UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOTICE OF ENTRY OF JUDGMENT ACCOMPANIED BY OPINION

OPINION FILED AND JUDGMENT ENTERED: 7/11/2016

The attached opinion announcing the judgment of the court in your case was filed and judgment was entered on the date indicated above. The mandate will be issued in due course.

Information is also provided about petitions for rehearing and suggestions for rehearing en banc. The questions and answers are those frequently asked and answered by the Clerk's Office.

Regarding exhibits and visual aids: Your attention is directed Fed. R. App. P. 34(g) which states that the clerk may destroy or dispose of the exhibits if counsel does not reclaim them within a reasonable time after the clerk gives notice to remove them. (The clerk deems a reasonable time to be 15 days from the date the final mandate is issued.)

FOR THE COURT

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

14-1469, 14-1504 - Medicines Company v. Hospira, Inc.
United States District Court for the District of Delaware, Case No. 1:09-cv-00750-RGA

United States Court of Appeals for the Federal Circuit

THE MEDICINES COMPANY,
Plaintiff-Appellant

v.

HOSPIRA, INC.,
Defendant-Cross-Appellant

2014-1469, 2014-1504

Appeals from the United States District Court for the District of Delaware in No. 1:09-cv-00750-RGA, Judge Richard G. Andrews.

Decided: July 11, 2016

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

O'MALLEY, *Circuit Judge.*

Today, we consider the circumstances under which a product produced pursuant to the claims of a product-by-process patent is "on sale" under 35 U.S.C. § 102(b). This is important because, if "on sale" more than one year before the filing of an application for a patent on the governing claims, any issued patent is invalid and the right to exclude others from making, using, and selling the resulting product is lost. We conclude that, to be "on sale" under § 102(b), a product must be the subject of a commercial sale or offer for sale, and that a commercial sale is one that bears the general hallmarks of a sale pursuant to Section 2-106 of the Uniform Commercial Code. We conclude, moreover, that no such invalidating commercial sale occurred in this case. We, therefore, affirm the district court's judgment that the transactions

at issue did not render the asserted claims of U.S. Patent Nos. 7,582,727 ("the '727 patent") and 7,598,343 ("the '343 patent"), owned by Plaintiff-Appellant The Medicines Company ("MedCo"), invalid under § 102(b).

I. BACKGROUND

A. The Patents and Transactions at Issue

This suit arises from the submission of two Abbreviated New Drug Applications ("ANDAs"), ANDA Nos. 90-811 and 90-816, by Defendant-Cross-Appellant Hospira, Inc. ("Hospira"). In these ANDAs, Hospira sought Food and Drug Administration ("FDA") approval to sell generic bivalirudin drug products before the expiration of the patents-in-suit: the '727 patent and the '343 patent. The two patents-in-suit are listed in the FDA's Orange Book as covering Angiomax, the trade name of a form of bivalirudin that MedCo markets in the United States.

The patents-at-suit have nearly identical specifications. They claim pH-adjusted pharmaceutical batches of a drug product comprising bivalirudin, a synthetic peptide comprised of twenty amino acid residues that is used as an anticoagulant, and a pharmaceutically acceptable carrier. Bivalirudin drug products are used to prevent blood from clotting and are regarded as highly effective anticoagulants for use during coronary surgery.

The bivalirudin active pharmaceutical ingredient ("API"), without further processing, is too acidic for human injection. MedCo thus prepares Angiomax using a compounding process in which it creates a bivalirudin solution, adjusts the solution's pH with a base, and then freeze-dries the solution. A potential adverse consequence of the compounding process used to make the product, however, is the degradation of bivalirudin, which may form impurities such as Asp^9-bivalirudin ("Asp^9"). The bivalirudin may become unusable if high levels of Asp^9

form. The manufacture of batches with unacceptably high Asp^9 levels led to the creation of the patented solution.

MedCo is a specialty pharmaceutical company that does not have its own manufacturing facilities and is not capable of making its products in-house. Instead, since 1997, MedCo has contracted with Ben Venue Laboratories ("Ben Venue"), a third-party provider, for Ben Venue to manufacture commercial quantities of an original formula of Angiomax, which is not covered under the patents-in-suit. In June 2005, Ben Venue manufactured a batch of bivalirudin drug product with an Asp^9 level of 3.6%, which exceeded the FDA's approved maximum level of 1.5%. MedCo discarded that batch and shut down production of Angiomax for six months to investigate the problem and revise its process. In 2006, another batch had an unacceptable Asp^9 level, so MedCo again shut down production of Angiomax and hired a peptide specialist to investigate and resolve the issue.

The investigation led to the development of the new compounding process claimed in the patents-in-suit. MedCo incorporated the new process into a revised Master Batch Record, and Ben Venue has made all batches since October 2006 using the new process. According to MedCo, the new compounding process produces an improved Angiomax product that does not have randomly high Asp^9 levels, but instead has a maximum Asp^9 level of 0.6%. The '727 and '343 patents contain product and product-by-process claims, respectively, for pharmaceutical batches of the improved drug product with a maximum impurity level of Asp^9 of 0.6%.

The patents, respectively, claim:

> Pharmaceutical batches of a drug product comprising bivalirudin (SEQ ID NO: 1) and a pharmaceutically acceptable carrier for use as an anticoagulant in a subject in need thereof, wherein the batches have a pH adjusted by a base, said

> pH is about 5-6 when reconstituted in an aqueous solution for injection, and wherein the batches have a maximum impurity level of Asp^9-bivalirudin that does not exceed about 0.6% as measured by HPLC.

Claim 1 of the '727 patent.

> Pharmaceutical batches of a drug product comprising bivalirudin (SEQ ID NO: 1) and a pharmaceutically acceptable carrier, for use as an anticoagulant in a subject in need thereof, said batches prepared by a compounding process comprising:
>
> (i) dissolving bivalirudin in a solvent to form a first solution;
>
> (ii) efficiently mixing a pH-adjusting solution with the first solution to form a second solution, wherein the pH adjusting solution comprises a pH-adjusting solution solvent; and
>
> (iii) removing the solvent and pH-adjusting solution solvent from the second solution;
>
> wherein the batches have a pH adjusted by a base, said pH is about 5-6 when reconstituted in an aqueous solution for injection, and wherein the batches have a maximum impurity level of Asp^9-bivalirudin that does not exceed about 0.6% as measured by HPLC.

Claim 1 of the '343 patent.

The applications for the '727 and '343 patents were filed on July 27, 2008. The critical date from which the on-sale bar of § 102(b) must be measured is, therefore, July 27, 2007.

In late 2006, MedCo paid Ben Venue $347,500 to manufacture three batches of bivalirudin according to the

patents-at-issue. Ben Venue completed the first such batch on October 31, 2006 for $67,500. That batch contained 5,746 vials of commercially saleable bivalirudin. On November 21 and December 14, 2006, Ben Venue completed two more batches of bivalirudin containing 27,594 and 26,918 vials, respectively, for $140,000 each. Each full commercial-sized batch of 28,000 vials of Angiomax has a market value of approximately $10 million when sold on the open market as anticoagulants. Thus, collectively, the three batches had a market value of well over $20 million. Specifically, Hospira represents that the three batches were "worth between $23 million and $45 million." Hospira's En Banc Br. 7.

The manufacturing protocol between MedCo and Ben Venue governing the three batches stated that "[t]he solution will be filled for commercial use" and that the three batches "will be placed on quality hold until all testing has been successfully completed." Joint Appendix ("J.A.") 14884. The invoice for each of the three batches stated: "Charge to manufacture Bivalirudin lot," and indicated that the bivalirudin lot was or will be released to MedCo. J.A. 17177-83. Each batch received a "Commercial Product Code," a customer lot number, and each stated that the batch was "[r]eleased [to MedCo] for commercial and clinical packaging." J.A. 14959-60; J.A. 15210-11; J.A. 15452-53.

Once manufactured by Ben Venue, the batches were placed in quarantine with MedCo's distributor and logistics coordinator, Integrated Commercialization Solutions ("ICS"), pending FDA approval. MedCo and ICS entered into a Distribution Agreement effective February 27, 2007. The Distribution Agreement made ICS the exclusive authorized distributor of Angiomax in the United States and stated that title and risk of loss would pass to ICS following release from quarantine. Under the Distribution Agreement, ICS would place individual purchase orders with MedCo on a weekly basis, which MedCo could

accept or reject. J.A. 14676. It was not until August 2007, after the July 27, 2007 critical date, that MedCo released the three batches from quarantine and made them available for sale.

B. The Procedural History

On August 19, 2010, MedCo sued Hospira in the United States District Court for the District of Delaware, alleging that Hospira's two ANDA filings infringed claims 1-3, 7-10, and 17 of the '727 patent and claims 1-3 and 7-11 of the '343 patent. The district court construed the asserted claims, and, after a three-day bench trial in September 2013, found the patents not invalid and not infringed.

Hospira contended that MedCo failed to prove infringement of three claim limitations: "efficient mixing," "pharmaceutical batches," and "a maximum impurity level of Asp^9-bivalirudin that does not exceed about 0.6%." *Meds. Co. v. Hospira, Inc.*, No. 1:09-cv-00750-RGA, 2014 U.S. Dist. LEXIS 43126, at *5 (D. Del. Mar. 31, 2014). The district court found that Hospira's generic product met the "pharmaceutical batch" and "maximum impurity level" limitations, but did not meet the "efficient mixing" limitation either literally or under the doctrine of equivalents. *Id.* at *15-26. Based on this conclusion, the district court held that Hospira's generic product did not infringe the asserted claims.

Hospira also alleged several grounds of invalidity. First, Hospira argued that the invention was sold or offered for sale before the critical date under § 102(b) based on two sets of transactions. Hospira contended that the on-sale bar was triggered when MedCo paid Ben Venue to manufacture Angiomax before the critical date. Hospira also contended that the on-sale bar was triggered because MedCo offered to sell the Angiomax produced according to the patents to its distributor, ICS, before the critical date. Hospira also contended that the asserted

claims were obvious under § 103 and invalid under § 112 because they lack written description, are not enabled, and are indefinite. *Id.*

Applying the two-step framework of *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), the district court found that the three batches Ben Venue manufactured for MedCo did not trigger the on-sale bar. *Pfaff*'s two-step framework requires that the claimed invention was (1) the subject of a commercial offer for sale; and (2) ready for patenting. 525 U.S. at 67-68. The court held that the claimed invention was ready for patenting under the second prong of *Pfaff* because MedCo had developed two enabling disclosures prior to the critical date, or, alternatively, reduced the invention to practice before the critical date. *Meds. Co.*, 2014 U.S. Dist. LEXIS 43126, at *33-34. Specifically, the enabling disclosures were: (1) the Master Batch Record, which was printed on October 25, 2006, and which Ben Venue followed in order to manufacture a batch on October 31, 2006; and (2) the validation study protocol, which the inventors signed in November 2006. In the alternative, the court concluded that the invention was reduced to practice before the critical date because Ben Venue produced batches according to the invention in October 2006.

The district court concluded that the first prong of *Pfaff* was not met, however, because the claimed invention was not commercially offered for sale prior to the critical date. The court agreed with MedCo that the transactions between MedCo and Ben Venue were sales of contract manufacturing services in which title to the Angiomax always resided with MedCo. It found that "this does not end the inquiry," however. *Id.* at *35. The district court identified the purpose of § 102(b) as precluding attempts by an inventor or its assignee to profit from the commercial use of an invention for more than a year before filing for a patent. Because the batches were for "validation purposes," the court held—sua sponte—that

the batches were not made for commercial profit, but were for experimental purposes, thereby avoiding the on-sale bar.

Next, the court held that MedCo's distribution agreement with ICS also did not constitute an invalidating sale. It held that the agreement was merely "an agreement for ICS to be the sole U.S. distributor of Angiomax." *Id.* at *38. The court concluded that the contract was merely "a contract to enter into a contract" for future sales of the Angiomax product. *Id.* *See In re Kollar*, 286 F.3d 1326, 1330-1331 (Fed. Cir. 2002) ("We have held that merely granting a license to an invention, without more, does not trigger the on-sale bar of § 102(b).").

As to Hospira's other alleged grounds of invalidity, the district court held that the asserted claims were not obvious under § 103(a). The court also held that the asserted claims satisfied the written description and enablement requirements of, and were not indefinite under, § 112.

MedCo appealed two of the district court's claim construction rulings and the district court's non-infringement ruling. Hospira cross-appealed the district court's decisions regarding the on-sale bar, obviousness, and indefiniteness. Because the district court found the invention was "ready for patenting," Hospira focused only on the first prong of *Pfaff* on appeal: whether the invention was the subject of a commercial offer for sale. Among other things, Hospira criticized the district court's conclusion that the batches of Angiomax were for experimental purposes, pointing out that MedCo had not relied upon the experimental use exception to § 102(b) and that Hospira, accordingly, had no incentive or opportunity to address the issue. Hospira contended that, had the question of experimental use been debated before the district court, Hospira would have pointed to the fact that there were eight additional batches of Angiomax manu-

factured by Ben Venue after the original three, all of which Hospira says occurred after MedCo was satisfied that the inventive process would result in a product that did not exceed the desired Asp[9] level of 0.6%. Hospira's En Banc Br. 38, 41.

Hospira also disagreed with the district court's conclusion that no commercial sale or offer for sale occurred. Hospira contended that any transaction that provides a commercial benefit to the inventor is enough to trigger the on-sale bar. Because MedCo was able to stockpile its product for future sale, and, thus, replenish the pipeline that had been depleted when it had to cease use of its previous manufacturing methods, Hospira argued that MedCo received a commercial benefit from the transactions with Ben Venue. According to Hospira, the fact that title did not transfer—a point the district court found important—was irrelevant because the immediate financial benefit to MedCo of having a ready supply of product for sale constituted "commercialization" or "commercial exploitation," which is enough to trigger the on-sale bar. Hospira's Opening Br. 30-31 (citing *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147 (Fed. Cir. 1983)).

A merits panel of this court agreed with Hospira and reversed the district court's ruling regarding the applicability of the on-sale bar. *Meds. Co. v. Hospira, Inc.*, 791 F.3d 1368 (Fed. Cir. 2015). The panel acknowledged that "Ben Venue invoiced the sale as manufacturing services and title to the pharmaceutical batches did not change hands," but disagreed with the district court's conclusion that Ben Venue's sale of services did not constitute a commercial sale of the claimed product. The panel explained that, "where the evidence clearly demonstrated that the inventor *commercially exploited* the invention before the critical date, even if the inventor did not transfer title to the commercial embodiment of the invention," the on-sale bar applies. *Id.* at 1370-71 (emphasis added).

The panel found no distinction between the offer to sell products prepared by a patented method in *D.L. Auld*, 714 F.2d at 1147, and the commercial sale of services that result in a patented product-by-process. *Id.* at 1371. The panel reasoned that, because MedCo paid Ben Venue for services that resulted in the patented product, the transactions were commercial sales. *Id.* According to the panel, to hold otherwise would conflict with the "no 'supplier' exception" under *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355 (Fed. Cir. 2001). The panel also found that the transactions between MedCo and Ben Venue were "not the type of 'secret, personal use'" described in *Trading Technologies International, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1362 (Fed. Cir. 2010), but rather were "batches prepared for commercial exploitation." *Meds. Co.*, 791 F.3d at 1371.

The panel also found that the district court erred in applying the experimental use exception to Ben Venue's batches. *Id.* at 1372. Because the invention had been reduced to practice, the panel concluded that the inventor could not have been experimenting to determine whether the process by which the product was formulated achieved the desired results. *Id.*

Finally, the panel affirmed the district court's determination that the claimed invention was ready for patenting prior to the critical date "because the invention was sold." *Id.* at 1372. Because it found that the invention was both commercially exploited and ready for patenting, the panel held the asserted claims invalid under § 102(b). The panel neither reached the district court's claim construction and non-infringement rulings that MedCo had appealed nor addressed the other grounds of invalidity raised in Hospira's cross-appeal.

MedCo petitioned for panel rehearing or rehearing en banc. On November 13, 2015, we granted rehearing en

banc, vacated the panel's decision, reinstated the appeal, and ordered new briefing on the following issues:

> (a) Do the circumstances presented here constitute a commercial sale under the on-sale bar of 35 U.S.C. § 102(b)?
>
> > (i) Was there a sale for the purposes of § 102(b) despite the absence of a transfer of title?
> >
> > (ii) Was the sale commercial in nature for the purposes of § 102(b) or an experimental use?
>
> (b) Should this court overrule or revise the principle in *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), that there is no "supplier exception" to the on-sale bar of 35 U.S.C. § 102(b)?

Order Granting En Banc Rehearing at 2, *Meds. Co.*, 791 F.3d 1368 (No. 2014-1469, -1504), ECF No. 68. MedCo asks that we hold en banc "that the on sale bar is not triggered by an inventor's retention of a third party to develop or manufacture the claimed invention confidentially and under the inventor's direction and control." MedCo's En Banc Br. 3. MedCo contends that stockpiling does not constitute commercial activity under § 102(b) and that § 102(b) should not apply because no products were placed in the public domain prior to the critical date, which it says is the overriding concern of § 102(b).

For its part, Hospira argues that MedCo's transactions with Ben Venue constitute a commercial sale under § 102(b) because "this arrangement constituted commercial exploitation from the standpoint of both companies." Hospira's En Banc Br. 29. Hospira points to the fact that MedCo requested that the batches be "filled for commercial use," were given a "commercial product code" and were "[r]eleased for commercial and clinical packaging."

Id. at 28-29. Hospira contends that the fact that title to the patented product and/or invention did not transfer is of no moment because the on-sale bar is triggered by "any commercialization" that confers a commercial benefit. *Id.* at 26. Finally, Hospira contends that the confidential nature of the relationship between Ben Venue and MedCo does not remove the transactions between them from the purview of § 102(b) because this court has never held that *only* public sales can trigger the on-sale bar. Hospira's En Banc Reply Br. 22.

II. DISCUSSION

A. Legal Standard

Whether the on-sale bar applies is a question of law based on underlying factual findings. *See Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1045-46 (Fed. Cir. 2001). We review the district court's factual findings with deference, but examine the ultimate question of validity de novo. *See Leader Techs., Inc. v. Facebook, Inc.*, 678 F.3d 1300, 1305 (Fed. Cir. 2012) ("Whether a patent is invalid for a public use or sale is a question of law, reviewed de novo, based on underlying facts, reviewed for substantial evidence following a jury verdict."); *Electromotive Div. of GMC v. Transp. Sys. Div. of GE*, 417 F.3d 1203, 1209-10 (Fed. Cir. 2005) ("Whether an invention was on sale within the meaning of § 102(b) is a question of law that we review de novo based upon underlying facts, which we review for clear error.").

We provide a brief overview of the development of the on-sale bar for context. Section 1 of the Patent Act of 1793 required that an invention for which a patent was sought be "not known or used before the application." Act of Feb. 21, 1793, ch. 11, § 1, 1 Stat. 318. The Supreme Court interpreted this statute in *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1 (1829), holding 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 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 v. Thunder Craft Boats*, 489 U.S. 141, 149 (1989) (describing *Pennock*, 27 U.S. at 20-22); *see also Shaw v. Cooper*, 32 U.S. 292, 320-21 (1833) (third-party sale invalidating where statute required invention not be "known or used before the [patent] application").

Against this backdrop, Congress first codified the on-sale bar in Section 6 of the Patent Act of 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. *See* Brief for the United States as Amicus Curiae 9-11. 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 softened 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"). 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).

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

1212. And when Congress reenacted and recodified the patent laws in the Patent Act of 1952, it again provided that "[a] person shall be entitled to a patent unless," *inter alia*, "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." 35 U.S.C. 102(b).[1]

For many years this court applied a "totality of circumstances" standard in applying the on-sale bar. *Lacks Indus. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1347 (Fed. Cir. 2003) (citing *Envirotech Corp. v. Westech Eng'g Inc.*, 904 F.2d 1571, 1574 (Fed. Cir. 1990)). "Under that test 'no single finding or conclusion of law [was] a sine qua non' to a holding that the statutory bar arose." *Id.* We considered all the facts and circumstances surrounding any particular transaction and considered those in light of the policies underlying section § 102(b), finding an on-sale bar in circumstances where the policies were furthered. *See, e.g.*, *Micro Chem., Inc. v. Great Plains Chem. Co.*, 103 F.3d 1538, 1544 (Fed. Cir. 1997) ("all of the circumstances surrounding the sale or offer to sell, including the stage of development of the invention and the nature of the invention, must be considered and weighed against the policies underlying section 102(b)"); *Ferag AG v. Quipp Inc.*, 45 F.3d 1562, 1566 (Fed. Cir. 1995) ("While a wide variety of factors may influence the on sale determination, no single one controls the application of section 102(b), for the ultimate conclusion depends on the totality of the circumstances.");

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[1] Congress amended 35 U.S.C. § 102 in 2011 as part of the America Invents Act ("AIA"). *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 35, 125 Stat. 84, 341 (2011). References to § 102 and other sections of Title 35 of the United States Code in this opinion refer to the pre-AIA version of the statute, the version that applies here.

UMC Elecs. Co. v. *United States*, 816 F.2d 647, 656 (Fed. Cir. 1987) (stating that the on-sale bar "does not lend itself to formulation into a set of precise requirements"). We identified several policies underlying § 102(b): to promote the early filing of patent applications—i.e., to foster disclosure of patented inventions to the public; to prevent an inventor from profiting from the commercial use of an invention for a prolonged period before filing a patent application claiming that invention; to discourage the removal of inventions from the public domain; and to give inventors a reasonable time to discern the potential value of an invention. *See, e.g.*, *Ferag AG*, 45 F.3d at 1566; *Envirotech*, 904 F.2d at 1574; *King Instrument Corp. v. Otari Corp.*, 767 F.2d 853, 860 (Fed. Cir. 1985); *Gould Inc. v. United States*, 579 F.2d 571, 580 (Ct. Cl. 1978).

Although, applying this test, we held that a "definite offer for sale" was required, we found that this did not necessarily require commercial activity that rose to the level of a formal "offer" under contract law principles. *Lacks Indus.*, 322 F.3d at 1347 (citing *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1062 (Fed. Cir. 1989)). And, we reviewed transactions and their impact without strict regard to whether they qualified as commercial activity under any definable standard. *See id.*; *Ferag AG*, 45 F.3d at 1566.

This changed with *Pfaff*, in which the Supreme Court replaced the "totality of the circumstances" test—which the Court noted had been criticized as "unnecessarily vague"—with a two-pronged test. 525 U.S. at 66 n.11. As discussed above, *Pfaff* clarified that the on-sale bar under 35 U.S.C. § 102(b) applies when, before the critical date, the claimed invention (1) was the subject of a commercial offer for sale; and (2) was ready for patenting. *Id.* at 67-68. *Pfaff* itself focused on the second prong of its newly articulated test—ready for patenting. *Id.* at 57. It held that the "ready for patenting" requirement can be met in

at least two ways: (1) proof of a reduction to practice; or (2) drawings or other descriptions sufficiently specific to enable a person of ordinary skill to practice the invention. *Id.* at 67-68. *Pfaff* itself said little about the first prong of the two-prong test—what constitutes a patent-defeating "commercial offer for sale"—however. The Court did emphasize that "[a]n inventor can both understand and control the timing of the first *commercial marketing* of his invention," and that a transaction that is "experimental in character" is distinct from one that is for purposes of such commercial marketing. *Id.* at 67 (emphasis added).

Since *Pfaff*, this court has applied the Supreme Court's "two-part test 'without balancing various policies [of the bar] according to the totality of the circumstances.'" *Electromotive Div. of GMC*, 417 F.3d at 1209 (citation omitted); *see also Dana Corp. v. American Axle & Mfg., Inc.*, 279 F.3d 1372, 1377 (Fed. Cir. 2002) (district court "erroneously invoked the 'totality of the circumstances' test that was disavowed by *Pfaff*."); *EZ Dock, Inc. v. Schafer Systems, Inc.*, 276 F.3d 1347, 1351 (Fed. Cir. 2002) ("Before the Supreme Court's decision in *Pfaff*, this court used a multifactor, 'totality of the circumstances' test to enforce the on-sale bar. . . . [This court] now follows the Supreme Court's two-part test.") (internal quotation marks and citations omitted).

Unlike *Pfaff* itself, the focus of this en banc appeal is on the first prong of the *Pfaff* test: whether the invention was the subject of a commercial sale or offer for sale. We have held that "the 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." *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047 (Fed. Cir. 2001). We also have held that, to be true to *Pfaff* when assessing prong one of § 102(b), we must focus on those activities that would be understood to be commercial sales and offers for sale "in the commercial community." *Id.*

We have also indicated that, "[a]s a general proposition, we will look to the Uniform Commercial Code ('UCC') to define whether . . . a communication or series of communications rises to the level of a commercial offer for sale." *Id.* And we have made clear that, post-*Pfaff*, "[t]he transaction at issue must be a 'sale' in a commercial law sense," and that "[a] sale is a contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold." *Trading Techs.*, 595 F.3d at 1361 (quotation marks omitted).

Applying § 102(b) in light of *Pfaff*, we conclude that the transactions between MedCo and Ben Venue in 2006 and 2007 did not constitute commercial sales of the patented product. We, thus, affirm the district court's conclusion that those transactions were not invalidating under § 102(b). In the discussion that follows, we first clarify that the mere sale of manufacturing services by a contract manufacturer to an inventor to create embodiments of a patented product for the inventor does not constitute a "commercial sale" of the invention. We then address the issue of "stockpiling" by an inventor and clarify that "stockpiling" by the purchaser of manufacturing services is not improper commercialization under § 102(b). We explain that commercial benefit—even to both parties in a transaction—is not enough to trigger the on-sale bar of § 102(b); the transaction must be one in which the product is "on sale" in the sense that it is "commercially marketed." There are, broadly speaking, three reasons for our judgment in this case: (1) only manufacturing services were sold to the inventor—the invention was not; (2) the inventor maintained control of the invention, as shown by the retention of title to the embodiments and the absence of any authorization to Ben Venue to sell the product to others; and (3) "stockpiling," standing alone, does not trigger the on-sale bar.

B. No Commercial Sale of the Invention

We begin with the language of § 102(b), which requires that "the invention" be "on sale." The "invention" is defined by the patent's claims. *See* 35 U.S.C. § 112, ¶ 2 ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."). In this case, all of the asserted claims cover products. The asserted claims of the '727 patent cover "pharmaceutical batches," while the asserted claims of the '343 patent "claim[ ] the same subject matter as that of claim 1 of the '727 patent, but as a product-by-process," *viz.* "pharmaceutical batches . . . prepared by a compounding process comprising" the claimed steps. *Meds. Co.*, 2014 U.S. Dist. LEXIS 43126, at *3-4. For validity purposes, the "invention" in a product-by-process claim is the product. *See Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1369 (Fed. Cir. 2009) ("In determining validity of a product-by-process claim, the focus is on the product and not on the process of making it."); *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1317 (Fed. Cir. 2006) ("Regardless of how broadly or narrowly one construes a product-by-process claim, it is clear that such claims are always to a product, not a process."); *In re Lyons*, 364 F.2d 1005, 1016 (C.C.P.A. 1966) ("a product-by-process claim is a product, not a process.").

Hospira argues that, by manufacturing embodiments of the patented product for MedCo, Ben Venue put the invention "on sale." But we have never espoused the notion that, where the patent is to a product, the performance of the unclaimed process of creating the product, without an accompanying "commercial sale" of the product itself, triggers the on-sale bar. The cases on which Hospira relies uniformly involve process or method patents in which the (1) inventors sought compensation (2) from the buying public for (3) performing the claimed processes or methods. In *Metallizing Engineering Co. v.*

Kenyon Bearing & Auto Parts Co., the patentee used a secret process to recondition worn metal parts for its customers, for compensation, before the critical date. 153 F.2d 516, 517-18 (2d Cir. 1946). In *D.L. Auld*, the patentee offered to sell a product made by the claimed method to prospective customers, i.e., it offered to practice the method in return for compensation. 714 F.2d at 1148. Similarly, in both *Plumtree* and *Scaltech*, we found that offering to perform the steps of the patented methods for customers in exchange for payment triggers the on-sale bar. *Plumtree Software, Inc. v. Datamize, LLC*, 473 F.3d 1152, 1163 (Fed. Cir. 2006); *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1328-29 (Fed. Cir. 2001).

Though those cases are distinguishable on multiple grounds, we find particularly significant the fact that the inventions-at-issue there were processes or methods. Hospira even acknowledges as much. Hospira's En Banc Br. 31 ("To be sure, the above-cited cases involve patented processes or methods."). While "a process is a series of acts, and the concept of sale as applied to those acts is ambiguous," "[t]he sale of a tangible item is[, by contrast,] usually a straightforward event; the item is transferred from the seller to the buyer, who normally owns it outright." *Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1378 (Fed. Cir. 2003). Similarly, in *In re Kollar*, we vacated a decision that "fail[ed] to recognize the distinction between a claim to a product, device, or apparatus, all of which are tangible items, and a claim to a process, which consists of a series of acts or steps" in applying the on-sale bar. 286 F.3d at 1332. We stated that, while "[a] tangible item is on sale when . . . the transaction 'rises to the level of a commercial offer for sale' under the Uniform Commercial Code," "[a] process, however, is a different kind of invention . . . [and] thus [is] not sold in the same sense as is a tangible item." *Id.*

The most natural conclusion to draw from all of the evidence presented in this case is that Ben Venue sold

contract manufacturing services—not the patented invention—to MedCo. Under MedCo's instructions and using an API supplied by MedCo, Ben Venue acted as a pair of "laboratory hands" to reduce MedCo's invention to practice. The invoices for the manufacturing service stated, "Charge to *manufacture* Bivalirudin lot." J.A. 17177-83 (emphasis added). In addition, MedCo paid Ben Venue only about 1% of the ultimate market value of the product Ben Venue manufactured. As described above, MedCo paid Ben Venue a total of $347,500 to make the three batches, even though these batches were commercially valued at well over $20 million. Unsurprisingly, therefore, the district court chose MedCo's description of the transaction as one in which "Ben Venue was paid to manufacture Angiomax for [MedCo]," over Hospira's description of the transaction as a "sale of the validation batches." *Meds. Co.*, 2014 U.S. Dist. LEXIS 43126, at *35. As the original panel of this court stated, "the district court is correct that Ben Venue invoiced the sale as manufacturing services and title to the pharmaceutical batches did not change hands." *Meds. Co.*, 791 F.3d at 1370. Thus, under the plain text of § 102(b), there was no sale of the "invention."

The absence of title transfer further underscores that the sale was only of Ben Venue's manufacturing services. Because Ben Venue lacked title, it was not free to use or sell the claimed products or to deliver the patented products to anyone other than MedCo, nor did it do so. Section 2-106(1) of the Uniform Commercial Code describes a "sale" as "the passing of title from the seller to the buyer for a price." U.C.C. § 2-106(1). The passage of title is a helpful indicator of whether a product is "on sale," as it suggests when the inventor gives up its interest and control over the product. A "sale" under § 102(b) "occurs when the parties . . . give and pass rights of property for consideration." *Special Devices*, 270 F.3d at 1355 (quoting *Zacharin v. United States*, 213 F.3d 1366, 1370 (Fed. Cir.

2000)); *see also Trading Techs.*, 595 F.3d at 1361 ("The transaction at issue must be a 'sale' in a commercial law sense.").

As noted, since *Pfaff*, we have generally looked to the UCC for the definition of a "sale." In *Group One*, an early post-*Pfaff* case reversing the district court's grant of summary judgment based on the on-sale bar, we stated that:

> As a general proposition, we will look to the Uniform Commercial Code ("UCC") to define whether, as in this case, a communication or series of communications rises to the level of a commercial offer for sale. As this court has previously pointed out, "[t]he UCC has been recognized as the general law governing the sale of goods and is another useful, though not authoritative, source in determining the ordinary commercial meaning of" terms used by the parties.

254 F.3d at 1047-48 (quoting *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376, 1382 (Fed. Cir. 1998)). We have since reaffirmed the usefulness of the UCC in analyzing the on-sale bar. *See In re Kollar*, 286 F.3d at 1332; *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1048 (Fed. Cir. 2001) (stating that "*Group One* further instructs that the Uniform Commercial Code ('UCC') should inform the analysis of the contractual issues" in connection to the on-sale bar).

While we agree with Hospira that the UCC does not have "talismanic significance" with respect to the on-sale bar, and we decline to draw a bright line rule making the passage of title dispositive, we find the absence of title transfer significant because, in most instances, that fact indicates an absence of commercial marketing of the product by the inventor. As Hospira points out, an inventor could commercially exploit a newly invented machine by charging others a fee to use it without transferring

title to it. Hospira's En Banc Reply Br. 8. In such a case, the "invention" would still likely be considered "on-sale" because use of the invention is on-sale for a price. That is not what occurred here, however.

It is with vigilance that we have held that the sale of products made using patented methods triggers the on-sale bar, even though title to the claimed method itself did not pass. *See, e.g.*, *D.L. Auld*, 714 F.2d at 1147; *Plumtree*, 473 F.3d at 1163. In such cases, the literal subject matter of the claims is incapable of being sold. Similarly, we held that sales of software licenses to end-users can trigger the on-sale bar. *See Group One*, 254 F.3d at 1049 n.2 (stating that "[couching] a sale of an interest that entitles the purchaser to possession and use of the machine, unrelated to any patent present or future, . . . as a 'license'[ ] would not prevent the transaction from triggering the on-sale bar"); *In re Kollar*, 286 F.3d at 1330 n.3 (stating that certain transactions framed as a "license" but that are to an embodiment of the claimed invention "may be tantamount to a sale (e.g., a standard computer software license)").

Like the absence of title transfer, the confidential nature of the transactions is a factor which weighs against the conclusion that the transactions were commercial in nature. Again, this factor is not disqualifying in all instances—it too is not of talismanic significance. Indeed, we, and our predecessors, have found confidential transactions to be patent invalidating sales under § 102(b). *See In re Caveney*, 761 F.2d at 676 ("It is well established . . . that a single sale or offer to sell is enough to bar patentability" even if kept secret from the trade) (citing *Gen. Elec. Co. v. United States*, 654 F.2d 55, 60 (1981); *Mfg. Research Corp. v. Graybar Elec. Corp.*, 679 F.2d 1355, 1362 (11th Cir. 1982)); *Gould*, 579 F.2d at 580 ("[A] sale . . . pursuant to a secret military contract . . . was still held to be a sale proscribed by 35 U.S.C. § 102(b).") (citing *Piet v. United States*, 176 F. Supp. 576 (S.D. Cal. 1959), *aff'd*,

283 F.2d 693 (9th Cir. 1960)); *Hobbs v. U.S. Atomic Energy Comm'n*, 451 F.2d 849, 860 (5th Cir. 1971) (stating that the court "cannot attach any relevance to any conditions of secrecy which may have existed at the time the [invention] was placed 'on sale.'"). In this case, however, we find that the scope and nature of the confidentiality imposed on Ben Venue supports the view that the sale was not for commercial marketing purposes.

Rather than rest our decision on formalities, our focus is on what makes our on-sale bar jurisprudence coherent: preventing inventors from filing for patents a year or more after the invention has been commercially marketed, whether marketed by the inventor himself or a third party.[2] *Pfaff* itself quoted two seminal cases reciting this principle: "[*a*]*ny attempt to use it for a profit*, and not by way of experiment, for a longer period than two years before the application, would deprive the inventor of his right to a patent," 525 U.S. at 65 (quoting *Elizabeth*, 97 U.S. at 137) (emphasis added), and "it is a condition upon an inventor's right to a patent that he *shall not exploit his discovery competitively* after it is ready for patenting," *id.* at 68 (quoting *Metallizing*, 153 F.2d at 520) (emphasis added). *See also Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1365 (Fed. Cir. 2008) ("The overriding concern of the on-sale bar is an inventor's attempt to commercialize his invention beyond the statutory term.") (citing *Netscape Commc'ns. Corp. v. Konrad*, 295 F.3d 1315, 1323 (Fed. Cir. 2002)); *Plumtree*, 473 F.3d

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[2] We have held that sales by third parties can be invalidating sales under § 102(b) in certain circumstances. *See, e.g.*, *J.A. La Porte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577, 1581 (Fed. Cir. 1986); *see also Zacharin v. United States*, 213 F.3d 1366, 1371 (Fed. Cir. 2000); *Evans Cooling Sys., Inc. v. Gen. Motors Corp.*, 125 F.3d 1448, 1453 (Fed. Cir. 1997).

at 1163 ("the intent of [§ 102(b)] is to preclude attempts by the inventor or his assignee to *profit from commercial use* of an invention for more than a year before an application for patent is filed") (emphasis added) (quoting *D.L. Auld*, 714 F.2d at 1147) (internal quotation marks omitted).

Despite this fairly constant refrain in the case law, Hospira argues that finding the bar inapplicable here "would improperly permit an inventor to commercially stockpile his invention," in order to "restock its long-depleted commercial pipeline." Hospira's En Banc Br. 19, 47. But commercial benefit generally is not what triggers § 102(b); there must be a commercial sale or offer for sale. The statute itself says the invention must be "on sale," or that there must be an offer for sale of the invention. *Pfaff* made this distinction clear and explained that we are not to look to broad policy rationales in assessing whether the on-sale bar applies; we are to apply a straightforward two-step process—one which permits an inventor to "both understand and control the first commercial marketing of his invention." 525 U.S. at 67. For this reason, we find that the mere stockpiling of a patented invention by the purchaser of manufacturing services does not constitute a "commercial sale" under § 102(b). Stockpiling—or building inventory—is, when not accompanied by an actual sale or offer for sale of the invention, mere pre-commercial activity in preparation for future sale. This is true regardless of how the stockpiled material is packaged. The on-sale bar is triggered by actual commercial marketing of the invention, not preparation for potential or eventual marketing. Contrary to Hospira's assertions, not every activity that inures some commercial benefit to the inventor can be considered a commercial sale. Instead, stockpiling by an inventor with the assistance of a contract manufacturer is no more improper than is stockpiling by an inventor in-house.

It is well-settled that mere preparations for commercial sales are not themselves "commercial sales" or "commercial offers for sale" under the on-sale bar. *See, e.g.*, *In re Kollar*, 286 F.3d at 1334 (holding that "[t]he pre-commercialization process aimed at making the invention commercial" does not implicate the on-sale bar); *Intel Corp. v. Int'l Trade Comm'n*, 946 F.2d 821, 830 (Fed. Cir. 1991) ("It is not a violation of the on-sale bar to make preparations for the sale of a claimed invention—an actual sale or offer to sell must be proved."). Instead, when no actual sale is present, "[o]nly 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)" triggers the on-sale bar. *Group One,* 254 F.3d at 1048.

Indeed, we have held that an inventor that has publicized that a product will soon be placed on sale has not created an offer that another party could make binding by simple acceptance. *See, e.g.*, *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1050 (Fed. Cir. 2001) (holding that promotional activity was insufficient to create an on-sale event: "[p]reparation alone cannot give rise to an on-sale bar under *Group One*"). To the contrary, such an inventor has told buyers that it cannot have access to the invention yet, regardless of a customer's interest in buying.

And, we have never held that stockpiling by an inventor in-house triggers the on-sale bar. *See* Leah C. Fletcher, *Equal Treatment Under Patent Law: A Proposed Exception To The On-Sale Bar*, 13 TEX. INTELL. PROP. L.J. 209, 235-36 (2005) ("The unchallenged ability of the in-house manufacturer to stockpile strongly suggests that, in fact, the on-sale bar is not really intended to deter stockpiling."); Christopher G. Darrow, *Recent Developments: Recent Developments in Patent Law*, 10 TEX. INTELL. PROP. L.J. 379, 388 (2002) ("Inventors having manufacturing capacity can begin the sometimes long manufacturing process, and even stockpile commercial embodiments of

the invention, before filing a patent application."). Stockpiling is merely a type of preparation for *future* commercial sales. If Congress wanted to prevent stockpiling or any form of commercial benefit, it could have added "or stockpiled" or "engaged in a transaction conferring commercial benefit" to the list of statutory bars in § 102(b), in addition to "public use or on sale." It did not. Stockpiling by the purchaser of manufacturing services is not a trigger to the on-sale bar; discouraging it is not even an identifiable goal of the on-sale bar.

Expanding the on-sale bar to encompass stockpiling by inventors that outsource manufacturing might encourage earlier filing of patents. But we cannot endorse any blunt instrument that rewards earlier patent applications when so doing ignores the wording Congress chose when enacting the on-sale bar. *See Gould*, 579 F.2d at 580 ("It appears certain that the purpose of the on sale bar and the 1-year grace period is an attempt by Congress to balance the interests of the inventor with the interests of the public."). Unlike those in cases to which Hospira cites, such as *D.L. Auld*, in which we applied the on-sale bar to the performance of patented methods for commercial gain, MedCo's transactions with Ben Venue did not involve invalidating sales or offers for sale of the invention. MedCo did not market or release its invention to any purchasers by contracting with Ben Venue, nor did it give Ben Venue approval to do so. Rather, MedCo made a pre-commercial investment—an outlay of $347,500—when it paid Ben Venue for the service of reducing its invention to practice. We see no reason to treat MedCo differently than we would a company with in-house manufacturing capabilities.

Hospira itself concedes that "[w]hether the on-sale bar applies should not depend on differences that do not alter a transaction's basic economics." Hospira's En Banc Br. 32, 35. Yet, penalizing a company for relying, by choice or by necessity, on the confidential services of a contract

manufacturer, does exactly that. Applying the on-sale bar to the transaction-at-issue would be: (1) arbitrary, as it treats companies making the same pre-commercial preparations differently; (2) ineffective to discourage stockpiling, as it does not penalize or prevent companies with in-house manufacturing capabilities from stockpiling; (3) and unnecessary, as stockpiling by the purchaser of manufacturing services is not the type of commercial activity with which the on-sale bar is concerned. *See* Brief for Roberta J. Morris as Amicus Curiae 6-7. There is no room in the statute and no principled reason raised by the parties or any of the amici to apply a different set of on-sale bar rules to inventors depending on whether their business model is to outsource manufacturing or to manufacture in-house. In fact, the amici uniformly argue that applying the on-sale bar to the type of transaction that occurred here would only make the drug development process more costly, punish efficient use of resources, and deter future investments in innovation. *See e.g.*, Brief for Biotechnology Innovation Organization as Amicus Curiae 11; Brief for American Intellectual Property Law Association as Amicus Curiae 3, 19; Brief for Gilead Sciences, Inc. as Amicus Curiae 17-18; Brief of Pharmaceutical Research and Manufacturers of America as Amicus Curiae 4, 6.

C. Post-*Pfaff* Cases Applying § 102(b) to Supplier/Inventor Transactions

Hospira argues that a number of our post-*Pfaff* cases are inconsistent with the district court's failure to find § 102(b) to have been triggered by MedCo's transactions with Ben Venue and, by extension, would be inconsistent with the conclusion we reach here. Specifically, Hospira points to *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 182 F.3d 888, 891 (Fed. Cir. 1999), *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), and *Hamilton Beach Brands, Inc. v. Sunbeam Products*, 726 F.3d 1370, 1375 (Fed. Cir. 2013). In each, according to Hospira, we

invalidated patent claims under § 102(b) based on transfers of product by a supplier to an inventor. Indeed, as Hospira emphasizes, in *Special Devices*, we expressly held that there is no "supplier exception" to the on-sale bar, *Special Devices*, 270 F.3d at 1357, a point we reiterated in *Hamilton Beach*.

In none of those cases were the precise facts and arguments we consider today presented by the parties. In *Brasseler*, we noted that the transaction was indisputably one in which the rights in the patented invention passed between the parties for consideration. *Brasseler*, 182 F.3d at 890 ("The transaction at issue undisputedly was a 'sale' in a commercial law sense."). In *Brasseler*, we found that "[t]he transaction was invoiced as a sale of product, and the parties understood the transaction to be such," *id.* at 891, and that the transaction was for purposes of marketing by Brasseler. *Id.* Brasseler argued that it and the supplier from whom the purchase was made were not truly separate entities, that we should apply a joint development exception to the on-sale bar because Brasseler and its supplier each employed co-inventors, and that the fact that Brasseler retained equitable, though not legal, title to the patented product was meaningful. We rejected each of those specific contentions, but did not say transactions with suppliers should always be deemed commercial sales.

Similarly, in *Special Devices*, while we declined to adopt a "supplier exception" to the on-sale bar, we did so in the face of a concession by the inventor that the transaction between it and its supplier was a commercial sale. Thus, the import of *Special* Devices is simply that the fact that a sale is made by a supplier is not, *standing alone*, sufficient grounds upon which to characterize a transaction having all of the hallmarks of a commercial sale under the UCC as something other than a commercial sale.

So, too, in *Hamilton Beach*. The inventor made only two arguments against the application of § 102(b): (1) that the offer for sale was insufficiently firm under contract law and the UCC to constitute a commercial offer for sale; and (2) that the invention was not yet ready for patenting under the second prong of *Pfaff*. The inventor did not even urge a supplier exception to § 102(b) or argue that no commercial sale of the patented product would occur if the inventor purchased it from its supplier.

Thus, examining the arguments made by the parties and the facts not in dispute in those cases, the precise holdings in those cases are not inconsistent with the analysis we employ or conclusions we reach here. Lest there be any doubt, however, to the extent language in those cases might be viewed as dictating a different result here, they are overruled with one important caveat. We still do not recognize a blanket "supplier exception" to what would otherwise constitute a commercial sale as we have characterized it today. While the fact that a transaction is between a supplier and inventor is an important indicator that the transaction is not a commercial sale, understood as such in the commercial marketplace, it is not alone determinative. Where the supplier has title to the patented product or process, the supplier receives blanket authority to market the product or disclose the process for manufacturing the product to others, or the transaction is a sale of product at full market value, even a transfer of product to the inventor may constitute a commercial sale under § 102(b). The focus must be on the commercial character of the transaction, not solely on the identity of the participants.

We believe our focus on those characteristics that make a sale "commercial" in the most well-understood sense of that term and on what constitutes commercial marketing of a product, as distinct from merely obtaining some commercial benefit from a transaction, best adheres to the language of § 102(b), the Supreme Court's guidance

in *Pfaff*, and the policy and jurisprudential concerns, respectively, underlying both.[3]

D. Experimental Use

MedCo argues that because its transactions with Ben Venue were for purposes of validating whether its processes (1) would continue to work as claimed and (2) generate consistently acceptable product, those transactions were for experimental purposes. Specifically, it asserts that, even if ready for patenting, the transactions with Ben Venue were not for commercial purposes, only experimental ones. Hospira counters that MedCo never asserted an experimental use exception below and cannot do so now, especially when Hospira was never given an opportunity to present evidence regarding the other eight batches of product prepared for MedCo by Ben Venue. Hospira also argues that validation of a manufacturing process for purposes of satisfying FDA requirements is not experimental within the meaning of § 102(b).

While the parties spend significant time addressing the question, most amici, including the government, urge that, if we conclude the transactions between Ben Venue and MedCo were not commercial sales for other reasons, we refrain from reaching the district court's experimental use finding. The only exception to this fairly unanimous view is an oft-repeated request that we make clear that the panel's statement that there can be no experimental use after a reduction to practice is inaccurate. *See, e.g.*, Brief for the United States as Amicus Curiae 25-26; Brief

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[3] The government argues that recent amendments to § 102 in the AIA reflects Congress's view that the public use bar and the on-sale bar both turn on the "public" nature of the activity at issue. We do not address here whether or to what extent § 102(b) may differ post-AIA from the pre-AIA description we now employ.

for the Houston Intellectual Property Law Association 9-12; Brief for Gilead Sciences, Inc. as Amicus Curiae 10-11.

Given our conclusion that there was no "commercial sale" of the inventions in the '727 and '343 patents, we agree that we need not reach the question of experimental use. Since the panel opinion has been vacated, we also decline to parse individual statements therein that are not determinative of the question presented. For the same reason, we do not reach the second prong of *Pfaff*—whether the invention was ready for patenting—despite the fact that MedCo argued at the district court that it was not and challenges the district court's finding to the contrary on appeal.

Ultimately, we reach the same conclusion the district court did regarding the inapplicability of the on-sale bar to MedCo's transactions with Ben Venue, but do so on modified grounds. All other issues are remanded to the merits panel for consideration in the first instance.

CONCLUSION

We hold today that a contract manufacturer's sale to the inventor of manufacturing services where neither title to the embodiments nor the right to market the same passes to the supplier does not constitute an invalidating sale under § 102(b). We, therefore, affirm the district court's holding that the transactions between Ben Venue and MedCo did not trigger the on-sale bar. Because the original panel held that the '727 patent and the '343 patent were invalid under the on-sale bar as a result of MedCo's transactions with Ben Venue, it did not reach the other issues raised on appeal. Specifically, the original panel did not reach the issue of whether the invention was ready for patenting at the time of the 2006 and 2007 transactions, or whether the Distribution Agreement between MedCo and ICS triggered the on-sale bar. It also did not reach either MedCo's appeal of the district court's claim construction and non-infringement rulings or Hos-

pira's cross-appeal of the district court's obviousness and indefiniteness rulings. We, therefore, remand the appeal to the original panel for further proceedings consistent with this opinion.

AFFIRMED-IN-PART AND REMANDED TO THE MERITS PANEL

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

INFORMATION SHEET

FILING A PETITION FOR A WRIT OF CERTIORARI

There is no automatic right of appeal to the Supreme Court of the United States from judgments of the Federal Circuit. You must file a petition for a writ of certiorari which the Supreme Court will grant only when there are compelling reasons. (See Rule 10 of the Rules of the Supreme Court of the United States, hereinafter called Rules.)

Time. The petition must be filed in the Supreme Court of the United States within 90 days of the entry of judgment in this Court or within 90 days of the denial of a timely petition for rehearing. The judgment is entered on the day the Federal Circuit issues a final decision in your case. [The time does not run from the issuance of the mandate, which has no effect on the right to petition.] (See Rule 13 of the Rules.)

Fees. Either the $300 docketing fee or a motion for leave to proceed in forma pauperis with an affidavit in support thereof must accompany the petition. (See Rules 38 and 39.)

Authorized Filer. The petition must be filed by a member of the bar of the Supreme Court of the United States or by the petitioner representing himself or herself.

Format of a Petition. The Rules are very specific about the order of the required information and should be consulted before you start drafting your petition. (See Rule 14.) Rules 33 and 34 should be consulted regarding type size and font, paper size, paper weight, margins, page limits, cover, etc.

Number of Copies. Forty copies of a petition must be filed unless the petitioner is proceeding in forma pauperis, in which case an original and ten copies of the petition for writ of certiorari and of the motion for leave to proceed in forma pauperis. (See Rule 12.)

Where to File. You must file your documents at the Supreme Court.

Clerk
Supreme Court of the United States
1 First Street, NE
Washington, DC 20543
(202) 479-3000

No documents are filed at the Federal Circuit and the Federal Circuit provides no information to the Supreme Court unless the Supreme Court asks for the information.

Access to the Rules. The current rules can be found in Title 28 of the United States Code Annotated and other legal publications available in many public libraries.

Revised December 16, 1999