

Nos. 16-1284, -1787

United States Court of Appeals for the Federal Circuit

Helsinn Healthcare S.A. and Roche Palo Alto LLC,

Plaintiffs-Appellees,

v.

Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd.,

Defendants-Appellants.

Appeal from the United States District Court for the District of New Jersey,
Case Nos. 3:11-CV-3962, -5579, -5815, Judge Mary Cooper

**BRIEF OF AMICUS CURIAE
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION
IN SUPPORT OF PLAINTIFFS-APPELLEES**

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Date: May 2, 2016

2016-1284, -1787

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

HELSINN HEALTHCARE S.A. AND ROCHE PALO ALTO LLC,

Plaintiffs-Appellees,

v.

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

Defendants-Appellants.

CERTIFICATE OF INTEREST

In accordance with FED. CIR. R. 47.4 and FED. R. APP. P. 26.1, counsel for the Amicus the American Intellectual Property Law Association certifies the following:

1. The full name of every party represented by me is:

American Intellectual Property Law Association.

2. The name of the real party in interest represented by me is: **N/A.**

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the parties represented by me are:

None.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me and that are expected to appear in this court are:

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STATEMENT OF INTEREST OF AMICUS CURIAE

The American Intellectual Property Law Association (“AIPLA”) is a national bar association of approximately 14,000 members who are primarily lawyers engaged in private and corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. AIPLA’s mission includes providing courts with objective analysis to promote an intellectual property system that stimulates and rewards 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 AIPLA’s only interest is in seeking correct and consistent interpretation of the law as it relates to intellectual property issues. This brief is filed with the

¹ After reasonable investigation, AIPLA believes that (a) no member of its Board or Amicus Committee who voted to prepare this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation in this matter, (b) no representative of any party to this litigation participated in the authorship of this brief, and (c) no one other than AIPLA, its members who authored this brief, and their law firms or employees, made a monetary contribution to the preparation or submission of this brief.

consent of Appellants Teva Pharmaceuticals USA Inc. and Teva Pharmaceutical Industries Ltd., and Appellees Helsinn Healthcare S.A. and Roche Palo Alto LLC.

SUMMARY OF ARGUMENT

With the enactment of the Leahy-Smith America Invents Act (“AIA”), U.S. patent law was substantially changed to achieve increased objectivity, predictability, simplicity, and transparency. Among the most significant changes, the United States shifted from awarding patents based on the date of invention (a “first to invent” or FTI system) to giving priority based on the date an inventor files an application for a patent (a “first-inventor-to-file” or FITF system).

An important feature of the patent system is the grant of exclusive rights in exchange for full and early disclosure of the invention to permit unlimited public use of the invention at the end of the patent term. The first-to-invent system achieved this with provisions designed to encourage inventors to seek patents promptly and to discourage delayed filing and secret use of the invention that would unfairly extend the exclusive period in which the invention could be commercially exploited. Thus, it included provisions that prohibited the patenting of an invention that was “in public use” or “on sale” more than a year before the application was filed. Those provisions, however, sometimes led to harsh and anomalous results, and expensive litigation, particularly for small and/or unsophisticated inventors.

The first-inventor-to-file system, by contrast, inherently provides a powerful incentive for inventors to file patent applications promptly after making an invention. Moreover, delayed filing and secret use of the invention are deterred by

amendments stating that any public use or on-sale activity will have no prior art effect unless they are “available to the public.” Thus, such behavior could permit a competing inventor to win the race to the Patent Office, unencumbered by any priority effect of a secret use.

The district court’s conclusion that the language of 35 U.S.C. § 102(a)(1)—“or in public use, on sale, or *otherwise* available to public” (emphasis added)—applies a public availability requirement to the on-sale doctrine is borne out both in the plain language of the statute and in the purposes outlined above that the statute was intended to accomplish, as evidenced in the legislative history of the AIA. Retaining an inventor’s the right to obtain a patent, under the first-inventor-to-file system, notwithstanding a secret sale was not only consistent with the purpose of encouraging prompt filing and discouraging extensions of period of exclusivity; it was also consistent with the goals of the legislation to increase objectivity, predictability, simplicity, and transparency in the acquisition and enforcement of patent rights.

ARGUMENT

I. The “Big Picture” Confirms The AIA Intentionally Limited Prior Art to What is Publicly Available.

The district court held that AIA section 102(a)(1) required that a sale be public to qualify as prior art and that certain agreements at issue did not qualify. As

a matter of statutory construction and policy, the district court was correct in its interpretation of section 102(a)(1).

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)). Thus, to put the issue here regarding section 102(a)(1) in context, this brief examines some other provisions of the AIA which support the district court’s decision that limits prior art to information which was publicly available.²

A. The AIA Reflects Congress’s Overall Objective to Simplify Patent Law, Making it More Objective, Predictable, and Transparent.

Along with converting U.S. patent law to a first-inventor-to-file system, the AIA made a variety of amendments to improve the process of obtaining and enforcing patent rights. According to the House Report on H.R. 1249, “[t]he legislation is designed to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs.” H.R. Rep. No. 112-98, at 40 (2011). Some of the major changes

² Also to add context, the issues in this case are distinguishable from the on-sale issues currently before the *en banc* court in *The Medicines Company v. Hospira Inc.*, Fed. Cir., No. 2014-1469,-1504, en banc order November 12, 2015 (“*TMC*”). Whereas this case concerns an amendment to the patent statute and its effect on secret sales, the issue in *TMC* is whether a secret sale between a patent owner and a supplier meets the requirement under the prior statute that a prior art sale must be a “commercial” sale that exploits the value of the invention in the marketplace. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998).

along these lines included eliminating fact-sensitive, discovery-intensive, and subjective elements such as the “best mode” defense from pre-AIA section 112 and “deceptive intention” from pre-AIA sections 116, 251, 253, 256, 288, and adding new (*i.e.*, post-AIA) section 257 on supplemental examination to address the fact-sensitive, discovery-intensive, and subjective inequitable conduct doctrine.³

To further promote predictability, simplicity and transparency, the AIA revised section 102(a)(1) to introduce the new statutory requirement of “public availability” for the sale of an invention more than one year before the application filing date to qualify as prior art. The change brought the on-sale doctrine into conformity with the public nature of the other prior art items listed in the statute (patents, printed publications, and public use). 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;

As the accompanying House Report explained, “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.” H.R. REP. NO. 112-98, at 42-43 (2011). This change legislatively overruled the line of judicial precedent that had allowed

³ See generally Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 10-14 (2012) (“Armitage”).

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.⁴ *Gen. Elec. Co. v. United States*, 654 F.2d 55, 61 (Cl. Ct. 1981). An important source for much of the judicial analysis on secret prior art was the Second Circuit’s decision in *Metallizing Eng’g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946). 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 giving the secret use a prior art effect apparently was the court’s concern that the patent owner was simultaneously benefitting from 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.*” *Metallizing Eng’g Co.*, 153 F.2d at 520 (emphasis added).

⁴ 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).

The introduction of a requirement of “public availability” to the on-sale doctrine is entirely 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....” Armitage, 40 AIPLA Q.J. at 9. The addition of the “public availability” requirement to the on-sale doctrine eliminated the need for time-consuming and expensive discovery into an inventor’s pre-filing activities, the results of which could not be predicted in advance.

Reading the “public availability” requirement out of the on-sale doctrine would abrogate Congress’s intent to simplify patent law by restoring the on-sale doctrine to its accepted role: to encourage inventors to promptly file for patent protection and to discourage them from exploiting the value of their invention for more than one year before seeking a patent. *Pfaff*, 525 U.S. at 63.

B. The Incentives of The First-Inventor-To-File System.

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. To the extent that patent systems provide exclusive rights in exchange for disclosure of inventions to the public, incentives for prompt and complete disclosure are necessary to the bargain between the inventor and the government. The needed incentives to file

promptly are particularly important where an invention can be kept secret while it is being commercialized. In the first-to-invent system, inventors had a compelling incentive to defer seeking a patent. The inventor could wait to seek a patent until the invention became public, through either another's (1) public disclosure of the invention or (2) efforts to obtain a patent for the invention.

The incentive provided under the first-to-invent system was that an inventor that used or sold its invention more than a year before filing was at risk of losing his 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 (daily ed. March 8, 2011) (Remarks of Senator Kyl discussing section 102 of S. 23, which was identical to section 102 of House bill 1249 that became the AIA).⁵ Small and/or unsophisticated inventors, for example, 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

⁵ All citations to the Congressional Record in this brief are to volume 157 of the daily edition. Future citations will be abbreviated "Cong. Rec. [page] (date)."

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 Cong. Rec. S1371 (1st & 2d col.).

every patent case, and to punish small inventors who are unaware of the pitfalls of the [pre-AIA section 102(b)].” Cong. Rec. S1371 (March 8, 2011) (1st col.).⁷

Under a first-inventor-to-file standard, however, the reasons for barring an inventor from seeking a valid patent after a prolonged period of non-informing or 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.

By maintaining an inventor’s right to obtain patent protection even after secret commercial use of an invention, post-AIA section 102(a) provides a continuing incentive to disclose an invention that can then be more readily and rapidly improved by others and otherwise progress the useful arts. If Congress had not acted to retain 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 as soon as the one-year period after the disclosure had expired. Encouraging such secrecy would actually have the effect of retarding rather than promoting the

⁷ See also cases discussed at note 4 *supra*.

progress of the useful arts. Thus, instead of discouraging disclosure by maintaining the old loss of right 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 Plain Language of § 102(a)(1) Excludes Secret Sales as Prior Art.

As noted above, post-AIA section 102(a)(1) both implements the “first-inventor-to-file” system and, along with section 102(a)(2), defines the prior art.

Section 102(a)(1) reads:

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) (emphasis added).⁸ “Otherwise” means “in a different way or manner.” *Merriam-Webster’s Collegiate Dictionary*, at 823 (10th Ed. 1998). For the last category to be available to the public “in a different way or manner,” the prior categories, including “on sale,” must also be available to the public. The position that secret sales may qualify as prior art⁹ reads the word “otherwise” out of section

⁸ For a detailed review of the changes from pre-AIA section 102 to post-AIA section 102, *see* Armitage, *supra*, 40 AIPLA Q.J. at 39-60.

⁹ The position that secret sales qualify as prior art under pre-AIA section 102(b) is over-simplified. Under *Pfaff*, *supra*, an offer for sale must be “commercial” and the invention must be “ready for patenting” to implicate the statutory bar. 525 U.S. at 67. In contrast, an “experimental” offer for sale does not implicate the on sale bar of pre-AIA section 102(b). One factor used to determine if a sale or offer for sale was

102(a)(1), contrary to a basic canon of statutory construction. *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.").

A clause, such as "or otherwise," that is set off from a series of antecedent clauses by a comma applies to each of the preceding antecedents. In *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323 (Fed. Cir. 2008), this Court wrote that "when a modifier is set off from a series of antecedents by a comma, the modifier should be read to apply to each of those antecedents." *Id.* at 1336-37 (citation omitted). Moreover, both *Finisar* and the preceding quotation are included in the Senate's record from the day it voted on its version of the Act. Cong. Rec. S1370 (March 8, 2011) (3d col.). *Finisar* is cited in support of the conclusion that "although different categories of prior art are listed, all of them are limited to that which makes the invention 'available to the public.'" *Id.* (2d col.) (also stating at col. 1-2 that "[t]he word 'otherwise' makes clear that the preceding clauses describe things that are of the same quality or nature as the final clause"). *See also Res. Conservation Group*,

experimental is whether there was a secrecy obligation in connection with the sale or offer. *E.g.*, *Allen Eng'g, Inc. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1353 (Fed. Cir. 2002) (*quoting EZ Dock v. Schafer Sys., Inc.*, 276 F.3d 1347, 1357 (Fed. Cir. 2002) (Linn, J., concurring)). Determining whether a sale was commercial or experimental requires fact-intensive discovery and the associated expense, both of which Congress sought to minimize when enacting section 102(a)(1), as noted above.

LLC v. United States, 597 F.3d 1238, 1245 (Fed. Cir. 2010) (holding that the language “in connection with a procurement or a proposed procurement” at the end of a statutory paragraph applied to all preceding antecedents, and not only to the one immediately preceding it).

Further, as also recognized in the Congressional Record on the same day, Cong. Rec. S1370 (March 8, 2011) (3d col.), courts have consistently interpreted such an “otherwise” or “other” clause to limit the meaning of preceding clauses. For example, *Strom v. Goldman, Sachs & Co.*, 202 F.3d 138 (2d Cir. 1999), *overruled on other grounds*, *Pereira v. Farace*, 413 F.3d 330, 340 (2d Cir. 2005), construed the phrase “may include * * * back pay, * * * or any other equitable relief” and held:

The position of the phrase “or any other equitable relief” in the sentence in which it appears indicates that it modifies one or both of the two specific remedies referred to just before it in the same sentence * * * [T]he use of the words “other” immediately after the reference to back pay and before “equitable relief” demonstrated Congress’ understanding that the back pay remedy is equitable in nature.

Id. at 146–47.

Similarly, *Universal City Studios, Inc. v. Reimerdes*, 111 F. Supp. 2d 294 (S.D.N.Y. 2000), construed the phrase “offer to the public, provide, or otherwise traffic in any technology” and concluded:

The statute makes it unlawful to offer, provide or otherwise traffic in described technology. To ‘traffic’ in something is to engage in dealings in it, conduct that necessarily involves awareness of the nature of the subject of the trafficking. * * * The phrase ‘or otherwise traffic in’ modifies and gives meaning to the words “offer” and “provide.” In consequence, the anti-trafficking provision of the DMCA is implicated where one presents, holds out or makes a circumvention technology or device available, knowing its nature, for the purpose of allowing others to acquire it.

Id. at 325.

Finally, *Williamson v. Southern Regional Council, Inc.*, 223 Ga. 179, 154 S.E.2d 21 (1967), construed the phrase “carrying on propaganda, or otherwise attempting to influence legislation” noted that:

The words “carrying on propaganda” in this statute must be construed in connection with the words following it, “or otherwise attempting to influence legislation.” The use of the word “otherwise” indicates that “carrying on propaganda” relates to “attempting to influence legislation.”

223 Ga. at 184, 154 S.E.2d at 25. The result in these cases is not surprising given the ordinary meaning of “otherwise” as discussed above.¹⁰

¹⁰ The experts at the Patent Office studied the language of section 102(a)(1) and reached the same conclusion about its plain meaning. Examination Guidelines for Implementing the First Inventor To File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11059, 11062 (2d col.) and 11075 (2d col.) (Feb. 14, 2013).

Based on *Finisar* and these other cases, the phrase “or otherwise available to the public” in § 102(a)(1) modifies at least “or in public use, on sale” if not all of “patented, described in a printed publication, or in public use, on sale” given that patents and printed publications are necessarily public.

Even post-AIA section 102’s title shows Congress’s intent to limit prior art to public disclosures. Pre-AIA section 102 was titled, “Conditions for patentability; novelty *and loss of right to patent.*” 35 U.S.C. § 102 (2006) (emphasis added). Post-AIA section 102 is titled simply, “Conditions for patentability; novelty.” 35 U.S.C. § 102. In other words, the title no longer includes “and loss of right to patent.” The “on sale” provision of the pre-AIA section 102 was a statutory bar or loss of right provision, not a prior art or novelty provision. *E.g.*, 1 Donald S. Chisum, *Chisum on Patents* § 3.01, at 3-9 (2012) (“The novelty provisions should not be confused with the ‘statutory bar’ or ‘loss of right’ provisions in Section 102. Sections 102(b), 102(c) and 102(d) all relate to events and acts by the inventor or by other persons prior to the date when the inventor applies for a patent. The point of a statutory bar is that an inventor of a product or process ... can lose the right to obtain a patent by tardiness in applying for a patent.”).

Other changes between pre-AIA section 102(a) and (b) and post-AIA section 102(a)(1) reinforce the conclusion that post-AIA section 102(a)(1) prior art must be public. Pre-AIA section 102(b) read “or in public use *or* on sale in this country”

(emphasis added). Post-AIA section 102(a)(1) now reads “or in public use, on sale, or otherwise available to the public....” Instead of being set off as its own category by a separate “or,” “on sale” is now in a series of at least three items (“or in public use, on sale, or otherwise available to the public”), reinforcing that “on sale” now includes a requirement of public availability.

Another change from pre-AIA section 102(b) to post-AIA section 102(a)(1) is the deletion of “in this country” from pre-AIA section 102(b)’s “or in public use or on sale in this country.” Under post-AIA section 102(a)(1), a public use or sale of the claimed invention *anywhere in the world* can qualify as prior art.¹¹ Because sales of the claimed invention anywhere in the world can be prior art, there are compelling policy reasons to limit such sales to ones available to the public. Senator Kyl stated the following:

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.

Cong. Rec. S5320 (Sept. 6, 2011)(3d col.). In other words, limiting the prior art under post-AIA section 102(a)(1) to publicly available information will make it more difficult for a third party to invalidate a U.S. patent (or obtain its own patent)

¹¹ As a company whose business model largely depends on avoiding patents, Teva stands to benefit from having secret sales anywhere in the world qualify as prior art.

based on secret alleged activity that took place anywhere in the world. In contrast, to allow secret sales anywhere in the world to serve as prior art would facilitate the theft of U.S. inventions and increase the discovery burdens and expense of patent litigation, contrary to Congress's express objectives when enacting the AIA.

Amici 42 Patent Law Professors (“*Amici* professors”) express angst over alleged uncertainty in the construction of “in public use” or “on sale” if the court affirms the district court’s decision on this issue. This concern is misplaced because the terms will have the same meaning they have always had with the added requirement of being available to the public. Further, public availability can be judged by the settled standards of cases such as *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1333 (Fed. Cir. 2009), and *In re Lister*, 583 F.3d 1307 (Fed. Cir. 2009). *See* Cong. Rec. S1042 (March 1, 2011) (1st - 2d cols.) (“And ‘available to the public’ means the same thing that ‘publicly accessible’ does in the context of a publication.”) and S1370 (March 8, 2011) (3d col.).¹²

In short, the plain language of section 102(a)(1), supported by sound policy reasons, requires that all the different types of prior art under section 102(a)(1) be publicly available.

¹² *Amici* professors express particular concern about *Egbert* and *Metallizing Engineering, supra*. The fate of those cases is clear. “The present definition thus abrogates the rule announced in *Egbert v. Lippman*....” Cong. Rec. S1371 (March 8, 2011). The PTO recognized that Congress rejected the policies underlying the decision in *Metallizing Engineering*. 78 Fed. Reg. at 11062 (3d col.).

III. The Legislative History Establishes Prior Art Must Be Publicly Available.

The legislative history of the AIA supports the district court's construction of the plain language of section 102(a)(1) as imposing a public availability requirement. Most importantly, addressing the exact issue before the Court, the House Judiciary Committee Report on the AIA states "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*" (emphasis added). H. Rep. No. 112-98, at 43 (2011).¹³ The report also cites a colloquy that took place between Senators Hatch and Leahy the day after the Senate had passed its version of the bill (but addressing the same language in section 102(a)(1) and long before the AIA was passed). *Id.* at 43 n.20. In that colloquy, discussing the interplay between post-AIA sections 102(a) and 102(b), Senator Hatch stated:

But, the important point is that *if an inventor's disclosure triggers the 102(a) bar* with respect to an invention, *which can only be done by a disclosure that is both made available to the public and enabled*, then he or she had thereby triggered the grace period under 102(b).

Cong. Rec. S1496 (March 9, 2011) (3d col.) (emphasis added). Senator Leahy, one of the AIA's two namesakes, responded in part:

¹³ See also H.R. REP. NO. 112-98 at 42 ("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." (emphasis added)).

[S]ubsection 102(a) was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art. That will no longer be the case.

Id. Thus, the House Judiciary Committee’s report recognized that private offers for sale or sales would not be prior art under post-AIA section 102(a)(1).¹⁴

Again, speaking to the very issue before the Court, Representative Smith, the AIA’s other namesake, stated “contrary to current precedent, in order to trigger the bar in the new 102(a) in our legislation, an action must make the patented subject matter ‘available to the public’ before the effective filing date.” Cong. Rec. H4429 (June 22, 2011) (1st col.). These statements demonstrate that, when Congress passed the AIA, it knew prior art would be limited to publicly-available references or events.

IV. Section 102(b)(1)(B) Is Not to the Contrary.

It is not necessary for AIA section 102(a)(1)’s “on sale” language to treat secret sales as prior art to maintain a distinction between “disclosed” and “publicly disclosed” under post-AIA section 102(b)(1)(B). *See* Teva’s Brief at 55-58. To the

¹⁴ The legislative history of the AIA is chock full of statements expressly recognizing that, for example, “although different categories of prior art are listed, *all of them are limited to that which makes the invention ‘available to the public’*” Cong. Rec. S1370 (March 8, 2011) (2d col.) (emphasis added). Many of these statements were made by Senator Kyl, one of the sponsors of the Senate version. *See also* S1366 (1st col.), S1370 (1st col.), S1371 (2d col.) (March 8, 2011)

contrary, the AIA's legislative history again refutes this position. Explaining the one-year grace period of post-AIA section 102(b), Senator Leahy stated:

We intend that if an inventor's actions are such as to constitute prior art under subsection 102(a), then those actions *necessarily* trigger subsection 102(b)'s protections for the inventor and, what would otherwise have been section 102(a) prior art, would be excluded as prior art by the grace period provided by subsection 102(b). *Indeed, as an example of this, subsection 102(b)(1)(A), as written, was deliberately couched in broader terms than subsection 102(a)(1).* This means that any disclosure by the inventor whatsoever, whether or not in a form that resulted in the disclosure being made available to the public, is wholly disregarded as prior art.

Cong. Rec. S1496 (March 9, 2011) (2d – 3d cols.) (emphasis added). Immediately afterwards, Senator Hatch stated:

The Senator from Vermont is correct. For the purposes of grace-period protection, the legislation intends parallelism between the treatment of an inventor's actions under subsection 102(a) that might create prior art and the treatment of those actions that negate any prior-art effect under subsection 102(b).

Id. (3d col.).

Senators Hatch and Leahy's comments were echoed in the House by Representatives Bass and Smith as follows:

Mr. SMITH of Texas. I want to respond to the gentleman from New Hampshire and say that one key issue for clarification is the interplay between actions under section 102(a) and actions under section 102(b). *We intend for there to be an identity between 102(a) and 102(b). If an inventor's action is such that it triggers one of the bars*

under 102(a), then it inherently triggers the grace period subsection 102(b).

Mr. BASS of New Hampshire. I believe that the chairman is correct. *The legislation intends parallelism between the treatment of an inventor's action under 102(a) and 102(b).* In this way, small inventors and others will not accidentally stumble into a bar by their pre-filing actions.

Cong. Rec. H4429 (June 22, 2011) (1st col.). Congress's express intent was for post-AIA sections 102(a) and 102(b) to be co-extensive. Thus, because a non-public sale by definition falls outside the grace period of post-AIA section 102(b), a non-public sale cannot constitute prior art under post-AIA section 102(a)(1).

Moreover, the word "disclosed" alone in section 102(b)(1)(B) means "publicly disclosed." Again, the plain meaning of the word is clear enough, but to the extent there is any ambiguity, the only indicia of Congressional intent is dispositive:

I would have thought that the meaning of the word would be clear: a disclosure is something that makes the invention available to the public - the same test applied by section 102(a) to define the scope of the prior art. And "available to the public" means the same thing that "publicly accessible" does in the context of a publication.

Cong. Rec. S1042 (March 1, 2011) (1st col.; remarks of Sen. Kyl). In short, there is no distinction between "disclosed" and "publicly disclosed" in section 102(b)(1)(B).

V. Allowing Secret Sales to be Prior Art Would be Antagonistic to the AIA's Objectives.

According to the final House Committee Report on the AIA, “[t]he Act also 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) (emphasis added). Indeed, the Congressional record is replete with references to the goals of reducing costs related to patents, particularly litigation costs. For example, on the day the Senate passed its version of the AIA, Senator Leahy stated the “bill will establish a more efficient and streamlined patent system and limit unnecessary and counterproductive litigation costs....” Cong. Rec. S1361 (March 8, 2011) (1st col.). He added the AIA “will provide more certainty in litigation.” *Id.* at S1362 (1st col.). Shortly before final passage, Senator Kyl stated the AIA “will ultimately reduce litigation costs and reduce the need to hire patent lawyers.” Cong. Rec. S5319 (Sept. 6, 2011) (1st col.).

Under pre-AIA section 102(b), none of the parties to a patent infringement case could know with any certainty at the start of a case whether any defenses of patent invalidity had merit. Had there been a secret use in the U.S. more than a year prior to the date of the application for the patent was filed? Had the inventor (or even a third party) engaged in some sort of arguable sales activity in the U.S. more than one year before the application was filed? If so, was that activity experimental? Was the invention “ready for patenting” at the time? These questions could only be

answered after completing extensive document review and multiple depositions. By limiting the prior art under post-AIA section 102(a)(1) to activities that made the invention available to the public, Congress enhanced the certainty with which parties can approach patent litigation and reduced the amount of discovery that will be required to prepare cases for summary judgment and trial. Resources that had been directed to litigation under the prior law can now be directed to enhancing innovation (*i.e.*, furthering progress in the useful art). *See, e.g.*, Cong. Rec. S5320 (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.”).

Maintaining the menace of “secret prior art,” on the other hand, would make it difficult or impossible to know with reasonable certainty whether a patent claim is valid or not without the high -- indeed, increased -- cost of litigation. Being able to assess patentability from publicly-accessible information is essential for making timely and prudent business decisions, both for patentees and for infringers. Further, as noted above, post-AIA section 102(a)(1) eliminated the geographic restriction on public uses and secret sales as prior art. Thus, treating secret sales as

prior art would also increase litigation expenses. Parties would now have to take depositions or other discovery all over the world (assuming the laws of any applicable foreign countries permitted such discovery) to develop the facts surrounding an alleged public use or secret sale.

Old “public use” and “on-sale” law led to too many outcomes that defied logic and served no policy objective any longer under the AIA.¹⁵ As one knowledgeable 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 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).¹⁶ Further, the PTO recognized that its interpretation of section 102(a)(1), combined with the grace period of post-AIA section 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

¹⁵ *See, e.g.*, the cases cited in notes 4 and 6 *supra*.

¹⁶ Mr. Matal served as a Judiciary Committee Counsel to Senator Kyl from 2002 through at least passage of the AIA, except for when he served as the Minority General Counsel of the Judiciary Committee from May 2009 to January 2011 while Senator Jeff Sessions was the ranking member of the committee. *Id.* at n. *.

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).¹⁷ 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, oddity, and pointlessness that the old interpretation entailed. Further, it will undermine Congress’s objective to streamline patent litigation and make the outcome more predictable at the outset.

VI. Other Policy Considerations Support The District Court’s Decision.

Several policy considerations support the district court’s interpretation of Section 102(a)(1) to exclude secret sales from the prior art. Some of those considerations have been discussed above, such as (1) the fact that the first-inventor-to-file standard provides ample incentive to file patent applications promptly, (2) eliminating secret sales as a loss of right to patent provides a continuing incentive to file a patent application, facilitating continued progress in the useful arts, (3) deterring the theft of U.S. inventions, and (4) the needs for increased business certainty and reduced litigation expenses.

A final consideration is that upholding Congress’s removal of secret sales as a basis for the loss of right to a patent will assist in achieving a greater level of

¹⁷ 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.” *Id.* (3d col.)

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.¹⁸ Additional harmonization of U.S. patent law with that of other countries was another of the express goals of the AIA. The House Judiciary Committee 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 despite Congress’s efforts to eliminate it would detract from Congress’s goal of further harmonizing U.S. patent law with that of other major industrialized nations.

CONCLUSION

For these reasons, this Court should affirm the district court’s decision that to qualify as prior art under section 102(a)(1), as amended by the AIA, the disclosure in question must have been publicly available.

¹⁸ This absence confirms that the adoption of a first-inventor-to-file system provides a sufficient policy incentive to elicit early disclosure.

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Respectfully submitted,

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PROOF OF SERVICE

The undersigned hereby certifies that on May 2, 2016, I caused a true and correct copy of the foregoing **BRIEF OF AMICUS CURIAE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF PLAINTIFFS-APPELLEES** to be filed via CM/ECF with the Clerk of the Court and thereby to be served electronically upon all counsel of record in this matter.

Dated: May 2, 2016

/s/ Lynn C. Tyler

Lynn C. Tyler

Principal Attorney for Amicus Curiae

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 29(c)(5), I certify that according to the word-processing system used in preparing it (Microsoft Word 2010), the foregoing **BRIEF OF AMICUS CURIAE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN PARTIAL SUPPORT OF PLAINTIFF-APPELLEES** in relevant part is 6,339 words in length, excluding those portions exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b), and therefore complies with the type-volume limitation set forth in Fed. R. App. P 29(d).

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