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

THE BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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STATEMENT OF INTEREST OF AMICUS CURIAE

The Biotechnology Innovation Organization ("BIO") is the principal trade association representing the biotechnology industry. BIO has more than 1,000 members, which span the for-profit and non-profit sectors and range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. Approximately 90% of BIO's corporate members are small or mid-size enterprises that have annual revenues of under $25 million, and that count their patents among their most valuable business assets. Because modern biotechnological products commonly involve lengthy, resource and investment-intensive development periods, BIO's members depend heavily on robust patent rights and a fair system for adjudicating their validity. Accordingly, certainty regarding the types of transactions and what must be publicly disclosed about those transactions to qualify as invalidating activities under the on-sale bar of the America Invents Act (AIA) is of great importance to BIO.[1]

SUMMARY OF THE ARGUMENT

The 2011 Amendments to the Patent Act converted the U.S. patent system from a first-to-invent to a first-to-file system, thereby necessitating certain fine tuning in order to achieve Congress's goal. In this vein, Congress

1. BIO has no stake in the result of this appeal. Pursuant to Supreme Court Rule 37, all parties have consented in writing to the filing of this brief. No party other than the *amicus curiae,* its members, or its counsel, have authored the brief in whole or in part or made any monetary contribution intended to fund its preparation or submission.

made important changes to the prior art provisions of 35 U.S.C. § 102, broadening the territorial reach of prior art and limiting its scope to that which makes the invention "available to the public." This was a sensical balance that flowed from the first-to-file nature of the amendments: when the yardstick for patenting is whether someone files an application before another, secret disclosures that could have established prior inventorship under the old system are no longer relevant. Instead, because the emphasis is now on who files first, the prior art inquiry should—and under Petitioner's interpretation now does—inquire into what was available to the public.

As correctly urged by Petitioner, "prior art" defined under § 102 must make the invention available to the public to destroy novelty. This is compelled by the plain language of the 2011 Amendments and is the only interpretation that implements Congress's policy goals. But the Court of Appeals concluded otherwise, without construing the statutory language, and without explaining what effect should be given to the amended language requiring that "the claimed invention was … on sale, or otherwise available to the public." By avoiding discussion of this text, and by ruling that "if the existence of the sale is public, the details of the invention need not be publicly disclosed," *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1371 (Fed. Cir. 2017), the Federal Circuit created not only unmanageable uncertainty about the validity of patents, but also an unnatural reading of § 102(a). The America Invents Act ("AIA") Pub. L. 112-29-Sept. 16, 2011 requires that knowledge of the "claimed invention," not knowledge of the sale, be "otherwise available to the public."

A requirement that an invention must have been made available to the public in order to have prior art effect follows from a natural reading of 35 U.S.C. § 102(a)(1) and, contrary to Respondent's arguments, creates no tension with the "grace period" provisions at § 102(b)(1). Also contrary to Respondent's arguments, adopting a public-availability requirement for prior art would in no way sweep away decades of lower court caselaw or overturn this Court's precedent.

No policy purpose is served by letting the lower court opinion stand. To the contrary, the decision conflicts with Congress' stated policy goals, including substantive harmonization, and creating more predictability for businesses and the public. If the Federal Circuit decision stands, patents will be denied to deserving inventors who could not have been aware of invalidating business transactions, with no attendant benefits to the public. This effect is compounded by the expansion of the scope of such secret prior art to the rest of the world. Because the USPTO policy under the AIA has been consistent with Petitioner's interpretation of § 102(a), issued patents are also at risk.

The lower court's decision is particularly detrimental to research and development intensive businesses that engage in partnered agreements, or that use expert contractors for specialty services. In biotechnology, a majority of the new product development pipeline is held by small companies that depend on development and investment partnerships that may need to be undertaken before a patent application is filed. In instances where, as here, a partnering transaction is undertaken in a clearly pre-commercial context, involving a product under

development that requires further investment before it can be marketed, it cannot be said that the patentee engaged in premature commercial exploitation of his invention, or unduly extended his right to exclude. The Court should reverse.

ARGUMENT

I. The Court Should Reverse and Require that Placing an Invention On Sale Constitutes Prior Art Only When the Invention is Thereby Made Available to the Public.

As this Court has long emphasized "the starting point for interpreting a statute is the language of the statute itself." *Consumer Product Safety Commission v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980). Yet, the court below decided against this approach. This Court therefore has the opportunity to provide clarity on the on-sale bar embodied in 35 U.S.C. § 102, as amended in 2011 by the AIA. And as Petitioner and amicus respectfully submit, under the proper interpretation of the statute, a commercial transaction that does not inform the public about the claimed invention, nor make the invention available to the public, does not constitute prior art under the 2011 amendments to 35 U.S.C. § 102.

(a) Significant Ambiguities Created by the Court of Appeals' Atextual Interpretation of the AIA Require Resolution through Statutory Construction

The Court of Appeals declined to engage in any statutory construction of the 2011 amendments to 35

U.S.C. § 102, even though statutory construction was central to the district court holding and necessary to the disposition of the case. The amendments to 35 U.S.C. § 102 are significant, substantive, and generated more legislative commentary than any other section of the AIA. *See* J. Matal, A Guide to the Legislative History of the America Invents Act: Part I of II, 21 Fed. Cir. B.J., 435, at 449 (2012). In such a case, statutory construction is necessary.

Congress made several important changes to the language of § 102. Prior to the AIA, prior art consisting of patents, printed publications, prior use, and on-sale activities were spread over 35 U.S.C. § 102(a) and (b). In enacting the AIA, Congress chose to group these prior art categories into a single provision in § 102(a), followed by the addition of the previously-unseen modifier, "or otherwise available to the public." The Court of Appeals acknowledged that Helsinn's argument relied on this new language, 855 F.3d, at 1368, yet, rather than construing it, the Court of Appeals declined to give it any weight because it would "work a foundational change" to the on-sale bar, *Helsinn*, 855 F.3d, at 1369, thus leaving the import of the new modifier unclear.

While the Court of Appeals declined to say that the AIA modifies any aspect of its caselaw, it balked at saying that it does not. On the one hand, the panel's analysis contains an implicit acknowledgement that the AIA might incorporate a public disclosure requirement that modifies the lower court's on-sale caselaw in some unstated way, as shown by the panel's repeated emphasis on the content of public press releases, MGI's 8-K, and previously available public information. 855 F.3d at 1369-70. The panel's

holding that "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed," *Id.*, at 1369 indicates the same. Notably, *before the AIA*, public knowledge of the existence of a sale was not relevant to whether a commercial sale had prior art effect or not. *See, e.g.*, *In Re Caveney*, 761 F.2d 671, 675 (Fed. Cir. 1985); *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355 (Fed. Cir. 2001).

While the lower court's reasoning thus suggests that under the AIA a completely confidential business transaction would not operate as patent-defeating prior art, this is not necessarily so. The Court of Appeals unhelpfully warns that even entirely secret commercial sales may continue to have a prior art effect under its caselaw in the future, just as would have been the case before the AIA. *Helsinn*, 855 F.3d 1356, 1369 and FN 7.

Judge O'Malley's opinion concurring from denial of *en banc* rehearing does little to clarify the uncertainty caused by the panel's hedging. Judge O'Malley writes:

> [We did] not suggest that publicly announced agreements will always trigger the on-sale bar, nor [did we] suggest that secret sales never will. As we explained in *Medicines*, the confidential nature of a transaction is just one of several factors for determining whether the transaction rises to the level of a commercial sale such that the on-sale bar would apply.

Pet. App. at 4a-5a. Judge O'Malley's statement, while correct, distracts from the main issue of this case. The critical question is not how to determine when a

transaction "rises to the level of a commercial sale." The critical question is how to determine when a commercial sale rises to the level of prior art.

(b) Judge O'Malley's Proposed Statutory Construction Does Not Support a Proposition that a Sale can have Prior Art Effect if it Does Not Make the Invention Available to the Public.

The only textual analysis of the 2011 amendments to 35 U.S.C. § 102 in the court below is found in Judge O'Malley's concurrence from denial of *en banc* rehearing,[2] in which Judge O'Malley explains that the words "otherwise available to the public" in section 102(a)(1) do not modify the preceding clauses. Pet. App. at 8a-9a. For support, Judge O'Malley points to the provisions at § 102(b)(1)(B), which juxtapose the terms "disclosure" and "publicly disclosed," thereby suggesting that not all prior art disclosures are necessarily "public."

This interpretation reads too much into section 102(b)(1)(B). The relevant section provides:

> (b) Exceptions.—
>
> > (1) […] 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— […]

2. Judge O'Malley's analysis was not part of the precedential panel opinion, and it is unknown whether the other panel members share her reasoning.

> (B) the subject matter disclosed had, **before such disclosure, been publicly disclosed** by the inventor […].

(*emphasis added*). Judge O'Malley's interpretation relies on a fundamental flaw: she conflates the word "prior art" with "disclosure." Pet. App. at 11a ("all prior art events—i.e., all 'disclosures'"); *see also* Respondent's Brief Opposing Certiorari at 26 ("Because disclosures means all types of prior art—includ[ing] some that are not public.") (internal quotations and citations omitted). But not every disclosure is also prior art. For example, the mere sharing of the details of an invention between prospective business partners under an obligation of confidentiality would constitute a disclosure, but would not fall into any of the prior art categories of § 102(a)(1). Likewise, subject matter appearing in a patent application can constitute a "disclosure," 35 U.S.C. § 102(b)(2), but it would not be prior art under § 102(a)(2) if the patent application never matured into a patent and was never published or deemed published.

Thus, Congress's use of different words, "disclosure" and "prior art," shows that the two are not coextensive.[3]

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3. *See also* 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011) (statement of Sen. Leahy) ("Indeed. . . subsection 102(b)(1)(A), as written, was deliberately couched in broader terms than subsection 102(a)(1). This means that any disclosure by the inventor whatsoever, whether or not in a form that resulted in the disclosure being available to the public, is wholly disregarded as prior art."); (statement of Senator Hatch) ("Indeed, a disclosure that does not satisfy the requirements to be prior art under §102(a), nonetheless constitutes a disclosure that is fully protected under the more inclusive language of § 102(b).").

Congress amended § 102(b) to specify what kind of event would not constitute patent-defeating prior art if it occurred within one year before the invention's effective filing date, referred to as the "grace period." Section 102(b)(1)(B) does not address whether prior art under the AIA must be publicly available or not, although a reasonable reading lends support for the proposition that Congress intended prior art to be publicly available, as explained below. And on the simplest level, a reading of subsections 102(a)(1) and (b)(1) together reasonably stands only for the proposition that **all prior art events are disclosures, but not all disclosures are prior art**.

Section 102(b)(1) provides:

> 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— […]

This sentence confirms that not all "disclosures" matter for purposes of the grace period – disclosures of the invention are relevant only if they would constitute "prior art under subsection (a)(1)," that is, an instance of patenting, printed publication, public use, on sale, or otherwise being made available to the public. 35 U.S.C. § 102(a)(1). Other disclosures that do not constitute "prior art … under subsection (a)(1)" (for example a confidential exchange of technical information between prospective business partners) are of course irrelevant, because they are immaterial for the patentability of a subsequent patent application, and the patent applicant would have no need to invoke a grace period.

Subparagraphs (A) and (B) of § 102(b)(1) then permit the patent applicant to disqualify those disclosures that would constitute prior art under § 102(a)(1) and that were made one year or less before the effective filing date. Subparagraph (A) disqualifies disclosures of the inventor whereas subparagraph (B) disqualifies disclosures of someone other than the inventor. Under § 102(b)(1)(A), the inventor's own disclosures (however made) during the year prior to filing are not prior art to her own patent application. Thus the only disclosures that can still be removed as prior art by subparagraph (B) during the year prior to filing are a third party's disclosures.

The fact that § 102(a)(1)(B) addresses disclosures by third parties has important implications for construing the AIA's prior art provisions. Subparagraph (B) provides that a prior art disclosure made one year or less before the filing of the patent application is disqualified as prior art if "the subject matter disclosed [by the third party] had, before such [third-party] disclosure, been publicly disclosed by the inventor … ." Critically, § 102(a)(1)(B) does not refer to these third party disclosures as "public disclosures." In fact, Judge O'Malley's interpretation hinges on the juxtaposition of "disclosures" (which can emanate from third parties and, under her reading, be non-public) and "public disclosures" (which must be the inventor's).

Under Judge O'Malley's interpretation, if a sale that does not make the invention available to the public can be prior art, such a non-public sale *between third parties* would necessarily create prior art against a subsequent unrelated patent applicant. If that confidential third-party sale occurred one year or less before the

application date, the unrelated later patent applicant can attempt to disqualify it from being prior art under § 102(a)(1)(B), assuming that applicant would somehow learn of the sale. If the secret sale between third parties occurred more than one year before the application date, it would constitute an absolute bar against the unrelated patent applicant.

To provide an example of the untenable results that would follow from Judge O'Malley's and Respondent's interpretation, assume that a Chinese and a Japanese company transact confidential business in Hong Kong. An exclusive, confidential sale of the invention takes place, and no technical details of the invention are made public. Subsequently, an unrelated U.S. patent applicant who independently invented the invention applies for a patent in the USPTO. The applicant (and the patent examiner) would have no way of knowing that a prior art event had occurred,[4] and in all likelihood an invalid patent would issue.

But, it has been asked, if Congress intended all prior art to be publicly available, why did Congress specify in § 102(a)(1)(B) that only *public* disclosures by the patent applicant would be sufficient to remove the prior art effect of a third party disclosure? In other words, if all "disclosures" are public anyway, would not the word "publicly" be superfluous?

4. The AIA removed all geographic restrictions from the scope of prior art. Thus, if a confidential sale can constitute prior art if conducted in the US, it must do so if conducted in Hong Kong.

Properly construed, a public availability requirement for all prior art would not render any words superfluous in subparagraph (B). Subparagraph (B) provides that a third-party disclosure that qualifies as prior art, if it occurs one year or less before filing, can be antedated by the applicant's own public disclosure. But subparagraph (B) does not otherwise specify when that antedating disclosure must occur. For example, a patent applicant could properly disqualify a third party's printed publication of the claimed invention made one year or less before the effective filing date with a public disclosure the applicant made five years before the effective filing date. Of course that would not do the applicant much good, because her own public disclosure, made so long before she applied for a patent, would itself constitute prior art against her patent application.

And therein lies the crux. Because not every conceivable disclosure the applicant might have made is necessarily also prior art, the addition of the word "publicly" ensures that the applicant's antedating disclosure would *itself* have prior art effect, as it must in order to avoid untenable results. For example, absent a strict requirement for "public" disclosure, under the plain terms of § 102(a)(1)(B) an applicant could secretly disclose her invention in ways that do not constitute prior art, wait indefinitely until someone else discloses the invention in a form that *does* constitute prior art, and then wait another whole year before filing a patent application.

Thus, Congress's choice of the terms "disclosure" and "publicly disclosed" in § 102(b)(1)(B) can most simply and reasonably be explained as an effort to ensure that the AIA's grace period and prior art provisions work together

harmoniously without producing aberrant results. If care is taken to not conflate the terms "prior art" and "disclosure," Congress's choice of words makes perfect sense under Petitioner's (and the USPTO's) interpretation of publicly-available post-AIA prior art. In contrast, if Respondent's interpretation is adopted, § 102(b)(1)(B) would create a strong implication that Congress would have wanted to create a new class of secret (and global) prior art that operates against unrelated subsequent patent applicants who were never a party to any confidential prior sales or secret commercial uses.

(c) Reversal Here Will Not Fundamentally Affect Prior On-Sale Jurisprudence.

Petitioner's interpretation of 35 U.S.C § 102(a) will not render centuries of prior on-sale jurisprudence inapplicable. The Federal Circuit has developed comprehensive guidance on whether a transaction qualifies as a commercial sale or offer for sale, involving legally and factually complicated questions of offer, acceptance, and contract formation; of delivery and payment terms; and whether the object of such a sale was sufficiently developed to qualify as a complete invention, ready for patenting. This body of caselaw continues to be applicable because the new § 102(a) still requires courts to engage in all the same inquiries. Only after these elements are established would courts additionally now ask: "and did this commercial sale make the invention available to the public?" Congress understood that, after the AIA, a transaction will still need to qualify as a commercial sale, the date of the sale will still need to be determined, and the invention will still need to be found ready for patenting. This was good reason to retain the well-established words "on sale" in the new § 102(a).

Thus, the meaning courts have given to the words "on sale" for over a century remains largely undisturbed by the AIA. Likewise, nothing in the AIA abrogates this Court's seminal guidance in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), establishing the two principal conditions: (1) an invention must be the subject of a commercial offer for sale, and (2) the invention need not be reduced to practice so long as it is ready for patenting. Properly viewed, the 2011 amendments to 35 U.S.C. § 102 merely specify a third condition, public availability, without displacing the other two.

Nor is it certain, or even likely, that the explicit inclusion of a public-availability requirement would otherwise disturb the results this Court reached in past cases where an inventor exploited his invention long before applying for a patent. For example, in the seminal case of *Pennock v. Dialogue*, 27 U.S. 1 (1829), the validity of an 1818 patent for an improvement in making pressure-resistant leather hoses was at issue.[5] As was typical for U.S. patents prior to 1836, the patent likely did not

5. Respondent has inaccurately characterized the 1818 Pennock and Sellers patent as "claim[ing] a process of making hose with pressure-resistant joints. The joints did not reveal the process." (Resp. br. opposing cert, at 5)(Internal citations omitted). This is unsupported and almost certainly incorrect. First, as a pre-1836 patent, the patent was unlikely to have contained a "claim," and, as the *Pennock* circuit court opinion makes clear, 19 F. Cas. 171 (C.C.E.D. Pa. 1825), the patent was not understood to be limited to just the manufacturing process. This is also apparent in Justice Story's opinion. Second, there is nothing in the Court's or the circuit court's opinion to suggest that an inspection of the improved hose would not have revealed the process by which it was made.

contain claims, and its scope of protection would have been understood to protect not only the specified process for making leather hose but also the improved hose so made. See *Pennock v. Dialogue*, 19 F. Cas. 171 at 173 (referring to "the hose for which this patent was granted," and referring to the hose as "the article so publicly used, and afterwards patented"). During the seven years preceding the application for patent, the patentee had authorized a third party to commercially manufacture and sell 13,000 feet of hose to various purchasers. 27 U.S. at 9. The authorized manufacturer was under no apparent obligation of confidentiality. Id. at 1. It was undisputed that the invention was openly available to the public, and nothing in the *Pennock* opinions indicates that there was anything non-public about the manufacture or sales of the improved hose.

Similarly, in *Pfaff* it is not at all clear whether the sale that occurred in that case would be deemed public or non-public in a post-AIA setting. The Court was focused on whether the invention had to have been reduced to practice before the critical date in order for the sale to have prior art effect, not on whether Pfaff made his invention available to the public. Neither the Court's opinion nor those of the lower courts indicate that the circumstances of Pfaff's sale were necessarily confidential, non-public, or exclusive.

Nor does the occurrence of only one sale to one buyer in *Pfaff* mean that the sale would necessarily be deemed non-public. Custom-designed products, such as the one in *Pfaff*, or those that are made to exacting buyer specifications under, *e.g.*, Government defense or aerospace procurement contracts, would be expected to

have very small – even single-buyer – markets. Thus, just like public use by one user can be enough to trigger the public use bar, *Egbert v. Lippmann,* 104 U.S. 333 (1881),[6] a public sale to the one (and only) buyer of a product could be enough to trigger the on-sale bar.[7] At any rate, such questions are better left for future caselaw development, and it is unnecessary to speculate about the hypothetical outcome when *Pfaff* is applied to post-AIA scenarios. It suffices that the holding of *Pfaff* would remain undisturbed if Petitioner's interpretation of publicly-available prior art were adopted.

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6. To the extent it could be argued that a public-availability requirement for prior art would overturn the Court's decision in *Egbert*, that concern, too, is misplaced. The *Egbert* Court acknowledged that the patented corset springs may have been capable of use "only where they cannot be seen or observed by the public eye." In this respect, the *Egbert* invention is similar to a patented internal component part of a machine, a patented implanted medical device, or myriad other inventions in widespread daily use today or then. Mere unobservability in public use does not make such an invention unavailable to the public. More importantly, it was undisputed that Ms. Egbert was gifted the inventive corsets with no restriction of confidentiality or any other condition, that she used them only for their ordinary purpose, and was free to regift, sell, demonstrate or replicate them. The inventor himself apparently demonstrated the invention on occasion. *Egbert v. Lippmann,* 104 U.S. at 335.

7. Conversely, an invention need not necessarily be deemed unavailable to the public when all sales activities are kept confidential. For example, where it is apparent that a seller of a specialty product is willing to meet market demand for that product and to supply all buyers, but requires all buyers to sign confidentiality agreements, such a seller could nevertheless be deemed to make the invention available to the public.

II. The Lower Court's Decision Has Extraordinary Extraterritorial Implications That Were Likely Unintended by Congress.

Congress eliminated the pre-AIA requirement that an invalidating public use or sale occur "in this country." Prior to the AIA, the types of prior art embodied in 35 U.S.C. § 102(a) and (b) could be grouped into two categories: (1) patents and printed publications, and (2) knowledge, use, and on-sale activities. Category (1) prior art could exist "in this or a foreign country" whereas category (2) prior art was explicitly limited to those activities occurring "in this country." Foreign sales, use, and knowledge did not qualify. Thus, for over 100 years the policy of the on-sale bar was concerned with the domestic market and the interests of the American public. In harmonizing United States patent law with international practices through the AIA, Congress removed territorial restrictions on category (2) prior art.

The Federal Circuit's decision elevates purely foreign conduct to have a negative effect on the patentability of inventions made in this country, contrary to law. By including within the ambit of § 102(a)'s on-sale bar, commercial activity that does not convey an invention to the public, the Court of Appeals' decision for the first time extends a patent-defeating effect to foreign conduct having no nexus with, and being undetectable from, the United States.

But the result of the Federal Circuit's decision is at odds with the legislative history. Congress removed all territorial restrictions on prior art from § 102(a), meaning that prior art references arising anywhere in the world can

invalidate patents. Only two rationales are relevant to the "otherwise available to the public" inquiry: (i) Congress meant to make prior art global, but publicly accessible, or (ii) Congress meant to preserve secret prior art, but make it global. The legislative history includes support for only one interpretation. This is not an instance of competing legislator narratives and contradictory Congressional statements. Both the House and Senate Reports, for example, state plainly that Congress intended prior art under section 102(a) to be art that is "available to the public." *See* H.R. Rep. No. 112-98, at 42, 43 (2011); S. Rep. No. 110-259, at 9, 32 (2008).

No public policy is served by the result of the Court of Appeal's decision, indicating that it was not intended by Congress. The rationale underpinning the pre-AIA on-sale bar was to prevent products long on sale in this country from being later withdrawn from the public by delinquent patenting. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148-49 (1989). Similarly, courts were concerned that secret commercialization would permit an inventor to exploit his invention for an extended period of time before filing for patent protection, effectively extending his period of exclusivity to the detriment of the public. *See, e.g.*, *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 517 (2d Cir. 1946). But secret foreign sales do not implicate either of these concerns. For example, a non-public transaction between Japanese and Korean companies in Seoul, without more, does not impact what goods are available to American consumers, nor does it have any relevance to an unknowing domestic inventor's likelihood of obtaining patent protection.

Indeed, the Federal Circuit's ruling conflicts with United States patent law's focus on how a patentee orders his affairs, not the unknowable activities of third parties. This Court and the Federal Circuit have focused on the concern that the **patent applicant** will delay his patent filing in order to commercially profit from his invention beyond the statutory term. As expressed in *Pfaff*, the patent laws seek to protect "**the inventor's right** to control whether and when he may patent his invention." *Pfaff*, 525 U.S. at 65 (*emphasis added*). And even in other contexts, such as patent exhaustion, this Court has explained that it is the patentee's own decisions that determine when his rights will be extinguished. *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 137 S. Ct. 1523, 1537 (2017). To be sure, foreign activities that make inventions available to the public are relevant to United States patent law in an age of the internet, borderless social media, and international online retail sales. But there is no statutory basis for our patent laws to suddenly focus on secret foreign activities that inherently cannot affect U.S. inventors and the American public.

III. The Policy Ramifications of the Federal Circuit Decision are Contrary to the Purposes of the AIA and Negatively Impact Biotechnological Innovation.

No productive policy is served by permitting the lower court decision to stand. To the contrary, the decision stands in tension with Congress' stated policy goals, including fostering harmonization with international practice[8] and creating more predictability for businesses

8. The patent laws of significant United States trading partners do not bar patents on the basis of secret sales. For

and the public. It also operates inconsistently with the long-standing principles underlying the "on-sale bar," namely this Court's concern that patenting inventions previously on sale will remove existing knowledge from the public. *Pfaff*, 525 U.S. at 64; *Bonito Boats*, 489 U.S. at 141. Yet under the Court of Appeals' decision, a patent that removes no knowledge from the public (because the claimed invention was never available to the public) is nonetheless invalid if the invention is deemed to have been "on sale" in a confidential transaction.

The Federal Circuit thus set up a scenario wherein a particularly problematic category of secret prior art would be preserved and expanded in the amended 35 U.S.C. § 102, thereby denying patents to deserving, and innocent inventors who could not have known of invalidating prior business transactions. This is because the amended prior art provisions at 35 U.S.C. § 102(a) treat all patent applicants the same, regardless of who created such prior art. Thus, if a prior "secret sale" constitutes prior art, it does so against any patent applicant – not just against applicants that were parties to the sale, but also against applicants who independently invented, diligently disclosed their invention in a patent application, and who could not have known of that sale at all. This was never

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example, under European Patent Office law there is no bar for patenting after a confidential disclosure related to commercial use, *e.g.*, a sales agreement. *E.g.*, *Union Carbide Corp. v. Linde A.G.* [1991] T024188 [E.P.O.] Japan has a sale bar, but if the invention is offered for sale in secret, or under a duty of confidentiality, novelty is preserved. Article 29 Japan Patent Office ("JPO"). One skilled in the relevant art must be able to understand the invention as a result of the public sale. JPO Examination Guidelines Part II. Chapter 2. Section 1.5.3(3)(II).

the law before the AIA, but it would be compelled by Respondent's, and Judge O'Malley's interpretation. *See* section I(b), *supra*.

This unfairness is compounded by expanding the scope of such secret prior art to the rest of the world. There is no competing policy support for the regime created by the Federal Circuit's system; only inscrutable uncertainty for businesses and inventors. Smaller innovative businesses that are not vertically integrated and that depend on external investment and product development partnerships, as is typical in biotechnology, are especially impacted.

Small biotechnology companies are responsible for 70% of the global clinical pipeline and 84% of all drug development programs for the more than 7,000 rare diseases that affect one out of five Americans.[9] Many of the more than 2,000 small biotech companies in the United States were founded as university spinoffs to undertake research that is deemed too speculative by larger, established biopharmaceutical companies. A typical small biotech company has fewer than 50 employees, occupies a leased facility, is burning upwards of $10 million per year, and has access to only enough venture capital to finance a few years of operations at most.

But even if initial research results are promising, it takes on average more than ten years of R&D before a

9. David Thomas and Chad Vessel, Emerging Therapeutic Company Investment and Deal Trends, BIO Industry Analysis 2017, available at: https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report%202007-2016.pdf

new biotech therapy can be approved by the U.S. Food and Drug Administration.[10] And chances of that happening are slim: the likelihood that a new medicinal molecule will even advance to human testing is less than 1:1000. And the few compounds that do enter human testing empirically have a close to 90% failure rate.[11] Small biotechnology companies typically have neither the funds (the out-of-pocket costs of commercializing a biotech drug exceed $1.3 billion[12]) nor the expertise to conduct human clinical testing (this being the domain of larger biopharmaceutical companies). For these reasons, small biotechnology companies very often need multiple rounds of investment, and depend on business and development partnerships to spread the expense and risk of product development.

Given the need for interactions with potential investors and business partners, small biotechnology companies are far more likely than large companies to engage in pre-commercial disclosures of their inventions. Potential partners and investors of course want sufficient details about a company's research, but are often reluctant to sign confidentiality and non-disclosure agreements early in a relationship. Concern about what can be disclosed

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10. Jorge Mestre-Ferrandiz, Jon Sussex, Adrian Towne, The R&D Cost of a New Medicine, Office Of Health Economics, London 2012, available at https://www.ohe.org/system/files/private/publications/380%20-%20R%26D%20Cost%20NME%20Mestre-Ferrandiz%202012.pdf?download=1.

11. *Id.*

12. Joseph A. DiMasi, Henry G. Grabowski, Ronald W. Hansen, Innovation in the pharmaceutical industry: New estimates of R&D costs, *Journal of Health Economics*, Volume 47 May 2016, pp. 20-33.

in partnering and investor meetings is common among small biotech companies whose research programs include valuable trade secrets. And filing patent applications first may not always be a reasonable option.

For example, a company's research program may have produced thousands of medicinal molecules, or thousands of therapeutic antibody candidates, but it may at that stage be completely unknown which candidate will be best suited for human testing and should therefore be patented. Proactively filing hundreds of patent applications would be wasteful and unrealistic.[13] Such molecules may be "ready for patenting" within the meaning of patent law, but be far from "ready for patenting" under reasonable business practices. Nor would public policy be served by systematically encouraging the premature patenting of molecules that will, for the most part, turn out to be not commercially viable.

Further business uncertainty arises from the many forms of business transactions under which a development-stage biotech invention might be deemed transferred between businesses for consideration. Small and large companies sometimes contract work out to specialist companies, where medicinal molecules or antibody candidates are made to specification under purchase orders. Development partnerships between

13. Indiscriminate pre-emptive patent filing would tend to suppress pre-patent exploration of an invention to avoid potential "public" disclosure, thus stifling innovation and creating burdens on the patent system. *See* Cotropia, *The Folly of Early Filing in Patent Law*, 61 Hastings L.J. 65 (2009); Karshtedt, *The Riddle of Secret Public Use: A Response to Professor Lemley*, 93 Tex. L. Rev 159 (2015).

companies often take the form of licenses involving upfront payments and the transfer of materials or processes; or sometimes a larger company acquires the smaller company's research program and grants a license of co-development rights back to the small company. Sometimes potential partners are willing to make a preliminary investment in the small company's research program, but demand contingent assignment rights under which the larger company would get to own the program for a predetermined payment if certain future milestones are met. Under the lower court's decision there is a real risk that such typical transactions, even if they are conducted under strict confidentiality, would be deemed to place the invention in the public domain.

No such business uncertainty would be experienced by large pharmaceutical companies that are likely to have the resources to develop their own products without seeking partners. But the decision below impacts innovative businesses of all sizes – large companies would be impacted because their ability to access interesting small-company innovations to feed their product pipelines is diminished. And large companies are typically the ones who spend hundreds of millions, if not billions of dollars to bring a drug to market. Such investment would be put at risk if a confidential transaction involving the candidate drug were to be deemed a "sale" in litigation a decade or more later, after a drug product has been brought to market against all odds. And smaller companies would be impacted more directly, and more harshly, because they depend on partnering and external funding, and are more likely to have to report business transactions publicly, which would greatly increase the risk of unfairly triggering a patent-defeating event. The result below is

especially harsh when a "sale" is deemed to have occurred in a clearly pre-commercial setting, long before it is even clear whether a biotech invention can receive FDA approval and actually be sold to the public, and where the transaction was undertaken to fund the development of the invention.

CONCLUSION

The Federal Circuit's decision is contrary to the AIA and this Court's precedent, is contrary to sound public policy, and should be reversed.

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