Intellectual Property and Innovation American Inn of Court

Thursday, May 16, 2019

Inn Luncheon Roundtable

CLE Materials

Topic
Helsinn Healthcare v. Teva Pharmaceuticals and the On-Sale Bar

Facilitated By
Albany | Shahrokh Falati, Assistant Professor and Director of Programs for Patents, Technology Transfer, Innovation and Entrepreneurship, Albany Law School

Syracuse | George McGuire, Member, Bond Schoeneck & King

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Helsinn Healthcare v. Teva Pharmaceuticals and the On-Sale Bar

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Pre-AIA On-Sale Bar

- 35 U.S.C. 102(b) (pre-AIA) provides, "A person shall be entitled to a patent unless . . . 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."
  - The on-sale bar is only triggered by domestic sales.
- In *Pfaff v. Wells Electronics* (1998), the Supreme Court established a two-part test for apply the on-sale bar.
  - "First, the product must be the subject of a commercial offer for sale."
  - "Second, the invention must be ready for patenting."
    - "[This] condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention."

AIA On-Sale Bar

- 35 U.S.C. 102(a)(1) now provides, "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."
  - The on-sale bar is triggered by sales anywhere in the world.
  - The phrase "otherwise available to the public" might suggest that sales must be public to trigger the on-sale bar.
- In *Helsinn Healthcare v. Teva Pharmaceuticals* (2019) , the Supreme Court addressed "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 th[is current] meaning of §102(a)."

Helsinn Healthcare v. Teva Pharmaceuticals | Facts of the Case

- Helsinn Healthcare owns four patents describing various formulations of a drug that treats chemotherapy-related nausea and vomiting that claim priority to a provisional patent application filed on January 30, 2003.
- Therefore, the critical date for the on-sale bar is January 30, 2002 and any sales before that date can invalidate the patent.
- Prior to January 30, 2002, Helsinn Healthcare entered into a license agreement and a supply and purchase agreement with MGI Pharma.
    - Under the license agreement, Helsinn Healthcare granted MGI Pharma the right to distribute, promote, market, and sell the drug in the United States.
    - Under the supply and purchase agreement, MGI Pharma agreed to purchase the drug exclusively from Helsinn Healthcare.
    - Although the agreements required the parties to keep proprietary information confidential, their execution was announced in a joint press release.
- In 2011, Teva Pharmaceuticals sought FDA approval for a generic version of the drug.

Helsinn Healthcare v. Teva Pharmaceuticals | Procedural History

- Helsinn Healthcare sued Teva Pharmaceuticals for patent infringement. Teva Pharmaceuticals countered that the patents are invalid because the agreements with MGI Pharma put the drug "on sale" more than one year before the provisional application was filed on January 30, 2003.
- The District Court upheld the patents and concluded the on-sale bar requires that the sale make the invention available to the public. (The press release did not disclose the technical details of the invention.)
- The Federal Circuit reversed, concluding that because the existence of the sale was made public, the on-sale bar is applicable.

Helsinn Healthcare v. Teva Pharmaceuticals | Opinion

- The Supreme Court held 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)."
- The Supreme Court explained that the added phrase "or otherwise available to the public" to the AIA on-sale bar does not alter the pre-AIA judicial interpretation of the phrase "on sale."

Post-*Helsinn* Hypothetical

- HoodiePillow® is a start-up company that has developed a travel pillow with a sweatshirt hood that provides travelers with increased warmth, privacy, and comfort. HoodiePillow® has not yet filed a patent application on this product. To date, they have made very small quantities of pillows by hand but they do not have the manufacturing facilities or capacity for larger, commercial runs of pillows. To produce adequate quantities of product, HoodiePillow® is interested in using a third-party manufacturer.
- What should HoodiePillow® consider to minimize the risk that an agreement with a third-party manufacturer will be considered a public sale (or other disclosure) under 35 U.S.C. 102?

35 U.S.C. 102 (PRE-AIA) CONDITIONS FOR PATENTABILITY; NOVELTY AND LOSS OF RIGHT TO PATENT.

[Editor Note: With the exception of subsection (g)*), not applicable to any patent application subject to the first inventor to file provisions of the AIA (see 35 U.S.C. 100 (note)). See 35 U.S.C. 102 for the law otherwise applicable.]

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 invention 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, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in — (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or

(f) he did not himself invent the subject matter sought to be patented, or

(g) (1) during the course of an interference conducted under section 135 orsection 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

(Amended July 28, 1972, Public Law 92-358, sec. 2, 86 Stat. 501; Nov. 14, 1975, Public Law 94-131, sec. 5, 89 Stat. 691; subsection (e) amended Nov. 29, 1999, Public Law 106-113, sec. 1000(a)(9), 113 Stat. 1501A-565 (S. 1948 sec. 4505); subsection (g) amended Nov. 29, 1999, Public Law 106-113, sec. 1000(a)(9), 113 Stat. 1501A-590 (S. 1948 sec. 4806); subsection (e) amended Nov. 2, 2002, Public Law 107-273, sec. 13205, 116 Stat. 1903.)

(Public Law 112-29, sec. 14, 125 Stat. 284 (Sept. 16, 2011) provided that tax strategies are deemed to be within the prior art (see AIA § 14).)

*NOTE: The provisions of 35 U.S.C. 102(g), as in effect on March 15, 2013, shall apply to each claim of an application for patent, and any patent issued thereon, for which the first inventor to file provisions of the AIA apply (see 35 U.S.C. 100 (note), if such application or patent contains or contained at any time—

(A) a claim to an invention having an effective filing date as defined in section 100(i) of title 35, United States Code, that occurs before March 16, 2013; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

SUPREME COURT OF THE UNITED STATES

Syllabus

PFAFF *v.* WELLS ELECTRONICS, INC.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 97–1130. Argued October 6, 1998– Decided November 10, 1998

Under §102(b) of the Patent Act of 1952, no one can patent an "invention" that has been "on sale" more than one year before filing a patent application. In early 1981, petitioner Pfaff designed a new computer chip socket and sent detailed engineering drawings of the socket to a manufacturer. He also showed a sketch of his concept to Texas Instruments, which placed an order for the new sockets prior to April 8, 1981. In accord with his normal practice, Pfaff did not make and test a prototype before offering to sell the socket in commercial quantities. He filled the order in July 1981, and thus the evidence indicates that he first reduced his invention to practice that summer. He applied for a patent on April 19, 1982, making April 19, 1981, the critical date for §102(b)'s on-sale bar. After the patent issued, he lost an infringement action he filed against respondent, Wells Electronics, Inc. Subsequently, he brought this suit, alleging that a modified version of Wells' socket infringed six of his patent's claims. The District Court held, *inter alia,* that three of the claims were infringed, rejecting Wells'§102(b) defense on the ground that Pfaff had filed the patent application less than a year after reducing the invention to practice. In reversing, the Court of Appeals concluded, among other things, that §102(b)'s 1-year period began to run when the invention was offered for sale commercially, not when it was reduced to practice.

Held: Pfaff's patent is invalid because the invention had been on sale for more than one year in this country before he filed his patent application. Pp. 5–13.

(a) The primary meaning of "invention" in the Patent Act unquestionably refers to the inventor's conception rather than to a physical embodiment of that idea. The statute contains no express "reduction to practice" requirement, see §§100, 101, 102(g), and it is well settled that an invention may be patented before it is reduced to practice. In *The Telephone Cases,* 126 U. S. 1, 535–536, this Court upheld a patent issued to Alexander Graham Bell even though he had filed his application before constructing a working telephone. Applying the reasoning of *The Telephone Cases* to the facts of this case, it is evident that Pfaff could have obtained a patent when he accepted Texas Instruments' order, for at that time he provided the manufacturer with a description and drawings of "sufficient clearness and precision to enable those skilled in the matter" to produce the device, *id.,* at 536. Pp. 5–7.

(b) Pfaff's nontextual argument—that longstanding precedent, buttressed by the interest in providing inventors with a clear standard identifying the onset of the 1-year period, justifies a special interpretation of "invention" in §102(b)—is rejected. While reduction to practice provides sufficient evidence that an invention is complete, the facts of *The Telephone Cases* and this case show that such proof is not necessary in every case. Pp. 7–11.

(c) The on-sale bar applies when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale. Here, the acceptance of the purchase order prior to April 8, 1981, makes it clear that such an offer had been made, and there is no question that the sale was commercial. Second, the invention must be ready for patenting. That condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention. This condition is satisfied here because the drawings sent to the manufacturer before the critical date fully disclosed the invention. Pp. 11–13.

124 F. 3d 1429, affirmed.

STEVENS, J., delivered the opinion for a unanimous Court.

SUPREME COURT OF THE UNITED STATES

No. 97–1130

WAYNE K. PFAFF, PETITIONER *v.* WELLS ELECTRONICS, INC.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[November 10, 1998]

JUSTICE STEVENS delivered the opinion of the Court.

Section 102(b) of the Patent Act of 1952 provides that no person is entitled to patent an "invention" that has been "on sale" more than one year before filing a patent application.[1] We granted certiorari to determine whether the commercial marketing of a newly invented product may mark the beginning of the 1-year period even though the invention has not yet been reduced to practice.[2]

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[1] "A person shall be entitled to a patent unless—

. . . . .

"(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, or . . . ." 35 U. S. C. §102.

[2] "A process is reduced to practice when it is successfully performed. A machine is reduced to practice when it is assembled adjusted and used. A manufacture is reduced to practice when it is completely manufactured. A composition of matter is reduced to practice when it is completely composed." *Corona Cord Tire Co.* v. *Dovan Chemical Corp.*, 276 U. S. 358, 383 (1928).

I

On April 19, 1982, petitioner, Wayne Pfaff, filed an application for a patent on a computer chip socket. Therefore, April 19, 1981, constitutes the critical date for purposes of the on-sale bar of 35 U. S. C. §102(b); if the 1-year period began to run before that date, Pfaff lost his right to patent his invention.

Pfaff commenced work on the socket in November 1980, when representatives of Texas Instruments asked him to develop a new device for mounting and removing semiconductor chip carriers. In response to this request, he prepared detailed engineering drawings that described the design, the dimensions, and the materials to be used in making the socket. Pfaff sent those drawings to a manufacturer in February or March 1981.

Prior to March 17, 1981, Pfaff showed a sketch of his concept to representatives of Texas Instruments. On April 8, 1981, they provided Pfaff with a written confirmation of a previously placed oral purchase order for 30,100 of his new sockets for a total price of $91,155. In accord with his normal practice, Pfaff did not make and test a prototype of the new device before offering to sell it in commercial quantities.[3]

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[3]At his deposition, respondent's counsel engaged in the following colloquy with Pfaff:

"Q. Now, at this time [late 1980 or early 1981] did we *[sic]* have any prototypes developed or anything of that nature, working embodiment?

"A. No.

"Q. It was in a drawing. Is that correct?

"A. Strictly in a drawing. Went from the drawing to the hard tooling. That's the way I do my business.

"Q. Boom-boom?

"A. You got it.

"Q. You are satisfied, obviously, when you come up with some drawings that it is going to go— it works?

"A. I know what I'm doing, yes, most of the time." App. 96–97.

The manufacturer took several months to develop the customized tooling necessary to produce the device, and Pfaff did not fill the order until July 1981. The evidence therefore indicates that Pfaff first reduced his invention to practice in the summer of 1981. The socket achieved substantial commercial success before Patent No. 4,491,377 (the '377 patent) issued to Pfaff on January 1, 1985.[4]

After the patent issued, petitioner brought an infringement action against respondent, Wells Electronics, Inc., the manufacturer of a competing socket. Wells prevailed on the basis of a finding of no infringement.[5] When respondent began to market a modified device, petitioner brought this suit, alleging that the modifications infringed six of the claims in the '377 patent.

After a full evidentiary hearing before a Special Master,[6] the District Court held that two of those claims (1 and 6) were invalid because they had been anticipated in the prior art. Nevertheless, the court concluded that four other claims (7, 10, 11, and 19) were valid and three (7, 10, and 11) were infringed by various models of respondent's sockets. App. to Pet. for Cert. 21a–22a. Adopting the

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[4] Initial sales of the patented device were:

1981	$350,000
1982	$937,000
1983	$2,800,000
1984	$3,430,000

App. to Pet. for Cert. 223.

[5] *Pfaff* v. *Wells Electronics, Inc.*, 9 USPQ 2d 1366 (ND Ind. 1988). The court found that the Wells device did not literally infringe on Pfaff's '377 patent based on the physical location of the sockets' conductive pins.

[6] Initially the District Court entered summary judgment in favor of respondent, but the Court of Appeals reversed and remanded for trial because issues of fact were in dispute. See 5 F. 3d 514 (CA Fed. 1993).

Special Master's findings, the District Court rejected respondent's §102(b) defense because Pfaff had filed the application for the '377 patent less than a year after reducing the invention to practice.

The Court of Appeals reversed, finding all six claims invalid. 124 F. 3d 1429 (CA Fed. 1997). Four of the claims (1, 6, 7, and 10) described the socket that Pfaff had sold to Texas Instruments prior to April 8, 1981. Because that device had been offered for sale on a commercial basis more than one year before the patent application was filed on April 19, 1982, the court concluded that those claims were invalid under §102(b). That conclusion rested on the court's view that as long as the invention was "substantially complete at the time of sale," the 1-year period began to run, even though the invention had not yet been reduced to practice. *Id.*, at 1434. The other two claims (11 and 19) described a feature that had not been included in Pfaff's initial design, but the Court of Appeals concluded as a matter of law that the additional feature was not itself patentable because it was an obvious addition to the prior art.[7] Given the court's §102(b) holding, the prior art included Pfaff's first four claims.

Because other courts have held or assumed that an invention cannot be "on sale" within the meaning of §102(b) unless and until it has been reduced to practice, see, *e. g., Timely Products Corp.* v. *Arron*, 523 F. 2d 288, 299–302 (CA2 1975); *Dart Industries, Inc.* v. *E. I. Du Pont de Nemours & Co.*, 489 F.2d 1359, 1365, n. 11 (CA7 1973), cert. denied, 417 U. S. 933 (1974), and because the text of

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[7] Title 35 U. S. C. §103 provides: "A patent may not be obtained though the invention is not identically disclosed or described . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

§102(b) makes no reference to "substantial completion" of an invention, we granted certiorari. 523 U. S. ___ (1998).

II

The primary meaning of the word "invention" in the Patent Act unquestionably refers to the inventor's conception rather than to a physical embodiment of that idea. The statute does not contain any express requirement that an invention must be reduced to practice before it can be patented. Neither the statutory definition of the term in §100[8] nor the basic conditions for obtaining a patent set forth in §101[9] make any mention of "reduction to practice." The statute's only specific reference to that term is found in §102(g), which sets forth the standard for resolving priority contests between two competing claimants to a patent. That subsection provides:

> "In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other."

Thus, assuming diligence on the part of the applicant, it is normally the first inventor to conceive, rather than the

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[8] Title 35 §100, "Definitions," states,

"When used in this title unless the context otherwise indicates—

"(a) The term 'invention' means invention or discovery. . . ."

[9] Section 101, "Inventions patentable," provides, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

first to reduce to practice, who establishes the right to the patent.

It is well settled that an invention may be patented before it is reduced to practice. In 1888, this Court upheld a patent issued to Alexander Graham Bell even though he had filed his application before constructing a working telephone. Chief Justice Waite's reasoning in that case merits quoting at length:

> "It is quite true that when Bell applied for his patent he had never actually transmitted telegraphically spoken words so that they could be distinctly heard and understood at the receiving end of his line, but in his specification he did describe accurately and with admirable clearness his process, that is to say, the exact electrical condition that must be created to accomplish his purpose, and he also described, with sufficient precision to enable one of ordinary skill in such matters to make it, a form of apparatus which, if used in the way pointed out, would produce the required effect, receive the words, and carry them to and deliver them at the appointed place. The particular instrument which he had, and which he used in his experiments, did not, under the circumstances in which it was tried, reproduce the words spoken, so that they could be clearly understood, but the proof is abundant and of the most convincing character, that other instruments, carefully constructed and made exactly in accordance with the specification, without any additions whatever, have operated and will operate successfully. A good mechanic of proper skill in matters of the kind can take the patent and, by following the specification strictly, can, without more, construct an apparatus which, when used in the way pointed out, will do all that it is claimed the method or process will do . . . .

> "The law does not require that a discoverer or inventor, in order to get a patent for a process, must have succeeded in bringing his art to the highest degree of perfection. It is enough if he describes his method with sufficient clearness and precision to enable those skilled in the matter to understand what the process is, and if he points out some practicable way of putting it into operation." *The Telephone Cases*, 126 U. S. 1, 535–536 (1888).[10]

When we apply the reasoning of *The Telephone Cases* to the facts of the case before us today, it is evident that Pfaff could have obtained a patent on his novel socket when he accepted the purchase order from Texas Instruments for 30,100 units. At that time he provided the manufacturer with a description and drawings that had "sufficient clearness and precision to enable those skilled in the matter" to produce the device. The parties agree that the sockets manufactured to fill that order embody Pfaff's conception as set forth in claims 1, 6, 7, and 10 of the '377 patent. We can find no basis in the text of §102(b) or in the facts of this case for concluding that Pfaff's invention was not "on sale" within the meaning of the statute until after it had been reduced to practice.

III

Pfaff nevertheless argues that longstanding precedent, buttressed by the strong interest in providing inventors with a clear standard identifying the onset of the 1-year

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[10] This Court has also held a patent invalid because the invention had previously been disclosed in a prior patent application, although that application did not claim the invention and the first invention apparently had not been reduced to practice. *Alexander Milburn Co.* v. *Davis-Bournonville Co.*, 270 U. S. 390, 401–402 (1926).

period, justifies a special interpretation of the word "invention" as used in §102(b). We are persuaded that this nontextual argument should be rejected.

As we have often explained, most recently in *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U. S. 141, 151 (1989), 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. The balance between the interest in motivating innovation and enlightenment by rewarding invention with patent protection on the one hand, and the interest in avoiding monopolies that unnecessarily stifle competition on the other, has been a feature of the federal patent laws since their inception. As this Court explained in 1871:

> "Letters patent are not to be regarded as monopolies . . . but as public franchises granted to the inventors of new and useful improvements for the purpose of securing to them, as such inventors, for the limited term therein mentioned, the exclusive right and liberty to make and use and vend to others to be used their own inventions, as tending to promote the progress of science and the useful arts, and as matter of compensation to the inventors for their labor, toil, and expense in making the inventions, and reducing the same to practice for the public benefit, as contemplated by the Constitution and sanctioned by the laws of Congress." *Seymour* v. *Osborne*, 11 Wall. 516, 533–534.

Consistent with these ends, §102 of the Patent Act 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. See, *e.g.*, *Frantz Mfg. Co.* v. *Phenix Mfg. Co.*, 457 F. 2d 314, 320 (CA7 1972).

We originally held that an inventor loses his right to a patent if he puts his invention into public use before filing a patent application. "His voluntary act or acquiescence in the public sale and use is an abandonment of his right" *Pennock* v. *Dialogue*, 2 Pet. 1, 24 (1829) (Story, J.). A similar reluctance to allow an inventor to remove existing knowledge from public use undergirds the on-sale bar.

Nevertheless, an inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention– even if such testing occurs in the public eye. The law has long recognized the distinction between inventions put to experimental use and products sold commercially. In 1878, we explained why patentability may turn on an inventor's use of his product.

> "It is sometimes said that an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law; but this cannot be said with justice 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. His monopoly only continues for the allotted period, in any event; and it is the interest of the public, as well as himself, that the invention should be perfect and properly tested, before a patent is granted for it. *Any attempt to use it for a profit, and not by way of experiment, for a longer period than two years before the application, would deprive the inventor of his right to a patent.*" *Elizabeth* v. *Pavement Co.*, 97 U. S. 126, 137 (emphasis added).

The patent laws therefore seek both to protect the public's right to retain knowledge already in the public domain and the inventor's right to control whether and when he may patent his invention. The Patent Act of 1836, 5 Stat. 117, was the first statute that expressly included an on-sale bar to the issuance of a patent. Like the earlier holding in *Pennock*, that provision precluded patentability if the invention had been placed on sale at any time before the patent application was filed. In 1839, Congress ameliorated that requirement by enacting a 2-year grace period in which the inventor could file an application. 5 Stat. 353.

In *Andrews* v. *Hovey*, 123 U. S. 267, 274 (1887), we noted that the purpose of that amendment was "to fix a period of limitation which should be certain"; it required the inventor to make sure that a patent application was filed "within two years from the completion of his invention," *ibid.* In 1939, Congress reduced the grace period from two years to one year. 53 Stat. 1212.

Petitioner correctly argues that these provisions identify an interest in providing inventors with a definite standard for determining when a patent application must be filed. A rule that makes the timeliness of an application depend on the date when an invention is "substantially complete" seriously undermines the interest in certainty.[11] Moreover, such a rule finds no support in the text of the stat-

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[11] The Federal Circuit has developed a multifactor, "totality of the circumstances" test to determine the trigger for the on-sale bar. See, *e. g., Micro Chemical, Inc.* v. *Great Plains Chemical Co.*, 103 F. 3d 1538, 1544 (1997) (stating that, in determining whether an invention is on sale for purposes of 102(b), " 'all of the circumstances surrounding the sale or offer to sell, including the stage of development of the invention and the nature of the invention, must be considered and weighed against the policies underlying section 102(b)' "); see also *UMC Electronics Co.* v. *United States*, 816 F. 2d 647, 656 (1987) (stating the on-sale bar "does not lend itself to formulation into a set of precise requirements"). As the Federal Circuit itself has noted, this test "has been criticized as unnecessarily vague." *Seal-Flex, Inc.* v. *Athletic Track & Court Construction*, 98 F. 3d 1318, 1323, n. 2 (1996).

ute. Thus, petitioner's argument calls into question the standard applied by the Court of Appeals, but it does not persuade us that it is necessary to engraft a reduction to practice element into the meaning of the term "invention" as used in §102(b).

The word "invention" must refer to a concept that is complete, rather than merely one that is "substantially complete." It is true that reduction to practice ordinarily provides the best evidence that an invention is complete. But just because reduction to practice is sufficient evidence of completion, it does not follow that proof of reduction to practice is necessary in every case. Indeed, both the facts of the *Telephone Cases* and the facts of this case demonstrate that one can prove that an invention is complete and ready for patenting before it has actually been reduced to practice.[12]

We conclude, therefore, that the on-sale bar applies when two conditions are satisfied before the critical date.

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[12] Several of this Court's early decisions stating that an invention is not complete until it has been reduced to practice are best understood as indicating that the invention's reduction to practice demonstrated that the concept was no longer in an experimental phase. See, *e.g.*, *Seymour* v. *Os-borne*, 11 Wall. 516, 552 (1871) ("Crude and imperfect experiments are not sufficient to confer a right to a patent; but in order to constitute an invention, the party must have proceeded so far as to have reduced his idea to practice, and embodied it in some distinct form"); *Clark Thread Co.* v. *Willimantic Linen Co.*, 140 U. S. 481, 489 (1891) (describing how inventor continued to alter his thread winding machine until July 1858, when "he put it in visible form in the shape of a machine. . . . It is evident that the invention was not completed until the construction of the machine"); *Corona Cord Tire Co.* v. *Dovan Chemical Corp.*, 276 U. S., at 382–383 (stating that an invention did not need to be subsequently commercialized to constitute prior art after the inventor had finished his experimentation. "It was the fact that it would work with great activity as an accelerator that was the discovery, and that was all, and the necessary reduction to use is shown by in-stances making clear that it did so work, and was a completed discovery").

First, the product must be the subject of a commercial offer for sale. An inventor can both understand and control the timing of the first commercial marketing of his invention. The experimental use doctrine, for example, has not generated concerns about indefiniteness,[13] and we perceive no reason why unmanageable uncertainty should attend a rule that measures the application of the on-sale bar of §102(b) against the date when an invention that is ready for patenting is first marketed commercially. In this case the acceptance of the purchase order prior to April 8, 1981, makes it clear that such an offer had been made, and there is no question that the sale was commercial rather than experimental in character.

Second, the invention must be ready for patenting. That condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.[14] In this case the second condition

[13] See, *e.g.*, Rooklidge & Jensen, Common Sense, Simplicity and Experimental Use Negation of the Public Use and On Sale Bars to Patentability, 29 John Marshall L. Rev. 1, 29 (1995) (stating that "whether a particular activity is experimental is often clear").

[14] The Solicitor General has argued that the rule governing on-sale bar should be phrased somewhat differently. In his opinion, "if the sale or offer in question embodies the invention for which a patent is later sought, a sale or offer to sell that is primarily for commercial purposes and that occurs more than one year before the application renders the invention unpatentable. *Seal-Flex, Inc.* v. *Athletic Track and Court Constr.*, 98 F. 3d 1318, 1325 (Fed. Cir. 1996) (Bryson, J., concurring in part and concurring in the result)." It is true that evidence satisfying this test might be sufficient to prove that the invention was ready for patenting at the time of the sale if it is clear that no aspect of the invention was developed after the critical date. However, the possibility of additional development after the offer for sale in these circumstances counsels against adoption of the rule proposed by the Solicitor General.

of the on-sale bar is satisfied because the drawings Pfaff sent to the manufacturer before the critical date fully disclosed the invention.

The evidence in this case thus fulfills the two essential conditions of the on-sale bar. As succinctly stated by Learned Hand:

> "[I]t is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly." *Metallizing Engineering Co.* v. *Kenyon Bearing & Auto Parts Co.*, 153 F. 2d 516, 520 (CA2 1946).

The judgment of the Court of Appeals finds support not only in the text of the statute but also in the basic policies underlying the statutory scheme, including §102(b). When Pfaff accepted the purchase order for his new sockets prior to April 8, 1981, his invention was ready for patenting. The fact that the manufacturer was able to produce the socket using his detailed drawings and specifications demonstrates this fact. Furthermore, those sockets contained all the elements of the invention claimed in the '377 patent. Therefore, Pfaff's '377 patent is invalid because the invention had been on sale for more than one year in this country before he filed his patent application. Accordingly, the judgment of the Court of Appeals is affirmed.

It is so ordered.

35 U.S.C. 102 CONDITIONS FOR PATENTABILITY; NOVELTY.

[Editor Note: Applicable to any patent application subject to the first inventor to file provisions of the AIA (see 35 U.S.C. 100 (note)). See 35 U.S.C. 102 (pre-AIA) for the law otherwise applicable.]

(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—

(1) 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; or

(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

(b) EXCEPTIONS.—

(1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—

(A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

(B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

(2) DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS.—A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if—

(A) the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor;

(B) the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

(C) the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

(c) COMMON OWNERSHIP UNDER JOINT RESEARCH AGREEMENTS.—Subject matter disclosed and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person in applying the provisions of subsection (b)(2)(C) if—

(1) the subject matter disclosed was developed and the claimed invention was made by, or on behalf of, 1 or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention;

(2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(d) PATENTS AND PUBLISHED APPLICATIONS EFFECTIVE AS PRIOR ART.—For purposes of determining whether a patent or application for patent is prior art to a claimed invention under subsection (a)(2), such patent or application shall be considered to have been effectively filed, with respect to any subject matter described in the patent or application—

(1) if paragraph (2) does not apply, as of the actual filing date of the patent or the application for patent; or

(2) if the patent or application for patent is entitled to claim a right of priority under section 119, 365(a), 365(b), 386(a), or 386(b), or to claim the benefit of an earlier filing date under

section 120, 121, 365(c), or 386(c) based upon 1 or more prior filed applications for patent, as of the filing date of the earliest such application that describes the subject matter.

(Amended July 28, 1972, Public Law 92-358, sec. 2, 86 Stat. 501; Nov. 14, 1975, Public Law 94-131, sec. 5, 89 Stat. 691; subsection (e) amended Nov. 29, 1999, Public Law 106-113, sec. 1000(a)(9), 113 Stat. 1501A-565 (S. 1948 sec. 4505); subsection (g) amended Nov. 29, 1999, Public Law 106-113, sec. 1000(a)(9), 113 Stat. 1501A-590 (S. 1948 sec. 4806); subsection (e) amended Nov. 2, 2002, Public Law 107-273, sec. 13205, 116 Stat. 1903; amended Sept. 16, 2011, Public Law 112-29, sec. 3(b), 125 Stat. 284, effective March 16, 2013.*; subsection (d)(2) amended Dec. 18, 2012, Public Law 112-211, sec. 102(2) (effective May 13, 2015), 126 Stat. 1531.))

(Public Law 112-29, sec. 14, 125 Stat. 284 (Sept. 16, 2011) provided that tax strategies are deemed to be within the prior art (see AIA § 14).)

*NOTE: The provisions of 35 U.S.C. 102(g), as in effect on March 15, 2013, shall also apply to each claim of an application for patent, and any patent issued thereon, for which the first inventor to file provisions of the AIA apply (see 35 U.S.C. 100 (note)), if such application or patent contains or contained at any time a claim to a claimed invention to which is not subject to the first inventor to file provisions of the AIA.]

Syllabus

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, Helsinn filed a provisional patent application covering a 0.25 mg dose of palonosetron. Over the next 10 years, Helsinn filed four patent applications 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 countered that the '219 patent was invalid under the "on sale" provision of the AIA—which precludes a person from obtaining 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)—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 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 agreements.

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 included an on-sale bar. This Court's precedent interpreting that provision 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 Federal Circuit had made explicit what was implicit in this Court's pre-AIA precedent, holding that "secret sales" could invalidate a patent. *Special Devices, Inc.* v. *OEA, Inc.*, 270 F. 3d 1353, 1357. Given this settled pre-AIA precedent, the Court applies the presumption that when Congress reenacted the same "on sale" language in the AIA, it adopted 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.

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 further require that the sale make the details of the invention available to the public. In light of this earlier construction, 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 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. Helsinn 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 approved 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 Commission. Although the 8–K filing included redacted copies of the agreements, neither the 8–K filing nor the press 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 application. 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 product. 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 January 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) (emphasis added).

See also §102(b)(1) (exception for certain disclosures made 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 invention 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" provision did not apply. It concluded that, under the AIA, an invention is not "on sale" unless the sale or offer in question 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 who is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability 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 Discoveries." Art. 1, §8, cl. 8. Under this grant of authority, Congress has crafted a federal patent system that encourages "the creation and disclosure of new, useful, and nonobvious advances in technology and design" by granting inventors "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 enlightenment" while also "avoiding monopolies that unnecessarily stifle competition," *Pfaff*, 525 U. S., at 63, Congress 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 inventor 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 immediately before the AIA prevented a person from receiving 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 otherwise 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 disclosed. *E.g., Consolidated Fruit-Jar Co.* v. *Wright*, 94

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 . . . "); *Elizabeth* v. *Pavement Co.*, 97 U. S. 126, 136 (1878) ("It is not a public knowledge of his invention that precludes the inventor 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 inventor'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 meaning of "on sale," we presume that when Congress reenacted the same language in the AIA, it adopted the earlier judicial 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 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 requires 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 addresses the reenactment of terms that had acquired a well-settled judicial interpretation. And Helsinn's argument places too much weight on §102's catchall phrase. Like other such phrases, "otherwise available to the public" 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 acquired 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 interpretation 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 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 affirm the judgment of the Federal Circuit.

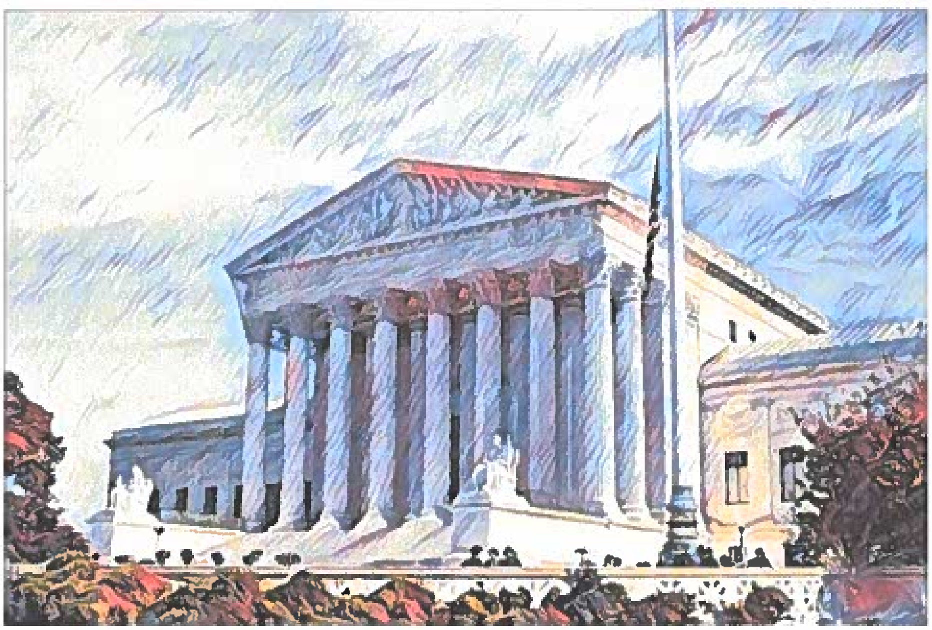
It is so ordered.

Supreme Court decides Helsinn v. Teva, Secret Sale Qualifies as Prior Art Under the AIA

By **Gene Quinn**
January 22, 2019

Pr

The Supreme Court held today in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc*. that a secret sale does qualify as prior art under the AIA, affirming the judgment of the Federal Circuit.



Earlier today the United States Supreme Court issued its decision in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.* The single question presented by *Helsinn* was whether under the America Invents Act (AIA) an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining patentability. In other words, does a so-called secret sale qualify as prior art under the AIA. The Supreme Court held today that secret sales do qualify as prior art under the AIA.

In a relatively short, unanimous decision authored by Justice Thomas, the Court begins by explaining that twenty-years ago in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67 (1998) the Court determined that an invention was *on sale* within the meaning of pre-AIA § 102 if it was subject to a commercial offer for sale and it was ready for patenting. Moreover, Thomas recognized that prior to passage of the AIA the Federal Circuit had clearly established that a secret sale could invalidate a patent. Therefore, given the settled precedent, Justice Thomas explained that there was a presumption "that when Congress reenacted the same language in the AIA, it adopted the earlier judicial construction of that phrase." The Court also found the catch all phrase "or otherwise available to the public" was "simply not enough of a change… to conclude that Congress intended to alter the meaning of the reenacted term 'on sale.'"

The speed with which the Supreme Court decided *Helsinn* will surprise some given that oral arguments were held just 7 weeks ago today. The fact that the Supreme Court affirmed the judgment of the Federal Circuit will likely also surprise many.

Also, of interest to many will be the Supreme Court citing precedent and the well-established expectations. Indeed, at one-point Justice Thomas writes: "In light of this settled pre-AIA precedent on the meaning of 'on sale,' we presume that when Congress reenacted the same language in the AIA, it adopted the earlier judicial construction of that phrase."

Where was this same concern for settled precedent when the Supreme Court overruled the primary holding in *Diamond v. Chakrabarty* and when the Supreme Court overruled the mandate in *Diamond v. Diehr* that one must not conflate novelty with patent eligibility? Both of those cases were over 30 years old when the Supreme Court unceremoniously chose to forge a different path with respect to patent eligibility; a path that now has the U.S. as one of the least favorable jurisdictions among developed nations for software, artificial intelligence, biotech, medical diagnostics and genetics.

The Supreme Court seems to have gotten *Helsinn* correct, and rather surprisingly affirmed the judgment of the Federal Circuit. The Supreme Court even provided a citation in the case explaining that the Federal Circuit has exclusive jurisdiction of patent matters. So, the question will be whether this signals a potential philosophical shift for the Court, or whether this is just the Supreme Court relying on precedent when it is convenient to achieve the end they prefer.

It is worth noting, however, that earlier this month the Supreme Court did issue a non-patent decision with great significance in the fight over patent eligibility. In a unanimous decision authored by Justice Kavanaugh in *Henry Schein, Inc. v. Archer & White Sales, Inc.*, the Court explained there is no authority for the existence of judicial exceptions to the Federal Arbitration Act (FAA). "[W]e are not at liberty to rewrite the statute passed by Congress and signed by the President," Kavanaugh wrote for the Court. *See A New Court a New Fix for Alice*.

Time will tell whether *Helsinn* and *Schein* are a blip on the radar, or whether they signal a Court that recognizes it has traveled too far from its Constitutional role. In the meantime, the language of both decision can and should be generously applied to the patent eligibility debate in briefs at the Patent Trial and Appeal Board (PTAB), in federal district court and at the Federal Circuit.

For more on *Helsinn* please see our prior coverage by viewing our *Helsinn* Archive.

Image Source: Photograph taken by Gene Quinn © 2009.

Tags: 35 USC 102, aia, America Invents Act, Helsinn Healthcare S.A., Helsinn Healthcare S.A. v. Teva Pharmaceuticals, justice thomas, on sale, patent, patents, SCOTUS, Section 102, US Supreme Court, § 102
Posted In: Courts, IP News, IPWatchdog Articles, Patents, US Supreme Court

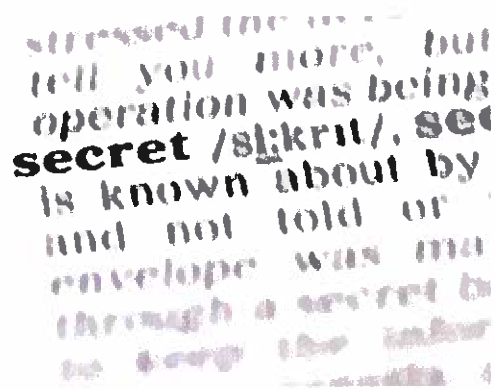
Of Secret Sales and Public Uses: The Practical Consequences of the Supreme Court's *Helsinn* Decision

By **James Pooley**
February 21, 2019

Pr

"Key to avoiding patent forfeiture is to focus on the role of third parties in the process of commercializing your product. This is especially tricky for smaller companies, which have to depend on outsiders to test and improve their innovations."

When I use a word, it means just what I choose it to mean, neither more nor less
— Humpty Dumpty (to Alice)



It seemed like a trade secret trifecta when Congress in 2011 passed the America Invents Act (AIA). Although the statute was aimed at patent reform, it made three helpful changes in how trade secrets are treated. First, companies could hold onto secret information about an invention without risking invalidation of their patents for failing to disclose the "best mode" of implementing it. Second, the "prior user right" that guarantees continuing use of a secret invention, even if someone else later patents it, was extended to cover all technologies. And third, the law would no longer deny a patent simply because the inventor had already commercialized the invention in a way that didn't reveal it to the public.

Or so we thought. That last change depended on how you read the legislation. The long-standing requirement that an invention could not be "on sale" or "in public use" more than a year before filing a patent application was still there. But Congress added a qualifier to 35 U.S.C. §102: there would be no patent if the invention had been "in public use, on sale, or otherwise available to the public . . . ."

Before the AIA, the courts were strict about the consequences of choosing trade secret protection over patents. If the inventor used the invention for commercial purposes, the patent clock started ticking, even if the use was behind closed doors and did not inform the public about the invention itself. The same was true of a commercial sale of a product that used the invention, even though the contract of sale was confidential. The only real exception was for "experimental use" to refine the invention before it became ready for patenting. But even getting a prototype tested under a nondisclosure agreement could fail to qualify if there were other terms implying commercialization, like payment to the inventor.

The Forfeiture Doctrine

The logic behind this interpretation of "public use" was explained eloquently by Second Circuit Judge Learned Hand in *Metallizing Engineering Co. v. Kenyon Bearing & AP Co.*, 153 F.2d 516 (2d Cir. 1946). An inventor may indefinitely "practice his invention for his private purposes of his own enjoyment and later patent it." However, once an invention is "ready for patenting" the inventor may not "exploit his discovery competitively" for more than the one-year grace period; otherwise "he forfeits his right regardless of how little the public may have learned about the invention."

The insertion in the AIA of the phrase "or otherwise available to the public" indicated that Congress intended to change this rule and to provide that only uses or sales that informed the public of the invention would bar a patent. This seemed apparent just from normal standards for interpreting English, in which "otherwise" should be understood to refer to the terms coming before it. In addition, during consideration of the legislation, sponsors of the bill had taken the floor of the Senate to express their views that the new phrase would have the effect of limiting patent forfeiture to situations where the public had been informed of the invention and not just enjoyed its outputs.

Most commentators (myself included) embraced this interpretation of the AIA. And so did the U.S. Patent and Trademark Office (USPTO), which in its official regulations concluded that new section 102 "does not cover secret sales or offers for sales." It seemed as though companies considering patenting would be able to engage in a variety of transactions to bring the benefit of their innovations to the public without risking their right to patent, so long as they didn't publicly reveal the specifics of their invention.

Choose Your Meaning

Alas, assuming this is what Congress intended, they weren't clear enough about it. In a case that tested the assumptions of the IP community, the Supreme Court recently decided that the law on public use and sale had not changed with the AIA. In *Helsinn Healthcare v. Teva Pharmaceuticals*, the owner of a new drug gave exclusive marketing rights to another firm, more than a year before applying for a patent. The agreement itself was publicly announced, but the dosage information claimed in the patent was kept confidential. Although something like a "sale" had taken place, the invention had not at that point been "available to the public."

No matter, said the Supreme Court. Citing to its opinions going back as early as 1829, the court emphasized the significance of a public "sale" that effectively put the invention in commerce and beyond the ability of the patent system to pull it back. Judicial decisions about public use and sale never required that the invention itself be revealed to the public; and such a long-standing and clear interpretation could not be overturned by the "oblique" language of the AIA.

So where are we now? First, it's still true that trade secret protection received a big boost from the AIA, through its changes to the "best mode" doctrine and the broad extension of prior user rights, which allow a company that had been practicing an invention in secret to keep using it in spite of a later patent (so long as the location and scope of use don't change). These amendments removed a significant amount of the "trade secret anxiety" that had been created by patent law.

Basically, companies are free to classify and protect information assets through secrecy, even if the information closely relates to a patented invention, without fear that their patent will be invalidated. And by choosing to use secrecy rather than patenting to protect their innovative technology, executives can still sleep soundly knowing that a later patent can't block them from continuing to use that technology.

But what about those "secret sales" and "public uses" that aren't fully public? What can be done to stay out of trouble as the enterprise moves from invention to commercialization? How can you preserve your option to choose between secrecy and patenting as you get closer to market introduction?

The 18-Month Secrecy Option

One general piece of advice is to file for a patent at the earliest time. (Your patent lawyer can help you decide when an invention is "ready for patenting.") The AIA was designed to encourage and reward early filing, and one of the best ways to keep your options open is to file a provisional patent application. That application, and the non-provisional application that follows it, remain unpublished for 18 months, giving the business time to consider the relative advantages and drawbacks of a patent over a trade secret, as well as the scope of what might go into a patent and what might be kept out. At any time during the 18-month period the application can be pulled and the information maintained in secret.

Key to avoiding patent forfeiture is to focus on the role of third parties in the process of commercializing your product. This is especially tricky for smaller companies, which can't always afford to optimize the innovation in-house but have to depend on outsiders to test and improve it. Here, the good news is that you are in control of the risk, so long as you are keenly aware of it. To claim the benefit of the "experimental use exception," make sure that your external testing programs are focused only on refining the product, not getting paid for it. And require that all participants sign strong nondisclosure agreements.

As your company builds and executes its go-to-market plan, you will often want to sign up distributors, resellers and other partners ahead of a product launch. There's nothing wrong with that in the abstract, but you need to pay attention to how those transactions might affect your right to file a patent on an important invention. Even if no product has actually changed hands, you might have engaged in a "sale." And even if no one else knows the still-secret invention you want to patent, your use of it may be deemed "public."

Yes, this stretches the logic inherent in English grammar. But what can I say? It's the law.

Tags: 35 USC 102, America Invents Act, Congress, Guest Contributor, Helsinn Healthcare S.A. v. Teva Pharmaceuticals, independent inventor, innovation, intellectual property, James Pooley, patent, patent office, patentability requirements, patents, SCOTUS, Trade Secrets, US Supreme Court, USPTO

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