No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A., PETITIONER

v.

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

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

REPLY BRIEF FOR THE PETITIONER

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REPLY BRIEF FOR THE PETITIONER

Faced with an indefensible Federal Circuit opinion, respondents resort to comically bad misdirection. Respondents repeatedly assert that this case is a poor vehicle for the Court's review because petitioner is merely challenging the Federal Circuit's factual determination that petitioner disclosed its invention in detail to the public. But the Federal Circuit made no such determination; at most, the court noted that petitioner disclosed its invention *confidentially to its partner MGI*, and the court did so in analyzing whether petitioner's agreements with MGI invalidated its *pre-AIA* patents—a question that is not even presented here. As to petitioner's post-AIA patent, the Federal Circuit held, as a matter of law, that a

sale that does *not* disclose (or otherwise make available) the invention to the public nevertheless qualifies as prior art under the AIA's on-sale bar as long as the *fact* of the sale is known. It is that question of statutory interpretation on which petitioner seeks this Court's review, and there is no obstacle to the Court's reaching and resolving that question here.

Once their pervasive mischaracterization is taken away, respondents have little left to say. Parroting the Federal Circuit, respondents attempt to characterize the decision below as limited to the facts of this case. But a court of appeals cannot shield its opinion from this Court's review simply by including such a disclaimer, and the Federal Circuit's opinion announces a broad interpretation of the AIA's on-sale bar in Section 102(a)(1). The overwhelming support petitioner has received from diverse amici on that question of law underscores the importance of this case and highlights the urgent need for the Court's intervention.

Finally, respondents' brief is most remarkable for what it does not do: namely, defend the Federal Circuit's reasoning on the merits. There is an explanation for that omission: the Federal Circuit used a manifestly unsound method of interpretation to reach a conclusion untethered to the statutory text. While respondents devote most of their brief to the merits of the statutory-interpretation question (belying their assertions that the decision below was "narrow" and "fact-bound"), they rely not on the Federal Circuit's opinion, but on arguments made by Judge O'Malley in her subsequent effort to clean up that opinion. Respondents are of course free to advance those arguments at the merits stage if the Court grants certiorari. But no matter how it is defended, the Federal Circuit's interpretation of Section 102(a)(1) is profoundly flawed.

This case is an obvious candidate for further review, and the petition for a writ of certiorari should be granted.

1. Starting with their reformulation of the question presented, respondents repeatedly insist that this case is a poor vehicle because petitioner purportedly seeks review of "the Federal Circuit's factual conclusion that [its] sale agreement with a third party publicly disclosed its claimed invention 'in detail.'" Br. in Opp. i (quoting Pet. App. 33a); see *id.* at 16-19.

That is a wild and disingenuous contention. For starters, petitioner does not "challenge" any of the Federal Circuit's "factual conclusion[s]." Br. in Opp. 17 (emphasis omitted). As petitioner unconditionally stated in the petition, "this Court may assume that the Federal Circuit correctly determined that the MGI agreements satisfy the pre-AIA on-sale bar; it is the Federal Circuit's core holding about the effect of the AIA that demands this Court's review." Pet. 33. Petitioner is here challenging the interpretation of the AIA's on-sale bar—a question, the Federal Circuit recognized, that is "ultimately a question of law." Pet. App. 27a.

In any event, respondents' claim that petitioner disclosed the claimed formulation "in detail" to the public mischaracterizes both the record and the decision below. As to the record: respondents do not cite anywhere in the Federal Circuit that they made such a claim about petitioner's purported public disclosure. As petitioner has noted, they did not in fact do so. See Pet. 11.[1] Indeed, at oral argument below, counsel for respondents conceded that the "details of the formulation" "w[ere] not described

[1] Respondents claim they made such an argument at page 12 of their reply brief in the Federal Circuit. See Br. in Opp. 17. But respondents made no such argument either on that page (where they were discussing the pre-AIA on-sale bar) or anywhere else in their Federal Circuit briefs.

publicly." C.A. Oral Arg. at 5:30-5:38 (Oct. 4, 2016) <tinyurl.com/c-a-argument>.

As to the decision below: the Federal Circuit made no finding that petitioner had disclosed its claimed formulation to the public. The Federal Circuit addressed the on-sale bar in two separate sections of its opinion, corresponding to the pre- and post-AIA versions of the bar. It first considered whether three patents issued before enactment of the AIA were "subject to a sale or offer for sale prior to the critical date." Pet. App. 28a. Applying its pre-AIA precedent, the Federal Circuit determined that a sale had occurred. In so doing, the court observed that petitioner had "described the [claimed] formulation in detail" *in its confidential agreements with MGI*. *Id.* at 33a. It is this statement in the pre-AIA discussion that respondents misleadingly cite in their reformulated question presented (and at least ten times in the body of their brief). See Br. in Opp. i, 1, 2, 10, 11, 14, 18, 19.

The Federal Circuit then proceeded to "address whether * * * there was [a] qualifying sale" with respect to the remaining patent in suit. Pet. App. 35a. Because that patent issued after the effective date of the AIA, the court had to confront the question presented here: namely, whether an inventor's sale of an invention to a third party obligated to keep the invention confidential qualifies as prior art under the AIA's on-sale bar. The Federal Circuit answered that question in the affirmative, concluding that Congress did not "intend[] to work * * * a sweeping change to [the Federal Circuit's] on-sale bar jurisprudence" when it enacted the AIA. *Id.* at 43a. Notably, in reaching that conclusion, the court acknowledged that the specific "dosage level[]" of palonosetron—the invention claimed by the post-AIA patent—was *not* disclosed to the public. *Id.* at 39a. The court explained 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." Pet. App. 43a (emphasis added).[2]

Respondents' contention that the Federal Circuit found the details of the invention were publicly disclosed is thus entirely incorrect. To the extent that petitioner made a "detailed" disclosure about its invention, it made that disclosure *confidentially to MGI*, not to the public at large. That is a feature, not a bug, of this case: the legal question that this case presents is whether the sale of an invention to a third party that is obligated to keep the details of the invention confidential qualifies as prior art that triggers the AIA's on-sale bar in Section 102(a)(1). There is no factual dispute that could serve as an obstacle to the Court's resolving that legal question; the Federal Circuit correctly understood the facts, but simply got the law wrong.[3]

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[2] Respondents emphasize the government's statement at oral argument that it would not have "heartburn" if the Federal Circuit "conclude[d] that this was in fact a sale that made the invention available to the public." Br. in Opp. 18. As discussed above, however, the Federal Circuit did not reach any such conclusion; rather, it concluded that petitioner's sale to MGI triggered the AIA's on-sale bar even though the invention was *not* disclosed to the public.

[3] Respondents assert that petitioner "affirmatively disclaimed the position that an invalidating offer requires disclosure of the details of the invention." Br. in Opp. 18 (internal quotation marks and alterations omitted). That is also incorrect. Petitioner noted that it had "never contended that an invalidating offer requires disclosure of 'the details of the * * * invention,' and in fact argued * * * that the AIA left the inherency doctrine intact." C.A. Pet. for Reh'g 10. In so noting, petitioner was merely reaffirming the unremarkable proposition that, under the doctrine of inherency, the *public sale* of a product embodying a claimed invention may trigger the on-sale bar, regardless of whether it is accompanied by a disclosure of the details making up the invention. But the invalidating sale must still be made "to the

2. In an effort to diminish the importance of this case, respondents insist that the decision below is "narrow" and limited to the "circumstances involved" here. See Br. in Opp. 13-16. That contention is untenable.

a. The reasoning of both the Federal Circuit's opinion and Judge O'Malley's subsequent concurring opinion fatally undercuts respondents' contention. While the Federal Circuit and Judge O'Malley (in an apparent attempt to shield the court's decision from review) each insisted that the decision was narrow, both painted with broad brushes in their legal analyses. The Federal Circuit reasoned that the AIA did not "work * * * a sweeping change to [the court's] on-sale bar jurisprudence," and ultimately held 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." Pet. App. 43a. Judge O'Malley likewise characterized the Federal Circuit's opinion as standing for the proposition that the AIA "did not change" the on-sale bar. *Id.* at 3a-4a. In light of those broad statements, respondents cannot seriously contend that the decision below was somehow limited to the facts of this case; the decision plainly embodies a legal conclusion about the interpretation of the AIA's provision defining prior art.

Respondents further contend that the decision below does not affect the PTO's guidance to its examiners because its guidelines "state[] only that a secret sale or use activity does not qualify as prior art." Br. in Opp. 18 (internal quotation marks and citation omitted). But that is a misrepresentation of the guidelines. The PTO expressly instructed its examiners that sales "among individuals having an obligation of confidentiality to the inventor"—

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public" within the meaning of the AIA; the sale to MGI here plainly was not.

such as petitioner's sale to MGI—do not qualify as prior art under the AIA's on-sale bar. 78 Fed. Reg. 11,075 (Feb. 14, 2013). The impact of the decision below on the PTO's guidelines is reason enough to grant the petition—especially because the government has already taken the position that petitioner should prevail under the correct interpretation of Section 102(a)(1). See Gov't C.A. Br. 4.

b. Perhaps the strongest indication of the broader significance of the decision below is the vast array of amici that have filed briefs supporting the petition. Petitioner's amici include representatives of small manufacturers and innovators, individual intellectual-property owners, large pharmaceutical manufacturers, midsize biotechnology companies, and patent attorneys; organizations dedicated to the study of intellectual-property law and policy; and even Representative Lamar Smith, the eponymous sponsor of the AIA.

That diverse group of amici shares a common concern: that the decision below misconstrues the AIA and jeopardizes innovators' ability to invest in research and bring new products to market. As Representative Smith explained, the new statutory language "leaves no room for doubt" that confidential sales (such as petitioner's to MGI) are no longer prior art. Rep. Smith Br. 4. The PTO confirmed that interpretation in its guidelines, and companies and their investors have allocated resources in reliance on it. See PhRMA Br. 6.

The decision below upends the patent community's shared understanding of the AIA. And the community has responded in force, making clear that the decision below will not only jeopardize patent portfolios but chill the very innovation the patent system is designed to protect. See, *e.g.*, U.S. Inventor Br. 7; BIO Br. 1-5. That concern is especially acute for small companies and inventors, which are the engine of innovation in this country and are

increasingly responsible for the development of new drugs. See U.S. Inventor Br. 6-7; BIO Br. 1-5, 7. Small inventors are dependent on partnerships and risk-sharing agreements such as the one between petitioner and MGI to bring their inventions to market.[4]

In addition, small and large companies alike must decide whether to pursue a new drug years before the drug will hit the market. The decision whether to proceed with the development of a drug often depends on the expected strength of the drug's patents. See PhRMA Br. 5-6. Uncertainty about the validity of the patents naturally impedes that development. But such uncertainty is just what the Federal Circuit's decision has sown: more than one million patents have issued since the AIA's revised on-sale bar took effect, and many of those patents are now in question. See *id.* at 3.

What is more, as amici have explained, the Federal Circuit's decision is directly contrary to the AIA's stated goal of harmonizing American patent law with the law of other jurisdictions. If the decision below is allowed to stand, the United States would be the only industrialized country to invalidate patents on the basis of "secret" prior art. See Rep. Smith Br. 21; Gov't C.A. Br. 10. Indeed, the decision below actually *expands* the scope of prior art beyond pre-AIA standards: while sales and uses could not serve as prior art before the enactment of the AIA unless

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[4] Respondent Teva Pharmaceutical Industries—the largest generic drug manufacturer in the world, with over $22 billion in annual revenue—chastises petitioner for characterizing itself as a "small" company, citing petitioner's annual revenue of over $500 million. See Br. in Opp. 33. Petitioner, however, was able to grow to its current size only because it shared the risks and pooled the resources needed to develop Aloxi with its partner MGI; petitioner would otherwise have been unable to bring Aloxi, its most commercially successful drug, to market.

they occurred "in this country," see 35 U.S.C. 102(b) (2006), the AIA eliminated that restriction, with the result that, under the decision below, even confidential transactions that occurred outside the United States could qualify as prior art. See Pet. 25.

In light of the array of amici, there can be no doubt that the Federal Circuit's decision is sowing considerable uncertainty about the interpretation of the on-sale bar in Section 102(a)(1)—one of the most important provisions defining the scope of patent protection under the AIA. That decision warrants the Court's immediate review.

3. Respondents dedicate the majority of their brief to an assortment of merits arguments. See Br. in Opp. 4-9, 19-34. Petitioner has already addressed many of those arguments in its petition for certiorari, and it will address them in more detail at the appropriate time if the Court grants review. For present purposes, just a few additional points are warranted here.

a. Respondents first make a series of textual arguments. See Br. in Opp. 19-27. Those arguments are nowhere to be found in the decision below, and petitioner has anticipated virtually all of them in the petition. For example, respondents argue that applying the requirement that a sale make an invention "available to the public" to "public use[s]" would create redundancy. *Id.* at 23. The Federal Circuit, however, has long considered certain secret uses to be invalidating "public use[s]." See Pet. 17-18. Respondents summarily dispute that proposition, see Br. in Opp. 23, but even the decision below acknowledged that "[Federal Circuit] precedent had held certain secret uses to be invalidating under the 'public use' prong of [Section] 102(b)." Pet. App. 37a-38a.

b. Respondents devote considerable attention to the historical meaning of "on sale." See Br. in Opp. 30-32. That is a sleight of hand. The question presented by this

case is not which transactions qualify as "sales" under pre-AIA precedent, but whether a confidential commercial "sale" qualifies as prior art after the AIA. The text of the AIA—not pre-AIA precedent—answers that question.

c. Respondents' reliance on pre-AIA authorities such as *Metallizing Engineering Co.* v. *Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946), see Br. in Opp. 7-8, is similarly unavailing. The AIA's authoritative committee reports—which respondents ignore in their one-sided rendition of the legislative history, see *id.* at 8-9, 27-30—make clear that Congress intended to overturn cases such as *Metallizing* by eliminating "secret sales" from the definition of prior art. See Pet. 7 (citing House and Senate Reports). In their floor statements, the AIA's sponsors were even more explicit: Senator Leahy explained that the statute would "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), and Representative Smith agreed that, "contrary to current precedent, * * * an action must make the patented subject matter 'available to the public' before the effective filing date," 157 Cong. Rec. H4429 (daily ed. June 22, 2011).

Respondents attempt to tie the pre-AIA lower-court authorities on which they rely to this Court's decision in *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1 (1829). See Br. in Opp. 4-6. But that decision unequivocally supports petitioner, not respondents. In *Pennock*, this Court explained that, "[i]f the public were already in possession and common use of an invention," then "there might be sound reason for presuming[] that the legislature did not intend to grant an exclusive right to any one." 27 U.S. (2 Pet.) at 23. The Court thus emphasized that a sale *to the public* could invalidate a patent. See *id.* at 23-24. That reasoning

is entirely consistent with petitioner's interpretation of the AIA, under which a public sale may trigger the on-sale bar. See p. 5 n.3, *supra*.

We could go on. For now, however, respondents' extended discussion of the merits only confirms the need for this Court's intervention. The Federal Circuit's decision has created tremendous uncertainty in the patent community on an exceptionally important question of statutory interpretation. This Court's review is necessary to resolve that uncertainty and to correct the Federal Circuit's deeply flawed decision.

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The petition for a writ of certiorari should be granted.

Respectfully submitted.

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