

No.

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A., PETITIONER

v.

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

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.

CORPORATE DISCLOSURE STATEMENT

Petitioner Helsinn Healthcare S.A. is a subsidiary of Helsinn Holding S.A. Helsinn Holding S.A. has no parent corporation, and no publicly held company holds 10% or more of its stock.

TABLE OF CONTENTS

	Page
Opinions below	1
Jurisdiction	2
Statutory provisions involved	2
Statement.....	3
A. Background	5
B. Facts and procedural history.....	8
Reasons for granting the petition.....	14
A. The decision below is erroneous.....	15
1. The decision below is inconsistent with the statutory text	15
2. The decision below is inconsistent with the broader statutory structure	23
3. The decision below is inconsistent with the functions of prior art and the on-sale bar in the patent system	26
4. The decision below is inconsistent with the legislative history	27
B. The question presented is exceptionally important and warrants review in this case	28
Conclusion.....	34

TABLE OF AUTHORITIES

Cases:

<i>Barnhart v. Thomas</i> , 540 U.S. 20 (2003).....	17
<i>Bonito Boats, Inc. v. Thunder Craft Boats, Inc.</i> , 489 U.S. 141 (1989)	26
<i>Brenner v. Manson</i> , 383 U.S. 519 (1966)	26
<i>Caveney, In re</i> , 761 F.2d 671 (Fed. Cir. 1985).....	6
<i>Exxon Mobil Corp. v. Allapattah Services, Inc.</i> , 545 U.S. 546 (2005)	20
<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966).....	27

IV

	Page
Cases—continued:	
<i>Hall, In re</i> , 781 F.2d 897 (Fed. Cir. 1986).....	27
<i>Halo Electronics, Inc. v. Pulse Electronics, Inc.</i> , 136 S. Ct. 1923 (2016)	32
<i>Kappos v. Hyatt</i> , 566 U.S. 431 (2012).....	6
<i>Life Technologies Corp. v. Promega Corp.</i> , 137 S. Ct. 734 (2017)	20
<i>Limelight Networks, Inc. v. Akamai Technologies, Inc.</i> , 134 S. Ct. 2111 (2014)	3, 32
<i>Medicines Co. v. Hospira, Inc.</i> , 827 F.3d 1363 (Fed. Cir. 2016) (en banc).....	33
<i>OddzOn Products, Inc. v. Just Toys, Inc.</i> , 122 F.3d 1396 (Fed. Cir. 1997).....	24
<i>Paroline v. United States</i> , 134 S. Ct. 1710 (2014).....	16, 17
<i>Pennock v. Dialogue</i> , 27 U.S. (2 Pet.) 1 (1829)	5, 26
<i>Pfaff v. Wells Electronics, Inc.</i> , 525 U.S. 55 (1998) ...	5, 6, 27
<i>Samsung Electronics Co. v. Apple Inc.</i> , 137 S. Ct. 429 (2016)	32
<i>Special Devices, Inc. v. OEA, Inc.</i> , 270 F.3d 1353 (Fed. Cir. 2001).....	6
<i>United States v. Menasche</i> , 348 U.S. 528 (1955).....	16
<i>United States v. Standard Brewery, Inc.</i> , 251 U.S. 210 (1920)	16
Statutes:	
Leahy-Smith America Invents Act,	
Pub. L. No. 112-29, 125 Stat. 284 (2011).....	<i>passim</i>
§ 3(a), 125 Stat. 285.....	3
§ 3(b)(1), 125 Stat. 285-286	2
§ 3(p), 125 Stat. 293	23
35 U.S.C. 100	3
35 U.S.C. 100(j)	7, 22
35 U.S.C. 102	2, 14, 26
35 U.S.C. 102(a)	6
35 U.S.C. 102(a)(1).....	<i>passim</i>
35 U.S.C. 102(a)(2).....	20
35 U.S.C. 102(b)	6

	Page
Statutes—continued:	
35 U.S.C. 102(b)(1).....	18
35 U.S.C. 102(b)(1)(A).....	18, 19
35 U.S.C. 102(b)(1)(B).....	18, 19, 20
35 U.S.C. 103.....	26
35 U.S.C. 321-329.....	25
Drug Price Competition and Patent Term Restoration	
Act of 1984 (Hatch-Waxman Act),	
Pub. L. No. 98-417, 98 Stat. 1585.....	10
28 U.S.C. 1254(1).....	2
35 U.S.C. 102(b) (2006).....	5, 7, 25
35 U.S.C. 102(g) (2006).....	24
35 U.S.C. 111(b).....	10
35 U.S.C. 119(e).....	10
Miscellaneous:	
Lawrence E. Ashery, <i>The Risk of Losing Patent</i>	
<i>Rights When an Invention Is ‘On Sale,’</i>	
Legal Intelligencer (May 23, 2017).....	31
Andrew D. Cohen & Irena Royzman, <i>The Federal</i>	
<i>Circuit’s First Application of the AIA’s On-Sale</i>	
<i>Bar: Implications for Bio/Pharma,</i>	
Biologics Blog (May 16, 2017)	
<tinyurl.com/biologicsblog>.....	30
157 Cong. Rec. H4429 (daily ed. June 22, 2011).....	8
157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011).....	8, 24
157 Cong. Rec. S1371 (daily ed. Mar. 8, 2011).....	24, 25
157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011).....	8
European Patent Convention, Art. 54(2), Oct. 5, 1973,	
13 I.L.M. 268.....	23
Scott Graham, <i>(On-Sale) Bar Fight Heads to</i>	
<i>SCOTUS</i> , Law.com (Jan. 25, 2018)	
<tinyurl.com/on-sale-bar-fight>.....	13, 31
H.R. Rep. No. 98, 112th Cong., 1st Sess.	
(2011).....	7, 23, 25, 27

VI

	Page
Miscellaneous—continued:	
Dmitry Karshedt, <i>Did Learned Hand Get It Wrong?: The Questionable Patent Forfeiture Rule of 'Metallizing Engineering,'</i> 57 Vill. L. Rev. 261 (2012).....	23
Michael Loney, <i>Federal Circuit Issues Important Helsinn On-Sale Bar Ruling, Managing Intellectual Property</i> (May 2, 2017).....	31
Joe Matal, <i>A Guide to the Legislative History of the America Invents Act: Part I of II,</i> 21 Fed. Cir. B.J. 435 (2011).....	7
<i>Merriam-Webster's Collegiate Dictionary</i> (11th ed. 2005).....	16
Janice M. Mueller, <i>Patent Law</i> (5th ed. 2016).....	28
Pranay Pattani & Thomas Kelton, <i>The On-Sale Bar And USPTO Practices After 'Helsinn,'</i> Law360 (May 30, 2017).....	29
S. Rep. No. 259, 110th Cong., 2d Sess. (2008).....	7
S. Rep. No. 18, 111th Cong., 1st Sess. (2009).....	7, 28
Antonin Scalia & Bryan A. Garner, <i>Reading Law: The Interpretation of Legal Texts</i> (2012).....	16
Jerry Selinger, <i>Pre- And Post-AIA On-Sale Bar After 'Medicines' and 'Helsinn,'</i> Law360 (May 2, 2017).....	31
United States Patent & Trademark Office, <i>Examination Guidelines for Implementing the First Inventor To File Provisions of the Leahy- Smith America Invents Act,</i> 78 Fed. Reg. 11,059 (Feb. 14, 2013).....	8, 29
United States Patent & Trademark Office, Manual of Patent Examining Procedures § 2152.02(d) (9th ed. 2014).....	8
Warren Woessner, <i>Federal Circuit in 'Helsinn v. Teva' Declines Limiting Requirements of 'On Sale' Bar,</i> Nat'l L. Rev. (May 4, 2017).....	31

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Helsinn Healthcare S.A. respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 17a-52a) is reported at 855 F.3d 1356. The opinion of the district court (App., *infra*, 235a-241a) is unreported. The supplemental opinion of the district court (App., *infra*, 53a-231a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 1, 2017. A petition for rehearing was denied on January 16, 2018 (App., *infra*, 1a-16a). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

1. Section 3(b)(1) of the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284, 285-286 (2011), provides:

Section 102 of title 35, United States Code, is amended to read 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[.]

* * *

(b) EXCEPTIONS.—

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

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

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

* * *

2. Section 3(a) of the AIA, 125 Stat. 285, provides:

DEFINITIONS.—Section 100 of title 35, United States Code, is amended—

* * *

(2) by adding at the end the following:

* * *

(j) The term ‘claimed invention’ means the subject matter defined by a claim in a patent or an application for a patent.

* * *

STATEMENT

Yet again, the Federal Circuit has issued a decision that is “untethered to the statutory text” of the patent laws. *Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 134 S. Ct. 2111, 2120 (2014). This case involves the Federal Circuit’s interpretation of the Leahy-Smith America Invents Act (AIA), the most significant revision to our Nation’s patent laws in more than half a century. As part of the transformative revisions in the AIA, Congress amended the definition of prior art, which identifies the universe of existing knowledge against which an invention’s patentability is measured. The decision below involves a commonly litigated category of prior art: prior sales of an invention.

Under the AIA, an inventor is entitled to a patent unless “the claimed invention was * * * in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention.” 35 U.S.C. 102(a)(1) (emphasis added). Critically, in amending the existing definition of prior art, Congress added the residual phrase “or otherwise available to the public.” That phrase informs the meaning of the phrases that precede it, requiring that sales make the claimed invention “available to the public” to qualify as prior art. That was the expressed intent of the congressional committee that first introduced the residual phrase, as well as the AIA’s sponsors. And it is how the Patent and Trademark Office (PTO) interprets the statute: the PTO adopted that interpretation in examination guidelines issued shortly after the AIA’s enactment and reaffirmed it in an amicus brief supporting petitioner below.

Yet the Federal Circuit rejected the foregoing interpretation. In the decision below, it held that, under the AIA, public disclosure of the *existence* of a commercial sale invalidates a patent, even if the claimed invention itself remains secret and is not “available to the public”—a position that no party or amicus advocated. The Federal Circuit did not reach that decision by applying anything resembling the usual approach to statutory construction. Instead, it held that the floor statements of the AIA’s sponsors were not sufficiently clear to abrogate the Federal Circuit’s pre-AIA precedent—in part because the sponsors did not cite specific cases by name. Needless to say, that is not how courts are supposed to construe statutes. The Federal Circuit’s flawed decision cries out for this Court’s review.

The proper interpretation of the AIA’s definition of prior art is critically important to the patent community and the PTO. The definition of prior art goes to the heart

of patentability, and the AIA’s definition is a foundational building block of the first-inventor-to-file patent system that the AIA creates. The Federal Circuit’s decision threatens to upend that carefully constructed system. Of particular relevance here, prospective patentees commonly enter confidential agreements such as the ones at issue in this case, and the securities laws often require disclosure of the existence of such agreements, particularly for smaller companies. The Federal Circuit’s decision casts doubt on the validity of countless patents issued since the AIA took effect and will chill valuable collaborations by smaller innovators. The Court should grant review to restore the AIA’s definition of prior art to its intended, plain-text meaning.

A. Background

1. As early as 1829, this Court held that an inventor’s “voluntary act or acquiescence in the *public sale* and use” of his invention before the filing of a patent application is an “abandonment of his right.” *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 24 (1829) (emphasis added). That long-standing principle of patent law, known as the “on-sale bar,” stemmed from the law’s “reluctance to allow an inventor to remove existing knowledge from public use.” *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 64 (1998).

Before the AIA, the operative version of the on-sale bar was found in 35 U.S.C. 102(b), which provided that a patent could not issue if “the invention was patented or described in a printed publication in this or a foreign country or in public use or *on sale* in this country, more than one year prior to the date of application for patent in the United States.” 35 U.S.C. 102(b) (2006) (emphasis added). Applying that provision, this Court held that two conditions must be satisfied for the on-sale bar to apply: first, “the product must be the subject of a commercial offer for

sale,” and, second, “the invention must be ready for patenting.” *Pfaff*, 525 U.S. at 67.

With respect to the first of those conditions, the Federal Circuit held before the AIA that an inventor’s secret sale of an invention to another party could constitute a “commercial offer for sale.” See, e.g., *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1354, 1357 (Fed. Cir. 2001); *In re Caveney*, 761 F.2d 671, 675 (Fed. Cir. 1985). For example, in *Special Devices*, the Federal Circuit held that a patentee’s contract with a supplier to produce and stockpile an invention was a disqualifying “sale,” even if it occurred in “secret.” 270 F.3d at 1354, 1357.

2. This case concerns the version of the on-sale bar adopted by Congress in the AIA. Enacted in 2011, the AIA significantly transformed our Nation’s patent laws. *Kappos v. Hyatt*, 566 U.S. 431, 434 n.1 (2012). Most important among the AIA’s reforms was the creation of a first-inventor-to-file patent system, which replaced the preexisting first-to-invent system. In the same provision of the AIA that created the first-inventor-to-file system, Congress amended the definition of prior art. Prior art is the foundation of existing knowledge against which an invention’s novelty and nonobviousness are measured. As amended by the AIA, 35 U.S.C. 102(a), entitled “Novelty; prior art,” 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).¹

¹ Section 102(b) exempts from the definition of prior art certain disclosures made one year or less before the effective filing date of the claimed invention. That exemption is inapplicable in this case.

The AIA’s definition of prior art differs from its pre-AIA counterpart in several important respects. *First*, Congress added the residual phrase “or otherwise available to the public” in the AIA, appending it to the preceding phrases “in public use” and “on sale.” *Second*, Congress eliminated the pre-AIA territorial restriction requiring invalidating public uses or sales to occur “in this country.” 35 U.S.C. 102(b) (2006). *Third*, Congress replaced the term “invention” with the phrase “claimed invention,” and it defined “claimed invention” as “the subject matter defined by a claim in a patent or an application for a patent.” 35 U.S.C. 100(j).

The legislative history confirms that Congress’s intent in adding the residual phrase “or otherwise available to the public” was to eliminate “secret sales” as prior art and to require that the sale make the “claimed invention” “available to the public.” See generally Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 466-475 (2011). The phrase originated in the Senate Judiciary Committee, which explained that it was adding the phrase to “emphasize the fact that [prior art] must be publicly available.” S. Rep. No. 259, 110th Cong., 2d Sess. 9 (2008); accord S. Rep. No. 18, 111th Cong., 1st Sess. 6 (2009). After the Senate bill passed, the House Judiciary Committee considered a revised bill that became the AIA. That bill contained the same residual phrase, and the House Committee echoed the explanation that the phrase was intended to “emphasize the fact that [prior art] must be publicly accessible.” H.R. Rep. No. 98, 112th Cong., 1st Sess., Pt. I, at 42-43 (2011); see *id.* at 43 n.20 (citing floor statements of the Senate sponsors).

Several of the AIA’s sponsors reiterated the point in floor statements. Senator Kyl explained that the new residual phrase operated on the preceding phrases, thus

“limit[ing] all non-patent prior art to that which is available to the public.” 157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011). Senator Leahy, the AIA’s lead sponsor in the Senate, similarly explained that the statute would “do away with precedent under current law that private offers for sale or private uses of secret processes * * * may be deemed patent-defeating prior art.” 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011). The AIA’s lead sponsor in the House, Representative Lamar Smith, agreed: “[C]ontrary to current precedent, in order to trigger the bar in the new [Section] 102(a) in our legislation, an action must make the patented subject matter ‘available to the public’ before the effective filing date.” 157 Cong. Rec. H4429 (daily ed. June 22, 2011).

3. Following the AIA’s enactment, the PTO issued revised guidelines for examining patent applications. See 78 Fed. Reg. 11,059 (Feb. 14, 2013). Of particular relevance here, the PTO instructed its examiners that, under the AIA, a sale “must make the invention available to the public” to be prior art. *Id.* at 11,075. Under that interpretation, the PTO explained, sales “among individuals having an obligation of confidentiality to the inventor” do not constitute prior art under the AIA. *Ibid.* The PTO later incorporated its interpretation into the Manual of Patent Examining Procedures (MPEP). See MPEP § 2152.02(d) (9th ed. 2014) (stating that “[t]he ‘or otherwise available to the public’ residual clause of * * * 35 U.S.C. 102(a)(1) [as amended] * * * indicates that [it] does not cover secret sales or offers for sale”).

B. Facts And Procedural History

1. Petitioner is a small, family-owned pharmaceutical company based in Switzerland. Petitioner focuses on supportive care for cancer patients through the research, de-

velopment, and production of innovative products that improve patients' health and quality of life. This case involves petitioner's flagship drug, Aloxi[®], a pathbreaking treatment for cancer patients suffering from chemotherapy-induced nausea and vomiting. C.A. App. 516, 594-595, 1176-1777.

The active pharmaceutical ingredient in Aloxi is palonosetron. Petitioner acquired the rights to palonosetron in 1998. In 2000, petitioner submitted protocols for Phase III clinical trials to the Food and Drug Administration (FDA), proposing to study two dosages of palonosetron (0.25 mg and 0.75 mg). Petitioner, which had never before sought approval for a drug product in the United States, underestimated the costs of developing Aloxi. As a result, the project was in danger of being terminated. To sustain the project and defray costs, petitioner sought a business partner. App., *infra*, 22a; C.A. App. 597, 608, 918.

In 2001, petitioner entered a license agreement and a supply and purchase agreement with MGI Pharma, a small Minnesota company. Under the agreements, MGI agreed to make upfront payments, and to pay future royalties if petitioner's products obtained FDA approval. The agreements described the potential products then being tested, including the 0.25 and 0.75 mg palonosetron doses. MGI agreed to purchase from petitioner whichever palonosetron product, if any, FDA approved. The agreements bound MGI to keep confidential petitioner's proprietary knowledge related to the products, including the proposed novel formulations. App., *infra*, 22a-23a; C.A. App. 608, 1516.

MGI was a public company, and it filed a Form 8-K with the Securities and Exchange Commission disclosing the agreements. While MGI attached the agreements to

the filing, it redacted the covered palonosetron formulations, consistent with its contractual obligation of confidentiality to petitioner. Petitioner and MGI simultaneously announced the agreements in a press release, again omitting the details of the palonosetron formulations. App., *infra*, 22a-24a.

In 2002, after the successful completion of Phase III clinical trials, petitioner submitted a new drug application to FDA for the 0.25 mg dose. FDA approved the application in July 2003. App., *infra*, 25a.

In 2003, petitioner filed a provisional (*i.e.*, preliminary) patent application covering the 0.25 mg dose. See 35 U.S.C. 111(b). Petitioner then filed a series of further applications claiming priority to the 2003 provisional application, culminating in a 2013 application that issued as U.S. Patent No. 8,598,219 (the '219 patent). See 35 U.S.C. 119(e). That patent is listed in FDA's Orange Book and expires in 2024. It is undisputed that, by virtue of its effective application date, the patent is governed by the AIA. App., *infra*, 19a, 25a, 234a.²

2. In 2011, respondents filed an abbreviated new drug application (ANDA) seeking FDA approval to market a generic version of petitioner's 0.25 mg palonosetron product. Respondents' ANDA included a so-called "Paragraph IV" certification that petitioner's patents were invalid or would not be infringed by respondents' generic version. Pursuant to the Hatch-Waxman Act, petitioner commenced a patent-infringement action against respondents in the United States District Court for the District of New Jersey. App., *infra*, 26a.

² This case also involved three other patents governed by the pre-AIA on-sale bar. Although petitioner disagrees with the Federal Circuit's determination that the pre-AIA on-sale bar invalidates those patents, see App., *infra*, 27a-34a, petitioner is not seeking review of that determination here.

After a bench trial, the district court held that petitioner's patent was valid and would be infringed by respondents' generic version. App., *infra*, 233a-234a. Of relevance here, the court rejected respondents' argument that petitioner's agreements with MGI invalidated the '219 patent under the AIA's on-sale bar. *Id.* at 164a, 180a. According to the court, the AIA requires that the sale make the claimed invention available to the public; the redacted agreements did not disclose petitioner's claimed palonosetron formulation and thus did not make it publicly available. *Ibid.* The district court enjoined respondents from manufacturing or selling their generic version of Aloxi until the expiration of petitioner's patent in 2024. *Id.* at 234a.

3. Respondents appealed to the Federal Circuit. Notably, respondents did not argue that the MGI agreements made Helsinn's invention "available to the public"; they conceded that "the allegedly invalidating sale at issue did not make the invention publicly available." Gov't C.A. Br. 2-3. Respondents offered only the legal argument that, under the AIA, the residual phrase "or otherwise available to the public" does not inform the meaning of the preceding phrase "on sale." See Resp. C.A. Br. 51-55; but see Pet. C.A. Br. 34-36 (arguing to the contrary).

The government filed a brief as *amicus curiae* in support of petitioner. Reaffirming petitioner's arguments and the PTO's guidance to patent examiners, the government stated that "[t]he plain text of section 102(a)(1) makes clear that only sales or offers for sale that make an invention 'available to the public' trigger the on-sale bar, and the purpose and structure of the AIA support that plain-text reading." Gov't C.A. Br. 4 (citation omitted). The government also participated in oral argument as *amicus curiae*. Five other amici, including Representative Smith, likewise endorsed petitioner's reading.

4. The Federal Circuit reversed. App., *infra*, 17a-52a.

In its opinion, the Federal Circuit did not resolve the parties' competing interpretations of the statute; it did not consult the AIA's statutory definitions; and it did not apply the traditional tools of statutory construction. Instead, the court surveyed a selection of the floor statements of the AIA's sponsors. App., *infra*, 34a-43a. As discussed above, those floor statements, as well as the Senate and House committee reports, addressed the on-sale bar and explained that the AIA would require that the claimed invention be "available to the public" to defeat patentability. See pp. 7-8, *supra*. The Federal Circuit, however, observed that the only cases "explicitly referenced" by name by the AIA's sponsors involved the "in public use" bar. App., *infra*, 38a. According to the court, "[t]he floor statements do not identify any *sale* cases that would be overturned by the amendments." *Ibid.* On that basis, the court implied that the AIA had no effect on the on-sale bar. *Ibid.*

Notwithstanding that implication, the Federal Circuit went on to state that, "[e]ven if the floor statements were intended to overrule [the court's] secret or confidential sale cases[,] * * * that would have no effect here since those cases were concerned entirely with whether the *existence* of a sale or offer was public." App., *infra*, 38a (emphasis added). The court asserted that it had held before the AIA's enactment that the on-sale bar was satisfied where "there is a commercial offer or contract to sell a product embodying the invention and that sale is made public," regardless of whether "the details of the invention [were] disclosed in the terms of sale." *Id.* at 40a. The court found no clear indication in the floor statements that Congress intended to abrogate that precedent. *Id.* at 43a.

The Federal Circuit thus concluded that, “after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of the sale”—even if, as here, the counterparty was required to keep those details confidential. App., *infra*, 43a. Applying that interpretation, the court determined that, because the existence of the agreements between petitioner and MGI was publicly known, the agreements invalidated petitioner’s patent. *Id.* at 43a, 52a.³

5. Petitioner filed a petition for rehearing. Six amici, including Representative Smith, supported the petition. More than six months after the petition was filed, the Federal Circuit denied rehearing. App., *infra*, 2a.

In an apparent effort to mitigate the damage done by the Federal Circuit’s opinion, Judge O’Malley, a member of the original panel, issued an opinion concurring in the denial of rehearing that one commentator has described as a “judicial brief in opposition.” Scott Graham, (*On-Sale*) *Bar Fight Heads to SCOTUS*, Law.com (Jan. 25, 2018) <tinyurl.com/on-sale-bar-fight>; see App., *infra*, 3a-16a. Judge O’Malley sought to portray the Federal Circuit’s opinion as narrow, contending that the court had held only that “the *particular* agreement at issue triggered the on-sale bar, in part—but not exclusively—because it was made public.” App., *infra*, 5a. At the same time, Judge O’Malley categorically stated that the court had “correctly concluded that the AIA did not change longstanding precedent governing the on-sale bar.” *Id.* at 3a-4a. In the wake of the court’s failure to analyze the

³ The Federal Circuit also determined that petitioner’s invention satisfied the second condition of the on-sale bar: namely, that the invention was ready for patenting. App., *infra*, 43a-52a. Petitioner is not seeking review of that determination.

AIA's text in reaching its conclusion, Judge O'Malley proceeded to supply her own textual analysis, which largely adopted respondents' arguments. *Id.* at 8a-11a.

Judge O'Malley concluded by acknowledging that "[i]t is fair to question whether * * * distribution agreements [such as the agreements at issue] *should* fall within the scope of the on-sale bar," and she observed that the existing rule has long provoked criticism. App., *infra*, 15a-16a. Notwithstanding that Congress had amended Section 102 in the AIA, Judge O'Malley stated that, "[u]ntil Congress amends § 102 to exclude such agreements from its scope, or the Supreme Court changes the analysis we are to employ when considering such transactions, these criticisms will continue." *Id.* at 16a.

REASONS FOR GRANTING THE PETITION

This case presents a question of exceptional importance to the patent community and the Patent and Trademark Office. The identification of prior art is a critical component of patent examination and litigation because of the central role of prior art in determining the validity of patents. Accordingly, stakeholders at all levels of the patent process need to have a clear and accurate understanding of which sales of an invention qualify as prior art.

Without this Court's guidance, the patent community will have no choice but to attempt to apply a Federal Circuit decision that is deeply flawed both in its reasoning and in its outcome. The Federal Circuit purported to construe the AIA without actually analyzing its text. The Federal Circuit's rule has no basis in the text; indeed, no party or amicus even argued for it. And the Federal Circuit rejected the position of the PTO, as codified in examination guidelines that have governed the issuance of more than one million patents. This Court should grant

certiorari to review and reverse the Federal Circuit’s misinterpretation of a critical provision of the patent laws.

A. The Decision Below Is Erroneous

As the government observed below, the text, structure, and history of the AIA unequivocally support the conclusion that “an invention is only ‘on sale’ under the AIA if the sale or offer for sale makes the invention ‘available to the public.’” Gov’t C.A. Br. 1. The Federal Circuit’s contrary holding was the result of a profoundly flawed analysis. The Court should grant review to correct the Federal Circuit’s indefensible interpretation.

1. The Decision Below Is Inconsistent With The Statutory Text

By its plain terms, the AIA requires that a sale make an invention “available to the public” in order to qualify as prior art.

a. As amended by the AIA, 35 U.S.C. 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.” As the PTO and the AIA’s sponsors have recognized, the AIA’s text and structure demonstrate that the phrase “otherwise available to the public” clarifies the scope of the preceding phrase “on sale.”

i. Section 102(a)(1) identifies five categories of prior art. The first two—patents and printed publications—are, by their very nature, publicly available. Following the intervening word “or,” the statute identifies a series of three additional categories: claimed inventions that are “in public use, on sale, or *otherwise* available to the public.” 35 U.S.C. 102(a)(1) (emphasis added).

That final series—“in public use, on sale, or otherwise available to the public”—has a familiar structure. It consists of “several [phrases] * * * followed by a [phrase] which is applicable as much to the first and other words as to the last.” *Paroline v. United States*, 134 S. Ct. 1710, 1721 (2014) (citation omitted). Where that is the case, “the natural construction of the language demands that the [phrase] be read as applicable to all.” *Ibid.* (citation omitted); see also Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 147-151 (2012) (discussing the series-modifier canon). Put another way, the final “catchall” phrase identifies a defining characteristic of all of the categories of prior art identified in the series, *Paroline*, 134 S. Ct. at 1721 (citation omitted): they make the claimed invention “available to the public.”

Congress’s choice of the word “otherwise” in the final phrase confirms that reading of the statute. “Otherwise” means “in a different way or manner.” *Merriam-Webster’s Collegiate Dictionary* 879 (11th ed. 2005). By using that word, Congress made clear that prior art consists of (1) sales or public uses that make the claimed invention “available to the public,” as well as (2) other actions that make the claimed invention “available to the public” “in a different way or manner.” Any other reading of the three-part series would render the word “otherwise” superfluous. See *United States v. Menasche*, 348 U.S. 528, 538-539 (1955). This Court has applied identical logic to a similar statute to reach the same result. See *United States v. Standard Brewery, Inc.*, 251 U.S. 210, 218 (1920) (rejecting the government’s position that a statute prohibiting “beer, wine, or other intoxicating malt or vinous liquor for beverage purposes” encompassed all “beer and wine whether intoxicating or not”).

ii. In the proceedings below, respondents argued that a “limiting clause” like the one in section 102(a)(1) “normally only applies to the ‘last antecedent.’” Resp. C.A. Br. 4, 52-54 (quoting *Barnhart v. Thomas*, 540 U.S. 20, 26 (2003)). By that logic, respondents urged, the phrase “to the public” modifies only “otherwise available” and not the words before it. See *ibid.*

The relevant issue, however, is not whether “to the public” modifies “otherwise available” (it does), but whether the *whole phrase* “or otherwise available to the public” informs the meaning of the two parallel phrases that precede it (again, it does). In *Paroline*, this Court applied the series-modifier canon to reject a materially identical argument based on the last-antecedent rule, noting that the argument would have “require[d] accepting unlikely premises.” 134 S. Ct. at 1721 (internal quotation marks and citation omitted).

The other textual arguments advanced by respondents (and by Judge O’Malley in her opinion concurring in the denial of rehearing) fare no better. *First*, respondents argued that interpreting the phrase “or otherwise available to the public” as informing the meaning of the preceding phrases creates redundancy because the phrase “in public use” already includes the word “public.” Resp. C.A. Reply Br. 16-18; see App., *infra*, 8a n.2. But that argument overlooks that, before the AIA, the Federal Circuit had interpreted the phrase “in public use” to include certain types of secret uses. See App., *infra*, 37a-38a. It thus makes perfect sense that Congress intended for the phrase “or otherwise available to the public” to bear on the meaning of the phrase “in public use” (as well as the

phrase “on sale”).⁴ Judge O’Malley further contended that petitioner’s interpretation conflates “on sale” with “public use,” App., *infra*, 10a, but “uses” and “sales” may make an invention available to the public in different ways, preserving separate meaning for those terms.

Second, respondents argued that petitioner’s interpretation of Section 102(a)(1) conflicts with an exemption in Section 102(b)(1) for certain disclosures made less than one year before a patent’s effective filing date. Resp. C.A. Br. 55-58; see App., *infra*, 10a-11a (O’Malley, J., concurring in the denial of rehearing). According to respondents, Congress’s use of the term “disclosure” in Section 102(b)(1)(A), contrasted with its use of the phrase “public[] disclos[ure]” in Section 102(b)(1)(B), necessarily means that some prior art in Section 102(a)(1) is not available to the public.

As the government and Representative Smith argued below, that argument misunderstands Section 102(b)(1). See Gov’t C.A. Br. 21-23; Rep. Smith C.A. Br. 3-16. Section 102(b)(1) provides that certain disclosures that would otherwise be prior art will not disqualify a patent if they are made within the one-year period before the patent’s effective filing date. The provision identifies two different categories of disclosures that will not disqualify a patent.

⁴ In a similar vein, Judge O’Malley suggested that petitioner’s interpretation creates “redundancies” with the other categories of prior art in Section 102(a)(1)—namely, patents and printed publications. App., *infra*, 8a n.2. That suggestion overlooks the structure of Section 102(a)(1). The residual phrase informs the meaning only of the phrases “in public use” and “on sale”; the other forms of prior art in Section 102(a)(1) stand apart from the final three-item series. And even if the residual phrase operates on all the forms of prior art in Section 102(a)(1), the presence of some terms that are always consistent with that phrase does not rob the phrase of its limiting effect upon other terms, including “on sale.”

Section 102(b)(1)(A) exempts “disclosure[s]” that meet the requirements of Section 102(a)(1)—*i.e.*, that satisfy the definition of prior art—and were made by an inventor (or someone who obtained the subject matter from an inventor). In other words, once an inventor makes a disclosure that qualifies as prior art, the inventor has one year to submit a patent application. Congress had no need to use the term “public” to describe those disclosures, because all prior art under Section 102(a)(1) is necessarily available to the public.

The exemption in Section 102(b)(1)(A) is limited to prior-art disclosures by, or derived directly from, the inventor; prior-art disclosures by *third parties* within that one-year period are not exempt as a general matter. Section 102(b)(1)(B) creates a limited exception to that rule. If the inventor “publicly disclose[s]” his invention, subsequent disclosures within the one-year period that meet the requirements of Section 102(a)(1) will be exempt, regardless of who makes the disclosure. Again, as in Section 102(b)(1)(A), Congress did not use the word “publicly” to describe the disclosures subject to the exemption. To the contrary, the words “publicly disclosed” in Section 102(b)(1)(B) refer to a different, antecedent disclosure: when an inventor publicly discloses the subject matter of an invention, he is entitled to “a one-year grace period, starting on the date [he] discloses an invention to the public, during which even disclosures of the same invention by third parties will not be deemed patent-defeating prior art.” Gov’t C.A. Br. 22. Congress’s use of the term “public[.]” in that provision does nothing to undermine the proposition that

all Section 102(a)(1) prior art must be “available to the public.”⁵

b. In construing Section 102(a)(1), the Federal Circuit did not apply the traditional tools of statutory interpretation. It barely discussed the text of the provision, and it altogether ignored the AIA’s definition of the term “claimed invention.” Instead, the Federal Circuit parsed legislators’ floor statements for indications of a specific intent to abrogate its pre-AIA decisions, which had construed materially different statutory text. See pp. 12-13, *supra*.

To say the least, that is not an acceptable approach to statutory interpretation. “[T]he authoritative statement” of the law is “the statutory text, not the legislative history or any other extrinsic material.” *Exxon Mobil Corp. v. Allapattah Services, Inc.*, 545 U.S. 546, 568 (2005). Patent law is not subject to different rules: as in all statutory-interpretation cases, courts interpreting the patent laws must “look first to the text of the statute.” *Life Technologies Corp. v. Promega Corp.*, 137 S. Ct. 734, 739 (2017).

The court of appeals departed from that principle by turning directly to portions of the legislative history. See, e.g., App., *infra*, 37a-38a (analyzing whether “the floor statements were intended to overrule * * * secret or confidential sale cases”). This Court has famously cautioned that “[j]udicial investigation of legislative history has a tendency to become * * * an exercise in looking over a crowd and picking out your friends.” *Exxon Mobil*, 545 U.S. at 568 (internal quotation marks and citation

⁵ By contrast, Section 102(a)(2)—which identifies patent *applications* as prior art—encompasses certain non-public prior art. See Gov’t C.A. Br. 21-22; Rep. Smith C.A. Br. 4-5. The fact that an inventor’s “disclosures” could include non-public prior art further explains Congress’s choice of the word “publicly” in Section 102(b)(1)(B). See Gov’t C.A. Br. 22.

omitted). But here, there were no friends to be found: the committee reports and floor statements unambiguously support petitioner's interpretation. See pp. 7-8, *supra*. The Federal Circuit thus resorted to picking apart the floor statements of the AIA's sponsors, faulting them for an insufficiently clear statement of intent to abrogate specific Federal Circuit precedents.

The Federal Circuit first implied that the AIA has no effect on the scope of the on-sale bar simply because its sponsors did not cite cases involving the on-sale bar by name. App., *infra*, 37a-38a; see *id.* at 3a-4a (O'Malley, J., concurring in the denial of rehearing) (stating that "the panel correctly concluded that the AIA did not change longstanding precedent governing the on-sale bar"). Unsurprisingly, the Federal Circuit did not cite any precedent requiring an act's sponsors to cite the Federal Reporter in order to change the law. That suggestion is at best bizarre and at worst betrays a reluctance on the part of the Federal Circuit to recognize congressional abrogation of its precedent, even when Congress alters the very statutory provision the Federal Circuit was previously construing.

In a similar vein, the Federal Circuit dismissed statements showing an intent to eliminate secret sales as prior art, on the ground that they did not demonstrate with sufficient clarity an intent to abrogate pre-AIA precedent holding that a sale occurs for purposes of the on-sale bar even when the details of the invention are not "disclosed in the terms of sale" or when delivery of the product does not occur. App., *infra*, 39a-43a. Finding no floor statements evincing Congress's intent to overrule those cases, the court concluded that, "if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale." *Id.* at 43a.

Again, however, the statutory text is the paramount evidence of congressional intent. See p. 20, *supra*. And in any event, many of the pre-AIA cases cited by the Federal Circuit may be consistent with the AIA’s requirement that a sale make the claimed invention “available to the public.” 35 U.S.C. 102(a)(1). As the Federal Circuit explained, many of those cases were based on the rationale that “publicly offering a product for sale that embodies the claimed invention places it in the public domain.” App., *infra*, 42a. This case does not involve a sale to the public or a product in the public domain. It involves a secret sale—that is, a sale to a party with an obligation of confidentiality to the inventor—and, as respondents conceded below, nothing about that sale or the disclosure of the fact of the sale made the “claimed invention” “available to the public.” 35 U.S.C. 102(a)(1); see p. 11, *supra*.⁶

As a result of its flawed approach, the Federal Circuit all but ignored the statutory phrase “claimed invention.” The court concluded that a commercial sale can be prior art when the *fact* of a sale is “publicly disclosed.” App., *infra*, 42a-43a. But the AIA does not require that the fact of a sale be made available to the public. It requires that the “*claimed invention*” be made available. 35 U.S.C. 102(a)(1) (emphasis added). Under the AIA, a “claimed invention” is “the subject matter defined by a claim in a patent or an application for a patent.” 35 U.S.C. 100(j). The Federal Circuit completely ignored that definition, and its decision effectively reads the words “claimed invention” out of the statute.

⁶ In her opinion concurring in the denial of rehearing, Judge O’Malley stated that the MGI agreements “described the claimed drug formulation in detail.” App., *infra*, 5a (internal quotation marks and citation omitted). But the “claimed invention”—*i.e.*, the drug formulation—was redacted from the publicly disclosed agreements and thus was not available to the public, as respondents conceded.

By contrast, petitioner’s interpretation of Section 102(a)(1) affords the phrase “claimed invention” the meaning the AIA provides. When an inventor sells its invention to a party that is required to keep the invention confidential, the “subject matter” of the patent claims is not “available to the public,” even if the public learns of the fact of the sale.

2. *The Decision Below Is Inconsistent With The Broader Statutory Structure*

a. The broader statutory scheme further supports petitioner’s interpretation. In the AIA, Congress moved the United States to a first-inventor-to-file system in order to “harmoniz[e]” the United States “with the patent systems commonly used in nearly all other countries throughout the world.” AIA § 3(p), 125 Stat. 293; see H.R. Rep. No. 98, *supra*, Pt. I, at 39. Congress’s elimination of secret prior art is part of that harmonization effort. As the government explained below, “[n]o other industrialized nation includes secret sales within the prior art.” Gov’t C.A. Br. 10 (citing Dmitry Karshtedt, *Did Learned Hand Get It Wrong?: The Questionable Patent Forfeiture Rule of ‘Metallizing Engineering,’* 57 Vill. L. Rev. 261, 316 (2012)). For example, mirroring the language chosen by Congress in the AIA, the European Patent Convention provides that “[t]he state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.” European Patent Convention, Art. 54(2), Oct. 5, 1973, 13 I.L.M. 268. If allowed to stand, the Federal Circuit’s decision will mean that the United States will once again stand alone in invalidating patents based on secret “prior art.”

b. In addition, Congress's creation of a first-inventor-to-file system informs many of the other revisions in the AIA, including the revision to the definition of prior art. Before the AIA, patentability hinged on who first invented something, rather than who first applied to patent it. Consistent with that fact, the law recognized certain categories of "secret" prior art. For example, a patent could not issue if another person had invented the invention before the relevant priority date, even if the invention was not then available to the public. See 35 U.S.C. 102(g) (2006); *OddzOn Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1401-1404 (Fed. Cir. 1997). It is uncontested that the AIA abolished several categories of "secret" prior art, such as the one just discussed.

Congress's revision of the on-sale bar should be understood in that context. Before the AIA, the on-sale bar operated to prevent *de facto* patent-term extensions. Under a first-to-invent system, inventors had an incentive to profit from their inventions for as long as possible without disclosing them; if a competitor later sought to patent the same invention, the original inventor could claim priority. The on-sale bar, as construed by the Federal Circuit, thus motivated inventors to enter the patent system within the one-year grace period.

But under the AIA's first-inventor-to-file system, no such motivation is needed. An inventor cannot secretly exploit its invention while waiting for competition to come along because the competition might beat the first inventor to the Patent Office. Limiting the on-sale bar to sales that make the invention publicly available thus goes hand-in-hand with the AIA's first-inventor-to-file system, as Senator Kyl explained. See 157 Cong. Rec. S1370-S1371 (daily ed. Mar. 8, 2011); Gov't C.A. Br. 11-12. The Federal Circuit's decision ignores that statutory framework.

c. The Federal Circuit's interpretation also creates anomalies in light of Congress's decision to eliminate territorial restrictions on prior art, including the on-sale bar. As discussed above, in the AIA, Congress deleted language that previously restricted disqualifying sales to those occurring in the United States. See p. 7, *supra*; 35 U.S.C. 102(b) (2006). That undisputed geographic expansion demonstrates the error in Judge O'Malley's assertion that "Congress meant to leave the on-sale bar intact." App., *infra*, 9a. If allowed to stand, the Federal Circuit's decision will have the perverse effect of expanding the on-sale bar to include secret sales occurring outside the United States despite clear statutory language designed to limit it. That anomaly is further proof that the Federal Circuit's interpretation is incorrect.

d. Finally with regard to the statutory structure, the Federal Circuit's interpretation is inconsistent with the AIA's creation of a procedure for post-grant review. See 35 U.S.C. 321-329. Congress designed post-grant review to provide a "more efficient system for challenging patents that should not have issued," H.R. Rep. No. 98, *supra*, Pt. I, at 39-40, and Congress limited discovery in such proceedings to further that end. As the government explained below, "invalidity challenges based on secret prior art are entirely unsuited to adjudication in these expedited proceedings." Gov't C.A. Br. 9; see 157 Cong. Rec. S1371 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl). Whether the fact of the sale is secret, or the fact of the sale is public but the content of the sale is secret, proving a "secret sale" requires burdensome discovery not contemplated by post-grant review. Congress's limitation of post-grant review to AIA patents therefore makes perfect sense under petitioner's interpretation, but not the Federal Circuit's.

3. *The Decision Below Is Inconsistent With The Functions Of Prior Art And The On-Sale Bar In The Patent System*

The Federal Circuit's holding is also at odds with the fundamental policy rationale of the patent system—a rationale that underlies both the concept of prior art more generally and the on-sale bar in particular.

“The basic quid pro quo * * * for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.” *Brenner v. Manson*, 383 U.S. 519, 534 (1966). A patent grant represents a fair trade. The public gives monopoly rights and prices to the patentee; in exchange, the patentee gives the public disclosure of a new and useful invention. If the patentee tried to give the public something it already had, the public would not receive the benefit of its bargain: it would forfeit its right to free and unrestricted use of an idea without receiving anything in return. See *Pennock*, 27 U.S. (2 Pet.) at 23.

To ensure that the public does not give away something in exchange for nothing, the law permits patents only on inventions that are both novel and nonobvious. See 35 U.S.C. 102 (novelty); 35 U.S.C. 103 (nonobviousness). Together, the novelty and nonobviousness requirements prohibit patents on anything that “is already available to the public or * * * which may be readily discerned from publicly available material.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989). To ascertain whether a patent application discloses something that was not “already available to the public,” the patent system needs a practical way of expressing what the public already has. The concept of “prior art” serves that function. See *id.* at 148-150.

The definition of prior art is appropriately guided by its function—namely, to define what is in the public domain. For example, courts evaluate printed publications for prior-art status based on whether they were sufficiently accessible to the public as of the relevant date, reasoning that the publication bar “is grounded on the principle that once an invention is in the public domain, it is no longer patentable by anyone.” *In re Hall*, 781 F.2d 897, 898-899 (Fed. Cir. 1986). This Court has described the rationale for the on-sale bar in similar terms, noting that “reluctance to allow an inventor to remove existing knowledge from public use undergirds the on-sale bar.” *Pfaff*, 525 U.S. at 64.

The Federal Circuit’s interpretation of the AIA ignores the functions of prior art and the on-sale bar in the patent system. The sale of an invention to a party that is obligated to keep it secret does not place the invention in the public domain, even if the public learns of the fact of the sale. The issuance of a patent protecting such an invention thus does not “remove existent knowledge from the public domain.” *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966); see Gov’t C.A. Br. 18-21.

4. The Decision Below Is Inconsistent With The Legislative History

Although the Court need not consult the legislative history to decide the question presented, that history overwhelmingly supports the conclusion that the AIA’s on-sale bar does not cover sales to parties having an obligation of confidentiality to the inventor. Neither the Federal Circuit nor Judge O’Malley even acknowledged the Senate and House reports, both of which state that the residual phrase was added to “emphasize the fact that [prior art] must be publicly accessible.” H.R. Rep. No. 98, *supra*, Pt. I, at 42-43; accord S. Rep. No. 18, *supra*, at 6. And

the AIA’s sponsors—including Representative Smith, who filed amicus briefs supporting petitioner below at the merits and rehearing stages—likewise made their intentions clear. See p. 7, *supra*.⁷

The legislative history thus confirms that the Federal Circuit’s interpretation is profoundly flawed. The Court should grant certiorari to review and correct that interpretation.

B. The Question Presented Is Exceptionally Important And Warrants Review In This Case

1. Whether and when a transaction triggers the on-sale bar is a question of exceptional importance to the entire patent community. Prior art is a foundational concept of patent law, see pp. 26-27, *supra*, and inventors, the PTO, and the public must be able to define its boundaries with accuracy. The on-sale bar, in particular, “is probably the greatest source of litigation involving * * * challenges to patent validity” involving the definition of prior art. Janice M. Mueller, *Patent Law* 263 (5th ed. 2016). The Federal Circuit’s interpretation, under which public reference to the fact of a sale can invalidate a patent even if the claimed invention is not *available* to the public, has created significant uncertainty for stakeholders at all stages of the patent process and warrants this Court’s immediate review.

a. The decision below has significant implications for the more than one million patent holders who have been

⁷ Although Judge O’Malley dismissed certain floor statements as “statements by individual Senators made the day after the bill was passed,” App., *infra*, 11a n.4, in fact Senator Kyl and Representative Smith both spoke *before* passage of the bills in their respective chambers, and all of the floor statements preceded the vote in both chambers on the final House bill that was enacted.

granted patents since the PTO issued its post-AIA guidance in 2012. As discussed above, the PTO's post-AIA guidelines provide that a sale "must make the invention available to the public" to satisfy the on-sale bar, and further provide that sales "among individuals having an obligation of confidentiality to the inventor" do not constitute prior art under the AIA. 78 Fed. Reg. at 11,075; see p. 8, *supra*. Petitioner's agreements with MGI fall squarely within the PTO's definition of "secret"—again, a fact that respondents did not dispute below—but the Federal Circuit's interpretation directly contradicts the agency's guidance. The Federal Circuit's decision thus casts substantial doubt on countless patents issued pursuant to that guidance since the AIA.

Prospectively, absent clarification from this Court, the PTO must consider how to revise its instructions to its examiners. And examiners will now bear the substantial burden of conducting searches for prior art that include public references to the existence of otherwise secret sales, which may contain no indication on their face that they implicate the claimed invention. The PTO—which has already stated its position on the question presented—thus has a strong and urgent interest in the prompt resolution of that question by this Court. See Pranan Pattani & Thomas Kelton, *The On-Sale Bar And USPTO Practices After 'Helsinn,'* Law360 (May 30, 2017) (noting that the decision below "places the [PTO] in the difficult position of deciding whether to continue to apply its stated position or whether to change its position to align with the Federal Circuit in the near term").

b. The Federal Circuit's interpretation of the on-sale bar has particular significance for small innovators such as petitioner. As the history of this case illustrates, drug discovery is expensive and unpredictable. Even large pharmaceutical firms enter development partnerships to

share risk and defray cost. But small firms often have no choice, because they lack the resources to develop and bring a drug to market on their own. See PhRMA C.A. Br. 22-23. And as Judge O'Malley observed, "there is often a need to make distribution agreements public to induce investors to supply funding for product development." App., *infra*, 15a (opinion concurring in the denial of rehearing).

Under the Federal Circuit's interpretation, any public reference to such a partnership could defeat patentability, depending on the structure or timing of the transaction. And small public firms may find that such disclosure is outside their control: a given development partnership is more likely to be material under the securities laws, and thus subject to mandatory disclosure, for a small firm than for a large one. Thus, small firms are both more likely to require partners and more likely to have to disclose them than their larger counterparts.

At a minimum, then, the Federal Circuit's decision has the "potential to chill deals between small bio/pharma companies and potential commercialization partners." Andrew D. Cohen & Irena Royzman, *The Federal Circuit's First Application of the AIA's On-Sale Bar: Implications for Bio/Pharma*, Biologics Blog (May 16, 2017) <tinyurl.com/biologicsblog>. At worst, it will prevent small firms from bringing new drugs such as Aloxi to market altogether.

If that is the case, inventors will not be the only ones to suffer. The public substantially benefits from drugs such as Aloxi, and Aloxi's history demonstrates that it would not be on the market without the perseverance of small firms—and the contractual arrangements between them. The molecule was discovered by a small company (Syntex), which was bought by a large company (Roche) that promptly deemed the project too risky. App., *infra*,

75a. Roche divested the molecule to a second small company (petitioner), which sought a development partner. *Id.* at 75a-77a, 81a-82a. Ultimately, a third small firm (MGI) agreed to share petitioner's risk, providing the funding that allowed Aloxi to come to market, dramatically improving the quality of life of cancer patients. The Federal Circuit's decision threatens to complicate and impede such risk-sharing.

c. Given those practical consequences, it is unsurprising that this case has attracted substantial attention. The United States, Representative Smith, industry groups, academics, and other interested individuals filed amicus briefs at the merits stage in the Federal Circuit, and many of those amici supported petitioner's petition for rehearing en banc. The participation of these amici in the proceedings below confirms the importance of this case to stakeholders throughout the patent community.

In the wake of the Federal Circuit's decision, moreover, academics and other commentators have emphasized the issue's importance. Donald Chisum, the author of a venerable treatise on patent law, described the decision as "hugely significant." Michael Loney, *Federal Circuit Issues Important Helsinn On-Sale Bar Ruling*, Managing Intellectual Property (May 2, 2017). Janice Mueller, another patent-law scholar, agreed. See *ibid.* And many others have discussed and analyzed the opinion at length. See, e.g., *ibid.*; Graham, *supra*; Lawrence E. Ashery, *The Risk of Losing Patent Rights When an Invention Is 'On Sale,'* Legal Intelligencer (May 23, 2017); Warren Woessner, *Federal Circuit in 'Helsinn v. Teva' Declines Limiting Requirements of 'On Sale' Bar*, Nat'l L. Rev. (May 4, 2017); Jerry Selinger, *Pre- And Post-AIA On-Sale Bar After 'Medicines' and 'Helsinn,'* Law360 (May 2, 2017).

2. This case is an ideal vehicle to decide the question presented. In the decision below, the Federal Circuit squarely held that the on-sale bar applies when the existence of a commercial sale is publicly disclosed, whether or not the disclosure made the claimed invention available to the public. App., *infra*, 43a. That holding is case-dispositive, and (given respondent’s concession below) there is no factual dispute that would prevent the Court from resolving the pure question of statutory interpretation that this case presents.

Nor is there any colorable possibility of a circuit conflict in light of the Federal Circuit’s exclusive jurisdiction over appeals relating to patents. The Federal Circuit’s decision will remain the controlling interpretation of Section 102(a)(1)’s on-sale bar unless and until this Court considers the question. This Court has frequently intervened in recent years to correct the Federal Circuit’s aberrant interpretations of the patent laws. See, *e.g.*, *Samsung Electronics Co. v. Apple Inc.*, 137 S. Ct. 429, 435-436 (2016); *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 136 S. Ct. 1923, 1928 (2016); *Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 134 S. Ct. 2111, 2120 (2014). It should do so again here.

The Federal Circuit’s purported reservation of the question whether undisclosed commercial sales would foreclose patentability under the AIA, App., *infra*, 43a, provides no basis for deferring review. For starters, Judge O’Malley, who was a member of the original panel, understood the panel’s decision unequivocally to hold that the AIA “did not change” the on-sale bar, which had previously been construed to reach undisclosed sales. See *id.* at 3a-4a. The panel itself suggested that its holding would extend to undisclosed sales, on the ground that the AIA’s sponsors failed to cite by name (and therefore abrogate) pre-AIA cases applying the on-sale bar. See p. 12, *supra*.

But even on its own terms, the Federal Circuit swept broadly, holding that, “after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale.” *Id.* at 43a. That holding applies to all commercial sales that are publicly disclosed—for example, in securities filings.

Moreover, no party or amicus argued below that the disclosure of the *fact* of a sale is legally relevant. See p. 11, *supra*. The distinction between “disclosed secret sales” and “undisclosed secret sales” was an invention of the Federal Circuit, and, for all the reasons discussed above, it has no basis in the text of the statute. This Court should not reward the Federal Circuit’s attempt to shield its decision from further review by portraying it as narrow.

For the same reasons, Judge O’Malley’s revisionist effort to characterize the panel’s decision as fact-bound is unavailing. The facts recited by Judge O’Malley in her concurring opinion at the rehearing stage informed the Federal Circuit’s determination whether petitioner’s agreements qualified as a commercial sale under its precedents applying the pre-AIA on-sale bar (most notably, *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) (en banc)). Compare App., *infra*, 27a-34a, with *id.* at 4a-7a (O’Malley, J., concurring in the denial of rehearing). But they have nothing to do with the Federal Circuit’s *legal* conclusion that, after the AIA, the disclosure of the existence of a commercial sale invalidates a patent.

For purposes of this petition, this Court may assume that the Federal Circuit correctly determined that the MGI agreements satisfy the pre-AIA on-sale bar; it is the Federal Circuit’s core holding about the effect of the AIA that demands this Court’s review. That holding has created tremendous uncertainty regarding the scope of the AIA’s on-sale bar. A grant of certiorari in this case is nec-

essary to resolve that uncertainty and to correct the Federal Circuit's profoundly flawed and outmoded approach to statutory interpretation.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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