No. 16A74

IN THE SUPREME COURT OF THE UNITED STATES

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

v.

WATSON LABORATORIES, INC.,
Respondent.

REPLY IN SUPPORT OF APPLICATION OF MERCK & CIE, BAYER PHARMA AG, AND BAYER HEALTHCARE PHARMACEUTICALS INC. FOR IMMEDIATE STAY OF ACTION PENDING APPELLATE REVIEW

DIRECTED TO THE HONORABLE JOHN G. ROBERTS, JR., CHIEF JUSTICE OF THE UNITED STATES AND CIRCUIT JUSTICE FOR THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, applicants state as follows:

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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REPLY IN SUPPORT OF APPLICATION TO STAY THE FEDERAL CIRCUIT'S MANDATE

INTRODUCTION

Well aware that the United States Department of Justice filed a brief seeking to "overrule" Federal Circuit precedent, *see* En Banc Brief for the United States as Amicus Curiae in Support of Appellant at 17, *The Medicines Co. v. Hospira, Inc.*, Nos. 14-1469, -1504 (Fed. Cir. Mar. 2, 2016) ("U.S. Amicus Br. Ex. A"), Watson chooses to misrepresent that brief, *see* Resp. Opp. at 26-27. By no means did the United States endorse the Federal Circuit's approach to the on-sale bar or otherwise suggest that confidential offers could trigger it. To the contrary, the United States expressly criticized the court's holdings "that the on-sale bar was triggered by non-public sales, *such as sales made under contractual commitments of exclusivity and confidentiality*," and requested the en banc court to bring itself in line with this Court's long-standing case law. U.S. Amicus Br. Ex. A, at 17-18.

That is precisely what Applicants ask this Court to do here. And, if the Court agrees with Applicants (and the United States) on this point, the Court should grant certiorari and reverse. There is no reason to let the Federal Circuit's erroneous rule remain on the books, calling into doubt countless patents for which there was no public sale or offer.

The remainder of Watson's arguments against a stay are equally meritless. Citing an inapposite decision pertaining to the review of *state* court decisions, Watson misconstrues this Court's "pressed or passed upon" rulings. *See* Resp. Opp. at 17-18. This Court has never held that an en banc petition is "too late" to ask a

court of appeals to overturn circuit precedent. Rather, this Court has expressly recognized that raising such a request sooner would be "futile." In any event, there is no mystery where the Federal Circuit lands on the question presented; in *The Medicines Co. v. Hospira, Inc.*, Nos. 14-1469, -1504 (Fed. Cir. July 11, 2016), it squarely passed upon the issue. There is no reason to delay review.

Finally, Watson's irreparable harm analysis is grasping at straws. Lower courts routinely hold that genericizing a market constitutes irreparable harm, and for good reason: monetary damages are not readily ascertainable. *Teva Pharm. USA, Inc. v. Sandoz, Inc.* 134 S. Ct. 1621 (2014) (Roberts, C.J., in chambers) is inapposite, because the applicant there had publicly stated that its loss of market share and profits were compensable by money damages. Here, unlike in *Teva*, Applicants have made crystal clear that they will suffer irreparable harm in the absence of a stay because the market will become genericized.

ARGUMENT

I. THE FEDERAL CIRCUIT'S DECISION IS INCONSISTENT WITH SUPREME COURT PRECEDENT AND LIKELY TO BE REVERSED.

Applicants agree with the United States: Sales and offers made under confidentiality agreements are not "public" and do not trigger the on-sale bar. *See* Stay Appl. at 10-14. Watson mischaracterizes the United States' position in *The Medicines Company* by claiming that the Government endorses a "multi-factor test." *See* Resp. Opp. at 26. But the United States proposed a simple rule for cases like this one, in which "sales [were] made under contractual commitments of exclusivity and confidentiality." The United States asked the Federal Circuit to "overrule" its

precedents applying the on-sale bar to such sales, and to hold that "the on-sale bar is triggered only by sales or offers for sale that make the invention available to the public." U.S. Amicus Br. Ex A, at 17-18.[1] Watson ignores this part of the United States' brief.

Watson also fails to grapple with the practical consequences of its position. As Applicants explained, *see* Stay Appl. at 18, in bringing a product to market, inventors routinely must engage in confidential discussions with numerous suppliers, distributors, and other members of the supply chain. Federal Circuit precedent risks invalidating the inventors' patents whenever such discussions first occurred more than a year before the patent filing. Nowhere does Watson justify this result or explain how Congress could have intended it.

Nor does Watson reconcile the Federal Circuit's multi-factor test with this Court's decision in *Pfaff*, which rejected the lower court's "totality-of-the-circumstances" test. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998); Stay Appl. at 14. Instead, Watson wrongly claims that *Pfaff* somehow supports the decision

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[1] Watson accepts that the confidentiality and disclosure agreement ("CDA") between Applicants and Weider was in force during the fall 1998 discussions, but it questions whether the CDA covers the transaction at issue. *See* Resp. Opp. at 19-20 n.3. However, the district court obviously found that the CDA covered the discussions at issue. *See Merck & Cie v. Watson Labs., Inc.*, Nos. 13-978, -1272, slip op. at 7 (D. Del. Aug. 31, 2015) (explaining that Applicants had not waived a provision of the CDA and that the CDA therefore required a signed agreement between the parties to constitute an offer for sale). And on appeal, the Federal Circuit *had* to accept the applicability of the CDA because Watson's counsel failed to challenge that legal conclusion in its briefing. In fact Watson's counsel *conceded* that it had waived such a challenge. *See* Oral Argument at 5:08, *Merck & Cie v. Watson Labs., Inc.*, Nos. 15-2063, -2064 (Fed. Cir. May 13, 2016), http://oralarguments.cafc.uscourts.gov/ default.aspx?fl=2015-2063.mp3; *see also Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 833 (Fed. Cir. 2010) (explaining that so long as a party "clearly understood the issue, but simply never made the argument" that party "waives an argument not raised in its opening brief").

below. *See* Resp. Opp. at 23 (quoting *Pfaff*, 525 U.S. at 67). But Watson points to nothing suggesting that the *Pfaff* Court meant to jettison the long-standing publicity requirement.[2] And less than a decade before *Pfaff*, a unanimous Court in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989), continued to maintain that "the *public* sale of an unpatented article" precludes patenting "the idea embodied in the article thus placed in *public* commerce." *Id.* at 149 (emphasis added). The *Pfaff* Court was well aware of *Bonito Boats* and even cited it. *See Pfaff*, 525 U.S. at 63. There is no indication that the *Pfaff* Court *sub silentio* overturned it.[3]

The Federal Circuit recognized the overwhelming significance of the scope of the on-sale bar when it granted *en banc* review and sought the views of the United States. But, having disregarded those views, that court should not have the last

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[2] Moreover, as the United States recognized in its amicus brief to the Federal Circuit, *Pfaff*'s justification for requiring a "commercial offer for sale" to trigger the on-sale is consistent with the rule Applicants now advance. *See* U.S. Amicus Br. Ex. A, at 13. *Pfaff* explained that a "commercial offer for sale" is an appropriate trigger for the bar because "[a]n inventor can both understand and control the timing of the first commercial marketing of his invention." *Pfaff*, 525 U.S. at 67. The entire point of a confidentiality and disclosure agreement like the one here is to *prohibit* the commercial marketing of any product sold or offered for sale; it ensures that the product cannot be "commercial[ly] marketed" in a way that would trigger the bar under *Pfaff*.

[3] Watson also appeals to language in *Pfaff*, quoting *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126, 137 (1878), that "[a]ny attempt to use [an invention] for a profit . . . would deprive the inventor of his right to a patent." *See* Resp. Opp. at 25 (alterations in original) (emphasis omitted). Of course, this language only addresses the public-use provision of § 102(b), not the on-sale bar. Second, this snippet of *City of Elizabeth* overlooks that the Court there seemingly connected the use of an invention for a profit with being "on sale for *general* use" and being "in public use *and on public sale*, within the meaning of" § 102(b). *City of Elizabeth*, 97 U.S. at 135 (emphasis added). Again, Watson cannot escape that even if the on-sale bar requires commercial exploitation, it *also* requires publicity.

word on this issue. As the United States argued below, confidential transactions do not trigger the bar.[4] This Court should grant a stay, grant review, and reverse.

II. APPLICANTS PROPERLY PRESERVED THE ON-SALE BAR ISSUE HERE.

Watson argues that the Court is unlikely to grant certiorari because Applicants did not raise the issue of confidential offers until their en banc petition. *See* Resp. Opp. at 16-18. But this Court has explained that petitioners need not press futile arguments to three-judge panels that are bound by circuit precedent. For example, in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), the Court held that a party's decision not to fully press an argument precluded by circuit precedent "does not suggest a waiver; it merely reflects counsel's sound assessment that the argument would be futile" because the panel "had no authority to overrule" the precedent. *Id.* at 125. A three-judge panel of the Federal Circuit could do nothing to alter the circuit precedents that unambiguously rejected the publicity requirement of § 102(b). *See Deckers Corp. v. United States*, 752 F.3d 949, 964 (Fed. Cir. 2014) ("[A] panel of this court . . . is bound by the precedential decisions of prior panels unless and until overruled by an intervening Supreme Court or en banc decision."). Here, as both Applicants and the United States have demonstrated,

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[4] Watson suggests that the America Invents Act's revisions to the on-sale bar demonstrate that the question of how to interpret the pre-2011 statute is "of declining significance." Resp. Opp. at 21. This is mistaken. Between 2005 and 2010 alone, well more than 1 million patents were granted by the United States Patent and Trademark Office. *See* U.S. Pat. & Trademark Office, *U.S. Patent Statistics Chart: Calendar Years 1963-2015* (last modified July 26, 2016), http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm. Watson cannot seriously argue that Federal Circuit case law jeopardizing the validity of this number of patents is insignificant.

decades-old Federal Circuit precedent regarding the on-sale bar left no doubt where the Court of Appeals stood. *See* Stay Appl. at 13; U.S. Amicus Br. Ex. A, at 17-19.

Moreover, Applicants *did* alert the panel to the issue. One week after the United States submitted its amicus brief in *The Medicines Company*, Applicants submitted a letter, pursuant to Fed. R. App. P. 28(j), alerting the panel of the United States' brief. *Merck*, Nos. 15-2063, -2064, Dkt. No. 50 (Fed. Cir.). Applicants' letter asked the panel to hold the appeal pending the Court's en banc decision in *The Medicines Company*—which could have changed the state of Federal Circuit law on the on-sale bar.[5] After the panel decision, Applicants' petition for rehearing en banc squarely presented the issue, emphasizing many of the same arguments raised by the United States' in *The Medicines Company*. *See* Combined Petition of Plaintiffs-Appellees for Panel Rehearing and Rehearing En Banc at 9-12, *Merck*, Nos. 15-2063, -2064 (Fed. Cir. June 13, 2016). Applicants did precisely what they should have done.

The sole case on which Watson relies, *Adams v. Robertson*, 520 U.S. 83 (1997) (per curiam), is inapposite. *See* Resp. Opp. at 18. *Adams* involved a rehearing petition made to the Alabama Supreme Court, not an en banc petition to a federal court of appeals. *See* 520 U.S. at 89 n.3. This is a critical distinction. As this Court has recognized, "'due regard for the appropriate relationship of this Court to state courts' may suggest greater restraint in applying our 'pressed or passed upon' rule."

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[5] Watson mischaracterizes the point of Applicants' 28(j) letter. Far from calling on the panel below to rule on a "supplemental" or "new" argument, *see* Resp. Opp. at 18, Applicants merely asked the panel to hold the case *until* a potential authoritative change in the law could be made by the en banc court in *The Medicines Company*.

United States v. Williams, 504 U.S. 36, 44 n.5 (1992) (quoting *McGoldrick v. Compagnie Generale Transatlantique*, 309 U.S. 430, 434-35 (1940)). Further, the Alabama Supreme Court does not sit in three-judge panels that are unable to overrule prior court decisions. A state supreme court, like Alabama's, can always overrule its own precedent—so there was no futility issue, unlike here.

In any event, Watson's argument rests on a pointless formality. There is no question of where the Federal Circuit stands on the issue Applicants present to this Court. In *The Medicines Company*, the Federal Circuit en banc squarely passed on this issue, after inviting the participation of the United States and rejecting the rule that the United States advanced. It is unclear what sort of "percolat[ion]" Watson is waiting for. Resp. Opp. at 21.

III. WATSON'S GENERIC LAUNCH WOULD INFLICT INCALCULABLE AND IRREPARABLE HARM ON APPLICANTS.

Watson argues that the impending generic launch will not cause Applicants irreparable harm because Watson would be able to pay money damages. *See* Resp. Opp. at 10-14. This argument is unavailing. Courts assessing the launch of infringing generic drug products routinely recognize that patentees face irreparable harm from such a launch. *See* Stay Appl. at 15 (collecting cases); *see also Celsis in Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) ("Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm."); *cf. Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1304-05 (Fed. Cir. 2013) (reversing district finding of no irreparable harm because assumptions that price erosion and loss of market share can be

recovered by compensatory damages would cause the patent to "lose their character as an exclusive right . . . and become at best a judicially imposed and monitored compulsory license"). The "long tradition of equity practice," *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 320 (1982), has demonstrated that almost without exception, courts have found irreparable harm to patentees from infringing generics, and absent extraordinary circumstances, the Court should not depart from this tradition.[6]

Watson points to two contrary cases, one of which relied on the reasoning of the other. *See* Resp. Opp. at 11-12. These cases are inapposite. , There, "calculating lost profits would be a relatively simple task," *Eli Lily & Co. v. Am. Cynamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996), "because the parties to [the] suit [were] responsible for all of the [drug] sold in the United States." *Eli Lily* & Co. v. *Am. Cyanamid Co.*, 896 F. Supp. 851, 860 (S.D. Ind. 1995).

By contrast, Applicants' lost profits are not easily calculable. Applicants and Watson would not be the only companies in the market. Applicants have entered into a contract for an "authorized generic," which will be released if Watson's products launch. *See* Vellturo Decl. Appl. Ex. E at 5, 16-18.

With two generic competitors entering the market and aggressively pricing their products to capture sales, it will become practically impossible to untangle how the fully genericized market affects Applicants' sales and profits. *See id.* at 17.

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[6] When it comes to applying equitable standards in patent infringement cases, often "a page of history is worth a volume of logic." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) (Roberts, C.J., concurring) (quoting *N.Y. Tr. Co. v. Eisner*, 256 U.S. 345, 349 (1921)).

Simply "tally[ing] the number of [generic] units" sold by Watson through the expiration date of Applicants' patent and "multiply[ing] that number by [Applicants'] expected profit margin per [branded] unit," *Eli Lily*, 896 F. Supp. at 860, will not come close to capturing the effects that dueling generics would have on Applicants' sales and profit loss. By fundamentally transforming the market, Watson's proposed launch renders money damages an inadequate remedy. *See i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 862 (Fed. Cir. 2010) (explaining that loss of market share, brand recognition, and customer goodwill "frequently defy attempts at valuation, *particularly when the infringing acts significantly change the relevant market* (emphasis added)), *aff'd*, 564 U.S. 91 (2011).

Furthermore, there are severe financial and reputational harms resulting from the impending demotion of "formulary position" on numerous third-party reimbursement schedules. *See* Vellturo Decl. Appl. Ex. E at 5-6. Other courts have faced this precise issue and found that patentees will suffer irreversible price erosion by being "forced to offer discounted rates and price concessions to third-party payors" in order to keep the branded drug "on a favorable pricing tier, which governs what consumers pay for that drug." *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006). The availability of a generic competitor "encourages third party payors to place [a branded drug] on a less favorable tier, thereby requiring consumers to pay a higher co-pay, and perhaps deterring them from purchasing" the branded drug. *Id.* Applicants' products, Safyral® and Beyaz®, currently reside on Tier 3 or Tier 2 on third party formularies, and with a generic

entry, they "will likely be taken off formulary in many instances." Vellturo Decl. Appl. Ex. E at 5. Only a stay from this Court can prevent this irreparable harm.

Watson asserts that Applicants' authorized generic agreement is a "self-inflicted" harm. *See* Resp. Opp. at 15-16. But a harm is "self-inflicted" only if it is "readily avoidable;" if a company's choice to implement a certain policy is not "a true choice," it cannot "be fairly categorized as a self-inflicted injury." *Stuller, Inc. v. Steak N Shake Enters., Inc.*, 695 F.3d 676, 679 (7th Cir. 2012). Watson cannot plausibly argue that Applicants' decision to *mitigate* its losses by launching an authorized generic "*following* the launch of generic . . . products by a third party," Vellturo Decl. Appl. Ex. E at 16, was a true choice.[7] Applicants faced the Hobson's choice of introducing the authorized generic or losing its place in the market outright.

Watson also criticizes Applicants for not having a contractual right to claw back the authorized generic if Watson were to exit the market. *See* Resp. Opp. at 15-16; Blackburn Decl. Ex. 1, at 13-16. But the absence of a clawback provision is not unusual; it can be dictated by market and other constraints. In any event, this issue is a red herring. Regardless of whether the authorized generic is on the market

[7] As the Third Circuit has recently explained, "[A] brand's commitment not to produce an authorized generic means that it must give up the valuable right to capture profits in the new two-tiered market." *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 405 (3d Cir. 2015), *petition for cert. filed*, No. 15-1055 (U.S. Feb. 22, 2016). With a generic already present in the market, refusing to produce an authorized generic "transfers the profits the patentee would have made from its authorized generic to the settling generic—plus potentially more, in the form of higher prices, because there will now be a generic monopoly instead of a generic duopoly." *Id.* Therefore, with a generic competitor already in the market, "launching an authorized generic would seem to be economically rational for the brand." *Id.*

permanently or just during the pendency of this Court's review, calculating damages in this multi-party market with price competition and changing formulary status is no easy task.

Watson cites the in-chambers denial of a stay in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 134 S. Ct. 1621 (2014) (Roberts, C.J., in chambers) for failure to demonstrate irreparable harm. *See, e.g.*, Resp. Opp. at 9, 11, but *Teva* is distinguishable. First, Teva had demonstrated the calculability of its harm in its own publications to investors. *See* Respondents' Joint Opp. to Teva's Second Appl. to Recall and Stay the Mandate at 26-27, *Teva* (U.S. Apr. 14, 2014). Second, Teva had recently argued in other litigation that loss of market share and profits were compensable by money damages, in stark contradiction to its position in this Court. *See id.* at 26, 28. Applicants have made no such concessions because their harm is irreparable.

CONCLUSION

For the foregoing reasons and those stated in the application, the Court should grant Applicant's request for a stay.

Respectfully submitted,

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CERTIFICATE OF SERVICE

No. 16A74.

Merck& Cie, Bayer Pharma AG, and Bayer HealthCare Pharmaceuticals Inc.,

Applicants,

v.

Watson Laboratories, Inc.,

Respondent.

I, Carter G. Phillips, do hereby certify that, on this twenty-seventh day of July, 2016, I caused a copy and an electronic copy of the Application Of Merck& Cie, Bayer Pharma AG, And Bayer HeathCare Pharmaceuticals Inc. For Immediate Stay Of Action Pending Appellate Review in the foregoing case to be served by first class mail, postage prepaid, and by email, on the following parties:

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Exhibit A

Nos. 2014-1469, 2014-1504

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

THE MEDICINES COMPANY,

Plaintiff-Appellant,

v.

HOSPIRA, INC.,

Defendant-Cross-Appellant,

On Appeal from the United States District Court for the District of Delaware, Case No. 1:09-cv-00750-RGA (Judge Richard G. Andrews)

EN BANC BRIEF FOR THE UNITED STATES AS AMICUS CURIAE IN SUPPORT OF APPELLANT

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INTRODUCTION

Section 102(b) of Title 35 prohibits patenting an "invention" that was "on sale" in this country more than one year before the date the patent application was filed. 35 U.S.C. § 102(b).[1] At issue here are confidential transactions between a patent owner, the Medicines Company, and a third-party manufacturer, Ben Venue Laboratories (Ben Venue), to produce drug products that the Medicines Company later patented. Under the correct interpretation of the statute, those transactions did not place the invention "on sale" before the critical date for two reasons.

First, the statutory term "on sale" requires not merely commercial activity, but a commercial sale or offer for sale. Where, as here, the patented invention is a product (or product-by-process), the traditional hallmark of a sale is the transfer of title.[2] In this case, the parties do not dispute that the Medicines Company retained title to the drug product at all times. Nor is there anything about the nature of the transaction or Ben Venue's manufacturing services that would warrant disregarding the parties' agreement that this was a sale of manufacturing services. Because the patented drug product was never the subject of a commercial sale or offer for sale before the critical date, section 102(b) does not apply.

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[1] Section 102(b) was amended by the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, § 3(b)(1), 125 Stat. 284, 285-86 (2011). All references to Section 102 are to the pre-AIA version unless otherwise noted.

[2] As discussed below, the fact that some of the Medicines Company's claims are product-by-process claims does not affect the analysis.

Second, section 102(b) requires not merely evidence that a sale or offer for sale occurred, but also proof that the invention was "on sale." The Supreme Court has long construed that phrase to mean a sale or offer for sale that makes the invention available to the public. The on-sale bar, the Court has explained, reflects a fundamental policy of the patent laws: that an inventor should not be permitted to remove from the public an invention that was lawfully in the public's hands. Congress has repeatedly ratified that interpretation of the on-sale bar, and in 2011 it expressly confirmed it in the AIA: by adding the phrase "or otherwise available to the public" without revising the long-standing term "on sale," Congress made clear its understanding that "on sale" means sales or offers for sale that make the invention "available to the public." Even if the transactions between the Medicines Company and Ben Venue involved a sale of the invention, therefore, section 102(b) would not apply because the invention was never made available for sale to the public. It appears to be undisputed that the transactions were confidential and exclusive, such that no member of the public could have purchased the drug product from Ben Venue.

Adopting the correct statutory interpretation of the term "on sale" obviates any need for a "supplier exception" to the bar, as the facts of this case demonstrate. Many startup companies and small-scale inventors are unable to produce their inventions in-house. But when an inventor contracts confidentially with a third party to manufacture the invention on its behalf, that transaction may not make the

invention available to the public any more than a large company's confidential in-house manufacturing does. Even if (unlike here) such an arrangement involves a transfer of title, it does not place the invention "on sale" within the meaning of section 102(b).

Finally, because the on-sale bar does not apply, this Court need not reach the question of whether the "experimental use" doctrine applies. If the Court addresses this question, however, it should take the opportunity to revisit its bright-line rule that experimental use cannot occur after an invention is reduced to practice.

INTEREST OF THE UNITED STATES

The question presented here implicates the expertise and responsibilities of several federal agencies and components, including the Department of Commerce and the Patent and Trademark Office. On November 13, 2015, this Court invited the United States Department of Justice to file a brief expressing the views of the United States.

QUESTION PRESENTED

The on-sale bar 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 patent in the United States." 35 U.S.C. § 102(b) (emphasis added).

The question presented is whether the on-sale bar applies where an inventor confidentially contracts with a third-party manufacturer to produce the invention for later sale by the inventor to the public.

ARGUMENT

THE CIRCUMSTANCES OF THIS CASE DO NOT TRIGGER THE ON-SALE BAR

A. The Statutory Term "On Sale" Means A Sale Or Offer For Sale Of The Invention To The Public

Section 102(b) precludes patenting an "invention" that was "on sale" before the critical date. In *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67 (1998), the Supreme Court clarified that the bar applies when two conditions are met: (1) "the product must be the subject of a commercial offer for sale;" and (2) "the invention must be ready for patenting."[3] *Pfaff* thus made clear that there must be a commercial sale or offer for sale of the invention. And for more than 180 years, the Supreme Court has consistently held that an invalidating sale or offer is one that makes the invention available to interested members of the public before the critical date and thereby places the invention in the public domain.

Congress repeatedly reenacted the on-sale bar against the backdrop of that settled understanding. In the AIA, Congress made that longstanding requirement explicit: an invention cannot be patented when it has been placed "on sale," meaning

[3] The "ready for patenting" prong of *Pfaff* is not at issue in this en banc proceeding.

that the invention has been made "available to the public" through a sale or offer for sale. 35 U.S.C. § 102(a)(1) (2012) ("in public use, on sale, or otherwise available to the public"). By retaining the language "on sale," Congress indicated its understanding that only sales or offers for sale that make the invention available to the public fall within the scope of the bar.

1. The on-sale bar requires a sale or offer for sale of the invention

The statutory text requires that the invention be "on sale," meaning that "the product must be the subject of a commercial offer for sale." *Pfaff*, 525 U.S. at 67. Hospira elides this basic statutory requirement in arguing that, where the two sides to a transaction were "commercially exploiting the invention prior to the critical date, it was necessarily 'on sale' within the meaning of § 102(b)." Hospira Br. 29-30. Under the plain language of the statute, what triggers the bar is not any form of commercial exploitation, but a specific one: selling or offering to sell the invention. In a case such as this, therefore, where the patented invention is a product or a product-by-process, section 102(b) requires evidence of a sale or offer for sale of goods embodying the invention.

The term "sale" is used throughout the patent laws. *See, e.g.*, 35 U.S.C. § 154(a)(1) (exclusive rights conferred by a patent include "offering for sale, or selling the invention"); *id.* § 271(a) (acts constituting direct infringement include "offers to sell, or sell[ing]" the invention). The traditional hallmark of a sale of goods is the

transfer of title. *Butler v. Thomson*, 92 U.S. 412, 415 (1876) ("The essential idea of a sale is that of an agreement or meeting of minds by which a title passes from one, and vests in another."); *Black's Law Dictionary* (10th ed. 2014) (defining "sale" as "[t]he transfer of property or title for a price"); *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1319 (Fed. Cir. 2005) (explaining, in context of direct infringement, that "the ordinary meaning of a sale includes the concept of a transfer of title or property"), *abrogated in part on other grounds by Zoltek Corp. v. United States*, 672 F.3d 1309, 1322 (Fed. Cir. 2012) (en banc).

Indeed, the Uniform Commercial Code (UCC) specifically defines a "sale" as "the passing of title from the seller to the buyer for a price." UCC § 2-106(1). As this Court has explained, the Supreme Court's reference in *Pfaff* to a "'a *commercial* offer for sale'" as part of the on-sale bar test "strongly suggests 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." *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1046 (Fed. Cir. 2001); *see also id.* at 1048 (observing that *Pfaff* "also supports consulting the UCC"). This Court has, therefore, appropriately "look[ed] to the Uniform Commercial Code … to define whether … a communication or series of communications rises to the level of a commercial offer for sale" under section 102(b). *Id.* at 1047 (noting that the "UCC has been recognized as the general law governing the sale of goods"); *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1328 (Fed. Cir. 2001) (explaining that the UCC is "[a]n important relevant source of general

contract law" for determining whether an offer for sale has occurred); *In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002) (citing the UCC and concluding that, "[w]hen money changes hands as a result of the transfer of title to the tangible item, a sale normally has occurred").

In some cases, it may be difficult to determine whether title has transferred and a sale of goods has occurred. As discussed below, this is not such a case, because no one disputes that the Medicines Company retained title to the drug product at all times. In *United States v. Eurodif S.A.*, 555 U.S. 305 (2009), however, a case involving the "antidumping" provisions of the Tariff Act, the Supreme Court provided helpful guidance in distinguishing a sale of goods from a sale of services in those difficult cases. The issue in *Eurodif* was whether the transactions between domestic utilities and foreign uranium enrichers were sales of uranium enrichment services or of enriched uranium. *Id.* at 308. The Supreme Court upheld the Department of Commerce's decision to treat the transactions "as sales of goods rather than services," *id.*, emphasizing that the proper inquiry focused not on "the legal fiction" created by the parties' contracts but instead on the "substance" and "economic reality," *id.* at 317-18 (quotation marks omitted).

The Supreme Court observed that "the exchange of cash combined with a commodity for a product that uses that very commodity as a constituent material is sometimes a sale of services and sometimes a sale of goods, the distinction being clear at the extremes." *Eurodif*, 555 U.S. at 318. On one extreme, "[a] customer who

comes to a laundry with cash and dirty shirts is clearly purchasing cleaning services, not clean shirts." *Id.* On the other, "a customer who provides cash and sand to a manufacturer of generic silicon processors is clearly buying computer chips rather than sand enhancement services." *Id.*

In concluding that the Department of Commerce had permissibly characterized the uranium transactions in *Eurodif* as a sale of goods, the Court emphasized that the uranium that was supplied to the enrichers was "a fungible commodity that [was] not tracked after its delivery," and was thus effectively treated as owned by the enrichers. 555 U.S. at 319 & n.9. In other words, the utilities did not receive back at the end of the transaction the same uranium that they had originally sent to the enrichers, as might be expected in a sale of services. Rather, in exchange for their contributions, they received new, different uranium, suggesting that the transaction was in substance a sale of goods. The Court observed that, in the laundry example, "there are no good reasons to treat [the shirts] as owned for a time by the laundry, and no one does." *Id.* "And without any transfer of ownership, the salient feature of the transaction is the cleaning of the shirt, a service." *Id.* By contrast, where the "constituent material is untracked and fungible, ownership is usually seen as transferred, and the transaction is less likely to be a sale of services." *Id.*

2. The sale or offer for sale of the invention must be public

Section 102(b) requires more, however, than a sale or offer for sale of the invention. The Supreme Court has long construed the on-sale bar to mean that the invention must be available for sale to the public.

The Supreme Court has explained that "[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) (emphasis added). The Court has stressed that the patent laws, including the on-sale bar, reflect Congress's 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 148. Thus, it is Congress's "reluctance to allow an inventor to remove existing knowledge from public use [that] undergirds the on-sale bar." *Pfaff*, 525 U.S. at 64.

Congress first codified the on-sale bar in 1836, prohibiting the patenting of any invention that, at the time the application was filed, was "in public use or on sale, with [the inventor's] consent or allowance." Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119. Congress enacted that provision against the backdrop of the Supreme Court's decision only a few years earlier in *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1 (1829), which held that an inventor loses his right to 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. His voluntary act or acquiescence in *the public sale* and use is an abandonment of his right." *Id.* at 23-24 (emphases added). The Court in *Pennock* noted "that under the common law of England, letters patent were unavailable for the protection of articles in public commerce at the time of the application, and that this same doctrine was immediately embodied in the first patent laws passed in this country." *Bonito Boats, Inc.*, 489 U.S. at 149 (citation omitted) (describing *Pennock*, 27 U.S. at 20-22).

The on-sale bar thus codified the principle announced in *Pennock* that an invention already "in public commerce" cannot be made the subject of a patent. *See Cannon v. University of Chi.*, 441 U.S. 677, 698-99 (1979) (explaining that "evaluation of congressional action … must take into account its contemporary legal context"); *Procter & Gamble Co. v. Kraft Foods Glob., Inc.*, 549 F.3d 842, 848 (Fed. Cir. 2008). The legislative history of the 1836 statute indicates that Congress was motivated by a concern that the then-existing patent laws accorded "no power to the Secretary to refuse a patent for want of either novelty or usefulness." S. Rep. No. 24-338, at 2 (1836). This enabled the "reprehensible" practice "of taking out patents for what has been long in public use, and what every one has therefore a right to use." *Id.* at 3-4. The "on sale" bar was part of Congress's answer to that problem. As a leading 19th century commentator explained, the early public-use and on-sale statutory restrictions were premised on the principle that "no invention, which has already passed from the

control of the inventor into the possession of the public is entitled to protection." 1 William C. Robinson, *The Law of Patents for Useful Inventions* § 71, 109 (1890).

Congress retained the public-use and on-sale bars in subsequent amendments to the patent laws, although it soon ameliorated the effect of those bars "by enacting a 2-year grace period" after the public use or sale "in which the inventor could file an application." *Pfaff*, 525 U.S. at 65; *see* Act of Mar. 3, 1839, ch. 88, 5 Stat. 353, 354 (1839 Act) (providing that a prior "purchase, sale, or use" would not invalidate a patent "except on proof of abandonment of such invention to the public; or that such purchase, sale or prior use has been for more than two years prior to such application for a patent").[4] The Patent Act of 1870, for example, provided that a patent was not available for an invention that was "in public use or on sale for more than two years prior to [the] application, unless the same is proved to have been abandoned." Act of July 8, 1870, ch. 230, 16 Stat. 198, 201.[5] And when Congress reenacted and recodified the patent laws in the Patent Act of 1952, it again provided that no person would be entitled to a patent on an invention that that was "in public use or on sale" prior to the critical date. 35 U.S.C. § 102(b).

Over the nearly two centuries during which Congress has reenacted the on-sale bar without changing the "on sale" language, the Supreme Court has repeatedly

[4] Congress also eliminated the "consent or allowance requirement" in 1839. *See* 1839 Act, 5 Stat. at 354; *see also Andrews v. Hovey*, 123 U.S. 267, 274 (1887).

[5] In 1939, Congress reduced the grace period from two years to one. Act of Aug. 5, 1939, ch. 450, 53 Stat. 1212.

described the statute as addressed to *public* sales, consistent with the Court's original articulation in *Pennock* of the policy underlying on-sale bar. In 1877, for example, the Supreme Court considered whether a patented invention for the construction of wooden pavement had been "in public use or on sale" within the meaning of the 1836 and 1839 statutes where the inventor had placed the pavement on a public road and tested it for six years before filing his patent application. *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126, 133 (1878). The Supreme Court concluded that the inventor had "intended this piece of pavement as an experiment, to test its usefulness and durability," which the Court concluded was not a "public use" within the meaning of the law. *Id.* at 134-35. In reaching this conclusion, the Court emphasized that, so long as the inventor "does not voluntarily allow others to make it and use it, and so long as it is not *on sale for general use*, he keeps the invention under his own control, and does not lose his title to a patent." *Id.* at 135 (emphasis added). And the Court distinguished the inventor's testing of pavement from circumstances where "the inventor allows his machine to be used by other persons generally … [or] put on sale for such use." *Id.* In the latter case, the Court explained, the invention "will be in public use *and on public sale*, within the meaning of the law." *Id.* (emphasis added).[6]

[6] *See also, e.g.*, *Muncie Gear Works v. Outboard, Marine & Mfg. Co.*, 315 U.S. 759, 766-68 (1942) (holding that where licensee "popularized" outboard motors containing patented invention and competitor copied motors more than two years before critical

Continued on next page.

More recently, the Supreme Court has reiterated this understanding of the phrase "on sale," explaining that "the public sale of an unpatented article" precludes patenting "the idea embodied in the article thus placed in public commerce." *Bonito Boats, Inc.*, 489 U.S. at 149; *see also Pfaff*, 525 U.S. at 64. In *Pfaff*, the Supreme Court explained that a "commercial offer of sale" is an appropriate trigger for the on-sale bar because "[a]n inventor can both understand and control the timing of the first commercial marketing of his invention." 525 U.S. at 67; *see also id.* (noting that the "rule … measures the application of the on-sale bar of § 102(b) against the date when an invention that is ready for patenting is first marketed commercially").

An invalidating sale or offer for sale under section 102(b), therefore, is one that makes the invention available to interested members of the public. This does not mean that the offer must be broadcast to the public at large. Indeed, in *Pfaff*, the invalidating sale was an arm's-length agreement between the inventor of a computer

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date, claims were invalid because "conclusion [wa]s inescapable that there was public use, or sale of devices embodying the asserted invention"); *Consolidated Fruit-Jar Co. v. Wright*, 94 U.S. 92, 93-94 (1877) (holding that sale of more than a dozen fruit jars to members of the public "to get the money which they yielded, and to test their salability in the market" invalidated patent); *Delemater v. Heath*, 58 F. 414, 416 (2d Cir. 1893) (differentiating sales in which the inventor "retain[s] his control over the machine which embodies his invention" from sales "which not only allows the individual purchaser to use it, but leaves him free to transfer machine and use to whom he will," and noting that "[w]hether the purchaser choose to resell it or not is immaterial; he has the power to do so, and that is enough"). *Cf. Egbert v. Lippmann*, 104 U.S. 333, 339 (1881) (Miller, J., dissenting) ("If on sale, of course the public who buy can use it, and if used in public with his consent, it may be copied by others. In either event there is an end of his exclusive right of use or sale.").

chip socket and a single company that wanted to purchase the invention. *See* 525 U.S. at 58. In determining whether a sale is public, this Court should look to the Supreme Court's interpretation of the public-use bar, because the two provisions reflect a "similar reluctance to allow an inventor to remove existing knowledge from public use." *Id.* at 64.

The Supreme Court has identified several factors as relevant to determining whether a use makes the invention publicly available, including whether the issuance of a patent on the invention would "'remove existent knowledge from the public domain, or [would] restrict free access to materials already available,'" *Bonito Boats*, 489 U.S. at 146 (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966)); whether the "use is mainly for the purposes of trade and profit," *International Tooth-Crown Co. v. Gaylord*, 140 U.S. 55, 62-63 (1891) (quotation marks omitted), or to "conduct the [manufacturer's] business," *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 265 (1887); whether "the public were already in possession and common use of an invention," *Pennock*, 27 U.S. at 23; whether the inventor maintained control over the invention, *see City of Elizabeth*, 97 U.S. at 135, and the degree of public accessibility to the invention, *compare Coffin v. Ogden*, 85 U.S. (18 Wall.) 120, 124-25 (1873) (finding public use where invention was known to others), *with Gayler v. Wilder*, 51 U.S. (10 How.) 477, 497-98 (1851) (finding no public use where prior discovery was not made public). *See generally* 1 Anthony William Deller, *Walker on Patents* § 83, 345-36 (1937). These factors capture the commonsense notion that whether an invention is

accessible to the public depends on whether members of the interested public could have obtained the information if they so desired. Thus, although a single transaction with an interested member of the public may trigger the on-sale bar as it did in *Pfaff*, the absence of any practical ability of the public to gain access to the later-patented invention would weigh against finding that there had been a public sale.[7]

3. Congress's 2011 amendments confirm that "on sale" means a sale that makes the invention available to the public

Congress's recent amendment to section 102 in the AIA confirms that the phrase "on sale" refers to a sale that makes the invention available to the public. While retaining the "on sale" language, Congress revised the relevant section to provide that no person would be entitled to a patent on an invention that was "in public use, on sale, or otherwise available to the public before the effective filing date." AIA, 125 Stat. at 286 (codified at 35 U.S.C. § 102(a)). If Congress had understood the term "on sale" to mean anything other than a sale that makes the invention available to the public, it would not have retained the "on sale" language without change while adding "or otherwise available to the public." Congress's use of the modifying phrase "or otherwise available to the public," thus indicates that the preceding terms—"in public use" and "on sale"—also make the invention "available

[7] This Court has similarly emphasized public accessibility in applying the printed-publication bar. *See, e.g., In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986) (holding that a single dissertation copy in a university library was "sufficiently accessible, at least to the public interested in the art").

to the public." Any other construction fails to give effect to the term "or otherwise." *United States v. Menasche*, 348 U.S. 528, 538-39 (1955) ("It is our duty 'to give effect, if possible, to every clause and word of a statute.'" (quoting *Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883))).

The legislative history of the AIA underscores that Congress chose the word "otherwise" to "make[] clear 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)); *see also* H.R. Rep. No. 112-98, at 43 (explaining that "the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it must be publicly accessible"). When Congress added the words "or otherwise available to the public," it understood that "[c]ourts have consistently found that when the words 'or otherwise' or 'or other' are used to add a modifier at the end of a string of clauses, the modifier thus added restricts the meaning of the preceding clauses." 157 Cong. Rec. at S1370 (statement of Sen. Kyl) (citing *Strom v. Goldman, Sachs & Co.*, 202 F.3d 138, 146-47 (2d Cir. 1999), *Universal City Studios, Inc. v. Reimerdes*, 111 F. Supp. 2d 294, 325 (S.D.N.Y. 2000), and *Williamson v. Southern Reg'l Council, Inc.*, 154 S.E.2d 21, 25 (Ga. 1967)). Moreover, "the fact that the clause 'or otherwise available to the public' is set off from its preceding clauses by a comma confirms that

it applies to both 'public use' and 'on sale.'" *Id.* (citing *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1336 (Fed. Cir. 2008)). Thus, the "new section 102(a)(1) imposes a public-availability standard on the definition of all prior art enumerated by the bill—an understanding on which the remainder of the bill is predicated." *Id.*

In the Manual of Patent Examining Procedure (MPEP), the U.S. Patent and Trademark Office has interpreted the AIA's "or otherwise available to the public" language to mean that secret sales between a supplier and a patent owner do not trigger the on-sale bar. Section 2152.02(d) states that "the 'or otherwise available to the public' residual clause … indicates that AIA 35 U.S.C. 102(a)(1) does not cover secret sales or offers for sale." MPEP § 2152.02(d) (9th ed. Mar. 2014). The MPEP cites as an example sales "among individuals having an obligation of confidentiality to the inventor." *Id.*[8]

4. This Court should overrule its decisions interpreting the on-sale bar to reach non-public sales, including confidential supplier agreements

Although the Supreme Court has consistently understood the on-sale bar to prohibit the patenting of articles "in public commerce," *Bonito Boats*, 489 U.S. at 149, this Court has in several instances concluded that the on-sale bar was triggered by

[8] The MPEP's discussion of pre-AIA section 102(b) reflects decisions of this Court and other courts concluding that the on-sale bar applies to secret as well as public sales. *See* MPEP § 2133.03(b)(III)(A) (citing *Hobbs v. United States*, 451 F.2d 849 (5th Cir. 1971), for the proposition that "public" modifies only "use" and not "on sale"). For the reasons we explain, those decisions are incorrect.

non-public sales, such as sales made under contractual commitments of exclusivity and confidentiality. The Court should overrule those decisions and hold that the on-sale bar is triggered only by sales or offers for sale that make the invention available to the public. By restoring that traditional understanding of the on-sale bar, the Court would obviate any need to create a "supplier exception" to section 102.

In *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 182 F.3d 888, 889-90 (Fed. Cir. 1999), for example, this Court concluded that the on-sale bar was triggered by sales of surgical saw blades solely between two companies, each of which was owned by or employed some of the named inventors. The Court found that it was sufficient for purposes of section 102(b) that the sale was between separate corporate entities, reasoning that it did not matter that the purchaser "may have retained control over the manufacturing of the patented invention as a result of the alleged exclusive relationship between the two companies." *Id.* at 890.

Similarly, in *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355 (Fed. Cir. 2001), this Court expressly rejected the argument that there should be a "supplier exception" to the on-sale bar, concluding that "neither the statutory text, nor precedent nor the primary purpose of the on-sale bar" allowed for such an exception. In *Special Devices*, the patent owner, OEA, Inc., conceded that there had been commercial offers to sell the patented invention before the critical date, and it did not contest that at the time of those offers the invention was ready for patenting. *Id.* OEA only argued that this Court should create a supplier exception that would excuse

its purchase of the patented invention from "the Coors Ceramics, Co., which (unlike OEA) had the capacity to mass-produce OEA's invention." *Id.* at 1354.

Because applying the on-sale bar to confidential supplier arrangements may prejudice small companies, individual inventors, and others who lack the ability to manufacture their own inventions in-house, the Court has been urged to recognize a "supplier exception" to the on-sale bar. The better approach is instead to clarify that, consistent with longstanding Supreme Court precedent and congressional intent, the on-sale bar is triggered only by sales or offers for sale that make the invention available to the public. So understood, confidential supplier agreements will typically fall outside the statutory limitation, because such agreements do not generally place the invention "on sale" in the necessary sense. A confidential agreement by a third-party manufacturer to make an invention for the inventor (a sale of services) or to make and sell an invention solely back to the inventor (a sale of goods) will not normally place the invention in the hands of the public because no member of the public will have the ability to purchase it. In such circumstances, the invention is not "in public commerce," and the on-sale bar has no application. This Court should overrule its prior cases to the extent they are inconsistent with this interpretation of the on-sale bar.

B. The Medicines Company's Purchase Of Manufacturing Services Did Not Trigger The On-Sale Bar

For two reasons, the transactions at issue in this case did not trigger the on-sale bar under a proper interpretation of section 102(b). First, there was no sale or offer for sale of "the invention"—here, a drug product—prior to the critical date. Second, even if the transactions between Ben Venue and the Medicines Company constituted sales of the drug product, they did not make the invention available to the public.

1. There was no sale or offer for sale of the patented drug product

Identifying "the invention" at issue is the first step in determining whether an invalidating sale has occurred. For invalidity purposes, all of the claims at issue in this litigation are product claims. The Medicines Company asserted infringement of claims 1-3, 7-10, and 17 of U.S. Patent No. 7,582,727 ("the '727 patent") and claims 1-3 and 7-11 of U.S. Patent No. 7,598,343 ("the '343 patent"). A1. The asserted claims of the '727 patent are product claims covering "[p]harmaceutical batches of a drug product comprising bivalirudin … and a pharmaceutically acceptable carrier" (independent claim 1) with certain pH and maximum impurity levels. A60-A61. The asserted claims of the '343 patent are product-by-process claims covering "[p]harmaceutical batches of a drug product comprising bivalirudin … and a pharmaceutically acceptable carrier" that are prepared by "a compounding process" comprising various steps (independent claim 1), wherein the batches have certain pH and maximum impurity levels. A76. For purposes of the on-sale bar, product-by-

process claims are product claims. *See Purdue Pharma L.P. v. Epic Pharma, LLC*, __ F.3d __, 2016 WL 380174, at *7 (Fed. Cir. Feb. 1, 2016) (reiterating that, "[i]n determining validity of a product-by-process claim, the focus is on the product and not the process of making it" (brackets in original)).

Because the asserted claims all relate to products or products-by-process, whether "the invention" was "on sale" depends on whether there was a commercial sale or offer to sell the claimed drug products.[9] Put differently, the question is whether the Ben Venue/Medicines Company contracts provided for a sale of *goods* or a sale of *services*. The panel concluded that an invalidating sale occurred because "[t]he Medicines Company paid Ben Venue for performing services that resulted in the patented product-by-process, and thus *a 'sale' of services* occurred." *Medicines Co. v. Hospira, Inc.*, 791 F.3d 1368, 1371 (Fed. Cir. 2015) (emphasis added). But that is not sufficient to trigger section 102(b) because "the invention" at issue is a product, not a process. *Cf. In re Kollar*, 286 F.3d at 1332 (discussing difference between sale of "tangible items" such as "a product, device, or apparatus," and sale of "a process, which consists of a series of acts or steps," and "is thus not sold in the same sense as is a tangible item").

In this case, the Medicines Company provided the bivalirudin active pharmaceutical ingredient to Ben Venue, which manufactured Angiomax, the drug

[9] It is undisputed that the transactions at issue occurred before the critical date.

product. Ben Venue then shipped the Angiomax to the Medicines Company's distributor for sale to others. A16053. In 2006 and 2007, the Medicines Company paid Ben Venue approximately $350,000 to manufacture and deliver the first three batches of Angiomax using its revised process. A17177-78; A17183. The commercial resale value of the Angiomax in those batches was approximately $20-40 million in total. *See* A14959; A15210; A15452; A16055-56.

These facts corroborate the Medicines Company's argument that what it purchased from Ben Venue was manufacturing services, not drug products. As discussed, the traditional hallmark of a sale of goods—and the definition of a commercial sale under the UCC—is the transfer of title. Hospira does not dispute that title to the bivalirudin never transferred from the Medicines Company to Ben Venue. Nor does it suggest that Ben Venue ever held title to the completed Angiomax. This case is thus similar to the laundry example from *Eurodif*, where "without any transfer of ownership, the salient feature of the transaction is the cleaning of the shirt, a service." 555 U.S. at 320.

Hospira argues that "it is immaterial whether title" transferred, but it cites only cases that, as Hospira concedes, "involve patented processes or methods," not products. Hospira Br. 30-31. Hospira does not point to anything about the nature of the transaction or Ben Venue's manufacturing services that would warrant disregarding the parties' understanding that title remained at all times in the Medicines Company. Hospira does not contend, for example, that Ben Venue treated the

bivalirudin it received from the Medicines Company as an undifferentiated "fungible commodity," like sand to a manufacturer of computer chips, such that Ben Venue is best understood as the owner of the bivalirudin during the manufacturing process. *Eurodif*, 555 U.S. at 319.

Because the transactions between the Medicines Company and Ben Venue involved a sale of services—the manufacture of Angiomax pursuant to a specific process ordered by the Medicines Company—and not a sale of drug products from Ben Venue to the Medicines Company, this Court should hold that the patented invention was not "on sale" in these transactions as required by section 102(b).

2. Even if there were a sale or offer for sale, it was not public

Even if there had been a sale of the patented drug, the agreements between Ben Venue and the Medicines Company appear to have been confidential supplier contracts that did not make knowledge of the patented invention available to the public. *See* A16093; A16855. As discussed, the public's inability to access the invention indicates that a public sale has not occurred. There is no suggestion that an interested member of the public, such as a competing company, could have contracted with Ben Venue to produce the invention for sale to it.

In general, an inventor's confidential agreement with a third-party manufacturer to produce the patented invention for the inventor's own use will not make the invention available to interested members of the public. Consequently, it should not trigger the on-sale bar. This interpretation of the on-sale bar will level the

playing field between startups that lack manufacturing capabilities and large companies that have the resources to manufacture and test an invention in-house, without any need to recognize a special "supplier exception." Although Hospira objects that this would allow an inventor to "stockpile" his invention before seeking patent protection (Hospira Br. 47), there is nothing in the Patent Act that prevents large companies with internal manufacturing facilities from doing exactly that already. Nor does Hospira explain why allowing pre-filing stockpiling where manufacturing is confidentially outsourced, rather than conducted confidentially in-house, would "remove existing knowledge from public use." *Pfaff*, 525 U.S. at 64.

C. The Experimental Use Doctrine Does Not Apply

For the reasons already discussed, the on-sale bar does not apply in this case because there was no sale of the patented product and, even if there were such a sale, it was not a public sale. This Court therefore need not decide how the "experimental use" doctrine might apply on the facts of this case. But if the Court does reach that question, the Medicines Company argues that the three validation batches at issue "were experimental because they were made to determine whether the inventions worked for their intended purposes, i.e., that the inventions had a low maximum Asp[9] level." Medicines Co. Br. 32. As discussed below, the experimental use doctrine should apply if the Medicines Company established that fact to the satisfaction of the district court.

If this Court addresses the experimental use doctrine, it should take the opportunity to clarify its law on this issue. The cases cited in the panel decision highlight the confusion on this score. The panel first relied on this Court's rule that "[e]xperimental use cannot occur after a reduction to practice." *Medicines Co.*, 791 F.3d at 1372 (quoting *In re Cygnus Telecomm. Tech., LLC Patent Litig.*, 536 F.3d 1343, 1356 (Fed. Cir. 2008)). The better view, which the panel also articulated, is that "the experimental use defense may be available even if the invention had been reduced to practice if the inventor was unaware that the invention had been reduced to practice (i.e., worked for its intended purpose) and continued to experiment." *Id.*

A categorical bright-line rule is not well-suited for the unpredictable arts, including medical devices, pharmaceuticals, chemistry, and biotechnology, where extensive testing after a reduction to practice may be needed to ascertain whether an invention works for its intended purpose. It is also inconsistent with the Supreme Court's recognition in *City of Elizabeth* that "[i]f durability is one of the qualities to be attained, a long period, perhaps years, may be necessary to enable the inventor to discover whether his purpose is accomplished." 97 U.S. at 135. As the Supreme Court explained, "[a]nd though, during all that period, he may not find that any changes are necessary, yet he may be justly said to be using his machine only by way of experiment; and no one would say that such a use, pursued with a *bona fide* intent of testing the qualities of the machine, would be a public use, within the meaning of the statute." *Id.* In the same way, the evidence might show in an appropriate case that an

inventor's limited sale of his invention prior to the critical date was made only with the "*bona fide* intent" to determine whether the invention worked for its intended purpose, even though "he may not find that any changes are necessary." *Id.*

A bright-line rule that experimental use cannot occur after reduction to practice is also difficult to reconcile with *Pfaff*, which held that an invention is not "on sale" at all unless it is "ready for patenting." If the inventor must show that his invention was not yet reduced to practice to establish experimental use, then he does not need the doctrine at all. *See Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1369 (Fed. Cir. 2008) (Prost, J. , concurring). Accordingly, if the Court addresses the experimental use doctrine in this case, it should adopt a rule that would allow small-scale inventors and startups to outsource manufacturing, while still maintaining the ability to conduct appropriate, bona fide tests of their products—*e.g.*, for durability and utility.

CONCLUSION

For the foregoing reasons, the judgment of the district court that the on-sale bar does not apply in this case should be affirmed.

Respectfully submitted,

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MARCH 2016

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it has been prepared in 14-point Garamond, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(d) and 32(a)(7)(B) because it contains 6,973 words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

s/ Megan Barbero
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CERTIFICATE OF SERVICE

I hereby certify that on March 2, 2016, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

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