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