

Nos. 2016-1284, 2016-1787

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC,

Plaintiffs-Appellees,

v.

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

Defendants-Appellants.

On Appeal from the United States District Court for the
District of New Jersey, Case Nos. 3:11-cv-03962-MLC-DEA,
3:11-cv-05579-MLC-DEA, 3:13-cv-05815-MLC-DEA (Judge Mary L. Cooper)

**BRIEF FOR THE UNITED STATES AS AMICUS CURIAE
IN SUPPORT OF APPELLEES**

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INTRODUCTION AND SUMMARY

Since 1836, Congress has prohibited the patenting of any invention that was placed “on sale” more than one year (originally two years) before the date on which the inventor filed a patent application. As the Supreme Court has emphasized, this “on-sale bar” reflects the fundamental policy of the patent laws that an inventor should not be permitted to remove from the public what was lawfully placed in the public’s hands. *See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998) (explaining that it is Congress’s “reluctance to allow an inventor to remove existing knowledge from public use [that] undergirds the on-sale bar”).

In the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (Sept. 16, 2011), Congress amended the Patent Act to underscore that legislative purpose, specifying that an inventor shall be entitled to a patent unless the invention was “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) (emphasis added). Congress thereby made explicit what the statutory phrase “on sale” had always implied—that the sale or offer for sale of an invention acts as a bar to patentability only if the sale makes the invention “available to the public.”

This appeal presents this Court’s first opportunity to construe the AIA’s on-sale bar. Pursuant to the plain language, purpose, and structure of the AIA, the Court should hold that the statute means what it says: an invention is only “on sale” under the AIA if the sale or offer for sale makes the invention “available to the public.”

Because the parties in this case do not dispute that the allegedly invalidating sale at issue did not make the invention publicly available, this Court should affirm the judgment of the district court.

INTEREST OF THE UNITED STATES

The question presented concerns the proper interpretation of the AIA’s on-sale bar and implicates the responsibilities of the United States Patent and Trademark Office (PTO) in administering the patent laws.

QUESTION PRESENTED

The Patent Act, as amended by the AIA, provides that an applicant is entitled to a patent unless “the claimed invention was . . . 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). This brief addresses the question whether a sale or offer for sale must make the invention “available to the public” to trigger the on-sale bar.

ARGUMENT

Appellant Teva Pharmaceuticals USA, Inc. (Teva) challenges the validity of four patents owned by Appellee Helsinn Healthcare S.A. (Helsinn). Three of those patents (the ’724, ’725, and ’424 patents) are governed by the pre-AIA on-sale bar, and one (the ’219 patent) is governed by the AIA. Teva argues that a licensing and supply contract signed by Helsinn in 2001—more than one year prior to Helsinn’s patent applications—invalidates all four patents. But Teva does not dispute that the

2001 agreement was secret and did not make the invention available to the public. That concession is dispositive of this appeal.

As the government has explained in its amicus brief in *The Medicines Company v. Hospira, Inc.*, Nos. 14-1469, 14-1504 (Fed. Cir.) (en banc) (to be argued May 5, 2016), the Supreme Court has emphasized for more than 180 years that a sale or offer for sale will invalidate a patent only if it makes the invention available to interested members of the public, thereby placing the invention in the public domain. The inventions claimed in Helsinn's three pre-AIA patents were never "on sale" under a proper interpretation of the pre-AIA on-sale bar, therefore, because the 2001 supply and licensing contract was confidential.

Although the district court correctly held that the on-sale bar did not invalidate Helsinn's three pre-AIA patents, it did so on the ground that the patents were not "ready for patenting" at the time of the 2001 marketing agreement. *See Pfaff v. Wells Elec., Inc.*, 525 U.S. 55, 67 (1998) (the on-sale bar applies if the product was the subject of "a commercial offer for sale" and was "ready for patenting" before the critical date). The government takes no position on whether Helsinn's patents were "ready for patenting." Nor does the government address whether the 2001 licensing and supply contract properly constitutes a "sale"—a conclusion that Helsinn disputes on appeal. But if the en banc Court in *The Medicines Company* overrules circuit precedent concerning secret sales under pre-AIA law, this Court can affirm with

respect to the three disputed pre-AIA patents on the alternative ground that Helsinn's inventions were never sold publicly.

Regardless, Congress in the AIA eliminated any doubt that secret sales do not trigger the on-sale bar. The plain text of section 102(a)(1) makes clear that only sales or offers for sale that make an invention "available to the public" trigger the on-sale bar, 35 U.S.C. § 102(a)(1), and the purpose and structure of the AIA support that plain-text reading. Thus, no matter the outcome of *The Medicines Company*, Helsinn's post-AIA patent is not invalid under the on-sale bar.

I. Only Sales Or Offers For Sale That Make An Invention "Available To The Public" Trigger The AIA's On-Sale Bar.

A. Statutory construction always "begins with the plain language of the statute." *Jimenez v. Quarterman*, 555 U.S. 113, 118 (2009). The AIA provides that an applicant is entitled to a patent unless "the claimed invention was . . . 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) (emphasis added). The residual clause that Congress enacted in the AIA—"or otherwise available to the public"—confirms that the preceding terms—including the term "on sale"—also involve making the invention "available to the public." Any other interpretation of the statutory text would fail to give effect to the term "or otherwise." See *American Heritage Dictionary* (4th ed. 2006) (defining "otherwise" to mean "[i]n another way"); *Webster's New International Dictionary* (2d ed. 1958) (same).

Congress's addition of the residual clause confirms what would otherwise be the most natural understanding of the term "on sale." An item may be "sold" in a secret transfer between two parties, but one would not naturally describe such an item as having been placed "on sale," a phrase that connotes making the item available more broadly. *See American Heritage Dictionary* (5th ed. 2015) (defining "on sale" to mean "[a]vailable to customers"). By adding the residual clause in the AIA, Congress underscored that it intended to give the term "on sale" its most natural reading.

The PTO has therefore instructed its examiners that "secret sale or use activity does not qualify as prior art" under the AIA. *Examination Guidelines for Implementing the First Inventor To File Provisions of the Leahy-Smith America Invents Act*, 78 Fed. Reg. 11,059, 11,062 (Feb. 14, 2013). The Manual of Patent Examining Procedure (MPEP) cites sales "among individuals having an obligation of confidentiality to the inventor" as an example of secret sale activity excluded from the on-sale bar. MPEP § 2152.02(d) (9th ed. 2015); *see Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995) (the MPEP is "commonly relied upon as a guide to patent attorneys and patent examiners on procedural matters").

Accordingly, an invalidating sale or offer for sale under section 102(a)(1) is one that makes the invention "available" to one or more interested members of the public. An offer for sale need not be broadcast to the public at large to meet that standard. Indeed, in *Pfaff*, the invalidating sale was an arm's-length agreement between the inventor of a computer chip socket and a single company that wanted to purchase the

invention. *See* 525 U.S. at 58. But the plain language of the AIA’s on-sale bar makes clear that confidential supplier agreements, such as the agreement at issue here, do not trigger the on-sale bar because such sales do not make the invention available to interested members of the public. *See In re Klopfenstein*, 380 F.3d 1345, 1348 (Fed. Cir. 2004) (holding in the context of printed publications that “the key inquiry” is whether the reference “has been made ‘publicly accessible’”). Because Teva accepts that the 2001 contract was non-public, this Court need not consider other circumstances in which a sale or offer for sale may fail to make an invention “available to the public.”

B. A court must construe statutory provisions in light of the statute’s “relevant purposes.” *Lozman v. City of Riviera Beach*, 133 S. Ct. 735, 741 (2013). Here, Congress in the AIA amended the on-sale bar specifically to correct decisions of the courts of appeals misinterpreting the on-sale bar to encompass secret sales.

As explained in the government’s brief in *The Medicines Company*, the on-sale bar was never intended to reach secret sales. Rather, as the Supreme Court has emphasized, the on-sale bar reflects Congress’s judgment that an inventor should not be permitted to remove an invention from the public domain after the invention has been placed there through a public sale or offer for sale. “From the Patent Act of 1790 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, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148-49 (1989) (emphases added). Even before the Patent Act expressly prohibited the patenting of

inventions placed on sale, the Supreme Court in *Pennock v. Dialogue* recognized 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 applying for a patent. 27 U.S. (2 Pet.) 1, 23-24 (1829). *Pennock* thus construed the Patent Act impliedly to preclude a patent where a product had previously been “publicly sold.” Seven years later, Congress codified the principle announced in *Pennock* by amending the Patent Act to include the first on-sale bar. *See* Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119.

In the ensuing 180 years, during which Congress repeatedly reenacted the on-sale bar without materially changing its text, the Supreme Court has reiterated that the on-sale bar encompasses only public sales. *See City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126, 135 (1878) (Patent Act does not preclude obtaining a patent if the invention “is not *on sale for general use*”) (emphasis added); *Bonito Boats*, 489 U.S. at 149 (the “*public sale* of an unpatented article” precludes patenting the invention) (emphasis added); *see also Pfaff*, 525 U.S. at 64 (recognizing that Congress’s “reluctance to allow an inventor to remove existing knowledge from *public* use undergirds the on-sale bar”) (emphasis added).

Notwithstanding this Supreme Court precedent, various lower courts, including this Court, interpreted the on-sale bar to encompass secret commercial activity that does not make the invention available to interested members of the public. *See, e.g., D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1148-50 (Fed. Cir. 1983); *Metallizing Eng’g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 518-20 (2d Cir.

1946). Congress in the AIA amended the on-sale bar to correct that error and restore the historical meaning of the phrase “on sale.” As explained in the AIA’s House Committee Report, Congress added the phrase “or otherwise available to the public” to make clear that the preceding terms encompass only “art that *publicly* exists prior to the filing date” and to emphasize “that [prior art] must be *publicly* accessible” in order to trigger the on-sale bar. H.R. Rep. No. 112-98, at 42-43 (June 1, 2011) (emphases added). As one sponsor of the bill explained, the residual clause “imposes a public-availability standard on the definition of all prior art enumerated by the bill—an understanding on which the remainder of the bill is predicated.” 157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl).

C. Statutory provisions “must be read in their context and with a view to their place in the overall statutory scheme.” *King v. Burwell*, 135 S. Ct. 2480, 2492 (2015). Three features of the AIA’s statutory scheme further demonstrate Congress’s intent to exclude secret sales from the on-sale bar. Interpreting the AIA’s on-sale bar to the contrary would be “untenable in light of the statute as a whole.” *Id.* at 2495 (alteration omitted).

First, construing the on-sale bar to encompass secret sales would undermine the efficacy of post-grant reviews, *see* 35 U.S.C. §§ 321-329, which are among the AIA’s primary innovations. In a post-grant review, a party other than the patent owner may petition the PTO to reevaluate the patentability of certain previously issued patents on any invalidity ground, including on the ground that the patent is precluded by the on-

sale bar. *See id.* § 321(b) (cross-referencing *id.* § 282(b)). Congress created post-grant reviews to provide “a more efficient system for challenging patents that should not have issued” and to “improve patent quality and limit unnecessary and counterproductive litigation costs.” H.R. Rep. No. 112-98, at 39-40. To ensure the efficiency of post-grant reviews, Congress strictly limited discovery in these proceedings and mandated (with certain exceptions) that they be completed within one year of their institution. *See* 35 U.S.C. § 326(a)(5), (a)(11); *see also* *PPC Broadband, Inc. v. Corning Optical Commc’ns RF, LLC*, 815 F.3d 734, 741 (Fed. Cir. 2016).

But invalidity challenges based on secret prior art are entirely unsuited to adjudication in these expedited proceedings. Secret sales are not in the public domain, and they cannot be found by searching publicly available material. Rather, the existence and details of secret sales must often be developed through extensive discovery. *See, e.g., Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1363 (Fed. Cir. 2008). Construing the AIA’s on-sale bar to encompass secret sales would undermine the value of these proceedings and would make it difficult for the PTO to complete the administrative process within the statutorily mandated timeframes.

Congress enacted the AIA with this problem in mind. With limited exceptions, only AIA patents—rather than pre-AIA patents—may be challenged in post-grant review proceedings, *see* Pub. L. No. 112-29, § 6(f)(2)(A), 125 Stat. at 311 (post-grant review provisions “shall apply only to” AIA patents), precisely because pre-AIA patents “raise discovery-intensive invention-date and secret-prior-art issues that would

be difficult to address in an administrative proceeding,” 157 Cong. Rec. S1366 (Mar. 8, 2011) (summary of Senate managers’ amendment). And the Senate rejected a proposed amendment to the AIA that would have omitted the residual clause from the new on-sale bar, reasoning in part that the amendment would make post-grant reviews “utterly unmanageable.” *Id.* at S1371 (statement of Sen. Kyl). Post-grant reviews would be too time-consuming and expensive “if the validity of all patents subject to review under the new system continued to depend on discovery-intensive searches for secret offers for sale and non-disclosing uses.” *Id.*

Second, construing the on-sale bar to encompass secret sales would undermine the AIA’s goal of “harmonizing our system for granting patents with the best parts of other major patent systems throughout the industrialized world.” H.R. Rep. No. 112-98, at 39. No other industrialized nation includes secret sales within the prior art. *See* Dmitry Karshedt, *Did Learned Hand Get It Wrong?: The Questionable Patent Forfeiture Rule of Metallizing Engineering*, 57 Vill. L. Rev. 261, 316 (2012). Given that it is today “common for inventors and companies to file for protection in several countries at the same time,” Congress in the AIA sought to eliminate the need for patent applicants to comply with multiple incompatible patent systems. H.R. Rep. No. 112-98, at 41-42. Most significantly, the AIA transformed the American patent system from a first-to-invent system into a first-inventor-to-file system, which more closely resembles the system used by “[e]very industrialized nation other than the United States.” *Id.* at 40. The AIA also “necessarily” modified “the prior-art sections of the

patent law,” harmonizing them with other nations’ laws by removing preexisting “geographic limitations” to prior art and by encompassing within prior art “all art that *publicly* exists prior to the filing date.” *Id.* at 42 (emphasis added). Construing the on-sale bar to encompass secret sales would undermine Congress’s goal of ensuring that prior art under American law is consistent with prior art recognized by other nations.

Third, the AIA weakens the policy rationale for construing the on-sale bar to reach secret sales. Prior to the AIA, this Court concluded that secret sales should be encompassed within the on-sale bar to prevent patentees from engaging in “commercial exploitation of the [invention] beyond the statutorily prescribed time period.” *Continental Plastic Containers v. Owens Brockway Plastic Prods., Inc.*, 141 F.3d 1073, 1079 (Fed. Cir. 1998). The Court reasoned that prohibiting patents for products sold secretly would encourage inventors “to enter the patent system promptly” rather than capitalizing on their invention indefinitely through secret sales, only to apply for a patent when they faced competition. *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998).

The AIA substantially undermines that policy rationale. Under the first-to-invent system that predated the AIA, an inventor could potentially capitalize on his invention through secret sales knowing that he could rely on his earlier invention date to win priority over any later-arising competition. But under the AIA’s first-inventor-to-file system, the inventor who applies for a patent first wins priority even over a competitor who invented the product first. Accordingly, an inventor who sells his

product secretly and declines to apply for a patent risks losing priority to a competitor who invents the product later but applies for a patent earlier. The AIA's first-inventor-to-file rule thereby provides significant "new statutory pressures for early filing," *Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 769 F.3d 1339, 1349 (Fed. Cir. 2014) (Newman, J., dissenting from denial of rehearing en banc), making it unnecessary to construe the on-sale bar to provide that same incentive.

II. Teva's And Amici's Arguments To The Contrary Lack Merit.

A. Teva and the amici law professors provide no plausible explanation why Congress would have chosen to employ the phrase "or otherwise available to the public" unless Congress intended to clarify that an invalidating sale or offer must be made to the public. Indeed, amici concede (Amici Br. 10, 21) that the district court's textual reading is "plausible" and that "it is not completely clear what the residual category covers" under their theory. Their inability to offer a colorable alternative interpretation of the residual clause indicates that the clause means what it says.

Teva's textual argument proceeds by interpreting language that Congress did not use. Teva contends (Teva Br. 42) that the noun "sale" may encompass public sales and secret sales alike. But that is irrelevant, as Congress did not use the noun "sale," but instead used the phrase "on sale." As already explained, that phrase most naturally connotes a sale or offer for sale that makes a product "available" more broadly. And Congress in the AIA confirmed this interpretation by characterizing the term "on sale" as one way to make the invention "available to the public."

Teva also repeatedly conflates (Teva Br. 45-46, 51-53) the adverb “otherwise” with the adjective “other” in insisting that the phrase “otherwise available to the public” does not describe the preceding phrase “on sale.” Teva specifically argues that the “rule of the last antecedent,” which provides that a limiting clause “should ordinarily be read as modifying only the noun or phrase that it immediately follows,” *Barnhart v. Thomas*, 540 U.S. 20, 26 (2003), limits the reach of clauses that employ the term “or other.”

But the terms “other” and “otherwise” are not synonymous, and the last-antecedent rule does not apply here. The relevant question is not whether the clause “otherwise available to the public” describes the noun “invention” (it plainly does), but rather why Congress employed the word “otherwise” in modifying the term “available to the public.” Contrary to Teva’s suggestion, Congress inserted the word “otherwise” for a reason: to clarify that “the preceding clauses describe things that are of the same quality or nature as the final clause.” 157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl). Teva’s various examples—all of which apply the last-antecedent rule in cases involving the distinct term “other”—are therefore inapposite. *See, e.g.*, Teva Br. 45-46 (applying last-antecedent rule to list of animals ending with clause “or *other* dangerous animals”) (emphasis added); *Barnhart*, 540 U.S. at 27 (applying last-antecedent rule to prohibition on “throw[ing] a party or engag[ing] in any *other* activity that damages the house”) (emphasis added); *but see Paroline v. United States*, 134 S. Ct. 1710, 1720 (2014) (declining to apply last-antecedent rule to list of

statutory terms ending with clause or “any other losses suffered by the victim as a proximate result of the offense”).

A familiar example highlights the significance of Congress’s choice of words. The Administrative Procedure Act (APA) provides that a reviewing court must set aside agency action that is “arbitrary, capricious, an abuse of discretion, *or otherwise not in accordance with law.*” 5 U.S.C. § 706(2)(A) (emphasis added). Congress’s use of the term “otherwise” in the final clause makes clear that the previous terms—“arbitrary,” “capricious,” and “abuse of discretion”—similarly describe agency actions that are “not in accordance with law.” There is no way to accord a contrary meaning to the term “otherwise” in the APA, and doing so would upend decades of administrative law. Congress has used the term “or otherwise” to similar effect in dozens of provisions of the United States Code.¹ Teva cites no circumstance in which the term is susceptible to a contrary meaning.

Teva’s reliance (Teva Br. 47) on *Graham County Soil & Water Conservation District v. United States ex rel. Wilson*, 559 U.S. 280 (2010), is similarly unavailing. There, the

¹ See, e.g., 12 U.S.C. § 5517(a)(2)(B)(i) (describing Consumer Financial Protection Bureau authority over “debt that is delinquent *or otherwise in default*”) (emphasis added); 20 U.S.C. § 75e(1) (Board of Smithsonian may “purchase, accept, borrow, *or otherwise acquire*” art) (emphasis added); 31 U.S.C. § 5367(1) (regulating websites “at which unlawful bets or wagers may be placed, received, *or otherwise made*”) (emphasis added); 31 U.S.C. § 5364(a) (requiring the promulgation of regulations “to identify and block *or otherwise prevent or prohibit* restricted transactions”) (emphasis added); 42 U.S.C. § 2096(a) (Atomic Energy Commission may “purchase, take, requisition, condemn, *or otherwise acquire* supplies of source material”) (emphasis added).

Supreme Court held that the adjective “administrative” in a list of three types of reports—“congressional, administrative, or Government Accounting Office”—encompassed both state and federal administrative reports even though the other two listed adjectives encompassed only federal reports. *Id.* at 286, 293. In reaching that conclusion, the Court noted that the statutory term “‘administrative’ is not itself modified by ‘federal,’” and hence concluded that “there is no immediately apparent textual basis for excluding [non-federal activities] from its ambit.” *Id.* at 287. In this case, by contrast, Congress unambiguously described the term “on sale” as meaning “available to the public”—providing the very textual limitation absent in *Graham*.

The district court therefore correctly rejected Teva’s interpretation for failure to give effect to the term “or otherwise.” Teva contends (Teva Br. 55) that, under its interpretation, the residual clause “captur[es] new norms for disseminating information” not covered by the other listed categories of prior art. *See also* Amici Br. 20 (advancing a similar argument). Teva is surely correct that Congress enacted the AIA’s residual clause as a catchall to encompass publicly available inventions not captured by the preceding categories of prior art. But that does not explain why Congress modified the residual clause with the specific term “otherwise.” Because Congress does not use statutory terms superfluously, the only explanation is that Congress intended the residual clause both to operate as a catchall *and* to clarify that the preceding terms describe activities that similarly make an invention “available to the public.” *See Paroline*, 134 S. Ct. at 1721 (noting the “familiar canon of statutory

construction that catchall clauses are to be read as bringing within a statute categories similar in type to those specifically enumerated”) (alteration omitted).

B. For the foregoing reasons, the plain language of the AIA’s on-sale bar precludes Teva’s challenge to Helsinn’s post-AIA patent. The remaining arguments advanced by Teva and amici do not call that conclusion into doubt.

First, Teva and amici assume (Teva Br. 44-45; Amici Br. 18-19) that, prior to the AIA, Congress intended the on-sale bar to encompass secret sales, and that Congress cannot have intended to reverse course when it reenacted the statutory term “on sale.” This contention is doubly mistaken. As the government has explained in *The Medicines Company*, even before the AIA, Congress did not intend to encompass private sales within the on-sale bar. And in any event, while it is true that Congress is presumed to acquiesce to judicial interpretations of statutory language when it reenacts that language without change, *see Neder v. United States*, 527 U.S. 1, 21 (1999), Congress here specifically amended the relevant statutory language to reject prior judicial interpretations of the on-sale bar.

Teva wonders (Teva Br. 20, 44-45) why Congress declined to modify the term “on sale” directly with the adverb “publicly” if it sought to limit the on-sale bar to public sales. But the language that Congress enacted unambiguously accomplished that result, and further clarified that any other conduct by the inventor that makes an invention “available to the public” will likewise bar a later patent. Moreover, by retaining the phrase “on sale” without direct modification, Congress underscored that

the on-sale bar has *always* been limited to public sales and offers for sale. Where Congress modifies a statutory term with a limiting adjective, a negative inference may be drawn that the term previously included no such limitation. *See, e.g., Mudge v. United States*, 308 F.3d 1220, 1227 (Fed. Cir. 2002) (Congress’s amendment of the term “exclusive procedures” with adjective “administrative” indicated that original provision encompassed non-administrative procedures). Adopting Teva’s proposed language could have implied that the pre-AIA statute properly encompassed secret sales—the interpretation that Congress enacted the residual clause to reject.

Teva further argues (Teva Br. 51) that according the residual clause its plain meaning would amount to a “fundamental change[] in the scope” of the AIA, and that stronger evidence would be needed to demonstrate that Congress intended that result. *See also* Amici Br. 10 (natural reading of residual clause should be rejected because Congress would not have “radically” changed existing law through a mere “add-on phrase”). But the plain text of the AIA indisputably demonstrates Congress’s intent to limit the on-sale bar to sales or offers for sale that make an invention publicly available, and, in any event, the consequences of limiting the on-sale bar to public sales are less dramatic than Teva and amici suggest. As Teva acknowledges (Teva Br. 42-43), every other category of prior art in the corresponding provision of the pre-AIA Patent Act encompassed public information. *See Klopfenstein*, 380 F.3d at 1350) (explaining that “throughout our case law, public accessibility has been the criterion by which a prior art reference will be judged for the purposes of

§ 102(b)”). The AIA merely harmonizes the on-sale bar with these other categories of prior art.² And although Teva and amici are correct that Congress’s amendment of the on-sale bar will require this Court to revisit its secret-sale precedents for the AIA era, Congress amended the statute to achieve precisely that result—and thereby to clarify the “confused status” of the case law in this area. *See Atlanta Attachment*, 516 F.3d at 1368 (Prost, J., concurring). In the context of “the most substantial overhaul of the patent system in the past sixty years,” Mark A. Lemley, *Does “Public Use” Mean the Same Thing It Did Last Year?*, 93 Tex. L. Rev. 1119, 1119 (2015), Congress’s clarification of the on-sale bar’s scope was hardly radical.

Second, Teva and amici believe (Teva Br. 49-50; Amici Br. 15) that construing the on-sale bar to exclude secret sales would undermine the on-sale bar’s primary purpose, which, in their view, is to prevent “the extension of the patent monopoly.” They recognize (Teva Br. 49-50) that the public-use bar serves the distinct purpose of

² Although the public-use bar is limited by its plain terms to uses that are “public,” courts have construed that provision to encompass certain secret uses. *See Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1382 (Fed. Cir. 2005) (“there are instances in which a secret or confidential use of an invention will nonetheless give rise to the public use bar”); *D.L. Auld*, 714 F.2d at 1147 (construing *Metallizing Engineering* to hold that the public-use bar encompasses an inventor’s secret commercial use of his own invention). The AIA’s legislative history suggests an intent to overrule such cases. *See* 157 Cong. Rec. S1371 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (explaining that the AIA’s “new section 102(a)” will abrogate “extreme” cases involving secret public uses, which serve only “to create heavy discovery costs in every patent case, and to punish small inventors who are unaware of the pitfalls of the current definition of prior art”). This case, however, does not implicate the public-use bar, and the Court therefore need not address it.

preventing inventors from monopolizing knowledge in the public domain. Relying on *Metallizing Engineering* and its progeny, however, they argue that the on-sale bar serves the different function of preventing the extension of the inventor's exclusive rights.

Teva and amici misconstrue the primary purpose of the on-sale bar. Although this Court has stated that the public-use bar and the on-sale bar are “grounded on different policy emphases,” *Continental Plastic*, 141 F.3d at 1079, the Court has also recognized that “both the ‘on sale’ and ‘public use’ bars [a]re based on the *same* policy considerations”—*i.e.*, “the same reluctance to allow an inventor to remove existing knowledge from public use,” *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005) (emphasis added) (quotation marks omitted). And the Supreme Court has explained that Congress’s “reluctance to allow an inventor to remove existing knowledge from public use undergirds the on-sale bar.” *Pfaff*, 525 U.S. at 64.

Teva and amici therefore err in contending that Congress intended the on-sale bar to regulate secret activity. The on-sale bar instead advances the fundamental precept of patent law that an inventor should not be permitted to remove from the public domain “knowledge that is already available to the public.” *Bonito Boats*, 489 U.S. at 148. To a striking degree, the case law on which Teva and amici rely only exposes their error. *See, e.g.*, Teva Br. 48-49 (relying on *Pennock* for the proposition that an inventor loses his right to a patent where he “suffers the thing invented . . . to be *publicly* sold”) (emphasis added); Amici Br. 15 (relying on *Pennock*'s statement that

an inventor should not be able to withhold from “the *public* the secrets of his invention” while “sell[ing] his invention *publicly*”) (emphases added).

It is of course true that patent law encourages early disclosure of inventions in order to provide “the public at large a right to . . . use[] and vend the thing invented, at as early a period as possible.” *Pennock*, 27 U.S. at 19. As explained above, however, Congress’s shift from a first-to-invent system to a first-inventor-to-file system provides a powerful incentive for inventors to file early for patent protection. Moreover, as many amici in *The Medicines Company* have explained, treating secret sales as invalidating acts under the on-sale bar has the practical effect of favoring large and sophisticated inventors over smaller ones. Teva and amici offer no reason why the patent laws should permit a large company to manufacture a product in-house without triggering the on-sale bar while forbidding an individual inventor from manufacturing the same product through a non-disclosing contract with a third-party supplier. The individual inventor is no more extending his patent monopoly than the large company, but the secret-sale doctrine treats them differently. See *Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc.*, 726 F.3d 1370, 1375 (Fed. Cir. 2013) (invalidating a patent where the offer for sale “was made by [the patentee’s] own supplier and was made to [the patentee] itself”). This case—in which a family-owned company contracted with third-party manufacturers in order to produce a drug in sufficient quantities to complete Phase III clinical trials, satisfy the FDA’s new drug approval

requirements, and bring the drug to market (D. Ct. Op. 30-33, 55-61)—highlights the unfair and incongruous results produced by the pre-AIA rule.

Congress obviated the need to read into the on-sale bar an atextual “supplier exception” by clarifying that confidential transactions—that is, sales and offers for sale that do not make the invention available to the public—do not trigger the on-sale bar. Teva’s suggestion (Teva Br. 50-51) that the Constitution’s Intellectual Property Clause, U.S. Constitution, Article I, Section 8, prohibited Congress from making that policy judgment is plainly meritless. Legislation enacted under that Clause is subject to judicial review only to ensure that Congress had a rational basis for its policy choices. *See Figueroa v. United States*, 466 F.3d 1023, 1032 (Fed. Cir. 2006). Congress had numerous rational bases for clarifying that the on-sale bar reaches only public sales, including reducing the expense and burden associated with identifying invalidating sales; harmonizing United States patent law with the laws of other industrialized nations; and promoting the equal treatment of large companies and small inventors.

Third, Teva and amici err in suggesting that the AIA’s grace-period provision, 35 U.S.C. § 102(b), implies that nonpublic sales qualify as prior art. Section 102(b) provides for two distinct grace periods. The first, located in section 102(b)(1), creates a one-year grace period for prior art described in section 102(a)(1)—the provision which includes the on-sale bar and encompasses only publicly available prior art. The second, located in section 102(b)(2), creates a grace period for prior art described in

section 102(a)(2)—the provision that includes patent applications as prior art. Under the AIA, a patent application becomes prior art as soon as it is filed, *see id.* § 102(d) (cross-referencing section 102(b)(2)), even though most patent applications are not published—and thus are not available to the public—until eighteen months after they are filed. *See id.* § 122. Accordingly, it is undisputed that the section 102(b) grace periods *do* encompass certain nonpublic prior art, which explains Congress’s distinction between “disclosures” and “public disclosures.”

That “disclosures” may include nonpublic prior art (*i.e.*, unpublished patent applications) also explains Congress’s language in the “first-to-publish” grace period of section 102(b)(1)(B), which provides that a third party’s disclosure of an invention less than a year before the inventor files for a patent will not be prior art if “the subject matter disclosed had, before such disclosure, been *publicly* disclosed by the inventor.” 35 U.S.C. § 102(b)(1)(B) (emphasis added). This provision creates a one-year grace period, starting on the date an inventor discloses an invention to the public, during which even disclosures of the same invention by third parties will not be deemed patent-defeating prior art. Congress’s use of the term “disclosed” to describe third-party disclosures reflects that certain prior art may be nonpublic, and its distinct use of the term “publicly disclosed” to describe the inventor’s own disclosure clarifies that an inventor may not remove subsequent third-party disclosures from the prior art merely by sharing the subject matter privately. *See* 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011) (statement of Sen. Leahy) (explaining that the disclosure provisions

were “deliberately couched in broader terms than subsection 102(a)(1)” and that “any disclosure by the inventor whatsoever, whether or not in a form that resulted in the disclosure being available to the public, is wholly disregarded as prior art”).

The contrary argument that Teva and amici advance cannot be correct. Even this Court’s pre-AIA secret-sale jurisprudence recognizes that only secret commercial activity involving *the inventor himself* triggers the on-sale bar, and that secret commercial activity involving only third parties does not. *See W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983) (prior secret sales by inventor can bar patent, but “secret commercialization of a process [by third parties]” does not bar “the grant of a patent to [the inventor] on that process”). Section 102(b)(1)(B), however, refers to the acts of third parties as “disclosures” rather than “public disclosures.” If Teva and amici were correct that section 102(b)(1)(B)’s reference to “disclosures” encompasses secret sales, that would mean that even the secret sale of an invention by a third party would operate as prior art. Congress cannot plausibly have intended to *expand* the universe of secret prior art when it added the residual clause limiting the on-sale bar to sales that make an invention “available to the public.”

Fourth, Teva and amici mischaracterize the legislative record. Teva ignores (Teva Br. 60) that the language that became the residual clause was introduced by the Senate Judiciary Committee in 2007. *See* S. 1145, § 2(b)(1), 110th Cong. (reported bill). The Committee Report for that bill explained that the clause was added to “emphasize the fact that [prior art] must be publicly available.” S. Rep. No. 110-259,

at 9 (Jan. 24, 2008). When the full Senate considered the bill in March 2011, Senator Kyl noted that the on-sale bar “imposes a public-availability standard on the definition of all prior art.” 157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl). One day later, Senator Leahy explained that the language was “drafted in part to do away with precedent under current law that private offers for sale or private uses . . . may be deemed patent-defeating prior art.” 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011) (statement of Sen. Leahy); *see also id.* (statement of Sen. Hatch) (a disclosure will “not constitute patent-defeating prior art under 102(a)” if it “is not made available to the public”).

Three weeks after the Senate bill passed, the House Judiciary Committee introduced a revised patent reform bill that became the AIA. *See* H.R. 1249, 112th Cong. (as introduced) (Mar. 30, 2011). That House bill adopted the residual clause verbatim. *Id.* § 3(b)(1). If there were any doubt that the House intended to adopt the Senate’s interpretation of the residual clause, the House Committee Report erases that doubt, explaining that the clause was added to “emphasize the fact that [prior art] must be publicly available” and citing the statements of Senators Kyl, Leahy, and Hatch that the clause eliminates private sales as prior art. H.R. Rep. No. 112-98, at 43 & n.20. Thus, though this Court need not rely on the AIA’s legislative history to conclude that the on-sale bar encompasses only public sales, the legislative record wholly supports that conclusion.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 2, 2016, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 32(a). This brief contains 6,495 words.

s/ William E. Havemann

WILLIAM E. HAVEMANN