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Helsinn v. Teva: Lingering Ambiguity After the U.S. Supreme Court Holds the AIA Did Not Alter the On-Sale Bar to Patentability

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Helsinn v. Teva: Lingering Ambiguity after the U.S. Supreme Court Holds the AIA Did Not Alter the On-Sale Bar to Patentability

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ABSTRACT

The American Innovation Act of 2011 (AIA) retained §102 of the pre-AIA Patent Act's "in public use" and "on-sale" bars to patentability, but introduced an additional "or otherwise available to the public" category of prior art. Federal Circuit precedent pre-dating the AIA has held that, as a general matter, a sale or offer for sale can create an on-sale bar to patentability even if the sale or offer for sale is "secret" and does not render the invention available to the public. Some believed that the AIA's introduction of the phrase "or otherwise available to the public" altered the meaning of "on sale," introducing a requirement that a sale or offer for sale render an invention "available to the public" in order to create a statutory bar to patentability. In other words, under this interpretation a "secret" offer for sale would no longer constitute an on-sale statutory bar. In January, 2019, the Supreme Court addressed this contention in *Helsinn v. Teva*, and essentially held that the AIA had not changed the meaning of "on sale" for purposes of §102. This article provides a historical overview of the pre-AIA on-sale bar, considers the argument that in enacting the AIA Congress intended to do away with non-public prior art, reviews *Helsinn*, including the decisions below and amicus curiae briefs filed with the Supreme Court in connection with the case, and concludes with a discussion of lingering questions with respect to the judicial interpretation of the on-sale and public use bars.

The United States' statutory "on-sale" bar to patentability dates back to the Patent Act of 1839. Prior to Congress's enactment of the American Innovation Act (AIA) in 2011, the on-sale bar resided in §102(b) of the statute (referred to herein as "pre-AIA§102(b)"). The pre-AIA version of §102 remains the applicable law for patent applications filed before March 16, 2013, the effective date of the AIA. More particularly, pre-AIA §102(b) precludes an applicant from

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obtaining a patent on an invention that was "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."[1]

The AIA retained the on-sale bar in §102(a)(1) of the amended Patent Act (referred to herein as "AIA §102(a)(1)"), which provides that an applicant will be barred from obtaining a patent claiming an invention that was "in public use, *on sale*, or otherwise available to the public before the effective filing date of the claimed invention."[2] The AIA version of the Patent Act thus retains the "public use" and "on sale" language of the pre-AIA statute, while incorporating three notable changes, two of which appear straightforward, while the third was to prove ambiguous and controversial. The straightforward changes are the omission of the "in this country" limitation of the pre-AIA §102(b), presumably expanding the scope of the public use and on-sale statutory bars to encompass activities occurring outside the U.S., and the changing of the critical date from "one year prior to the date of application" to "the effective filing date." The third and more interesting change is the introduction of the catch-all language "or otherwise available to the public," which became the focus of a recent Supreme Court decision in *Helsinn v. Teva*, and is the subject of this Holman Report.[3]

Federal Circuit precedent pre-dating the AIA has held that, as a general matter, a sale or offer for sale can create an on-sale bar to patentability even if the sale or offer for sale is "secret" and does not render the invention available to the public. Many believed that the AIA's introduction of the phrase "or otherwise available to the public" altered the meaning of "on sale," introducing a requirement that a sale or offer for sale render an invention "available to the public" in order to create a statutory bar to patentability. In other words, under this interpretation a "secret" offer for sale would no longer constitute an on-sale statutory bar.

In January, 2019, the Supreme Court addressed this contention in *Helsinn*, and essentially held that the AIA had not changed the meaning of "on sale" for purposes of §102. Still, a number of ambiguities remain unresolved. This Holman Report provides a historical overview of the pre-AIA on-sale bar, considers the argument that in enacting the AIA Congress intended to do away with non-public prior art, reviews *Helsinn*, including the decisions below and amicus curiae briefs filed with the Supreme Court in connection with the case, and concludes with a discussion of lingering questions with respect to the judicial interpretation of the on-sale and public use bars.

Pre-AIA on-sale precedent

The *Pfaff* decision

Pfaff v. Wells Elecs., Inc., decided in 1998, is the only Supreme Court decision to specifically address the on-sale bar prior to *Helsinn*, and it sets the basic parameters defining the doctrine.[4] The case involved Wayne Pfaff, an independent inventor who was approached by representatives

[1] Pre-AIA 35 U.S.C. §102.
[2] AIA 35 U.S.C. §102.
[3] *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628 (2019).
[4] *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998).

of Texas Instruments (TI) and asked to develop a new device for mounting and removing semiconductor chip carriers. In response to this request, Pfaff prepared detailed engineering drawings that described the design, the dimensions, and the materials to be used in making a socket satisfying TI's specifications, and sent those drawings to a manufacturer prior to the critical date, i.e., more than one year before the filing date.[5] He showed a sketch of his concept to representatives of TI, and prior to the critical date 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. Significantly, Pfaff did not make and test a prototype of the new device before offering to sell it in commercial quantities, and did not reduce the invention to practice until after the critical date.[6]

Pfaff received a patent on his device and sued Wells for infringement. The district court held that patent claims directed toward the socket were not invalid under the on-sale bar because the invention had not been reduced to practice prior to the critical date. There was precedent from the Second Circuit and Seventh Circuit pre-dating the creation of the Federal Circuit that held or assumed that an invention cannot be "on sale" within the meaning of §102(b) until it has been reduced to practice. The Federal Circuit reversed, holding that reduction to practice is not required in order to trigger the on-sale bar, and that in this case the on-sale bar had been triggered because Pfaff's invention was "substantially complete" at the time he offered it for sale to TI. The Supreme Court granted certiorari to address this split between the Federal Circuit and pre-Federal Circuit case law.

In *Pfaff*, the Supreme Court rejected the Federal Circuit's "substantially complete" standard, finding no support for it in the text of the statute, and also finding that such an amorphous standard would seriously undermine patent law's interest in certainty, by failing to provide inventors with a definite standard for determining when a patent application must be filed. On the other hand, the court found that actual reduction to practice is not required for an offer for sale to trigger the on-sale bar. Rather, it is sufficient that the invention be "ready for patenting."

The "ready for patenting" standard requires more than mere conception of an invention, but does not necessarily require actual reduction to practice. *Pfaff* did not provide a detailed definition of "ready for patenting," but held that the standard to be met in "at least" two ways: (1) proof of actual reduction to practice before the critical date, or (2) 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.

Pfaff further held that in order for the on-sale bar to be triggered the invention must be the subject of a "commercial offer" for sale. The Court provides little in terms of a definition for a "commercial offer" for sale, other than implying that it entails commercial marketing of the invention. The Court did find that Pfaff had made a commercial offer, stating that the acceptance

[5] The critical date is one year prior to the filing date under the pre-AIA statute, and the filing date under the AIA statute, subject to AIA §102's limited one-year grace period.

[6] An invention is "reduced to practice" when a working embodiment of the invention is actually made when the claimed invention is a product or performed in the case of a claimed process.

of the purchase order prior to the critical date makes it clear that such an offer had been made, and finding there to be no question that the sale was commercial rather than experimental in character. Subsequent decisions of the Federal Circuit have interpreted *Pfaff*'s requirement of a "commercial offer" as requiring an offer that is sufficiently definite to qualify as an "offer" under general contract law, as exemplified by the definition of an "offer" under the Uniform Commercial Code (UCC).[7] *Pfaff* also implicitly rejected the multifactor, policy-driven "totality of the circumstances" test previously used by the Federal Circuit to determine whether an on-sale event had occurred.

To summarize, *Pfaff* sets forth two conditions that must be satisfied prior to the critical date in order for the on-sale bar to be triggered: (1) the invention must be the subject of a commercial offer for sale, and (2) the invention must be ready for patenting.

Activities that have triggered the on-sale bar

This section of the article summarizes activities that have been found to trigger the pre-AIA on-sale bar. Note that some of the key precedent pre-dates *Pfaff*, and as discussed below some of this case law might be subject to challenge based on the Supreme Court's intervening decision in *Pfaff*.

Patentable inventions fall into two categories, products (i.e., a machine, composition of matter, and/or article of manufacture) and processes, both of which can be rendered unpatentable by activity triggering the on-sale bar. The application of the on-sale bar to product claims is more straightforward; as a general matter, the offer for sale of an embodiment covered by a product claim will trigger the on sale bar so long as the two conditions set forth in *Pfaff* are met, i.e., the product is ready for patenting and the offer for sale is a commercial offer. An offer to use an apparatus for monetary compensation has been found to trigger the on-sale bar with respect to a claim directed toward the apparatus, even though the apparatus itself was not offered for sale.

Application of the on-sale bar to process claims is a bit more complex. An offer to perform a process in return for monetary compensation has generally been found to trigger the on-sale bar with respect to claims reciting the process. Use of a process to produce a product that is subsequently sold has also been found to trigger the on-sale bar with respect to the process, at least when it is the inventor or an assignee that used the process for this purpose. The leading Federal Circuit decision standing for this proposition is *D.L. Auld Co. v. Chroma Graphics Corp.*, decided in 1983, the year after Congress created the Federal Circuit, and years before the Supreme Court decided *Pfaff*.[8] In *Auld*, the claimed invention is a process for "forming foil-backed inserts in the form of cast decorative emblems." Prior to the critical date, the assignee of the patent (Auld) use the claimed process to produce samples which were offered for sale to a number of potential buyers. The Federal Circuit held that these offers triggered the on-sale bar with respect to the process, regardless of whether any actual sale was made, and even if the

[7] *See Group One, Ltd. V. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047-48 (Fed. Cir. 2001)("Only an offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance (assuming consideration), constitutes an offer for sale under 102(b).").
[8] *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144 (Fed. Cir. 1983).

process was maintained as a secret and remained secret after the sale of the products. Significantly, *Auld* states as dicta that "where a method is kept secret, and remained secret after a sale of the product of the method, that sale will not, of course, bar *another inventor* from the grant of a patent on that method. The situation is different where, as here, that sale is made by the applicant for patent or his assignee."[9]

Significantly, *Auld* provides little if any explanation of the rationale behind the court's conclusion that sale of a product made by means of a secret process creates an on-sale bar with respect to the inventor or his assignee, but not with respect to another inventor, except for a citation to *Metallizing Engineering*, a famous Second Circuit decision dating back to 1946.[10] According to the Federal Circuit, "the 'forfeiture' theory expressed in *Metallizing* parallels the statutory scheme of 35 U.S.C. § 102(b), the intent of which is to preclude attempts by the inventor or his assignee to profit from commercial use of an invention for more than a year before an application for patent is filed."[11] Note that *Metallizing Engineering* does not refer directly to the on-sale bar, and has generally been interpreted as an application of the "public use" statutory bar, although the decision does not explicitly identify which statutory bar is triggered by this sort of "non-informing commercial use." The exception for non-informing commercial use appearing as dicta in *Auld* was confirmed shortly thereafter in *W.L. Gore & Assocs., Inc. v. Garlock, Inc*., as discussed in more detail below.[12]

The Federal Circuit has issued a number of decisions defining the scope of the on-sale bar that appear to be generally applicable to both product and process claims. For example, it is well established that the on-sale bar is triggered not only by the consummated sale of the invention, but also by the mere offering of the invention for sale, regardless of whether the sale is consummated or the offer accepted.[13] It also appears well established that a single sale or offer to sell is enough to bar patentability.[14] In most instances, it does not matter whether the offer for sale comes from the inventor or from an unrelated third party, although as alluded to above this can make a difference in the case of a non-informing commercial use.

According to CHISUM ON PATENTS, the "prevailing view" is that the on-sale bar can be triggered even when the product or process offered for sale is not identical to an embodiment falling within the scope of the claim, so long as "the differences between the claimed thing [or process] and the sold or used thing [or process] are obvious to one skilled in the art."[15] This stands in contrast with the well-established doctrine that novelty is lacking (i.e., there is anticipation) for

[9] *Id.* at 1147-48.
[10] *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2nd Cir.1946).
[11] 714 F.2d at 1147.
[12] *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983).
[13] *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1368 (Fed. Cir. 2017) (stating the on-sale bar applies if, among other things, "the product [is] the subject of a commercial offer for sale")
[14] *In re Caveney*, 761 F.2d 671, 675–76 (Fed. Cir. 1985)("A single instance of sale or of use by the patentee may, under the circumstances, be fatal to the patent.").
[15] 2A Chisum on Patents § 6.02 (2019).

purposes of the pre-AIA §102(a) novelty provision only when the prior art product or process is identical to the claimed product or process.[16]

In general, the sale or offer for sale of an invention need not disclose the details of the invention in order to trigger the on-sale bar.[17] In *Abbott Laboratories v. Geneva Pharmaceuticals, Inc*., for example, the Federal Circuit held the on-sale bar to be triggered even though neither party to the transaction knew at the time of the sale whether the product sold embodied the claimed invention, and there was no easy way to determine what the product was.[18]

In the past some have argued in favor of a "supplier exception" to the on-sale bar that would allow a patentee to stockpile commercial embodiments of their patented invention via commercial contracts with suppliers more than a year before they file their patent application.[19] The rationale for such an exception is that such conduct is substantially equivalent to a patentee producing the patented invention internally, an activity that would not create an on-sale bar. Without a supplier exception, smaller enterprises that choose to outsource the manufacture of the invention are put at a relative disadvantage to a larger enterprise better able to manufacture the invention internally. Regardless of the validity of this policy-based argument, it was rejected by the Federal Circuit in *Special Devices, Inc. v. OEA* in 2001, and again in 2016 by the en banc Federal Circuit in *Medicines Co. v. Hospira, Inc.*.[20] The court in *Medicines Co.* noted, however:

> The fact that a transaction is between a supplier and inventor is an important indicator that the transaction is not a commercial sale, understood as such in the commercial marketplace, [but] it is not alone determinative. Where the supplier has title to the patented product or process, the supplier receives blanket authority to market the product or disclose the process for manufacturing the product to others, or the transaction is a sale of product at full market value, even a transfer of product to the inventor may constitute a commercial sale under §102(b). The focus must be on the commercial character of the transaction, not solely on the identity of the participants.[21]

Activities that have not triggered the bar

Federal Circuit case law has also identified a number of circumstances under which an offer for sale does not necessarily trigger the on-sale bar. One of these is when the offer for sale falls under the experimental use exception (more is more accurately thought of as an experimental use

[16] *Id.*
[17] *Helsinn*, 855 F.3d at 1370.
[18] *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 182 F.3d 1315, 1317-18 (Fed. Cir. 1999).
[19] *Special Devices, Inc. v. OEA, Inc*., 270 F.3d 1353 (Fed. Cir. 2001).
[20] *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363, 1379-80 (Fed. Cir. 2016).
[21] *Id.* at 1380.

negation).[22] This judge-made doctrine, which is not reflected in the statutory language of the Patent Act, provides that activity that would otherwise constitute placing an invention in "public use" or "on sale" will not trigger the Section 102(b) statutory bar if the use or sale was incidental to experimentation. The Supreme Court recognized the validity of the doctrine in the leading case of *City of Elizabeth v. The American Nicholson Pavement Co.* (1877), and it has been the subject of judicial development ever since.[23]

In *Pfaff* the Court voiced its continued approval of the experimental use doctrine, noting that "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."[24] However, ten years later Judge Prost wrote a concurring opinion in *Atlanta Attachment Co. v. Leggett & Platt, Inc.*to "point out the confusion in our caselaw regarding the applicability of the experimental use doctrine to [*Pfaff*'s] two prong test for the on-sale bar."[25] Prior to *Pfaff*, the experimental use doctrine was considered inapplicable once an invention had been reduced to practice, and, as pointed out by Judge Prost, the Federal Circuit had stated on several occasions post-*Pfaff* that the experimental use doctrine cannot provide an exception to the on-sale bar once an invention is reduced to practice. Judge Prost expressed her view that post-*Pfaff* experimental use:

> represents the counterpoint to commercial sale or public use. Assuming a complete invention, ready for patenting, inventors should be able to continue to privately develop any claimed aspect of that invention without risking invalidation, if they conduct development activities in a way that is neither public nor simply commercial, even if there is some commercial benefit to the inventor in connection with the experimental use…When the inventor conducts a commercial transaction in order to facilitate development, but the development activity meets the requirements of the experimental use doctrine, the inventor avoids the on-sale bar. This exception to the on-sale bar does not evaporate upon reduction to practice. In essence, just as inventors could develop any aspect of the invention privately, they may employ the concepts of agency and confidentiality to also accomplish the same result.[26]

Judge Prost's concerns were raised by three amici curiae, including the United States government, when the en banc Federal Circuit too up the on-sale bar in *Medicines Company*. The solicitor general, for example, asked court to "make clear that the panel's statement that there

[22] *Atlanta Attachment Co. v. Leggett & Platt, Inc*., 516 F.3d 1361, 1369 n. 1 (Fed. Cir. 2008) ("the experimental use doctrine is more accurately characterized as a negation of a statutory bar").
[23] 2A Chisum on Patents § 6.02 (2019) (citing *City of Elizabeth v. American Nicholson Pavement Co*., 97 U.S. 126 (1877)).
[24] *Pfaff*, 525 U.S. at 64.
[25] *Atlanta Attachment Co*., 516 F.3d at 1368.
[26] *Id*. at 1369-70.

can be no experimental use after a reduction to practice is inaccurate." In deciding the case, however, the court explicitly declined to "reach the question of experimental use."

Another way in which an apparent offer for sale can avoid the on-sale bar is when the court characterizes it as the purchase of contracted manufacturing services rather than purchase of a product. This is what occurred in *Medicines Company*. Interestingly, the Federal Circuit panel that first heard the case initially rejected the patentee's argument that it had only purchased contracted manufacturing services, and characterized the contractor's offer to produce the product as an offer for sale triggering the on-sale bar.[27] However, on rehearing the en banc Federal Circuit reversed course and came to the opposite conclusion, with the three original panelists changing their mind and agreeing that under the facts of the case the arrangement between the patentee and contract manufacture constituted a contract manufacturer's sale of manufacturing services rather than an offer to sell the claimed product.[28]

Medicines Company identified three reasons for its judgment that the on-sale bar had not been triggered: "(1) only manufacturing services were sold to the inventor—the invention was not; (2) the inventor maintained control of the invention, as shown by the retention of title to the embodiments and the absence of any authorization to [the contract manufacturer] to sell the product to others; and (3) 'stockpiling,' standing alone, does not trigger the on-sale bar."[29] One explanation for the en banc court's decision to characterize the transaction as the sale of contract manufacturing services rather than sale of the patented product is that to some extent it tempers the effect of its decision to not recognize a "suppliers exception."

Another scenario that has been found not to trigger the on-sale bar is when someone other than the inventor or assignee uses a later claimed method secretly to manufacture a product that is subsequently sold while maintaining the secrecy of the method, i.e., a non-informing commercial use by a third party. As described above, in *Auld* the Federal Circuit held that such a sale does trigger the on-sale bar when it is offered by the inventor or assignee, but stated in dicta that such a sale would not bar another inventor from the grant of a patent on the method. Shortly after *Auld*, the Federal Circuit issued a decision in W*.L. Gore & Assocs., Inc. v. Garlock, Inc*. explicitly holding that a non-informing commercial use by a third party did not trigger the public use and on-sale statutory bars.[30]

In *Gore*, the court found "no reason or statutory basis" upon which a third party's secret commercialization of a process could create a bar to the grant of a patent to another inventor of that process. There was some factual dispute as to what had actually occurred, but the court held that to the extent the third-party offered and sold anything, it was only the product of the process, not whatever process was used in producing it. The court pointed out that neither party had contended, and there was no evidence, that the public could learn the claimed process by examining the product. As was the case in *Auld*, the *Gore* panel provided little explanation

[27] *Medicines Co. v. Hospira, Inc.*, 791 F.3d 1368 (Fed. Cir. 2015).
[28] *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016).
[29] *Id.* at 1373–74.
[30] *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1549–50 (Fed. Cir. 1983).

regarding the basis for its interpretation of the §102(b) statutory bars beyond citations to *Auld* and *Metallizing Engineering*.

The outcome in *Gore* might have hinged upon the degree to which the third party maintained the secrecy of the process. The process itself was performed by a machine, and the Federal Circuit noted that the third party had told its employees that the machine "was confidential and required them to sign a confidentiality agreement." The court further observed that there was "no evidence that a viewer of the machine could thereby learn anything of which process, among all possible processes, the machine is being used to practice," nor any evidence that the third parties secret use of the machine "made knowledge of the claimed process accessible to the public."

In *In re Caveney*, decided in 1985, the Federal Circuit endorsed the holdings in *Auld* and *Gore*, calling *Gore* an exception to the general rule that third-party sales or offers for sale can create an on-sale bar in cases "where a patented method is kept secret and remains secret after a sale of the unpatented product of the method. Such a sale prior to the critical date is a bar if engaged in by the patentee or patent applicant, but not if engaged in by another."[31] *Caveney* held that a third-party sale of the patented invention created an on-sale bar even though the invention was kept secret from the purchasing public in general, because the claimed invention was disclosed to the purchaser and thus was not sufficiently secret. The court found the case distinguishable over *Gore* and *Auld* based on this disclosure of the invention to the purchaser. Another important distinction between the facts of *Caveney* and *Gore* is that in *Caveney* the claimed invention is a product, which was literally offered for sale, while in *Gore* the claimed invention, a process, is not itself the subject of an offer of sale, nor was the process disclosed by the sale of the product manufactured by means of the process.

The on-sale bar post-AIA

As discussed above, it has long been the "general rule" that a sale or offer for sale of a later claimed invention will constitute a statutory bar if it occurs before the critical date, whether the invention is sold or offered for sale by the applicant or by a third party.[32] When the AIA amended Section 102, it retained the "public use" and "on sale" language of the pre-AIA statute, but added the catch-all phrase "or otherwise made available to the public." Many argued that the addition of the catch-all phrase was intended to, and indeed did have the effect of modifying the meaning of the terms "public use" and "on sale" such that only public uses and on-sale events that make the invention publicly accessible will constitute a statutory bars. This section of the article summarizes some of the argument that have been made in favor of this interpretation of the statute, and then describes the Supreme Court's response in *Helsinn* essentially rejecting the argument.

[31] *In re Caveney*, 761 F.2d 671 (Fed.Cir.1985)).
[32] *Special Devices, Inc. v. OEA, Inc*., 270 F.3d 1353, 1357 (Fed. Cir. 2001)("we stated in *Woodland Trust* that the on-sale bar would apply even if a patentee's commercial activities took place in secret.").

Argument that under AIA on sale of that must make invention available to the public

There are statements in the AIA's legislative history indicating that at least some members of Congress believed that the introduction of the catch-all phrase was intended to clarify that categories of prior art, including the public use and on-sale bars, must render an invention "available to the public."[33] For example, the House Judiciary Committee Report on the AIA states that the revision of Section 102:

> also, and necessarily, modifies the prior-art sections of the patent law. Prior art will be measured from the filing date of the application and will typically include all art that *publicly exists* prior to the filing date, other than disclosures by the inventor within 1 year of filing. Prior art also will no longer have any geographic limitations. Thus, in section 102 the "in this country" limitation as applied to "public use" and "on sale" is removed, and the phrase "available to the public" is added to clarify the broad scope of relevant prior art, as well as to *emphasize the fact that it must be publicly accessible*.[34]

In an amicus brief filed with the Supreme Court, the Intellectual Property Owner's Association (IPO) pointed out:

> Several of the AIA's sponsors, including the two eponymous sponsors, reiterated the point in extensive floor statements. Senator Kyl explained that the new catch-all phrase operated on the preceding phrases, including "on sale," thus "limit[ing] all non-patent prior art to that which is available to the public." 157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011). Senator Leahy, the lead sponsor in the Senate, similarly explained that the statute would "do away with precedent under current law that private offers for sale or private uses or secret processes *** may be deemed patent-defeating prior art." 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011). Representative Lamar Smith, the lead sponsor in the House, added that, "contrary to current precedent, in order to trigger the bar in the new [Section] 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date."[35]

Congressman Smith went so far as to file an amicus brief with the Supreme Court in *Helsinn* arguing that this was indeed Congress's intent, with the AIA effectively introducing a public

[33] See Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 466-475 (2012).
[34] H.R. Rep. No. 112-98 at 54 (June 1, 2011).
[35] *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc*., Supreme Court of the United States Docket No. 17-1229, Brief of Amicus Curiae Intellectual Property Owners Association in Support of Neither Party, 2018 WL 4091714 (August 23, 2018)(citing 157 Cong. Rec. H4429 (daily ed. June 22, 2011)).

availability component to the statutory bars.[36] This brief was authored by Robert Armitage, former general counsel for Eli Lilly and Company, who was involved in the process of drafting the AIA and its non-enacted predecessors, and who wrote an interesting article explaining the legislative history and his understanding of Congress' intended interpretation and implementation of the AIA.[37]

In a floor statement, Senator Kyl explained that "a general public availability standard is a necessary accompaniment to this bill's elimination of geographic restrictions on the definition of prior art."[38] He pointed out that a public sale "is relatively hard to falsify," but that if a "secret offer for sale" in a foreign country were sufficient, it "would place U.S. inventors at grave risk of having their inventions stolen through fraud."

Section 3 of the AIA includes two "Sense of Congress" provisions stating the objectives and policies of the legislation which appear to support the proposition that under the AIA a public use or on-sale event must render an invention available to the public in order to create a statutory bar. These provisions state that the AIA's amendments to the Patent Act were intended to harmonize the United States patent system with other patent systems and to provide "greater certainty regarding the scope of protection" provided by U.S. patents. The Naples Roundtable (a patent law and policy think tank) argued in its amicus brief that Congress's intent to harmonize U.S. law with other jurisdictions would be furthered by eliminating secret prior art in the U.S.[39] The change would also improve certainty in the patent system by making it easier to determine what is or is not prior art without resorting to expensive discovery.

The Naples Roundtable brief identifies the top five national intellectual property offices, based on the number of patent applications processed, as the European Patent Office, the Japan Patent Office, the Korean Intellectual Property Office, the State Intellectual Property Office of the People's Republic of China, and the U.S. Patent and Trademark Office (PTO). Putting aside the United States, none of these jurisdictions consider a sale or use of an invention to constitute prior art unless the activity has rendered the invention available to the public. For example, the Strasbourg Convention on the harmonization of European national patent laws and the European Patent Convention define prior art to include "everything made available to the public by means of a written or oral description" before the effective filing date.[40]

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[36] *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc*., Supreme Court of the United States Docket No. 17-1229, Brief for Amicus Curiae Congressman Lamar Smith in Support of Petitioner, 2018 WL 4043325 (August 23, 2018).

[37] Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q. J. 1 (2012).

[38] 157 Cong. Rec. S1371.

[39] *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc*., Supreme Court of the United States Docket No. 17-1229, Brief of Amicus Curiae the Naples Roundtable in Support of Neither Party, 2018 WL 4252016 (August 30, 2018). *See also*, 157 Cong. Rec. S5319 - S5320 (daily ed. Sept. 6, 2011) (statement of Sen. Kyl) ("The main benefit of the AIA public availability standard of prior art is that it is relatively inexpensive to establish the existence of events that make an invention available to the public").

[40] 2A Chisum on Patents § 6.02 (2019).

The argument that the AIA introduced a public availability requirement to the public use and on-sale bars finds further support in certain established principles of statutory interpretation. For example, in its amicus brief IPO argues that courts generally strive to give effect to all statutory language, and that interpreting "or otherwise available to the public" as modifying "on sale" would give effect to the language. IPO also asserts that "courts have consistently construed the words "or otherwise" or "or other" at the end of a string as modifying the preceding clauses." Thus, "under the principle of *noscitur a sociis, i.e.*, *a*, word is known by the company it keeps, the phrase "on sale" should be interpreted by association with the phrases around it, namely, "in public use" and "otherwise available to the public."

In *Helsinn*, the patent owner (Helsinn) argued before the Supreme Court that catch-all provisions such as "otherwise available to the public" are familiar features of federal statutes, allowing Congress to avoid the necessity of listing each matter falling within them, while still reaching "other devices not specifically enumerated but similar in purpose and effect" to the enumerated categories.[41] According to Helsinn, "where, as here, a catch-all provision follows a list of more specific provisions, the items enumerated in the specific provisions must be read in light of the final, comprehensive category."[42] Helsinn points to earlier Supreme Court decision wherein it argues the Court has recognized the function that "otherwise" and analogous linking terms serve on lists of parallel words or phrases.[43]

Prior to the Supreme Court's decision in *Helsinn* the PTO interpreted "otherwise available to the public" as changing the definition of public use and on sale in the AIA version of Section 102 to incorporate a public accessibility requirement. In particular, the Manual of Patent Examining Procedure (MPEP) states:

> The pre-AIA 35 U.S.C. 102(b) "on sale" provision has been interpreted as including commercial activity even if the activity is secret. See MPEP § 2133.03(b), subsection III.A. AIA 35 U.S.C. 102(a)(1) uses the same "on sale" term as pre-AIA 35 U.S.C. 102(b). The "or otherwise available to the public" residual clause of AIA 35 U.S.C. 102(a)(1), however, indicates that *AIA 35 U.S.C. 102(a)(1) does not cover secret sales or offers for sale*. For example, an activity (such as a sale, offer for sale, or other commercial activity) is secret (non-public) if it is among individuals having an obligation of confidentiality to the inventor.[44]

The PTO came to the same conclusion with respect to public use under the AIA:

> Patent-defeating "use," under pre-AIA 35 U.S.C. 102(a) includes only that "use which is accessible to the public." [P]ublic use under AIA 35 U.S.C.

[41] *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc*., Supreme Court of the United States Docket No. 17-1229, Brief for the Petitioner, 2018 WL 4043179 (August 23, 2018)(citing *CSX Transportation, Inc. v. Alabama Department of Revenue*, 562 U.S. 277, 292 (2011) and *Federal Maritime Board v. Isbrandtsen Co*., 356 U.S. 481, 492 (1958).
[42] *Id.* (citing *Federal Maritime Commission v. Seatrain Lines, Inc*., 411 U.S. 726, 734 (1973)).
[43] *Id.* (citing *United States v. Standard Brewery*, 251 U.S. 210, 218 (1920).
[44] MPEP § 2152.02(d)(Ninth Edition, Revision 08.2017)(emphasis added).

> 102(a)(1) is *limited to those uses that are available to the public*. The public use provision of AIA 35 U.S.C. 102(a)(1) thus has the same substantive scope, with respect to uses by either the inventor or a third party, as public uses under pre-AIA 35 U.S.C. 102(b) by unrelated third parties or others under pre-AIA 35 U.S.C. 102(a).[45]

In arriving at its interpretation of the import of the catch-all phrase, the PTO found that "[r]esidual clauses such as 'or otherwise' or 'or other' are generally viewed as modifying the preceding phrase or phrases," and that "[t]herefore, the Office views the 'or otherwise available to the public' residual clause of the AIA's 35 U.S.C. 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art."[46] In its amicus brief, IPO points out that the PTO has examined hundreds of thousands of patents based on this interpretation of the on-sale bar.[47]

The decisions below in *Helsinn*

Helsinn Healthcare S.A. is the owner of the four patents directed to intravenous formulations of palonosetron for use in reducing or reducing the likelihood of chemotherapy-induced nausea and vomiting ("CINV"). Helsinn brought suit against Teva Pharmaceuticals alleging that the filing of Teva's Abbreviated New Drug Application ("ANDA") constituted an infringement of various claims of those patents. Teva defended on the ground that the asserted claims were invalid under the on-sale provision of 35 U.S.C. §102, but the district court found that the patents-in-suit were not invalid.[48] With respect to three of the patents, which are governed by the pre-AIA version of §102, the district court concluded that although there was a commercial offer for sale before the critical date, the invention was not ready for patenting before the critical date. With respect to the fourth patent, which is governed by the AIA version of §102, the district court concluded that there was no commercial offer for sale because the AIA changed the relevant standard and that, in any event, the invention was not ready for patenting before the critical date.

The use of palonosetron to treat CINV was not new, but the patents at issue disclose intravenous formulations using low concentrations of palonosetron that were purportedly neither taught nor suggested by the prior art. It was undisputed that each asserted claim covers the 0.25 mg dose of palonosetron, and in order to simplify the relevant discussion the court simply referred to all of the patents as being directed toward the use of a 0.25 mg dose of palonosetron. All four of the patents claim priority to a provisional patent application filed on January 30, 2003. Thus, the pre-AIA critical date is January 30, 2002, and the post-AIA critical date was assumed to be January 30, 2003, and in any event could be no earlier than the pre-AIA critical date.

On April 6, 2001, almost two years before applying for a patent, Helsinn entered into two agreements with MGI Pharma, Inc. ("MGI," an oncology-focused pharmaceutical company that

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[45] MPEP § 2152.02(c) (Ninth Edition, Revision 08.2017)(emphasis added).
[46] U.S. Patent and Trademark Office, Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11059-01,11062 (Feb. 14, 2013) (citations omitted).
[47] *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc*., Supreme Court of the United States Docket No. 17-1229, Brief of Amicus Curiae Intellectual Property Owners Association in Support of Neither Party, 2018 WL 4091714 (August 23, 2018)(citing 157 Cong. Rec. H4429 (daily ed. June 22, 2011)).
[48] *Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd.*, No. CV 11-3962 (MLC), 2016 WL 832089.

markets and distributes in the United States): (1) a License Agreement and (2) a Supply and Purchase Agreement. These agreements were announced in a joint press release of the two corporations and in MGI's Form 8-K filing with the Securities and Exchange Commission ("SEC"), which included partially-redacted copies of both agreements.

Under the terms of the License Agreement, MGI agreed to pay $11 million in initial payments to Helsinn, plus additional future royalties on distribution of "products" in the United States. The parties agree that the "products" covered by the License Agreement were 0.25 mg and 0.75 mg doses of palonosetron.

Under the Supply and Purchase Agreement, MGI agreed to purchase exclusively from Helsinn, and Helsinn agreed to supply MGI's requirements of the 0.25 mg and 0.75 mg palonosetron products, or whichever of the two dosages were approved for sale by FDA. The agreement required MGI to submit purchase forecasts to Helsinn and to place firm orders at least 90 days before delivery. It also specified that such orders would be "subject to written acceptance and confirmation by [Helsinn] before becoming binding." In the event that Helsinn was unable to meet MGI's firm orders and to the extent they fell within the previously forecasted amount, Helsinn would then be obligated to designate a third party manufacturer to supply MGI with the product. The agreement specified price, method of payment, and method of delivery.

The License Agreement made reference to the ongoing clinical trials and stated that in the event that the results were unfavorable and FDA did not approve the sale of either dosage of the product, Helsinn could terminate the agreement. If the License Agreement were terminated, the Supply and Purchase Agreement would "terminate automatically." All of the above information about the transaction was publicly disclosed with two exceptions: the price terms and the specific dosage formulations covered by the agreements—that is the 0.25 and 0.75 mg doses.

Helsinn admitted that the agreement was binding as of its effective date, April 6, 2001, and that it would cover either or both of the 0.25 and 0.75 mg doses, subject to FDA approval. Helsinn also agreed that, if the Phase III trials were successful and the products were approved by FDA, then the agreement obligated MGI to purchase and Helsinn to supply the approved doses.

In 2011, Teva filed an ANDA seeking FDA approval to market a generic 0.25 mg palonosetron product. Teva's ANDA filing included a Paragraph IV certification that the claims directed to the 0.25 mg dose were invalid and/or not infringed. Helsinn sued under the Hatch–Waxman Act.

The district court held that Teva's 0.25 mg dose infringed all of the patents-in-suit. In addressing the on-sale issue, the court applied the two-step framework of *Pfaff*. As to three of the patents, the court found that pre-AIA law applied under §102(b) and that the MGI Supply and Purchase Agreement was a contract for a future sale of a commercial product embodying the 0.25 mg dose and therefore constituted a sale under §102(b). But, the court found that the claimed invention was not reduced to practice before the critical date of January 30, 2002, and therefore was not ready for patenting under the second prong of *Pfaff*.

Turning to the fourth patent (the '219 patent), which was filed March 23, 2013 (one week after the effective date of the AIA), the court held that the AIA changed the meaning of the on-sale bar and that AIA §102(a)(1) "requires a public sale or offer for sale of the claimed invention." The court concluded that, to be "public" under the AIA, a sale must publicly disclose the details of the invention. The court found that the MGI Supply and Purchase Agreement did not constitute a public sale or commercial offer for sale because, although it disclosed the sale agreement and substance of the transaction, it failed to publicly disclose the 0.25 mg dose. The Court further found that the subject matter claimed '219 patent was not ready for patenting before the critical date.

On appeal, the Federal Circuit reversed.[49] The court first addressed the pre-AIA patents, and found that with respect to these patents, the Supply and Purchase Agreement satisfied the "commercial offer for sale" prong of the *Pfaff* test. In arriving at this outcome, the court applied the framework established in its en banc decision in *Medicines Co. v. Hospira, Inc*. for determining whether there has been an offer for sale.[50] In *Medicines*, the court explained that the question must be "analyzed under the law of contracts as generally understood" and "must focus on those activities that would be understood to be commercial sales and offers for sale in the commercial community." As a general proposition, the court will look to the Uniform Commercial Code (UCC) to define whether a communication or series of communications rises to the level of a commercial offer for sale. Under the UCC, a sale occurs when there is a "contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold."[51]

Medicines points to additional factors that are important to this analysis, but noted that, like the UCC itself, none is determinative individually. In particular, the *absence of the passage of title*, the *confidential nature of a transaction*, and the *absence of commercial marketing* of the invention all counsel against applying the on-sale bar. These factors are relevant because they can shed light on whether a transaction would be understood "in the commercial community" to constitute a commercial offer for sale.

The court found that these additional factors did not weigh against finding that the Supply and Purchase Agreement constituted a commercial offer for sale, pointing out that the Agreement expressly contemplated a transfer of title. And while certain details were redacted from the publicly disclosed copy of the Agreement, the transaction itself did not remain confidential. The court further found that Helsinn had commercially marketed its invention before the critical date, by publicly seeking marketing partners for its patented product, and ultimately contracting with MGI "to distribute, promote, market, and sell" the claimed invention.

The Agreement also satisfied the requirements of the UCC: it was binding as of its effective date, it obligated Helsinn to sell and MGI to purchase the 0.25 mg dose of palonosetron (contingent upon FDA approval), and it included other specific terms, such as price, method of payment, and

[49] *Helsinn*, 855 F.3d at 1356.
[50] *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016).
[51] *Trading Techs. Int'l, Inc. v. eSpeed, Inc*., 595 F.3d 1340, 1361 (Fed. Cir. 2010).

method of delivery. The court note that "[i]t has been implicit in our prior opinions that the absence of FDA or other regulatory approval before the critical date does not prevent a sale or offer for sale from triggering the on-sale bar. The court contrasted this with the situation in *Elan Corp., PLC v. Andrx Pharm., Inc.*, where the purported offer concerned a product "when and if it had been developed," and there was no price or quantity term.[52] *Medicines* also made clear that the offer or contract for sale must unambiguously place the invention, as defined by the patent's claims, on sale. The court found this clearly to be the case with respect to the Agreement, which describes the 0.25 mg dose embodying the asserted method claims.

Turning next to the '219 patent, the Federal Circuit found that, in spite of numerous "floor statements" to the contrary by members of Congress, the AIA had not changed the definition of "on sale," and in particular had not introduced a "public availability" requirement on the on-sale bar. The court found that at most the floor statements show an intent "to do away certain secret uses to be invalidating under the public use prong of § 102(b)," and that the "public use" statutory bar was not at issue in this case. The court found that these floor statements were not referring to any precedent having to do specifically with the on-sale bar, and thus were of no consequence to it decision in the case at hand since the court was not addressing the question of whether the AIA had altered the definition of "public use."

The court found that even if Congressional floor statements voiced an intent to overrule certain secret or confidential sale cases, those cases were concerned entirely with whether the existence of a sale or offer was public, and thus are not applicable here since the existence of the sale, i.e., the Supply and Purchase Agreement between Helsinn and MGI, was publicly announced in MGI's 8-K filing with the SEC. The SEC filing included a copy of the contract for sale as an attachment, albeit partially redacted. Detailed information about palonosetron, its benefits and uses in treating CINV were also disclosed. The statements disclosed the chemical structure of palonosetron and specified that the covered products were "pharmaceutical preparations for human use in [intravenous] dosage form, containing [palonosetron] as an active ingredient." In short, the agreements disclosed all the pertinent details of the transaction other than the price and dosage levels.

Helsinn argued that under the AIA, not only is it necessary that the existence of the offer for sale be publicly available, but also that the offer must publicly disclose the details of the invention, and that since the 0.25 mg dose was not disclosed, the invention was not disclosed and the on-sale bar does not apply. But the Federal Circuit rejected this argument. The court found that requiring an offer for sale to disclose the details of an invention would "work a foundational change in the theory of the statutory on-sale bar." The court found that such a requirement would be inconsistent with Supreme Court and Federal Circuit precedent. The court noted that publicly offering a product for sale that embodies the claimed invention places it in the public domain, regardless of when or whether actual delivery occurs, and regardless of whether the offer is accepted or whether members of the public are aware that the products sold actually

[52] *Elan Corp., PLC v. Andrx Pharm., Inc.*, 366 F.3d 1336 (Fed. Cir. 2004).

embodies the claimed invention. The court found that if "Congress intended to work such a sweeping change to our on-sale bar jurisprudence … it would do so by clear language."

In short, according to this panel of the Federal Circuit, if the existence of the sale is public, then under the AIA the details of the invention need not be publicly disclosed in the terms of sale. Significantly, the court does not answer the question of whether a confidential offer for sale, the existence of which is not public information, would create an on-sale bar under the AIA. The court explicitly noted that it had not held that distribution agreements will always be invalidating under AIA §102, only that this particular Supply and Purchase Agreement is. The court also left unanswered the question of whether the AIA had in any way altered the standard for the public use statutory bar.

The court went on to conclude that the invention here was ready for patenting because it was reduced to practice before the critical date. It was uncontested that the formulation had been made and was stable prior to the critical date. Accordingly, the only issue with respect to ready for patenting was whether Helsinn had determined that the invention would work for its intended purpose, which, according to the claims, is "reducing the likelihood" of emesis and CINV. The court found that this had been established, in spite of the fact that the 0.25 mg did not receive FDA approval until after the critical date, pointing to Federal Circuit precedent that distinguishes between the standard required to show that a particular invention would work for its intended purpose and the more demanding standard that governs FDA approval of new drugs. In this case, the Federal Circuit found that the district court appeared to believe that Teva needed to meet the FDA standard, which requires finalized reports with fully analyzed results from successful Phase III trials. In so doing, the Federal Circuit held, the district court had clearly erred. The Federal Circuit found overwhelming evidence that before the critical date, it was established that the patented invention would work for its intended purpose of reducing the likelihood of emesis.

Note that if the court had upheld the patentability of the '219 patent claims, the counterintuitive effect would have been that by delaying the filing of the continuing patent application Helsinn would have eliminated prior art that would have invalidated the claims if the continuing patent application had been filed a couple of weeks earlier.

Amici weigh in on both sides

The Supreme Court granted Helsinn's petition for certiorari to answer the question of 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." A number of groups weighed in by filing amicus curiae briefs with the Supreme Court, and the positions taken in these briefs shed some light on the perceived winners and losers of the Federal Circuit's interpretation of the AIA in the decision belwo.

Support for affirmance came primarily from generic drug companies and the high-tech sector. In particular , the Association for Accessible Medicines ("AAM"), an organization that represents the interests of the generic and biosimilar medicines industry, filed a brief in support of Teva, as

did the High Tech Inventors Alliance, The Institute of Electrical and Electronics Engineers, Inc. (IEEE), and Intel. Congresswoman Zoe Lofgren, who represents the 19th Congressional District of California, based in the heart of Silicon Valley, filed a brief on her own behalf, asserting that she was actively involved in the drafting and passage of the AIA through her work on the House Committee on the Judiciary, and that she in fact was the one who proposed the amendment containing the language retaining the on-sale bar, which ultimately became law with the enactment of the AIA.[53] She asserts that Congress considered several alternative bills to the AIA that would have replaced the on-sale bar with a "pure publicity standard," and that Congress did not adopt the language of those proposals, choosing instead to preserve the on-sale bar as it had previously existed. According to Representative Lofgren, advocates and opponents of the on-sale bar both acknowledged contemporaneously that by retaining the on-sale bar the AIA retained its judicially-defined meaning.

On the other side, the U.S. government aligned with organizations representing small inventors, intellectual property owners, intellectual property attorneys, and the biotechnology and pharmaceutical industries. The list of amici arguing that secret offers for sale are not –on-sale events under the AIA thus included the U.S. solicitor general, US Inventor, Inc. (an association representing individual inventors and small companies), the Intellectual Property Owners Association (IPO), the American Intellectual Property Association (AIPLA) the Biotechnology Innovation Organization (BIO), the Pharmaceutical Research and Manufacturers Association (PhRMA), and a number of regional organizations representing biotechnology interests and intellectual property attorneys.

Providing a counterpoint to Representative Lofgren's brief, Congressman Lamar Smith filed his own brief asserting that Congress had in fact intended to limit the on-sale bar to offers for sale that rendered the invention available to the public, as part of an effort to bring U.S. patent law in step with every other country in the world.[54] Congressman Smith was the lead sponsor of the bill (the full name of the AIA is the Leahy-*Smith* America Invents Act) and managed its consideration in the House, serving as Chairman of the Committee on the Judiciary of the U.S. House of Representatives during the pendency of the AIA.

Amici brief's supporting Helsinn made a number of public policy arguments in support of an interpretation of the AIA which would require an offer of sale to make the invention available to the public. The U.S. solicitor general (SG) argued, for example, that the Federal Circuit's interpretation will "produce unwarranted disparities between large, vertically integrated companies that can perform in-house the various steps needed to prepare an invention for public

[53] *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc*., Supreme Court of the United States Docket No. 17-1229, Brief for Amicus Curiae Congresswoman Zoe Lofgren in Support of Respondents, 2018 WL 5096051 (August 16, 2018).

[54] *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc*., Supreme Court of the United States Docket No. 17-1229, Brief for Amicus Curiae Congressman Lamar Smith in Support of Petitioner, 2018 WL 4043325 (August 23, 2018).

sale, and smaller companies that rely on third-party distributors to disseminate their inventions to the public."[55] According to the SG, the agreement between Helsinn and MGI is similar to arrangements commonly made between corporate subsidiaries in a large organization intended to facilitate future marketing efforts, which do not render the invention available to its ultimate purchasers and which do not create a statutory bar.

BIO voiced similar concerns in its brief, arguing that "smaller innovative businesses that are not vertically integrated and that depend on external investment and product development partnerships, as is typical in biotechnology, are especially impacted."[56] BIO went on to point out that by "including within the ambit of § 102(a)'s on-sale bar, commercial activity that does not convey an invention to the public, the Court of Appeals' decision [in combination with the AIA's removal of territorial restrictions] the first time extends a patent-defeating effect to foreign conduct having no nexus with, and being undetectable from, the United States."[57]

BIO emphasized the negative ramifications of the Federal Circuit's decision for small biotechnology companies:

> Given the need for interactions with potential investors and business partners, small biotechnology companies are far more likely than large companies to engage in pre-commercial disclosures of their inventions. Potential partners and investors of course want sufficient details about a company's research, but are often reluctant to sign confidentiality and non-disclosure agreements early in a relationship. Concern about what can be disclosed in partnering and investor meetings is common among small biotech companies whose research programs include valuable trade secrets. And filing patent applications first may not always be a reasonable option.
>
> For example, a company's research program may have produced thousands of medicinal molecules, or thousands of therapeutic antibody candidates, but it may at that stage be completely unknown which candidate will be best suited for human testing and should therefore be patented. Proactively filing hundreds of patent applications would be wasteful and unrealistic. Such molecules may be "ready for patenting" within the meaning of patent law, but be far from "ready for patenting" under reasonable business practices. Nor would public policy be served by systematically encouraging the premature patenting of molecules that will, for the most part, turn out to be not commercially viable.

[55] *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc*., Supreme Court of the United States Docket No. 17-1229, Brief for the United States as Amicus Curiae Supporting Petitioner, 2018 WL 4179034 (August 30, 2018).
[56] *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc*., Supreme Court of the United States Docket No. 17-1229, The Biotechnology Innovation Organization (BIO) as Amicus Curiae in Support of Petitioner, 2018 WL 4252017 (August 30, 2018).
[57] *Id.*

> Further business uncertainty arises from the many forms of business transactions under which a development-stage biotech invention might be deemed transferred between businesses for consideration. Small and large companies sometimes contract work out to specialist companies, where medicinal molecules or antibody candidates are made to specification under purchase orders. Development partnerships between companies often take the form of licenses involving upfront payments and the transfer of materials or processes; or sometimes a larger company acquires the smaller company's research program and grants a license of co-development rights back to the small company. Sometimes potential partners are willing to make a preliminary investment in the small company's research program, but demand contingent assignment rights under which the larger company would get to own the program for a predetermined payment if certain future milestones are met. Under the lower court's decision there is a real risk that such typical transactions, even if they are conducted under strict confidentiality, would be deemed to place the invention in the public domain.
>
> No such business uncertainty would be experienced by large pharmaceutical companies that are likely to have the resources to develop their own products without seeking partners. But the decision below impacts innovative businesses of all sizes - large companies would be impacted because their ability to access interesting small-company innovations to feed their product pipelines is diminished. And large companies are typically the ones who spend hundreds of millions, if not billions of dollars to bring a drug to market. Such investment would be put at risk if a confidential transaction involving the candidate drug were to be deemed a "sale" in litigation a decade or more later, after a drug product has been brought to market against all odds. And smaller companies would be impacted more directly, and more harshly, because they depend on partnering and external funding, and are more likely to have to report business transactions publicly, which would greatly increase the risk of unfairly triggering a patent-defeating event. The result below is especially harsh when a "sale" is deemed to have occurred in a clearly pre-commercial setting, long before it is even clear whether a biotech invention can receive FDA approval and actually be sold to the public, and where the transaction was undertaken to fund the development of the invention.[58]

The Supreme Court's decision in *Helsinn*

In its January 2019 decision, a unanimous Supreme Court affirmed the judgment of the Federal Circuit and held that "an inventor's sale of an invention to a third party who is obligated to keep

[58] *Id.*

the invention confidential ***can*** qualify as prior art under § 102(a)."[59] It arrived at this holding based on its conclusion that Congress had not altered the meaning of "on sale" when it enacted the AIA.

The Court noted that Congress had enacted the AIA against the backdrop of a substantial body of law interpreting §102's on-sale bar, and that although it had previously never addressed the precise question presented in this case, the Court's precedents suggest that a sale or offer of sale need not make an invention available to the public. For instance, *Pfaff* held 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. The Court went on to state that what was implicit in its precedents had been made explicit by the Federal Circuit.[60]

The Court found it relevant that the new §102 retained the exact "on sale" language that appears in the pre-AIA statute, and that the addition of "or otherwise available to the public" was simply not enough of a change to conclude that Congress intended to alter the meaning of the term. The Court declined the invitation of the SG and others to read the addition of a broad catch-all phrase as upsetting the body of precedent surrounding the meaning of "on sale," and found that the phrase "otherwise available to the public" simply captures material that does not fit neatly into the statute's enumerated categories but is nevertheless meant to be covered. In other words, the catch-all phrase does not limit the scope of prior art under §102, if anything it expands it.

Lingering ambiguity

The Supreme Court's decision was decided relatively narrowly, leaving a number of important questions unanswered. In particular, the Court explicitly noted that it had not addressed the proper interpretation of pre-AIA Section §102. *Helsinn* simply holds that the AIA did not change the requirements for triggering the on sale bar, the Court did not address the continuing viability of the Federal Circuit's pre-AIA precedent.

As discussed in an earlier Holman Report, the SG filed an amicus brief in *Medicines* asking the en banc Federal Circuit to "clarify that, consistent with long-standing Supreme Court precedent and congressional intent, the [pre-AIA] on-sale bar is triggered only by sales or offers for sale that make the invention available to the public," and to "overrule its prior cases to the extent they are inconsistent with this interpretation of the on-sale bar."[61] In its brief, the SG argued that Congress's amendment of §102 in the AIA merely confirmed that the phrase "on sale" refers to a sale that makes an invention available to the public, and that Congress's use of the modifying

[59] *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S. Ct. 628 (2019).
[60] *Id.* (citing *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").
[61] *Medicines Co. v. Hospira, Inc.*, Federal Circuit Court of Appeals Docket No. 2014-1469, En Banc Brief for the United States as *Amicus Curiae* in Support of Appellant (March 2, 2016). Discussed in Christopher M. Holman, *The Medicines Company v. Hospira: When Does Outsourcing Drug Manufacture to a Third-Party Contractor Trigger an On-Sale Bar to Patentability?*, 35 Biotechnology L. Rep. 129 (2016).

phrase "or otherwise available to the public," indicates that the preceding terms "in public use" and "on sale" also make the invention "available to the public."

When the Federal Circuit decided *Helsinn*, it went to great lengths in explaining that while the sales agreement did not render the specific nature of the invention publicly accessible, the existence of the sale, along with the general nature of the subject matter, was publicly available information as a result of the press release and SEC filing. In its decision, the Federal Circuit explicitly distinguished between the case at hand and an alternative scenario involving an offer for sale the existence of which was not public information, and acknowledged the potential significance of floor statements made by members of Congress arguably expressing an intent to overrule cases holding that such sales create an on-sale bar.[62] The Federal Circuit specifically noted that under its interpretation of *Pfaff's* "commercial offer for sale" test, the *confidential nature of a transaction*, along with the *absence of commercial marketing*, weigh against a finding that the on-sale bar has been triggered.

To my mind, there is some doubt as to whether *Gore* and *Auld* remain good law post-*Pfaff*. Recall that, aside from a citation to *Metallizing Engineering*, neither decision provided any reasoned explanation for their holdings that the secret, non-informing use of a process to manufacture a product for sale creates an on-sale bar with respect to the process, if, and only if, it was the inventor or an assignee that used the process in such a manner. For one thing, *Metallizing Engineering* is generally understood as an interpretation of the public use statutory bar; the on-sale bar is never mentioned in the decision. Furthermore, the decision pre-dates the 1952 Patent Statute. One could argue that the Federal Circuit erred in *Auld* in finding that the claimed invention, a process, was even on sale, since it was not the process that was on sale, but rather a product made using the process. Furthermore, there is nothing in the language of the statute suggesting any basis for *Gore*'s distinction between the activities of the inventor and third parties. On the other hand, the Supreme Court's holding in *Helsinn* is explicitly directed towards "an inventor's sale of an invention to a third party," perhaps leaving open the possibility that a confidential offer for sale by a third party might still be treated differently for prior art purposes.

Significantly, both *Auld* and *Gore* were decided pre-*Pfaff*, and an argument could be made that *Pfaff* implicitly abrogated these decisions. The Federal Circuit in *Helsinn* explicitly noted that *Pfaff* had made clear "that we are not to look to broad policy rationales in assessing whether the on-sale bar applies." Prior to *Pfaff*, the Federal Circuit's "totality of the circumstances" test explicitly took into account the policy goals underlying the on-sale bar.[63] In her concurrence to the Federal Circuit's decision not to rehear *Helsinn* en banc, Judge O'Malley pointed out that the

[62] *Helsinn*, 855 F.3d at 1369 ("Even if the floor statements were intended to overrule those secret or confidential sale cases discussed above and cited in footnote 7, that would have no effect here since those cases were concerned entirely with whether the existence of a sale or offer was public.").

[63] *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc*., No. 2016-1284, 2018 WL 1583031 at *5 (Fed. Cir. Jan. 16, 2018) ("*See, e.g., Evans Cooling Sys., Inc. v. Gen. Motors Corp*., 125 F.3d 1448, 1451 (Fed. Cir. 1997) ("[T]he totality of the circumstances and the policies underlying the bar must be considered in determining whether a definite offer for sale triggering section 102(b) has been made."), abrogated by *Pfaff*, 525 U.S. 55; *Ferag AG v. Quipp Inc*., 45 F.3d 1562, 1566 (Fed. Cir. 1995) ("The underlying policies are what drives the section 102(b) analysis."), abrogated by *Pfaff*, 525 U.S. 55; *Medicines*, 827 F.3d at 1372.")

test under *Pfaff* "leaves little room for policy-based inquiries. Unless and until the Supreme Court articulates a more flexible test that allows courts to expressly consider the policies that animate the on-sale bar, and to give priority to one of those goals over others, our on-sale bar jurisprudence will not necessarily promote any given policy goal."[64]

Auld and *Gore* find no support in the literal language of §102, and their atextual interpretation of the on-sale bar can only be rationalized as an attempt to advance perceived policy objectives. Likewise *Metallizing Engineering*, which the Federal Circuit points to as supporting *Auld* and *Gore*, embodies an interpretation of the statute based entirely on policy considerations that flies in the face of the express language of the statute. While this sort of policy-driven interpretation of the statute might have been acceptable pre-*Pfaff*, one could argue that these decisions were implicitly abrogated by *Pfaff.*

Beyond *Pfaff*, recent Supreme Court jurisprudence addressing interpretation of the Patent and Copyright Acts have repeatedly rejected policy-driven atextual interpretations of these statutes, favoring instead a "plain meaning" approach to statutory interpretation.[65] *Metallizing Engineering*'s interpretation of "public use" as encompassing secret, non-informing uses seems clearly inconsistent with the statutory language, and the text of §102 provides no support for *Metallizing Engineering*'s divergent treatment prior use inventors as opposed to third parties. *Auld* and *Gore* would also appear to be susceptible to a "plain meaning" challenge before the Supreme Court. The Federal Circuit might agree, if given the opportunity to address its pre-*Pfaff* precedent in a future case. In short, substantial ambiguity with respect to the contours of the on-sale and public use bars remains alive post-*Helsinn*, as evidenced not only by Judge O'Malley's concurrence in the denial of en banc reconsideration of *Helsinn*, but also in the Federal Circuit's en banc *Medicines* decision, wherein upon reconsideration all three of the judges on the initial panel reversed their earlier interpretation of the on-sale bar.

[64] *Id.*

[65] *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 546 (2014) ("Our analysis begins and ends with the text of § 285"); *Star Athletica, L.L.C. v. Varsity Brands, Inc.*, 137 S. Ct. 1002, 1010 (2017) ("We thus begin and end our inquiry with the text, giving each word its 'ordinary, contemporary, common meaning.'").