Appeal Nos. 2014-1469, 2014-1504

United States Court of Appeals

for the

Federal Circuit

THE MEDICINES COMPANY,

Plaintiff-Appellant,

– v. –

HOSPIRA, INC.,

Defendant-Cross-Appellant.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE
CASE NO. 09-CV-750-RGA, JUDGE RICHARD G. ANDREWS

EN BANC BRIEF OF PLAINTIFF-APPELLANT THE MEDICINES COMPANY

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February 24, 2016

CERTIFICATE OF INTEREST

Counsel for Plaintiff-Appellant The Medicines Company certifies the following:

1. The full name of every party or amicus represented by me is:

The Medicines Company.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court are:

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Date: February 24, 2016

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TABLE OF ABBREVIATIONS

"'727 patent"	U.S. Patent No. 7,582,727 (A47–61)
"'343 patent"	U.S. Patent No. 7,598,343 (A62–76)
"patents-in-suit"	The '727 patent and the '343 patent
"A____"	Joint Appendix page number(s)
"ANDA"	Abbreviated New Drug Application
"API"	Active pharmaceutical ingredient
"Ben Venue"	Ben Venue Laboratories
"FDA"	Food and Drug Administration
"HBr.__"	Page number(s) of Hospira's Principal En Banc Brief, ECF No. 73

STATEMENT OF RELATED CASES

Plaintiff-Appellant identifies the following related case that is before this Court, in that it concerns the same patents-in-suit:

- *The Medicines Company v. Mylan, Inc.*, Appeal No. 15-1113, 15-1151, 15-1181.

Plaintiff-Appellant also identifies the following district court cases that are related to the instant case, in that each concerns the same patents-in-suit:

- *The Medicines Company v. Dr. Reddy's Laboratories Ltd. et al.*, No. 11-2456 (D.N.J.);
- *The Medicines Company v. Apotex Inc. et al.*, No. 13-2801 (D.N.J.);
- *The Medicines Company v. Aurobindo Pharma Ltd. et al.*, No. 14-2367 (D.N.J.);
- *The Medicines Company v. Exela Pharma Sciences, LLC et al.*, No. 14-58 (W.D.N.C.);
- *The Medicines Company v. Accord Healthcare, Inc. et al.*, No. 14-626 (M.D.N.C.); and
- *The Medicines Company v. Sagent Pharmaceuticals, Inc.*, No. 1:15-cv-07507 (N.D. Ill.).

STATEMENT OF THE ISSUES

1. Do the circumstances presented here constitute a commercial sale under the on-sale bar of 35 U.S.C. § 102(b)?

(a) Was there a sale for the purposes of § 102(b) despite the absence of a transfer of title?

(b) Was the sale commercial in nature for the purposes of § 102(b) or an experimental use?

2. 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)?

INTRODUCTION

The on-sale bar does not apply in this case because "[i]nventors can request another entity's services in developing products embodying the invention without triggering the on-sale bar." *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1361-62 (Fed. Cir. 2010). Contract manufacturing services, performed confidentially and under the direction and control of the inventor, do not invoke the on-sale bar. *Id.*; *see also Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1370 (Fed. Cir. 2008) (Prost, J., concurring) ("[J]ust as inventors could develop any aspect of the invention privately, they may employ the concepts of agency and confidentiality to also accomplish the same result."). The Medicines

Company did just what the inventor in *Trading Techs.* was permitted to do—it employed Ben Venue, a third party contract manufacturer, to produce the claimed invention on its behalf. Ben Venue performed manufacturing services confidentially, under The Medicines Company's control and using The Medicines Company's ingredients. Ben Venue never had any right or title to the products. Neither The Medicines Company nor its contract manufacturer sold, offered to sell, or commercially exploited the claimed products before the critical date. Accordingly, nothing in the transaction at issue here triggered the on-sale bar of section 102(b).

As evidenced by the Panel's decision, the Court's application of the on-sale bar has led to inequitable results. Inventors who have their own in-house manufacturing facilities can develop and produce their products without concern that these actions trigger the on-sale bar, but inventors without in-house manufacturing facilities are treated differently and inequitably. The same product development that does not trigger the bar when done in house may create a bar when outsourced by the inventor. These disparate results cannot be reconciled with this Court's precedent or the policies underpinning section 102(b). The unequal application of the on-sale bar to confidential transactions between inventors and manufacturers who are working to develop a claimed product stifles innovation and hampers an inventor's ability to create his or her invention. *See*

Hamilton Beach Brands, Inc. v. Sunbeam Prods., 726 F.3d 1370, 1381 (Fed. Cir. 2013) (Reyna, J., dissenting) ("My greatest concerns involve the implications this case will have for future innovators, most notably small enterprises and individual inventors who lack in-house prototyping and fabricating capabilities.").

To provide uniformity and dispel any uncertainty surrounding the application of the on-sale bar, the Court should hold 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. Accordingly, the transaction between Ben Venue and The Medicines Company does not trigger the on-sale bar of section 102(b).

STATEMENT OF THE CASE

This case involves The Medicines Company's patented drug product sold under the trade name Angiomax®. The two patents-in-suit—the '727 and '343 patents—are both listed in the FDA's Orange Book as covering Angiomax®. Hospira filed ANDAs seeking approval to engage in the commercial manufacture, importation, use, or sale of generic Angiomax® products for injection before the expiration of the listed patents-in-suit. As a result, The Medicines Company sued Hospira for infringement of the '727 and '343 patents, both of which are at issue in this en banc proceeding. The '727 patent has product claims and the '343 patent has product-by-process claims. Both patents have nearly identical specifications.

The United States District Court for the District of Delaware ("District Court") held a three-day bench trial on September 23-25, 2013, where it had the ability to evaluate the credibility of the testifying witnesses and documentary evidence. Hospira alleged that the asserted claims of the patents-in-suit were invalid under the on-sale bar of 35 U.S.C. § 102(b). In addition to the on-sale bar, Hospira alleged that the asserted claims were invalid due to obviousness, lack of written description, nonenablement, and indefiniteness. Following the trial with seven fact witnesses, five experts, and post-trial briefing, the District Court rejected all of Hospira's invalidity allegations and found that Hospira had not proven (by clear and convincing evidence) that any of the asserted claims of the patents-in-suit were invalid. The District Court also found that the asserted claims of the patents-in-suit were not infringed.

With respect to the on-sale bar, the District Court rejected Hospira's allegations that Ben Venue "sold The Medicines Company three validation batches." (A23-24.) In support of its decision, the District Court found, factually, that:

- "The Medicines Company paid Ben Venue to ***manufacture*** validation batches." (A21 (emphasis added));
- "Hospira admit[ted] that the batches were for validation purposes." (A24 (citing A15896));

- "The Medicines Company's payment to Ben Venue for the validation batches was for experimental purposes." (A21); and
- "[A]t the time of the supposed sale, the batches were ***not for commercial purposes, but experimental batches*** made in order to verify that the invention worked for its intended purpose." (A24 (emphasis added).)

Furthermore, the District Court agreed that the transaction between The Medicines Company and Ben Venue was a "contract manufacturing relationship in which Ben Venue was paid to manufacture Angiomax for The Medicines Company, but wherein the ***title*** to the Angiomax ***always resided*** with The Medicines Company." (A24 (internal citations omitted) (emphasis added).) The District Court also stated that "[t]he fact that the batches were later sold does not change the underlying transaction from experimental to commercial." (A24, n.11.)

On appeal, Hospira argued, among other things, that the District Court erred in finding that the asserted claims were not invalid under the on-sale bar of section 102(b). The Panel agreed, reversed the District Court's validity determination, and held that the asserted claims were invalid under the on-sale bar. *The Medicines Co. v. Hospira, Inc.*, 791 F.3d 1368 (Fed. Cir. 2015). The claim construction and non-infringement rulings that The Medicines Company appealed (A17083) were never reached by the Panel.

On November 13, 2015, this Court granted rehearing en banc and vacated the Panel opinion.

STATEMENT OF THE FACTS

A. Background: Bivalirudin and Angiomax®

The patents-in-suit claim pharmaceutical batches of a drug product comprising bivalirudin, a peptide comprised of twenty amino acid residues. (A60, col.25 ll.56-57; A76, col.27 ll.13-14; A50, col.5 ll.58-66.) Bivalirudin drug products are used to prevent blood from clotting and are regarded as highly effective anticoagulants for use during coronary surgical procedures, including angioplasty. (A48, col.1 ll.44-56; A63, col.1 ll.44-56; A36.)

It is important that bivalirudin formulations maintain a high level of purity. (A48, col.2 ll.1-7; A63, col.2 ll.1-7.) Under certain conditions, however, bivalirudin may degrade and form impurities. (A48, col.2 ll.8-19; A63, col.2 ll.8-19.) When the ninth amino acid in the bivalirudin peptide chain, asparagine, degrades, an impurity is formed. (A48, col.2 ll.8-9; A63, col.2 ll.8-9.) As a result of this degradation, asparagine converts to another amino acid, aspartic acid (abbreviated Asp^9), forming the "Asp^9-bivalirudin" or "Asp^9" impurity. (A48, col.2 ll.8-9; A63, col.2 ll.8-9.)

The Medicines Company's prior compounding process resulted in pharmaceutical batches with high and variable Asp^9 levels ("Original

Angiomax®"). (A58-59, col.21 l.44-col.22 l.28; A73-74, col.22 l.21-col.23 l.4.) Original Angiomax® refers to the Angiomax® product made before the inventions at issue here, and is not covered by the patents-in-suit. (A58-59, col.21 l.44-col.22 l.28; A73-74, col.22 l.21-col.23 l.4.) Original Angiomax® had a maximum level of Asp^9-bivalirudin of 3.6%. (A58, col.22 ll.15-16; A73, col.22 ll.60-61.)

B. The Patented Inventions

The patents-in-suit were intended to solve the problem of high and variable levels of Asp^9 in Original Angiomax®. (A16111, 131:7-17; A16896, 914:6-11; A48, col.2 ll.8-22; A63, col.2 ll.8-22.) Specifically, The Medicines Company found that certain batches of Original Angiomax® had randomly high levels of Asp^9, which rendered those batches unsuitable for sale or use as a pharmaceutical product. (A16056-57, 76:24-77:21; A16067, 87:13-22.) For example, in 2005, The Medicines Company experienced a batch failure when Lot 716184 was found to have an Asp^9 level of 3.6%, which exceeded the allowed Asp^9 impurity limit at that time. (A16055, 75:9-14; A16059-60, 79:3-80:5.) Another batch, Lot 896002 (manufactured in May 2006), had a high Asp^9 level of 2.4%. (A16062, 82:9-16; A16063-64, 83:1-84:2.) Batch failures, such as those of Lots 716184 and 896002, presented significant concerns for The Medicines Company. (A16056-57, 76:24-77:21.) Batches with excessively high Asp^9 impurity levels had to be discarded and destroyed. (A16056-57, 76:24-77:6.)

The inventors of the patents-in-suit investigated the randomly high Asp^9 levels. (A16093-94, 113:19-114:21.) Based on this work, they developed an improved Angiomax® product ("Improved Angiomax®") that did not have the randomly high Asp^9 levels. (A16104-5, 124:23-125:4.) As part of the development process, the inventors oversaw the manufacture of experimental batches to investigate whether the problem of randomly high Asp^9 levels had been solved—i.e., to determine whether Improved Angiomax® had a reduced maximum Asp^9 level. (A16487, 506:11-20; A16496, 515:21-24; A58-59, col.22 l.65-col.23 l.8; A74, col.23 ll.37-48.) The patent applications that resulted in the patents-in-suit were filed on July 27, 2008. (A47; A62.)

Independent claim 1 of the '727 patent and independent claim 1 of the '343 patent claim products with a maximum Asp^9 level "that does not exceed about 0.6%." (A60, col.25 ll.62-64; A76, col.27 ll.29-31.) This limitation was not disclosed in the prior art, which included 89 batches of Original Angiomax® with a maximum Asp^9 level of 3.6%. (A58, col.22 ll.4-16; A73, col.22 ll.49-61.) In contrast to Original Angiomax®, Improved Angiomax® has a maximum Asp^9 level of about 0.6%. (A58-59, col.22 l.65-col.23 l.8; A74, col.23 ll.37-48.) Both patents require (claim) that Improved Angiomax® have a maximum Asp^9 level that does not exceed about 0.6%.

C. The Transaction at Issue

The Medicines Company is a specialty pharmaceutical company that does not have its own manufacturing facilities and is not capable of making its products in house. (A16053, 73:2-13.) Ben Venue began manufacturing Original Angiomax® under confidential conditions for The Medicines Company in 1997. (A16014, 34:13-15; A16058, 78:8-17; A16093, 113:2-9; A16855, 873:12-19.) The Medicines Company provided the ingredients to Ben Venue who, acting as a pair of laboratory hands, converted The Medicines Company's API into the drug product at Ben Venue's manufacturing facility. (A16053-54, 73:2-74:17.)

In late 2006, at the direction of The Medicines Company and the inventors, Ben Venue manufactured three batches of Improved Angiomax®—lot numbers 896012, 896013, and 896014. (A15120; A15361; A15596; A14881; A14883-84 ("These lots will be manufactured . . . in accordance to TMC [The Medicines Company] designed experimental challenge.").) These batches were prepared as part of The Medicines Company's efforts to solve the variable and high Asp[9] problem. (A24; A14884; A16893-94, 911:15-912:9; A16487, 506:11-20; A16496, 515:21-24; A16661, 679:21-24; A74, col.23 ll.37-48; A58-59, col.22 l.65-col.23 l.8.) The Medicines Company instructed Ben Venue to follow a "test protocol" using various "experimental" mixing parameters in preparing these lots at different batch sizes. (A14881; A14883; A14884; A14886.) For example, Ben Venue

manufactured the first batch at 40 liters, and the second and third batch at 160 liters. (A14884.) The Medicines Company further modified the manufacturing steps for each of the three batches, including varying the mixing rates, mixing times, batch temperatures, and ingredient addition rates. (A14884.)

The three validation batches were also prepared to meet statutory and regulatory FDA requirements. 21 U.S.C. § 351(a)(2)(B); 21 C.F.R. § 211.110(a). After they were made, these batches were placed in quarantine, under The Medicines Company's control, pending quality review and testing. (A14881; A14884; A16863, 881:2-12.) Under The Medicines Company's operating procedures, batches placed in quarantine are not available for sale. (A16808-9, 826:18-827:1; A16863, 881:2-12.) Ben Venue invoiced The Medicines Company for its ***services*** in manufacturing the three batches. (A16864-65, 882:24-883:11 ("Those Ben Venue invoices to The Medicines Company were invoices for services rendered . . . .").) The invoices clearly stated, "Charge to ***manufacture*** Bivalirudin lot." (A17183; A17177-78 (emphasis added).)

The three validation batches had Asp^9 levels of 0.3%. (A14970; A15223; A15454.) Subsequent batches were prepared and the Asp^9 level increased, reaching a maximum value of 0.6%. (A58-59, col.22 l.65-col.23 l.8; A74, col.23 ll.37-48.) The inventors did not appreciate the claimed maximum Asp^9 impurity level of about 0.6% until after the 25th batch was made and analyzed around

December 2007. (A16893-94, 911:15-912:9; A16487, 506:11-20; A16496, 515:21-24; A16661, 679:21-24; A74, col.23 ll.37-48; A58-59, col.22 l.65-col.23 l.8.)

At all times (including packaging and warehousing), the three validation batches were under The Medicines Company's quarantine in an unsalable form. (A16805-6, 823:17-824:7; A14960; A15211; A15453; A16841-42, 859:22-860:5; A16808-9, 826:18-827:1.) It was not until August 2007, after the July 27, 2007 critical date, that The Medicines Company released the batches from quarantine and made them available for sale. (A14634; A16862-64, 880:9-882:10.) Only Original Angiomax® was sold before the critical date. (A16847-48, 865:9-866:2; A16865, 883:12-17.)

SUMMARY OF THE ARGUMENT

The Medicines Company addresses each of the Federal Circuit's en banc questions set forth in the Statement of Issues. The responses to Questions 1, 1(a), 1(b), and 2 are found below in Sections I, I.A, I.B, and II, respectively.

Question 1

The circumstances here do not constitute a commercial sale under the on-sale bar of section 102(b). The on-sale bar requires that the invention is commercially sold or offered for sale prior to the critical date. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998); *Trading Techs.*, 595 F.3d at 1361.

(a) Hospira fails to establish that the claimed products were sold or offered for sale before the critical date. Ben Venue—acting merely as a pair of hands—performed confidential services to convert The Medicines Company's API into the finished drug product. This transaction is not invalidating because "[i]nventors can request another entity's services in developing products embodying the invention without triggering the on-sale bar." *Trading Techs.*, 595 F.3d at 1361-62. Ben Venue did not sell any product to anyone and acted under The Medicines Company's direction and control. Moreover, Ben Venue could not have sold or offered to sell the claimed invention to anyone as it did not have title to the product. Accordingly, the circumstances presented here do not constitute a sale under section 102(b).

(b) The record also clearly establishes that the transaction at issue here was not "commercial" in nature. The type of testing and experimental work performed by Ben Venue has long been recognized as lacking any commercial attributes and does not trigger the on-sale bar. "[A]n inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention . . . ." *Pfaff*, 525 U.S. at 64.

The three batches at issue were made according to a "test protocol" (A14881) using different mixing parameters and were required by the FDA for regulatory purposes. The test protocol states that "[t]hese lots will be

manufactured as specified in BVL [Ben Venue] batch record and in accordance to TMC [The Medicines Company] designed ***experimental*** challenge." (A14884 (emphasis added).)

The inventions were not ready for patenting or reduced to practice until after the inventors reviewed and analyzed the Asp^9 levels from the 25 batches in December 2007, after the July 2007 critical date. Even if the Court holds that there was an earlier reduction-to-practice date, experimental use continues to be available to negate the on-sale bar after a reduction to practice. *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 134 (1878); *Atlanta Attachment*, 516 F.3d at 1370 (Prost, J., concurring) ("[The experimental use] exception to the on-sale bar does not evaporate upon reduction to practice.") (emphasis in original).

Question 2

This Court should clarify the principle in *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), so that it is consistent with the statute and the policies underlying section 102(b). *Special Devices* invites courts to assume that a transfer of goods from a supplier to an inventor triggers the on-sale bar without fully analyzing whether such a transfer is a sale, let alone a commercial sale, as required by the Supreme Court in *Pfaff*. *See, e.g., Hamilton Beach*, 726 F.3d at 1379 (Reyna, J. dissenting) (noting that the majority opinion's application of the no-supplier-exception rule "overlooks the Supreme Court's requirement that the

offer be a 'commercial' one"). Under the patent statute, its underlying policies, and this Court's precedent, the on-sale bar is not implicated when: (1) the invention is not publicly disclosed by anyone, and (2) the inventor does not commercially sell or offer to sell the invention before the critical date. Under this standard, confidential contract manufacturing services performed by third parties, under the inventor's direction and control, do not trigger the on-sale bar of section 102(b).

ARGUMENT

I. The Circumstances Here Do Not Constitute a Commercial Sale Under the On-Sale Bar of 35 U.S.C. § 102(b)

A. The Patented Products Were Never Sold or Commercialized Before the Critical Date

"A person shall be entitled to a patent unless . . . [the invention was] ***on sale*** in this country, more than one year prior to the date of application for patent in the United States." 35 U.S.C. § 102(b) (emphasis added).[1] The Supreme Court in *Pfaff* set forth the requirements for the on-sale bar. 525 U.S. at 67-68. An invention is "on sale" only when there is (1) a "commercial" sale or offer for sale of the invention, and (2) the invention is ready for patenting. *Id.*; *see also Trading Techs.*, 595 F.3d at 1361.

[1] All references to Title 35 of the U.S. Code refer to the pre-America Invents Act version.

The premise behind *Pfaff* is that the patent laws seek to preserve "the inventor's right to control whether and when he may patent his invention." *Pfaff*, 525 U.S. at 65. With respect to the on-sale bar, *Pfaff* contemplates that an inventor "both understand and control the timing of the first commercial marketing of his invention." *Id*. at 67. Indeed, *Pfaff* notes this first commercial marketing of the invention is the date against which application of the on-sale bar is measured. *Id.*

1. Ben Venue's Performance of Services Does Not Trigger the On-Sale Bar

The Medicines Company's contract manufacturer, Ben Venue, performed confidential manufacturing services under The Medicines Company's direction and control, using ingredients supplied by The Medicines Company. (A16014, 34:13-15; A16053-54, 73:2-74:17; A16058, 78:8-17; A16093, 113:2-9; A16855, 873:12-19; A16863, 881:2-12; A14881; A14883-84.) Ben Venue, acting as a pair of laboratory hands, converted The Medicines Company's API into finished drug product. (A16053-54, 73:2-74:17.) Ben Venue was paid for its ***services*** to manufacture Angiomax®, not for the sale of any product. (A24 ("[T]he invoices clearly stated, 'Charge to manufacture Bivalirudin lot.'"); A16864-65, 882:24-883:17 ("Those Ben Venue invoices to The Medicines Company were invoices for services rendered . . . ."); A17183; A17177-78.) Moreover, Ben Venue did not sell the patented products.

This Court has made it clear that "[i]nventors can request another entity's ***services*** in developing products embodying the invention without triggering the on-sale bar." *Trading Techs*., 595 F.3d at 1361-62 (emphasis added). In *Trading Techs.*, the inventor contracted with a software company to develop specialized software based on his idea. The company built the software "according to specifications provided to [it] by [the inventor]." *Id.* at 1361. The inventor paid the company "for the custom software." *Id*. The Federal Circuit affirmed the District Court's finding that the transaction did not trigger the on-sale bar: "Under [the agreement], [the software company] promised to develop trading software for [the inventor] because he lacked the technical expertise to do so. [The agreement] was a contract for providing hourly programming ***services*** to [the inventor]—not a computer software license." *Id*. (emphasis added).

Here, just as in *Trading Techs.*, The Medicines Company hired Ben Venue to perform services, as The Medicines Company did not have its own manufacturing facilities. The Medicines Company provided the materials and instructions to Ben Venue and paid Ben Venue for the manufacturing services, which were invoiced as such. (A14881; A14884; A17183; A17177-78; A16864-65, 882:24-883:17; A24.) Ben Venue's services to develop and manufacture the product for "[the inventor's] own secret, personal use could not constitute a sale under 35 U.S.C. § 102(b)." *Trading Techs.*, 595 F.3d at 1361-62; *see also Atlanta*

Attachment, 516 F.3d at 1370 (Prost, J., concurring) ("[J]ust as inventors could develop any aspect of the invention privately, they may employ the concepts of agency and confidentiality to also accomplish the same result."). Like the inventor in *Trading Techs.*, The Medicines Company received the batches for its "own secret, personal use," as it "did not sell or offer for sale anything embodying the invention" before the critical date. *Trading Techs.*, 595 F.3d at 1361-62. And The Medicines Company maintained control over the invention. (A16863, 881:2-12; A14881; A14884.) The fact that the batches were subsequently sold after the critical date does not change the nature of the pre-critical-date transaction between Ben Venue and The Medicines Company. The Medicines Company should be permitted to use the services of another entity in manufacturing its invention. *Trading Techs.*, 595 F.3d at 1361-62.

Further, the District Court correctly rejected Hospira's assertion that Ben Venue sold the validation batches to The Medicines Company, and instead found that "The Medicines Company paid Ben Venue to ***manufacture*** validation batches." (A24, (emphasis added); *see* A23.) This finding of fact is not clearly erroneous and is entitled to deference. *Mas-Hamilton Grp. v. LaGard, Inc.*, 156 F.3d 1206, 1216-17 (Fed. Cir. 1998). Ben Venue was merely a pair of hands and acted on The Medicines Company's behalf to manufacture the three validation batches to ascertain whether the inventions worked for their intended purpose, i.e.,

that the inventions had a low maximum Asp[9] level. (A24.) Ben Venue's services cost between $67,500 and $140,000 per validation batch, which is only about 1% of the potential value of each validation batch. (A17177-78; A17183.) This demonstrates that Ben Venue was not attempting to sell the claimed products under the guise of services.

2. The Patented Products Were Not Sold Before the Critical Date

a. The Medicines Company Did Not Sell or Offer to Sell the Patented Products Before the Critical Date

None of the three validations batches were sold or offered for sale—let alone placed in the public domain—before the critical date. (A14634; A16862-64, 880:9-882:10.) Upon manufacture, the three batches were placed in quarantine, under The Medicines Company's control, pending quality review and testing. (A14881; A14884; A16863, 881:2-12.) In August 2007, ***after*** the July 27, 2007 critical date, The Medicines Company released these batches from quarantine and made them available for sale. (A14634; A16862-64, 880:9-882:10.) It is ***undisputed*** that The Medicines Company ***did not sell*** the batches until after the critical date had passed.

b. Ben Venue Did Not and Could Not Sell or Offer to Sell the Patented Products as It Did Not Have Title or Legal Right to Sell Them

It is also undisputed that Ben Venue—a mere contract manufacturer—never had title to any batches of Angiomax®, and therefore could not give or pass rights

in those batches to any other person or entity. Contrary to Hospira's assertions, title or rights of property are highly relevant to the on-sale bar. (HBr. 30.) With respect to goods, which are at issue in this case, The Medicines Company relies on this Court's precedent and the Uniform Commercial Code ("U.C.C."). *See Trading Techs.*, 595 F.3d at 1361 ("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."); *see also* U.C.C. § 2-102 ("Unless the context otherwise requires, this Article applies to transactions in goods . . . . ").

While title does not actually have to pass to trigger the on-sale bar, both a sale and an offer for the sale of goods contemplate a transfer of title. *See Special Devices*, 270 F.3d at 1355. An entity that does not have title to goods cannot sell or offer to sell those goods. "It is axiomatic that a person cannot effectively convey property in which he has no ownership rights." *See Rhone-Poulenc Agro, S.A. v. DeKalb Genetics Corp.*, 284 F.3d 1323, 1329 (Fed. Cir. 2002) (citations omitted). Therefore, title or the right to make a sale is a necessary precondition to a sale or an offer for sale of goods.

Furthermore, consistent with this Court's precedent, the U.C.C. defines a "sale" as "the passing of title from the seller to the buyer for a price." U.C.C. § 2-106(1). Despite Hospira's contrary assertion (HBr. 35), the Federal Circuit routinely relies on the U.C.C. to determine the meaning of commercial terms such

as "sale." *See Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047-48 (Fed. Cir. 2001) (relying on the U.C.C. for the definition of a "commercial offer to sale" under *Pfaff*); *see also Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 769 F.3d 1371, 1379 (Fed. Cir. 2014) *cert. denied*, 136 S. Ct. 236 (2015) *and cert. granted*, 136 S. Ct. 356 (2015) (relying on the U.C.C.'s definition of "sale" in construing 35 U.S.C. § 271(a)); *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376, 1382 (Fed. Cir. 1998) (construing "sale" under 19 U.S.C. § 337 and relying on the U.C.C.'s "defining the term 'sale' as having been accomplished when a contract for the transfer of goods has been completed."); *Rumsfeld v. United Techs. Corp.*, 315 F.3d 1361, 1371 (Fed. Cir. 2003) (relying on the U.C.C.'s definition of "sale" for the interpretation of a government contract).

Hospira incorrectly asserts that The Medicines Company is seeking a "rule" that requires passage of title. (HBr. 34.) Rather, as explained above, title is highly relevant in determining whether products or goods can be sold or offered for sale by a party. As Hospira acknowledges, the cases it cites—to support its assertion that title is immaterial—involve patented ***processes*** and ***methods***. (HBr. 31 ("To be sure, the above-cited cases involve patented processes or methods.") (citing, *e.g., Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1328 (Fed. Cir. 2001); *Plumtree*, *Software, Inc. v. Datamize, LLC*, 473 F.3d 1152, 1163 (Fed. Cir. 2006); *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147 (Fed. Cir. 1983)).)

While process and method patents may not implicate transfer of property rights in the same way, this provides no rationale for ignoring title in the context of a transaction involving goods. *See Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1378 (Fed. Cir. 2003) ("The sale of a tangible item is usually a straightforward event; the item is transferred from the seller to the buyer, who normally owns it outright. In contrast, a process is a series of acts, and the concept of sale as applied to those acts is ambiguous.").

The patented products here are just that—products. Hospira improperly tries to rewrite the '727 and '343 product and product-by-process claims into pure process claims in an attempt to make the facts here fit Hospira's cited method-patent cases.[2] (HBr. 30-33.) But these are clearly not method patents. Although Hospira asserts that the invention is, at its core, a process (HBr. 33), Hospira ignores that "[t]here is 'no legally recognizable or protected essential element, gist or heart of the invention,'" which is instead "defined by the claims on appeal." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1565 (Fed. Cir. 1991) (quoting *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 345 (1961)). For

[2] Hospira's attempts to rewrite the claims are central to the claim-construction issues that The Medicines Company appealed. The Panel did not address any claim construction issues in the now-vacated July 2, 2015 Opinion. The District Court improperly added the phrase "efficient mixing" from the '343 patent into the claims of the '727 patent, thus transforming the pure product claims of the '727 patent into product-by-process claims. ECF No. 22 at 23-26. This error was compounded when the term "efficiently mixing" was construed to have specific limitations from one of the examples in the patent specification. *Id*. at 27-28.

patentability purposes, product-by-process patents—like the '343 patent on appeal here—are treated as product patents. *Amgen Inc. v. F. Hoffman-La Roche Ltd.,* 580 F.3d 1340, 1369 (Fed. Cir. 2009). Accordingly, both the '727 and '343 patents claim products and should not be treated as method patents.

Hospira also argues that title is irrelevant because "there is nothing novel here about the product alone." (HBr. 33.) But Hospira ignores express limitations contained in the claims of the patents-in-suit—"a ***maximum*** impurity level of Asp^9" of "about 0.6%." (A60, col.25 ll.62-64; A76, col.27 ll.29-31 (emphasis added).) This product limitation was not disclosed in the prior art, which had a maximum level of Asp^9 of 3.6%. (A58, col.22 ll.4-17; A73, col.22 ll.49-61.)

As described above, a sale or an offer for sale of goods (i.e., products) contemplates a transfer of title and rights to the product. Possession of title or right to sell is highly relevant to whether a product was sold or offered for sale. Ben Venue did not have title or the right to sell any of The Medicines Company's products.

3. The Patented Products Were Not Commercialized Before the Critical Date

a. The Medicines Company Did Not Commercially Exploit The Patented Products Before the Critical Date

Unable to prove a sale of the actual patented products before the critical date, Hospira attempts to argue that The Medicines Company "commercially

exploited" the invention. (*See, e.g.*, HBr. 2, 29, 30.) Hospira erroneously relies on *D.L. Auld*, *Metallizing*, *Plumtree*, and *Scaltech* to support its theory. (*See, e.g.*, HBr. 26, 29-30.) These cases are inapposite, however, as the patentees in those cases sought compensation from the public for performing the claimed 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); *see Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 62 F. Supp. 42, 46 (D. Conn. 1945). In *D.L. Auld*, the patentee offered to sell a product made by the claimed method to prospective customers. 714 F.2d at 1148. Similarly, in both *Plumtree* and *Scaltech*, the patentees offered to perform the steps of the patented methods for customers in exchange for compensation. *Plumtree*, 473 F.3d at 1163; *Scaltech*, 269 F.3d at 1328-29.

Unlike the patentees in *Metallizing*, *D.L. Auld*, *Plumtree*, and *Scaltech*, it is undisputed that The Medicines Company ***did not*** sell, offer to sell, seek any compensation, or receive any money before the critical date for the batches of Improved Angiomax® manufactured by Ben Venue. *See New Railhead Mfg., L.L.C. v. Vermeer Mfg., Co.*, 298 F.3d 1290, 1301 (Fed. Cir. 2002) (Dyk, J., dissenting) ("[T]he use must provide a profit or commercial advantage *to the inventor*.") (emphasis in original). There was no "sale for general use." *City of*

Elizabeth, 97 U.S. at 135 ("So long as [the inventor] does not voluntarily allow others to make [the invention] 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.").

i. Potential Sales Prices and Product Codes Are Not Evidence of Commercial Exploitation

While Hospira relies on the potential value of each batch (HBr. 7, 29 ("$10 to $20 million")), the potential eventual sales price of an unproven new pharmaceutical product is speculative and irrelevant to the question of patentability. It should be ignored as a classic red herring. At the time the validation batches were made, there was no guarantee that the new batches could ever be sold under FDA regulations. Any subsequent commercial value associated with the three validation batches did not occur until ***after the critical date*** and therefore, the potential sales price for the validation batches is irrelevant. The Medicines Company did not profit from the three batches prior to the critical date and did not receive any money at all from Ben Venue. The fact that the products might ultimately be sold after the critical date has nothing to do with the on-sale bar.

In another diversion, Hospira argues that the "commercial product code" given to each batch and the release for packaging are evidence of commercial exploitation (HBr. 28-29). They are not. First, regardless of whether the batch is

to be subsequently sold or to be destroyed, product codes are ***required*** by FDA regulations and do not demonstrate that a batch is for commercial use. Specifically, 21 C.F.R. § 211.80(d) requires that drug products be labeled with a distinctive code, even if the batch is rejected:

> Each container . . . for components or drug product containers, or closures shall be ***identified with a distinctive code*** for each lot in each shipment received. This code shall be used in recording the disposition of each lot. Each lot shall be appropriately identified as to its status (i.e., quarantined, approved, or rejected).

(emphasis added). Hospira's own ANDA exhibit batch had a product code ("08300-015") before the FDA approved Hospira's products for commercialization. (A14295.) Because the validation batches were required by FDA regulations to contain product codes, the existence of those codes has no bearing on whether the manufacture of those batches was commercial in nature. Second, while The Medicines Company allowed the batches to be shipped to its packaging service provider, Catalent, the batches remained under The Medicines Company's quarantine in an unsalable form.[3] (A16805-6, 823:17-824:7; A14960; A15211; A15453; A16841-42, 859:22-860:5; A16808-9, 826:18-827:1.)

[3] During packaging and warehousing, title to the products was "always with The Medicines Company." (A16856, 874:1-7.)

ii. The Medicines Company Did Not Stockpile the Invention, and Stockpiling Does Not Implicate the On-Sale Bar

Hospira claims that The Medicines Company "derived a massive commercial benefit" because it was it was able to "fully restock" its commercial pipeline. (HBr. 29.) To support this argument, Hospira asserts—for the first time and without any citation—that The Medicines Company had a "long-depleted commercial pipeline." (HBr. 3, 19, 48.) Hospira also argues that the allegedly replenished pipeline provided The Medicines Company with confidence to enter into a 2007 distribution agreement with ICS Distributor.[4] (HBr. 48.) Hospira is wrong. The Medicines Company had sufficient inventory to continue selling only ***Original*** Angiomax® until after the critical date. (A16847-48, 865:9-866:2; A16865, 883:12-17.) The three experimental validation batches did not become part of The Medicines Company's stock of Angiomax® until August 2007—after the critical date—when they were released from The Medicines Company's quarantine and made available for sale. *See supra*.

[4] ICS Distributor is separate from ICS 3PL, which warehoused Angiomax® on The Medicines Company's behalf. (A16849, 867:4-9.) The District Court found factually that the distribution agreement "was not an offer to sell Angiomax, as individual purchase orders were required." (A25.) The District Court further found that those purchase orders "could be rejected by The Medicines Company" (A26; A14676 ¶ 3.1) and that "[t]he Distribution Agreement is a contract to enter into a contract." (A26.)

Hospira's argument that "stockpiling" constitutes commercial exploitation that raises the on-sale bar of section 102(b) is also incorrect and unsupported by any precedent of this Court. (HBr. 29-30 (citing *Special Devices*, 270 F.3d at 1357).) Hospira does not cite to a single case holding that stockpiling triggers the bar when there is no sale or offer for sale of the claimed invention before the critical date. In *Special Devices*, unlike this case, it was undisputed that there ***was*** a ***commercial sale*** of the patented product before the critical date. *Id*.; *see supra* Section I.A.2.

Even when characterizing stockpiling as placing a product into a "commercial pipeline," stockpiling does not implicate the on-sale bar. *See infra*, Section II.B. The on-sale bar applies when there has been a commercial sale or offer for sale of the invention before the critical date. *Trading Techs.*, 595 at 1361. Stockpiling is ***not*** a sale or an offer to sell. An eventual sale down the road—after the critical date—is not a triggering "sale" under section 102(b). In any event, as discussed above, The Medicines Company did not stockpile, let alone sell or offer to sale the batches prior to the critical date. *See supra*.

b. Ben Venue Did Not Commercially Exploit the Patented Products

Hospira argues that Ben Venue commercially exploited the claimed invention prior to the critical date by performing "MedCo's revised process." (HBr. 29.) As explained above, however, the patents at issue are product and

product-by-process patents, ***not*** method or process patents. Ben Venue did not commercially exploit the claimed invention when it performed contract manufacturing services on The Medicines Company's behalf.

Hospira relies on cases such as *Plumtree* and *Scaltech*. (HBr. 25-26.) These cases, however, simply stand for the proposition that performing or offering to perform the steps of a claimed ***method***—the inventions at issue in those cases—for consideration triggers the on-sale bar. *Scaltech*, 269 F.3d at 1328 ("The on sale bar rule applies to the sale of an 'invention,' and in this case, the invention was a process, as permitted by § 101"); *Plumtree*, 473 F.3d at 1163. Here, however, the inventions, i.e., the claimed ***products***, were not sold or offered for sale by Ben Venue prior to the critical date. As evidenced by the Ben Venue invoices and the District Court's findings, Ben Venue merely charged The Medicines Company for performing services. *Supra* Section I.A.1; (A21; A24.)

4. Hospira Improperly Relies on Eight Additional Batches that It Failed to Raise in the District Court

Having failed to prove that the three validation batches triggered the on-sale bar, Hospira now attempts to rely on a new on-sale allegation that it never raised in the District Court concerning eight more batches that are not part of the record. (*See, e.g.*, HBr. 9, 29, 41.) Hospira has the burden of proving invalidity by clear and convincing evidence and this burden never shifts to The Medicines Company. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011).

At trial, Hospira alleged that Ben Venue sold The Medicines Company ***three*** validation batches and therefore, the asserted claims of the patents-in-suit were invalid due to the on-sale bar. (HBr. 14; A23; A15893-94.) Hospira never presented any evidence concerning any sale or transfer to The Medicines Company of the "8 more batches" that Hospira now seeks to introduce. Hospira cites only to a demonstrative (HBr. 9)—which is not evidence—and a conclusory statement by its technical expert that other batches were made before the critical date. *Duncan v. Dep't of the Air Force*, 674 F.3d 1359, 1363 (Fed. Cir. 2012) ("Mr. Duncan relied solely upon his own oral testimony and documents created by his counsel's office to prove those elements. Though the counsel-created calendar and table visually show the dates on which he testified, these were similar to demonstratives summarizing his testimony and not evidence independent of his testimony to prove the underlying facts."). Furthermore, Hospira's brief makes it clear that its on-sale bar allegations in the District Court were limited to the three batches: "As relevant here, Hospira argued that ***the first three batches*** of Example 5—which MedCo paid BVL to manufacture prior to the critical date—were invalidating under the on-sale bar of § 102(b)." (HBr. 14 (emphasis added).)

The District Court and the Panel made their ruling based on the factual record in this case and discussed only the three validation batches. (*See, e.g.*, A23 ("Hospira contends that Ben Venue sold The Medicines Company the ***three***

validation batches . . . .") (emphasis added).) Hospira now attempts to interject eight additional batches into the facts of this case—after the District Court held a full trial and rejected its on-sale bar allegations based on the three validation batches. Hospira should not be given a second bite at the invalidity apple to raise new on-sale allegations on appeal. *Golden Bridge Tech.*, 527 F.3d at 1323 (A party "cannot simply choose to make its arguments in iterative fashion, raising a new one on appeal after losing on its others at the district court.").

Any attempt to raise these eight additional batches now should be rejected. *Golden Bridge Tech., Inc. v. Nokia, Inc.*, 527 F.3d 1318, 1323 (Fed. Cir. 2008). According to this Court's precedent, any argument that is not made in the district court is considered waived and cannot be raised for the first time on appeal. *Id.* Hospira is improperly "asking an appellate court to make factual findings," but it is well settled that "[a]ppellate courts review district court judgments; [] not find facts." *Id.*

Even if the Court were to go outside the factual record to consider additional batches, they too do not support Hospira's invalidity assertions. Just like the three validation batches, the eight additional batches were made by Ben Venue confidentially, under The Medicines Company's direction and control. Ben Venue never sold these eight batches to The Medicines Company. Moreover, The

Medicines Company did not sell, offer to sell, or otherwise profit from these eight batches prior to the critical date.

B. The Batches Prepared Before the Critical Date Were Not Commercial

As demonstrated above, there was no sale of the patented products before the critical date. *Supra* Section I.A. But even if this Court were somehow to find that this form of contract manufacturing services should be deemed a sale, the transactions at issue here were experimental—not commercial—and thus do not implicate the on-sale bar.

"[A]n inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention . . . . The law has long recognized the distinction between inventions put to experimental use and products sold commercially." *Pfaff*, 525 U.S. at 64. "Experimentation evidence includes tests needed to convince [the inventor] that the invention is capable of performing its intended purpose in its intended environment." *EZ Dock, Inc. v. Schafer Sys.*, 276 F.3d 1347, 1352 (Fed. Cir. 2002) (internal quotations omitted). "Indeed in *Pfaff*, the Supreme Court reiterated its guidance in [*City of Elizabeth*, 97 U.S. at 137], that an inventor does not inappropriately delay filing 'by a bona fide effort to bring his invention to perfection, or to ascertain whether it will answer the purpose intended.'" *EZ Dock*, 276 F.3d at 1352 (citing *Pfaff*, 525 U.S. at 64-65). "When an evaluation period is reasonably needed to determine if the invention will

serve its intended purpose, the § 102(b) bar does not start to accrue while such determination is being made." *New Railhead*, 298 F.3d at 1297.

The validation batches were experimental and therefore do not invalidate the asserted claims under section 102(b). The District Court agreed and found that the batches were "not for commercial purposes but ***experimental batches*** made in order to verify that the invention worked for its intended purpose." (A24, emphasis added.) Since Hospira has not demonstrated that this factual finding is clearly erroneous, there is no basis to disturb the District Court's finding. *Mas-Hamilton Grp.*, 156 F.3d at 1216-17 (concluding no clear error in the district court's finding that there was not a definite sale or offer for sale). As described in further detail below, the batches were made using varying mixing parameters at differing scales and were prepared for regulatory purposes.

1. The Three Batches Were Experimental Because They Tested Varying Mixing Parameters

The three validation batches at issue here 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. (A24); *City of Elizabeth*, 97 U.S. at 137 (holding that an on-sale bar is negated by experimentation "when the delay is occasioned by a bona fide effort to bring his invention to perfection, or to ascertain whether it will answer the purpose intended"). Contrary to Hospira's allegations, the primary purpose of the batches

was experimentation. (HBr. 21.) Indeed, the District Court considered the factual question of whether the batches were commercial and found "[t]he fact that the batches were later sold does not change the underlying transaction from experimental to commercial." (A24, n.11.)

The Asp[9] levels were evaluated in batches prepared using different mixing parameters and at various sizes. The Medicines Company asked Ben Venue to manufacture ***one*** 40-liter batch (at target parameters), ***one*** 160-liter batch (using one extreme of the batch record parameters, e.g., lowest mixing rate, lowest mixing time, lowest temperature, and fastest addition rate), and ***one*** 160-liter batch (using the other extreme of the batch record parameters, e.g., highest mixing rate, highest mixing time, highest temperature, and slowest addition rate). (A14880; A14884.) These varying parameters further demonstrate that the experimental validation batches were made to determine whether the invention worked for its intended purpose.

Hospira relies on selected portions of the validation study in an attempt to demonstrate that the three validation batches here were "commercial." (HBr. 28-29.) Hospira is wrong. The study demonstrates the experimental nature of the three batches, which were manufactured according to a "***test protocol***." (A14881 (emphasis added).) The validation study clearly states that "[t]hese lots will be manufactured as specified in BVL [Ben Venue] batch record and in accordance to

TMC [The Medicines Company] designed ***experimental*** challenge." (A14884 (emphasis added).) The document sets forth a "***testing methodology***" which includes using a variety of mixing parameters and different batch sizes. (A14883 (emphasis added).) The validation study specifically addressed the possibility of failure: "In the event that further optimizations are required as testing proceeds, additional lots will be manufactured and tested to ensure that the changes are effective." (A14883.) Furthermore, the batches could not be released and therefore could not be commercially sold until experimentation was completed: "All three (3) lots will be placed on quality hold until all testing has been successfully completed." (A14884.)

2. The Three Batches Were Experimental Because They Were Made for Statutory and Regulatory Purposes

The three batches were also prepared to meet statutory and regulatory FDA requirements. Drug manufacturers are required under 21 U.S.C. § 351(a)(2)(B) to conform to current good manufacturing practices (CGMP), which require drug manufacturers to validate their process:

> To assure batch uniformity and integrity of drug products, written procedures shall be established and followed that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. ***Such control procedures shall be established to monitor the output and to validate the performance*** of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

21 C.F.R. § 211.110(a) (emphasis added). The Medicines Company follows CGMP requirements. (A16863, 881:2-12.)

The FDA Guidance in effect when the experimental validation batches were manufactured recommended that drug manufacturers conduct "performance ***testing*** under conditions that ***simulate actual use***." FDA, *Guideline on General Principles of Process Validation*, 1987 WL 959474, at *7 (1987) (emphasis added). This further confirms that these batches were made for validation purposes and were experimental in nature. The District Court, relying in part on Hospira's admission that the batches were made for validation purposes, made the factual determination that the batches were experimental. (A21; A24.) There is no justification to reverse the District Court's reasoned and supported factual finding.

Consistent with FDA requirements and industry practice, The Medicines Company made three validation batches. W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. Rev. 491, 515 (2014) (In view of the FDA guidelines, "the industry almost uniformly accepted a procedure of using exactly three batches for validation of every process . . . ."). Hospira misleadingly attempts to reframe these validation batches as commercial because "more than 60,000 vials" were filled. (HBr. 28, 38.) But there were only three validation batches, which had to be made under large scale conditions—e.g., close to manufacturing scale—and filled into vials to

simulate actual use and conditions. FDA, *Guideline on General Principles of Process Validation*, 1987 WL 959474, at *7 (1987); (A16053-54, 73:17-74:17 (the product is filled into vials and freeze-dried).) It makes sense to test drug products under conditions that are close to manufacturing scale, as drug products are under close scrutiny. *See Pfaff*, 525 U.S. at 65 ("It is the interest of the public, as well as [the inventor], that the invention should be perfect and properly tested, before a patent is granted for it."). Testing at laboratory scale is inadequate, as it is unknown how the product would scale. In view of the above, there is no way that the three required experimental batches could constitute "vast commercial quantities" as Hospira alleges. (HBr. 28.)

Finally, contrary to Hospira's allegations (HBr. 36), The Medicines Company did raise the issue that the transaction here was "not a commercial one" in its post-trial brief. (A16987.) The District Court found that "at the time of the supposed sale, the batches were ***not for commercial purposes*** but experimental batches made in order to verify that the invention worked for its intended purpose." (A24.) In finding the batches were experimental, the District Court relied on Hospira's admissions in its own post-trial brief that "the batches were for validation purposes." (A24 (citing A15896).) Hospira appealed from this decision, and the District Court's finding of experimental use is properly before this Court.

3. All Batches Prepared Before the Critical Date Were Experimental

The validation batches, as well as the eight additional batches that Hospira improperly raises, are experimental and do not result in an on-sale bar. The Panel, in its opinion, stated that "experimental use cannot occur after a reduction to practice." *The Medicines Co. v. Hospira, Inc.*, 791 F.3d at 1372 (citing *In re Cygnus Telecomm. Tech., LLC Patent Litig.*, 536 F.3d 1343, 1356 (Fed. Cir. 2008)). This is contrary to precedent, and the experimental-use exception should continue to be available to The Medicines Company even after the invention has been completed and reduced to practice.

In accordance with Supreme Court precedent, experimental use continues to be available even ***after*** a reduction to practice. *City of Elizabeth*, 97 U.S. at 134 ("The use of an invention by the inventor himself, or of any other person under his direction, by way of experiment, and in order to bring the invention to perfection, has never been regarded as such [an invalidating] use."); *Atlanta Attachment*, 516 F.3d at 1369 (Prost, J., concurring) ("Assuming a complete invention, ready for patenting, inventors should be able to continue to privately develop any claimed aspect of that invention without risking invalidation . . . even if there is some commercial benefit to the inventor in connection with the experimental use."). "The better and prevailing view is that ***experimental use can*** indeed ***continue even after the invention has been completed and reduced to practice*** . . . ." 2 Donald

S. Chisum, *Chisum on Patents* § 6.02[7][b][i] (2015) (emphasis added); *see also Atlanta Attachment*, 516 F.3d at 1370 (Prost, J., concurring) ("[The experimental use] exception to the on-sale bar does not evaporate upon reduction to practice.") (emphasis in original). A reduction to practice cut-off for experimental use is in conflict with Supreme Court precedent. Under the correct reasoning, an inventor is free to experiment until he or she knows that the invention is perfected, and is able to use a third party to do so.

In this case, the invention was not ready for patenting before the critical date because the inventors had not determined or appreciated every element of the claims. Indeed, Hospira did not identify a single enabling reference or document before the critical date that discloses the claimed maximum Asp^9 impurity level, i.e., not exceeding about 0.6%, at trial. *Cf. Pfaff*, 525 U.S. at 68 (drawings "sent to the manufacturer before the critical date ***fully disclosed*** the invention.") (emphasis added). Nor could they, as the inventors did not appreciate the maximum Asp^9 impurity level until after the 25th batch was made and analyzed. (A16893-94, 911:15-912:9; A16487, 506:11-20; A16496, 515:21-24; A16661, 679:21-24; A74, col.23 ll.37-48; A58-59, col.22 l.65-col.23 l.8.)

For reduction to practice, "a party must prove that the inventor (1) constructed an embodiment or performed a process that met all the limitations and (2) determined that the invention would work for its intended purpose." *In re*

Omeprazole Patent Litig., 536 F.3d 1361, 1373 (Fed. Cir. 2008) (internal quotations omitted). At the time the three validation batches were made, the inventors did not know that the invention worked for its intended purpose, i.e., a product with a low maximum Asp^9 level. (A16496, 515:21-24.) While the three validation batches had Asp^9 levels of 0.3% (A14970; A15223; A15454), the Asp^9 level increased in subsequent batches and reached a maximum value of 0.6%. (A58-59, col.22 l.65-col.23 l.8; A74, col.23 ll.37-48.) It was not until after the inventors reviewed and analyzed the Asp^9 values from 25 batches—around December 2007—that they determined that the Asp^9 levels did not exceed 0.6%. (A16893-94, 911:15-912:9; A16487, 506:11-20; A16496, 515:21-24.)

Even the eight additional batches, which Hospira attempts to improperly and untimely raise on appeal, were experimental. They were made to determine whether the inventions worked for their intended purpose. *City of Elizabeth*, 97 U.S. at 137; *EZ Dock*, 276 F.3d at 1352. The invention was not complete before December 2007, when the inventors determined that the Asp^9 levels did not exceed 0.6%. *Supra*. If the Court finds that the inventions were reduced to practice before December 2007, experimental use continues to be available to negate the on-sale bar even after a reduction to practice—all the batches prepared before the critical date were experimental. *City of Elizabeth*, 97 U.S. at 134; *Atlanta Attachment*, 516 F.3d at 1369-70 (Prost, J., concurring).

4. The Policies Underlying the On-Sale Bar Do Not Support Its Application to the Transaction Here

In addition to the reasons above, the transaction between Ben Venue and The Medicines Company does not implicate any of the underlying policies of the on-sale bar. As the Supreme Court stated in *Pfaff*:

> As we have often explained . . . the patent system represents a carefully crafted bargain that ***encourages both the creation and the public disclosure of new and useful advances in technology***, in return for an exclusive monopoly for a limited period of time.

Pfaff, 525 U.S. at 63 (emphasis added). Consistent with this, section 102 "serves as a limiting provision, both ***excluding ideas that are in the public domain*** from patent protection ***and confining the duration of the monopoly*** to the statutory term." *Pfaff*, 525 U.S. at 64 (emphasis added). Furthermore, the on-sale bar encourages prompt disclosures of inventions to the public. *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998).

The transaction with Ben Venue does not undermine any of these policies. First, the claimed products were not in the public domain prior to the critical date. *Cf. Abbott Labs. v. Geneva Pharm.*, 182 F.3d 1315, 1319 (Fed. Cir. 1999). Neither The Medicines Company, nor anyone else disclosed Improved Angiomax® to the public prior to the critical date.

Second, The Medicines Company did not extend its monopoly, as it did not sell, offer to sell, or commercially exploit the claimed product prior to the critical

date. Furthermore, as discussed above, The Medicines Company did not even know that the claimed invention worked for its intended purpose. *See Pfaff*, 525 U.S. at 64-65 (An inventor does not extend the monopoly "when the delay is occasioned by a *bona fide* effort to bring his invention to perfection, or to ascertain whether it will answer the purpose intended.") (quoting *City of Elizabeth.*, 97 U.S. at 137).

Third, The Medicines Company did not delay disclosure of its invention. At the time the validation batches were made, the inventors did not appreciate the maximum Asp[9] level of about 0.6%. It was only after the 25th batch of Improved Angiomax® was manufactured and analyzed in December 2007—after the July 27, 2007 critical date—that the full scope of the claimed invention was recognized. Once the maximum of about 0.6% was determined, The Medicines Company was able to prepare the patent applications, which were filed on July 27, 2008.

II. This Court Should Clarify the Principles of Law Set Forth in *Special Devices*

The "no supplier exception" of *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), invites courts to assume that a supplier-to-inventor transaction automatically constitutes a commercial sale under section 102(b) without performing the full *Pfaff* analysis. This Court should clarify that the no-supplier-exception principle in *Special Devices* still requires that courts perform a full *Pfaff* analysis. Further, a supplier-to-inventor transaction is not a *per se* trigger

of the on-sale bar. Specifically, an inventor's use of a third party to manufacture or develop the claimed invention confidentially, and under the inventor's direction and control should not create an on-sale bar. More broadly, the on-sale bar is not implicated when (1) the invention is not publicly disclosed by anyone, and (2) the inventor does not commercially sell or offer to sell the invention before the critical date. Recognizing these principles would ensure uniformity and predictability in the application of the on-sale bar.

A. *Special Devices* Invites Courts to Misapply the On-Sale Bar Analysis

In *Special Devices*, the Court determined that there was an invalidating commercial sale. 270 F.3d at 1355-56. In support of this determination, the Court: (i) held that the manufacturer made an offer to sell the claimed invention for purposes of section 102(b); (ii) noted that the patentee did not contest that the transactions at issue were commercial; and (iii) found the transactions were not experimental. *Id.* ***After*** finding an invalidating commercial sale, the Court declined to create a special supplier exception to remove supplier sales from the reach of the on-sale bar.

Since *Special Devices*, however, the no-supplier-exception principle has led courts to conclude that the on-sale bar is *per se* met by any supplier-to-inventor transaction without analyzing whether the inventor has commercially sold or offered his invention for sale as required by *Pfaff*. This, in turn, has improperly

shifted the burden of proof onto the patentee to demonstrate that a supplier-to-inventor transaction is not a commercial sale. *See TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 971 (Fed. Cir. 1984) (Section 282 "*permanently* places the burden of proving facts necessary to a conclusion of invalidity on the party asserting such invalidity.") (emphasis in original).

For example, in *Hamilton Beach* the Court applied the no-supplier-exception rule and held that there was an invalidating offer for sale without analyzing whether the transaction was commercial. *Hamilton Beach*, 726 F.3d at 1375, 1379 (Reyna, J. dissenting) (noting that the majority's application of the no-supplier-exception rule "overlooks the Supreme Court's requirement that the offer be a 'commercial' one"). Recognizing the dangers of the no-supplier-exception rule, the *Hamilton Beach* dissent states that "this court must refrain from overlooking the Supreme Court's express requirement for a *commercial* offer for sale when deploying the no-supplier-exception rule." *Id.* at 1381 (emphasis in original). With respect to experimental use, the *Hamilton Beach* dissent further notes that "an overly-broad application of the no-supplier-exception rule would all but abolish this distinction and render the experimental-use exception useless for a significant class of innovators." *Id.* at 1380.

Likewise, in the now-vacated Panel decision in this case, the Panel relied on *Special Devices* to find a commercial sale when none existed, thus shortcutting the

Pfaff analysis.[5] Applying the no-supplier-exception rule, the Panel held that "the Ben Venue sale of services" constituted a commercial sale of the claimed invention, even though the product itself was not sold nor offered for sale. *The Medicines Co. v. Hospira, Inc.*, 791 F.3d at 1371 (citing *Special Devices*, 270 F.3d at 1357).

As demonstrated above, *Special Devices* has led courts to improperly shortcut the *Pfaff* analysis and assume that transactions between inventors and their contract manufacturers are commercial sales or offers for sale, and then shift the burden to the patentee to prove otherwise. This Court can now clarify and correct the improper application of *Special Devices* by holding that there is no invalidating commercial sale when a supplier-to-inventor transaction is confidential and under the inventor's control.

B. *Special Devices* Disadvantages Parties Without In-House Manufacturing Capabilities

Application of the on-sale bar to transactions where a contract manufacturer confidentially produces a product on behalf of the patentee (and where the product is not sold or offered for sale by the patentee prior to the critical date) penalizes

[5] The Panel then relied on this finding of a "sale of services" to summarily conclude that "because the invention was sold, for the reasons described Supra Section II(A), we find that the Ben Venue batches reduced the invention to practice." *The Medicines Co. v. Hospira, Inc.*, 791 F.3d. at 1372. By doing so, the Panel collapsed the two-prong *Pfaff* inquiry into a single prong, failing to analyze whether the invention was ready for patenting.

companies that do not have the resources or facilities to conduct large-scale manufacturing or development work in house.

Inventors that use in-house manufacturing can develop and retain their inventions and, consistent with *Pfaff*, have the ability to understand and control the timing of a commercial sale or offer for sale of those inventions. 525 U.S. at 67 ("An inventor can both understand and control the timing of the first commercial marketing of his invention."). Under *Special Devices*, however, an inventor who uses a contract manufacturer to make or develop a product may trigger the on-sale bar ***before*** the inventor even has any opportunity to commercially sell or offer to sell his invention. This is incorrect and should not be the legacy of *Special Devices*.

Hospira's interpretation of *Special Devices* would create additional inequalities. Hospira argues that a supplier exception "would improperly permit an inventor to commercially stockpile . . . ." (HBr. 47.) Companies with in-house manufacturing, however, ***can*** stockpile and accumulate large quantities of products prior to a commercial sale without triggering the on-sale bar. Therefore, a holding that bars inventors who use contract manufacturers from stockpiling discriminates against those inventors in comparison to their vertically-integrated competitors who are able to manufacture for themselves.

Moreover, stockpiling is a pre-commercial activity that does not trigger the on-sale bar. *See In re Kollar*, 286 F.3d 1326, 1334 (Fed. Cir. 2002) (holding that "[t]he pre-commercialization process aimed at making the invention commercial" does not implicate the on-sale bar). 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), constitutes an offer for sale under [section] 102(b)." *Group One,* 254 F.3d at 1048. Stockpiling is the exact opposite as there is ***no offer*** to accept and ***no sale*** of the invention. *See 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."). Even 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) (promotional activity was insufficient to create an on-sale event—"[p]reparation alone cannot give rise to an on-sale bar."). To the contrary, such an inventor has told the public that it cannot have the invention yet, regardless of a customer's desire to contract.

Hospira disputes that an inventor who uses a contract manufacturer is disadvantaged and alleges that such an inventor is merely required to "file a patent

application—even a provisional one—within a year of the commercial exploitation of the invention." (HBr. 49.) This argument ignores that an inventor who uses third-party manufacturing may have to file his application before a vertically-integrated competitor. Thus, an inventor who outsources product development may have to file an application before that development is complete, while a vertically-integrated competitor can wait until a later date when he is ready to commercially offer or sell the invention to the public. This unfair and unequal treatment should not be the law.

C. Confidential Supplier-to-Inventor Transactions Under the Inventor's Control Should Not Trigger the On-Sale Bar

Supplier-to-inventor transactions do not implicate the on-sale bar when they are confidential and under the inventor's control. More broadly, the on-sale bar is not implicated when (1) the invention is not publicly disclosed by anyone, and (2) the inventor does not commercially sell or offer to sell the invention before the critical date. Indeed, the Supreme Court has explained that "[s]o long as [the inventor] does not voluntarily allow others to make [the invention] 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." *City of Elizabeth*, 97 U.S. at 135; *see also In re Kollar,* 286 F.3d at 1334 ("[T]he real benefit from commercializing an invention occurs when the invention is actually utilized commercially or made available to the public . . . ."); *Atlanta Attachment*, 516 F.3d at 1370 (Prost, J.,

concurring) ("[J]ust as inventors could develop any aspect of the invention privately, they may employ the concepts of agency and confidentiality to also accomplish the same result."). These principles are consistent with both this Court's precedent and the underlying policy concerns of section 102(b).

1. This Standard Is Consistent with This Court's Precedent

As explained above in Section I.A.1, this Court held in *Trading Techs.* that "[i]nventors can request another entity's services in developing products embodying the invention without triggering the on-sale bar." 595 F.3d at 1361-62. And, an inventor's request to a third party to develop and manufacture a product for "[the inventor's] own ***secret***, personal use could not constitute a sale under 35 U.S.C. § 102(b)." *Trading Techs.* 595 F.3d at 1362 (emphasis added). Likewise, prior to *Special Devices* this Court has endorsed the use of testers other than the inventor when the testers are held to secrecy and are under the inventors' control. *See, e.g., City of Elizabeth*, 97 U.S. at 133-36; *TP Labs., Inc.*, 724 F.2d at 972 (finding no invalidating use even in the presence of a financial transaction); *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1259-60 (Fed. Cir. 2001) (inventor-controlled use by a paying third party can be experimental).

Hospira broadly states that "[s]ales by third parties are sufficient to trigger the bar." (HBr. 26 (citing *In re Caveney*, 761 F.2d 671, 675 (Fed. Cir. 1985); *Zacharin v. United States*, 213 F.3d 1366, 1371 (Fed. Cir. 2000)).) The cases

Hospira cites, however, are not inconsistent with The Medicines Company's proposed standard. In *Caveney*, there was a third-party sale of the claimed invention to the public, which triggered the on-sale bar. *In re Caveney*, 761 F.2d at 676. And in *Zacharin*, the inventor disclosed his invention to a third party, "placed no restrictions on the [third party's] use or disclosure of the [invention]," and the third party entered into a contract with a supplier, thus placing the invention on sale. *Zacharin*, 231 F.3d at 1370. These cases do not support applying the on-sale bar to inventor-controlled transactions that do not place the invention in the public domain.

Hospira also argues that the *Buildex*, *Brasseler*, and *Ferag* decisions refused to "weaken the on-sale bar by excepting certain transactions based on the identity of the buyer or seller." (HBr. 45 (citing *Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1466 (Fed. Cir. 1988); *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 182 F.3d 888, 890 (Fed. Cir. 1999); *Ferag AG v. Quipp Inc.*, 45 F.3d 1562, 1565-67 (Fed. Cir. 1995)).) Yet in each of these cases, the on-sale bar was triggered because ***the patentee*** offered the invention for sale. As demonstrated below, these cases simply confirm that a patent holder's attempt to profit by offering the invention for sale triggers the on-sale bar. These cases do not support finding that confidential supplier-to-inventor transactions, under the inventor's control, are invalidating.

In *Buildex*, the patentee offered to sell the patented product to one of its customers. 849 F.2d at 1462. The Court held that "[the customer's] participation in the development of [the invention] does not excuse [the patentee's] attempt to commercialize the invention by offering it for sale" before the critical date. *Id*. at 1466.

In *Brasseler*, the buyer of the patented product (Brasseler) employed two of the four inventors. 182 F.3d at 889. DS Manufacturing (the seller) was owned by one of the inventors and it employed a second inventor. *Id*. Distinguishing a situation where a manufacturer sold the invention to a corporation employing the inventor, the Court held that "[b]y way of the sale to Brasseler, these inventors [DS Manufacturing] commercially exploited the invention prior to the critical date." *Id*. at 891.

Ferag concerned a transaction between a patentee and its U.S. distributor. 45 F.3d at 1564. For purposes of the on-sale bar, the Court treated the patentee and the distributor as separate entities because the patentee shared control over its distributor with another party. *Id*. at 1567. The Court held that when the patentee sent an order confirmation to its distributor for the patented product, the on-sale bar was triggered.[6] *Id*. at 1565-67.

[6] The Court also held that the patentee's sale of the invention to a newspaper publisher "independently supports the conclusion that [the patentee] had placed the invention on sale before the critical date." *Id*. at 1567.

2. This Standard Is Consistent with the Policies Underlying the On-Sale Bar

Applying *Special Devices* to find confidential supplier-to-inventor transactions invalidating does not further the policy goals of the on-sale bar. As articulated by the Supreme Court in *Pfaff*, the on-sale bar "serves as a limiting provision, both excluding ideas that are in the public domain from patent protection and confining the duration of the monopoly to the statutory term." 525 U.S. at 64. Furthermore, the on-sale bar encourages prompt disclosures of inventions to the public. *Woodland Trust*, 148 F.3d at 1370. None of these policy goals are implicated by contract manufacturing.

a. Contract Manufacturing Does Not Extend the Inventor's Market Exclusivity Beyond the Statutory Term

"The overriding concern of the on-sale bar is an inventor's attempt to commercialize his invention beyond the statutory term." *Atlanta Attachment*, 516 F.3d at 1365. But supplier-to-inventor transactions that are confidential and under the control of the inventor do not undermine this policy. They are merely the small inventor's means to do exactly what the large, vertically integrated company does when it can afford its own manufacturing plant. When the inventor does not release the invention to the market—i.e., does not sell or offer to sell it—he cannot profit from it and is not commercializing the invention.

b. Contract Manufacturing Does Not Remove Inventions from the Public Domain

A policy goal of the on-sale bar is to prevent removal of inventions from the public domain that the public has reasonably come to believe are freely available. *Pfaff*, 525 U.S. at 64. A supplier-to-inventor transaction that is confidential and remains under the control of the inventor, however, keeps the invention available only to the inventor for his "own secret, personal use" and does not remove the invention from the public domain. *Trading Techs.* 595 F.3d at 1361-62. Indeed, under such circumstances, the invention is not in the public domain in the first instance.

c. Contract Manufacturing Encourages Widespread Prompt Disclosure of the Invention

The use of contract manufacturing does not slow the disclosure of inventions, but in fact enables its introduction to the public. Inventors that employ contract manufacturers, such as The Medicines Company, do so because they lack their own manufacturing capabilities, or because they find it cost beneficial to use another entity's facilities instead of their own. *In re Kollar*, 286 F.3d at 1334 ("Many inventors do not have the resources to produce commercial embodiments of their inventions."). The use of contract manufacturing allows patentees to produce a product that they could not efficiently or otherwise create themselves, facilitating its release to the public.

Additionally, there are many pressures to file a patent application as soon as possible. These pressures include, for example: (i) the ever increasing universe of prior art that can be used against a patent application; (ii) the possibility that someone else will file an earlier application that covers the invention; (iii) the inability to obtain licensing revenue; and (iv) the difficulty in obtaining investment capital. Br. for the United States as *Amicus Curiae* at 17-18, *Micrel, Inc. v. Linear Tech. Corp.*, No. 02-39 (S. Ct. Apr. 18, 2003), http://www.justice.gov/sites/default/files/osg/briefs/2002/01/01/2002-0039.pet.ami.inv.pdf (last visited Feb. 23, 2016). Accordingly, it is unlikely that an inventor would deliberately delay filing a patent application for the sole purpose of postponing the critical date under the on-sale bar.

D. *Stare Decisis* Is Not an Obstacle to Clarifying the Principle of *Special Devices*

As discussed above, The Medicines Company requests that this Court clarify the no-supplier-exception principle in *Special Devices* to require that courts perform the full *Pfaff* analysis and recognize that not all supplier transactions trigger the on-sale bar. *Supra* Section II.C. Accordingly, an inventor's retention of a third party to manufacture or develop a claimed invention, confidentially and under the inventor's direction and control, is not and should not be an invalidating act under section 102(b). Hospira asserts that "*stare decisis* requires adherence to the principle of *Special Devices*." (HBr. 50.) However, because The Medicines

Company's request is consistent with the precedent of this Court and the Supreme Court, *stare decisis* is not applicable here. Indeed, this request is to ensure that the Supreme Court's principles, enunciated in *Pfaff*, are properly employed when analyzing supplier-to-inventor transactions.

Even if *stare decisis* were a consideration here, as Hospira contends, there is special justification to clarify the no-supplier-exception principle. The no-supplier-exception principle of *Special Devices* has caused courts to render decisions that are inconsistent with the Supreme Court's statutory decision in *Pfaff*. *Supra* Section II.A. Specifically, the no-supplier-exception principle has led courts to assume that supplier-to-inventor transactions are automatically "commercial" sales without performing the required *Pfaff* analysis. *Supra* Section II.A.

Contrary to Hospira's allegations, subsequent decisions, including those cited by Hospira, do call the no-supplier-exception rule of *Special Devices* into question. The *Hamilton Beach* dissent warned that "this [C]ourt must refrain from overlooking the Supreme Court's express requirement for a *commercial* offer for sale when deploying the no-supplier-exception rule." *Hamilton Beach*, 726 F.3d at 1381 (emphasis in original). And, this Court's precedent has held that "[i]nventors ***can*** request another entity's services in developing products embodying the invention without triggering the on-sale bar." *Trading Techs.*, 595 F.3d at 1361-62 (emphasis added). This precedent is consistent with the principle that confidential

supplier-to-inventor transactions under an inventor's direction and control do not trigger the on-sale bar.

Finally, Hospira asserts that when The Medicines Company "undertook the transactions at issue here, *Special Devices* was settled law." (HBr. 55.) This argument fails because *Special Devices* does not apply to these facts, and The Medicines Company never relied on a supplier exception. Unlike in *Special Devices*, the patented products here were not sold or offered for sale before the critical date. *Special Devices*, 270 F.3d at 1355 (The patentee did not contest that the transaction "constituted an offer for sale for purposes of section 102(b)."). Ben Venue acted on behalf of The Medicines Company and performed confidential manufacturing services to convert The Medicines Company's API into the finished drug product. Furthermore, as recognized by the District Court, the on-sale bar was not triggered because The Medicines Company paid Ben Venue for services, and Ben Venue never had title to a product that it could sell or offer to sell to anyone. Additionally, the batches at issue were experimental, as they were made to determine both whether the inventions solved the randomly high Asp^9 problem and to satisfy regulatory requirements. And, finally, The Medicines Company held the patented products under quarantine for its own secret, personal use until after the critical date.

CONCLUSION

In view of the above, the asserted claims of the patents-in-suit are not invalid under the on-sale bar of section 102(b). There was no commercial sale or offer for sale of the claimed products before the critical date. Ben Venue performed manufacturing services and never held title to any of the batches, and the pre-critical-date batches were experimental. Finally, to ensure predictability and uniformity, *Special Devices* should be clarified to recognize that confidential transactions from a supplier to an inventor, that are under the inventor's control, are not commercial sales and do not trigger the on-sale bar.

Dated: February 24, 2016

Respectfully submitted,

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