No. 16-1284, -1787

In the United States Court of Appeals for the Federal Circuit

---

HELSINN HEALTHCARE S.A.,
PLAINTIFF-APPELLEE

v.

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD.,
DEFENDANTS-APPELLANTS

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY, NO. 3:11-CV-5579, 5815, 3962
HON. MARY COOPER, PRESIDING

BRIEF IN OPPOSITION TO REHEARING EN BANC

GEORGE C. LOMBARDI
JULIA M. JOHNSON
TYLER G. JOHANNES
Winston & Strawn LLP
35 W. Wacker Drive
Chicago, IL 60601
(312) 558-5600

STEFFEN N. JOHNSON
JOVIAL WONG
ANDREW C. NICHOLS
Winston & Strawn LLP
1700 K Street, N.W.
Washington, DC 20006
(202) 282-5000
sjohnson@winston.com

Counsel for Defendants-Appellants
Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd.

CERTIFICATE OF INTEREST

Pursuant to Circuit Rule 47.4, undersigned counsel for Defendants-Appellants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. certifies the following:

1. The full name of every party or amicus represented by us is:

   Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by us is:

   Not applicable.

3. All parent corporations and any publicly held companies that own 10% or more of the stock of any party represented by us are:

   The parent companies of Teva Pharmaceuticals USA, Inc. are: Orvet UK Unlimited, Teva Pharmaceutical Holdings Cooperative U.A., Ivax LLC (f/k/a IVAX Corporation), Teva Pharmaceuticals Europe, B.V., and Teva Pharmaceutical Industries Ltd.; Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Pharmaceuticals USA, Inc. Teva Pharmaceutical Industries Ltd. has no parent company, and no publicly traded company owns 10% or more of Teva Pharmaceutical Industries Ltd.

4. The names of all law firms and the partners or associates that appeared for the parties now represented by us in the trial court or expected to appear in this court are:

   Winston & Strawn LLP (George Lombardi, Steffen Johnson, Lynn MacDonald Ulrich, Jovial Wong, Julia Johnson, Andrew Nichols, Lindsay Beyer, Brandon Barker, Karl Leonard, Tyler Johannes, David Luger); Lite DePalma Greenberg, LLC and Patunas Tarantino LLC (Michael Patunas, Mayra Tarantino).

Dated: August 25, 2017

/s/ *Steffen N. Johnson*
STEFFEN N. JOHNSON
Counsel for Defendants-Appellants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

LEGISLATIVE HISTORY

OTHER AUTHORITIES

INTRODUCTION

Helsinn has not shown that the panel's unanimous, fact-bound ruling satisfies the "exceptional importance" or "uniformity" requirements of FRAP 35. The panel declined to rule "more broadly than necessary," holding only that "the AIA did not change the statutory meaning of 'on sale' in the circumstances involved here." Op. 3, 21. The panel "d[id] not find that distribution agreements will always be invalidating under [the AIA]. [It] simply f[ound] that this particular Supply and Purchase Agreement is." Op. 27. Thus, as Helsinn's amicus notes, the panel "tailor[ed] its holding" and "cabin[ed] [it] to the facts." BPLA Br. 4. Indeed, Helsinn itself appears not to contest the panel's core holding—disclaiming the position "that an invalidating offer requires disclosure of 'the details of the … invention.'" Pet. 10.

In any event, that holding is compelled by the AIA's text, structure, and drafting history. As this Court has repeatedly held, the phrase "on sale" naturally includes both public and private sales. In adding the phrase "otherwise available to the public" to §102, Congress simply confirmed that public disclosures always bar patentability—even when made orally, or via new technologies. Earlier decisions held that "printed publication" did not capture oral presentations, sound recordings, or video footage. *In re Klopfenstein*, 380 F.3d 1345, 1349 n.4 (Fed Cir. 2004) (oral); *Diomed, Inc. v. Angiodynamics, Inc*., 450 F. Supp. 2d 130, 141 (D. Mass. 2006) (video). By adding a catchall clause, Congress addressed these "known unknowns."

As the panel recognized, "[i]f Congress intended" to do more—making "a sweeping change to our on-sale bar jurisprudence"—"it would do so by clear language." Op. 26 (citation omitted). "Fundamental changes in the scope of a statute are not typically accomplished with so subtle a move" (*Kellogg Brown & Root Servs., Inc. v. U.S. ex rel. Carter*, 135 S. Ct. 1970, 1977 (2015)), and Helsinn concedes that "on sale" was a "term[] of art" under prior precedent—an "established term[]" that has always been listed with "public" activities, yet covered non-public sales. Opp. Br. 41; *see* Op. 18-19 & n.7, 23-26 (citing numerous decisions holding that "on sale" covers non-public sales). "[W]hen Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached." *Air Wis. Airlines Corp. v. Hoeper*, 134 S. Ct. 852, 861-62 (2014).

Helsinn does not address numerous other points supporting the panel's decision. For example, if Congress meant to change the settled meaning of "on sale," it could have added one word—"publicly"—to match the surrounding bars. Further, reading "otherwise available to the public" to modify each statutory bar creates several awkward redundancies (e.g., "in public use *available to the public*"). And the Act's next subsection distinguishes between "disclosures" and "public disclosures"—an incoherent distinction if all §102(a) disclosures are public.

Helsinn repeatedly criticizes the panel for observing that "the existence of the sale" here was public (Pet. 1, 13), but that just makes this an especially easy case.

The same is true of Helsinn's disclosure of all "pertinent details" of the sale "other than the price and dosage." Op. 22. Helsinn cites no cases with similar facts. Thus, this case is a poor vehicle to address the on-sale bar's ultimate scope. These facts are not recurring, and the Court may take up more common issues when they arise. Op. 21-22 ("we decline to address" "cases [that] involved a public use where the invention was not … disclosed to the public" or "'secret sale' cases"). Not surprisingly, the United States, after participating in the panel proceedings, does not support review, foreclosing the notion that the ruling will disrupt the PTO's operations.

Finally, Helsinn's claim of a conflict with circuit precedent relies solely on *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) (en banc) ("*MedCo*."), a *pre*-AIA case involving an upstream supply agreement rather than, as here, a downstream distribution agreement. Even then, Helsinn ignores the panel's reaffirmation of *MedCo*.'s teaching that "confidentiality," while not dispositive, "weighs against application of the on-sale bar." Op. 18. There is no conflict.

En banc review is not "favored." FRAP 35(a). Given the fact-bound nature of the panel's unanimous decision, Helsinn's further narrowing of the dispute, and the decision's consistency with text, structure, precedent, and drafting history, this case is no exception.

ISSUE STATEMENT

Whether the full Court should review the unanimous panel's correct and fact-bound ruling that Helsinn's publicly disclosed sale to another company, which authorized that company to distribute Helsinn's claimed invention over one year before the priority patent application was filed, triggered the AIA's on-sale bar.

BACKGROUND

This case involves a low-dosage formulation of palonosetron, a drug long used to treat chemotherapy-induced nausea and vomiting. In 2001—over a year before it sought the relevant patent—Helsinn entered a Supply and Purchase Agreement with MGI Pharma, Inc., wherein MGI agreed "to distribute, promote, market, and sell" Helsinn's later-patented "0.25 mg and 0.75 mg palonosetron products, or whichever of the two dosages were approved for sale by FDA." Op. 12, 7.

MGI disclosed the sale, and a partially redacted copy of the MGI Agreement, to the SEC. Op. 6. Together, the parties publicly announced the Agreement. Just "two features … were not publicly disclosed"—the drug's "price" and "specific dosage formulations." Op. 8.

Later, when Helsinn sued Teva for infringement, Teva answered that the MGI Agreement triggered the on-sale bar, which prohibits issuing a patent where, more than a year before the priority date, "the claimed invention was patented, described

in a printed publication, or in public use, on sale, or otherwise available to the public." 35 U.S.C. §102(a)(1). The district court recognized that the Agreement "was a contract for a future commercial product." A113. Nevertheless, it held the on-sale bar inapplicable, reasoning that the invention was not "ready for patenting" by the critical date and was not made "available to the public."

The panel unanimously reversed. On the "ready for patenting" issue, it held that the district court applied "too demanding a standard," finding "overwhelming" evidence that, before the critical date, "the patented invention would work for its intended purpose." Op. 30. Concerning whether the MGI Agreement triggered the on-sale bar, the panel affirmed that the Agreement "constituted a sale of the claimed invention—the 0.25 mg dose—before the critical date." Op. 27. The Agreement "described the palonosetron formulation in detail and Helsinn does not assert that the 0.25 mg dose described in the [MGI] Agreement does not embody the asserted claims." Op. 17. Helsinn does not challenge these holdings.

The panel also held that the MGI Agreement placed the invention "on sale." In so holding, the panel stated that the AIA "did not change the statutory meaning of 'on sale' in the circumstances involved here." Op. 3. Although some legislators may have wished to overturn certain "secret or confidential sale cases," that "would have no effect" where, as here, "the existence of a sale" was "public." Op. 21.

The panel reaffirmed that "the confidential nature of a transaction … counsel[s] against applying the on-sale bar," but declined to hold that the AIA required disclosing the invention's "details." Op. 12, 18, 22-27. "If Congress intended to work … a sweeping change to our on-sale bar jurisprudence," the panel stated, "it would do so by clear language." Op. 26. Further, the legislative history nowhere suggested that Congress overruled this Court's numerous decisions "explicitly reject[ing] a requirement that the details of the invention be disclosed." Op. 23, 26. Accordingly, Helsinn's sale to MGI triggered the on-sale bar.

REASONS FOR DENYING REVIEW

The panel's unanimous, fact-bound ruling correctly determined that the on-sale bar was triggered here, and raises no issue of exceptional importance or divided precedent.

A. The AIA's text, structure, history, and purpose support the panel's ruling that the sale need not disclose the invention's details.

Applying the plain terms of the AIA's on-sale bar, the panel correctly held that selling an invention will bar a patent even if "the details" are not disclosed. Op. 22-27. As the panel recognized: "If Congress intended to work … a sweeping change to our on-sale bar jurisprudence," "it would do so by clear language." Op. 26 (citation omitted); *see Kellogg*, 135 S. Ct. at 1977 ("Fundamental changes in the scope of a statute are not typically accomplished with so subtle a move."). In adding the phrase "otherwise available to the public" to §102, Congress simply confirmed

that public disclosures will always bar patentability—even when made orally, or via new technologies, rather than, as before, in a "printed publication."

1. Helsinn concedes that "on sale" is a term of art that has long covered sales that do not disclose the invention's details, and Congress did not overrule this longstanding interpretation.

Helsinn concedes that "on sale" was a "term[] of art" under prior precedent—an "established term[]" that has always been listed with "public" activities, yet also captured sales that conceal the invention's details. Opp. Br. 41. The panel agreed, citing numerous precedents holding that "on sale" covers non-public sales. Op. 18-19 & n.7, 23-26. And "when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached." *Hoeper*, 134 S. Ct. at 861-62.

Moreover, had Congress wished to overrule the settled interpretation of "on sale," it could have added just one word—"publicly." That is how Congress limited the surrounding bars, and "Congress generally acts intentionally when it uses particular language in one [part] of a statute but omits it in another"—particularly where the disparate terms appear "repeatedly" or "in the same sentence." *Dep't of Homeland Sec. v. MacLean*, 135 S. Ct. 913, 919-20 (2015) (citations omitted).

Helsinn's main argument—that "otherwise available to the public" is a "series modifier" that "restrict[s]" every preceding term to public activities (Pet. 6)—creates glaring redundancies. The series-modifier rule applies only "[w]hen several words are followed by a clause which is applicable as much to the first and other words as

to the last." *Paroline v. United States*, 134 S. Ct. 1710, 1721 (2014). But §102(a)'s catchall clause is *not* equally applicable "to the first and other words as to the last," because all those words except two—"on sale"—are by definition public or pre-labeled as public.

Section 102(a)(1) bars granting a patent if "the claimed invention was *patented*, described in a printed *publication*, or in *public* use, on sale, or otherwise available to the public" (emphases added). "Patented" needed no modification because "[p]atents are public records." *Boyden v. Burke*, 55 U.S. 575, 582 (1852). The same is true of "printed *publications*" and items "in *public* use." *Klopfenstein*, 380 F.3d at 1348 ("the key inquiry" is whether references are "publicly accessible"). To read "otherwise available to the public" as modifying these terms creates "hopeless[] redundan[cies]" (*Lockhart v. United States*, 136 S. Ct. 958, 965 (2016))—such as "in public use *available to the public*." And the series-modifier rule is inapplicable where "it takes more than a little mental energy to process the individual entries in the list, making it a heavy lift to carry the modifier across them all." *Id*. at 963.

Moreover, if all details of the invention were publicly disclosed in sale documents, the invention would be anticipated by a printed publication—leaving the on-sale bar no work to do. But "[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous." *Hibbs v. Winn*, 542 U.S. 88, 101 (2004).

Most importantly, as to "on sale"—the only item not pre-labeled or inherently public—Congress conspicuously declined to say "*publicly* on sale." Opening Br. 42-48. By contrast, none of Helsinn's cases involved a similar series. In *United States v. Standard Brewery, Inc.*, 251 U.S. 210, 218 (1920), for example, the statute referred to "beer, wine, or other intoxicating [beverages]." But to be analogous to §102(a), either "beer" or "wine" would have to be pre-labeled as "intoxicating." And since the catchall phrase is not a series modifier, it falls within the general rule that a "limiting clause" applies "only to the last antecedent." *Barnhart v. Thomas*, 540 U.S. 20, 27 (2003). Here, this means "to the public" limits only "otherwise available." Opening Br. 53-54.

2. Helsinn's reading is foreclosed by §102(b), which expressly distinguishes between public and private disclosures.

Helsinn admits that courts must consider "a statute's full text," "structure," and design "as a whole" (Pet. 5, 11), but its reading nullifies critical language in §102's next subsection—which distinguishes between "disclosures" and "public disclosures." Specifically, §102(b)(1) provides "[e]xceptions" to §102(a)—including a grace period whereby "[a] disclosure made 1 year or less before" the filing date "shall not be prior art … if" either "(A) the disclosure was made by the inventor"; or "(B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor." Thus, an inventor's "'disclosure' … will not bar her from

patenting … within a year after that disclosure"; and an inventor's "public disclosure" immunizes her application "from *all* prior art, not just [her own]." Lemley, *Does "Public Use" Mean the Same Thing It Did Last Year?*, 93 Tex. L. Rev. 1119, 1128 (2015).

If, as Helsinn posits, *all* §102(a) disclosures are "public," then distinguishing between "disclosures" and "public disclosures" is incoherent. But if "'public use' and 'on sale' have the same meaning they have always had"—if "on sale" captures private sales—"the distinction between disclosures and public disclosures makes sense." *Id*. Why? Because "'disclosures' means all types of 'prior art' … and that includes some that are not public." *Id*.; *see* 42 Intellectual Property Professors' Amicus Br. (Dkt. 43) 2-5.

Helsinn and its *amici* nowhere address this point.

3. Congress rejected bills that did what Helsinn wishes.

As the panel recognized, Helsinn's legislative history argument "primarily relies on floor statements," which "are typically not reliable." Op. 19. Indeed, "even a bill's sponsor['s views] are not controlling." *Mims v. Arrow Fin. Servs., LLC*, 132 S. Ct. 740, 752 (2012). And Helsinn's own case acknowledges that "[r]esort to legislative history"—including committee reports—"is only justified where the face of the Act is inescapably ambiguous." *Garcia v. United States*, 469 U.S. 70, 76 n.3, 79

(1984); *see also Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568 (2005) (criticizing "reliance" on "committee reports"). That is not so here.[1]

Yet the panel rightly recognized that, even taken on their own terms, the floor statements "[a]t most" voiced concern with "extreme" cases holding "certain secret uses to be invalidating under the 'public use' [bar]"; the statements "do not identify any sale cases that would be overturned," and "[e]ven if the floor statements were intended to overrule th[e] secret or confidential sale cases," "that would have no effect here since those cases were concerned entirely with whether the existence of a sale or offer was public." Op. 21.

Further, Congress "reject[ed] … the very language that would have achieved the result [that Helsinn] urges here," which "weighs heavily against [Helsinn's] interpretation." *Hamdan v. Rumsfeld*, 548 U.S. 557, 579-80 (2006). Early bills proposed repealing the on-sale bar, thus "eliminating confidential sales and other secret activities as grounds for invalidity." 154 Cong. Rec. 22,631 (2008) (Sen. Kyl). But consider how the legislation evolved:

2005	"(1) the claimed invention was patented, described in a printed publication, *or otherwise publicly known*" (H.R. 2795)
2006	"(1) the claimed invention was patented, described in a printed publication, *or otherwise publicly known*" (S. 3818)

[1] The House Committee Report here merely referenced Senate floor statements, and only for the unrelated fact that the "'current law's grace period' 'is maintained.'" Opening Br. 58 & n.9.

2008 "(1) the claimed invention was patented, described in a printed publication, *or otherwise made available to the public (other than through testing undertaken to reduce the invention to practice)*" (S. 3600)

2011 "(1) the claimed invention was patented, described in a printed publication, *or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention*" (H.R. 1249)

Thus, from 2005 to 2008, the bills included an "otherwise available" catchall clause while eliminating the on-sale bar. By 2011, however, it was back to stay.

Having failed in committee, some senators insisted that §102 did not mean what it said. But these statements are "strategic manipulations of legislative history to secure results [members] were unable to achieve through the statutory text." *Exxon*, 545 U.S. at 568. And courts may "not assume that Congress intended to enact statutory language that it has earlier discarded." *Chickasaw Nation v. United States*, 534 U.S. 84, 93 (2001).

Thus, the legislative history here supports the panel's conclusion.

4. Helsinn's policy arguments do not support review.

Helsinn's policy arguments would not justify en banc review even if they had merit, but they are unfounded.

a. Helsinn and its *amici* say the decision leaves the PTO without guidance. Pet. 3; IP Owners' Br. 6-8; PhRMA Br. 6-8. But the United States, which filed at the merits stage and has reason to highlight any practical difficulties created by the

decision, did not support review. Nor is that surprising. The panel ruled narrowly, preserving *Medco*.'s teaching that confidentiality "counsel[s] against applying the on-sale bar." Op. 12. Further, the PTO's guidance states only that a "secret sale or use activity does not qualify as prior art" (78 Fed. Reg. 11062-63 (Fed. 14, 2013))—and here, as the panel noted, the sale was publicized. Op. 27.

b. Next, Helsinn says the ruling conflicts with Congress's "remov[al of] the geographical restrictions of [§102(b)]," which "limited the public-use and on-sale bars to activities occurring 'in this country.'" Pet. 1. But that is no reason to think the meaning of "sale" changed. The geographic limitation is unnecessary "[g]iven advances in communications technology and transportation" that provide knowledge "about activities in a foreign land." H.R. Rep. No. 110-314, at 57 (2007).

c. Helsinn complains that the ruling harms small drug companies, which "rely on pre-launch confidential distribution agreements" to "ensure the ability to launch upon FDA approval," and companies with "regulatory disclosure obligations." Pet. 13-15. Not so. As the panel recognized (in a ruling that Helsinn does not challenge), the "completion of Phase III studies and final FDA approval are not pre-requisites for the invention here to be ready for patenting"; and Helsinn's data "consistently showed that the invention worked"—"from the final report for the 1995 Phase II trial" onward. Op. 30, 34. Thus, small companies can avoid the on-sale bar simply by applying for a patent sooner—potentially up to one year after any sale.

d. Helsinn next says the decision, by requiring "discovery-intensive searches for secret offers for sale," interferes with Congress's "purpose" of "creating efficient post-grant review proceedings." Pet. 13. But even if post-grant reviews are less likely in cases involving foreign prior art, the AIA makes relevant "all prior uses or sales worldwide." Crawley, *America Invents Act: Promoting Progress or Spurring Secrecy?*, 36 U. Haw. L. Rev. 1, 8 (2014). Thus, Congress's purpose was broader than streamlining post-grant proceedings, and courts are not "simplistically to assume that whatever furthers" one "[statutory] objective must be the law." *Rodriguez v. United States*, 480 U.S. 522, 526 (1987).

e. The same problem afflicts Helsinn's point that the panel's ruling "thwarts Congress's goal of harmonizing prior art rules" with international practice. Pet. 12. The AIA harmonized U.S. and foreign law in some ways, but not others. For example, some "foreign patent systems" do not have "grace period rules," but Congress provided a grace period "[i]n a significant number of cases." Merges, *Priority and Novelty Under the AIA*, 27 Berkeley Tech. L.J. 1023, 1030, 1032 & n.25 (2012). Further, reading the "otherwise available" clause to capture disclosures not "described in a printed publication" itself harmonizes U.S. and foreign law.

B. Helsinn's repeated criticism of the panel's emphasis on the public fact of the sale underscores the narrowness of this dispute.

Rather than address broader questions, the panel concluded that under the AIA "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." Op. 23. Finding those circumstances present, the panel held that the on-sale bar had been triggered. Op. 27; *see* Op. 16 (patentees "must unambiguously place the invention on sale, as defined by the patent's claims," and "that is clearly the case here"); Op. 21 ("the existence of the sale" was "public"). It is this aspect of the opinion that Helsinn repeatedly criticizes. Pet. 1-3, 8, 13-15. Apparently Helsinn believes that, to trigger the on-sale bar, disclosing "the *existence*" of the sale is not enough (*id*.), disclosing "the *details*" of the invention is more than enough (Pet. 10), but disclosing the invention without the details is just right.

Helsinn does not elaborate on its "Goldilocks" theory, but its position confirms that it faults the panel's *application* of its legal framework, not the framework itself. Helsinn objects that the on-sale bar was triggered here, where the transaction "disclosed all the pertinent details of the transaction other than the price and dosage levels." Op. 22. That fact-pattern is limited to "the circumstances involved here" (Op. 3), and does not warrant full-Court review. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 469 F.3d 1039, 1043 (Fed Cir. 2006) (Lourie, J., concurring in denial of rehearing) ("case-specific" questions "do[] not … raise a question of uniformity of decision or exceptional importance"). Indeed, the public nature of Helsinn's sale makes this an especially easy case.

Moreover, by emphasizing Helsinn's announcement of the sale, the panel furthered Congress's purpose in reenacting the term "on sale"—preventing commercial exploitation of otherwise-secret inventions. Even before Congress adopted the on-sale bar, the Supreme Court held that, if inventors could exploit inventions while "hold[ing] back from the knowledge of the public the secrets [thereof]," and later "take out a patent," that "would materially retard the progress of science." Op. 23 n.10 (quoting *Pennock v. Dialogue*, 27 U.S. 1, 19 (1829)). Inventors who publicize their sales benefit even more—by intimidating the competition.

Helsinn says there is no "substantial risk of secret pre-filing exploitation" because, "under the AIA's first-to-file system, a patentee is incentivized to file" early. Pet. 11. But many inventions, including "manufacturing processes," are "easily concealable"; and inventors "could keep their process inventions secret for years or even decades and then surface and file a patent application"—"tak[ing] an existing industry by surprise." Lemley, 93 Tex. L. Rev. at 1132. This would violate *Pennock*'s teaching, rooted in the Constitution (Art. I, §8, cl. 8), that such delays "retard the progress of science." 27 U.S. at 19. It would be still more perverse to allow inventors to *tell* the public that they were exploiting their inventions, while concealing their details. Such announcements favor applying the on-sale bar.

C. The panel's decision does not conflict with *Medicines Co*.

Finally, arguing that the on-sale bar is not triggered by "mere preparations for commercial sales" (*MedCo*., 827 F.3d at 1377), Helsinn asserts a conflict with Circuit precedent. Pet. 14-15. But *MedCo*. is a pre-AIA decision involving a supplier agreement to "outsource manufacturing"—"pre-commercial activity." 827 F.3d at 1378, 1377. This case involves an agreement "to distribute, promote, market, and sell" a finished product (Op. 12)—a classic sale "for commercial marketing purposes." *MedCo*., 827 F.3d at 1376. There is no conflict.

CONCLUSION

Rehearing should be denied.

Respectfully submitted,

/s/ Steffen N. Johnson

GEORGE C. LOMBARDI
JULIA M. JOHNSON
TYLER G. JOHANNES
Winston & Strawn LLP
35 W. Wacker Drive
Chicago, IL 60601
(312) 558-5600

STEFFEN N. JOHNSON
JOVIAL WONG
ANDREW C. NICHOLS
Winston & Strawn LLP
1700 K Street, N.W.
Washington, DC 20006
(202) 282-5000
sjohnson@winston.com

Counsel for Defendants-Appellants
Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd.

AUGUST 25, 2017

CERTIFICATE OF SERVICE

I certify that, on August 25, 2017, I caused the foregoing Brief in Opposition to Rehearing En Banc to be electronically filed with the Clerk of Court using the CM/ECF system, and thereby served via CM/ECF on counsel for Plaintiffs-Appellees.

Date: AUGUST 25, 2017

/s/ Steffen N. Johnson
STEFFEN N. JOHNSON
Counsel for Defendants-Appellants

CERTIFICATE OF COMPLIANCE
WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 3,897 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in 14-point Times New Roman, a proportionally spaced typeface, using Microsoft Word 2010.

Dated: AUGUST 25, 2017

/s/ Steffen N. Johnson
STEFFEN N. JOHNSON
Counsel for Defendants-Appellants