

No. 17-1229

IN THE
Supreme Court of the United States

HELFINN HEALTHCARE S.A.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Respondents.

**On Petition for Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit**

**BRIEF FOR THE AMERICAN INTELLECTUAL
PROPERTY LAW ASSOCIATION AS *AMICUS
CURIAE* IN SUPPORT OF PETITION FOR
WRIT OF CERTIORARI**

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March 30, 2018

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INTEREST OF AMICUS CURIAE

The American Intellectual Property Law Association (“AIPLA”) is a national bar association of approximately 13,500 members who are primarily lawyers engaged in private and corporate practice, in government service, and in the academic community. AIPLA’s members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly and indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public’s interest in healthy competition, reasonable costs, and basic fairness.

AIPLA has no stake in any of the parties to this litigation or in the result of this case.¹

¹ In accordance with Supreme Court Rule 37.6, AIPLA states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than AIPLA and its counsel. Specifically, after reasonable investigation, AIPLA believes that (i) no member of its Board or Amicus Committee who voted to file this brief, or any attorney in the law firm or corporation of such a member, represents a party to the litigation in this matter, (ii) no representative of any party to this litigation participated in the authorship of this brief, and (iii) no one other than AIPLA, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief.

AIPLA has no stake in the parties to this litigation or in the result of this case, other than its interest in the correct and consistent interpretation of the laws affecting intellectual property.²

SUMMARY OF ARGUMENT

This case requires Supreme Court review to resolve the confusion created by the Federal Circuit's failure to give effect to a revision of the "on sale" doctrine, which Congress enacted to bring transparency, objectivity, and predictability to the patent system.

Under the 1952 Patent Act, the "on sale" doctrine prevented an inventor from obtaining a patent on an invention that was commercially sold more than a year before the application was filed. Its purpose was to incentivize prompt filings of patent applications and to discourage the commercial exploitation outside of the patent term.

When the America Invents Act ("AIA") replaced our "first to invent" patent system with a "first inventor to file" patent system, it did so to harmonize U.S. law with patent systems around the world and to incentivize prompt filing of patent applications, thereby promoting disclosure and accelerating innovation. Its changes to the "on sale" provision

² AIPLA has the consent of the parties to file this amicus brief, pursuant to Supreme Court Rule 37.3(a), based on the blanket consents filed with this Court by Petitioner on March 13, 2018 and by Respondent dated March 19, 2018. Pursuant to this Court's Rule 37.2(a), Counsel of Record for Petitioner and Respondent received notice of AIPLA's intent to file this brief on March 15, 2018.

implemented those objectives by imposing a “public availability” requirement not only on the fact of the sale transaction itself, but also on subject matter of the sale transaction, i.e., the “claimed invention.” These changes abandoned the forfeiture model of the former on-sale provision, which had become a trap for unwary inventors, and adopted a pro-disclosure model which is based on prior art categories that serve as conditions of patentability.

Although the meaning of “available to the public” may need to be developed on a case-by-case basis for different types of inventions, any such questions cannot justify turning a blind eye to the express language of the statute. That language, at a minimum, requires that the “claimed invention”—with all of its claim limitations—be “available to the public. Moreover, the decision below will convert what should be a legal issue in most cases into a fact-intensive issue in many cases. This will not only jeopardize the prior investment in inventions claimed in the patent(s)-in-suit, but will also increase the time and expense required for discovery, motion practice, trial, and appellate review.

This Court’s intervention is urgently needed to ensure that the statutory mandate is observed and that the congressional objectives of the AIA are fulfilled.

ARGUMENT

I. The Court Should Review This Case To Restore The Statutory Definition of Prior Art.

This Court should review this case because the Federal Circuit's interpretation of the AIA's "on sale" provision distorts the meaning of prior art by undermining the statutory requirement of "public availability," a feature central to the AIA's purpose of improving the efficiency and predictability of the U.S. patent system.

According to the House Report, "[t]he Act . . . simplifies how prior art is determined, provides more certainty, and reduces the cost associated with filing and litigating patents." H.R. REP. NO. 112-98, at 42 (2011). *See also id.* at 40 (the "legislation is designed to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs."). The AIA § 102(a)(1) requirement that claimed inventions be publicly available to qualify as prior art simplifies the decision to pursue patent protection by minimizing the cost to investigate whether the invention has been publicly used or sold. This requirement also lessens discovery in litigation by eliminating an otherwise fact-intensive inquiry into whether the claimed invention was subject to any potentially invalidating uses or sales.

A. The Amended Text Of The AIA Was Erroneously Interpreted By Federal Circuit.

As amended, section 102(a)(1) provides as follows:

(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....

35 U.S.C. § 102(a)(1) (2012) (emphasis added). Inventors cannot obtain patents “unless” they can overcome the prior art, making the definition of prior art fundamental to the patent system.

Congress passed the AIA in 2011 as the first major reform of U.S. patent law since the 1952 Patent Act, transforming the former “first-to-invent” system into the current “first-inventor-to-file” system. The AIA revised the language of §102(b) of the 1952 Act and moved it into a new § 102(a)(1), as follows:

(a) Novelty; Prior Art.—~~Conditions for patentability; novelty and loss of right to patent~~—A person shall be entitled to a patent unless—

(1) the claimed 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,~~ or otherwise available to the public before the

effective filing date of the claimed invention; more than one year prior to the date of the application for patent in the United States....

35 U.S.C. § 102(a)(1) (2012). The critical differences between the pre- and post-AIA versions of this language include:

- (1) the title is changed to strike “loss of right to patent” and to insert “Prior Art,” reflecting the provision’s focus on defining prior art rather than forfeiture events;
- (2) “claimed” now appears before “invention,”
- (3) “in this country” no longer appears after “in public use or on sale;”
- (4) “or otherwise available to the public” was added following the list of patent-defeating prior art; and,
- (5) “more than one year prior to the date of the application for patent in the United States” was changed to “before the effective filing date of the claimed invention.”³

³ The decision below reveals a misunderstanding of the AIA by referring in several places to the patent’s “critical date.” Pet. App. at 19a, 20a, and 25a-27a. “Critical date” refers to the date more than one year before the filing of a patent application under the 1952 Act to determine the grace period for such filings. *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1257 (Fed. Cir. 2001). However, the relevant term under § 102(a)(1) is “effective filing date,” defined at 35 U.S.C. § 100(i) as “the actual

The decision below failed to give full effect to these revisions, despite the plain language of § 102(a)(1).

The AIA defines “claimed invention” as “the subject matter defined by a claim in a patent...” 35 U.S.C. § 100(j). The subject matter of a claim is defined by all of the claim’s limitations. The statute places the “claimed invention” in the prior art only if it was on sale “or otherwise available to the public” before the patent’s “effective filing date.” The term “otherwise” means “in a different way or manner” (*Merriam-Webster’s Collegiate Dictionary*, at 823 (10th Ed. 1998)). Thus, the “claimed invention” is prior art only *where it is made available to the public, by sale or otherwise*. By not requiring the “claimed invention,” with all of its limitations, to be “available to the public,” the decision below effectively removed both terms—“claimed”⁴ and “otherwise”—from the statute. *E.g., TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (“It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.”).

The USPTO agrees with this plain reading of § 102(a)(1). In its examiner guidelines, the USPTO has stated that “otherwise available to the public” is a “catch-all” provision that focuses on whether the disclosure was “available to the public” rather than

filing date of the patent or the application for the patent containing a claim to the invention” or “the filing date of the earliest application for which the patent or application is entitled, as to such invention, to a right of priority....”

⁴ The decision below acknowledges that at least one element of the claimed invention, the dosage, was not disclosed to the public before the effective filing date of the patent. Pet. App. at 24a.

whether it falls within another prior art category defined by the statute. 78 Fed. Reg. 11059, 11075 (2d col.). Under those guidelines, secret sales do not qualify as prior art, only public ones do, and this applies to all documents and activities itemized in § 102(a)(1). *Id.* at 11062 (2d col.); *see also* Brief for the United States as *Amicus Curiae* at 5, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017), No. 16-1284 (“Brief of USA”). The USPTO’s reasonable interpretation is entitled to deference. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844, 865-66 (1984).

The concurring opinion on denial of rehearing *en banc* argued that under the “last antecedent” doctrine “to the public” modifies only “otherwise available.” Pet. App. at 11a. “Otherwise available to the public” is one phrase, however, and cannot be artificially divided in this manner. Moreover, “otherwise available to the public” is immediately followed by “before the effective filing date.” “Before the effective filing date” indisputably applies to all the listed forms of prior art – patents, printed publications, etc. But “or otherwise available to the public” *is actually part of the same phrase, not even separated by a comma* from “before the effective filing date.” Therefore, “or otherwise available to the public” must also apply to all the listed forms of prior art, including when the claimed invention is “on sale.”

**B. The Federal Circuit Misapplied
Pre-AIA Law To Interpret The New
AIA Text.**

The Federal Circuit relied on pre-AIA law to construe the AIA's § 102(a)(1) because it felt Congress's intent to change the law was not sufficiently clear. Pet. App. at 11a (citing *Dir., OWCP v. Perini N. River Assocs.*, 459 U.S. 297, 321 (1983)). In *Perini*, the Court considered whether an amendment to the Longshoremen's and Harbor Workers' Compensation and Health Act overruled this Court's decision in *Calbeck v. Travelers Ins. Co.*, 370 U.S. 114 (1962). *Calbeck* held that Congress did not incorporate a "maritime but local" exception to compensation into the Act. The Court wrote: "Surely, if Congress wished to repeal *Calbeck* and other cases legislatively, it would do so by clear language and not by removing from the statute the exact phrase that *Calbeck* found was responsible for continued emphasis on the 'maritime but local' doctrine." *Id.* at 321. Thus, the Court did not hold that Congress can only repeal a case legislatively by clear language.

In this case, Congress's intent to impose a public availability standard for prior art is clear from the express "or otherwise available to the public" language of the statute. The changes to § 102(a)(1) are analogous to the changes to 28 U.S.C. § 1367 which the Court considered in *Exxon Mobil Corp. v. Allapattah Servs.*, 545 U.S. 546 (2005). In *Exxon*, the Court addressed whether an amendment to § 1367 overruled *Zahn v. Int'l Paper Co.*, 414 U.S. 291 (1973). Rejecting an argument that the amended statute was ambiguous, so the Court should consider other canons

of construction, the Court wrote: “We can reject this argument at the very outset simply because § 1367 is not ambiguous.” *Id.* at 567. Earlier in the opinion, the Court wrote:

No sound canon of interpretation requires Congress to speak with extraordinary clarity in order to modify the rules of federal jurisdiction within appropriate constitutional bounds. Ordinary principles of statutory construction apply. In order to determine the scope of supplemental jurisdiction authorized by § 1367, then, we must examine the statute's text in light of context, structure, and related statutory provisions.

Id. at 558. Section 102(a)(1), after its amendment by the AIA, is likewise unambiguous. Congress is no more required to speak with “extraordinary clarity,” if that were possible, when amending it than when amending § 1367. The Court should construe § 102(a)(1) consistent with its express requirement that prior art must be “available to the public.”

The decision below also erred by construing § 102(a)(1) according to pre-AIA case law because, as illustrated in detail above, post-AIA § 102(a)(1) includes at least five major changes to pre-AIA § 102(b). Congress is presumed to adopt the prior interpretation of a statute only “when it re-enacts a statute without change.” *Lorillard v. Pons*, 434 U.S. 575, 580 (1978). Congress did not re-enact § 102 “without change,” so it cannot be presumed to have adopted any prior interpretations.

The plain language of § 102(a)(1) requires that, to qualify as prior art, the “claimed invention” must be “available to the public.” Even if the language of § 102(a)(1) were ambiguous, however, the legislative history would unambiguously impose a public availability standard on prior art. The House Report on the AIA explains that “[p]rior 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.” H.R. REP. NO. 112-98, at 42 (2011) (emphasis added). The House Report continues that “the phrase ‘available to the public’ [was] added to clarify the broad scope of relevant prior art, *as well as to emphasize the fact that it must be publicly accessible.*” *Id.* at 42-43 (emphasis added). This legislative history confirms the statutory language that all prior art, including sales, must make the invention available to the public. The decision below ignores this Report and incorrectly states that this reading of the statute depends upon “floor statements made by individual members of Congress.” Pet. App. at 36a.

In short, this case presents an important issue of the proper definition of prior art, which is fundamental to the patent system.

C. Secret Prior Art and The Incentives Of The First-Inventor-To-File System.

Incentives for prompt and complete disclosure of inventions are necessary to the bargain between the

inventor, who receives exclusive rights, and the government, which receives the disclosure. The incentive for the inventor to file promptly is particularly important to the government and the public where an invention can be kept secret while it is being commercialized. Under the first-to-invent system, inventors had a compelling incentive to defer filing for a patent. The first inventor could extend its exclusive use of the invention by waiting to seek a patent until the invention became public, through either another person's (1) public disclosure of the invention or (2) filing a patent application on the invention.

Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co., 153 F.2d 516 (2d Cir. 1946), is the seminal decision on secret prior art. In that case, the issue was the secret use of a process before the grace period and the sale of the unpatented products of that process. One basis for the secret use to be prior art was that the patent owner was benefitting from both trade secret and patent protection. As Judge Hand wrote, "it 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.*" *Id.* at 520 (emphasis added).⁵

Under the first-to-invent system, an inventor who used or sold an invention more than a year before

⁵ In response to comments that it should preserve the rule of *Metallizing Engineering* and related doctrines despite the AIA, the PTO wrote "some of the purposes ascribed to these doctrines in case law appear to be ill-suited to or inconsistent with the AIA." 78 Fed. Reg. 11059, 11075 (3d col.).

filing a patent application was at risk of losing the right to the patent. The harm of that loss, however, far outweighed the benefit of encouraging prompt filing. “The current forfeiture doctrines have become traps for unwary inventors and impose extreme results to no real purpose.” 157 Cong. Rec. S1371 (March 8, 2011) (1st col.) (Remarks of Senator Kyl discussing § 102 of S. 23, which was identical to § 102 of House bill 1249 that became the AIA). Individual and/or unsophisticated inventors forfeited their right to a patent because of limited and private uses that did not disclose the claimed invention to the public.⁶ “The only effect of rulings like these is to create heavy discovery costs in every patent case, and to punish small inventors who are unaware of the pitfalls of the [pre-AIA section 102(b)].” *Id.*⁷

As noted above, with the enactment of the AIA, the United States joined the rest of the industrialized world in having a system which awards patents to the first inventor to file an application covering the claimed invention. Under a first-inventor-to-file standard, the reasons for barring an inventor from

⁶ As examples, the Congressional Record cites *Egbert v. Lippman*, 104 U.S. 333 (1881) (corset spring inherently hidden from view and given to only one woman held to be “in public use”), *Beachcombers Int’l, Inc. v. Wildewood Creative Prods., Inc.*, 31 F.3d 1154, 1159-60 (Fed. Cir. 1994) (improved kaleidoscope “in public use” because shown to guests at private party), and *JumpSport, Inc. v. Jumpking, Inc.*, 191 Fed. Appx. 926 (Fed. Cir. 2006). See 157 Cong. Rec. S1371 (1st & 2d col.). All citations to the Congressional Record in this brief are to volume 157 of the daily edition.

⁷ See also cases discussed at note 12 *supra*.

seeking a valid patent after a prolonged period of secret commercial use disappear:

There is no need to also require forfeiture of patents simply because the inventor has made some use of the invention that has not made the invention available to the public. And the current on-sale bar [of pre-AIA section 102(b)] imposes penalties not demanded by any legitimate public interest. There is no reason to fear “commercialization” that merely consists of a secret sale or offer for sale but that does not operate to disclose the invention to the public.

Id. The first-inventor-to-file system provides a strong incentive to file promptly for patent protection and thereby disclose the invention to the public. Every day an inventor delays filing a patent application, even if it adds another day’s profit from the invention, risks losing twenty years of patent protection to another inventor who files first.

Finally, by maintaining an inventor’s right to obtain patent protection even after a confidential sale of an invention, §102(a)(1) provides a continuing incentive to disclose an invention. Once the invention has been disclosed in a patent application, others can improve it to progress the useful arts. On the other hand, if Congress had not protected an inventor’s right to a patent despite a secret sale, inventors would have a continuing incentive to maintain and use their invention in secret. Encouraging such secrecy would have the effect of retarding rather than promoting the

progress of the useful arts. Thus, instead of discouraging disclosure by maintaining the old forfeiture provisions, Congress “provide[d] ample incentive for an inventor to enter the patent system promptly” in the AIA “[b]y adopting the first-to-file system.” *Id.*

II. The “Public Availability” Requirement Reduces Prosecution, Transaction, and Litigation Risk and Expense Created By Secret Sales

Courts have a “duty to construe statutes, not isolated provisions.” *Graham County Water and Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 290 (2010) (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 568 (1995)).⁸ The introduction of the “public availability” requirement to the on-sale doctrine is consistent with the underlying purpose of the AIA to transform the U.S. patent system “from one of non-transparency, subjectivity, unpredictability and excessive complexity, to one that will operate with near-complete transparency, objectiveness, predictability and simplicity....” See Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 9 (2012) (“Armitage”). For example, the AIA eliminated fact-sensitive, discovery-intensive, and subjective elements such as the “best mode” defense from pre-AIA § 112⁹ and “deceptive intention” from

⁸ The Federal Circuit erred by focusing on only two words, “on sale,” not even an isolated provision, let alone the entire statute.

⁹ *Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306, 1314 (Fed. Cir. 2002) (whether best mode existed is subjective based on

pre-AIA §§ 116, 251, 253, 256, and 288. The AIA also added new § 257 on supplemental examination to address the fact-sensitive, discovery-intensive, and subjective inequitable conduct defense.¹⁰

Under pre-AIA § 102(b), interested parties cannot readily determine whether a patent will be subject to a public use or on-sale invalidity defense. This uncertainty affects decisions throughout a patent's lifecycle. Should a patent be pursued, licensed, acquired, or litigated? The answers to these questions depend on the answers to several others. Had there been a secret use in the U.S. more than a year prior to the filing of the patent application? Had the inventor (or a third party) engaged in some arguable sales activity in the U.S. more than one year before the application was filed? Was the invention "ready for patenting" at the time? If so, was that activity experimental? These questions can only be answered after completing extensive document review and multiple interviews or depositions.

The experimental use exception to the on-sale bar is particularly fact sensitive, requiring consideration of the following factors:

- (1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether

"what the inventor actually believed at the time the application was filed").

¹⁰ See Armitage, 40 AIPLA Q.J. at 9.

records of the experiment were kept, (8) who conducted the experiment, . . . (9) the degree of commercial exploitation during testing[,] . . . (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers.

Allen Eng'g, Inc. v. Bartell Indus., Inc., 299 F.3d 1336, 1353 (Fed. Cir. 2002). When the on-sale bar is at issue, the parties naturally will seek documents and testimony bearing on all these factors. In patent prosecution or transactions, this additional due diligence adds cost and risk and, in litigation, the discovery often triggers disputes that require court intervention, extends the length of any trial, and creates a voluminous record for appeal.

Because invalidating sales under AIA § 102(a)(1) are no longer confined to those taking place “in this country,” the decision below will even increase due diligence and discovery expenses for alleged sales that took place overseas. Parties to transactions or litigation may have to seek documents or take interviews or depositions or other discovery all over the world to develop the facts surrounding an alleged public use or secret sale.

By reducing the amount of due diligence or discovery required to determine if a sale is prior art under §102(a)(1), Congress created the certainty

required for parties investing in patent applications, pursuing licenses or acquisitions, and evaluating patent litigation. Resources that had been directed to investigations or litigation under the prior law can now be directed to enhancing innovation (*i.e.*, furthering progress in the useful arts). *See, e.g.*, 157 Cong. Rec. S5320 (daily Sept. 6, 2011) (2d col.); *see also id.* (1st col.) (“Also, for businesses seeking legal certainty, our current system can be a nightmare.... Given that both the product developer and competitor can rely on their own secret documents that the other side will not see until litigation over the patent commences, neither of these two parties can gain a clear picture of whether a patent is valid without years of litigation and millions of dollars of discovery and other litigation costs.”). Being able to assess patentability from publicly accessible information is essential for making timely and prudent business decisions, both for patentees and for potential infringers.

The costs to obtain and enforce a patent are not trivial, as demonstrated in biannual AIPLA surveys of its members. The 2017 Report of the Economic Survey (“2017 Report”) shows that the average cost for an original application of minimal complexity ranged from \$5,593 to \$11,679, depending on the geographic area. The average cost for a “relatively complex biotechnology/chemical” application ranged between \$9,050 and \$14,750. Of course, the cost of the application is just the beginning. The applicant must pay counsel to review and respond to Office Actions, prepare Information Disclosure Statements, and undertake other activities. Petitioner states that over one million patents have been issued under the AIA.

Petition for Writ of Certiorari (“Petition”) at 14. The minimum average investment in these patents at the 2017 rates is between \$5.5 billion and \$14.75 billion and the actual investment is undoubtedly much more. The decision below exposes that investment to additional risk, risk that was unanticipated in light of the PTO’s interpretation of § 102(a)(1). *See* text at pp. 7-8 *supra*.

Not surprisingly, the costs of patent litigation are much higher. For cases with over \$25 million at stake, the average cost through trial and appeal ranges from \$2.125 million to over \$5.467 million, depending on the location. Congress was understandably concerned with lowering these numbers by limiting prior art to publicly available references, or in other words, eliminating costly discovery into confidential sales.

Moreover, old “public use” and “on-sale” law led to many outcomes that defied logic and no longer serve any policy objective under the AIA.¹¹ As one commentator wrote:

It is one of the ironies of the pre-AIA patent law that § 102(a)’s invalidating “use” must make an invention accessible to the public, while § 102(b)’s “public use” can include private uses that are not accessible to the public. *See Woodland Trust*, 148 F.3d at 1370; *Trading Tech. Int’l, Inc. v. eSpeed, Inc.*, 507 F. Supp. 2d 883, 893 (N.D. Ill. 2007), *aff’d*, 595 F.3d 1340 (Fed. Cir. 2010) (finding that the secret commercial use

¹¹ *See, e.g.*, the cases cited in notes 6, *supra*, and 12, *infra*.

of an inventor's own invention may constitute public use).

Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 450 n.97 (2012). The PTO also recognized that its interpretation of §102(a)(1), combined with the grace period of post-AIA §102(b), “avoids the very odd potential result that the applicant who had made his invention accessible to the public for up to a year before filing an application could still obtain a patent, but the inventor who merely used his invention in secret one day before he filed an application could not obtain a patent.” 78 Fed. Reg. at 11062 (Feb. 14, 2019). Treating secret sales as prior art would lead to that “very odd potential result.” If the Court retains the pre-AIA construction of “on sale,” it will extend the uncertainty and oddity of the old interpretation. Further, it will undermine Congress’s objective to make the outcome of patent prosecution and litigation more predictable at the outset and reduce the related expenses.

The decision below will perpetuate the fact-intensive approach of pre-AIA case law. It states: (1) “the AIA did not change the statutory meaning of ‘on sale’ *in the circumstances involved here*,” Pet. App. at 20a (emphasis added); and (2) “[w]e do not find that distribution agreements will always be invalidating under § 102(b) [*sic* – 102(a)]. We simply find that this particular Supply and Purchase Agreement is.” Pet. App. at 43a. The opinion concurring in the denial of rehearing *en banc* also portrayed the decision as fact-specific. Pet. App. at 5a. Thus, the decision below will continue to require

substantial time and expense for investigation, discovery, motion practice, trial, and appeal to define the specific sales arrangements that do or do not constitute prior art. This result is contrary to the congressional intent “to reduce the costs associated with filing and litigating patents.” See H.R. REP. NO. 112-98, at 42.

The revision of § 102(a)(1) to introduce the requirement of “public availability” for the sale of an invention to qualify as prior art was consistent with the AIA’s overall shift towards objectivity, predictability, and efficiency. The change brought the on-sale doctrine into conformity with the public nature of the other prior art items listed in the statute (patents and printed publications). Further, it overruled the cases that had allowed the on-sale doctrine to reach “any commercial use, public or not, even where the subject matter of the offer is unavailable for purchase by members of the public” and thereby barred patentability.¹² *Gen. Elec. Co. v.*

¹² For example, *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357-1358 (Fed. Cir. 2001) (refusing to recognize a “supplier” exception to the on-sale bar); *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998) (finding an inventor’s own secret commercial use before the grace period may be a public use barring patentability); *Evans Cooling Systems, Inc. v. General Motors Corp.*, 125 F.3d 1448, 1454 (Fed. Cir. 1997) (refusing to create an exception to the on-sale bar for sales before the grace period that result from a misappropriation of the invention by a third party); *Metallizing Eng’g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946) (applying the on-sale bar to sales before the grace period of unpatented products made by the secret use of the patented process); *Hall v. Macneale*, 107 U.S. 90, 96 (1883) (finding the sale of “burglar-proof” safes to be a public use despite testimony that technology was completely concealed within the safe).

United States, 654 F.2d 55, 61 (Cl. Ct. 1981). The change is consistent with the other amendments made to U.S. patent law in the AIA, all of which eliminated subjective, fact-sensitive inquiries.

III. Other Policy Considerations Support The Public Availability Requirement.

Several policy considerations support §102(a)(1)'s exclusion of secret sales from the prior art. Some of those considerations have been discussed above, such as (1) the first-inventor-to-file standard provides ample incentive to file patent applications promptly; (2) eliminating secret sales as a forfeiture of patent rights provides a continuing incentive to file a patent application, facilitating continued progress in the useful arts; and, (3) the needs for increased business certainty and reduced litigation expenses.

Congress also imposed this public-availability requirement on prior art to protect U.S. businesses from having their inventions stolen or patents invalidated by unscrupulous foreign competitors. Senator Kyl stated:

Finally, *validating prior art will depend on publicly accessible information*, not private activities that take place, for example, in a foreign land. As a result, it will be impossible for a third party who derived the invention from a U.S. inventor's public disclosure or patent application to steal the invention or sabotage the U.S. inventor's patent.

157 Cong. Rec. S5320 (Sept. 6, 2011) (3d col.) (emphasis added). To allow secret sales anywhere in the world to serve as prior art would facilitate the theft of U.S. inventions, contrary to Congress's expressed intent. The Court can protect U.S. inventors against this risk by granting review and reinstating the public availability requirement for prior art mandated by the plain language of § 102(a)(1).

A final consideration is that upholding Congress's removal of secret sales as a forfeiture of patent rights will assist in achieving a greater level of substantive harmonization of patent laws among the U.S., Europe, Japan, and other countries. AIPLA is not aware of any foreign country that uses a first-inventor-to-file system and also includes secret sales as a basis for a loss of right to a patent.¹³ The House Report on the AIA cites "the value of harmonizing our system for granting patents with the best parts of other major patent systems throughout the industrialized world for the benefit of U.S. patent holders" as one of the motivations for the bill. H.R. REP. NO. 112-98, at 39. Conversely, maintaining secret sales as a basis for losing the right to a patent would detract from Congress's goal of further harmonizing U.S. patent law with that of other major industrialized nations.

¹³ The Government made a similar assertion in its amicus brief below. Brief of USA at 10. The fact no other country considers secret sales to be prior art confirms that the adoption of a first-inventor-to-file system provides a sufficient policy incentive to ensure early disclosure.

CONCLUSION

The Court should grant the Petitioner's writ to review this exceptionally important issue under the America Invents Act.

Respectfully submitted,

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