No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., ET AL.,

Respondents.

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

BRIEF FOR RESPONDENTS

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October 9, 2018

QUESTIONS PRESENTED

For nearly two centuries, the Patent Act has prohibited inventors from obtaining a patent if the invention is "on sale" before the inventor applies for a patent, subject to a grace period (currently one year). 35 U.S.C. § 102(a). Since 2011, the Patent Act has also prohibited inventors from obtaining a patent if the invention is "otherwise available to the public" outside the grace period. *Id.*

Petitioner's invention was ready for patenting, but petitioner did not apply for a patent until more than a year after selling the invention to a distributor for $11 million.

The questions presented are:

1. Whether the 2011 amendment changed the meaning of "on sale" so that commercial sales no longer start the grace period unless they *also* make the invention "available to the public."

2. If the 2011 amendment changed the meaning of "on sale," whether petitioner nonetheless placed its invention "on sale" when it sold the invention for $11 million and disclosed every element of the invention to the buyer.

RULE 29.6 STATEMENT

The parent companies of Teva Pharmaceuticals USA, Inc. are: Orvet UK Unlimited, Teva Pharmaceutical Holdings Coöperatieve U.A., Ivax LLC (f/k/a IVAX Corporation), Teva Pharmaceuticals Europe, B.V., and Teva Pharmaceutical Industries Ltd. Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Pharmaceuticals USA, Inc.

Teva Pharmaceutical Industries Ltd. has no parent company, and no publicly traded company owns 10% or more of the stock of Teva Pharmaceutical Industries Ltd.

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INTRODUCTION

This case is about the meaning of "on sale"—a term Helsinn never bothers to define. That term has a simple meaning that this Court has applied since the 1800s: an item is "on sale" if it is sold or offered for sale, even to a single buyer. Therefore, when Helsinn sold its pharmaceutical product to a commercial distributor for $11 million, the product was "on sale," and Helsinn had one year to seek a patent. Helsinn's attempt to avoid that straightforward conclusion depends on an unnatural meaning of "on sale" that focuses not on commercialization, but on disclosure.

Helsinn sought to do what this Court has held for nearly two centuries is impermissible: "exploit [a] discovery competitively after it is ready for patenting," while delaying applying for a patent. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68 (1998) (citation omitted). Patents confer a monopoly "'for limited times,'" and allowing inventors to place their inventions on sale immediately but to defer seeking a patent until much later—when they are faced with "the danger of competition"—would extend the period of monopoly, reward delay in publicizing discoveries, and "materially retard the progress of science." *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 16, 19 (1829) (Story, J.) (quoting U.S. Const. Art. I, § 8, cl. 8). That is why Congress enacted the on-sale bar that now appears in 35 U.S.C. § 102(a).

This Court has always read "on sale" as a term of art that encompasses even a single sale or offer to sell, whether or not the sale or offer publicly discloses the invention's details. The on-sale bar is triggered by commercial exploitation—*not* public dissemination of every detail of the invention. Offers for sale, for example, do not generally teach the public everything about the invention, but this Court has squarely held that an offer places the invention "on sale." And while other bars in Section 102(a) incorporate concepts of broader public availability—*e.g.*, "public use" or disclosure in a "printed publication"—this Court has always read "on sale" to encompass even "a single instance of sale." *Consol. Fruit-Jar Co. v. Wright*, 94 U.S. 92, 94 (1877). The on-sale bar asks not whether the *public* derives knowledge, but whether the *inventor* "derive[s] any benefit from the sale" of an invention that is ready for patenting. *Id.* (citation omitted).

According to Helsinn, the 2011 amendment fundamentally changed the scope and function of the on-sale bar—not directly, but with a bank shot. Congress did not change the phrase "on sale" at all; it added a *new* category of invalidating prior art, consisting of disclosures that make an invention "otherwise available to the public." Helsinn now agrees that the new phrase "to the public" does not modify "on sale" as a grammatical matter; instead, Helsinn contends that this new language "informs" the meaning of "on sale" in some less tangible way. But Congress does not generally alter the well-established meaning of a statutory term of art by amending *other* statutory language, and it did not do so here.

Indeed, Helsinn's reading would not only *change* the term of art's meaning, but *drain* it. A sale would be left as nothing more than an example of a disclosure that makes the invention "available to the public." That reading is not necessary to give the catchall phrase meaning, as Helsinn insists. The term "otherwise" merely acknowledges *some* overlap between that new category and the pre-existing ones in the statute (which include "public use" and disclosure in a "printed publication"). It does not signal that the settled meaning of "on sale" must be compressed to achieve *complete* overlap with the new category—which would leave the on-sale bar with nothing independent to do. Moreover, if all disclosures under Section 102(a) now are *necessarily* "public," it is impossible to make sense of the following subsection of the statute, which expressly distinguishes between "disclosures" and "public disclosures."

In adopting the 2011 amendment, Congress did not seek to neutralize the on-sale bar. To the contrary, Congress *retained* the on-sale bar, and proposals to do precisely what Helsinn wants were *rejected* based on "strenuous concerns" from "a wide range of stakeholders" about "delet[ing] specific categories of prior art with well established meanings in case law." House Comm. on the Judiciary, *Markup of H.R. 1249, The America Invents Act* 101 (Apr. 14, 2011) ("*Markup*") (statement of Rep. Lofgren).[1] The legislative history Helsinn now cites comes from Members of Congress who wanted to eliminate the on-sale bar; criticized the draft legislation for retaining it; and after failing to kill it, resorted to floor statements opining that the on-sale bar does not cover the very sales *they had criticized it for covering*. This Court should not do what Congress itself would not.

Even if Helsinn were right that a sale or offer must make the invention "available to the public," Helsinn does not even attempt to explain why its multimil-

[1] Available at https://tinyurl.com/MarkupTrans.

lion-dollar sale to a distributor did not do just that. Helsinn sold the entire invention to a member of the interested public—exactly the type of customer one would expect to buy a pharmaceutical from its manufacturer. The government's proposed standard, which focuses on whether the "ultimate customer" could acquire the invention, has no basis in the statute's text and would be impossible to administer.

This Court should affirm.

STATUTORY PROVISIONS INVOLVED

1. Section 3(b)(1) of the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284, 285-286 (2011), amended 35 U.S.C. § 102 to provide, in relevant part:

> (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—
>
> > (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention * * * .
> >
> > * * * *
>
> (b) EXCEPTIONS.—
>
> > (1)DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—

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

2. 35 U.S.C. § 102 (2006) provided, in relevant part:

> A person shall be entitled to a patent unless—
>
> * * *
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

STATEMENT

A. Well before the 2011 amendment, 200 years of precedent confirmed that an invention can be "on sale" without disclosing every element of the invention to the public.

An inventor must apply for a patent promptly after placing a completed invention "on sale." 35 U.S.C.

§ 102(a). For nearly two centuries, this Court has focused the on-sale analysis on sales and offers that commercially exploit the invention, regardless of whether they disclose every element of the invention to the public.

The Court first identified commercial exploitation as invalidating in *Pennock*. The inventor had used a new process to make fire hose and sold it to several companies before seeking a patent on the process. 27 U.S. at 3. The Court held that an inventor can no longer get a patent "if he suffers the thing invented to go into public use, or to be publicly sold for use, before he makes application for a patent." *Id.* at 23-24. The patent therefore was invalid—even though there was no indication that selling the hose had publicly disclosed the claimed manufacturing process.

Pennock established a principle that still animates the on-sale bar: inventors may not profit commercially from their inventions, but delay seeking patents (beyond a limited grace period, currently one year). As *Pennock* put it, allowing an inventor to "retain the monopoly, and make and sell his invention publicly; and thus gather the whole profits of it, relying upon his superior skill and knowledge of the structure," and then to "take out a patent, and thus exclude the public from any further use," only when "the danger of competition should force him to procure the exclusive right," would "materially retard the progress of science and the useful arts; and give a premium to those who should be least prompt to communicate their discoveries." *Id.* at 19.

Soon after *Pennock*, Congress expressly prohibited patenting an invention already "on sale." Patent Act of 1836, ch. 357, § 6, 5 Stat. 117. Ever since, courts applying the bar have followed *Pennock* in holding that "an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law." *Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 137 (1878). Similarly, "the inventor who designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public, … does not promote, and, if aided in his design, would impede, the progress of science and the useful arts." *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1859).

Judge Learned Hand likewise cited *Pennock* in a landmark decision holding that "secret" sales invalidated a patent. He concluded that "it is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly." *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2d Cir. 1946). Because the inventor sold his invention outside the grace period, the on-sale bar applied "regardless of how little the public may have learned about the invention" from the "secret" sales. *Id.* at 518, 520. As in *Pennock*, the key principle was preventing commercial exploitation before the patent application. This Court has twice unanimously endorsed *Metallizing*'s holding that an inventor "shall not exploit his discovery competitively after it is ready for patenting." *Pfaff*, 525 U.S. at 68; *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 149 (1989).

This Court most recently considered the scope of the on-sale bar in *Pfaff*. More than a year before applying for a patent, the inventor there made an agreement to sell to a single corporate buyer, based on "detailed engineering drawings" and "a sketch of his concept." 525 U.S. at 58. Although this agreement did not make the invention (as later patented) available to the general public, the sale triggered the on-sale bar. *Id.* at 68-69.

As the Court explained, the "patent system represents a carefully crafted balance … between the interest in motivating innovation and enlightenment by rewarding invention with patent protection on the one hand, and the interest in avoiding monopolies that unnecessarily stifle competition on the other." *Id.* at 63. Citing *Pennock* and *Metallizing*, the Court held that the on-sale bar "confin[es] the duration of the monopoly to the statutory term." *Id.* at 64. The Court thus applied a two-part test for finding an invention "on sale" and starting the one-year clock: The invention must be "the subject of a commercial offer for sale," as opposed to an experimental one, and must have been "ready for patenting." *Id.* at 67. Whether the offer fully disclosed the invention to the buyer was irrelevant.

Consistent with these precedents, the Federal Circuit has repeatedly applied the on-sale bar to nonpublic sales.[2] As that court has explained, "the pri-

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[2] *E.g.*, *Merck & Cie v. Watson Labs., Inc.*, 822 F.3d 1347, 1351 (Fed. Cir. 2016) (responding to a single customer's request to purchase product by returning price, delivery, and payment terms triggered the on-sale bar); *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1328 (Fed. Cir. 2001) (offer to sell a service

mary policy underlying an 'on-sale' case is that of prohibiting the commercial exploitation of the design beyond the statutorily prescribed time period." *Cont'l Plastic Containers v. Owens Brockway Plastic Prods., Inc.*, 141 F.3d 1073, 1079 (Fed. Cir. 1998). Indeed, the en banc Federal Circuit recently called it "'well established … that a single sale or offer to sell is enough to bar patentability' even if kept secret from the trade." *Meds. Co. v. Hospira, Inc.*, 827 F.3d 1363, 1376 (Fed. Cir. 2016) (en banc) (quoting *In re Caveney*, 761 F.2d 672, 676 (Fed. Cir. 1985)).

B. Members of Congress repeatedly tried and failed to amend the AIA to abandon the on-sale bar in favor of a general "public availability" inquiry.

The AIA retained the on-sale bar, despite attempts by some Members of Congress to eliminate it. While Congress added a new catchall category of invalidating prior art—art that makes the claimed invention "otherwise available to the public"—the statute continues to provide that a patent is invalid if the invention was "on sale" more than one year before the patent application. 35 U.S.C. § 102(a).[3] Throughout the multi-year process of drafting the AIA, proponents and opponents of the on-sale bar agreed that, *if* the bar remained (as it ultimately did), it would keep its longstanding meaning.

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that would have necessitated use of a certain process triggered the on-sale bar as to that process).

[3] The one-year grace period was moved into a separate subsection, Section 102(b). The AIA also amended that subsection to distinguish for certain purposes between "disclos[ures]" and "*public* disclos[ures]" by the inventor during the grace period. *See* pp. 37-39, *infra*.

The first two predecessor bills were introduced in 2005 and 2006 by Representative Smith and Senator Hatch. These bills would have removed the on-sale bar altogether, denying a patent only if "the claimed invention was patented, described in a printed publication, or otherwise publicly known." H.R. 2795, 109th Cong. § 3(b)(1) (2005); S. 3818, 109th Cong. § 3(b)(1) (2006). The "otherwise publicly known" language from this bill could not have been crafted to "inform" the meaning of "on sale," as the bill would have *deleted* that term.

The next year, the House considered a new bill that retained the on-sale bar, making a patent unavailable if the invention was "patented, described in a printed publication, or in public use or on sale" outside the grace period. H.R. 1908, 110th Cong. § 3(b)(1) (2007); *see also* S. 1145, 110th Cong., § 3(b)(1) (2007). The committee report stated that the bill used the phrase "on sale" because it "ha[d] been interpreted by the courts." H.R. Rep. No. 110-314, at 57 (2007).

The report also explained that the on-sale bar was intended to serve "very specific policy goals," including "encouraging inventors to file early for patent protection" and "preventing inventors from extending their monopoly in the invention." *Id.* The report confirmed that these incentives were still needed even if (as the bill also proposed) the United States shifted to "a first-to-file system." *Id.*

Subsequent proposals differed over whether to retain the "public use" and "on sale" bars (as in the House's 2007 bill) or replace them with a general "available to the public" standard (as in the House and Senate's 2005 and 2006 bills). In 2008, Senator

Leahy introduced a bill with language identical to the AIA's. S. 1145, 110th Cong. § 2(b)(1) (2008) ("patented, described in a printed publication, or in public use, on sale, or otherwise available to the public").

By contrast, Senator Kyl introduced a bill that deleted the "public use" and "on sale" bars in favor of "a uniform test of whether art has been made available to the public." S. 3600, 110th Cong. § 2(b)(1) (2008) ("patented, described in a printed publication, or otherwise made available to the public"). Senator Kyl said that his bill, *unlike Senator Leahy's*, would "eliminat[e] confidential sales and other secret activities as grounds for invalidity and impos[e] a general standard of public availability." 154 Cong. Rec. 22,631 (2008).

Senators Leahy and Kyl introduced similar bills the next year. S. 515, 111th Cong. § 2(b)(1) (2009); S. 610, 111th Cong. § 2(b)(1) (2009). Once again, Senator Kyl stated that he read Senator Leahy's bill to preserve the existing meaning of the on-sale bar, criticizing that bill for retaining "patent-forfeiture provisions that apply only to non-public prior art." S. Rep. No. 111-18, at 60 (2009) (minority views).

In reporting the bill that became the AIA, the House Judiciary Committee rebuffed a final attempt to replace the on-sale bar with a general "available to the public" standard. As introduced, the House bill included the language now found in the AIA. H.R. 1249, 112 Cong. § 2(b)(1) (2011). Representative Smith proposed amending Section 102(a) to "strike 'or in public use, on sale, or otherwise available to the public' and insert 'or otherwise disclosed to the public.'" Amendment to H.R. 1249 Offered by Mr.

Smith of Texas, at 2 (Apr. 12, 2011).[4] The effort quickly failed: Representative Lofgren proposed a successful amendment restoring the text of Section 102 as introduced (and as ultimately enacted). *Markup* 101.[5] As she explained: "I have now heard strenuous concerns about the broader change from a wide range of stakeholders. In particular, they are concerned about the deletion of specific categories of prior art with well established meanings in case law and replacing those terms with a more ambiguous term otherwise disclosed to the public." *Id.* Her amendment thus preserved the on-sale bar, with its "well established meaning[]." *Id.*

C. Helsinn earns millions of dollars selling the invention to its distributor, but delays seeking a patent.

1. This case involves the use of intravenous formulations of palonosetron to treat chemotherapy-induced nausea and vomiting ("CINV"). A prior-art patent disclosed the palonosetron compound and described it as useful for preventing and treating "emesis"—*i.e.*, nausea and vomiting, including CINV. The prior art disclosed that an ordinarily skilled artisan "will be able, without undue experimentation, to ascertain" the effective doses for particular diseases. Pet. App. 68a-69a. In turn, Phase II clinical trials demonstrated that the 0.25 mg (3 µg/kg) dosage was "effective in suppressing chemotherapy-induced emesis for 24 hours." J.A. 33.

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[4] Available at https://tinyurl.com/SmithAmdt.

[5] Available at https://tinyurl.com/LofgrenAmdt.

In 1998, Helsinn purchased a license to develop palonosetron. Pet. App. 78a. Helsinn's plan, according to internal minutes, was to "test effective doses seen in Phase 2," including "0.25 mg." J.A. 38. Over several years, Helsinn repeatedly reiterated that Phase II trial results had confirmed palonosetron's efficacy in treating CINV at dosages including 0.25 mg, telling FDA that "[0.25 mg] is the minimal *effective* dose." J.A. 48; *see also* J.A. 50.

Thus, when Helsinn acquired its license to palonosetron, the 0.25 mg dose had already been "shown … to work for its intended purpose." Pet. App. 44a. Nonetheless, Helsinn did not apply for a patent.

2. Meanwhile, Helsinn sought to profit commercially from the unpatented invention. In April 2001, Helsinn entered into a Supply and Purchase Agreement and a License Agreement with MGI Pharma, a distributor. J.A. 52-250. MGI agreed to buy the 0.25 mg dose and resell it to pharmacies. MGI paid Helsinn $11 million upon signing, and promised future payments, for Helsinn's commitment to supply MGI with whatever product it might need upon FDA approval. J.A. 80-87. Both courts below concluded (and Helsinn no longer disputes, *see* Pet. i) that Helsinn had made a "sale" of the invention under the Uniform Commercial Code ("UCC"), even though it was partially contingent on FDA approval. Pet. App. 33a, 164a.

Virtually every detail of the sale was publicized in a joint Helsinn/MGI press release and SEC filings. Both included a redacted version of the parties' agreements and described most of the financial terms. J.A. 253, 258. Copies of the agreements, including "[d]etailed information about palonosetron" and its "chemical structure," were attached to SEC Form 8-K. Pet. App. 38a; J.A. 333-370. The sale thus publicized every aspect of the invention, and "all the pertinent details of the transaction," "other than the price and dosage." Pet. App. 39a.

3. Nearly two years later, on January 20, 2003, Helsinn finally filed a provisional patent application. Pet. App. 61a. The critical date for the on-sale bar is thus January 20, 2002—one year earlier. *Id.* Helsinn ultimately obtained four patents. *Id.* at 61a-63a. Because only U.S. Patent No. 8,598,219 ("the '219 patent") is governed by the AIA, however, only that patent remains at issue. *Id.* at 61a. It describes an intravenous dose of 0.25 mg of palonosetron, in a 5 mL volume, for treating CINV. J.A. 484-485.

4. In 2011, Teva filed an Abbreviated New Drug Application ("ANDA") to produce a generic version of palonosetron at the 0.25 mg dose for treating CINV. Pet. App.144a-145a. Teva's ANDA included a "Paragraph IV" certification to the '219 patent, which asserts that the patent is invalid, unenforceable, or would not be infringed by the proposed generic product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

D. The district court finds a "sale" but upholds the patent.

Filing a Paragraph IV certification is itself an act of infringement, 35 U.S.C. § 271(e)(2)(A), so Helsinn sued Teva, alleging that the proposed generic product would infringe Helsinn's four patents. Pet. App. 53a-54a. Teva answered that the patents were invalid because of Helsinn's 2001 sale to MGI, arguing both that the on-sale bar still applied to private sales and that the MGI sale was to the public in any event.

After a bench trial, the district court held that the patents were all valid and infringed. As noted above, it found that the Helsinn/MGI Supply and Purchase Agreement qualified as a "commercial sale" for purposes of the pre-AIA on-sale bar. *Id.* at 164a. But the court held that "the post-AIA on-sale bar" requires not just a "sale" (or offer), but one that "make[s] the claimed invention available to the public." *Id.* at 180a. The court acknowledged that Helsinn and MGI had publicized their agreement, but deemed this insufficient because they did not disclose every limitation later claimed in the patent. *Id.*

E. The Federal Circuit holds that Helsinn's multimillion-dollar sale of the invention to its distributor started the clock to seek a patent.

1. The Federal Circuit reversed. It first affirmed that, under the UCC, Helsinn sold "the claimed invention—the 0.25 mg dose—before the critical date," noting that the parties' agreement "described the palonosetron formulation in detail" and that the 0.25 mg dose "embod[ies] the asserted claims." Pet. App. 33a.

Turning to whether the AIA "changed the meaning of the on-sale bar," the court declined to read the addition of "otherwise available to the public" to work "a foundational change in the theory of the statutory on-sale bar" dating back to *Pennock*. *Id.* at 39a. As the court explained, the bar has been applied in numerous situations, including: "when there is no delivery" of the product because an offer is rejected; "when delivery is set after the critical date" (*i.e.*, one year before the patent application); "or, even when, upon delivery, members of the public could not ascertain the claimed invention." *Id.* at 42a. "If," as Helsinn argued, "Congress intended to work … a sweeping change" to this broad scope, it would have used "clear language," rather than leaving the on-sale bar itself unchanged while adding a new, separate category of invalidating prior art. *Id.* at 43a.

The court also rejected Helsinn's legislative-history arguments, based primarily on "floor statements" of "individual members of Congress." *Id.* at 36a. Such statements, the court observed, are "typically not reliable." *Id.* Moreover, the statements at most suggested that Congress may have meant to "overrule" cases where the existence of the sale itself was confidential. *Id.* at 38a. Here, "the existence of the sale—*i.e.*, the Supply and Purchase Agreement between Helsinn and MGI—was publicly announced in MGI's 8-K filing," resulting in public disclosure of "all the pertinent details of the transaction other than the price and dosage levels." *Id.* Thus, even if Congress had incorporated a "public disclosure" requirement into the on-sale bar, Helsinn's sale would satisfy it.

Finally, the court held that Helsinn's invention had been "overwhelming[ly]" ready for patenting since the mid-1990s, and certainly as of January 30, 2002, the critical date. *Id.* at 47a, 43a-52a. Because both prongs of *Pfaff* were therefore satisfied, the court concluded that all four patents-in-suit were "invalid under the on-sale bar." *Id.* at 52a.

2. The Federal Circuit denied rehearing *en banc*. Judge O'Malley concurred. Citing "[the] cardinal rule" that, "when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the

body of learning from which it was taken," she stressed that "Congress chose not to modify the term 'on sale'" and thus "intended for that term to take on the meaning that courts had attributed to it for well over a century." *Id.* at 9a-10 (citation omitted).

Judge O'Malley also explained that "Helsinn's only argument directed to the text"—"that the new phrase 'or otherwise available to the public'" changes the settled meaning of "'on sale'"—had "several problems." *Id.* at 8a. For example, Helsinn had argued that "to the public" actually modifies "on sale" in addition to "otherwise available." Judge O'Malley explained that series modifiers must "appl[y] as much to the first and other words as to the last"; but "to the public" is "not equally applicable to all preceding phrases because each phrase … recites a disclosure that is necessarily public. Helsinn's reading … would therefore create redundancies." *Id.* at 9a & n.2. Further, Section 102(b)(1)—which creates a one-year grace period for Section 102(a) disclosures—distinguishes between "disclosures" and "public disclosures." *Id.* at 11a. But "[i]f all prior art events—i.e., all 'disclosures'—recited in §102(a) were already public disclosures, the word "publicly … would be redundant." *Id.*

Because Helsinn's reading conflicted "with so many principles of statutory interpretation," Judge O'Malley read the addition of "otherwise available" not as limiting what was already in the statute, but as broadening it with "a catchall provision that encompasses … disclos[ures] to the public that are not otherwise accounted for in § 102(a)." *Id.* at 9a. She saw no basis to disturb the on-sale bar's longstanding interpretation, especially given its "overriding concern" with preventing "an inventor" from "commercially exploit[ing] his invention beyond the statutory term." *Id.* at 11a, 13a.

SUMMARY OF ARGUMENT

I. Making an invention available for purchase by selling it or offering it for sale places that invention "on sale." That is what "on sale" has always meant and how this Court has consistently read it. The AIA did not give that phrase a new and unnatural meaning that would reverse centuries of precedent.

A. Placing something "on sale" means making it "available for purchase." *Merriam-Webster's Collegiate Dictionary* 1097 (11th ed. 2003) ("*Webster's Collegiate*"). A good or service that *has been* sold or offered for sale has thus necessarily been placed "on sale." Nothing about the ordinary meaning of "on sale" requires that a sale or offer be *public*, let alone that it publicly disclose any particular details about what is being sold.

Consistent with the ordinary meaning of "on sale," this Court has long held—from *Pennock* through *Pfaff*—that a sale or offer for sale to even *one* buyer, at any level of the distribution chain, triggers the on-sale bar regardless of what is disclosed to the public. What matters is whether the inventor derives commercial benefit, not whether the public derives knowledge.

B. Had Congress intended to change the ordinary and settled meaning of "on sale," it would have done so directly and expressly. When Congress intends to change the meaning of a term of art or language that this Court has construed, it does so clearly. The phrase "on sale" has just such a settled meaning.

The AIA did not amend "on sale" *at all*, and certainly did not clearly signal a radical change to its meaning.

C. Congress did not *indirectly* change the meaning of "on sale" by adding a new category of invalidating prior art—disclosures making the invention "otherwise available to the public." That new, catch-all category was added to ensure that the statute captures all public disclosures of the invention; oral presentations, for example, were not previously covered. That is not only the catch-all's "most obvious purpose," U.S. Br. 18, but its *only* purpose.

Helsinn claims (at 39) that if the catch-all did not also "inform"—*i.e.*, change—the meaning of "on sale," then "otherwise" would be superfluous. Helsinn is wrong. The word "otherwise" acknowledges the significant overlap between the catchall and the preexisting categories. But "otherwise" does not signal that *everything* previously covered would now fall into the catchall.

Helsinn's reliance (at 20) on the *noscitur a sociis* canon is misplaced. Whatever value that canon may have when an ambiguous term has multiple potential meanings, it cannot "create ambiguity where the statute's text and structure suggest none." *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 227 (2008). Helsinn improperly invokes *noscitur a sociis* to force an unnatural meaning onto an unambiguous term—based on language added to the statute long after the term's meaning was settled. Further, the canon does not apply where, as here, terms are not susceptible to a common interpretation without robbing them of their "independent and ordinary significance." *Graham Cty. Soil & Water Conservation Dist. v. United*

States ex rel. Wilson, 559 U.S. 280, 288 (2010) (citation omitted).

D. The distinction between "disclosure[s]" and "public[] disclos[ures]" in Section 102(b)(1)(B) is further evidence that Helsinn's interpretation is incorrect. If Helsinn were right that all disclosures under Section 102(a) must be public, then the word "publicly" in Section 102(b) would do no work.

E. The AIA's drafting history powerfully confirms that the amendment did not change the meaning of "on sale." The new prior-art category was added to the statute in bills that *did not include* the on-sale bar, and hence could not have been written to modify it. That history also refutes the notion that "otherwise" serves no function except to "inform" the on-sale bar. Further, the extended disagreement over whether to *replace* the on-sale bar with a public-availability standard belies Helsinn's argument that the two formulations mean the same thing. And contemporaneous statements confirm that retaining the bar meant retaining its existing meaning.

The floor statement by Senator Kyl on which Helsinn heavily relies (at 27-28) shows why floor statements "rank among the least illuminating forms of legislative history." *NLRB v. SW General, Inc.*, 137 S. Ct. 929, 943 (2017). Senator Kyl repeatedly urged his colleagues *not* to adopt the same wording that the AIA ultimately used, because that wording would *preserve* the existing meaning of the on-sale bar. When that effort failed, he began arguing that the AIA's language actually *changed* the bar's meaning—attempting to accomplish through the *Congressional Record* what he failed to do in the AIA itself.

F. Helsinn's position would leave the on-sale bar incapable of serving the role for which it was created: preventing monopolies from being extended by a lengthy period of commercialization before the patent term. Inventors could immunize an unlimited number of sales from the on-sale bar simply by having the purchasers sign non-disclosure agreements. And Helsinn's approach would effectively overturn this Court's holding that *offers* for sale place the invention "on sale," as an *offer* generally need not disclose the invention's details.

These concerns remain real in a first-to-file system. Many inventors—particularly inventors of manufacturing processes—will remain motivated by the profits from extending patent monopolies to conceal inventions before seeking a patent. And the House Judiciary Committee recognized that "preventing inventors from extending their monopoly" remains relevant "in a first-to-file system" because inventors will "mak[e] use of their inventions as trade secrets and then some time later fil[e] a patent application." H.R. Rep. No. 110-314, at 57.

G. Helsinn's arguments invoking other AIA provisions (at 33-35) are also unavailing. Because the AIA consciously retained the term "on sale," which does not appear in other countries' patent laws, it is unnecessary—indeed, impossible—to read the term as if the United States had fully adopted foreign conceptions of prior art. The fact that the AIA made international sales invalidating simply expands the bar's geographic scope; it does not change the meaning of "on sale." And applying the on-sale bar's longstanding interpretation would not complicate the post-grant-review process.

II. Even if the on-sale bar were limited to sales or offers that make inventions "available to the public," the Court should still affirm. The only way to harmonize the on-sale bar with a public-availability requirement is to hold that a sale or offer triggers the bar if it discloses the invention to a member of the public one would expect to purchase it. The government's test—that the invention must be available to "ultimate customers"—has no basis in *either* the phrase "on sale" or "available to the public." On the government's view, an invention could be *repeatedly* sold without having been placed "on sale." And while offering to sell to *one* "ultimate customer" would make the invention "available to the public," selling to *every wholesaler and retailer in the world* would not. That interpretation is neither correct nor coherent.

Helsinn's $11 million sale to its distributor made the invention available to the public. There is no dispute that Helsinn's sale disclosed every element of its invention to MGI. Nor is there any doubt that MGI, a pharmaceutical distributor, is *precisely* the kind of member of the public one would expect to purchase the invention. Selling the invention for millions of dollars and disclosing every element to the purchaser placed the invention "on sale."

ARGUMENT

I. The America Invents Act did not narrow the well-established meaning of the on-sale bar by adding a new category of invalidating prior art.

Offering an item for sale—whether to one private buyer or the whole world—places it "on sale." That is how this Court has long read the on-sale bar, and Congress has not changed the term's meaning. The addition of the "otherwise available" phrase at the end did not reverberate back through Section 102(a) to upset the settled meaning of other terms that Congress left in place.

A. An invention is "on sale" when offered for sale.

Helsinn's interpretation of "on sale" cannot be squared with its ordinary meaning—a meaning confirmed by this Court's longstanding interpretation. Helsinn has conceded that "on sale" is a term of art under that precedent, but says the AIA changed its meaning, such that inventors may offer or sell their inventions repeatedly without *ever* putting them "on sale." In reality, however, *any* sale or offer places the invention "on sale," regardless of whether it discloses the details of the invention to the public.

1. The phrase "on sale" encompasses *any* sale or offer for sale. A "sale" means simply a "transfer of ownership of and title to property … for a price." *Webster's Collegiate* 1097; *accord* N. Webster, *An American Dictionary of the English Language* 719 (13th ed. 1834) ("the exchange of a commodity for money of equivalent value"); *Concise Oxford English Dictionary* 1268 (12th ed. 2011) (defining "sale" as "the exchange of a commodity for money"). Sales are about *ownership*, not *disclosure*, and nothing in standard dictionary definitions of "sale" turns on whether the purchaser agreed to keep confidential the sale or the item sold.

To put a good or service "*on* sale" is thus simply to make the good or service "*available* for purchase"—

i.e., available for money. *Webster's Collegiate* 1097 (emphasis added); *accord Concise Oxford English Dictionary* 1269 ("offered for purchase"); J. Worcester, *Dictionary of the English Language* 1266 (1860) ("to be sold"). An item is no less "on sale" if it is "the subject of a commercial offer for sale" that is not accepted. *Pfaff*, 525 U.S. at 67. Moreover, *nothing* in the term's ordinary meaning suggests that whether an item is "on sale" requires asking whether a sale or offer occurs privately, or happens to publicly disclose the object of the sale. Consumer goods are no more "on sale" than, say, private-placement securities—which by definition are offered for sale privately.

Helsinn does not engage *at all* with the meaning of "on sale." As noted (p. 13, *supra*), Helsinn does not even dispute that there was a "sale" here. The government insists (at 15) that the term "inherently suggests a sale or offer to sell to the public." But its only support is a dictionary that defines "on sale" as "[a]vailable *to customers*." U.S. Br. 15. As the same dictionary confirms, a "customer" is simply "one that buys goods or services," not necessarily the end user or the public at large. *American Heritage Dictionary of the English Language* 449 (5th ed. 2011). And while the government cites several popular articles that use "on sale" to describe consumer products available to the general public, that does not narrow the term's meaning. The popular press uses "on sale" regardless of whether the "sale" will be to the general public. *E.g.*, *Technology Brief*, Wall St. J., Sept. 3, 2003, at A12 ("[T]he Gyricon unit's signs are expected to go *on sale to retailers* next year.") (emphasis added). A product is "on sale" if a buyer can buy it.

2. The ordinary meaning of "on sale" perfectly tracks this Court's longstanding interpretation of the on-sale bar. As Helsinn conceded below, by the time of the AIA, "on sale" had become a "term[] of art." C.A. Br. 43. Beginning in *Pennock* and continuing through *Pfaff*, the Court repeatedly applied the bar to offers and sales without asking whether the offers or sales were sufficiently broad or revealing to disclose the nature of the invention to the general public. For instance, the invalidating offer in *Pfaff* was made to a single corporation, Texas Instruments. 525 U.S. at 58. *See also, e.g.*, *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 257 (1887) ("A single sale to another"); *Hall v. Macneale*, 107 U.S. 90, 97 (1883) (sale of two safes containing patented bolts, which could not be viewed without "destruction of the safes"); pp. 5-8, *supra*.

The rationale of these cases—that the on-sale bar precludes attempts to extend the patent term and thus to gain a longer monopoly—confirms that triggering the bar does not turn on how much the sale or offer discloses. What matters is not whether the public derives knowledge, but whether the *inventor* "derive[s] any benefit from the sale." *Consol. Fruit-Jar*, 94 U.S. at 94 (citation omitted).

Indeed, this principle applies with the *most* force to inventions that are *not* publicly disclosed through an offer or a sale—when inventors have the least reason to fear competition. As in *Pennock*, for example, the inventor of a new manufacturing *process* can often sell the end product without disclosing the process itself. *See, e.g.*, *Metallizing*, 153 F.2d at 519.

Similarly, this Court's unambiguous holding that *offers* for sale trigger the bar, *Pfaff*, 525 U.S. at 67, did not ask whether the offer communicated the entire invention, and such a rule would make no sense. A seller marketing an unpatented invention would rarely (if ever) disclose every detail of the invention *in the offer*. Offers trigger the bar not because they teach the public anything, but because the inventor is commercializing an invention ready for patenting.

As this Court has held (quoting Judge Hand), an inventor "shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly." *Pfaff*, 525 U.S. at 68 (quoting *Metallizing*, 153 F.2d at 520). Inventors may not have it both ways—exploiting their inventions secretly while fearing no competition, and then getting patents (and extending their monopolies) once competition is threatened.

B. Congress would act expressly if it sought to change the term's settled meaning.

Rather than engage with the term "on sale" or the case law interpreting it, Helsinn and the government say Congress changed the term's meaning without actually touching it. By their lights, Congress's *expansion* of the categories of prior art that invalidate patents—to include inventions "otherwise available to the public"—*shrunk* the phrase "on sale" to reach only offers and sales of an invention that *publicly disclose every element of the invention*. But assertions that Congress changed the Court's settled interpretation of statutory language must clear a high bar, especially when based on changes to *nearby* statutory language rather than the operative text.

Helsinn cannot surmount that bar here. The AIA retained the term "on sale" unchanged, without limiting it to public sales, leaving it in a list of bars that *do* repeatedly include the word "public." Congress's word choice powerfully confirms that it did not "work a foundational change" in the on-sale bar. Pet. App. 39a. The change Congress did make—adding "otherwise available to the public"—fills a gap by creating a catchall category of invalidating prior art; it does not modify the scope of the preexisting categories.

1. "It is a cardinal rule of statutory construction that, when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it is taken." *Air Wisconsin Airlines Corp. v. Hoeper*, 571 U.S. 237, 248 (2014) (brackets omitted). The same principle applies to statutory amendments: "[t]he normal rule of statutory construction is that if Congress intends for legislation to change the interpretation of a judicially created concept, it makes that intent specific." *Midatlantic Nat'l Bank v. N.J. Dep't of Envtl. Prot.*, 474 U.S. 494 (1986); *accord United States v. Reorganized CF&I Fabricators of Utah, Inc.*, 518 U.S. 213, 221 (1996).

That principle is at its strongest when the relevant interpretation came from this Court, which authoritatively settles the meaning of federal statutes. "When Congress intends to" change the meaning of statutory language that this Court has construed, "it ordinarily provides a relatively clear indication of its intent in the text of the amended provision." *TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S. Ct. 1514, 1520 (2017). As the treatise cited to support that proposition explains, "[a] clear, authoritative judicial holding on the meaning of a particular provision should not be cast in doubt and subjected to challenge whenever a related though not utterly inconsistent provision is adopted," even if the new provision is "in the same statute." *Id.* (quoting Antonin Scalia & Bryan A. Garner, *Reading Law* 331 (2012)). "Legislative revision of law clearly established by judicial opinion ought to be by express language or unavoidably implied contradiction. We know of no case to the contrary." Scalia & Garner 331.

2. That rule controls here. By the time of the AIA, Congress understood that—as Helsinn acknowledged below (C.A. Br. 41)—"on sale" had become a "term of art," and its "established" meaning included non-public sales. Yet Congress left the bar's language intact.

Had Congress meant to change its established meaning as Helsinn suggests, it had several obvious ways to do so that would have tracked the surrounding bars ("*patented*," "described in a printed *publication*," or in "*public* use"). It could have said:

- "*publicly* on sale";
- "on sale *publicly*"; or
- "on sale *to the public*"

Congress's failure to do any of this—or to define "on sale" as meaning "publicly on sale"—confirms that it left the longstanding interpretation of "on sale" intact.

"Congress generally acts intentionally when it uses particular language in one [part] of a statute but omits it in another," particularly where, as here, "Congress used" the disparate terms "in close proximity—indeed, in the same sentence"—and "repeatedly." *Dep't of Homeland Sec. v. MacLean*, 135 S. Ct. 913, 919 (2015)) (citations omitted). That "make[s] Congress's choice" not to combine "public" and "on sale" here "seem quite deliberate." *Id.* Any other conclusion is "simply contrary to any reasonable interpretation of the text." *Id.* at 920 (citation omitted).

In short, there is no basis to the government's suggestion that the on-sale bar has *always* contained a public-availability requirement, such that the AIA simply ratified that view. U.S. Br. 18-20. (Helsinn makes no such argument. Helsinn Br. 40 n.8.) And as the Federal Circuit observed, if Congress intended "a sweeping change" to the law, "it would do so by clear language" not found in the AIA. Pet. App. 43a.

C. Congress retained the term of art "on sale" and did not indirectly change its meaning.

Helsinn nonetheless contends that the AIA dramatically changed the meaning of the on-sale bar—not directly, but with a carom shot. According to Helsinn, Congress's adoption of a *new* category of invalidating prior art—inventions "otherwise available to the public"—requires reinterpreting the *existing* ones by limiting *all* of them to matters "available to the public."

But "[f]undamental changes in the scope of a statute are not typically accomplished with so subtle a move." *Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970, 1977 (2015). Instead, the "otherwise available to the public" phrase creates a new category of prior art that prevents patentees from claiming knowledge that is already in the public domain. For example, before the AIA, an *oral* presentation was not prior art even if it disclosed the invention publicly and in detail. *In re Klopfenstein*, 380 F.3d 1345, 1349 n.4 (Fed Cir. 2004). Indeed, the government acknowledges (at 18) that this was the "most obvious purpose" of the new category. That is quite enough to justify the phrase as written; there is no need to stretch the language to give it *more* to do.

1. In attempting to show otherwise, Helsinn now acknowledges (at 38) that under the rule of the last antecedent, the phrase "to the public" does not literally modify "on sale," or anything else in the sentence except "otherwise available." That appears to be a retreat from its previous position that "otherwise available" is a full-blown "series modifier" restricting the preceding series to public activities. Pet. 15–16; C.A. Br. 34-36. Helsinn may have backtracked because reading "otherwise available" as a series modifier creates glaring redundancies, such as inventions "in public use … available to the public." See Pet. App. 9a n.2 (O'Malley, J., concurring). And as Helsinn's own authority holds, to be a series modifier a phrase must "appl[y] as much to the first and other words [in the series] as to the last." *Paroline*, 572 U.S. 434, 447 (2014) (citation omitted).[6]

[6] Helsinn seems to think that "otherwise available to the public" affects only the third and fourth terms in the series. *See* Br. 18. That kind of mental gymnastics only confirms that Section 102(a)'s catchall phrase is not a series modifier. Carrying the modifier across the entire list is such a "heavy lift," *Lock-*

Ultimately, Helsinn says that the "otherwise available" phrase does not actually *modify* (in the grammatical sense) anything in the pre-existing statute, but that it merely "inform[s]" the on-sale bar's meaning. Br. 4, 19, 36, 37, 38, 42. But the meaning of "on sale" is settled by two centuries of decisions; it does not need "informing" by a new statutory neighbor. Thus, Helsinn must offer some compelling reason to reinterpret a term of art that Congress declined to change directly—something Helsinn cannot do.

2. Helsinn next contends that "on sale" must be reinterpreted because if it means what it always has, the word "otherwise" would serve no function. Br. 39. Not so. The word "otherwise," which means "in a different way or manner" (Helsinn Br. 19 (citing *Webster's Collegiate* 879)), serves to acknowledge the obvious, but incomplete, overlap between the new category and the old ones, and to clarify that the catchall category captures methods of public disclosure not previously described.

Without the word "otherwise," the statute would read: "A person shall be entitled to a patent unless … the claimed invention was patented, described in a printed publication, or in public use, on sale, or ~~otherwise~~ available to the public before the effective filing date of the claimed invention[.]" That would ignore the overlap between the catchall phrase and the other settled terms in the list—potentially creating needless confusion by implying, for example, that printed publications are not available to the public, which of course they always have been.

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hart v. *United States*, 136 S. Ct. 958, 963 (2016), that Helsinn must lop off the front half of the list.

The notion that "otherwise" (or its variants) *must* reshape the meaning of preceding words ignores common usage. For instance, saying "I'd like to go see the Astros, the Dodgers, the Red Sox, the Orioles, or any other first-place team" does not imply that the Orioles are in first place (they are not). It means the speaker is willing to see the Orioles in addition to the identified first-place teams and other first-place teams captured by the catchall. Indeed, because "patents," "printed publications," and "public use" *already* connote availability to the public, the proper analogy would be: "I'd like to go see the *first-place* Astros, the *first-place* Dodgers, the *first-place* Red Sox, the Orioles, or any other *first-place* team."

Or take this Court's example in *Barnhart v. Thomas*, 540 U.S. 20 (2003)—parents who warn their son: "'You will be punished if you throw a party or engage in any other activity that damages the house.'" *Id.* at 27. If the son held a party but the house suffered no damage, the Court noted, he "should hardly be able to avoid punishment," as the parents had "proscribed (1) a party, and (2) any other activity that damages the house," and their "reasons for prohibiting the home-alone party may have had nothing to do with damage to the house." *Id.* As in *Barnhart*, Congress's reasons for starting the clock when an invention goes "on sale" "had nothing to do with" public *disclosure*. Congress was concerned with commercialization and extended monopolies, pp. 5-8, *supra*, and it chose to place the on-sale bar in Section 102 even though being "on sale," unlike the other invalidity grounds, does *not* inherently require public availability. *See, e.g.*, *MacLean*, 135 S. Ct. at 919. As *Barnhart*'s illustration shows, adding the catchall did not override that decision and change "on sale" into "on sale to the public."

3. Aware that "otherwise" is not enough to redefine "on-sale," Helsinn invokes the *noscitur a sociis* canon, under which "words in a statute are 'known by the company they keep.'" Br. 20 (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995)) (alterations omitted). But *noscitur a sociis* applies only when choosing between two possible meanings of an "ambiguous term." *United States v. Stevens*, 559 U.S. 460, 474 (2010). It cannot distort the ordinary definition of an unambiguous term, or unsettle the settled meaning of a term of art, to "create ambiguity when the statute's text and structure suggest none." *Ali*, 552 U.S. at 227; *see also, e.g.*, 2A *Sutherland Statutory Construction* § 47:16 (7th ed. 2018) (*noscitur a sociis* "clarif[ies] the meaning of doubtful words" and "does not apply absent ambiguity"). Helsinn seeks to use *noscitur a sociis* not to resolve ambiguity in the meaning of "on sale," but to *change* the phrase's meaning by imposing a public-disclosure limitation that has no basis in any ordinary understanding of the phrase.

Even if there were ambiguity for *noscitur a sociis* to resolve, that canon reflects the assumption that Congress has listed various items together because they share a "related meaning." *S.D. Warren Co. v. Me. Bd. of Envtl. Prot.*, 547 U.S. 370, 378 (2006). That assumption is unwarranted here.

First, Congress did not adopt the various Section 102(a) bars all at once. The other bars had already acquired their own settled independent meanings long before the AIA. Insofar as words are known by the company they keep, the phrase "otherwise available to the public" was late to the party—too late to upset the other terms' meanings.

Second, not every statutory list toes a single line, and *noscitur a sociis* therefore is "not an invariable rule." *Russell Motor Car Co. v. United State*s, 261 U.S. 514, 519 (1923). One word in a list "may have a character of its own not to be submerged by its association." *Id.* For example, this Court has refused to apply the canon where a statute provides a "disjunctive" list of items that are "each quite distinct from the other no matter how construed." *Graham Cty.*, 559 U.S. at 288. That is the situation here.

As Judge Hand recognized, the on-sale bar restricts "competitive exploitation" of an invention for "quite different reasons" than do the elements of Section 102 that consider a prior "contribution … to the art." *Metallizing*, 153 F.2d at 520. The former "confin[es] the duration of the monopoly to the statutory term"; the latter "exclud[es] ideas that are in the public domain from patent protection." *Pfaff*, 525 U.S. at 64. Accordingly, Section 102 has long included several bars that either expressly or inherently turn on what is "public," and one—the on-sale bar—that decidedly does not. The Court should not "'rob' any one of [the statutory bars] 'of its independent and ordinary significance.'" *Graham Cty.*, 559 U.S. at 288 (citation omitted).

4. For similar reasons, Helsinn's reliance on *Federal Maritime Commission v. Seatrain Lines, Inc.*, 411 U.S. 726 (1973), and *Paroline* is misplaced. In both cases Congress created the entire list at once, so it made more sense to read the items on the list consistently with the catchall provision that followed. That makes little sense here, where the items in the

list were added at different times and have taken on settled, independent meanings. It would dramatically weaken Congress's ability to add a new catchall category to close a statutory gap if such an addition *necessarily* upset the meaning of preexisting terms by reverberating back up the list.

As noted above, moreover, unlike the lists in *Seatrain* and *Paroline*, the catchall provision in Section 102(a) does not "appl[y] as much to the first and other words as to the last." *Paroline*, 572 U.S. at 447 (citation omitted). In *Paroline*, the statute listed five specific "categories of covered losses"—for example, "certain medical services" and "physical and occupational therapy"—and a sixth catchall category for "any other losses suffered by the victim as a proximate result of the offense." 572 U.S. at 446. Because none of the specific categories included a proximate-cause requirement, it made more sense to read the catchall category to impose that requirement on the list.

Likewise, in *Seatrain*, the statute listed six specific types of "agreements" between competitors—for example, agreements "fixing or regulating transportation rates or fares"—and a catchall category covering agreements "in any manner providing for an exclusive, preferential, or cooperative working arrangement." 411 U.S. at 732. Because all six categories could be read as limited to agreements forming "working arrangement[s]," it made more sense to read the catchall as "summariz[ing] the types of agreements covered," and excluding "one time, discrete transactions" from the statute. *Id.* at 734 (citation omitted). Here, by contrast, applying the catchall to every item in the list would create hopeless redundancies—such as "in public use … available to the public."

Aware of this difficulty, Helsinn says prior cases created "ambiguity about the scope of the public-use bar" by treating as public "some uses that did not disclose the claimed inventions to the public," and "the AIA eliminated that ambiguity." Br. 43. As an initial matter, the "otherwise available to the public" language cannot have been drafted to clarify "public use" (or "on sale"), because it was added to a draft of the statute at a time when it included neither "public use" nor "on sale." *See* p. 10, *supra*. And even if Congress thought the meaning of "public use" was unclear, using the catchall to fix it would create a different problem—the catchall would modify different preexisting categories differently. *See Paroline*, 572 U.S. at 447 (a clause is not a series-modifier where not "applicable as much to the first and other words [in the preceding series] as to the last" (citation omitted)); *cf. Lockhart*, 136 S. Ct. at 963 (a clause is not a series-modifier where "it takes more than a little mental energy to process the individual entries in the list, making it a heavy lift to carry the modifier across them all").

Making matters worse, Helsinn's interpretation would in substance read several categories out of the statute, in violation of the "cardinal principle" that "courts must give effect, if possible, to every clause and word of a statute." *Loughrin v. United States*, 134 S. Ct. 2384, 2390 (2014) (citation and internal quotation mark omitted). Under Helsinn's theory, a litigant seeking to prove that a particular invention was "in public use, on sale, or otherwise available to the public" could seek to prove: (1) that the matter is *both* “available to the public” *and* in “public use”; (2) that the matter is *both* “available to the public” *and* “on sale” (which includes proving the often-contentious “ready for patenting” element); or (3) *only* that the matter is “available to the public.” There would be no reason for litigants ever to accept the burden of proving “public availability” *and* something else—they could prevail by proving public availability alone. Interpreting the catchall category as filling a statutory gap rather than informing the meaning of the other listed bars avoids this problem.

D. Congress’s treatment of “public” disclosures in the AIA confirms that it did not upset the meaning of “on sale.”

Section 102(a)’s “place in the overall statutory scheme” confirms that Congress did not indirectly revise the scope of the on-sale bar. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citation omitted). In very next subsection, 35 U.S.C. § 102(b), Congress provided a grace period for “[a] disclosure made 1 year or less before the effective filing date of a claimed invention,” if one of two conditions is satisfied:

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

35 U.S.C. § 102(b)(1) (emphasis added).

A "disclosure" in Section 102(b) is one of the items referred to in Section 102(a), including a patent, printed publication, or sale. And according to Helsinn, every one of those "disclosures" is necessarily public. But Section 102(b)(1)(B) distinguishes between "disclosure[s]" generally and "public[] disclos[ures]." Helsinn's interpretation thus reads "publicly" out of the statute, again violating the "cardinal principle" that "courts must give effect, if possible, to every clause and word." *Loughrin*, 134 S. Ct. at 2390 (citation and internal quotation mark omitted). Under this Court's longstanding interpretation of the on-sale bar, by contrast, there is no surplusage: some non-public disclosures would fall within Section 102(a) and (b)(1)(A), but only public disclosures would fall within Section 102(b)(1)(B).

This view of the interplay between Sections 102(a) and (b) is also consistent with their drafting history. The Smith amendment that would have stricken the on-sale and public-use bars also would have inserted "to the public" after "disclosure" in the first sentence of Section 102(b)(1), making all Section 102(b) disclosures public and eliminating any surplusage. P. 12, *supra*. But the Lofgren amendment struck both aspects of the Smith amendment (*Markup* 101-102)—confirming that some Section 102(a) disclosures are *not* public.

The government ignores Section 102(b) entirely. Helsinn, by contrast, declares that Section 102(b)(1)(B) refers to "an earlier disclosure of the 'subject matter' that is ultimately included in a later Section 102(a)(1)-qualifying disclosure," and that the "word 'publicly' … ma[kes] clear that the earlier disclosure of the subject matter, like the later disclosure, must be public." Br. 45. Helsinn is correct that Section 102(b)(1)(B) envisions two disclosures, one earlier than the other. But Helsinn cannot explain why Congress needed to clarify that the earlier disclosure must be "public" if *all* Section 102(a) disclosures are *necessarily* public. Put differently, if "disclosure" necessarily implies "public disclosure," as Helsinn insists, then Congress had no need to say "publicly disclosed" in Section 102(b)(1)(B). But Congress did so, further confirming that Congress meant to preserve the on-sale bar's settled meaning.

E. The statute's drafting history shows that Congress intended to preserve the on-sale bar's established meaning.

After ignoring the plain, historically established meaning of "on sale" and doing what it can with the catchall added in 2011, Helsinn turns to the legislative history—especially a series of floor statements by Senator Kyl. Insofar as the Court finds legislative history illuminating, the full history disproves Helsinn's reading. Helsinn's sources are a *post hoc* concoction of statements made after the speaker had failed to change the text.

During the AIA's multi-year drafting process, numerous bills and amendments were introduced, most by Senator Kyl and Representative Smith, that would have done what Helsinn urges here: repeal the on-sale bar in favor of a general public-disclosure standard. Congress rejected that approach and enacted the language at issue here.

Tellingly, Senator Kyl repeatedly *criticized* the language ultimately adopted for *preserving* the existing understanding of the on-sale bar. Only after losing his fight to repeal the on-sale bar did he attempt to accomplish through the *Congressional Record* what he failed to accomplish in the AIA itself. This Court has repeatedly rejected such "strategic manipulations of legislative history to secure results [Members] were unable to achieve through the statutory text." *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568 (2005).

1. The AIA's drafting history shows Congress's understanding that a bill that included the on-sale bar would preserve its well-established meaning. As discussed above (pp. 9-12, *supra*), the relevant provision evolved as follows:

2005/ 2006	"(1) the claimed invention was patented, described in a printed publication, *or otherwise publicly known*" (H.R. 2795, 109th Cong. (2005); S. 3818, 109th Cong. (2006))
2007	"(1) the claimed invention was patented, described in a printed publication, or in public use, or <u>on sale</u>" (H.R. 1908, 110th Cong. (2007); S. 1145, 110th Cong. (2007))
2008/ 2009	"(1) the claimed invention was patented, described in a printed publication, or in public use, <u>on sale</u>, *or otherwise available to the public*" (S. 1145, 110th Cong. (2008); S. 515, 111th Cong. (2009))
2008/ 2009	"(1) the claimed invention was patented, described in a printed publication, *or otherwise made available to the public (other than through testing undertaken to reduce the invention to practice)*" (S. 3600, 110th Cong. (2008); S. 610, 111th Cong. (2009))

	(Sen. Kyl)
2011 (AIA)	"(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" (H.R. 1249, 112th Cong. (2011))

In several important ways, this drafting history confirms that the new catchall category of prior art was not intended to modify the on-sale bar. First, it shows that the new category could not have been written to modify (or "inform") the on-sale bar, because it was first proposed in 2005 and 2006 bills that *did not even include the on-sale bar*. The 2007 House bill, by contrast, included the on-sale bar but no catchall provision, and thus was unquestionably written to preserve the bar's settled meaning. Indeed, the House Judiciary Committee recognized that the phrase "on sale" has "been interpreted by the courts," and (thus interpreted) retained the vital policy role of "preventing inventors from extending their monopoly" even in a "first-to-file system." H.R. Rep. No. 110-314, at 57.

In the 2008 Senate bill, the features of the 2005 through 2008 bills were combined to form a bill that *both* added the new catchall provision *and* retained the on-sale bar. The 2008 bill thus captured the key features of both prior bills: the catchall prior-art category that did not modify the on-sale bar, and the pre-existing on-sale bar.

Second, the fixed meaning of "on sale" is confirmed by competing bills in 2008 and 2009 that alternately did, or did not, replace the on-sale bar with a general public-availability standard. If the claimed invention is only "on sale" under the AIA if the invention is "available to the public," then there would be no difference between:

> (1) barring a patent if the claimed invention were "patented, described in a printed publication, or in public use, <u>on sale</u>, or otherwise available to the public" (S. 1145, 110th Cong. § 2(b)(1) (2008)), and
>
> (2) barring a patent if the invention is "patented, described in a printed publication, or otherwise made available to the public" (S. 3600, 110th Cong. § 2(b)(1) (2008)).

The disagreement concerning which formulation to use confirms that they are different.

Third, contemporaneous statements of Senators and Representatives confirm that even those who opposed retaining the "on sale" language understood that keeping it meant keeping its existing meaning. Senator Kyl objected to the language that ultimately became the AIA because it retains "patent-forfeiture provisions that apply only to non-public prior art." S. Rep. No. 111-18, at 60. Thus, he proposed two different bills that *removed* the on-sale and public-use bars. S. 3600, 110th Cong. § 2(b)(1); S. 610, 111th Cong. § 2(b)(1).

According to Senator Kyl, these bills sought to "*significant*[*ly*] *change*" the language ultimately adopted by "eliminating confidential sales and other secret activities as grounds for invalidity and imposing a general standard of public availability." 154 Cong. Rec. 22,631 (statement of Sen. Kyl). Similarly, in the House Judiciary Committee, Representative Lofgren successfully opposed an attempt to strike the on-sale and public-use bars because a "range of stakeholders" had "strenuous[ly]" objected to "the deletion of *specific categories of prior art with well established meanings in case law*." *Markup* 102 (emphasis added).

Thus, throughout the AIA's drafting process, there was strenuous debate about *whether* to retain the pre-existing meaning of the on-sale bar, but general *agreement* that, if the on-sale bar remained, it retained that pre-existing meaning.

2. Helsinn ignores this drafting history, citing Senator Kyl's lengthy floor statement made shortly before the AIA passed. Br. 27-28. But "[t]his is a good example of why floor statements by individual legislators rank among the least illuminating forms of legislative history." *SW Gen.*, 137 S. Ct. at 943.

Throughout the drafting process, Senator Kyl repeatedly urged Congress *not* to adopt the language that became the AIA because it *preserved* the existing meaning of the on-sale and public-use bars. Having failed, he abruptly changed course, arguing that the language to which he had repeatedly objected actually *abandoned* the settled meaning of the on-sale bar and—*voilà*—created his preferred "uniform test" of public availability. 157 Cong. Rec. 3,423-24 (2011). In short, Senator Kyl's floor statement does not even reflect *his own* reading of the statute.

Helsinn dismisses the failure of bills that would have enacted Senator Kyl's position by characterizing that position (at 30) as going to "*which* sales trigger the AIA's on-sale bar," not whether "[t]he AIA eliminated the on-sale bar." But Helsinn's interpretation would achieve the same result.

Under Helsinn's view, the AIA makes proof that an invention was "on sale" under the pre-AIA standard *both* unnecessary *and* insufficient. If a given transaction makes the invention "available to the public," then it is disqualifying prior art *regardless* of whether it satisfies the pre-AIA standard for a commercial sale. And if a given transaction does *not* make the invention "available to the public," then it is *not* disqualifying prior art, even if it *does* meet the pre-AIA standard for a commercial sale. In other words, Helsinn's position would "eliminat[e] confidential sales and other secret activities as grounds for invalidity and impos[e] a general standard of public availability"—precisely what Senator Kyl repeatedly proposed and called a "significant change[]" from the language Congress adopted. 154 Cong. Rec. 22,631.[7]

3. Helsinn's isolated statements from committee reports (at 26) cannot overcome the general recognition that the on-sale bar, if retained, would keep its existing meaning. Helsinn's primary statement says only that "secret *collaborative agreements*" are not prior art. S. Rep. No. 110-259, at 39 (2008) (emphasis added). But a "collaborative agreement" is not a

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[7] Helsinn also relies (at 28-29) on statements from Representative Smith and Senator Leahy, made around the time of the AIA's enactment. Representative Smith, like Senator Kyl, had repeatedly tried to replace the on-sale bar with a general public-availability standard. *See* pp. 10-12, *supra*. And Senator Leahy's single floor statement involved the relationship between Section 102(a) and (b). 157 Cong. Rec. 3,415-16 (2011) (statement of Sen. Leahy).

sale (and vice versa); it refers to joint upstream efforts to develop products, not joint downstream efforts to commercialize them.

Helsinn also cites the statement that the "available to the public" language was added "to clarify the broad scope of *relevant* prior art, as well as to emphasize the fact that it must be publicly available." S. Rep. No. 110-259, at 9 (emphasis added); *see also* H.R. Rep. No. 112-98, Pt. 1, at 43 (2011). But this statement does not mention the on-sale bar, and its limitation to *relevant* prior art confirms that a sale need not make every claim limitation public to trigger the bar. Regardless, that statement cannot overcome Congress's consideration and rejection of bills replacing the on-sale bar with a general public-availability inquiry, and its decision to *preserve* the on-sale bar in the statute based on "strenuous" objection to "the deletion of *specific categories of prior art with well established meanings in case law*." *Markup* 102 (statement of Rep. Lofgren) (emphasis added). In sum, "Congress several times considered, but rejected, the very changes to the on-sale bar Helsinn urges … were actually made." Pet. App. 12a (O'Malley, J., concurring).

F. Helsinn's position would allow patentees to commercialize their inventions for years, and perhaps indefinitely, before seeking patent protection.

The Patent Act has always barred inventors from extending their patent monopoly by commercializing inventions before seeking to patent them. Pp. 5-8, *supra*. As this Court explained in *Pfaff*: "It is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly." 525 U.S. at 68 (quoting *Metallizing*, 153 F.2d at 520).

Helsinn does not dispute that reversal would up-end that purpose, allowing inventors to exploit inventions commercially for years before seeking patents. Helsinn simply says the on-sale bar's longstanding purpose is irrelevant in a first-to-file system. Not so. *Pennock* itself was decided under a first-to-file regime. *See* Patent Act of 1793, ch. 11, § 1, 1 Stat. 318 (1793) (tying validity to what was "known or used" as of the patent application's filing date).[8] But as Justice Story explained for that unanimous Court, if an inventor could "hold back from the knowledge of the public the secrets of his invention" even while selling it "publicly," and later "take out a patent," that would "give a premium to those … least prompt to communicate their discoveries." 27 U.S. at 19.

1. Allowing inventors to seek patents after selling their inventions, whenever those sales do not disclose *every* element, would allow for rampant pre-patenting commercialization—precisely what the on-sale bar has always prevented.

a. Most obviously, Helsinn's interpretation would allow pre-patent commercialization of inventions via nondisclosure agreements—as Helsinn did here. According to Helsinn, inventors can sell their inven-

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[8] The 1793 Act imposed *both* first-to-file *and* first-to-invent requirements. *See id.* § 3. Though the AIA is a pure first-to-file regime, any first-to-file requirement would, on Helsinn's view, incentivize inventors to file quickly to avoid losing the patent.

tions without triggering the on-sale bar, reaping millions, provided the buyers agree not to disclose every limitation of the claimed inventions or sell an embodiment of the invention without a confidentiality agreement.

Although Helsinn sold its invention to just one distributor, nothing would prevent inventors from selling to dozens of distributors who signed confidentiality agreements, or from making *further* sales protected by nondisclosure agreements. Even an invention's ultimate consumers could be required to sign nondisclosure agreements—*e.g.*, in click-wrap licenses for computer software—allowing them, too, to buy inventions in mass-market quantities without triggering the on-sale bar.

b. The problem of pre-patenting commercialization would be particularly acute for patents on methods of manufacturing or performing a service. Patents have never been awarded after sales of products produced using the would-be patented method. For example, the patent in *Pennock* covered an improvement "in the art of *making* leather tubes or hose." 27 U.S. at 14 (emphasis added). In invalidating the patent, the Court stated that, when selling the resulting product, an inventor may not "hold back from the knowledge of the public the secrets of his invention." 27 U.S. at 19; *see Metallizing*, 153 F.2d at 518 (*Pennock* gave no indication that selling the hose "in any way disclosed the process").

In *Metallizing*, Judge Hand cited *Pennock* in holding that selling products made using patented methods triggers the on-sale bar "regardless of how little the public may have learned about the invention." 153 F.2d at 520. As he put it—in reasoning *twice* endorsed by this Court—the on-sale bar prevents a patentee from "exploit[ing] his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly." *Id.*; *see Pfaff*, 525 U.S. at 68; *Bonito Boats*, 489 U.S. at 149. A contrary holding would allow inventors to "extend the period of his monopoly" by taking advantage of both "a practical monopoly by means of secrecy" and "a later legal monopoly by means of a patent." *Metallizing*, 153 F.2d at 519-20.

The Federal Circuit has consistently followed *Metallizing*, applying the on-sale bar to sales derived from patented methods whether or not those sales disclose the method, because the sales *commercialize the patented process* in the same way that sales of a patented machine would. *E.g.*, *In re Kollar*, 286 F.3d 1326, 1333 (Fed. Cir. 2002).[9] Helsinn's interpretation would reverse this longstanding precedent—legitimizing delayed patents on both methods of manufacturing physical items and methods for providing technical services, like cloud computing, that can be sold without disclosing how the service works. Inventors could protect such methods as trade secrets for years, perhaps decades, making millions, before ultimately claiming patent monopolies.

c. Helsinn's interpretation would also effectively overturn the longstanding rule that "commercial offers for sale" trigger the on-sale bar. *Pfaff*, 525 U.S. at 67; *see Meds. Co.*, 827 F.3d at 1376-77. An *offer* itself will virtually never make an invention "availa-

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[9] *Accord, e.g.*, *Plumtree Software, Inc. v. Datamize, LLC*, 473 F.3d 1152, 1162-63 (Fed. Cir. 2006); *Scaltech*, 269 F.3d at 1328; *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147-48 (Fed. Cir. 1983).

ble to the public." Often, an offer would not even disclose every element *to the potential buyer*. And even if disclosure to the potential buyer (1) were necessary and (2) made the invention "available to the public," the inventor could easily require the buyer to sign a nondisclosure agreement.

2. Helsinn disputes none of this. Instead, it says (at 32) the concerns motivating the on-sale bar simply disappear in a first-to-file system, as inventors will now apply for patents as soon as their inventions are patent-ready. But Helsinn's claim rests on the unrealistic assumption that inventors will always be so concerned about competing patent applications that they will never pursue the extended monopoly—and the associated profit—that the on-sale bar exists to combat.

If an invention is difficult to reverse-engineer, there is no reason to think its inventor will forgo the chance to multiply her earnings by extending her monopoly beyond the patent term. *See* pp. 47-48, *supra*. Many inventions are "easily concealable"; and inventors of such inventions "could keep their process inventions secret for years or even decades and then surface and file a patent application"—"encourag[ing] delay in patenting." Lemley, *Does "Public Use" Mean the Same Thing It Did Last Year?*, 93 Tex. L. Rev. 1119, 1132 (2015). Moreover, such delay "could take an existing industry by surprise because others who developed but did not patent the technology would not be able to use their own secret use as prior art to defeat the patent." *Id*. Indeed, the on-sale bar *only* affects patent applicants who engage in delay, because irrespective of the timing of any sales, the one-year clock does not start until the invention is ready for patenting. *Pfaff*, 525 U.S. at 67.

As the House Judiciary Committee recognized, the bar serves "very specific policy goals"—including "encouraging inventors to file early for patent protection" and "preventing inventors from extending their monopoly"—and "there is nothing inherent in a first-to-file system that will deter inventors from making use of their inventions as trade secrets and then some time later filing a patent application." H.R. Rep. No. 110-314, at 57. That was also the view of the Court in *Pennock*, which was decided under a first-to-file regime. P. 46, *supra*. By Helsinn's logic, the Court was wrong.

G. The on-sale bar's settled interpretation is consistent with the policies served by other provisions of the AIA.

Contrary to Helsinn and its *amici*, the on-sale bar's longstanding interpretation is fully consistent with the AIA's other provisions.

1. Noting that Congress repealed the on-sale bar's limitation to sales occurring "in this country" (35 U.S.C. § 102(b) (2006)),[10] Helsinn says this change went "hand in hand" with Congress's "clarification that an invalidating sale must make the claimed invention available to the public." Br. 34. But there is nothing inconsistent between extending the on-sale bar to international sales and otherwise leaving its scope intact. As the House Judiciary Committee explained, the geographic limitation was unnecessary "[g]iven advances in communications technology and

[10] This change similarly affected the public-use bar.

transportation" that provide knowledge "about activities in a foreign land." H.R. Rep. No. 110-314, at 57. That logic applies equally to public and non-public sales. After all, "[a]n inventor can both understand and control the timing of the first commercial marketing." *Pfaff*, 525 U.S. at 67.

2. Citing the AIA's creation of a post-grant-review process—a new avenue for challenging patents after issuance—Helsinn says on-sale bar challenges require "onerous discovery" not suited for such proceedings. Br. 35. But challengers who institute post-grant review based on a sale must have the grounds in hand, *without discovery*, when they file their petitions—typically, within nine months after the patent issues—or the PTAB will not institute review. *See* 35 U.S.C. §§ 321(c), 322(a)(3). The related *inter partes* reviews are not time-limited—but are barred from considering on-sale arguments. *See id.* § 311(b). Moreover, the AIA's purpose was far broader than streamlining post-grant proceedings, and "[i]t frustrates … legislative intent simplistically to assume that *whatever* furthers" one of "the statute's … objective[s] must be the law." *Norfolk S. Ry. Co. v. Sorrell*, 549 U.S. 158, 171 (2007) (citation omitted).

3. Helsinn's reliance on the law of other countries without an on-sale bar is likewise unpersuasive. True, some countries "require a claimed invention to be available to the public in order to qualify as prior art." Helsinn Br. 33. But the fact that the AIA aligned U.S. patent law with international law in *some* respects does not mean that it did so in *all* respects. The traditional scope of the on-sale bar is fully consistent with a first-to-file system, *see* pp. 49-50, *supra*, and Congress may have wished to move *to-*

ward the international consensus without going all the way. For example, Congress considered removing the on-sale bar in favor of a public prior-art requirement, which would have more substantially aligned the U.S. and foreign patent systems, but ultimately retained the on-sale bar without change. *See* pp. 10-11, *supra*.

4. Finally, several of Helsinn's *amici*—but notably not Helsinn—point to the removal of the phrase "loss of right to patent" from the title of Section 102, so that the title now reads, "Conditions for Patentability; Novelty." Representative Smith, for example, argues that, "[b]y jettisoning the 'loss of right to patent' from new § 102," Congress confined that provision "solely to the question of *novelty* in light of the *prior art*," and not the question of pre-patent commercialization. Smith Amicus Br. 8.

"The title of a statute," however, "cannot limit the plain meaning of the text." *Pa. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 212 (1998) (citation and brackets omitted). The title remained constant through the drafting process even as the substance changed. *E.g.*, H.R. 1908, 110th Cong. § 3(b)(1) (2007) (version lacking the "otherwise" phrase). And despite Representative Smith's best efforts, Congress did not "repeal" the on-sale bar. Smith Amicus Br. 8. Moreover, this Court has not grounded the commercial-exploitation principle in concepts of forfeiture and loss-of-right. The Court first articulated the principle in *Pennock*, which predates the on-sale bar and "loss of right to patent" language. P. 6, *supra*. *See also Consolidated Fruit-Jar*, 94 U.S. at 92, 94-96 (treating an on-sale bar challenge as separate from an "abandonment to the public" (forfeiture) challenge).

II. Helsinn's sale of the patented pharmaceutical product to its distributor made the invention available to the public.

This Court should affirm even if it were to limit the on-sale bar to offers and sales that make every element later claimed in the patent "available to the public." Because a single commercial sale or offer still suffices, a sale that discloses every element to a member of the interested public—*i.e.*, a likely commercial buyer—makes the invention "available to the public."

Here, Helsinn's sale *did* disclose every element to Helsinn's third-party distributor, MGI, and a distributor like MGI is precisely the member of the public one would expect to purchase a pharmaceutical invention. The government's claim that only sales to "ultimate customers" trigger the on-sale bar is both atextual and unworkable, especially in this context. Indeed, most patients likely have never purchased medication directly from a pharmaceutical company.[11]

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[11] Helsinn does not even attempt to describe a plausible standard for when a sale makes an invention "available to the public," claiming (at 24 n.3) that Teva forfeited this argument. But Teva consistently argued that Helsinn's sale to MGI made the invention available to the public, including at the certiorari stage. *See, e.g.*, Br. in Opp. 16-17; Pet. App. 151a (acknowledging Teva's argument that "MGI is a member of the public"). Helsinn's forfeiture argument rests entirely on the government's amicus brief below, but the government itself does not assert forfei-

A. A sale or offer that discloses the claimed invention to a commercial purchaser makes the invention available to the public.

1. If a sale also had to make the claimed invention "available to the public," then the proper inquiry would be whether a sale or offer discloses the claimed invention to a member of the public one would expect to purchase it. This interpretation gives meaning to both of the key statutory phrases. It retains the focus on commercialization inherent in the phrase "on sale"—*i.e.*, the idea that the invention must have either been sold or offered for sale. *See* pp. 23-24, *supra*. And it requires that any sale or offer disclose the invention to the member of the public one would expect to be the invention's commercial purchaser, hence making the invention "available to the public."

A single commercial sale has always sufficed to trigger the bar, no matter who buys the invention or what the buyer does with it. *See Cons. Fruit-Jar*, 94 U.S. at 94 ("a single instance of sale may … be fatal to the patent," even if the inventor does not know the purchaser or "what was done with" the products sold); pp. 5-8, *supra*.

It follows that a single sale is no less invalidating even if the buyer signs a non-disclosure agreement. *See Meds. Co.*, 827 F.3d at 1376 ("It is well established ... that a single sale or offer to sell is enough to

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ture—it addresses on the merits whether Helsinn's sale to MGI made the invention "available to the public." U.S. Br. 26-32. Under those circumstances, this Court may affirm based on any ground supported by the record.

bar patentability even if kept secret from the trade." (citation and internal quotation marks omitted)). After all, even a purchaser who does *not* sign a non-disclosure agreement might not discuss the invention with anyone else—for instance, to protect her own interest as an exclusive distributor. And if a non-disclosure agreement made a sale "not count," there would be no stopping point: inventors could sell to broad swathes of the public, as long as every buyer agreed to confidentiality. *See* pp. 46-47, *supra*. Notably, the government does not argue that the existence of a non-disclosure agreement, or the number of sales, is relevant to whether an invention is "available to the public."

2. The government's proposed test—that a "sale or offer for sale makes an invention available to the public when a product embodying the invention could be purchased by its expected ultimate customers," U.S. Br. 26—is divorced from the statute's text, and would be impossible to administer.

a. The government's focus on the "*ultimate* customer" has no basis in either "on sale" or "available to the public." A "sale" is simply the transfer of an item or service in exchange for value. *See* p. 23, *supra*. A manufacturer's sale to a distributor or retailer is as much a "sale" as the retailer's sale to the consumer. *E.g.*, *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 883, 885 (2007) (describing how a manufacturer "refused *to sell* to retailers" unless the retailers adhered to a "minimum *resale* price" (emphases added)). Similarly, an invention is "on sale" if it is "available for purchase" by distributors or retailers, pp. 23-24, *supra*, whether those buyers plan to resell it to the "ultimate customer" immediately or to stockpile it for the future.

The government's approach would strip any last shred of meaning from the term "on sale." As described above, pp. 30-31, *supra*, holding that "otherwise available to the public" changes the meaning of "on sale" would reduce the on-sale bar to an example of the type of conduct that makes inventions "available to the public." But the government's approach deprives "on sale" of even *that* limited function. In its view, the invention could be repeatedly and publicly sold, for millions of dollars, without ever placing the invention "on sale"—so long as those sales were to retailers or distributors and not "ultimate customers." The government *admits* (at 26) that, on its reading, Apple can sell millions of iPhones to retailers like Walmart without *ever* placing the iPhone "on sale"; only the retailer can place it on sale. That is true *even if every element of the invention is disclosed* to every purchasing retailer and distributor. That approach simply does not account for Congress's retention of the term "on sale."

Even ignoring "on sale," nothing in the phrase "available to the public" suggests that "ultimate customers" are the only members of the public who count. And the government does not contend that *every* member of the public must have access; its test would appear to include a few carefully controlled sales to individual consumers, perhaps as part of a trial. Yet the government's test would *exclude* multimillion-dollar bulk sales to the largest wholesalers and retailers. There is simply no reason that offering to sell an invention to a handful of "ultimate customers" makes the invention "available to the public" while offering to sell to *every distributor and retailer in the world* does not.

Finally, the government blithely assumes that the ultimate customer will be easy to identify. But as this case illustrates, it will not. Doctors administer Helsinn's injectable pharmaceutical product in hospitals. If not the distributor that buys from Helsinn, is the "ultimate customer" the hospital? The hospital pharmacy? Or the patient?

b. The government justifies its position based on a misplaced concern about unfairly disadvantaging small companies that do not have in-house distribution networks. U.S. Br. 28. But the point is not distribution, but commercialization. The inventor has begun to make money from the product—and shift the risk to someone else—at the first sale, whether to a distributor or a consumer. The primary benefit of selling to a third-party distributor is not avoiding the cost of in-house distribution, but immediately recognizing a profit. Indeed, as the government recognizes (at 31-32), Helsinn sold to MGI largely so that it could use the revenue from the transaction in the final stages of drug development. This benefit is not limited to small companies; even large pharmaceutical companies generally sell to drug distributors, *not* directly to retailers or consumers. *See* HDA Research Found., *HDA Factbook* 3 (87th ed. 2016) (more than 90 percent of pharmaceutical sales are through distributors).

B. Helsinn's sale to its distributor made the invention available to the public.

Under the correct legal framework, Helsinn's sale of its claimed invention to MGI made the invention "available to the public." That sale undisputedly disclosed every limitation of the claimed invention to MGI. And MGI, a pharmaceutical distributor, is not just a member of the public, but *precisely* the type of customer one would expect to buy a pharmaceutical product from a pharmaceutical company—whereas individual patients rarely buy medicines from the manufacturer. Even if the on-sale bar requires that sales make the invention "available to the public," it must include a sale that discloses every limitation of the claimed invention to the member of the public most likely to purchase it.

The government's claim (at 31-32) that the "relationship between petitioner and MGI was not a traditional buyer-seller relationship" is both wrong and irrelevant. The district court and the Federal Circuit concluded that the agreement between Helsinn and MGI *was* a commercial sale, and Helsinn did not seek certiorari on that issue. Pet. i; p. 13, *supra*. The fact that, as the government notes, sales were contingent on FDA approval makes no difference, as it is well established that sales can be contingent on uncertain future events. *See* Pet. App. 30a-31a; UCC § 2-105(2). Indeed, the Patent Act itself recognizes that sometimes an invention will be sold or offered for sale before FDA approval; that is one reason why sales that facilitate drug development fall into a safe harbor from infringement. *See* 35 U.S.C. § 271(e)(1); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

Helsinn could have sought an investor rather than a buyer. Or it could have collaborated with MGI without making a *sale*—for instance, MGI could have funded $11 million in development costs in exchange for a share of future profits. But Helsinn opted to fund its development by *selling* its invention, which was then ready for patenting (Pet. App. 43a-52a), to a distributor. Under any conceivable interpretation of the statute, that sale triggered the one-year grace period to seek a patent. Because Helsinn chose to wait, its patent is invalid.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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October 9, 2018