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

COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

EDGAR HAUG
PORTER F. FLEMING
ANGUS CHEN
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, New York 10151
(212) 588-0800

Attorneys for Plaintiff-Appellant
The Medicines Company

July 31, 2015

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:

Edgar H. Haug, Porter F. Fleming, Angus Chen, Robert E. Colletti, David A. Zwally, Mark P. Walters (former), Gina M. Bassi (former), all of Frommer Lawrence & Haug LLP; and

Frederick L. Cottrell, III, Jason J. Rawnsley, and Laura D. Hatcher (former), all of Richards, Layton & Finger, P.A.

Date: July 31, 2015

/s/ Edgar H. Haug
Edgar H. Haug
Counsel for Plaintiff-Appellant
The Medicines Company

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

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
"FDA"	United States Food and Drug Administration
"MBr.___"	Page number(s) of Response and Reply Brief of Plaintiff-Appellant The Medicines Company, ECF No. 29
"Op.___"	Citation to the Slip Opinion in *The Medicines Company v. Hospira, Inc.*, 14-1469 (Fed. Cir. July 2, 2015), attached as an addendum

FEDERAL CIRCUIT RULE 35(b) STATEMENT OF COUNSEL

Based on my professional judgment, I believe this appeal requires an answer to the following precedent-setting questions of exceptional importance:

(1) Whether contract manufacturing services confidentially performed by a third party on behalf of a patentee should invalidate product and product-by-process patents under the on-sale bar of 35 U.S.C. § 102(b) where:

(a) the claimed product was never sold, offered for sale, or commercially exploited before the critical date;

(b) the party accused of making a "sale" never had title to the product and only performed services for the patentee;

(c) the patentee held title to the product at all times before the critical date; and

(d) the third-party services concerned three experimental validation batches.

(2) Whether experimental validation batches, made to satisfy regulatory requirements and determine whether the inventions worked for their intended purpose, should fall within the "experimental use" exception of the on-sale bar.

(3) Whether a sale of services eliminates the need to show conception, reduction to practice, or that the invention is ready for patenting.

Based on my professional judgment, I further believe the Panel decision is at least contrary to the following decisions of the Supreme Court: *Pfaff v. Wells*

Electronics, Inc., 525 U.S. 55 (1998) and *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126 (1878).

Dated: July 31, 2015 By: /s/ Edgar H. Haug
Edgar H. Haug
Attorney of Record for
Plaintiff-Appellant The Medicines Company

PRELIMINARY STATEMENT

The Panel's decision held, for the first time, that "services" performed confidentially by a contract manufacturer constituted a "sale" of a patented product under 35 U.S.C. § 102(b). Although the claimed products at issue were not sold, offered for sale, or commercially exploited before the critical date, and were made for experimental purposes, these services were found to be a patent invalidating "sale." The Panel has now expanded the on-sale bar beyond any justifiable extension of precedent. As demonstrated below, there is no support for this outcome based on either the express language of the § 102 on-sale bar or controlling precedent, and the Panel and/or the Court en banc should rehear this case and fix this error.

The controlling facts in this case are undisputed. The patentee, The Medicines Company, retained a contract manufacturer, Ben Venue Laboratories ("Ben Venue"), to make three validation batches for regulatory purposes. The Medicines Company, a specialty pharmaceutical company, does not have its own manufacturing facilities and is not capable of making its products in-house. Ben

Venue—merely acting as a pair of laboratory hands—converted The Medicines Company's API into the drug product at its manufacturing facility. Ben Venue never held title or owned these experimental batches, let alone sold or offered to sell any of the batches. Before the critical date, these experimental batches were owned solely and at all times by The Medicines Company.

In addition to greatly expanding the on-sale bar, the Panel's holding also has wide-reaching consequences as it penalizes companies that cannot manufacture their products in their own facilities. Under this new precedent, companies with the ability to manufacture products in-house would have an advantage as the on-sale bar would not apply to such activities, while conversely companies that outsource manufacturing would be held to a different on-sale standard.

As discussed in further detail below, the Panel's decision is legally incorrect for at least the following reasons:

1. Finding an invalidating sale of "services" by a third party contract manufacturer where the patentee (and, for that matter, the contract manufacturer) did not sell, offer to sell, or commercially exploit the patented products in any way before the critical date;
2. Finding that the experimental use exception did not apply to the three validation batches, which were produced for FDA purposes and to determine whether the inventions actually worked for their intended purpose; and

3. Finding that a sale of "services" eliminated the need to show conception, reduction to practice, or that the invention was ready for patenting, thus disregarding the requirements of *Pfaff*.

ARGUMENT

I. The Panel Improperly Expanded the On-Sale Bar to Invalidate Patent Claims Based On a "Sale" of Manufacturing Services Where No Claimed Products Were Sold Before the Critical Date

A. The Claimed Product Was Not Sold Before the Critical Date

In its decision, the Panel found that "The Medicines Company paid Ben Venue for performing services that resulted in the patented product-by-process, and thus a 'sale' of services occurred." (Op.5.) Section 102(b) applies when "***the invention***" is sold or offered for sale. The patented inventions here are not services, and therefore there was no invalidating "sale of services." (Op.5.)

While it is ***undisputed*** that The Medicines Company retained title to its patented product and the ingredients used to make that product, the Panel incorrectly determined that Ben Venue's ***services*** in preparing three experimental validation batches constituted "a sale" of The Medicines Company's patented product under the on-sale bar provision of 35 U.S.C. § 102(b). Traditionally, this Court has found that section 102(b) applies when there has been a commercial sale or offer for sale of the invention. *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1361 (Fed. Cir. 2010). But now, in view of the Panel's decision, the on-sale bar will apply to contract manufacturing services for a patented product.

To support this enlargement of the on-sale bar, the Panel cites *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355 (Fed. Cir. 2001). (Op.5.) But *Special Devices* is inapposite because it held that:

> A "sale" under th[e on-sale bar] occurs when the parties offer or agree to reach "a contract . . . to give and ***pass rights of property*** for consideration which the buyer pays or promises to pay the seller for the thing bought or sold."

Id. (emphasis added). *Special Devices* does not support the Panel's new interpretation of the on-sale bar. The Court previously held that a "sale" occurs when "rights of property" are transferred. *Special Devices*, 270 F.3d at 1355; *Trading Techs.*, 595 F.3d at 1361. That did not occur in this case. Instead, The Medicines Company retained title at all times and did not pass rights of property to anyone. (Op.5.) Ben Venue merely performed laboratory services, was not a supplier, never held title, and could not pass any property rights to the patented product. Contrary to the Panel's statement, The Medicines Company never purchased pharmaceutical batches from Ben Venue. (Op.2.)

This new precedent is also inconsistent with the Uniform Commercial Code ("UCC"), which defines a "sale" as "the ***passing of title*** from the seller to the buyer for a price." UCC § 2-106(1) (emphasis added). This Court has consistently relied on the UCC in determining whether the on-sale bar of § 102(b) applies. *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047 (Fed. Cir. 2001). Nothing in the patent statute or this Court's precedent suggests that a sale of

services should be interpreted as a sale of a patented product. It was improper to equate an alleged sale of services with a commercial sale of products. (Op.5.)

B. The Medicines Company Did Not Commercially Exploit the Claimed Inventions Before the Critical Date

There was no commercial exploitation of the claimed product before the critical date. The Panel cited *D.L. Auld* for the proposition that "the intent of [invalidating claims under the on-sale bar] is to preclude attempts by the inventor or his assignee ***to profit from commercial use*** of an invention for more than a year before the application for patent is filed" and found that Ben Venue's "sale of the manufacturing services [] provided a ***commercial benefit*** to the inventor." (Op.4-5 (citing *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147 (Fed. Cir. 1983) (emphasis added)).) But the holding in *D.L. Auld* does not apply here. The patentee in *D.L. Auld* attempted to profit from his invention (a process) by actively shopping samples to potential customers. *Id.* In contrast, The Medicines Company did not sell or offer to sell, or attempt to profit from any of the claimed products before the critical date. (MBr.5, 47 (citing A16865, 883:12-17; A14634; A16860-64, 878:9-882:10; A14598; A14604; A14610).) Instead, the three validation batches at issue were made for regulatory FDA submission and to verify that the inventions worked for their intended purpose. Furthermore, Ben Venue—without any title or rights—did not sell or offer to sell any of the validation batches.

In addition, The Medicines Company did not receive "a commercial benefit" from the claimed product before the critical date. Contrary to the Panel's finding that "each batch had a commercial value of over $10 million" (Op.5), The Medicines Company did not make "over $10 million" for each validation batch before the critical date. *New Railhead Mfg., L.L.C. v. Vermeer Mfg., Co.*, 298 F.3d 1290, 1301 (Fed. Cir. 2002) (Dyk, J., dissenting) ("the use must provide a profit or commercial advantage *to the inventor*") (emphasis in original). The potential sales price of an unproven new pharmaceutical product is only a speculative "commercial benefit" that should not prospectively invalidate patent rights. At the time the validation batches were made, there was no guarantee that they could ever be sold under FDA regulations. Any 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 hired Ben Venue to perform manufacturing services for the validation batches to ascertain whether the intended product could be made. Ben Venue's services cost between $67,500 to $140,000 per validation batch, which is about 1% of the potential commercial value of each validation batch. (A17177-78; A17183.) This further demonstrates that Ben Venue was merely a pair of laboratory hands and was not attempting to sell the claimed product under the guise of services.

In finding that the validation batches were commercial, the Panel stated "Ben Venue marked the batches with commercial product codes and customer lot numbers and sent them to The Medicines Company for commercial and clinical packaging, consistent with the commercial sale of pharmaceutical drugs." (Op.5.) The Panel did not recognize, however, that these "product codes" and "lot numbers" are ***required*** by FDA regulations, regardless of whether the batch is to be sold or to be destroyed, and do not demonstrate that a batch is for commercial use. For example, 21 C.F.R. § 211.80(d) requires drug products to 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).

Likewise, records, such as the one relied upon by the Panel, are required to contain lot numbers and receiving codes. 21 C.F.R. § 211.184(a). Experimental pharmaceutical batches should not be artificially rendered "commercial" simply because they comply with FDA regulations. Indeed, even Hospira's own ANDA exhibit batch had a lot number ("PD8-021") and 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 lot

numbers and product codes, the existence of those numbers and codes has no bearing on whether the manufacture of those batches was commercial in nature. There is no record from the trial court to support the proposition that the three validation batches were "commercial."

In distinguishing the inventor's "secret, personal use" of the claimed methods in *Trading Techs.*, which did not give rise to the on-sale bar, the Panel incorrectly held that The Medicines Company's "batches were prepared for *commercial* exploitation . . . ." (Op.6. (citing *Trading Techs.*, 595 F.3d at 1361-62) (emphasis in original)). The Medicines Company, however, utilized Ben Venue as a mere set of hands to perform manufacturing services. (A16053, 73:5-13; A17177.) As in *Trading Techs.*, The Medicines Company hired Ben Venue to perform confidential services, none of which were performed in the public domain. Ben Venue never had title or property rights to the three experimental validation batches and thus was never in a position to offer to sell or sell those batches to The Medicines Company. (Op.4; A14673.) As in *Trading Techs.*, The Medicines Company "did not sell or offer for sale anything embodying the invention" before the critical date. *Trading Techs.*, 595 F.3d at 1361.

Further, the validation batches were not made for commercial purposes. The primary purpose of the validation batches was to ensure that they would meet FDA requirements and were thus experimental in nature. *See infra* Section II(B).

C. The Panel's Expansion of the On-Sale Bar Has Unintended Consequences and Places Parties on Unequal Footing

The Panel's expansion of the on-sale bar has the unintended consequence of penalizing companies that do not have the facilities or resources to conduct large-scale, in-house manufacturing or development work. These companies enlist and direct the services of third-party contract manufacturers to conduct experimental work. The Panel's decision sets an untenable precedent whereby utilizing a "set of hands" will trigger the on-sale bar.

In contrast, a company that can manufacture the claimed product at its own internal facilities will not trigger the on-sale bar. Likewise, a company with sufficient financial resources can enlist the services of a related corporate entity without engaging in a patent-invalidating activity. In effect, the Panel's decision places these two groups on unequal footing and stifles the innovative process of companies who are unable to manufacture their products at their own facilities.

II. The Panel Incorrectly Found that the Experimental Use Exception to the On-Sale Bar Did Not Apply

A. En Banc Review Is Warranted to Resolve a Conflict Between the Panel's Opinion and Precedent Regarding the Experimental Use Exception

The Panel makes conflicting statements regarding the legal standard for experimental use. First, it states that "experimental use cannot occur after a reduction to practice." (Op.6-7 (citing *In re Cygnus Telecomm. Tech., LLC Patent Litig.*, 536 F.3d 1343, 1356 (Fed. Cir. 2008)).) This is contrary to precedent,

which has found the experimental use exception to apply ***after*** a reduction to practice. *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 134 (1878) ("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 a use."); *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1369 (Fed. Cir. 2008) (Prost, J., concurring) ("Pfaff indicates that the experimental use doctrine should apply more broadly than the limited period suggested by a reduction to practice cutoff. . . . 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***.") (emphasis added); *see also* 2 Donald S. Chisum, *Chisum on Patents* § 6.02[7][b][i] (2015) (emphasis added) ("The better and prevailing view is that ***experimental use can*** indeed ***continue even after the invention has been completed and reduced to practice*** . . . ."). Second, later in its decision, the Panel states that "the experimental use defense may be available even if the invention had been reduced to practice if the inventor was unaware that the invention had been reduced to practice . . . ." (Op.7.) The inconsistent statements of law by this Panel highlight the confused status of the current experimental use framework. If the Panel used an incorrect legal framework to support its finding

that the experimental use exception does not apply here, its invalidity decision should be vacated.

B. The Validation Batches Were Prepared for FDA Regulatory Purposes—Not for Commercial Exploitation Before the Critical Date—and Were Experimental

Contrary to the Panel's finding, the three validation batches were experimental and therefore do not invalidate the asserted claims under section 102(b). Specifically, the batches were prepared to meet statutory and regulatory FDA requirements. Drug manufacturers are required under 21 U.S.C. § 351(a)(2)(B) to conform with current good manufacturing practices (CGMP):

> ***A drug . . . shall be deemed to be adulterated . . . if . . .*** the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding ***do not conform to or are not operated or administered in conformity with current good manufacturing practice*** to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

(emphasis added). CGMP regulations in turn 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 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.)

FDA Guidance documents that were in effect when the experimental validation batches were manufactured further confirm that these batches were made for validation purposes—not commercial purposes—and were experimental in nature. Specifically, the FDA's guidelines recommend 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 is why 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.) The above-described three validation batches were made using varying parameters to validate processes for FDA purposes. Furthermore, the batches were experimental in nature because they were made to determine whether the inventions worked for their intended purposes, i.e., that the inventions had low maximum Asp^9-bivalirudin impurity levels. *City of Elizabeth*, 97 U.S. at 137 (holding that an on-sale bar should not occur "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").

III. The Panel Improperly Collapsed the Two-Prong *Pfaff* Analysis When It Found that the Claimed Product Was Ready-for-Patenting Because It Was Allegedly "Sold"

The Panel's decision also undermines the Supreme Court's decision in *Pfaff v. Wells Electronics, Inc*., 525 U.S. 55, 67-68 (1998). Based solely on its determination that "the invention was sold," the Panel held that the inventions were ready for patenting.[1] (Op.8.) This is inconsistent with well-established Supreme Court precedent in *Pfaff*, which specifically held that the on-sale bar of § 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. *Pfaff*, 525 U.S. at 67-68. The Panel, however, collapsed the required two-prong *Pfaff* analysis into a single prong test—i.e., whether the invention was sold or offered for sale—and did not even analyze the second prong. This ignores the Supreme Court's clear statements in *Pfaff*, which require ***both*** prongs to be met in order for the on-sale bar to apply. *Id.*

Not only does the Panel's decision collapse the two-prong test of *Pfaff*, but it also finds that conception of the invention is not required. (Op.7.) The Panel cites *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.* (Op.6-7), but in that case it was undisputed that the claimed product was commercially sold prior to the critical

[1] The Panel did not construe the claims or address the appealed Markman issues before incorrectly finding that the "invention" was reduced to practice. The three validation batches were experimental and the inventors did not appreciate the claimed maximum Asp^9-bivalirudin impurity levels. (MBr. 33-36.)

date. 182 F.3d 1315, 1318 (Fed. Cir. 1999). That is not the case here. *See supra*. The Panel also ignores evidence that demonstrates that the inventors did not appreciate the claimed maximum Asp^9-bivalirudin impurity levels, and therefore could not have conceived—let alone reduced to practice—the patented inventions when the three validation batches were made. (A16893-94, 911:15-912:9; A16487, 506:11-20.) Accordingly, the inventions were not ready for patenting. It was wrong to ignore the second, required prong of *Pfaff*. The Panel's decision should be vacated.

CONCLUSION

The Panel's expansion of the on-sale bar to include contract manufacturing services for a patented product goes against and beyond the language of § 102(b) and well-established precedent. This decision will have a far-reaching impact on future patent litigations and would unfairly trigger the on-sale bar for companies that do not have the ability to manufacture their products in-house. It was also wrong to eliminate the experimental use exception here and to collapse the two-prong *Pfaff* requirement to a single prong. The Panel or the Court en banc should rehear this case and vacate the July 2, 2015 decision.

Dated: July 31, 2015

Respectfully submitted,

By: /s/ Edgar H. Haug

Edgar H. Haug
Porter F. Fleming
Angus Chen
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151
Tel: (212) 588-0800
Fax: (212) 588-0500

Counsel for Plaintiff-Appellant The Medicines Company

ADDENDUM

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, Judge Richard G. Andrews.

Decided: July 2, 2015

EDGAR HAUG, Frommer Lawrence & Haug LLP, New York, NY, argued for plaintiff-appellant. Also represented by PORTER F. FLEMING, ANGUS CHEN.

BRADFORD PETER LYERLA, Jenner & Block LLP, Chicago, IL, argued for defendant-cross-appellant. Also represented by SARA TONNIES HORTON, AARON A. BARLOW.

Before DYK, WALLACH, and HUGHES, *Circuit Judges*.

HUGHES, *Circuit Judge*.

The Medicines Company appeals the U.S. District Court for the District of Delaware's claim construction and non-infringement findings. Hospira, Inc. cross-appeals the district court's determination that the asserted claims are not invalid under the on-sale bar, obviousness, or indefiniteness. We conclude that the district court clearly erred in finding that the bivalirudin batches prepared by Ben Venue Laboratories before the critical date were not sold to The Medicines Company and were prepared primarily for an experimental purpose. Accordingly, we reverse the district court's validity determination and hold the asserted claims invalid under the on-sale bar.

I

The Medicines Company owns U.S. Patent No. 7,582,727 and U.S. Patent No. 7,598,343. The patents relate to the drug bivalirudin, a synthetic peptide used as an anti-coagulant. Bivalirudin is generally mixed with saline or water and administered intravenously. Because bivalirudin's acidity in saline or water makes it undesirable for injection, its pH is adjusted during compounding to make it more alkaline.

The Medicines Company sells a bivalirudin drug for injection under the Angiomax® brand. From 1997 to October 2006, The Medicines Company purchased pharmaceutical batches of Angiomax® from Ben Venue Laboratories. In 2005, Ben Venue created a batch of bivalirudin with levels of Asp^9-bivalirudin impurity that exceeded the Food and Drug Administration's approved maximum of 1.5%. Accordingly, The Medicines Company could not use the batch.

After another batch failure, The Medicines Company hired a consultant, Dr. Musso, to investigate and resolve the issue. Dr. Musso discovered that certain methods of

adding a pH-adjusting solution during the compounding process minimize the Asp^9-bivalirudin impurity to less than 0.6%. In July 2008, The Medicines Company filed applications for the '343 and '727 patents, which include product-by-process claims describing this discovery.

Over one year before filing these applications, however, The Medicines Company hired Ben Venue to prepare three batches of bivalirudin using an embodiment of the patented method. Each invoice for these services identifies a "charge to manufacture Bivalirudin lot." *See* JA17177–79. Each invoice also states that the bivalirudin lot was or will be released to The Medicines Company. JA17177 ("Release pending final validation report."); JA17178 (same); JA17179 ("Batch released and held at Ben Venue pending shipping instructions."). Each lot was marked with a commercial product code and a customer lot number, and was released to The Medicines Company for commercial and clinical packaging.

On August 19, 2010, The Medicines Company sued Hospira, Inc., alleging that two of Hospira's ANDA filings infringe 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 bench trial, found the patents not infringed and not invalid as obvious, indefinite, or under the on-sale bar. The Medicines Company appeals the district court's claim construction and finding of non-infringement. Hospira appeals the district court's holdings on obviousness, indefiniteness, and the on-sale bar. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II

On appeal from a bench trial, we review a district court's legal determinations de novo and factual findings for clear error. *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1358 (Fed. Cir. 2014). Invalidity under the on-sale bar is a question of law with underlying questions

of fact. *Robotic Vision Sys., Inc. v. View Eng'g, Inc.*, 249 F.3d 1307, 1310 (Fed. Cir. 2001).

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. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67–68 (1998).

The district court found that the claimed invention was ready for patenting but not commercially offered for sale before the critical date. Hospira disputes the district court's finding that the claimed invention was not commercially offered for sale, and The Medicines Company disputes the district court's finding that the claimed invention was ready for patenting.

A

The district court concluded that no commercial sale occurred because: (1) Ben Venue only sold manufacturing services, not pharmaceutical batches; and (2) the batches fall under the experimental use exception.

While the district court is correct that Ben Venue invoiced the sale as manufacturing services and title to the pharmaceutical batches did not change hands, that does not end the inquiry. As we have explained, "the intent of [invalidating claims under the on-sale bar] 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." *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147 (Fed. Cir. 1983). To ensure the doctrine is not easily circumvented, we have found the on-sale bar to apply 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. For example, in *D.L. Auld Co.*, we found the on-sale bar to apply where, before the critical

date, an inventor sold products made by the patented method. *Id.*; *see also W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983); *cf. Kinzenbaw v. Deere & Co.*, 741 F.2d 383, 390–91 (Fed. Cir. 1984) (finding a third party's testing of the "warrantability, durability, and acceptability" of a commercial embodiment of a patented product before the critical date was an invalidating public use under § 102(b) because it "served Deere's commercial purposes").

We find no principled distinction between the commercial sale of products prepared by the patented method at issue in *D.L. Auld Co.* and the commercial sale of services that result in the patented product-by-process here. The Medicines Company paid Ben Venue for performing services that resulted in the patented product-by-process, and thus a "sale" of services occurred. *See Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355 (Fed. Cir. 2001) ("A 'sale' under th[e on-sale bar] occurs when the parties offer or agree to reach 'a contract . . . to give and pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold.'" (quoting *Zacharin v. United States*, 213 F.3d 1366, 1370 (Fed. Cir. 2000))). As in *D.L. Auld Co.*, the sale of the manufacturing services here provided a commercial benefit to the inventor more than one year before a patent application was filed. Ben Venue's services were performed to prove to the FDA that The Medicines Company's product met the already-approved specifications for finished bivalirudin product. Additionally, Ben Venue marked the batches with commercial product codes and customer lot numbers and sent them to The Medicines Company for commercial and clinical packaging, consistent with the commercial sale of pharmaceutical drugs. This commercial activity was not insignificant; The Medicines Company admits that each batch had a commercial value of over $10 million.

Accordingly, we find that the district court clearly erred in finding the Ben Venue sale of services did not constitute a commercial sale. To find otherwise would allow The Medicines Company to circumvent the on-sale bar simply because its contracts happened to only cover the processes that produced the patented product-by-process. This would be inconsistent with our principle that "no 'supplier' exception exists for the on-sale bar." *Special Devices*, 270 F.3d at 1357.

This is not a case where the inventors have requested another entity's services in developing products embodying the invention without triggering the on-sale bar. *See Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1361–62 (Fed. Cir. 2010). The batches were prepared for *commercial* exploitation, and this is not the type of "secret, personal use" described in *Trading Technologies*. Indeed, the preparation of the batches was described as an "Optimization Study," and was performed because "several opportunities for further optimization of the formulation process were identified" after "successful[] validat[ion] in a previous validation study." J.A. 14882–83.

Moreover, "[i]f a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics." *Abbott Labs. v. Geneva Pharm.*, 182 F.3d 1315, 1319 (Fed. Cir. 1999). There is no dispute that the batches had the levels of Asp^9-bivalirudin required by the claims. Thus, it is irrelevant whether The Medicines Company knew that the process limitations of the asserted claims reliably and consistently produced levels of Asp^9-bivalirudin below 0.6%.

The district court also clearly erred in finding that the experimental use doctrine bars the application of the on-sale bar to the Ben Venue batches. "[E]xperimental use

cannot occur after a reduction to practice." *In re Cygnus Telecomm. Tech., LLC Patent Litig.*, 536 F.3d 1343, 1356 (Fed. Cir. 2008). The Medicines Company asserts that it had not reduced the invention to practice when the batches were made because it did not appreciate the maximum impurity level limitation of the claimed invention until after twenty-five batches of bivalirudin were manufactured according to The Medicine Company's new process. "However, we have held that where an invention is on sale, conception is not required to establish reduction to practice." *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1331 (Fed. Cir. 2001) (citation omitted). In other words, "[t]he sale of the [invention] in question obviates any need for inquiry into conception." *Abbott Labs.*, 182 F.3d at 1318–19. To be sure, *Abbott* and *Scaltech* did not involve experimental use, and the experimental use defense may be available even if the invention had been reduced to practice if the inventor was unaware that the invention had been reduced to practice (i.e., worked for its intended purpose) and continued to experiment. *See New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1297 (Fed. Cir. 2002) ("'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.' . . . Once an inventor realizes that the invention as later claimed works for its intended purpose, further 'experimentation' may constitute a barring public use." (quoting *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 98 F.3d 1318, 1324 (Fed. Cir. 1996))). This is not a situation in which the inventor was unaware that the invention had been reduced to practice, and was experimenting to determine whether that was the case. The batches sold satisfied the claim limitations, and the inventor was well aware that the batches had levels of Asp^9-bivalirudin well below the claimed levels of 0.6%.

B

An invention is ready for patenting when, before the critical date, the invention is reduced to practice; or is depicted in drawings or described in writings of sufficient nature to enable a person of ordinary skill in the art to practice the invention. *Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc.*, 726 F.3d 1370, 1375 (Fed. Cir. 2013).

The Medicines Company argues that the district court erred in finding its invention was ready for patenting because there was no reduction to practice and the inventors had not prepared drawings or written descriptions sufficient to enable a person skilled in the art to practice the invention. But 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. Thus, the district court did not clearly err in finding the invention was ready for patenting.

III

Because the district court did not err in finding that the claimed invention was ready for patenting, but clearly erred in finding that the claimed invention was not commercially offered for sale before the critical date, we reverse the district court's determination that the on-sale bar does not apply. Accordingly, we hold the asserted claims invalid, and decline to reach the other issues raised by the parties.

REVERSED

FORM 30. Certificate of Service

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF SERVICE

I certify that I served a copy on counsel of record on July 31, 2015 by:

- ☐ US mail
- ☐ Fax
- ☐ Hand
- ☒ Electronic Means
  (by email or CM/ECF)

Porter F. Fleming
Name of Counsel

/s/ Porter F. Fleming
Signature of Counsel

Law Firm: Frommer Lawrence & Haug LLP

Address: 745 Fifth Avenue

City, State, ZIP: New York, NY 10151

Telephone Number: 212-588-0800

FAX Number: 212-588-0500

E-mail Address: pfleming@flhlaw.com

NOTE: For attorneys filing documents electronically, the name of the filer under whose log-in and password a document is submitted must be preceded by an "/s/" and typed in the space where the signature would otherwise appear. Graphic and other electronic signatures are discouraged.