

Nos. 2016-1284, -1787

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

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

Plaintiffs-Appellees,

v.

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

Defendants-Appellants.

On Appeal from the United States District Court for the District of New Jersey,
Nos. 3:11-cv-03962, 3:11-cv-05579, 3:13-cv-05815, Judge Mary L. Cooper

**BRIEF FOR AMICI CURIAE PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY
INNOVATION ORGANIZATION IN SUPPORT OF PLAINTIFFS-
APPELLEES**

JAMIE T. WISZ
THOMAS G. SAUNDERS
ROBBIE MANHAS
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006
(202) 663-6000

*Attorneys for Amici Curiae
Pharmaceutical Research and
Manufacturers of America and
Biotechnology Innovation
Organization*

May 2, 2016

CERTIFICATE OF INTEREST

Counsel for amici curiae Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization certify the following:

1. The full name of every party or amicus represented by us is:

Pharmaceutical Research and Manufacturers of America (PhRMA)

Biotechnology Innovation Organization (BIO)

2. The names of the real party in interest represented by us is:

Not applicable

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

PhRMA has no parent corporation and no publicly traded company owns 10% of more of its stock. However, its membership includes companies that have issued stock or debt securities to the public. A list of PhRMA's members is available at <http://www.phrma.org/about/member-companies>.

BIO has no parent corporation and no publicly traded company owns 10% of more of its stock. However, its membership includes companies that have issued stock or debt securities to the public. A list of BIO's members is available at <https://www.bio.org/articles/bio-members-web-site-links>.

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

WILMER CUTLER PICKERING HALE AND DORR LLP: Robbie Manhas, Thomas G. Saunders, Jamie T. Wisz

Dated: May 2, 2016

/s/ Jamie T. Wisz

JAMIE T. WISZ

WILMER CUTLER PICKERING

HALE AND DORR LLP

1875 Pennsylvania Ave., NW

Washington, DC 20006

(202) 663-6000

TABLE OF CONTENTS

	Page
CERTIFICATE OF INTEREST	i
TABLE OF AUTHORITIES	iii
INTEREST OF AMICI CURIAE	1
SUMMARY OF THE ARGUMENT	2
ARGUMENT	5
I. THE AIA REQUIRES THAT “ON SALE” PRIOR ART BE “AVAILABLE TO THE PUBLIC”	5
A. The Text Of AIA Section 102(a)(1) Requires Public Availability	5
B. A Public Availability Reading Of AIA Section 102(a)(1) Is Most Consistent With The Statutory Scheme	10
C. The Legislative History Confirms A Public Availability Reading Of AIA Section 102(a)(1)	15
II. SOUND PATENT POLICY REQUIRES THAT “ON SALE” PRIOR ART BE PUBLICLY AVAILABLE.....	19
A. Eliminating Secret Prior Art Ensures A Simpler, More Predictable, And Fully Transparent Patent System	19
B. Eliminating Secret Prior Art Allows Inventive Companies Greater Flexibility, Fostering Competition And Innovation.....	22
C. The AIA’s First-To-File Regime Undercuts The Rationale That Originally Motivated An Unnatural, Secret-Prior-Art Reading Of Pre-AIA Section 102(b)—A Reading The Supreme Court Has Never Endorsed.....	24
CONCLUSION.....	27
CERTIFICATE OF SERVICE	
CERTIFICATE OF COMPLIANCE	

TABLE OF AUTHORITIES

CASES

	Page(s)
<i>Barnhart v. Thomas</i> , 540 U.S. 20 (2003).....	8
<i>Bates v. Coe</i> , 98 U.S. 31 (1878).....	26
<i>Beachcombers International, Inc. v. Wildewood Creative Products Inc.</i> , 31 F.3d 1154 (Fed. Cir. 1994).....	22
<i>Bonito Boats, Inc. v. Thunder Craft Boats, Inc.</i> , 489 U.S. 141 (1989).....	26
<i>Dey, L.P. v. Sunovion Pharmaceutivcals, Inc.</i> , 715 F.3d 1351 (Fed. Cir. 2013).....	18
<i>Egbert v. Lippmann</i> , 104 U.S. 333 (1881).....	25
<i>Electric Storage Battery Co. v. Shimadzu</i> , 307 U.S. 5 (1939).....	25
<i>Federal Maritime Commission v. Seatrain Lines, Inc.</i> , 411 U.S. 726 (1973).....	7
<i>Garcia v. United States</i> , 469 U.S. 70 (1984).....	15
<i>Hall v. Macneale</i> , 107 U.S. 90 (1883).....	25
<i>In re Eltgroth</i> , 419 F.2d 918 (C.C.P.A. 1970).....	14
<i>In re Theis</i> , 610 F.2d 786 (C.C.P.A. 1979).....	9
<i>Jama v. Immigration & Customs Enforcement</i> , 543 U.S. 335 (2005).....	8
<i>JumpSport, Inc. v. Jumpking, Inc.</i> , 191 F. App’x 926 (Fed. Cir. 2006).....	22
<i>Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.</i> , 153 F.2d 516 (2d Cir. 1946).....	10, 19, 24
<i>Montgomery v. United States</i> , 65 Ct. Cl. 526 (1928).....	14
<i>Nobelman v. American Savings Bank</i> , 508 U.S. 324 (1993).....	8
<i>PAR Pharmaceutical, Inc. v. TWI Pharmaceuticals, Inc.</i> , 773 F.3d 1186 (Fed. Cir. 2014).....	14

Parks v. Booth, 102 U.S. 96 (1880)26

Paroline v. United States, 134 S. Ct. 1710 (2014)6, 7

Paulik v. Rizkalla, 760 F.2d 1270 (Fed. Cir. 1985)22

Peeler v. Miller, 535 F.2d 647 (C.C.P.A. 1976)14

Pennock v. Dialogue, 27 U.S. (2 Pet.) 1 (1829)25

Porto Rico Railway, Light & Power Co. v. Mor, 253 U.S. 345 (1920).....7

Sanitary Refrigerator Co. v. Winters, 280 U.S. 30 (1929)14

Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368 (Fed. Cir. 1998)18

STATUTES, RULES, AND REGULATIONS

18 U.S.C. § 22596, 7

35 U.S.C. § 1025, 12

Examination Guidelines for Implementing the First Inventor To File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11,059 (Feb. 14, 2013)20

Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).....2

LEGISLATIVE MATERIALS

H.R. 2795, 109th Cong. (2005).....18

H.R. Rep. No. 112-98 (2011).....11, 12, 16

S. Rep. No. 110-259 (2008)16

157 Cong. Rec. H4420 (daily ed. June 22, 2011)15, 17

157 Cong. Rec. S1175 (daily ed. Mar. 3, 2011)14, 17

157 Cong. Rec. S1360 (daily ed. Mar. 8, 2011)8, 13, 17, 21, 22

157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011)16, 17

OTHER AUTHORITIES

Barner, Sharon R. & Harold C. Wegner, TACPI, *Second Generation Chinese Patent Sophistication* (Nov. 6, 2007)11

Black’s Law Dictionary (10th ed. 2014).....5

Cotropia, Christopher A., *The Folly of Early Filing in Patent Law*, 61 Hastings L.J. 65 (2009).....23

Cotropia, Christopher A., *Modernizing Patent Law’s Inequitable Conduct Doctrine*, 24 Berkeley Tech. L.J. 723 (2009)21

<http://www.phrma.org/about/member-companies> 1

<https://www.bio.org/articles/bio-members-web-site-links> 1

Intellectual Property Owners Association, *Comments on Proposed Rules and Examination Guidelines* (Oct. 5, 2012).....10

Karshtedt, Dmitry, *The Riddle of Secret Public Use: A Response to Professor Lemley*, 93 Tex. L. Rev. See Also 159 (2015).....23

Manual of Patent Examining Procedure § 2151 (2015)12

Matal, Joe, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435 (2012)9

PhRMA, *2015 Profile: Biopharmaceutical Research Industry* vi (2015), available at http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf.....2

Scalia, Antonin & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* (2012).....5, 8

White House Office of the Press Secretary, Press Release, *President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs* (Sept. 16, 2011).....20

INTEREST OF AMICI CURIAE¹

Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association of leading research-based pharmaceutical and biotechnology companies. PhRMA's members are the primary source of the many new drugs and biologics introduced each year. These new medicines have played a key role in extending longevity and improving the quality of human life.

Biotechnology Innovation Organization (BIO) is the world's largest trade association, representing over 1100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members research and develop biotechnological healthcare, agricultural, environmental, and industrial products. BIO members range from startup entities and university spinoffs to Fortune 500 multinational corporations, though the majority of BIO members are small companies that have yet to bring products to market or attain profitability, and thus depend on venture capital and other private investment for their growth.

Medical advances such as those made by PhRMA's and BIO's members require enormous investments in research and development. For example,

¹ No counsel for a party authored this brief in whole or part, and no person other than amici, their members, or their counsel made a monetary contribution to fund its preparation or submission. Both appellants and appellees have consented to the filing of this brief. A complete list of PhRMA members is available at <http://www.phrma.org/about/member-companies>. A complete list of BIO members is available at <https://www.bio.org/articles/bio-members-web-site-links>.

PhRMA member companies invested \$51.2 billion in research and development of new medicines in 2014 and over half a trillion dollars since 2000. PhRMA, *2015 Profile: Biopharmaceutical Research Industry* vi (2015), available at http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf.

The protections of patent law provide incentives for companies to take on the huge risks of drug development. For those incentives to work effectively, biopharmaceutical innovation requires stability and predictability in patent law. “Secret” prior art creates uncertainty that clouds investment decisions. PhRMA and BIO accordingly have an interest in ensuring that the America Invents Act is not misconstrued to revive the categories of secret prior art that Congress eliminated.

SUMMARY OF THE ARGUMENT

Secret prior art has long been recognized as a drag on the patent system. It creates uncertainty about the validity of issued patents, increases the burdens of litigation and administrative proceedings, and restrains corporate dealings in a way that stifles competition and innovation. The Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011), addressed these problems by eliminating most forms of secret prior art, including secret uses and sales that existed under pre-AIA Section 102(b). Such prior-art references no longer qualify under the plain text of AIA Section 102(a)(1), which added the modifier “or otherwise available to the public” at the end of a series of parallel terms to make

clear that all of the categories of prior art listed in AIA Section 102(a)(1) must be “available to the public.”

The meaning of this plain text is reinforced by the statutory context. In an effort to push the patent system toward international harmonization and overall efficiency, the AIA expanded the scope of prior art in certain respects by simplifying the categories of prior art now available. It eliminated geographic restrictions, meaning that references from anywhere in the world now qualify as prior art. It also eliminated temporal restrictions previously tied to the date of invention. In light of these changes, allowing secret prior art to qualify under AIA Section 102(a)(1) would have vastly increased the scope of secret art that could operate to invalidate a patent, transforming a carefully circumscribed category under pre-AIA versions of the statute into a sprawling and unpredictable form of new art. To prevent this unprecedented expansion, Congress modified AIA Section 102(a)(1) to eliminate most forms of secret prior art and to make clear that prior art under that section must be available to the public.

Disregarding Congress’s considered judgment to eliminate secret prior art would undermine the purposes of the AIA. Far from advancing international harmonization, expanding secret prior art would put the United States out of step with the rest of the world, which does not recognize secret prior art. Similarly, expanding the scope of secret prior art conflicts with novel AIA efficiency

measures, such as post-grant review, which are not equipped to handle the discovery-intensive burdens that secret prior art entails. The elimination of secret prior art therefore achieves intra-statutory harmony. And it is not inconsistent with the varying usage of “disclosure” and “publicly disclose” in AIA Section 102(b)(1), which merely reflects the fact that certain disclosures can be non-public, not that the prior-art categories under AIA Section 102(a)(1) can be.

The legislative history confirms the elimination of secret prior art under AIA Section 102(a)(1). It contains a number of explicit and powerful statements of such intent, including in the final Committee Report and in the statements of key sponsors. No such evidence of intent exists in favor of retaining secret prior art.

The district court’s recognition of Congress’s clear intent should therefore be affirmed. Not only does sound patent policy support eliminating secret prior art, but the rationale that motivated the pre-AIA rule that an applicant’s secret uses and sales should constitute prior art has little applicability in the AIA’s first-to-file regime. And the reading that rationale supports is made only weaker by the fact that the Supreme Court has never squarely endorsed it—indeed, the Court has made statements to the effect that secret uses and sales do not qualify as prior art. Because secret prior art is unsound as a matter of both general patent policy and the specific concerns the Court has said animate the public use and on-sale bars, secret activities should not be treated as prior art under AIA Section 102(a)(1).

ARGUMENT

I. THE AIA REQUIRES THAT “ON SALE” PRIOR ART BE “AVAILABLE TO THE PUBLIC”

Congress fundamentally altered patent law in multiple ways through passage of the AIA. One important change—signaled uniformly across the AIA’s text, structure, and legislative history—was the elimination of most forms of secret prior art, including secret prior-art sales that existed under pre-AIA Section 102(b). This Court should affirm the district court’s recognition of Congress’s clear intent with respect to this important reform.

A. The Text Of AIA Section 102(a)(1) Requires Public Availability

AIA Section 102(a)(1) provides that “[a] person shall be entitled to a patent unless ... the claimed invention was patented, described in a printed publication, or in public use, on sale, or *otherwise available to the public* before the effective filing date of the claimed invention.” 35 U.S.C. § 102(a)(1) (emphasis added). The plain text of this provision indicates that sales and offers to sell do not qualify as prior art unless they make the invention “available to the public.”

The bolded phrase is a series qualifier: a modifier at the end of list that applies to every item in the list. Scalia & Garner, *Reading Law: The Interpretation of Legal Texts* 147 (2012) (“When there is a straightforward, parallel construction that involves all nouns or verbs in a series, a prepositive or postpositive modifier normally applies to the entire series.”); see also *Black’s Law Dictionary* 1574 (10th

ed. 2014) (explaining the “series-qualifier canon”). The preceding clauses, including “on sale,” run parallel to the clause “otherwise available to the public.” Therefore, the most natural reading of the text is that “on sale” prior art must be “available to the public.”

The Supreme Court has repeatedly and recently applied the series-qualifier canon to provisions similar to AIA Section 102(a)(1). For example, in *Paroline v. United States*, 134 S. Ct. 1710 (2014), the Court interpreted 18 U.S.C. § 2259, a statute that provides restitution to victims of offenses involving sexual exploitation of children. At issue was the effect of the final clause of a list that defined the phrase “full amount of the victim’s losses”:

Definition.--For purposes of this subsection, the term “full amount of the victim’s losses” includes any costs incurred by the victim for—

- (A) medical services relating to physical, psychiatric, or psychological care;
- (B) physical and occupational therapy or rehabilitation;
- (C) necessary transportation, temporary housing, and child care expenses;
- (D) lost income;
- (E) attorneys’ fees, as well as other costs incurred; and
- (F) *any other losses suffered by the victim as a proximate result of the offense.*

18 U.S.C. § 2259(b)(3) (emphasis added). The Court determined that the final clause was a series qualifier—that every preceding loss in the list also had to be “a proximate result of the offense.” *Paroline*, 134 S. Ct. at 1720-1722.

In reaching this conclusion, the Court relied on commonsense grammatical principles. It noted that “[w]hen several words are followed by a clause which is applicable as much to the first and other words as to the last, the natural construction of the language demands that the clause be read as applicable to all.” *Paroline*, 134 S. Ct. at 1721 (quoting *Porto Rico Railway, Light & Power Co. v. Mor*, 253 U.S. 345, 348 (1920)). It also noted that “[catch-all] clauses are to be read as bringing within a statute categories similar in type to those specifically enumerated.” *Id.* (quoting *Federal Maritime Comm’n v. Seatrain Lines, Inc.*, 411 U.S. 726, 734 (1973)) (alteration in original).

Because AIA Section 102(a)(1)’s “otherwise available to the public”—like *Paroline*’s “any other losses”—“defines a broad, final category” of the same substantive character and syntactic structure as the items in the list preceding it, the phrase too should be read to restrict the meaning of every item in the list.²

Paroline, 134 S. Ct. at 1721. Indeed, Congress was well aware of the series-qualifier canon and expressly invoked it in connection with AIA Section 102(a)(1).

² At a minimum, under the series-qualifier canon, the catch-all clause would apply to the “in public use” and “on sale” categories of prior art, which are not affected by the “or” that immediately follows “described in a printed publication.”

See 157 Cong. Rec. S1360, S1370 (daily ed. Mar. 8, 2011) (statement of Senator Jon Kyl) (“Courts have consistently found that when the words ‘or otherwise’ or ‘or other’ are used to add a modifier at the end of a string of clauses, the modifier thus added restricts the meaning of the preceding clauses.” (citing case law from various jurisdictions)).

The so-called “rule of the last antecedent” is not to the contrary. That rule, which holds that “a limiting clause or phrase ... should ordinarily be read as modifying only the noun or phrase that it immediately follows,” applies only in limited circumstances not present here. *Barnhart v. Thomas*, 540 U.S. 20, 26 (2003) (last-antecedent rule “can assuredly be overcome by other indicia of meaning”); *see also, e.g., Nobelman v. American Savings Bank*, 508 U.S. 324, 330-331 (1993) (refusing to apply last-antecedent rule when a contrary interpretation was “the more reasonable one”). In particular, the last-antecedent rule applies where—unlike here—“the syntax involves something other than a parallel series of nouns or verbs,” Scalia & Garner, *Reading Law: The Interpretation of Legal Texts* 152 (2012), or lacks a linking word, such as “otherwise,” indicating commonality. The relevant clause at issue in AIA Section 102(a)(1) is not “a structurally discrete statutory provision” but “the end of a single, integrated list”—a context in which the last-antecedent rule holds no purchase. *Jama v. Immigration & Customs Enforcement*, 543 U.S. 335, 344 n.4 (2005).

Even if the last-antecedent rule were applied, the most logical modifier would be “otherwise available to the public” and the last antecedent would be “on sale.” To contend that “available to the public” is the modifier and “otherwise” is the last antecedent makes little sense: “otherwise” has no independent meaning in the series, which could not simply end “in public use, on sale, or otherwise” and be coherent. The only way to give “otherwise” meaning is to read it as part of the modifying phrase “otherwise available to the public”; in this capacity, the term acts as a bridge across different types of prior art, all of which share the characteristic of being publicly available.

Whatever canon is applied, interpreting “on sale” prior art to be “available to the public” accords with the AIA’s change to the title of Section 102. Pre-AIA Section 102 was entitled “Conditions for patentability; novelty and loss of right to patent.” AIA Section 102 is entitled “Conditions for patentability; novelty.” The removal of the phrase “and loss of right to patent” reflects that AIA Section 102(a)(1)’s “otherwise available to the public” language eliminates the pre-AIA loss-of-right rule of counting an inventor’s secret activities as prior art. Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 450 (2012) (“In light of the AIA’s repeal of all ‘loss of right to patent’ provisions based on secret activities from § 102, those words have been removed from the title of § 102.”); *see also In re Theis*, 610 F.2d 786, 792

(C.C.P.A. 1979) (citing *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2d Cir. 1946)), and noting that an “inventor’s *loss of right to patent* flows from the attempt to profit from the invention by commercial exploitation beyond the grace period” (emphasis added)).

B. A Public Availability Reading Of AIA Section 102(a)(1) Is Most Consistent With The Statutory Scheme

Statutory context reinforces the fact that “on sale” prior art must be publicly available. The AIA expanded the scope of prior art in several respects. For example, it eliminated geographic restrictions that had limited the on-sale and public use bars to activities in the United States. It also relaxed temporal restrictions as part of the move to a first-to-file system. At the same time, Congress added the qualifier “otherwise available to the public” to ensure that these expansions—intended to harmonize U.S. patent law with the law of other countries and to simplify patent litigation—would not have perverse consequences.

In the pre-AIA regime, secret prior art was a small, carefully circumscribed universe of potentially invalidating references. Even then it created tremendous uncertainty. See Intellectual Property Owners Association, *Comments on Proposed Rules and Examination Guidelines* 3 (Oct. 5, 2012) (“[P]atent litigation ... [is] burdened with extensive discovery into whether or not a patentee secretly sought to sell or offer to sell his invention.”). The last thing Congress wanted was to give that uncertainty global reach, exposing inventors to secret prior art from

around the world. Doing so would have vastly increased the scope of secret prior-art references, multiplying the burden and cost of patent-related litigation and administrative proceedings. *See infra* Part II.A; *see also, e.g.*, H.R. Rep. No. 112-98, at 42 (“[T]he America Invents Act ... simplifies how prior art is determined, provides more certainty, and reduces the cost associated with filing and litigating patents.”).

The amicus brief submitted by intellectual property professors ignores this critical context when it argues that Congress would not have abandoned prior interpretations of the terms “on sale” and “in public use.” *See* IP Professors’ Br. 11. The question before Congress was not whether to maintain the status quo with respect to those categories of prior art, but how far they would be allowed to *expand*. Congress drew the line at secret prior art, which was already problematic even when limited to the United States, by inserting the requirement that all AIA Section 102(a)(1) prior art be “available to the public.”

Indeed, creating a system of global secret prior art would have run against the AIA’s goal of international harmonization. *See, e.g.*, H.R. Rep. No. 112-98, at 42 (2011). Other countries do not follow any rule comparable to the pre-AIA’s “unique bar against patenting an applicant’s secret invention.” Barner & Wegner, TACPI, *Second Generation Chinese Patent Sophistication* 5 n.8 (Nov. 6, 2007) (“No other country has followed the lead of Learned Hand in *Metallizing*

Engineering.”). Expanding the scope of secret prior art would have made the United States even more of an outlier. The only place Congress did allow a type of secret prior art was in AIA Section 102(a)(2), which treats as prior art originally confidential patent applications later published under AIA Section 122(b). But unlike the proposed expansion of Section 102(a)(1), that provision was limited to art easily accessible to the PTO. Elsewhere, the AIA eliminated pre-AIA categories of secret prior art, such as derivation under pre-AIA Section 102(f) and prior invention under pre-AIA Section 102(g). *See* 35 U.S.C. § 102(f) (pre-AIA) (person not entitled to a patent if “he did not himself invent the subject matter sought to be patented”); *id.* § 102(g) (person not entitled to a patent if, “before such person’s invention[,] ... the invention was made” by another inventor meeting certain requirements); *see also* MPEP § 2151 (overview discussing the AIA’s elimination of pre-AIA Section 102(g) and (f) art).

Moreover, allowing secret prior art under AIA Section 102(a)(1) would undermine other provisions of the AIA. Particularly relevant are the provisions establishing post-grant review, which are meant to “make the patent system more efficient[,] ... improve the quality of patents and the patent system[,] ... and restore confidence in the presumption of validity that comes with issued patents in court.” H.R. Rep. No. 112-98, at 48. These goals would be thwarted by the inclusion of secret prior art. As Senator Kyl explained, “the bill’s new post-grant

review, in which any validity challenge can be raised, would be utterly unmanageable if the validity of all patents subject to review under the new system continued to depend on discovery-intensive searches for secret offers for sale and non-disclosing uses by third parties.” 157 Cong. Rec. at S1371. Congress explicitly acknowledged these problems and disclaimed the existence of secret prior art in AIA Section 102(a)(1) in the summary of the Senate floor managers’ amendment to the AIA: “PGR [post-grant review] is limited to only FTF [first-to-file] patents—no FTI [first-to-invent] patents can be challenged in PGR. This is done because FTI patents raise discovery-intensive invention-date and secret-prior-art issues that would be difficult to address in an administrative proceeding.” 157 Cong. Rec. at S1366.

Against this context reinforcing the elimination of secret prior art in AIA Section 102(a)(1), Teva and its amici offer only AIA Section 102(b)(1)’s varying usage of “disclosure” and “publicly disclose.” But the inconsistency they posit is illusory because it rests on an unsound premise: that “disclosure” is co-extensive with the prior-art categories listed in AIA Section 102(a)(1). *See* IP Professors’ Br. 2-5 & n.3. “Disclosure” is a broad term that cannot be confined to the categories listed in AIA Section 102(a)(1). That much is clear from the statute: AIA Section 102(b)(2)—which creates an exception to a limited form of secret prior art, the originally confidential patent applications of AIA Section 102(a)(2)—uses

“disclosure” in the exact same fashion as AIA Section 102(b)(1). “Disclosure” must therefore encompass subject matter including but not limited to the categories of prior art listed in AIA Section 102(a)(1). That some of this additional subject matter might be non-public does not imply the same for the prior-art categories of AIA Section 102(a)(1).

The case law accords with this interpretation. “Disclosure”—in all its varying forms—has been an imprecise, all-purpose byword since before the inception of the Federal Circuit. *See, e.g., PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1189-1199 (Fed. Cir. 2014) (using or quoting uses of “disclosure” and variations with regard to features of prior art, the doctrine of inherency, and information made available by inventors during prosecution); *Peeler v. Miller*, 535 F.2d 647, 649-654 (C.C.P.A. 1976) (using “disclosure” in the context of a pre-filing “invention disclosure” of an invention to be patented); *In re Eltgroth*, 419 F.2d 918, 919-921 (C.C.P.A. 1970) (using “disclosure” and variations with regard to three of the disclosure requirements of pre-AIA versions of Section 112: enablement, best mode, and definiteness); *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 32 (1929) (reciting argument that “each claim [was of] so narrow a field that infringement was not disclosed”); *Montgomery v. United States*, 65 Ct. Cl. 526, 544-566 (1928) (using “disclosure” and variations with regard to the scope of patent claims and the features of prior art); *cf.* 157 Cong. Rec. S1175, S1182

(daily ed. Mar. 3, 2011) (statement of Sen. Dianne Feinstein) (expressing concern regarding “the undefined term of ‘disclosure’”); 157 Cong. Rec. H4420, H4430 (daily ed. June 22, 2011) (statement of Rep. Zoe Lofgren) (expressing concern that the term “disclosure” creates ambiguity).

In light of the amorphous meaning of “disclosure,” it is unhelpful to put too fine a point on the term’s usage. A “disclosure,” as used in the context of AIA Section 102(b)(1), is an act or thing that imparts information (particularly about an invention or discovery) in some manner or another. The term represents a loose category, broader than the prior-art references listed in AIA Section 102(a)(1), best interpreted as including *possible* prior art that can ultimately not qualify for various reasons, such as those provided in the one-year grace period of AIA Section 102(b)(1) *or* a lack of public availability under AIA Section 102(a)(1). Such an interpretation achieves intra-statutory harmony and best accommodates congressional intent.

C. The Legislative History Confirms A Public Availability Reading Of AIA Section 102(a)(1)

The legislative history that led to the passage of the AIA clearly reflects that the phrase “available to the public” was added to ensure that the scope of AIA Section 102(a)(1) prior art would be limited to prior art that is publicly available. The most important example appears in the final Committee Report for the AIA. *See, e.g., Garcia v. United States*, 469 U.S. 70, 76 (1984) (“In surveying legislative

history[,] we have repeatedly stated that the authoritative source for finding the Legislature’s intent lies in the Committee Reports on the bill[.]”). That Committee Report is unequivocal: “‘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.” H.R. Rep. No. 112-98, at 43; *see also id.* at 42 (“Prior art ... will typically include all art that publicly exists prior to the filing date[.]”). The final Committee Report drew these statements verbatim from the Committee Report for S. 1145, the predecessor to the AIA that added the “or otherwise available to the public” language that is now part of AIA Section 102(a)(1). S. Rep. No. 110-259, at 9, 32 (2008). Given these unbroken statements of intent, “otherwise available to the public” means what it plainly says: references do not qualify under AIA Section 102(a)(1) unless they are publicly available.

The AIA’s key sponsors made statements that reinforce this view. Senators Hatch, Leahy, and Kyl, as well as Representative Smith, all agreed that secret art is not prior art under AIA Section 102(a)(1):

[T]he 102(a) bar with respect to an invention ... [can only be triggered] by a disclosure that is ... made available to the public If a disclosure ... is not made available to the public, then such a disclosure would not constitute patent-defeating prior art under 102(a) in the first place.

157 Cong. Rec. S1496, S1496 (daily ed. Mar. 9, 2011) (statement of Sen. Orin Hatch).

[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. In effect, the new paragraph 102(a)(1) imposes an overarching requirement for availability to the public, that is a public disclosure, which will limit paragraph 102(a)(1) prior art to subject matter meeting the public accessibility standard that is well-settled in current law, especially case law of the Federal Circuit.

157 Cong. Rec. at S1496 (statement of Sen. Patrick Leahy).

New section 102(a)(1) limits all non-patent prior art to that which is available to the public. ... The word “otherwise” makes clear that the preceding clauses describe things that are of the same quality or nature as the final clause—that is, although different categories of prior art are listed, all of them are limited to that which makes the invention “available to the public.”

157 Cong. Rec. at S1370 (statement of Sen. Jon Kyl).

[C]ontrary 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.

157 Cong. Rec. at H4429 (statement of Rep. Lamar Smith).

Other sources of legislative history confirm that these statements reflect congressional intent generally. For example, the summary of the Senate floor managers’ amendment explains that one of the reasons that post-grant review is limited to first-to-file patents is that pre-AIA “[first-to-invent] patents raise discovery-intensive ... secret-prior-art issues that would be difficult to address in an administrative proceeding.” 157 Cong. Rec. at S1366; *see also* 157 Cong. Rec.

at S1208 (materials entered by Sen. Jon Kyl by unanimous consent) (“Limit ‘prior art’ used to bar a patent from issuing to only those disclosures made available to the public before the patent was sought and disclosures in earlier-filed patent applications.”)

It is true that a rejected earlier bill “would have eliminated the categories of public use and on sale” entirely, IP Professors’ Br. 5, defining prior art as that which has been “patented, described in a printed publication, or otherwise publicly known,” H.R. 2795, 109th Cong. § 3 (2005). That does not mean, however, that the different phrasing ultimately adopted (or the legislative history explaining its purpose) is not sufficient to establish a public availability requirement. Indeed, “available to the public”—unlike the proposed language from the earlier bill—derives from precedent indicative of an intent to eliminate secret prior art: It was the pre-AIA standard that applied to third-party activities, for which non-informing and secret uses were *never* sufficient to qualify as prior art. *See Dey, L.P. v. Sunovion Pharm., Inc.*, 715 F.3d 1351, 1355 (Fed. Cir. 2013) (earlier cases establish that “being ‘accessible to the public’ ... requires public availability; secret or confidential third-party uses do not invalidate later-filed patents”); *see also Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1371 (Fed. Cir. 1998). The selection of a phrase taken from a context in which secret uses did not

qualify as prior art reinforces Congress's desire to exclude secret prior art from AIA Section 102(a)(1).

II. SOUND PATENT POLICY REQUIRES THAT "ON SALE" PRIOR ART BE PUBLICLY AVAILABLE

Congress eliminated secret prior art because it recognized that there were powerful public policy reasons to do so. Public availability serves an important notice function and grants inventive companies flexibility that facilitates innovation. Moreover, the original rationale for pre-AIA interpretations of Section 102(b)—namely, that counting an inventor's secret activities as prior art motivates early patenting, *see Metallizing Eng'g*, 153 F.2d at 520—is a vestige of the first-to-invent system that has little applicability in the first-to-file context. And it underpins a highly unnatural reading of pre-AIA Section 102(b) that has never been squarely endorsed by—and is in fact in tension with—Supreme Court precedent applying pre-AIA versions of the statute. Because a secret-prior-art reading of pre-AIA Section 102(b) is therefore already suspect, and because its underlying policy rationale is even weaker given the first-to-file rule, this Court should not interpret AIA Section 102(a)(1) in the same manner.

A. Eliminating Secret Prior Art Ensures A Simpler, More Predictable, And Fully Transparent Patent System

Secret prior art under AIA Section 102(a)(1) is problematic precisely because it is secret. Without an actual or constructive notice requirement, the

PTO, prospective patentees, and accused infringers are all hobbled in their efforts to operate in the patent space.

The potential existence of secret prior art requires expensive and time-consuming discovery (both in PTO proceedings or litigation) into an inventor's private dealings to determine whether a secret prior offer, sale, or use has occurred anywhere in the world. Such investigations present a considerable burden that is antithetical to the AIA's express purposes of enhancing efficiency. *See, e.g., Examination Guidelines for Implementing the First Inventor To File Provisions of the Leahy-Smith America Invents Act*, 78 Fed. Reg. 11,059, 11,062 (Feb. 14, 2013) (“[A] number of comments suggested that public availability should be a requirement for ‘on sale’ activities [under the AIA] [because] it would lower litigation costs by simplifying discovery[.]”); White House Office of the Press Secretary, Press Release, *President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs* (Sept. 16, 2011) (“[The AIA] will give a boost to American companies and inventors who have suffered costly delays and unnecessary litigation, and let them focus instead on innovation and job creation.”); *id.* (“key elements” of the AIA include “[r]educing the current patent backlog ... [and] litigation”). To the extent patent rights are more difficult to procure, maintain, and assert, patents provide less incentive to invent.

The availability of secret uses and sales as prior art also creates massive uncertainty about patent validity. During examination of a patent application, the PTO often has no way of knowing whether the claimed invention, or something similar enough to negate its patentability, has been secretly commercialized or placed on sale. *See Cotropia, Modernizing Patent Law's Inequitable Conduct Doctrine*, 24 Berkeley Tech. L.J. 723, 754 (2009) (examination highly dependent on the cooperation of the applicant). And even if aware of potentially relevant activity, the PTO cannot readily determine whether the technology embodied therein was commercialized or placed on sale early enough to qualify as prior art. Examination is therefore an inadequate initial gatekeeper of validity if AIA Section 102(a)(1) embraces secret prior art.

The situation is no different in post-grant review, which is intended to act as a quality check on issued patents: The proceeding runs on a fast track that similarly cannot cope with the discovery-intensive procedures necessary to uncover secret prior art. 157 Cong. Rec. at S1366 (summary of managers' amendment); 157 Cong. Rec. at S1371 (statement of Sen. Jon Kyl). Allowing secret activities to qualify as prior art creates lingering uncertainty that clouds the value of all patents, discouraging investment in the development of new technology and diverting resources into litigation with regard to issued patents.

Disallowing secret prior art under AIA Section 102(a)(1) mitigates these problems by ensuring that the PTO has access to the entire universe of relevant art. It frees inventors from the worry of invalidating secret sales and affords them flexibility that furthers “the principal reason for a patent system[,] [namely,] to encourage innovation and its fruits: new jobs and new industries, new consumer goods and trade benefits.” *Paulik v. Rizkalla*, 760 F.2d 1270, 1276 (Fed. Cir. 1985) (en banc). It also protects inventors who are unfamiliar with complicated forfeiture rules from accidentally creating prior art that invalidates a later-sought patent. *See, e.g.*, 157 Cong. Rec. at S1371 (statement of Sen. Jon Kyl) (citing *Beachcombers Int’l, Inc. v. Wildewood Creative Prods. Inc.*, 31 F.3d 1154, 1159-1160 (Fed. Cir. 1994); *JumpSport, Inc. v. Jumpking, Inc.*, 191 F. App’x 926 (Fed. Cir. 2006)). Such a rule is more efficient, more fair, and more in line with international practice than the pre-AIA standard.

B. Eliminating Secret Prior Art Allows Inventive Companies Greater Flexibility, Fostering Competition And Innovation

Eliminating secret prior art has the additional benefit of creating flexibility to structure business relations in a more efficient way. The currently pending *Medicines Company* en banc appeal presents one example of the need for such flexibility: confidential supplier arrangements, if deemed prior art under the on-sale bar, prejudice small companies, individual inventors, and others who (unlike large

corporations) lack the ability to manufacture inventions in-house. *See Medicines Co. v. Hospira, Inc.*, Nos. 2014-1469, -1504.

A public availability rule also provides more breathing space for pre-patent exploration of an invention's utility and value. This freedom can incentivize innovation, improve patent quality, and reduce burdens on the patent system by allowing inventors to more fully develop their inventions before they decide whether (or before they have the means necessary) to pursue patent protection. *See Cotropia, The Folly of Early Filing in Patent Law*, 61 *Hastings L.J.* 65 (2009) (arguing that patent law encourages a "file early, file often" mentality that aggravates systemic patent problems, such as too many patent applications, too many patents, underdevelopment of patented technology, increased assertion of patent rights, and fuzzy patent boundaries); *see also* Karshtedt, *The Riddle of Secret Public Use: A Response to Professor Lemley*, 93 *Tex. L. Rev.* See Also 159, 165 (2015) (noting that "[a] rule that forces early disclosure at the cost of punishing commercializing inventors—including those who might lack resources to file for a patent in the first few years of the invention's exploitation—might ... chill innovation," and that, "[u]nder the current rule, an inventor cannot obtain a patent when a year from the date of the first commercial exploitation of the invention has passed, and therefore has no inducement to disclose his or her invention through patenting" if that window has passed).

C. The AIA’s First-To-File Regime Undercuts The Rationale That Originally Motivated An Unnatural, Secret-Prior-Art Reading Of Pre-AIA Section 102(b)—A Reading The Supreme Court Has Never Endorsed

Even before the AIA added the phrase “or otherwise available to the public,” the forfeiture rule—that an inventor’s *secret* activities count as prior art—had long been recognized as a counterintuitive interpretation of the Patent Act. That strained reading was propped up, however, by the rationale that the threat of forfeiture motivates early disclosure. *Metallizing Eng’g*, 153 F.2d at 520. Interpretation of AIA Section 102(a)(1) should not follow suit: The forfeiture rule is untenable in light of the AIA’s plain language, the different default incentives that exist in a first-to-file regime, and Supreme Court precedent that suggests forfeiture pays too little heed to the need for public availability.

The forfeiture rule was created to address the incentive to file late that inventors have in a first-to-invent regime. In the pre-AIA context, an inventor could swear behind references and competing applications, and therefore try to extend his or her period of exclusivity by commercializing an invention while delaying pursuit of patent protection. That concern is greatly diminished for AIA patents. The AIA’s first-to-file system inherently creates a strong incentive for inventors to file for patent protection early—they lose out if another inventor files before they do.

Moreover, the Supreme Court has never squarely endorsed engrafting a forfeiture rule onto the public use and on sale bars. The Court has instead consistently required non-secret activity. *See, e.g., Electric Storage Battery Co. v. Shimadzu*, 307 U.S. 5, 20 (1939) (noting that “a single use for profit, **not purposefully hidden**, is [barred under the statute],” and finding public use where “the machine, process, and product [at issue] were [] well known to the employe[e]s in the plant, [or at least] that [**no**] **efforts were made to conceal** them from anyone who had a legitimate interest in understanding them” (emphases added)); *Hall v. Macneale*, 107 U.S. 90, 97 (1883) (justifying public-use bar on finding of “no concealment ... or use ... in secret”); *Egbert v. Lippmann*, 104 U.S. 333, 337 (1881) (finding public-use where woman used patented corset under her clothes under “no obligation of secrecy, nor any condition of restriction whatever”).³ Both in words and in policy, the Court has emphasized that the key

³ *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1 (1829), which *Metalizing* cited as inspiration for the forfeiture rule, is consistent with these cases. There, the Court found an invention barred where the invention had been “completed and published ... seven years before the application,” a period during which “[it] had been known and used as common public property, ... which any one might use as publicly known.” *Id.* at 8. Only in dicta did *Pennock* comment on a secret invention that might become unpatentable. *See id.* at 13. And even there, the Court seemingly assumed that the invention would be unpatentable only once it was no longer secret: once the “invention c[a]me[] into the most common or public use, ... [,] [w]hen the public ha[d] fully got possession of it,” such that “[t]hose who were engaged in making the article [had to] stop[,] [t]hose who had arranged for the making of it [had to] abandon their arrangements[,] [and] [t]hose who had

inquiry is whether the patentee has attempted to restrict the use of knowledge that exists (at least theoretically) in the public domain—a logic that does not apply to truly secret prior activities, which by definition the public cannot know about:

Sections 102(a) and (b) operate in tandem to exclude from consideration for patent protection ***knowledge that is already available to the public***. They express a congressional determination that the creation of a monopoly in such information would not only serve no socially useful purpose, but would in fact injure the public ***by removing existing knowledge from public use***. From the Patent Act of 1790 to the present day, the ***public sale*** of an unpatented article has acted as a complete bar to federal protection of ***the idea embodied in the article thus placed in public commerce***.

Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 148-149 (1989)

(emphases added). Indeed, in applying the public use and on-sale bars, the Court has explicitly stated that:

Inventors may, if they can, keep their invention secret; and if they do for any length of time, they do not forfeit their right to apply for a patent, unless another in the meantime has made the invention, and secured by patent the exclusive right to make, use, and vend the patented improvement. Within that rule and subject to that condition, inventors may delay to apply for a patent.

Bates v. Coe, 98 U.S. 31, 46 (1878) (emphasis added); *see also Parks v. Booth*, 102 U.S. 96, 105 (1880) (“Unless inventors keep their inventions secret[,] they are required to be vigilant in securing patents for their protection; and if they do not,

employed their time in learning to make it [had to] lose their time and their labor.”
Id.

and suffer the same to be in public use or on sale in this country for more than two years before they apply for a patent, they forfeit their right[.]”).

In light of the Supreme Court’s precedents, AIA Section 102(a)(1) should be interpreted as requiring public availability. *See* U.S. En Banc Br. 15, *Medicines Co.*, Nos. 2014-1469, -1504 (the Court’s case law requires public availability in the sense that “members of the interested public could have obtained the information if they so desired”).

CONCLUSION

The district court should be affirmed.

Respectfully submitted,

/s/ Jamie T. Wisz

JAMIE T. WISZ

THOMAS G. SAUNDERS

ROBBIE MANHAS

WILMER CUTLER PICKERING

HALE AND DORR LLP

1875 Pennsylvania Ave., NW

Washington, DC 20006

(202) 663-6286

*Attorneys for Amici Curiae
Pharmaceutical Research and
Manufacturers of America and
Biotechnology Innovation
Organization*

May 2, 2016

CERTIFICATE OF SERVICE

I hereby certify that, on this 2nd day of May, 2016, I filed the foregoing Brief for Amici Curiae Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization in Support of Plaintiffs-Appellees with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

/s/ Jamie T. Wisz

JAMIE T. WISZ

WILMER CUTLER PICKERING

HALE AND DORR LLP

1875 Pennsylvania Ave., NW

Washington, DC 20006

(202) 663-6000

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and Circuit Rule 32(b).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(a)(7)(B), the brief contains 6,454 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font. As permitted by Fed. R. App. P. 32(a)(7)(C), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Jamie T. Wisz

JAMIE T. WISZ
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., NW
Washington, DC 20006
(202) 663-6000

May 2, 2016