is not invalid for having been on sale in this country, more than one year prior to the date of application for the patent under 35 U.S.C. § 102(b), not invalid as anticipated under 35 U.S.C. § 102, not invalid for obviousness under 35 U.S.C. § 103, and not invalid for lack of written description under 35 U.S.C. § 112.

3. Pursuant to 35 U.S.C. § 271(e)(4)(A), the Food and Drug Administration ("FDA") is ordered to make the effective date of any final approval of Watson's ANDA No. 203593 to be a date that is not earlier than the date of expiration of the '168 patent inclusive of the patent term extension awarded to Plaintiffs under 35 U.S.C. § 156 (July 30, 2022).

4. Pursuant to 35 U.S.C. § 271(e)(4)(B), Watson and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Final Judgment by personal service or otherwise, are hereby permanently enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Watson's

proposed generic version of Bayer HealthCare's Beyaz® combined oral contraceptive that is the subject of Watson's ANDA No. 203593 during the term of the '168 patent.

Sept 14, 2015 /s/ Richard G. Andrews
DATED UNITED STATES DISTRICT JUDGE

APPENDIX D

UNITED STATES DISTRICT COURT,
D. DELAWARE

Civil Action Nos. 13-978-RGA

Civil Action No. 13-1272-RGA

MERCK & CIE, BAYER PHARMA AG AND BAYER HEALTHCARE PHARMACEUTICALS INC.,

Plaintiffs,

v.

WATSON LABORATORIES, INC.,

Defendant.

Signed August 31, 2015

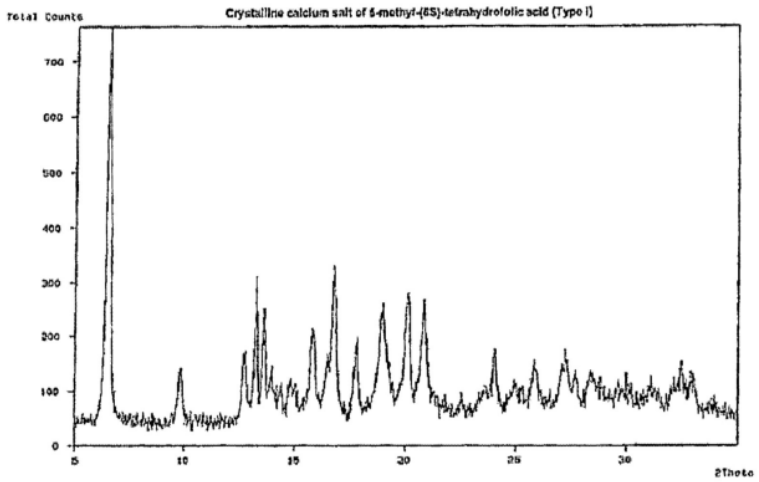
TRIAL OPINION

ANDREWS, District Judge

Merck & Cie, Bayer Pharma AG, and Bayer Healthcare Pharmaceuticals Inc, (collectively, "Merck" or "Plaintiff") brought this suit against Watson Laboratories, Inc. ("Watson" or "Defendant") alleging infringement of U.S. Patent No. 6,441,168 ("the '168 patent"). (D.I.1). Watson filed two Abbreviated New Drug Applications ("ANDAs") seeking approval to engage in the commercial manufacture, importation, use, or sale of generic versions of Safyral® and Beyaz®. This action centers on one ingredient of the proposed drugs: the Type I crystal form of calcium

5-methyl-(6S)-tetrahydrofolate ("MTHF"). (Tr.2025:8-10).[1]

Claim 4 of the patent 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 powder x-ray diffraction diagram in the specification shows peaks at the two theta values described in the claim:



The specification also states that the solubility of the Type I crystal is 1.1%, which meets the United States Pharmacopeia ("USP") definition of "sparingly soluble." ('168 patent, col. 4, l. 58; PTX195 at p. 6). The water content of the Type I crystal is 14.5%. ('168 patent, col. 5, l. 67).

[1] Citations to "Tr." refer to the transcript of the bench trial held on May 18, 2015 through May 21, 2015. Page numbers reflect the "PageID."

The parties stipulated that, if claim 4 of the '168 patent is valid and enforceable, (1) Defendant's filing of ANDA Nos. 203593 and 203594 would constitute an act of infringement and (2) commercial manufacture, use, offer for sale, sale, and/or importation of Defendant's Safyral® ANDA Product and/or Beyaz® ANDA Product would infringe the claim. (D.I.38). Watson asserts that claim 4 is not valid and enforceable. It contends that the asserted claim is invalid under the on-sale bar of 35 U.S.C. § 102(b), anticipated under 35 U.S.C. § 102(a), obvious under 35 U.S.C. § 103(a), and invalid under 35 U.S.C. § 112 for lack of written description. (D.I. 108 at p. 1).

I. ON-SALE BAR

A. Legal Standard

A patent claim is invalid under the on-sale bar of 35 U.S.C. § 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." The on-sale bar requires proof of two conditions: (i) the product is "ready for patenting," and (ii) the invention is "the subject of a commercial offer for sale." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 66-68, 119 S.Ct. 304, 142 L.Ed.2d 261 (1998); *Medicines Co. v. Hospira, Inc.*, 791 F.3d 1368, 1370 (Fed.Cir.2015). "An actual sale is not required for the activity to be an invalidating commercial offer for sale. An attempt to sell is sufficient so long as it is sufficiently definite that another party could make a binding contract by simple acceptance." *Hamilton Beach Brands, Inc. v. Sunbeam Products, Inc.*, 726 F.3d 1370, 1374-75 (Fed.Cir.2013) (internal citations omitted). "[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. Findings of Fact

1. The application for the '168 patent was filed on April 17, 2000.

2. The '168 patent issued on August 27, 2002.

3. The '168 patent was ready for patenting by September 1998.

4. In 1997, Merck and Weider Nutrition International ("Weider") were exploring a strategic partnership to introduce dietary supplements with Merck ingredients into the United States.

5. On February 25, 1998, Merck and Weider entered into a Confidentiality and Noncompetition Agreement ("CDA"). Section 5.2 of the CDA 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."

6. In August 1998, Weider notified Merck that it was no longer interested in an exclusive strategic partnership.

7. In August 1998, Weider inquired about a stand-alone purchase of two kilograms of MTHF.

8. Weider and Merck exchanged communications about the purchase throughout the fall of 1998.

9. On September 9, 1998, Roland Martin of Merck sent a fax to Weider with terms for the purchase, including price, quantity, delivery, and payment.

10. On September 16, 1998, Weider responded, confirming the delivery address and indicating that it would send a purchase order after receiving additional information required to add Merck as a supplier.

11. Weider did not receive the MTHF, and cancelled the purchase on January 9, 1999.

C. Conclusions of Law

In order to show that an invention was ready for patenting, there must be proof of a reduction to practice before the critical date or proof that the inventor prepared enabling drawings or descriptions of the invention. *Pfaff*, 525 U.S. at 67-68, 119 S.Ct. 304. Merck wrote to Weider on September 25, 1998 and stated that the MTHF to be delivered would be from Lot ESF-118. (DTX 27 at p. 2). Merck stipulated that (1) Lot ESF-118 is within the scope of claim 4 of the '168 patent, (2) the x-ray diffraction pattern of Lot ESF-118 is disclosed in Figure 1 of the patent, and (3) the x-ray diffraction pattern of Lot ESF-118 was obtained by Merck at least as of August 25, 1998. (D.I. 73 at 2). The MTHF was therefore ready for patenting by September 1998.

Watson argues that the September 9, 1998 and September 16, 1998 communications constitute a commercial sale. (Tr. 2800; D.I. 108 at p. 8). Watson contends that the September 9, 1998 fax contained all the material terms necessary for an offer to be sufficiently definite: a description of the product, quantity, price, delivery information, and payment terms. (D.I. 108 at p. 11). Watson argues that Weider understood at the time that a sale had occurred. (*Id.* at p. 11). It notes that Dr. Bucci of Weider testified that he was expecting Merck to deliver the MTHF.

(Tr. 2240 at 3-7). Even if a sale did not occur for the purposes of the on-sale bar, Watson maintains that the September 9, 1998 fax constituted a commercial offer for sale. (D.I. 108 at p. 7).

Watson also argues that § 5.2 of the CDA did not operate to prevent a commercial sale. (*Id.* at p. 12). Watson maintains that a "transaction" for the purposes of the agreement does not include a stand-alone purchase, but rather refers to the larger joint venture the companies were exploring. (*Id.* at p. 14). In addition, Watson argues that the September correspondence was a "definitive agreement." (*Id.*). Watson further argues that, even if the CDA did apply to the stand-alone purchase, Merck waived § 5.2 by inviting Weider to follow a process for sale that did not comply with § 5.2. (*Id.*).

Finally, Watson argues that there were no remaining terms or conditions that needed to be determined before a sale could occur. (*Id.* at p. 17). Watson argues that Dr. Bucci expected delivery and Merck promised to "arrange everything" for "immediate delivery," both of which contradict Merck's contention that there were outstanding conditions. (*Id.* at pp. 17-18; DTX 133).

Merck maintains that, in light of § 5.2 of the CDA, there was no commercial sale or offer for sale. (D.I. 111 at p. 4). The CDA provides that a transaction is not legally binding until there is a definitive agreement signed by both parties. (*Id.*). Merck argues that there was no such signed agreement, and thus there cannot be a legally binding sale. (*Id.*). Merck notes that both Dr. Buehholz of Merck and Dr. Bucci of Weider testified that there was no obligation to deliver a product absent a formal written agreement. (*Id.* at p. 5). Dr. Buchholz testified, "The conversations and discussions we had did not create any obligation to

Weider or from Weider to us unless we afterwards, after we had the discussion, signed a formal agreement and contract." (Tr. 2749:8-12). Dr. Bucci testified that it was his "understanding that until [they] had a signed agreement, it was all discussions." (*Id.* at 2227:6-8).

Merck argues that a "transaction" for the purposes of the CDA includes a stand-alone purchase, and is not limited to a long-term strategic partnership. (D.I. 111 at p. 13). Merck notes that in the September 1998 correspondence, the order was referred to as a "transaction." (*Id.*). Merck also argues that no document in the fall 1998 correspondence is signed by both parties. (*Id.* at p. 14). With respect to waiver, Merck contends that Watson's argument is circular because it would mean that the circumstances § 5.2 is designed to protect against would operate to waive it. (*Id.* at p. 15).

Merck further argues that a sale was not possible in the fall of 1998 because there were outstanding issues that needed to be resolved before a sale could occur. (D.I. 111 at p. 7). Merck contends that there could be no sale until toxicology tests were performed, intellectual property and regulatory matters were resolved, and liability apportionment was determined. (*Id.* at p. 8). Dr. Buchholz testified that it was industry standard to include safety information, liability apportionment, and intellectual property rights in a sale agreement. (Tr. 2750:19-2751:17). Merck argues that industry practice is a relevant consideration to determining whether there has been an offer for sale. (D.I. 111 at p. 8 (citing *Lacks Indus., Inc. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1348 (Fed.Cir.2003))).

Merck further argues that contemporaneous documentary evidence confirms that neither Weider nor Merck believed that there was a binding sale or offer at the time. (*Id.*). On January 6, 1999, there was an internal Weider email exchange regarding MTHF. A Weider employee wrote, "we had indicated an interest for 2Kg" of MTHF and asked for clarification on the order status. (PTX094). Preston Zoller forwarded the email to Dr. Bucci and another Weider employee. He noted that "Merck wasn't expecting us to buy any immediately" and "there wouldn't be any dire consequences to cancelling the P.O., (if one exists) until such time as a new 5-MTHF product is actually approved for launch." (*Id.*). Merck argues that this exchange is consistent with there being no contract in place. (D.I. 111 at p. 9). Merck contends it also shows that Weider believed regulatory approval was required before there could be a launch, which demonstrates that there were outstanding issues to resolve. (*Id.*).

A commercial "offer must be sufficiently definite that another party could make a binding contract by simple acceptance." *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1365 (Fed.Cir.2008). "A manifestation of willingness to enter into a bargain is not an offer if the person to whom it is addressed knows or has reason to know that the person making it does not intend to conclude a bargain until he has made a further manifestation of assent." RESTATEMENT (SECOND) OF CONTRACTS § 26 (1981). It is undisputed that the CDA remained in effect at least through January 1999. (Tr. 2817:10-16). I agree with Merck that the discussions in the fall of 1998 would not constitute a legally binding sale until reduced to writing and signed by both parties. Because a further manifestation of assent was required, the

correspondence was also not an offer that could be made binding upon acceptance.

I do not think that Merck waived § 5.2. As Merck noted, if its conduct were sufficient to waive § 5.2, that section would serve no purpose. The testimony at trial demonstrated that the parties understood that a signed agreement was necessary. In addition, contemporaneous evidence showed that Merck considered the discussions to be an indication of interest.

I also think that industry-standard terms were missing from the communications. It seems to me that determining liability apportionment for a potentially dangerous new drug would be very important to a sale. While an offer can sometimes be sufficiently definite with only the terms present in the September communications, which terms are necessary should be considered in light of the product. I do not think that the communications were sufficiently definite to constitute an offer given that important safety and liability terms, which Dr. Buchholtz testified were standard in the industry, were missing.

In sum, there was not a commercial offer or sale of MTHF that would invalidate the '168 patent under the on-sale bar.

II. ANTICIPATION

A. Legal Standard

"To show that a patent claim is invalid as anticipated, the accused infringer must show by clear and convincing evidence that a single prior art reference discloses each and every element of a claimed invention." *Silicon Graphics, Inc. v. ATI Tech., Inc.*, 607 F.3d 784, 796 (Fed.Cir.2010). "[E]very element of the claimed invention [must be described], either

expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed.Cir.2009). "Inherent anticipation requires that the missing descriptive material is necessarily present, not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed.Cir.2002). As with infringement, the court construes the claims and compares them against the prior art. *See Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1332 (Fed.Cir.2010).

B. Findings of Fact

1. Different crystal structures of the same chemical entity are polymorphs.

2. A hydrate is a crystalline solid where water is a part of the structure.

3. The Type I crystal is the only currently known pentahydrate polymorph of MTHF.

4. Powder x-ray diffraction ("PXRD") is a method of determining whether a substance has a crystalline content.

5. PXRDs of crystalline substances have features, or peaks, at given two theta values.

6. PXRDs of amorphous substances show less defined, broader humps.

7. Dr. Marsden's and Dr. Rogers's experiments did not follow the procedure in U.S. Patent No. 5,350,850 ("the '850 patent").

C. Conclusions of Law

Watson argues that claim 4 of the '168 patent is anticipated by the '850 patent. (D.I. 108 at p. 18).

Watson maintains that Example 3 of the '850 patent details a method of obtaining a crystalline pentahydrate of MTHF ("the '850 product"). (*Id.*). Watson argues that the Patent and Trademark Office examiner found that the '850 product was a pentahydrate of MTHF. (DTX 001 at pp. 216-17). Specifically, the examiner found that the '850 product had a moisture content of 15.27%, which corresponds to a pentahydrate. (*Id.*). Watson argues that Type I crystals are the only known crystalline pentahydrate of MTHF. (*Id.*). Watson's expert, Dr. Rogers, testified that it was "highly unlikely" that there is an undiscovered polymorph of MTHF. (Tr. 2428:14-18).

Watson further argues that the two theta values recited in claim 4 are inherently present in the '850 product. (D.I. 108 at p. 19). Watson notes that Dr. Rogers received a sample of MTHF from Dr. Marsden (Material 1), confirmed it was amorphous using PXRD, and performed the recrystallization process taught by the '850 patent. (*Id.* at p. 25). Dr. Rogers tested the resulting products (Materials 2 and 3) and found that they exhibited all four two theta values recited in claim 4. (*Id.*).

Merck argues that the '850 product is not a Type I crystal. (D.I. 111 at p. 17). Merck maintains that the '850 product is "practically insoluble," whereas the Type I crystal is "sparingly soluble." (*Id.*). "Practically insoluble" and "sparingly soluble" are terms of art understood by persons of ordinary skill. (*Id.* at 20). The USP defines "practically insoluble" as less than 0.001% solubility. (PTX195 at p. 6). The USP defines "sparingly soluble" as approximately 1% solubility. (*Id.*). Merck argues that the '850 product cannot be the Type I crystal because the Type I crystal is one

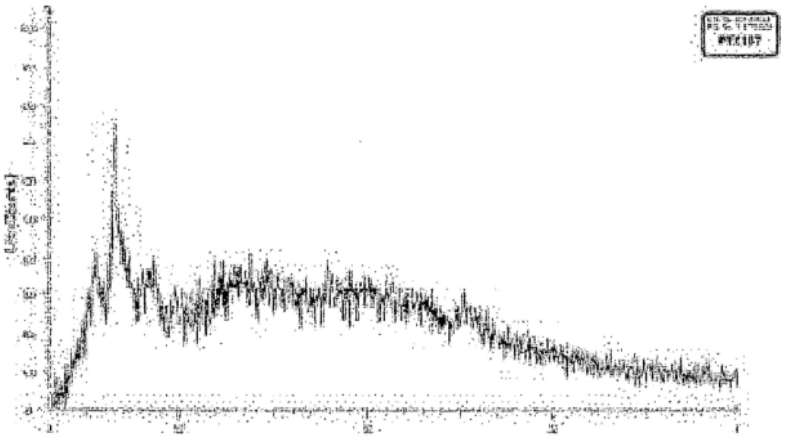
hundred times more soluble than the '850 product. (D.I. 111 at p. 20).

Merck further argues that it is possible that there are undiscovered polymorphs of MTHF. Watson therefore cannot prove that the '850 product is the claimed invention based solely on the fact that it is a pentahydrate of MTHF. (*Id.* at p. 21). Merck contends that the company Merck hired to look for new MTHF polymorphs noted that further testing "may reveal other unknown modifications with varying water contents." (*Id.* at p. 22 (quoting DTX302 at 25)). It notes that new polymorphs are often discovered years after a substance has been in use. (*Id.*).

In addition, Merck maintains that Watson cannot show that following the '850 procedure results in a product with the two theta values recited in claim 4 because Watson's experts did not follow the '850 process. (*Id.* at p. 23). Dr. Marsden prepared Material 1 using a different process than the '850 process. Dr. Rogers therefore recrystallized a different material than that produced by the '850 process. Merck argues that a prior art process can only inherently anticipate if the claimed invention inevitably occurs when the prior art procedure is "faithfully followed." (*Id.* at p. 24 (quoting *Valeant Int'l (Barbados) SRL v. Watson Pharm., Inc.*, 2011 WL 6792653, at *5 (S.D.Fla, Nov. 8, 2011), *aff'd sub nom. Valeant Int'l Bermuda v. Actavis, Inc.*, 534 Fed.Appx. 999 (Fed.Cir.2013))). Because Dr. Rogers and Dr. Marsden did not follow the procedure, Merck argues that Dr. Rogers's experiment is not probative of what the '850 procedure would inevitably produce. (*Id.*).

Merck further argues that, even if Dr. Rogers's experiment were relevant, its results would be invalid because Material 1 was seeded with Type I crystals.

(*Id.* at p. 26). Seeding is adding a small amount of a crystal form to a sample to facilitate the formation of that type of crystal. (*Id.*). Merck notes that seeding does not need to be intentional, and can occur through inadvertent contamination. (*Id.*). Merck argues that Dr, Myerson's PXRD testing found that Material 1 was seeded with Type I crystals. (*Id.*). Dr. Myerson's PXRD of Material 1 showed a large, defined peak at 6.5. (*Id.*). Merck argues that the peak at 6.5 is the characteristic peak of Type I crystals. (*Id.*). Dr. Myerson's PXRD (PTX167) is below:



I find that the '850 patent does not anticipate claim 4. The '850 product and the Type I crystal have different solubilities, which is not consistent with them being the same product. In addition, I think Dr. Rogers's experiment fails to show inherent anticipation. As shown above, the PXRD has a distinct feature at 6.5. I think that Dr. Myerson's testimony that he peak demonstrates that Material 1 was seeded with

a crystalline substance was credible.[2] Dr. Myerson noted that those of skill in the art look for the biggest characteristic peak when searching for a substance in a mixed sample. (*Id.* at 1222:18-22). Dr. Rogers agreed that, when a sample has impurities, not all peaks will be visible. (Tr. 2453:4-10). Therefore, the fact that only the 6.5 peak is visible does not mean that Type I crystal was not present in Material 1. Dr. Rogers explained the peak by arguing that calcium salts of long molecules often have a peak at a low two theta value. (Tr. 2273:6-8). This argument, however, is unsupported by the evidence.

I also agree with Merck that an experiment that did not follow the '850 procedure is not probative of what would inevitably occur if the '850 procedure were followed. This Court has previously held that experiments that do not follow the prior art procedure alleged to inherently anticipate cannot show inherent anticipation. *In re Armodafinil Patent Litig. Inc. (%2C722 Patent Litig.)*, 939 F.Supp.2d 456, 478-79 (D.Del.2013).

III. OBVIOUSNESS[3]

A. Legal Standard

A patent claim is invalid as obvious under 35 U.S.C. § 103 "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the

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[2] I do not mean to imply that Watson purposefully attempted to manipulate the experiment. Seeding can occur inadvertently.

[3] Though Watson did not technically waive its obviousness and written description arguments, its post-trial briefing suggests that it gives little weight to those defenses. (*See* D.I. 108 (fewer than two pages for each argument), D.I. 105 (no obviousness argument and fewer than two pages on written description)).

effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains," 35 U.S.C. § 103; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406-07, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007).

"Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or non-obviousness of the subject matter is determined." *KSR*, 550 U.S. at 406, 127 S.Ct. 1727 (internal citation omitted).

A court is required to consider secondary considerations, or objective indicia of nonobviousness, before reaching an obviousness determination, as a "check against hindsight bias." *See In re Cyclobenzaprine Hydrochloride Extended—Release Capsule Patent Litig.*, 676 F.3d 1063, 1078-79 (Fed.Cir.2012). "Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Graham v. John Deere Co, of Kansas City*, 383 U.S. 1, 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966).

B. Findings of Fact

1. The level of ordinary skill in the art is either (1) a person with a bachelor's degree in chemistry, chemical engineering, or a related field and at least three years of experience in the pharmaceutical industry doing crystallization or other tasks involving solid state form or (2) a person with an advanced degree in chemistry, chemical engineering, or a related field.

2. Different polymorphs of a substance have different chemical properties.

3. Crystalline calcium MTHF was a desired product with known therapeutic benefits.

4. There was motivation in the industry to find and characterize new crystalline polymorphs of MTHF.

5. Discovering an unknown polymorph is a process of trial and error.

6. Dr. Rogers testified that there was no evidence of industry acclaim with respect to the invention.

C. Conclusions of Law

Watson argues that claim 4 is obvious in light of the '850 patent alone or in combination with U.S. Patent No. 5,006,655 ("the '655 patent"). (D.I. 108 at p. 28). The '655 patent discloses the pentahydrate calcium MTHF. (Tr. 2834:3-6). Watson argues that a person of skill in the art would have a reasonable expectation of producing Type I crystals by combining the pentahydrate calcium MTHF with the recrystallization process taught in the '850 patent. (D.I. 108 at p. 28). Watson maintains that crystalline MTHF was known and preferred, and there was motivation in the industry to find and characterize crystalline forms. (*Id.*).

Merck argues that there was not a reasonable expectation of success of producing Type I crystals because discovering an unknown polymorph is a process of trial and error. (D.I. 111 at p. 28). Merck maintains that there cannot be a reasonable expectation of success where a process is "complicated, unpredictable, and largely conducted through trial and error." (*Id.* (quoting *Pfizer Inc. v. Teva Pharm.*

USA, Inc., 555 Fed.Appx. 961, 971 (Fed.Cir.2014))). Both Dr. Rogers and Dr. Myerson testified that finding an unknown polymorph is an unpredictable process of trial and error. (Tr. 2478:18-21, 2629:17-2630:7).

There was no post-trial briefing with respect to secondary considerations, and minimal testimony. I find that no secondary considerations have been proven.

Watson has not demonstrated that a person of skill in the art would have a reasonable expectation of success of producing Type I crystals in light of the prior art. For the reasons discussed above, the '850 patent does not anticipate claim 4. Adding the pentahydrate calcium MTHF disclosed in the '655 patent does not render the claim obvious. Both sides' experts agree that finding an unknown polymorph requires experimentation. While there may have been a motivation to discover new crystalline polymorphs of MTHF, doing so would have required a process of trial and error. There was therefore no reasonable expectation of success of finding Type I crystals.

IV. WRITTEN DESCRIPTION

A. Legal Standard

The written description "must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed.Cir.2010) (en banc). The test is whether the disclosure "conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* This requires an "objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.*

B. Findings of Fact

1. The level of ordinary skill in the art is either (1) a person with a bachelor's degree in chemistry, chemical engineering, or a related field and at least three years of experience in the pharmaceutical industry doing crystallization or other tasks involving solid state form or (2) a person with an advanced degree in chemistry, chemical engineering, or a related field.

C. Conclusions of Law

Watson argues that claim 4 lacks written description because the specification does not disclose any information from which a person of skill could conclude that the inventors possessed an MTHF polymorph with one water of crystallization, *i.e.*, a monohydrate. (D.I. 108 at pp. 29-30). Claim 4 calls for MTHF with "at least one" water of crystallization. ('168 patent, col. 10, l. 60). Dr. Rogers testified that the specification does not show that the inventors possessed MTHF with one water of crystallization. (Tr. 2370:3-9).

Merck responds that the patent states, "the Type I modification typically contains ≥3 equivalents of water." (D.I. 111 at p. 30 (quoting '168 patent, col. 2, ll. 15-16)). "Typically" is not limiting, meaning that sometimes Type I crystals have fewer than three waters of crystallization. (Tr. 2852:8-10, 2853:18-20).

I agree with Merck. A specification is not required to describe each and every embodiment of a claim. Disclosing that the Type I crystal typically has greater than three waters of crystallization does not indicate that it never has fewer.

CONCLUSION

Watson did not prove by clear and convincing evidence that claim 4 of the '168 patent is invalid. Merck is directed to submit an agreed upon final judgment within two weeks.

APPENDIX E

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 No. 1:13-cv-00978-RGA, 1:13-cv-01272-RGA, Judge Richard G. Andrews

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ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before PROST, *Chief Judge*, NEWMAN, MAYER[*], LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, HUGHES, and STOLL, *Circuit Judges*.

PER CURIAM.

ORDER

Appellees Merck & Cie, Bayer Pharma AG, and Bayer Healthcare Pharmaceuticals Inc. filed a combined

[*] Circuit Judge Mayer participated only in the decision on the petition for panel rehearing.

petition for panel rehearing and rehearing en banc. The petition was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on July 22, 2016.

FOR THE COURT

July 15, 2016
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court