SUPREME COURT OF THE UNITED STATES

Helsinn Healthcare S. A. v. Teva Pharmaceuticals USA, Inc.

139 S. Ct. 628 (2019) · No. 17-1229 · Decided January 22, 2019

OPINION

CLARENCE THOMAS, J.

(Slip Opinion) OCTOBER TERM, 2018 1 Syllabus NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See United States v. Detroit Timber & Lumber Co., 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES Syllabus HELSINN HEALTHCARE S. A. v. TEVA PHARMACEUTICALS USA, INC., ET AL. CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT No. 17–1229. Argued December 4, 2018 —Decided January 22, 2019 Petitioner Helsinn Healthcare S. A. makes a treatment for chemotherapy-induced nausea and vomiting using the chemical palonosetron.

While Helsinn was developing its palonosetron product, it entered into two agreements with another company granting that company the right to distribute, promote, market, and sell a 0.25 mg dose of palonosetron in the United States.

The agreements required that the company keep confidential any proprietary information received under the agreements. Nearly two years later, in January 2003, Hel- sinn filed a provisional patent application covering a 0.25 mg dose of palonosetron. Over the next 10 years, Helsinn filed four patent ap- plications that claimed priority to the January 2003 date.

Relevant here, Helsinn filed its fourth patent application in 2013. That patent (the ’219 patent) covers a fixed dose of 0.25 mg of palonosetron in a 5 ml solution and is covered by the Leahy-Smith America Invents Act (AIA).

In 2011, respondents Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc. (collectively Teva), sought approval to market a generic 0.25 mg palonosetron product. Helsinn sued Teva for infringing its patents, including the ’219 patent. Teva coun- tered that the ’219 patent was invalid under the “on sale” provision of the AIA—which precludes a person from obtaining a patent on an in- vention that was “in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention,” 35 U. S. C. §102(a)(1)—because the 0.25 mg dose was “on sale” more than one year before Helsinn filed the provisional patent application in 2003.

The District Court held that the AIA's "on sale" provision did not apply because the public disclosure of the agreements did not 2 HELSINN HEALTHCARE S. A. v. TEVA PHARMACEUTICALS USA, INC. Syllabus disclose the 0.25 mg dose.

The Federal Circuit reversed, holding that the sale was publicly disclosed, regardless of whether the details of the invention were publicly disclosed in the terms of the sale agree- ments. Held: A commercial sale to a third party who is required to keep the invention confidential may place the invention "on sale" under §102(a).

The patent statute in force immediately before the AIA in- cluded an on-sale bar. This Court's precedent interpreting that pro- vision supports the view that a sale or offer of sale need not make an invention available to the public to constitute invalidating prior art. See, e.g., Pfaff v. Wells Electronics, Inc., 525 U. S. 55, 67.

The Feder- al Circuit had made explicit what was implicit in this Court's pre-AIA precedent, holding that "secret sales" could invalidate a patent. Spe- cial Devices, Inc. v. OEA, Inc., 270 F. 3d 1353, 1357. Given this set- tled pre-AIA precedent, the Court applies the presumption that when Congress reenacted the same "on sale" language in the AIA, it adopt- ed the earlier judicial construction of that phrase.

The addition of the catchall phrase "or otherwise available to the public" is not enough of a change for the Court to conclude that Congress intended to alter the meaning of "on sale." Paroline v. United States, 572 U. S. 434, and Federal Maritime Comm'n v. Seatrain Lines, Inc., 411 U. S. 726, distinguished. Pp. 5–9. 855 F. 3d 1356, affirmed. THOMAS, J., delivered the opinion for a unanimous Court.

Cite as: 586 U. S. ____ (2019) 1 Opinion of the Court NOTICE: This opinion is subject to formal revision before publication in the preliminary print of the United States Reports. Readers are requested to notify the Reporter of Decisions, Supreme Court of the United States, Wash- ington, D. C. 20543, of any typographical or other formal errors, in order that corrections may be made before the preliminary print goes to press.

SUPREME COURT OF THE UNITED STATES _____ No. 17–1229 _____ HELSINN HEALTHCARE S. A., PETITIONER v. TEVA PHARMACEUTICALS USA, INC., ET AL. ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT [January 22, 2019] JUSTICE THOMAS delivered the opinion of the Court.

The Leahy-Smith America Invents Act (AIA) bars a person from receiving a patent on an invention that was "in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." 35 U. S. C. §102(a)(1). This case requires us to decide

whether the sale of an invention to a third party who is contractually obligated to keep the invention confidential places the invention “on sale” within the meaning of §102(a).

More than 20 years ago, this Court determined that an invention was “on sale” within the meaning of an earlier version of §102(a) when it was “the subject of a commercial offer for sale” and “ready for patenting.” Pfaff v. Wells Electronics, Inc., 525 U. S. 55, 67 (1998).

We did not fur- ther require that the sale make the details of the inven- tion available to the public. In light of this earlier con- struction, we determine that the reenactment of the phrase “on sale” in the AIA did not alter this meaning.

Accordingly, a commercial sale to a third party who is required to keep the invention confidential may place the 2 HELSINN HEALTHCARE S. A. v. TEVA PHARMACEUTICALS USA, INC. Opinion of the Court invention “on sale” under the AIA. I Petitioner Helsinn Healthcare S. A. (Helsinn) is a Swiss pharmaceutical company that makes Aloxi, a drug that treats chemotherapy-induced nausea and vomiting.

Hel- sinn acquired the right to develop palonosetron, the active ingredient in Aloxi, in 1998. In early 2000, it submitted protocols for Phase III clinical trials to the Food and Drug Administration (FDA), proposing to study a 0.25 mg and a 0.75 mg dose of palonosetron.

In September 2000, Helsinn announced that it was beginning Phase III clinical trials and was seeking marketing partners for its palonosetron product. Helsinn found its marketing partner in MGI Pharma, Inc. (MGI), a Minnesota pharmaceutical company that markets and distributes drugs in the United States. Helsinn and MGI entered into two agreements: a license agreement and a supply and purchase agreement.

The license agreement granted MGI the right to distribute, promote, market, and sell the 0.25 mg and 0.75 mg doses of palonosetron in the United States. In return, MGI agreed to make upfront payments to Helsinn and to pay future royalties on distribution of those doses.

Under the supply and purchase agreement, MGI agreed to purchase exclusively from Helsinn any palonosetron product ap- proved by the FDA. Helsinn in turn agreed to supply MGI however much of the approved doses it required. Both agreements included dosage information and required MGI to keep confidential any proprietary information received under the agreements.

Helsinn and MGI announced the agreements in a joint press release, and MGI also reported the agreements in its Form 8–K filing with the Securities and Exchange Com- mission. Although the 8–K filing included redacted copies of the agreements, neither the 8–K filing nor the press Cite as: 586 U. S. ____ (2019) 3 Opinion of the Court releases disclosed the specific dosage formulations covered by the agreements.

On January 30, 2003, nearly two years after Helsinn and MGI entered into the agreements, Helsinn filed a provisional patent application covering the 0.25 mg and 0.75 mg doses of palonosetron. Over the next 10 years, Helsinn filed four patent applications that claimed priority to the January 30, 2003, date of the provisional applica- tion. Helsinn filed its fourth patent application—the one relevant here—in May 2013, and it issued as U. S. Patent No. 8,598,219 ('219 patent).

The '219 patent covers a fixed dose of 0.25 mg of palonosetron in a 5 ml solution. By virtue of its effective date, the '219 patent is governed by the AIA. See §101(i). Respondents Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc. (Teva), are, respectively, an Israeli company that manufactures generic drugs and its American affiliate.

In 2011, Teva sought approval from the FDA to market a generic 0.25 mg palonosetron prod- uct. Helsinn then sued Teva for infringing its patents, including the '219 patent. In defense, Teva asserted that the '219 patent was invalid because the 0.25 mg dose was "on sale" more than one year before Helsinn filed the provisional patent application covering that dose in Janu- ary 2003.

The AIA precludes a person from obtaining a patent on an invention that was "on sale" before the effective filing date of the patent application: "A person shall be entitled to a patent unless... the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." 35 U. S. C. §102(a)(1) (em- phasis added).

See also §102(b)(1) (exception for certain disclosures made 4 HELSINN HEALTHCARE S. A. v. TEVA PHARMACEUTICALS USA, INC. Opinion of the Court within a year before the effective filing date). Disclosures described in §102(a)(1) are often referred to as "prior art." The patent statute in effect before the passage of the AIA included a similar proscription, known as the "on-sale bar": "A person shall be entitled to a patent unless— "(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the in- vention thereof by the applicant for patent, or "(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U. S. C. §§102(a)–(b) (2006 ed.) (emphasis added).

The District Court determined that the "on sale" provi- sion did not apply. It concluded that, under the AIA, an invention is not "on sale" unless the sale or offer in ques- tion made the claimed invention available to the public. Helsinn Healthcare S. A. v. Dr. Reddy's Labs. Ltd., 2016 WL 832089, *45, *51 (D NJ, Mar. 3, 2016).

Because the companies' public disclosure of the agreements between Helsinn and MGI did not disclose the 0.25 mg dose, the court determined that the invention was not "on sale" before the

critical date. Id., at *51–*52.

The Federal Circuit reversed. 855 F. 3d 1356, 1360 (2017). It concluded that “if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale” to fall within the AIA’s on- sale bar. Id., at 1371.

Because the sale between Helsinn and MGI was publicly disclosed, it held that the on-sale bar applied. Id., at 1364, 1371. We granted certiorari to determine whether, under the AIA, an inventor’s sale of an invention to a third party Cite as: 586 U. S. ____ (2019) 5 Opinion of the Court who is obligated to keep the invention confidential quali- fies as prior art for purposes of determining the patent- ability of the invention.

585 U. S. ___ (2018). We conclude that such a sale can qualify as prior art. II A The United States Constitution authorizes Congress “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discover- ies.” Art. 1, §8, cl. 8.

Under this grant of authority, Con- gress has crafted a federal patent system that encourages “the creation and disclosure of new, useful, and nonobvi- ous advances in technology and design” by granting inven- tors “the exclusive right to practice the invention for a period of years.” Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U. S. 141, 151 (1989).

To further the goal of “motivating innovation and en- lightenment” while also “avoiding monopolies that unnec- essarily stifle competition,” Pfaff, 525 U. S., at 63, Con- gress has imposed several conditions on the “limited opportunity to obtain a property right in an idea,” Bonito Boats, supra, at 149. One such condition is the on-sale bar, which reflects Congress’ “reluctance to allow an in- ventor to remove existing knowledge from public use” by obtaining a patent covering that knowledge.

Pfaff, supra, at 64; see also Pennock v. Dialogue, 2 Pet. 1, 19 (1829) (explaining that “it would materially retard the progress of science and the useful arts” to allow an inventor to “sell his invention publicly” and later “take out a patent” and “exclude the public from any farther use than what should be derived under it”). Every patent statute since 1836 has included an on-sale bar.

Pfaff, supra, at 65. The patent statute in force im- mediately before the AIA prevented a person from receiv- 6 HELSINN HEALTHCARE S. A. v. TEVA PHARMACEUTICALS USA, INC. Opinion of the Court ing a patent if, “more than one year prior to the date of the application for patent in the United States,” “the invention was... on sale” in the United States. 35 U. S. C. §102(b) (2006 ed., Supp. IV).

The AIA, as relevant here, retained the on-sale bar and added the catchall phrase “or other- wise available to the public.” §102(a)(1) (2012 ed.) (“A person shall be entitled to a patent unless” the

"claimed invention was... in public use, on sale, or otherwise available to the public... ").

We must decide whether these changes altered the meaning of the "on sale" bar. We hold that they did not. B Congress enacted the AIA in 2011 against the backdrop of a substantial body of law interpreting §102's on-sale bar.

In 1998, we determined that the pre-AIA on-sale bar applies "when two conditions are satisfied" more than a year before an inventor files a patent application. Pfaff, 525 U. S., at 67. "First, the product must be the subject of a commercial offer for sale." Ibid. "Second, the invention must be ready for patenting," which we explained could be shown by proof of "reduction to practice" or "drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." Id., at 67–68.

Although this Court has never addressed the precise question presented in this case, our precedents suggest that a sale or offer of sale need not make an invention available to the public. For instance, we held in Pfaff that an offer for sale could cause an inventor to lose the right to patent, without regard to whether the offer discloses each detail of the invention.

E.g., id., at 67. Other cases focus on whether the invention had been sold, not whether the details of the invention had been made available to the public or whether the sale itself had been publicly dis- closed. E.g., Consolidated Fruit-Jar Co. v. Wright, 94 Cite as: 586 U. S. ____ (2019) 7 Opinion of the Court U. S. 92, 94 (1877) ("[A] single instance of sale or of use by the patentee may, under the circumstances, be fatal to the patent... "); cf. Smith & Griggs Mfg.

Co. v. Sprague, 123 U. S. 249, 257 (1887) ("A single sale to another... would certainly have defeated his right to a patent... "); Eliza- beth v. Pavement Co., 97 U. S. 126, 136 (1878) ("It is not a public knowledge of his invention that precludes the in- ventor from obtaining a patent for it, but a public use or sale of it").

The Federal Circuit—which has "exclusive jurisdiction" over patent appeals, 28 U. S. C. §1295(a)—has made explicit what was implicit in our precedents. It has long held that "secret sales" can invalidate a patent. E.g., Special Devices, Inc. v. OEA, Inc., 270 F. 3d 1353, 1357 (2001) (invalidating patent claims based on "sales for the purpose of the commercial stockpiling of an invention" that "took place in secret"); Woodland Trust v. Flowertree Nursery, Inc., 148 F. 3d 1368, 1370 (1998) ("Thus an in- ventor's own prior commercial use, albeit kept secret, may constitute a public use or sale under §102(b), barring him from obtaining a patent").

In light of this settled pre-AIA precedent on the mean- ing of "on sale," we presume that when Congress reenacted the same language in the AIA, it adopted the earlier judi- cial construction of that phrase. See Shapiro v. United States, 335 U. S. 1, 16 (1948) ("In adopting the language used in the earlier act, Congress 'must be considered to have adopted also the construction given by this Court to such language, and made it a part of the enactment' ").

The new §102 retained the exact language used in its predecessor statute ("on sale") and, as relevant here, added only a new catchall clause ("or otherwise available to the public"). As amicus United States noted at oral argument, if "on sale" had a settled meaning before the AIA was adopted, then adding the phrase "or otherwise available to the public" to the statute "would be a fairly 8 HELSINN HEALTHCARE S. A. v. TEVA PHARMACEUTICALS USA, INC. Opinion of the Court oblique way of attempting to overturn" that "settled body of law." Tr. of Oral Arg.

28. The addition of "or otherwise available to the public" is simply not enough of a change for us to conclude that Congress intended to alter the meaning of the reenacted term "on sale." Cf. Holder v. Martinez Gutierrez, 566 U. S. 583, 593 (2012) (determining that a reenacted provision did not ratify an earlier judicial construction where the provision omitted the word on which the prior judicial constructions were based).

Helsinn disagrees, arguing that our construction reads "otherwise" out of the statute. Citing Paroline v. United States, 572 U. S. 434 (2014), and Federal Maritime Comm'n v. Seatrain Lines, Inc., 411 U. S. 726 (1973), Helsinn contends that the associated-words canon re- quires us to read "otherwise available to the public" to limit the preceding terms in §102 to disclosures that make the claimed invention available to the public.

As an initial matter, neither of the cited decisions ad- dresses the reenactment of terms that had acquired a well-settled judicial interpretation. And Helsinn's argu- ment places too much weight on §102's catchall phrase. Like other such phrases, "otherwise available to the pub- lic" captures material that does not fit neatly into the statute's enumerated categories but is nevertheless meant to be covered.

Given that the phrase "on sale" had ac- quired a well-settled meaning when the AIA was enacted, we decline to read the addition of a broad catchall phrase to upset that body of precedent. III Helsinn does not ask us to revisit our pre-AIA interpre- tation of the on-sale bar. Nor does it dispute the Federal Circuit's determination that the invention claimed in the '219 patent was "on sale" within the meaning of the pre- AIA statute.

Because we determine that Congress did not alter the meaning of "on sale" when it enacted the AIA, we Cite as: 586 U. S. ____ (2019) 9 Opinion of the Court hold that an inventor's sale of an invention to a third party who is obligated to keep the invention confidential can qualify as prior art under §102(a).

We therefore af- firm the judgment of the Federal Circuit. It is so ordered.