No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A., PETITIONER

v.

TEVA PHARMACEUTICALS USA, INC., ET AL.

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

BRIEF FOR THE UNITED STATES
AS AMICUS CURIAE SUPPORTING PETITIONER

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QUESTION PRESENTED

Whether an invention is "on sale" within the meaning of 35 U.S.C. 102(a)(1) when the public cannot obtain physical embodiments of the invention, but the invention is the subject of licensing and distribution agreements whose existence was disclosed to the public.

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INTEREST OF THE UNITED STATES

This case presents the question whether petitioner's invention was "on sale" within the meaning of 35 U.S.C. 102(a)(1) at a time when the public could not obtain physical embodiments of the invention, but the invention was the subject of licensing and distribution agreements whose existence had been disclosed to the public. The United States Patent and Trademark Office (USPTO) is responsible for examining all patent applications and for granting and issuing patents when the applicants satisfy the statutory conditions for patentability. 35 U.S.C. 2(a)(1), 131. Several other agencies of the federal government also have strong regulatory interests in the efficacy of the patent system. The United States therefore has a substantial interest in the Court's resolution of the question presented here.

STATEMENT

1. Since 1790, the patent laws have prohibited the issuance of patents for inventions to which the public already has access. See *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 146-149 (1989). Section 102(a)(1) of Title 35 of the United States Code is the current codification of this longstanding principle. Section 102(a)(1) states that "[a] person shall be entitled to a patent unless * * * the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." 35 U.S.C. 102(a)(1). Section 102(b) provides that, under specified circumstances involving disclosures by the inventor, "[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)." 35 U.S.C. 102(b)(1). In cases like this one, the patentability of an invention therefore turns on whether the invention was placed "on sale" more than one year before the effective filing date of the patent application. This version of Section 102 was enacted in 2011 as part of the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284.

Section 102(a)(1) contemplates two conceptually distinct ways in which an unpatented invention may be placed in the public domain so as to bar subsequent patenting. An invention is "described in a printed publication" within the meaning of Section 102(a)(1) if the inventive *idea* is disclosed in a sufficiently public way, and in sufficient detail, to enable a person skilled in the art to make or use it. See *Blue Calypso, LLC* v. *Groupon, Inc.*, 815 F.3d 1331, 1348 (Fed. Cir. 2016) ("To qualify as a printed publication, a reference must have been

sufficiently accessible to the public interested in the art.") (citation and internal quotation marks omitted); *In re Antor Media Corp.*, 689 F.3d 1282, 1288-1290 (Fed. Cir. 2012) (explaining that a printed publication must disclose enough information to enable a person of ordinary skill in the art to make or use the invention). That may occur even if no physical embodiment of the invention has ever been produced, let alone made accessible to the public. The inventive idea likewise will have been disclosed to the public if the invention has been patented, since a compliant patent application must "contain a written description of the invention, and of the manner and process of making and using it," that is sufficient "to enable any person skilled in the art * * * to make and use the" invention. 35 U.S.C. 112(a).

The on-sale bar, by contrast, is typically triggered by the public sale, or offering for sale, of *physical embodiments* of the invention. Such sales or offerings can place an invention in the public domain even if they do not enable a person skilled in the art to make or use it. That may occur if the embodiments are not susceptible to the sort of reverse engineering that would enable an expert to discern how the invention works. For purposes of Section 102(a)(1), a public sale or offering therefore can place the invention in the public domain—*i.e.*, make it "available to the public," 35 U.S.C. 102(a)(1)—even if the inventive *idea* remains secret.

The first United States patent law to include an express on-sale bar was the Patent Act of 1836, ch. 357, 5 Stat. 117, which prohibited the patenting of any invention that was "in public use or on sale, with [the inventor's] consent or allowance," when the patent application was filed. *Id.* § 6, 5 Stat. 119; see *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 65 (1998). Congress preserved

the on-sale bar in the Patent Act of 1952, ch. 950, 66 Stat. 792 (35 U.S.C. 1 *et seq.*), prohibiting the patenting of any invention that "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 before the date of the patent application. 35 U.S.C. 102(b) (1952). The AIA moved this provision to Section 102(a)(1) and revised some of its text. See 35 U.S.C. 102(a)(1).

2. a. This case involves a dispute over the validity of a patent covering a 0.25 mg dose of palonosetron in a 5 ml solution, an intravenous formulation directed to reducing the likelihood of chemotherapy-induced nausea and vomiting.[1] Pet. App. 19a-20a, 25a, 60a. On January 30, 2003, petitioner filed a provisional patent application covering the 0.25 mg dose, and the Food and Drug Administration (FDA) approved the 0.25 mg dose in July 2003. *Id.* at 25a. In 2013, petitioner applied for and obtained the patent at issue here, which also covers the 0.25 mg dose. *Id.* at 25a, 142a. The parties agree that this patent is subject to the AIA for purposes of this case. See *id.* at 61a. The parties further agree that the application of Section 102(a)(1) to this case turns on whether the 0.25 mg dose was "on sale" before January 30, 2002, *i.e.*, one year before petitioner filed its provisional patent application. *Id.* at 20a & n.1; see 35 U.S.C. 102(b).

b. Petitioner is a family-owned and family-run company with headquarters in Switzerland. Pet. App. 77a. During the period relevant here, petitioner's business

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[1] Four patents covering the 0.25 mg dose of palonosetron were initially at issue in this case, Pet. App. 19a-22a, but petitioner did not seek this Court's review of the court of appeals' invalidity determination with respect to three of those patents, Pet. 10 n.2.

model was to acquire rights to drug products in the early or middle stage of development, develop those products, and then license the developed products out for marketing and distribution. *Id.* at 78a-79a, 114a. In 1998, petitioner purchased the rights to palonosetron, including the existing development research, and began work to further develop palonosetron into a pharmaceutical product. *Id.* at 77a. By early 2000, petitioner was developing two palonosetron formulations, the 0.25 mg dose and a 0.75 mg dose. *Id.* at 22a.

In September 2000, petitioner issued a press release announcing that it was moving forward with the next phase of clinical trials involving the use of palonosetron to prevent chemotherapy-induced nausea and vomiting. J.A. 50. The press release stated that, "[u]pon market approval, Helsinn will be in a position to supply its marketing partners with a finished product ready for distribution." Pet. App. 108a n.26 (citation omitted). Petitioner's goal in licensing out a palonosetron product was to minimize financial risk for the palonosetron project, which had proved much costlier than petitioner had anticipated, and to plan for the future marketing and distribution of the product in the United States if the FDA approved it. *Id.* at 114a. After "conduct[ing] a lengthy and arduous search for a willing 'commercial partner' for the U.S. market," *id.* at 115a (citation omitted), petitioner entered into a supply-and-purchase agreement and a license agreement with MGI Pharma, Inc. (MGI), an oncology-focused pharmaceutical company. *Id.* at 22a-23a, 115a.

The supply-and-purchase agreement "set the stage" for MGI's "future purchase" from petitioner of the two palonosetron doses that petitioner was then testing. Pet. App. 116a. The agreement provided that, if the

FDA approved either dose, petitioner would sell MGI that palonosetron product. *Id.* at 29a. MGI agreed to purchase exclusively from petitioner, and petitioner agreed to supply, MGI's requirements of "Products," which the supply-and-purchase agreement defined as the pharmaceutical preparations of the palonosetron formulation that "will be described in" an official regulatory approval to market the drugs. *Id.* at 119a (citation omitted); JA. 218; see Pet. App. 23a. The supply-and-purchase agreement also described the purchase process that petitioner and MGI would implement if one of the doses received FDA approval. Pet. App. 23a-24a, 118a. The agreement further provided that, if the FDA did not approve either dose, the supply-and-purchase agreement would terminate automatically. *Id.* at 24a.

The supply-and-purchase agreement was subject to the license agreement. Pet. App. 115a-116a. That agreement gave MGI a license to distribute, promote, market, and sell "Products," which the agreement again defined as the pharmaceutical preparations of the palonosetron formulation that "will be described in" an official regulatory approval to market the drugs.[2] *Id.* at 119a (citation omitted); J.A. 59, 214. In return, MGI agreed to make $11 million in upfront payments to petitioner and to pay additional future royalties on any distributions of the palonosetron products in the United States. Pet. App. 23a.

According to one of petitioner's negotiators, "it was quite clear" to MGI that "this was a developmental . . . . product," which meant that MGI "w[as] not buying a product." Pet. App. 116a (citation omitted). Rather,

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[2] During the proceedings below, the parties agreed that the "products" covered by the license agreement were 0.25 mg and 0.75 mg doses of palonosetron. Pet. App. 23a.

the negotiator testified, MGI was "buying the rights to participate in the development effort to potentially have a product in the future." *Ibid.* (citation omitted).

Consistent with that testimony, the license agreement provided that, as of the date of the agreement, the palonosetron products were "under development" by petitioner in anticipation of a future application for FDA approval. J.A. 69; see Pet. App. 24a. MGI acknowledged in the license agreement that petitioner might interrupt or discontinue its development of the palonosetron products if that development became "commercially unreasonable" or if the results of the clinical trials were unfavorable. *Ibid.* The license agreement also stated that petitioner made "no warranty" that the palonosetron products would obtain FDA approval or "that a Product can be developed and registered." J.A. 69. Petitioner pledged, however, to "use commercially reasonable efforts to complete the development of the Products" and to file a new drug application with the FDA by the end of 2002, provided that the development was satisfactory and that no unforeseen events or additional FDA requests occurred. J.A. 69-70. The license agreement also allowed petitioner to terminate the agreement if the clinical-trial results were unfavorable and the FDA did not approve the sale of either dosage of the product. Pet. App. 24a.

Several provisions of the license agreement contemplated that the parties would work together on the future development, regulation, and patenting of palonosetron products. See J.A. 62-63, 70-72, 74, 105. Petitioner and MGI agreed that, if clinical trials produced unfavorable results, if the FDA denied approval, or if the products' development was interrupted or discontinued, the parties would "meet to discuss and seek an

agreement" on additional development efforts that the parties deemed appropriate, "including the direct performance and funding by MGI of the further development activities deemed necessary for the registration of the Products." J.A. 70.

The parties further agreed that, if the FDA approved one of the palonosetron doses, MGI would serve as petitioner's agent with respect to the new drug application and would manage and carry out all FDA communications and relations on petitioner's behalf, in close coordination with petitioner. J.A. 71-72. MGI further agreed to collaborate with and assist petitioner in obtaining regulatory approvals outside the United States, with petitioner reimbursing MGI for the expenses it incurred in providing such support. J.A. 74. And the parties agreed that MGI would cooperate with petitioner "for the purpose of filing for and obtaining patent extensions and supplementary or complementary protection certificates" of the existing palonosetron patents. J.A. 105.

Both the license agreement and the supply-and-purchase agreement included appendices that described in detail the palonosetron formulations that petitioner had submitted to the FDA. Pet. App. 33a, 119a-120a. Each agreement contained a confidentiality provision that required MGI to "treat as strictly confidential" any information, data, or documents it received under the agreements that were "not generally known to the trade." *Id.* at 120a.

Petitioner and MGI announced the agreements in a joint press release, and MGI reported the agreements in a Securities and Exchange Commission (SEC) filing that included partially redacted copies of both agree-

ments. Pet. App. 23a. The specific formulations covered by the agreements—*i.e.*, the 0.25 mg and 0.75 mg doses—were not publicly disclosed. *Id.* at 24a, 121a. Meanwhile, MGI's initial payments to petitioner helped fund the ongoing clinical trials of the palonosetron doses. *Id.* at 116a.

3. Respondents sought FDA approval to market a generic 0.25 mg palonosetron product, and petitioners sued respondents for infringing the patent at issue here. Pet. App. 26a. In their defense, respondents asserted that the patent was invalid under Section 102(a)(1) because petitioner's agreements with MGI had placed the 0.25 mg dose "on sale" in April 2001. *Id.* at 55a, 151a; see *id.* at 115a. After a bench trial, the district court held that respondents had not proved that the patent was invalid under Section 102(a)(1). *Id.* at 230a.

The district court held that Section 102(a)(1) "requires a public sale or offer for sale of the claimed invention." Pet. App. 164a. The court found that petitioner's agreements with MGI did not meet that standard because "the sale or offer o[f] sale did not make [the] claimed invention available to the public." *Id.* at 180a. The court rejected respondents' contention that the joint press release and SEC filing, which disclosed to the public the existence of the agreements between petitioner and MGI, had placed the invention "on sale" in April 2001. *Ibid.*; see *id.* at 23a, 120a-121a. The court explained that "the post-AIA on-sale bar inquiry is not focused on the public disclosure of the sale or offer for sale; rather, the 'sale' prong of the on-sale bar requires that the sale make the claimed invention available to the public." *Id.* at 180a. Here, the court concluded, respondents had failed to show how the press release or

SEC filing made petitioner's "*claimed invention*, i.e., its palonosetron formulation, available to the public." *Ibid.*

4. The court of appeals reversed, holding that the patent was invalid under Section 102(a)(1). Pet. App. 17a-52a. The court found that "an agreement contracting for the sale of the claimed invention contingent on regulatory approval is still a commercial sale as the commercial community would understand that term." *Id.* at 30a. The court stated that, under the Federal Circuit's precedents, "an invention is made available to the public when there is a commercial offer or contract to sell a product embodying the invention and that sale is made public," even if "the details of the invention" are not "disclosed in the terms of sale." *Id.* at 40a.

The court of appeals stated that "[a] primary rationale of the on-sale bar is that publicly offering a product for sale that embodies the claimed invention places it in the public domain, regardless of when or whether actual delivery occurs." Pet. App. 40a-41a. The court explained that prior Federal Circuit decisions had "applied the on-sale bar even when there is no delivery, when delivery is set after the critical date, or, even when, upon delivery, members of the public could not ascertain the claimed invention." *Id.* at 42a. The court considered the AIA's legislative history and found "no indication in the floor statements" by individual members of Congress that those members intended to overrule those earlier Federal Circuit rulings. *Ibid.*; see *id.* at 36a-38a. The court therefore concluded that, "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale" in order for Section 102(a)(1) to apply. *Id.* at 43a. The court of appeals found the on-sale bar to be

applicable here because the supply-and-purchase agreement between petitioner and MGI, which was consummated and publicly announced more than one year before petitioner submitted its provisional patent application, "constituted a sale of the claimed invention—the 0.25 mg dose." *Ibid.*; see *id.* at 20a, 24a.

5. a. The court of appeals denied rehearing and rehearing en banc. Pet. App. 1a-2a. Judge O'Malley concurred in the denial of panel rehearing and wrote separately to respond to points raised in petitioner's rehearing petition and in various amicus briefs. *Id.* at 3a-16a. Judge O'Malley described the panel decision as holding only "that the *particular* agreement at issue triggered the on-sale bar, in part—but not exclusively—because it was made public." *Id.* at 5a. She stated that "an offer for sale between a supplier and distributor can trigger the on-sale bar even though the transaction is several steps removed from the consuming public actually acquiring the invention." *Id.* at 15a-16a.

b. Petitioner filed a motion to stay the mandate, which the court of appeals denied in a per curiam order by the panel. Br. in Opp. App. 1-2. The order stated that, "[f]or the reasons set forth in the majority opinion, and in Judge O'Malley's concurrence to the denial of rehearing, the decision is a narrow one." *Id.* at 2.

SUMMARY OF ARGUMENT

I. Under 35 U.S.C. 102(a)(1), a sale or offer to sell must make an invention "available to the public" in order to trigger the on-sale bar.

A. The term "on sale" typically refers to a product that is sold or offered for sale to the public. Within Section 102(a)(1), the three terms that precede "on sale"—"patented," "described in a printed publication," and "in public use"—reinforce that understanding. All three

terms refer to situations in which either the inventive idea or physical embodiments of an invention are placed in the public domain. The phrase "otherwise available to the public," which was added in 2011 as part of the AIA, confirms that an invention is placed "on sale" only when it is made available for purchase by the public. 35 U.S.C. 102(a)(1).

B. Treating the on-sale bar as limited to sales and offers that make an invention "available to the public" is consistent with the balance that the patent laws have traditionally struck. The Court has repeatedly described the on-sale bar as applying to inventions that have been placed on "public sale" or in "public commerce." So understood, the bar has served to prevent use of the patent system to withdraw from public access inventions that had previously entered the public domain. Before the AIA was enacted, the on-sale bar also was sometimes viewed as an incentive to the prompt filing of patent applications. The AIA provided an alternative means to the same end, however, by amending United States patent law so that priority disputes are now resolved in favor of the first inventor to file a patent application.

C. The AIA's legislative history supports the conclusion that a sale or offer for sale triggers Section 102(a)(1)'s on-sale bar only if it makes the invention "available to the public." Both committee reports and floor statements made that point explicitly.

II. The agreements between petitioner and MGI did not make petitioner's invention "available to the public" and therefore did not trigger Section 102(a)(1)'s on-sale bar.

A. The Court should reject respondents' suggestion that, because petitioner sold its invention to MGI and

MGI is a member of the public, the on-sale bar applies. Treating every sale to a third-party distributor as making an invention "available to the public" is inconsistent with Section 102(a)(1)'s text and purposes and would produce untoward results. Among other things, it would produce unwarranted disparities between large, vertically integrated companies that can perform in-house the various steps needed to prepare an invention for public sale, and smaller companies that rely on third-party distributors to disseminate their inventions to the public.

B. The disclosures by petitioner and MGI concerning the existence and general contours of the agreements between them did not trigger the on-sale bar. For purposes of Section 102(a)(1), an invention can enter the public domain either when the *inventive idea* is disclosed with sufficient specificity to enable a person skilled in the art to make and use it, or when *physical embodiments* of the invention are made available for purchase by their ultimate customers. Public disclosure of a *redacted* version of the supply-and-purchase agreement between petitioner and MGI did not have either of those effects.

C. Petitioner's agreements with MGI did not place the invention "on sale" within the meaning of Section 102(a)(1). The agreements initiated a collaborative arrangement that the contracting parties hoped would culminate in sales of the invention to the public. But the contracting parties recognized that various intermediate steps were necessary before any such sales would occur, and that petitioner might ultimately deliver no palonosetron products even to MGI itself if, for example, the FDA did not approve the relevant palonosetron

doses or the ongoing clinical trials produced unfavorable results. Like similar arrangements between corporate subsidiaries in a large organization, the agreements were intended to facilitate future marketing efforts, but they did not make petitioner's invention available to its ultimate purchasers.

ARGUMENT

Under 35 U.S.C. 102, a patent shall not issue for a claimed invention that was "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before" a date specified in the statute—here, the date one year before petitioner filed its provisional patent application. 35 U.S.C. 102(a)(1); see 35 U.S.C. 102(b). That statutory text establishes that a claimed invention is "on sale" only when a sale or offer for sale makes the invention "available to the public." The agreements between petitioner and MGI for future distribution of palonosetron products, following further development and regulatory approval, did not satisfy that standard because they did not give the public the opportunity to buy any palonosetron drugs.

The public announcements that the agreements had been consummated did not trigger Section 102(a)(1)'s ban on patent issuance. Because the agreements were disclosed to the public only in redacted form, the disclosure did not enable persons skilled in the art to make or use the invention. And while the announcements alerted the public to the existence of the sale, they did not make the invention itself "available to the public." The judgment of the court of appeals should be reversed.

I. AN INVENTION IS "ON SALE" WITHIN THE MEANING OF SECTION 102(A)(1) ONLY WHEN A SALE OR OFFER FOR SALE MAKES THE INVENTION AVAILABLE TO THE PUBLIC

A. The Text Of Section 102(a)(1) Provides That An Invention Is "On Sale" Only When It Is Available To The Public

Section 102(a)(1) prohibits the issuance of a patent when "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before" a date specified in the statute. 35 U.S.C. 102(a)(1); see 35 U.S.C. 102(b). The term "on sale" inherently suggests a sale or offer to sell to the public. Within Section 102(a)(1), that inference is confirmed by the other enumerated bars to patent issuance, and by the residual phrase "otherwise available to the public."

1. The term "on sale" typically refers to a product that is sold or offered for sale to the public. A product is commonly understood to go "on sale" when consumers first have an opportunity to buy it. See, *e.g.*, *The American Heritage Dictionary of the English Language* 1547 (5th ed. 2016) (defining "on sale" to mean "[a]vailable to customers").[3] That natural understanding of "on sale" suggests that an invention goes "on

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[3] See also, *e.g.*, Suryatapa Bhattacharya, *Coca-Cola Serves Its First Alcoholic Drink*, Wall St. J., May 29, 2018, at B3 ("A fizzy lemon-flavored alcoholic drink that went on sale in Japan on Monday marked Coca-Cola Co.'s first fling at selling alcohol in its 132-year history."); Hayley Tsukayama, *Apple's iPad Pro goes on sale Wednesday*, Wash. Post, Nov. 9, 2015, https://www.washingtonpost.com/news/the-switch/wp/2015/11/09/apples-ipad-pro-goes-on-sale-wednesday/?noredirect=on ("Apple on Monday announced that it will begin accepting online orders for the iPad Pro on Wednesday and that the tablet should show up in stores by the end of the

sale" for purposes of Section 102(a)(1) when it first becomes available for sale to the public.

2. The three terms that precede "on sale" in Section 102(a)(1) reinforce that understanding. 35 U.S.C. 102(a)(1). The terms "patented," "described in a printed publication," and "in public use" all identify circumstances that place an invention in the public domain. *Ibid.* Section 102(a)(1) contemplates two distinct senses in which an invention may be placed in the public domain.

First, when a claimed invention is "patented" or "described in a printed publication," the inventive *idea* becomes publicly available. See *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) ("[A] patent must describe the exact scope of an invention and its manufacture * * * to apprise the public of what is still open to them.") (citation omitted); 35 U.S.C. 112(b); *Blue Calypso, LLC* v. *Groupon, Inc.*, 815 F.3d 1331, 1348 (Fed. Cir. 2016) ("To qualify as a printed publication, a reference must have been sufficiently accessible to the public interested in the art.") (citation and internal quotation marks omitted); *In re Antor Media Corp.*, 689 F.3d 1282, 1288-1290 (Fed. Cir. 2012) (explaining that a printed publication must disclose enough information to enable a person of ordinary skill in the art to make or use the invention). Those circumstances make the inventive idea publicly available by giving persons skilled in the art the knowledge required to make and use the invention.

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week."); Diane Cardwell, *The Swamp-Gas Station: Fuel From Landfill Methane Goes on Sale*, N.Y. Times, Oct. 3, 2013, at B9 ("Clean Energy Fuels will announce on Thursday that it has started selling a fuel made of methane from landfills and other waste sources at its more than 40 filling stations in California.").

Respondents have not contended, and the court of appeals did not suggest, that the invention at issue here had been "described in a printed publication" before January 30, 2002. The *unredacted* licensing and supply-and-purchase agreements between petitioner and MGI would have enabled persons skilled in the art to make the invention. The unredacted agreements were not "printed publication[s]," however, because they were shared only between the two contracting parties subject to a duty of confidentiality. See *Blue Calypso*, 815 F.3d at 1348. *Redacted* versions of the agreement were made available to the public in petitioner's SEC filings, and those redacted agreements *were* "printed publications." As a result of the redactions, however, those filings did not describe the invention in sufficient detail to enable a person skilled in the art to make it. See *Antor Media*, 689 F.3d at 1288-1290.

Second, when a claimed invention is "in public use," the public has access to a *physical embodiment* of the invention. See *Egbert* v. *Lippmann*, 104 U.S. 333, 336 (1881) ("If an inventor, having made his device, gives or sells it to another, to be used by the donee or vendee, without limitation or restriction, or injunction of secrecy, and it is so used, such use is public."). Placing that physical embodiment "in public use" therefore can preclude the patenting of that invention, even if the inventive idea remains hidden from the public.

This Court has often recognized that "[a] word is given more precise content by the neighboring words with which it is associated." *Life Techs. Corp.* v. *Promega Corp.*, 137 S. Ct. 734, 740 (2017) (quoting *United States* v. *Williams*, 553 U.S. 285, 294 (2008)). The Court relies on this interpretive principle, known as *noscitur a sociis*, "to 'avoid ascribing to one word a

meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress.'" *Yates* v. *United States*, 135 S. Ct. 1074, 1085 (2015) (quoting *Gustafson* v. *Alloyd Co.*, 513 U.S. 561, 575 (1995)). As explained above, the three specific terms that precede "on sale" all describe occurrences that make an invention available to the public, either in inventive concept or in physical form. Cf. Pet. App. 9a n.2 (O'Malley, J., concurring in denial of panel rehearing) ("[E]ach phrase—i.e., 'patented,' 'printed publication,' and 'public use'—recites a disclosure that is necessarily public."). The *noscitur a sociis* canon therefore suggests that the term "on sale" should be construed in the same manner. Cf. *Gustafson*, 513 U.S. at 573-575 (concluding that a statute's reference to "communication" meant "a public communication" because of its inclusion in a list of terms that "refer[red] to documents of wide dissemination").

3. Although United States patent laws have long barred the patenting of inventions that were "on sale" before a specified date, the phrase "or otherwise available to the public" was added to Section 102(a)(1) by the AIA. 35 U.S.C. 102(a)(1). The most obvious purpose of that language was to serve as a catchall, rendering an invention unpatentable if it was "available to the public" before the specified date, even if it was not covered by any of the four enumerated grounds of unpatentability. *Ibid.* In addition to serving that function, however, the new language sheds light on the proper understanding of the preexisting term "on sale." Cf. *United States* v. *Fausto*, 484 U.S. 439, 453 (1988) ("Th[e] classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be

altered by the implications of a later statute."). In particular, the word "otherwise" indicates that the terms preceding the catchall, including the term "on sale," describe ways in which a claimed invention is "available to the public." 35 U.S.C. 102(a)(1); see 10 *The Oxford English Dictionary* 984 (2d ed. 1989) (defining the adverb "otherwise" as "[i]n another way, or in other ways; in a different manner, or by other means; differently"); *American Heritage Dictionary* 1249 ("[i]n another way; differently," "[u]nder other circumstances," "[i]n other respects"); *Webster's Third New International Dictionary of the English Language* 1598 (1986) ("in a different way or manner," "in different circumstances: under other conditions," "in other respects").

In this respect, Section 102(a)(1) is similar to the statute that this Court construed in *Paroline* v. *United States*, 572 U.S. 434 (2014). For purposes of certain restitution awards, that law defined the term "full amount of the victim's losses" to include all costs incurred by the victim that fell into any of six categories. 18 U.S.C. 2259(b)(3). The first five categories enumerated specific types of costs, such as "physical and occupational therapy or rehabilitation" and "lost income," while the sixth category covered "any other losses suffered by the victim as a proximate result of the offense." *Ibid.* The Court recognized that the "broad, final category * * * is most naturally understood as a summary of the type of losses covered—*i.e.*, losses suffered as a proximate result of the offense." *Paroline*, 572 U.S. at 447. The phrase "otherwise available to the public" in Section 102(a)(1) performs a similar function.

Respondents have suggested that, if the phrase "otherwise available to the public" is read to imply that the preceding terms in Section 102(a)(1) require public

availability, the provision as a whole will be redundant. Br. in Opp. 21-23. That is incorrect. Most obviously, that catchall language makes clear that the enumerated categories of prior art are not exclusive. And, to the extent that the phrase "otherwise available to the public" *clarifies* the proper understanding of the preexisting term "on sale," it performs an additional useful function. Congress could not have reliably achieved the same result by deleting the enumerated categories of prior art and drafting Section 102(a)(1) to refer solely to an "invention" that was "available to the public" at a particular point in time. Such a dramatic textual change, including the elimination of an express "on sale" bar that had been part of United States patent law since 1836, might well have been construed as substantially altering prior patentability rules. Cf. *Paroline*, 572 U.S. at 447-448 (explaining that the catchall category of costs did not render the five enumerated categories superfluous because "[t]he first five categories provide guidance to district courts as to the specific types of losses Congress thought would often be the proximate result of a Chapter 110 offense and could as a general matter be included in an award of restitution").[4]

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[4] As respondents point out (Br. in Opp. 28), the phrase "otherwise available to the public" (and close variants of that phrase) first appeared in predecessor bills that did not contain the term "on sale." That sequence of events demonstrates that the phrase was not initially drafted for the purpose of clarifying that an invention is "on sale" only if it is publicly available. The phrase nevertheless serves that purpose as it appears in the version of Section 102 that Congress ultimately enacted.

B. Treating The On-Sale Bar As Limited To Sales And Offers That Make An Invention "Available To The Public" Is Consistent With The Balance That The Patent Laws Have Traditionally Struck

"From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). In seeking to achieve this "careful balance," *ibid.*, patent law has long restricted inventors' ability to commercially exploit their inventions in the public sphere before making the disclosures necessary to receive patent protection for their ideas. See *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1, 19-24 (1829).

"From the Patent Act of 1790[, ch.7, 1 Stat. 109,] to the present day, the public sale of an unpatented article has acted as a complete bar to federal protection of the idea embodied in the article thus placed in public commerce." *Bonito Boats*, 489 U.S. at 148-149. This Court first recognized the patent laws' focus on "public sale[s]," *id.* at 149, in *Pennock*. There, the Court held that an inventor loses his right to 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," because "[h]is voluntary act or acquiescence in the public sale and use is an abandonment of his right." 27 U.S. (2 Pet.) at 23-24. The Court described this doctrine as a carryover from English common law, under which "letters patent were unavailable for the protection of articles in public commerce at the time of the application."

Bonito Boats, 489 U.S. at 149 (citing *Pennock*, 27 U.S. (2 Pet.) at 20).

Congress codified that principle in the Patent Act of 1836 by prohibiting the patenting of any invention that, at the time the application was filed, was "in public use or on sale, with [the inventor's] consent or allowance." § 6, 5 Stat. 119; see *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 65 (1998). The legislative history of that statute reflects Congress's concern that then-existing patent laws accorded "no power to the Secretary to refuse a patent for want of either novelty or usefulness." S. Rep. No. 338, 24th Cong., 1st Sess. 2 (1836). That statutory gap had enabled the "reprehensible" practice "of taking out patents for what has been long in public use, and what every one has therefore a right to use." *Id.* at 3-4. That history suggests that, in barring the issuance of patents for inventions that were already "on sale," Congress sought to address sales or offers of sale that had made an invention publicly available.

Congress retained the "on sale" language in subsequent amendments to the patent laws, initially adding a two-year grace period in which the inventor could file an application and later reducing that grace period to one year. *Pfaff*, 525 U.S. at 65. Meanwhile, this Court recognized that the "on sale" bar did not preclude an inventor from patenting an invention when the inventor "does not voluntarily allow others to make it and use it, and so long as it is not on sale for general use." *Elizabeth* v. *Pavement Co.*, 97 U.S. 126, 135 (1878). In contrast, a sale that placed items embodying the invention in the public domain precluded a patent. See *Consolidated Fruit-Jar Co.* v. *Wright*, 94 U.S. 92, 93-94 (1877) (holding that patent for fruit jars was invalid where the inventor sold a dozen or more jars "to get the money

which they yielded, and to test their salability in the market").

The Patent Act of 1952 preserved the bar on patenting inventions that had been "on sale," prohibiting the issuance of patents for any invention that "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 before the date of the patent application. 35 U.S.C. 102(b) (1952). That provision and Section 102(a) of the same statute "operate[d] in tandem to exclude from consideration for patent protection knowledge that is already available to the public," thereby expressing a congressional judgment that patenting such inventions would "injure the public by removing existing knowledge from public use." *Bonito Boats*, 489 U.S. at 148. The Patent Act of 1952 therefore prohibited the patenting of an invention that had been "placed in public commerce" by a "public sale." *Id.* at 149.

Before the AIA was enacted, the Federal Circuit repeatedly held that "[t]he overriding concern of the on-sale bar is an inventor's attempt to commercialize his invention beyond the statutory term." *Atlanta Attachment Co.* v. *Leggett & Platt, Inc.*, 516 F.3d 1361, 1365 (2008); see *Netscape Commc'ns Corp.* v. *Konrad*, 295 F.3d 1315, 1323 (2002) (same); *STX, LLC* v. *Brine, Inc.*, 211 F.3d 588, 590 (2000) (same). Standing alone, that characterization of the on-sale bar's purpose might suggest that the bar is triggered by any transaction from which the inventor makes money on his invention. As explained above, however, this Court's decisions have emphasized the distinct purpose of preserving the public's access to inventions that have already entered the public domain. Congress's addition of the phrase "otherwise available to the public" in the

AIA confirms the primacy of that legislative purpose. 35 U.S.C. 102(a)(1).

That choice was particularly explicable given another feature of the AIA. Before the AIA was enacted, disputes as to priority among competing patent applicants were resolved in favor of the applicant who had first *invented* the invention for which a patent was sought. See *Pfaff*, 525 U.S. at 61 ("[I]t is normally the first inventor to conceive * * * who establishes the right to the patent."). Under that regime, the on-sale bar served in part to prod inventors to seek patents expeditiously, thereby hastening the time at which a patent would expire and the invention would reenter the public domain. Under the AIA, however, priority disputes are resolved in favor of the first inventor to *file a patent application*. See *Madstad Eng'g, Inc.* v. *United States Patent & Trademark Office*, 756 F.3d 1366, 1368 (Fed. Cir. 2014). Congress's addition of language ("otherwise available to the public") confirming that the on-sale bar should be confined to inventions that had previously entered the public domain thus coincided with its enactment of an alternative disincentive to artificial delay in applying for patents.

C. The AIA's Legislative History Supports The Conclusion That A Sale Or Offer For Sale Must Make An Invention "Available To The Public" In Order To Trigger Section 102(a)(1)'s On-Sale Bar

In its favorable report on the AIA, the House Judiciary Committee noted that inclusion of the phrase "available to the public" in proposed Section 102(a)(1) was intended in part "to emphasize the fact that [prior art] must be publicly accessible." H.R. Rep. No. 98, 112th Cong., 1st Sess., Pt. 1, at 43 (2011). An earlier Senate Committee Report on a predecessor bill that contained

the same language had likewise stated that "the phrase 'available to the public' is 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. 259, 110th Cong., 2d Sess. 9 (2008).

In a floor statement on the AIA, Senator Kyl described Section 102(a)(1)'s residual clause as clarifying that the preceding terms, including "on sale," were limited to acts that had made an invention "available to the public." 157 Cong. Rec. 3423 (2011). One of the bill's sponsors, Senator Leahy, expressed similar views, stating that Section 102(a)(1) "imposes an overarching requirement for availability to the public, that is a public disclosure," thereby limiting Section 102(a)(1) "to subject matter meeting the public accessibility standard." *Id.* at 3415. Senator Kyl also emphasized the connection between new Section 102(a)(1)'s express public-availability standard and the AIA's shift from a first-to-invent to a first-inventor-to-file rule of patent priority. See *id.* at 3423-3424. He explained that, "[b]y adopting the first-to-file system, * * * the present bill already provides ample incentive for an inventor to enter the patent system promptly. There is no need to also require forfeiture of patents simply because the inventor has made some use of the invention that has not made the invention available to the public." *Id.* at 3424; see Pet. Br. 27-28.[5]

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[5] With respect to the scope of the Section 102(a)(1) on-sale bar, the legislative history focused significantly on the inadvisability of treating certain "secret" sales or offers to sell as barriers to patent issuance. See Pet. Br. 7, 26, 28. The court of appeals found that this concern was not implicated here because the agreements between petitioner and MGI were disclosed to the public. See Pet. App. 37a-38a. The primary thrust of this aspect of the legislative history,

II. THE AGREEMENTS AT ISSUE IN THIS CASE DID NOT MAKE THE INVENTION "AVAILABLE TO THE PUBLIC" WITHIN THE MEANING OF SECTION 102(A)(1) AND THEREFORE DID NOT TRIGGER THE ON-SALE BAR

A. An Invention Is "On Sale" Within The Meaning Of Section 102(a)(1) Only When A Product Embodying The Invention Can Be Purchased By Its Expected Ultimate Customers

Respondents have suggested that, even if an invention must be "available to the public" in order for the on-sale bar to be triggered, that requirement is satisfied here in part because "MGI is a member of the public." Br. in Opp. 17 (quoting Pet. App. 151a). That is incorrect.

1. 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. A new model of the iPhone, for example, will be "on sale" when consumers have an opportunity to buy it, not when Apple ships the new iPhones to Walmart so that Walmart can sell them to the public. This paradigmatic understanding of what it means to make an invention "available to the public" comports with this Court's recognition that "[t]he aim of the patent laws is not only that members of the public shall be free to manufacture the product or employ the process disclosed by the expired patent, but also that the consuming public at large

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however was that such secret sales or offers to sell should not preclude patenting of an invention *because* those arrangements do not make an invention publicly available. That concern is directly implicated here, whether or not the relevant sale is properly characterized as "secret." See pp. 30-31, *infra*.

shall receive the benefits of the unrestricted exploitation, by others, of its disclosures." *Scott Paper Co.* v. *Marcalus Mfg. Co.*, 326 U.S. 249, 255 (1945); cf. *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. 111, 122 (1938) ("Sharing in the goodwill of an article unprotected by patent or trade-mark is the exercise of a right possessed by all—and in the free exercise of which the consuming public is deeply interested.").

Although many inventions are intended for ultimate purchase by ordinary individual consumers, the nature and contours of the expected customer base will vary from product to product. Some products (*e.g.*, cash registers or bulldozers) may as a practical matter be purchased only by businesses or by particular types of business; others may be legally available only to persons with a particular license. An inventor who makes his invention available to a purchaser of that character may thereby place his invention "on sale," even if ordinary consumers have no opportunity to buy it.

The fact that the relevant "public" may vary from invention to invention, however, does not mean that the on-sale bar is triggered by *every* commercial sale to a person other than the inventor. Such a rule would have obvious untoward results. It would mean that the on-sale bar is triggered by a secret sale or offer to sell (see pp. 25-26 n.5, *supra*), or by a sale to the inventor's corporate affiliate. If Congress had intended to make the on-sale bar so broadly applicable, it presumably would have used language tailored to that purpose, *e.g.*, by barring the issuance of a patent for an invention that "was sold or offered for sale to any person" before a specified date. And the fact that physical embodiments have been sold or offered for sale to a single entity other than the inventor does not, standing alone, necessarily

implicate Section 102(a)(1)'s core purpose of preventing the withdrawal from public accessibility of inventions that have already entered the public domain.

2. To be sure, third-party distributors like MGI often play an essential role in the overall process by which an invention is made available to its ultimate expected customers and thus is placed "on sale." But treating such a distributor as "the public" would place smaller companies (like petitioner) that require such assistance at an unwarranted disadvantage. Contracts like the supply-and-purchase agreement between petitioner and MGI mirror the arrangements that might occur within a large, vertically integrated company that has the in-house capacity to develop, manufacture, and distribute its own products. Preparatory steps within such a company would not trigger the on-sale bar until the product's expected ultimate purchasers were actually able to buy it. The fact that petitioner enlisted the help of a third-party distributor, rather than performing the same distribution functions in-house, did not cause its invention to become "available to the public" at an earlier date.

3. This Court's decision in *Pfaff* does not support a categorical rule of the sort described above. In *Pfaff*, representatives of Texas Instruments approached an inventor and asked him to develop a new device for mounting and removing semiconductor chip carriers. 525 U.S. at 58. The inventor prepared detailed drawings describing his design, and he showed a sketch of his concept to Texas Instruments. *Ibid.* Texas Instruments made an oral purchase order for 30,100 of the inventor's new sockets and gave the inventor written confirmation of that order in April 1981. *Ibid.* Because of

manufacturing delays, however, the inventor did not fill the order until July 1981. *Ibid.*

The *Pfaff* Court held that the on-sale bar set forth in the Patent Act of 1952, see 35 U.S.C. 102(b) (1994), was triggered when the relevant invention was (a) the subject of a commercial offer for sale, and (b) ready for patenting. 525 U.S. at 67. The Court's focus was on the latter requirement, see *id.* at 60-67, but the Court also concluded that the oral purchase order in that case had placed the invention "on sale" within the meaning of the statute, *id.* at 67.

Because *Pfaff* was decided under the pre-AIA version of the on-sale bar, the Court had no occasion to analyze whether the sale to Texas Instruments made the invention "available to the public" within the meaning of current Section 102(a)(1). In any event, the transaction at issue in *Pfaff* differed substantially from the April 2001 agreements between petitioner and MGI. The invention in *Pfaff* was a socket to mount and remove semiconductor chip carriers, which Texas Instruments presumably intended to use to manufacture its own products. See 525 U.S. at 58. Texas Instruments was thus the ultimate purchaser of the sockets as discrete units of commerce. The contract between the parties, moreover, committed the inventor to provide a specified commercial quantity of sockets, which were delivered approximately three months after the written confirmation of the oral purchase order.

In this case, by contrast, MGI "w[as] not buying a product," but rather was "buying the rights to participate in the development effort to potentially have a product in the future." Pet. App. 116a. The agreements between petitioner and MGI reflected the parties' understanding that it was uncertain whether, when, and in

what quantities petitioner would ultimately deliver palonosetron. See *id.* at 23a-24a. Although the Federal Circuit recognized those uncertainties, the court found it sufficient that the supply-and-purchase agreement would nevertheless qualify as a "contract to sell" under the Uniform Commercial Code. See *id.* at 30a-31a. But given the preliminary and contingent nature of the parties' agreement, that contract did not make petitioner's invention "available to the public," and therefore did not place it "on sale" within the meaning of Section 102(a)(1).

B. Public Disclosure Of The Existence Of The April 2001 Agreements Did Not Trigger The Section 102(a)(1) Bar

The court of appeals stated that "an invention is made available to the public when there is a commercial offer or contract to sell a product embodying the invention and that sale is made public." Pet. App. 40a; see *id.* at 43a ("conclud[ing] that, after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale"). The court's conclusion that the sale at issue here had been "made public" was based on the fact that the supply-and-purchase agreement between petitioner and MGI "was publicly announced in MGI's 8-K filing with the SEC." *Id.* at 38a. The court thus correctly (though implicitly) recognized that MGI's own status as a member of the "public" was insufficient to trigger the on-sale bar, and that some form of broader public accessibility was required. The court was wrong, however, in concluding that public disclosure of the *sale's existence* made the *invention* "available to the public."

As explained above (see pp. 2-3, 16-17, *supra*), Section 102(a)(1) contemplates two distinct senses in which an invention may be placed in the public domain so as to

preclude subsequent patenting. That may occur if the *inventive idea* is made public, with sufficient specificity to allow persons skilled in the art to make and use it, even if no physical embodiment of the invention yet exists. Or it may occur if *physical embodiments* of the invention become available to their expected ultimate purchasers, even if the idea itself remains secret.

In this case, the joint press release and MGI's SEC filing did not have either of those effects. The redacted version of the supply-and-purchase agreement that was publicly disclosed with the SEC filing did not reveal the inventive idea. And the fact that the sale's existence was publicized has no logical bearing on whether physical embodiments of the invention were made available to potential ultimate purchasers.

C. Petitioner's Agreements With MGI Did Not Make Products Embodying The 0.25 Mg Dose Of Palonosetron Available To The Public

The April 2001 agreements between petitioner and MGI did not place petitioner's invention "on sale" because those agreements did not make the 0.25 mg dose of palonosetron available to the public in its embodied form. Although those agreements "set the stage" for MGI's "future purchase" of palonosetron products, MGI "w[as] not buying a product," but rather was "buying the rights to participate in the development effort to potentially have a product in the future." Pet. App. 116a. The agreements also recognized that the FDA had not yet approved the marketing of the palonosetron drugs described in the agreements, and that such approval would be a prerequisite to any distribution of the drugs to the public. *Id.* at 23a-24a, 29a, 119a. The agreements further acknowledged that petitioner might not sell any palonosetron products to MGI at all

if, for example, the FDA did not approve the relevant palonosetron doses or the results of the ongoing clinical trials were unfavorable. *Id.* at 24a; J.A. 69-70.

The relationship between petitioner and MGI was not a traditional buyer-seller relationship. Rather, the license and supply-and-purchase agreements anticipated that petitioner and MGI would work together on future efforts to develop, regulate, and patent palonosetron products. See J.A. 62-63, 70-72, 74, 105. MGI gave petitioner initial infusions of capital, totaling $11 million, despite the contracting parties' recognition that there might never be a palonosetron product for MGI to purchase. Pet. App. 23a; J.A. 69-71. Petitioner in turn shared the innovative details of the palonosetron formula with MGI, subject to a confidentiality agreement between the parties. Pet. App. 119a-120a.

The April 2001 agreements thus reflected the contracting parties' shared objective that, through the combined efforts of petitioner and MGI, the palonosetron drugs would become available to their expected ultimate purchasers at some indefinite time in the future. The agreements allowed petitioner and MGI to collaborate on development and distribution projects that a larger organization might have handled in-house. But neither the arrangement between petitioner and MGI, nor similar in-house transactions between corporate subsidiaries in a larger, vertically integrated organization, make pre-market products "available to the public." Thus, while a new invention may be subject to intermediate transactions before its commercial marketing to the public, those preparatory transactions by themselves do not place the invention "on sale" within the meaning of Section 102(a)(1).

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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