No. 17-1229

In the

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

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

Respondents.

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

BRIEF OF *AMICUS CURIAE* HOUSTON INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF NEITHER PARTY

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INTEREST OF *AMICUS CURIAE*

The Houston Intellectual Property Law Association ("HIPLA") is an association of hundreds of lawyers and other professionals who predominately work in or near Houston, Texas (*see generally* www.hipla.org).[1] The practice of most of the HIPLA membership relates in substantial part to the field of intellectual property law. Founded in 1961, HIPLA is one of the largest associations of intellectual property practitioners in the United States. HIPLA represents the interests of its members and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. HIPLA has no stake in any of the parties to this litigation or in the outcome of this litigation.

HIPLA believes this amicus brief will assist the Court in deciding this important case involving U.S. patent law. HIPLA takes no position as to the merits of the case before the Court. HIPLA respectfully wishes to draw the Court's attention to some of the

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[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae* or its counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

Court's applicable precedent, underlying policy issues, and the potential impact of its decision.

SUMMARY OF THE ARGUMENT

The Federal Circuit held below that, notwithstanding every indication that Congress intended to require "public availability" for prior art under § 102(a) of the Patent Act, secret sales and offers for sale could render the invention to be "on sale."

Leading up to the enactment of the Leahy-Smith America Invents Act (AIA), the on-sale bar had long been the subject of criticism regarding its patent-barring reach over secret sales of a claimed invention that result in no disclosure of the invention to the public. Congress intended to and did eliminate this "secret" prior art as part of the AIA—arguably the most comprehensive reform of the law of patentability in U.S. history. In doing so, Congress sought to balance the rights of the patentee in obtaining patent protection with the rights of the public to inventions that have entered the public domain. On one hand, it expanded the scope of the on-sale bar to include foreign sales, while on the other, it excluded sales that did not disclose the invention to the public. The lynchpin to the balance that Congress sought to achieve lies in the addition of a public availability qualifier to patent-barring sales, a requirement that is abundantly clear both from the text of the statute and its lengthy legislative history.

The Federal Circuit's holding contravenes the plain text of the statute and ignores the expressed intent of Congress. The court's interpretation largely stands alone, conflicting with the understanding of the United States government, the Patent and Trademark Office (Patent Office), and the patent bar over the past five years. It expands radically the scope of patent-invalidating prior art, while frustrating Congress's attempt to harmonize U.S. patent laws with those of the rest of the developed world.

Allowing the on-sale bar to extend to secret sales furthers no policy goals and instead incentivizes inventors to maintain secrecy over their intellectual property, thereby preventing disclosure of inventions into the public domain and hindering the progress of science and the useful arts.

ARGUMENT

I. Under the AIA, "on sale" requires public availability to bar a patent.

Both the AIA and the preceding 1952 Patent Act set forth conditions for patentability. One of these conditions is novelty—a person is not entitled to a patent for an invention that is not new. Before the AIA, for instance, a patent applicant was not entitled to a patent if, more than one year before the date of the application for patent in the United States, the invention was "patented or described in a printed publication in this or a foreign country" or if the invention was "in public use or on sale in this country." 35 U.S.C. § 102(b) (2006). That is, the pre-AIA statute defined two broad categories of patent-barring prior art—documents (i.e., patents and printed publications) and activities (i.e., public use and on sale). These two categories had different geographic scope. While documents from any country could be used to bar a patent under pre-AIA § 102(b), the public-use and on-sale activities would only be patent-barring if performed in the United States.

The AIA moved the United States from a first-to-invent to a first-inventor-to-file patenting system and included significant changes to § 102. Like the previous statute, the new § 102 also identifies documents and activities that can bar a patent. The new statute, however, removes the geographic restriction from the public-use and on-sale activities. That is, while public-use or on-sale activities could bar a patent under pre-AIA § 102(b) only if these activities were in the United States, the new § 102 allows such activities to bar a patent regardless of where the activities were performed.

With this geographic restriction removed, Congress consolidated the patent-barring documents and activities enumerated in pre-AIA § 102(b) into the new § 102. But Congress also added a catch-all provision following the public-use and on-sale activities:

> (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—
>
> (1) the claimed invention was
>
> patented,
>
> described in a printed publication, or
>
> in public use, on sale, or *otherwise available to the public*
>
> before the effective filing date of the claimed invention[.]

35 U.S.C. § 102(a)(1) (italics and formatting added).

The inclusion of the catch-all phrase "*otherwise* available to the public" (emphasis added) informs the meaning of the preceding elements "in public use" and "on sale." *See, e.g., Third Nat'l Bank in Nashville v. Impac Ltd., Inc.*, 432 U.S. 312, 322 (1977) ("It is a familiar principle of statutory construction that words grouped in a list should be given related meaning."); *see also id.* at 322, n.16 ("'One hardly need rely on such Latin phrases as *ejusdem generis* and *noscitur a sociis* to reach this obvious conclusion.'") (quoting *United States v. Feola*, 420 U.S. 671, 708 (1975) (Stewart, J., dissenting)).

The adverb "otherwise" means "in a different way or manner." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 879 (11th ed. 2012). Consequently, § 102(a)(1) bars a patent if the claimed invention was in public use, on sale, or available to the public in a *different* way or manner—that is, in a way or manner that is different than being available to the public through sale or use of the claimed invention. Read in context, the plain language of the statute requires public disclosure of the claimed invention to bar a patent. The decision below contravenes this plain meaning and is in error.

II. The Federal Circuit's decision undermines the balance that Congress achieved through the AIA.

As Judge O'Malley acknowledged in her concurring opinion at the rehearing stage, the chief criticism of allowing the on-sale bar to cover secret sales is that, because such sales do not place the invention in the public domain, allowing a patent on the invention after such a sale does not remove the invention from the public domain. Pet. App. 12a–13a.[2] In fact, the pre-AIA rule has been the subject of such criticism for decades leading up to the enactment of the AIA.[3]

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[2] Judge O'Malley even questioned whether it was fair to consider distribution agreements as offers for sale within the scope of the on-sale bar. Pet. App. 15a.

[3] *See, e.g.*, Dmitry Karshtedt, *Did Learned Hand Get It Wrong? The Questionable Patent Forfeiture Rule of Metallizing Engineering*, 57 Vill. L. Rev. 261, 326 (2012) (noting that secret inventions are never in the public domain); Toshiko Takenaka, *Rethinking the United States First-To-Invent Principle from a Comparative Law Perspective: A Proposal to Restructure § 102 Novelty and Priority Provisions*, 39 Hous. L. Rev. 621, 634-36 (2002) (explaining that the "inclusion of secret commercial use within the meaning of 'public use or on sale'" pre-AIA provisions has "introduce[d] a significant uncertainty in U.S. patent validity"); Iftikhar Ahmed, *What They Don't Know Shouldn't Hurt You: Adding A Public Knowledge Prong to the On-Sale Bar Helps Provide Certainty to Inventors and Competitors Alike*, 45 Hous. L. Rev. 153, 181 (2008) (proposing that the on-sale inquiry focus on the amount of public

Yet, Judge O'Malley reasoned that in light of the fact that Congress chose not to modify the term "on sale," as it had previously appeared in § 102(b), Congress simply did not intend to alter the on-sale bar. Pet. App. 9a–10a (stating that absent a redefinition of "on sale" by Congress or the Supreme Court, the court would continue to apply years of pre-AIA case law regarding invalidating offers for sale).

Quite the contrary, the AIA represented perhaps the most comprehensive patent law reform in U.S. history.[4] The drafting history, which spans a period of six years, demonstrates that a public-availability requirement was always part of Congress's definition of prior art. *See* Pet. Br., at 25–26. In amending the on-sale bar, Congress sought to balance the rights of the patentee to work toward

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disclosure emanating from the sale); Timothy R. Holbrook, *The More Things Change, the More They Stay the Same: Implications of Pfaff v. Wells Electronics, Inc. and the Quest for Predictability in the On-Sale Bar*, 15 Berkeley Tech. L.J. 933, 991 (2000) (suggesting that the information surrounding any offer for sale should serve as prior art); Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 450 n.97 (2012).

[4] *See* Robert A. Armitage. *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 4 (2012) ("In a nutshell, the AIA completes a 30-year journey to remake, in their entirety, each of the foundational assumptions underlying the operation of the U.S. patent system.").

commercializing her invention with the rights of the public in an invention that was already in the public domain.[5]

A. Congress expanded the rights of the public by extending the territorial reach of the on-sale bar.

As noted above, the pre-AIA § 102 excused sales and offers for sale of the invention made outside of the United States from triggering the on-sale bar. 35 U.S.C. § 102(b) (2006) ("invention was . . . on sale *in this country*"). The territorial limitation unfairly benefitted foreign inventors, who were more likely to conduct business abroad, over domestic inventors. Taking into account the public-availability qualifier imposed by the amended on-sale bar, Congress eliminated the geographic restriction on this definition of prior art.[6] Undoubtedly, with the convergence of technology, U.S. inventors today regularly do business with foreign partners and the territorial restriction of the 1952 statute seems antiquated.

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[5] The fact that Congress chose not to modify the term "on sale" directly is of no moment given that the amended statute includes other unmodified terms, *e.g.*, "prior art," that clearly carry a different meaning under the amended law.

[6] *See* 157 Cong. Rec. S1371 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl).

The AIA further amended the statute to treat "on-sale" activity the same as all other prior art. *See* 35 U.S.C. § 102(a)(1). Because of the addition of a public-availability requirement to the amended on-sale bar, it becomes unnecessary to determine whether the patent-barring sale is attributable to a specific patent applicant.

Moreover, by implementing a first-inventor-to-file system, the AIA greatly diminished the concerns of allowing inventors an extension of a statutorily limited patent term. Documenting the dates of conception and reduction to practice of an invention no longer provides protection as to patentability of their inventions. An inventor who delays filing for a patent simply risks losing it entirely to another inventor who files first. Inventors are therefore incentivized to promptly seek patents on inventions. The AIA therefore brought some uniformity to the application of the on-sale bar, thereby providing certainty to the public in cases where a sale resulting in public disclosure of the invention does occur.

B. Congress balanced the rights of the patentee by restricting the types of sales that would trigger the bar.

The AIA balanced the expanded scope of the amended on-sale bar by providing certain protections to inventors who diligently seek patent protection. First, each of Congress's amendments to the scope of the on-sale bar can only be read in view of a public-availability requirement. A radical expansion of the scope of the amended statutory bar to reach secret sales anywhere in the world makes no sense.[7]

Second, the AIA amended 35 U.S.C. § 119 to allow foreign filings to stop the "on-sale" clock thereby eliminating the need for a U.S. filing where the invention was potentially on sale.[8]

The Federal Circuit's decision undermines the balance that Congress sought to achieve by vastly expanding the scope of the pre-AIA on-sale bar. The goal of the on-sale bar is to prohibit delinquent patenting from withdrawing inventions that have already been placed into the public domain through

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[7] *See, e.g.*, Armitage, 40 AIPLA Q.J. at 55, n.206 (recounting legislative history and explaining that reading § 102(a) as covering secret sales would be truly absurd); Matal, 21 Fed. Circuit B.J. at 472; Timothy R. Holbrook, *Territoriality and Tangibility After Transocean*, 61 Emory L.J. 1087, 1114 (2012) (a rule that allows secret foreign offers to bar patentability "could create a broad swath of prior art that is essentially unknowable to parties in the United States.").

[8] *See* 35 U.S.C. § 119(a) (deleting the exception that "no patent shall be granted on any application for patent for an invention which had been . . . on sale in this country more than one year prior to such filing").

commercialization. Expanding the bar to reach secret sales does nothing to advance that goal but instead deters inventors from seeking patent protection.

III. The Federal Circuit's decision jeopardizes many patents and is detrimental to innovation across many industries.

Ever since the AIA was enacted on September 16, 2011, there has been near consensus among the patent bar and the Patent Office that the revised on-sale bar provisions of the AIA do in fact overturn the concept of secret-sale-based prior art.[9]

A. The Federal Circuit's decision eviscerates the public's reliance on the USPTO's interpretation and the shared understanding of the AIA within the patent bar.

Shortly after the enactment of the AIA, the Patent Office issued guidelines for examining patent applications filed after the effective date of the AIA, March 16, 2013. *See* Examination Guidelines for Implementing the First Inventor to File Provisions

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[9] Armitage, 40 AIPLA Q.J. at 54 ("There is abundant ground for confidence that the clarity of the new statutory language will not be negated by the courts, and that the new law will be followed as written.").

of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11,059 (Feb. 14, 2013). Contrasting the pre-AIA law which "include[ed] commercial activity even if the activity is secret," the guidelines told examiners that the amended § 102 does not cover secret sales or offers for sale. *Id.* at 11,075. The guidelines specifically call out commercial activities "among individuals having an obligation of confidentiality to the inventor" as being excluded from the scope of the amended law. *Id.*; *see also* Patent Office's Manual of Patent Examining Procedure § 2152.02(d) (9th ed. 2014) (mimicking the instructions from Examination Guidelines). The patent community across the country has generally agreed with the Patent Office's understanding of the on-sale bar under the AIA.[10] More recently, the government has supported this interpretation in amicus briefs filed with the Federal Circuit. *See* Brief of United States as Amicus Curiae, pp. 4–5, *Helsinn Healthcare S.A.*

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[10] *See, e.g.*, Dennis Crouch, *Did the AIA Eliminate Secret Prior Art?*, Patently-O (Oct. 10, 2012), at http://www.patentlyo.com/-patent/2012/10/did-the-aia-eliminate-secret-prior-art.html (discussing major patent law associations, including the AIPLA, the ABA, and the IPO, have taken the position that the AIA statute does in fact overturn the concept of forfeiture); Joseph A. Lingenfelter, *Putting the "Public" Back in "Public Use" Interpreting the 2011 Leahy-Smith America Invents Act*, 31 Ga. St. U. L. Rev. 867, 889 (2015) (noting that many patent attorneys and patent law associations agree with the Patent Office's interpretation of the AIA).

v. Teva Pharms. USA, Inc., Nos. 2016-1284, 2016-1787, 2018 WL 1583031 (Fed. Cir. Jan. 16, 2018) (brief filed May 2, 2016); Brief of United States as Amicus Curiae, pp. 15–17, *The Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) (en banc) (brief filed March 2, 2016).

Over the past five years, millions of patent applications have been examined under the Patent Office's guidelines.[11] Inventors have likely entered into non-public commercial agreements in reliance on the Patent Office's examining guidelines allowing them to do so without triggering the on-sale clock. But given the Federal Circuit's contrary interpretation of the statute, these extensive patent rights are now at risk.

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[11] *See* USPTO Performance and Accountability Report FY 2017, at 168, 171, at https://www.uspto.gov/sites/default/files/documents/USPTOFY17PAR.pdf; *see also*, Dennis Crouch, *Utility and Design Patents – Up Again for 2017*, Patently-O (Dec. 26, 2017), at https://patentlyo.com/patent/2017/12/-utility-design-patents.html (noting that the patent office has issued record numbers of patents over the last three years).

B. The Federal Circuit's decision if affirmed would have a huge impact across a wide spectrum of industries and is especially detrimental to solo inventors and small companies.

The Federal Circuit's decision makes it difficult for small businesses across all industries to commercialize innovations that they intended to seek patent protection for. This is particularly true in the pharmaceutical industry given the cost of developing a new drug.[12] This very case exemplifies how a relatively small pharmaceutical company, faced with huge costs of obtaining approval for a drug product, is typically required to enter into purchase agreements with business partners to front the costs of clinical trials and other expenses. *See* Pet. Br. at 8–9. The process to obtain approval of a new drug from the Food and Drug Administration

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[12] While estimates vary, two different studies put the number between $648 million and $2.6 billion. *See* Vinay Prasad et al., *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval*, JAMA Internal Med. 1569–1575 (Nov. 2017), *available at* https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2653012 (finding the median cost of developing a single cancer drug to be $648.0 million); Aaron E. Carroll, *$2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions*, The New York Times (Nov. 18, 2014) (reporting on an estimate by The Tufts Center for the Study of Drug Development).

(FDA) is lengthy and expensive.[13] And while the Petitioner in this case managed to get through the preclinical research as well as the initial phases of clinical trials before seeking out a business partner, other pharmaceutical companies may need to seek out such partnerships at earlier stages of the FDA approval process, significantly lengthening the period between when an agreement is entered into and the time when the company decides to seek patent protection for the drug.[14] In contrast, larger pharmaceutical companies could possibly accomplish the same result in-house without the need for such third-party agreements and without triggering the on-sale bar.

Should the Federal Circuit's decision stand, pharmaceutical companies that relied on the Patent Office's understanding of the statute in delaying their patent filings could lose their ability to protect their intellectual property. Going forward, companies would be forced to avoid any activities that might trigger the on-sale bar even if those activities do not make the claimed invention publicly

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[13] *See* U.S. Food & Drug Administration, *Learn About Drug and Device Approvals*, at https://www.fda.gov/ForPatients/Approvals/default.htm.

[14] *See* FDAReview.org, A Project of the Independent Institute, *The Drug Development and Approval Process*, at http://www.fdareview.org/03_drug_development.php (listing potential timeframes for each stage).

available, thereby impairing a company's ability to raise revenue to support pharmaceutical research. Without partnerships with other companies or venture capital funding sources, smaller companies would be unable to conduct meaningful drug development. In this case, for example, it is possible that Helsinn's drug, which improves cancer patients' health and quality of life, would have never seen the light of day.

On the flip side, when companies do enter into revenue-generating agreements, even those in which, as here, there is no public disclosure of the invention, they would be forced to seek patent protection at early stages of clinical research resulting in premature disclosure of the inventions that would hardly be beneficial to the company or the public.

The Federal Circuit's decision also adversely impacts the software development world, where global collaboration on projects is the norm these days.[15] Today's complex software may comprise many components developed not just at different

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[15] *See, e.g.*, Mathias Strasser, *A New Paradigm in Intellectual Property Law? The Case Against Open Sources*, 2001 Stan. Tech. L. Rev. 4, 46 (2001) (discussing the Patent Office's difficulty in examining software patents owing to the fact that software development is a global and fast-paced process).

companies but in different countries. The Federal Circuit's decision likely reaches licensing agreements between parties executed during the development of such software. Especially in the context of enterprise software, where licensing agreements typically include non-disclosure obligations, software inventions could be "on sale" without any public disclosure of the invention.

The Federal Circuit's reading of the on-sale bar as applying to sales lacking any public disclosure also fails to recognize the new paradigm for software development and sale. In today's "app-based" world, a software vendor may sell an initial version of software to its users, but may decide to "release" features and improvements at a later time through access controls implemented on a server.[16] That is, software to implement a desired functionality may already be available within the software on a customer's device but may only be enabled at a later time of the software vendor's choosing. This practice has become common in cases where a feature may not be ready for release, may require different hardware parameters, or may depend on third party

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[16] *See* Matthew Fagan, *Secret Software Sales*, Patently-O (June 15, 2017), at https://patentlyo.com/patent/2017/06/guest-secret-software.html (discussing potential impact of the Federal Circuit's decision on the modern-day software release approaches).

software functionality that may be unavailable when the software is first "sold" to the user.[17] Under the Federal Circuit's interpretation of the AIA, it is possible that the earlier sale date would trigger the bar even though the "sale" was secret and resulted in no public disclosure.

Continued uncertainty surrounding patent eligibility has significantly discouraged inventors in the software industry from seeking patent protection for their innovations. Industry observers report that software inventors these days look to trade secrets as a more effective means of protecting their intellectual property.[18] Diminished software patenting results in a reduction in information sharing and cooperation, as well as a negative effect on investment in research and development.[19] The

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[17] *See id.* (reporting that feature-based software releases are becoming prevalent in the industry and are being used by large software vendors such as Google).

[18] *See* Samuel J. LaRoque, *Reverse Engineering and Trade Secrets in the Post-Alice World*, 66 U. Kan. L. Rev. 427, 435 (2017); Kaylee Beauchamp, *The Failures of Federalizing Trade Secrets: Why the Defend Trade Secrets Act of 2016 Should Preempt State Law*, 86 Miss. L.J. 1031, 1044 (2017).

[19] *See* David O. Taylor, *Confusing Patent Eligibility*, 84 Tenn. L. Rev. 157, 243 (2016) (reporting on views expressed by patent practitioners concerning the effect of *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014), on investment in research and development).

Federal Circuit's decision in this case simply exacerbates these problems.

Computer hardware and consumer electronics constitute yet another industry sector in which the impact of globalization is clearly evident. Unlike the original Macintosh computer that was built in California, today's iPhone is not only built abroad but includes electronic components from companies in many foreign countries.[20] The emergence of state-of-the-art fabrication-only facilities across the world has allowed semiconductor design and development to occur essentially anywhere in the world.[21] It is not uncommon for semiconductor companies, especially startups, to enter into confidential supply agreements with foreign suppliers for chip fabrication. *Id.* For today's complex consumer electronics, lead times from execution of such agreements to those components being used within

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[20] *See* David Barboza, *An iPhone's Journey, From the Factory Floor to the Retail Store*, The New York Times (Dec. 29, 2016) (reporting that Apple buys many of the components for iPhones from more than 200 suppliers around the world).

[21] Erol C. Basol, *Fabless Semiconductor Companies, the Patent On Sale Bar, and the New America Invents Act: Have Fabless Companies Been Shortchanged, or Is Change Coming?*, 16 UCLA J.L. & Tech. 1, 3 (Fall 2012) (explaining that the new model has allowed for smaller "fabless" semiconductor design companies to focuses solely on designing and developing new technologies and then contracting with companies that have fabrication facilities to produce the designs).

a publicly available final product can be significant. The Federal Circuit's ruling would prematurely trigger the on-sale bar based on such supply agreements, thereby depriving fabless players in the semiconductor industry from patent protection for their designs.[22]

The on-sale bar "seek[s] both to protect the public's right to retain knowledge already in the public domain and the inventor's right to control whether and when he may patent his invention." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 65 (1998). In each of the instances of third-party collaboration discussed above, there is no "knowledge already in the public domain" that needs to be protected by barring a patent. The Federal Circuit's decision therefore ignores this Court's stated policy underlying the on-sale bar.

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[22] *See id.* at 7, 23 (discussing that no exception exists under Federal Circuit precedent to prevent such supplier agreements from triggering the pre-AIA on-sale bar and hoping that the AIA fixed the problem) (citing *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001)).

IV. The Federal Circuit's interpretation would defeat the AIA's goal of harmonizing the U.S. patent system with those in other developed countries.

Through the enactment of the AIA, Congress intended to resolve differences between the patent laws of the United States and those of the rest of the industrialized world, thereby promoting greater international uniformity and certainty in the procedures used for securing the exclusive rights of inventors to their discoveries. AIA § 3(p). While the most significant change that the AIA made in this regard was converting the United States patent system from "first to invent" to a system of "first inventor to file," *id.*, another difference that it sought to resolve was that the rest of the world requires public disclosure in order for an activity to be patent-barring. *See* The Naples Roundtable Cert. Br. at 11–19 (discussing patent systems in Europe, China, Republic of Korea, and Japan—countries that, together with the United States, handle the vast majority of the world's patent applications). Patent examination guidelines from these countries make clear that agreements to maintain secrecy—even tacit ones—are effective to keep the subject matter out of the prior art.[23] Inventors who regularly

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[23] *See, e.g.*, State Intellectual Property Office of the People's

file patent applications under these systems undoubtedly have an expectation that secret activities, including secret sales, do not place their inventions in the public domain. United States inventors, on the other hand, have long risked patent forfeiture based on a hindsight analysis of a secret offer to sell the invention. Congress clearly intended to eliminate this glaring inconsistency in view of the AIA's expressed goal to promote "uniformity and certainty in the procedures used for securing the exclusive rights of inventors to their discoveries." AIA § 3(p).

The Federal Circuit's decision, on the contrary, broadens the disparity with global patent systems by expanding the scope of pre-AIA secret sales to include ones made outside of the United States. *See supra* Section II.A. For example, a confidential supply agreement or license agreement entered into in Beijing, one clearly not considered to be a patent-barring activity in China (or any other developed country), could now bar a U.S. patent filed a year later.

Republic of China, Guidelines for Patent Examination 171–72 (2010), available at http://www.sipo.gov.cn/zlsqzn/sczn2010-eng.pdf (excluding from prior art activity conducted in situations "where the obligation to keep secret arises from social customs or commercial practices, that is, from implicit agreements or understandings.").

Moreover, before the AIA "depositions and litigation discovery [were] required in order to identify all of the inventor's private dealings with third parties and determine whether those dealings constitute a secret offer for sale or third party use that invalidates the patent."[24] Under the Federal Circuit's rule, this discovery may now have to be conducted at a global level—including in countries that find such discovery entirely unnecessary—dramatically increasing the time and cost of litigation to resolve on-sale bar issues.

The disparity in secret prior art laws created by the Federal Circuit's decision makes it harder to obtain patent protection or enforce patent rights in the United States than in much of the rest of the world, consequently weakening our patent system and extending its decline among those of rest of the world.[25]

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[24] 157 Cong. Rec. S5319, S5319–21 (daily ed. Sept. 6, 2011) (statement of Sen. Kyl).

[25] *See* Create, U.S. Chamber of Commerce's International IP Index, at 35-36 (Feb. 2018), at http://www.theglobal-ipcenter.com/wp-content/uploads/2018/02/GIPC_IP_Index_20-18.pdf (ranking the U.S. patent system at *twelfth* in the world and attributing its decline to the uncertainty of our patentability standards and the ease with which U.S. patents can be invalidated).

CONCLUSION

HIPLA respectfully asks this Court to rule that that an offer for sale or sale of an invention to a third party that does not result in public disclosure of the invention does not qualify as prior art under 35 U.S.C. § 102(a).

Respectfully submitted,

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