No. 17-1229

IN THE Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

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

Respondents.

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

BRIEF OF AMICUS CURIAE THE NAPLES ROUNDTABLE IN SUPPORT OF NEITHER PARTY

ANDREW BALUCH SMITH BALUCH LLP 700 Pennsylvania Avenue, Suite 2060 Washington, DC 20003 MATTHEW J. DOWD Counsel of Record ROBERT J. SCHEFFEL DOWD SCHEFFEL PLLC 1717 Pennsylvania Avenue NW, Suite 1025 Washington, DC 20006 (202) 559-9175 mdowd@dowdscheffel.com

Counsel for Amicus Curiae

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| Mastro Plastics Corp. v. NLRB, 350 U.S. 270 (1956) |
| <i>McClurg v. Kingsland</i> , 42 U.S. 202 (1843) |
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$Cited \ Authorities$

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FOREIGN AUTHORITIES

| European Patent Convention Art. 54(2)13 |
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Cited Authorities

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| State Intellectual Property Office of the | |
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| People's Republic of China, Guidelines for | |
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OTHER SOURCES

| 157 Cong. Rec. S5319 (daily ed. Sept. 6, 2011) |
|---|
| 157 Cong. Rec. S1360 (Mar. 8, 2011) |
| Jay Erstling & Ryan Strom, Korea's Patent Policy and Its Impact on Economic Development: A Model for Emerging Countries?, 11 San Diego Int'l L.J. 441 (2010) |
| 1A Norman Singer & J.D. Shambie Singer, <i>Statutes</i> and <i>Statutory Construction</i> (7th ed. 2008)5 |
| Antonin Scalia & Bryan A. Garner, <i>Reading Law:</i> <i>The Interpretation of Legal Texts</i> (2012)4 |
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INTEREST OF AMICUS CURIAE¹

Amicus curiae The Naples Roundtable, Inc. is a 501(c)(3) non-profit organization whose primary mission is the exploration of ways to improve and strengthen the U.S. patent system. To achieve this goal, the Naples Roundtable supports the advanced study of both national and international intellectual property law and policy. The Naples Roundtable fosters the exchange of ideas and viewpoints among the leading intellectual property experts and scholars. It also organizes conferences and other public events to promote the development and exchange of ideas that improve and strengthen the U.S. patent system.

More information about the Naples Roundtable can be found on the organization's website: http://www. thenaplesroundtable.org. None of the Naples Roundtable, the individuals on its Board of Directors, or its counsel have any personal interest in the outcome of this case.

SUMMARY OF THE ARGUMENT

Amicus curiae submits this brief to focus on certain erroneous aspects of the Federal Circuit's methodology of statutory construction.

^{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.

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The Federal Circuit's approach to statutory construction in this case illustrates the appeals court's failure to properly consider the explicit statutory purpose when construing the statute. Statutory text remains paramount, of course, but a statute's purpose cannot be overlooked when a court also examines other interpretative evidence in order to construe the statute.

In certain instances, Congress memorializes the purpose of legislation by including one or more "Sense of Congress" provisions. When Congress includes such a Sense of Congress provision, and when that Sense of Congress speaks directly to the interpretative question, then a court should consider this evidence of legislative purpose when construing the statute. This Court and other courts have done so in the past, recognizing that a Sense of Congress provision is highly probative evidence of the statute's legislative purpose. Indeed, because a Sense of Congress provision is part of the enacted legislation, it can be the strongest evidence of legislative purpose, as it is here.

Here, the Federal Circuit erroneously overlooked two explicit statutory Sense of Congress provisions, setting forth the purpose of the statute. By overlooking these explicit statements—that are part of the statutory text the Federal Circuit's statutory analysis was incomplete and failed to account for the statutory objectives Congress sought to achieve when it passed the Leahy-Smith America Invents Act of 2011 ("AIA"), Pub. L. No. 112–29, 125 Stat. 284.

Within § 3 of the AIA are two Sense of Congress provisions that expressly state the objectives and

policies of the legislation. Behind the first-inventor-tofile regime, as embodied in revised 35 U.S.C. § 102, were Congress's expressly stated objectives of achieving both (1) "harmonization of the United States patent system" with those commonly used throughout the world and (2) "greater certainty regarding the scope of protection" provided by U.S. patents. AIA §§ 3(0), 3(p). Regarding the first objective, because the vast majority of patent applications filed outside the United States are filed in jurisdictions where secret commercialization is not regarded as prior art, the elimination of this category of prior art brings the U.S. patent system in line with the rest of the world. As for the second objective, Congress intended to create greater certainty in the patent system by making it easier to determine what is or is not prior art without resorting to expensive discovery. This second objective fits logically within the policy framework of a first-inventor-to-file system. Limiting prior art to information that is publicly known increases certainty about the validity of issued patents. Both legislative objectives are furthered by restricting the scope of prior art under § 102 to that which makes the claimed invention itself "available to the public."

Both congressional objectives were thwarted, however, by the Federal Circuit's incomplete statutory analysis. The appeals court did not cite, much less analyze, the Sense of Congress provisions, yet the court seemingly considered select arguments relating to legislative history. The court's incomplete analysis rests, in part, on its failure to consider the highly relevant Sense of Congress provisions.

ARGUMENT

I. The Correct Statutory Analysis Must Consider The Statute's Two "Sense Of Congress" Provisions

Congress's "authoritative statement is the statutory text, not the legislative history." Exxon Mobil Corp. v. Allapattah Servs., Inc., 545 U.S. 546, 568 (2005); see also Hoffman Plastic Compounds, Inc. v. NLRB, 535 U.S. 137, 149–50 n.4 (2002); Park 'N Fly, Inc. v. Dollar Park & Fly, Inc., 469 U.S. 189, 194 (1985) ("Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose."). For this reason, "the words of a governing text are of paramount concern, and what they convey in their context is what the text means." Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 441 (2012). The obligation of the courts is thus to interpret the statute as written. See Burrage v. United States, 134 S. Ct. 881, 892 (2014) ("The role of this Court is to apply the statute as it is written—even if we think some other approach might accord with good policy.").

Even so, it is a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000); *accord Sturgeon v. Frost*, 136 S. Ct. 1061, 1070 (2016). A word's meaning exists only in the context in which the word is used. *See Deal v. United States*, 508 U.S. 129, 132 (1993) (explaining the "fundamental principle of statutory construction (and, indeed, of language itself)" is that "the meaning of a word cannot be determined in isolation, but must be drawn from the context in which it is used").

Legislative text is not always clear. See, e.g., Utility Air Regulatory Group v. EPA, 134 S. Ct. 2427, 2441 (2014) (noting that the Clean Air Act "is far from a chef d'oeuvre of legislative draftsmanship"); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 679 (1990) ("No interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship."). When the text is unclear or subject to multiple interpretations, courts will and should routinely consider other evidence, such as the legislative purpose of the statute.

This Court and others have regularly turned to statutory purpose to ensure that the correct interpretation is reached.

We believe it fundamental that a section of a statute should not be read in isolation from the context of the whole Act, and that in fulfilling our responsibility in interpreting legislation, "we must not be guided by a single sentence or member of that sentence, but [should] look to the provisions of the whole law, and to its object and policy."

Richards v. United States, 369 U.S. 1, 11 (1962) (quoting *Mastro Plastics Corp. v. NLRB*, 350 U.S. 270, 285 (1956)); *see also* 1A Norman Singer & J.D. Shambie Singer, Statutes and Statutory Construction § 25:3 (7th ed. 2008) ("The statute should be construed according to its subject matter and the purpose for which it was enacted.").

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On occasion, the objective and policy behind a statute are readily discernible because Congress explicitly stated as much in provisions titled the "Sense of Congress." A Sense of Congress provision will frequently state what Congress wanted to accomplish with the particular legislation. The current U.S. Code is replete with Sense of Congress provisions. *See, e.g.*, 2 U.S.C. § 1511(a); 5 U.S.C. § 9701(f)(1); 15 U.S.C. § 2221(l)(1); 21 U.S.C. § 1961(a).

This Court and other courts have turned to and relied on Sense of Congress provisions when interpreting statutes. In Accardi v. Pennsylvania Railroad Co., 383 U.S. 225 (1966), the Court addressed whether a former employer had improperly denied World War II veterans their seniority rights guaranteed by the Selective Training and Service Act of 1940. The Court looked to the statute's language, noting that it "clearly manifests a purpose and desire on the part of Congress to provide as nearly as possible that persons called to serve their country in the armed forces should, upon returning to work in civilian life, resume their old employment without any loss because of their service to their country." Id. at 228. This "continuing purpose of Congress," as the Court observed, was further established by a Sense of Congress provision that spoke directly to the protection of employment rights to veterans returning to civilian life. Id. at 229.

Courts of appeals have similarly relied on Sense of Congress provisions when interpreting statutes. *See Hanson v. Espy*, 8 F.3d 469, 476 (7th Cir. 1993) (relying on a Sense of Congress provision to support the interpretation of the Disaster Assistance Act of 1988); *United States v. Ellis*, 714 F.2d 953, 955–56 (9th Cir. 1983) (relying on a Sense of Congress provision when interpreting the Consolidated Farm and Rural Development Act of 1961). While a Sense of Congress provision may not always be controlling, it "can be useful in resolving ambiguities in statutory construction" and in reinforcing the meaning of the law. *State Highway Comm'n v. Volpe*, 479 F.2d 1099, 1116 (8th Cir. 1973).

Of course, a Sense of Congress provision does not generally create legal rights. The plain text of the Sense of Congress statement may use non-mandatory language, such as the word "should." See, e.g., Monahan v. Dorchester Counseling Ctr., Inc., 961 F.2d 987, 994-95 (1st. Cir. 1992) (holding as non-binding a Sense of Congress that each state "should" review and revise its laws to ensure services for mental health patients); Yang v. Cal. Dep't of Social Servs., 183 F.3d 953, 958-61 (9th Cir. 1999) (noting the Sense of Congress that Hmong and other Lao refugees who fought in Vietnam war "should" be considered veterans for purposes of receiving certain welfare benefits). Or the Sense of Congress provision is issued in a non-binding House or Senate Resolution. Even so, a sense of Congress provision is almost always a direct statement of legislative intent, having bicameral approval.

In some cases, such as with the AIA, a Sense of Congress provision is the best evidence of what the statutory text was intended to achieve. This Court has long examined the Sense of Congress when understanding the purpose of legislation and construing the terms of the legislation—even in the absence of a formal Sense of Congress provision. See, e.g., Nat'l Cable Television Ass'n, Inc. v. United States, 415 U.S. 336, 337 (1974) (relying on a Sense of Congress provision in the Independent Offices Appropriation Act of 1952); see also Cameron Septic Tank Co. v. Knoxville, 227 U.S. 39, 50 (1913) (holding that it was "certainly the sense of Congress" that the Treaty of Brussels of December 14, 1900 did not affect the expiration of a U.S. patent); *McClurg v. Kingsland*, 42 U.S. 202, 207 (1843); *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 218 (1824). These examples and others confirm that the goal of statutory interpretation—understanding the meaning of the statute in the context of the statutory scheme and legislative purpose—can often be achieved by reference to a Sense of Congress provision.

In short, a Sense of Congress provision is a highly probative interpretative guidepost, which a court tasked with construing a statute should consider. Yet, the Federal Circuit entirely overlooked the Sense of Congress sections included in the AIA. Two Sense of Congress provisions in AIA § 3 speak directly to the issue of Congress's intent in adopting a first-inventor-to-file regime, as embodied in revised 35 U.S.C. § 102. As Petitioner explains, the Federal Circuit incorrectly limited its inquiry to select floor statements, to the exclusion of other statements, and at the same time diminished the importance of the statute's text. Pet. Br. 28–29.

Here, the two Sense of Congress provisions are perhaps the strongest evidence—beyond the text of § 102(a)(1)—about what Congress intended when it enacted the AIA. Instead of considering the Sense of Congress provisions, the Federal Circuit looked to and dismissed the value of—certain floor statements by several members of Congress. The court's error was to look to only these floor statements and ignore the explicit objectives embodied in the Sense of Congress provisions. The Federal Circuit's incomplete consideration of the interpretative evidence is an incorrect method of construing statutes. It leads to a misinformed view of legislative purpose. If this Court's interpretation of § 102(a)(1) considers interpretative evidence beyond that section itself, then this Court must reject the Federal Circuit's incomplete approach and must account for Congress's stated purposes for amending § 102, as set forth in the Sense of Congress provisions in the AIA.

II. The Federal Circuit Incorrectly Overlooked The Explicit Legislative Purpose Of The America Invents Act

In the present case, the Federal Circuit's interpretation of 35 U.S.C. § 102(a)(1), as enacted by the AIA, did not account for Congress's stated purpose for enacting the AIA. The purpose of the legislation is set forth in two Sense of Congress provisions. In the first, Congress stated its intent was to harmonize U.S. patent law with "the patent systems commonly used in nearly all other countries" by converting the U.S. patent system from a first-to-invent system to a first-to-file system. In the second provision, Congress stated its intent was to provide "greater certainty regarding the scope of protection." Both provisions underscore Congress's affirmative decision to eliminate the category of so-called "secret prior art," that is, any sales and uses that do not make available to the public "the subject matter defined by a claim in a patent or an application for a patent," as the term "claimed invention" is defined in 35 U.S.C. § 100(j).

A. Abrogating Non-Disclosing Sales and Uses as Prior Art is Consistent with Congress's Stated "Harmonization" Goal

One purpose of the AIA was to harmonize U.S. patent law with the patent systems of other major countries. This purpose is expressly stated in the AIA:

SENSE OF CONGRESS. —It is the sense of the Congress that converting the United States patent system from "first to invent" to a system of "first inventor to file" will improve the United States patent system and promote harmonization of the United States patent system with the patent systems commonly used in nearly all other countries throughout the world with whom the United States conducts trade and thereby promote greater international uniformity and certainty in the procedures used for securing the exclusive rights of inventors to their discoveries.

AIA § 3(p).

Because Congress amended 35 U.S.C. § 102 with the express intention of harmonizing U.S. law with foreign patent systems, the Federal Circuit should have considered what the other major patent systems in the world require for prior art in order to determine which interpretation of amended § 102 best accords with Congress's intent in enacting the AIA.

To be clear, looking to non-U.S. patent jurisdictions to understand what Congress intended is not the type of reliance on foreign law that is sometimes viewed skeptically. *Compare Atkins v. Virginia*, 536 U.S. 304, 316–17, n.21 (2002) (relying, in part, on an amicus brief by the European Union in a case about whether certain executions are prohibited by the Eighth Amendment), *with id.* at 322 (Rehnquist, C.J., dissenting) (writing separately "to call attention to the defects in the Court's decision to place weight on foreign laws . . . in reaching its conclusion").

Instead, examining non-U.S. patent systems is doing exactly what Congress did when it passed the AIA. It looked to what constituted prior art in the patent systems of the other major industrialized nations. It observed that most, if not all, nations require that prior art—and thus a prior art sale—must be known to the public. If the information is not known to the public, it is not prior art in the major non-U.S. patent systems. Knowing this, Congress included in the AIA its Sense of Congress provision indicating that its goal was to improve the U.S. patent system to be more like "the patent systems commonly used in nearly all other countries throughout the world with whom the United States conducts trade." AIA § 3(p). Accordingly, once the interpretative analysis of the AIA proceeds to the stage of considering statutory purpose and legislative history, it is entirely proper-and indeed necessary—to examine non-U.S. patent systems, as instructed by the Sense of Congress statement.

The top five national intellectual property offices are the European Patent Office, the Japan Patent Office, the Korean Intellectual Property Office, the State Intellectual Property Office of the People's Republic of China, and the United States Patent and Trademark Office. These five intellectual property offices collaborate as the "IP5," which is "a forum of the five largest intellectual property offices in the world that was set up to improve the efficiency of the examination process for patents worldwide."² The national patent offices of the IP5 "handle about 80 per cent of the world's patent applications, and 95 per cent of all work carried out under the Patent Cooperation Treaty (PCT)."³

Examining the foreign patent systems would have revealed that in all major jurisdictions in the world, a sale or use of an invention does not constitute prior art unless the *invention itself* was available to the public. In none of these jurisdictions is it sufficient that the mere fact of the sale was public when the details of the claimed invention were not publicly available. If the Federal Circuit's decision is allowed to stand, the United States will be the outlier among the IP5, despite the AIA's stated objective of harmonizing this country's patent laws with the rest of the world. See Mark Schafer, Note, How the Leahy-Smith America Invents Act Sought To Harmonize United States Patent Priority with the World, a Comparison with the European Patent Convention, 12 Wash. U. Global Stud. L. Rev. 807 (2013).

1. Europe

Examination of patent applications in Europe is generally governed by the European Patent Convention, formerly known as Convention on the Grant of European Patents ("EPC"). The EPC is a multilateral treaty

^{2.} See About IP5 Co-Operation, http://www.fiveipoffices.org/about.html.

^{3.} *Id*.

instituting the European Patent Organisation. The EPC established an autonomous legal system under which European patents are granted.⁴

The EPC requires that inventions claimed in European patents satisfy similar requirements as those in U.S. patents. Under the EPC, an invention must be novel, must involve an inventive step, and must be "susceptible to industrial application." EPC Art. 54, 56, 57. These three requirements are analogous to the novelty, nonobviousness, and utility requirements encoded in 35 U.S.C. § 102, § 103, and §§ 101 and 112, respectively.

Similar to U.S. law, Article 54(2) of the EPC defines what information constitutes "prior art" for purposes of novelty:

The 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.

EPC 54(2) (emphasis added). Thus, the EPC expressly includes a requirement that information be "made available to the public" in order to be considered as state of the art, *i.e.*, "prior art."

The European Patent Office has issued examination guidelines that further state that non-public use or sale of

^{4.} The complete, regularly updated text of the EPC is available on the European Patent Office's website. https://tinyurl. com/EuropeanPatentConvention.

the invention does not constitute prior art. One section of the guidelines, reproduced below, highlights the European rule that the use of an invention must be public in order to qualify as a bar to patenting.

7.2.2 Agreement on secrecy

The basic principle to be adopted is that subjectmatter has not been made available to the public by use or in any other way if there is an express or tacit agreement on secrecy which has not been broken.

In order to establish whether there is a tacit agreement, the division must consider the particular circumstances of the case, especially whether one or more parties had an objectively recognisable interest in maintaining secrecy. Important aspects in this regard are, inter alia, the commercial relationship between the parties (e.g. parent company and subsidiary, good faith and trust, joint venture or ordinary commercial transaction) and the exact object of the purported secrecy agreement (e.g. test specimens or parts for serial production).

A party alleging that subject-matter was not made publicly available due to an express or tacit agreement on secrecy must substantiate and, if contested, prove this allegation. A party alleging that an undisputed or proven agreement on secrecy was broken must substantiate and, if contested, prove this allegation. European Patent Office, *Guidelines for Examination in the European Patent Office*, Part G IV-7.2.2 (Nov. 2017).⁵ Thus, both the EPC and the European patent guidelines limit prior art to information that is known to the public.

2. China

The patent laws of China similarly require public use or sale of the invention in order for that activity to qualify as a bar to patenting.

Article 22.1 of the Patent Law of the People's Republic of China establishes that patents can issue only for those inventions that "are novel, creative and of practical use."⁶ These requirements track the U.S. requirements of novelty, nonobviousness, and utility encoded in 35 U.S.C. § 102, § 103, and §§ 101 and 112, respectively. Article 22.2 defines "novelty" to "mean[] that the invention or utility model concerned is not an existing technology."

Article 22.5 then states: "For the purposes of this Law, existing technologies mean the technologies known to the public both domestically and abroad before the date of application." This provision thus establishes that an invention lacks "novelty" only if it was "known to the public."

^{5.} The EPO's Guidelines for Examination in the European Patent Office is available on its website. https://tinyurl.com/EPOGuidelines.

^{6.} An English translation of the Patent Law of the People's Republic of China is available on the website of the State Intellectual Property Office of the People's Republic of China. *See* https://tinyurl.com/ChinesePatentLaw.

The examination guidelines for patent applications under Chinese law confirm this view. Section 2.1 of the Chinese guidelines, titled "Prior Art," provide:

According to Article 22.5, the prior art means any technology known to the public before the date of filing in China or abroad. The prior art includes any technology which has been disclosed in publications in China or abroad, or has been publicly used or made known to the public by any other means in China or abroad, before the date of filing (or the priority date where priority is claimed).

The prior art shall be the technical contents that are available to the public before the date of filing. In other words, the prior art shall be in such a state that it is available to the public before the date of filing and shall contain such contents from which the public can obtain substantial technical knowledge.

It should be noted that technical contents in the state of secrecy are not part of the prior art. The state of secrecy includes not only the situation where the obligation to keep secret arises from regulations or agreements regarding confidences but also the situation where the obligation to keep secret arises from social customs or commercial practices, that is, from implicit agreements or understandings.

However, if a person having the obligation to keep secret breaches the regulation, agreement, or implicit understanding, rendering the technical contents disclosed and making the technologies available to the public, these technologies shall form part of the prior art.

State Intellectual Property Office of the People's Republic of China, *Guidelines for Patent Examination* 171–72 (2010).⁷

The Chinese guidelines also explain that a "[d]isclosure by use means that by use the technical solution is disclosed or placed in the state of being available to the public." *Id.* at 173. The disclosure must be one through which "the relevant technical content is placed in such a state that the public can know it if they wish, disclosure by use can be established, and it is of no relevance whether the public had actually known it." *Id.* If "at an exhibition or demonstration of a product no explanation of the technical contents thereof is provided so that the structure and function or compositions of the product is not known to person skilled in the art, the exhibition or demonstration does not constitute a disclosure by use." *Id.*

3. Republic of Korea

Along the same lines, the patent laws of the Republic of Korea, *i.e.*, South Korea, require public disclosure in order to rise to the level of a patent-barring event. A non-public use or sale will not foreclose patenting of a novel invention in South Korea. *See* Jay Erstling & Ryan Strom, *Korea's Patent Policy and Its Impact on Economic Development:*

^{7.} https://tinyurl.com/ChinesePatentRules.

A Model for Emerging Countries?, 11 San Diego Int'l L.J. 441, 450–51 (2010) (describing the Korean Patent Act as "provid[ing] that an invention has novelty unless it is publicly known, used, or described in a 'distributed publication' or published through 'telecommunication means").

Article 29 of the South Korea Patent Act sets forth the requirements of patentability. Article 29(1).1 prohibits patents on "[i]nventions publicly known or worked in the Republic of Korea or in a foreign country prior to the filing of the patent application." Patent Act (Act No. 950, as amended up to Act. No. 14112), art. 29(1) (2016) (S. Kor.).⁸

The guidelines applying South Korean patent law expand upon what is meant by "publicly known":

A "publicly known" invention means an invention the contents of which have been known to an unspecified person without obligation of secrecy in the Republic of Korea or a foreign country prior to the filing of the application. The time of filing in the "prior to the filing of the application" refers to the exact point of time of filing, even to the hour and minute of the filing (if the invention is publicly known, the time is converted into Korean time). It does not mean the concept of the date of filing. "Unspecified persons" refers to the general public who does need to abide by secret observance duty.

^{8.} An English translation of the Korean Patent Act is available on the website of the Korean Intellectual Property Office. https://tinyurl.com/KoreanPatentAct.

Korean Intellectual Property Office, *Patent Examination Guidelines* 208–09 (July 2013)⁹; see also Korean Intellectual Property Office, *Understanding the Patent Act of the Republic of Korea* 49 (2017) ("If an invention is disclosed to a person who is obligated to keep it confidential, it is not public knowledge.").¹⁰

Similarly, the Korean patent guidelines describe what is meant by "publicly worked" and when an invention cannot be patented because it has been "publicly worked."

A "publicly worked" invention means an invention which has been worked under the conditions where the contents of the invention are to be publicly known or can potentially be publicly known in the Republic of Korea or a foreign country (Definition of "working" refers to the Patent Act Article 2). Also, "being public" means a situation where it is no longer kept in secret. So, even when a small fraction of inner part of an invention is kept in secret with regard to working of the invention, it shall not be considered as a publicly worked invention.

Korean Intellectual Property Office, *Patent Examination Guidelines*, *supra*, at 209. The thrust of the Korean patent law is the same as the other major jurisdictions—information must be publicly known in order to qualify as prior art.

^{9.} An English translation of the Korean Examination Guidelines is available on the website of the Korean Intellectual Property Office. https://tinyurl.com/KoreanPatentGuidelines.

^{10.} https://tinyurl.com/UnderstandingKoreaPatentAct.

4. Japan

Finally, Japanese patent law applies the same approach to public use and sale as the other IP5 countries. Article 29(1) of Japanese patent law establishes the requirements for patentability:

An inventor of an invention that is industrially applicable may be entitled to obtain a patent for the said invention, except for the following cases:

(i) inventions that were publicly known in Japan or a foreign country prior to the filing of the patent application;

(ii) inventions that were publicly worked in Japan or a foreign country prior to the filing of the patent application; or

(iii) inventions that were described in a distributed publication, or inventions that were made publicly available through an electric telecommunication line in Japan or a foreign country prior to the filing of the patent application.

Patent Act (Act No. 121 of April 13, 1959, as amended up to Act No. 36 of May 14, 2014), art. 29(1) (1959) (Japan).¹¹ Japanese law uses the same phrases "publicly known" and "publicly worked" as South Korean patent law.

^{11.} An English translation of the Japanese Patent Act is available on website of the World International Patent Organization ("WIPO"). https://tinyurl.com/JapanesePatentLaw.

The guidelines for patent examination under Japanese law expand upon the meanings of "publicly known" and "publicly worked":

3.1.3 Publicly known prior art (Article 29(1)(i))

"Publicly known prior art" means prior art which has become known to anyone as an art without an obligation of secrecy (Note).

(Note) Prior art disclosed by a person on whom obligation of secrecy is imposed to another person who [is] not aware of its secrecy is "publicly known prior art" irrespective of the inventor's or applicant's intent to keep it secret. Generally, an article of academic journal would not be put in public view even if it was just received. Therefore, prior art described in the article is not "publicly known prior art" until the article is published.

"Publicly known prior art" often become known in lecture, briefing session and so on generally. In this case, the examiner specifies the prior art on the basis of the matters explained in the lecture, briefing session and so on. In interpreting the explained matters, the examiner may use the matters derived by a person skilled in the art as a base for specifying "publicly known prior art" by considering the common general knowledge at the time of the lecture, briefing session and so on.

Japanese Patent Office, Examination Guidelines for Patent and Utility Model in Japan, Part III, ch. 2, § 3–3.1.3 (2018).¹² Again, the guidance of the Japanese Patent Office is no different than the guidance under the patent laws of Europe, China, and South Korea.

B. Abrogating Non-Disclosing Sales and Uses as Prior Art is Consistent with Congress's Stated Goal of Achieving Greater Certainty Regarding the Scope of Patent Protection

Another goal of the AIA was to increase certainty with respect to the scope of legal protection provided by issued patents. Congress stated its objective in a Sense of Congress provision in the AIA.

SENSE OF CONGRESS.—It is the sense of the Congress that converting the United States patent system from "first to invent" to a system of "first inventor to file" will promote the progress of science and the useful arts by securing for limited times to inventors the exclusive rights to their discoveries and provide inventors with greater certainty regarding the scope of protection provided by the grant of exclusive rights to their discoveries.

AIA § 3(0).

With § 3(o) of the AIA, Congress sought to eliminate "secret" prior art that has, for decades, caused problems

^{12.} An English translation of the *Examination Guidelines for Patent and Utility Model in Japan* is available on the Japanese Patent Office's website. https://tinyurl.com/JapanesePatentGuidelines.

in the U.S. patent system. The Sense of Congress provision in § 3(o) embodies Congress's deliberate decision to eliminate an entire area of contention and inquiry regarding the scope of confidential sales and uses as prior art. As Senator Kyl stated before passage of the AIA, this change will have particular benefit in increasing certainty and reducing litigation discovery costs:

Public uses and sales of an invention will remain prior art, but only if they make the invention available to the public. An inventor's confidential sale of his invention, his demonstration of its use to a private group, or a third party's unrestricted but private use of the invention will no longer constitute private [*sic*, prior] art. Only the sale or offer for sale of the invention to the relevant public or its use in a way that makes it publicly accessible will constitute prior art.

The main benefit of the AIA public availability standard of prior art is that it is relatively inexpensive to establish the existence of events that make an invention available to the public. Under current law, depositions and litigation discovery are 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 under the current law's forfeiture doctrines. The need for such discovery is eliminated once the definition of "prior art" is limited to those activities that make the [invention] accessible to the public. This will greatly reduce the time and cost of

patent litigation and allow the courts and the [USPTO] to operate much more efficiently.

157 Cong. Rec. S5319, S5319–21 (daily ed. Sept. 6, 2011) (statement of Sen. Kyl). This statement thus directly links Congress's stated objective in AIA § 3(o) of achieving greater certainty, with Congress's redrafting of 35 U.S.C. § 102(a)(1), limiting prior art to those sales and uses that make the invention itself available and known to the public.

Notably, the above statement of Senator Kyl refers to both categories of prior art—"offer for sale or third party use." 157 Cong. Rec. at S5320 ("Public uses and sales of an invention will remain prior art, but only if they make the invention available to the public."). The Federal Circuit's opinion below, however, dismissed Senator Kyl's floor statements because the specific examples of judicial decisions that the senator mentioned would be abrogated upon enactment of 102(a)(1) were, according to the Federal Circuit, "public use" cases, not "sale" cases. App. 38a ("The floor statements do not identify any sale cases that would be overturned by the amendments." (emphasis in original)). It seems trivial to quibble about the specific cases cited by the Senator on the Senate floor when the statements explicitly and unambiguously referred to both categories of prior art—"[p]ublic uses and sales." 157 Cong. Rec. at S5320; accord 157 Cong. Rec. S1360, S1371 (Mar. 8, 2011) (statement of Sen. Kyl) ("A contrary construction of section 102(a)(1), which allowed private and non-disclosing uses and sales to constitute invalidating prior art, would be fairly disastrous for the U.S. patent system." (emphasis added)).

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Thus, the AIA's abrogation of non-disclosing uses and sales as prior art in § 102(a)(1) was an intentional policy decision, one that achieves greater certainty in the scope of prior art and decreases litigation costs.

CONCLUSION

For these reasons, the Naples Roundtable respectfully submits that, to the extent the legislative purpose and legislative history are considered in construing post-AIA § 102(a), the Court must also consider the AIA's two Sense of Congress provisions as part of the statutory interpretation.

ANDREW BALUCH SMITH BALUCH LLP 700 Pennsylvania Avenue, Suite 2060 Washington, DC 20003 MATTHEW J. DOWD Counsel of Record ROBERT J. SCHEFFEL DOWD SCHEFFEL PLLC 1717 Pennsylvania Avenue NW, Suite 1025 Washington, DC 20006 (202) 559-9175 mdowd@dowdscheffel.com

Respectfully submitted,

Counsel for Amicus Curiae

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