No. 16-493

IN THE

Supreme Court of the United States

MERCK & CIE, BAYER PHARMA AG, AND BAYER HEALTHCARE PHARMACEUTICALS INC.,
Petitioners,

v.

WATSON LABORATORIES, INC.,
Respondent.

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

REPLY BRIEF OF PETITIONERS

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INTRODUCTION

Watson's brief in opposition ("Opp.") confirms the need for this Court's immediate review. As Merck explained in its petition, the Federal Circuit's misguided interpretation of the on-sale bar is contrary to the Patent Act, this Court's precedent, and the views of the United States. The Federal Circuit's decision also subjects millions of patentees to a nebulous, multi-factored test that is inconsistent with foreign law and the scope of which remains opaque.

The most Watson can say in response is that the Court has not yet resolved the issue. Watson maintains that the Court "has never rejected" Watson's view of the statutory text and that the Court "has never affirmatively held that invalidating sales or offers must be public." Watson also argues that it is "far from clear" how the Court's most recent decision in *Pfaff* v. *Wells Electronics, Inc.*, 525 U.S. 55 (1998), affects this issue. Opp. 24–25.

Merck disagrees with these incorrect assertions, but even if Watson were right and the issue remained open, that would only highlight the need for this Court's intervention and clarification. This Court has recognized the crucial interest of "certainty" and "a definite standard for determining when a patent application must be filed." *Pfaff*, 525 U.S. at 65–68 & n.11. Thus, regardless of whether the Federal Circuit's decision contradicts this Court's precedent or is merely a valiant effort in the face of uncertainty, this Court should set things straight. Only then will patentees have "a definite standard."

The Federal Circuit's recent en banc proceeding in *Medicines* reinforces the need for certiorari. As Merck explained, the Federal Circuit refused the United

States' request to "overrule" cases that were inconsistent with "longstanding Supreme Court precedent and congressional intent." En Banc Brief for the United States as *Amicus Curiae*, at 17, 19, *Medicines Co.* v. *Hospira, Inc.*, Nos. 2014-1469, -1504 (Fed. Cir. filed Mar. 2, 2016) (en banc) (ECF No. 132) (U.S. Amicus Br.). The Federal Circuit did so while also "rul[ing] for the patentee," Opp. 12, and thus the patentee did not file a cert petition. This case is currently the only vehicle to clarify when the on-sale bar applies.

Further, Watson's attempt to reconcile the position of the United States with the Federal Circuit's decision is unavailing. The United States urged the Federal Circuit to hold that the on-sale bar applies only to sales that make the invention available to the public, and the Federal Circuit rejected that invitation. But, if there were any doubt as to the United States' position, the Court should call for the views of the Solicitor General. There is no basis to deny certiorari.

With no persuasive response on the merits of the petition, Watson spends the majority of its brief on procedural distractions. Watson principally argues that Merck waived the question presented, despite the fact that Merck has argued from day one that its confidential pre-launch discussions did not trigger the on-sale bar, and despite the fact that Merck raised the issue presented at the first point it made sense to do so in light of existing Federal Circuit precedent. Just last Term, this Court heard—and was unmoved by—the same argument that Watson makes here. In *Halo Electronics, Inc.* v. *Pulse Electronics, Inc.*, 136 S. Ct. 1923 (2016), the respondent argued waiver when the petitioner's specific question presented had not been argued in the panel briefs (because existing precedent foreclosed it) but was made

to the full Federal Circuit in a petition for rehearing en banc. This Court did not credit the respondent's argument, granted the petition, and reversed. It should follow the same course here.

I. THE FEDERAL CIRCUIT'S FLAWED APPROACH TO THE ON-SALE BAR REQUIRES THIS COURT'S IMMEDIATE ATTENTION.

The Federal Circuit's decision warrants certiorari because it conflicts with the text of the Patent Act, this Court's precedents, and the views of the United States. Watson's responses confirm the pressing need for this Court's immediate review. Watson asserts that "[t]his Court has never rejected" the Federal Circuit's position, and "has never affirmatively held that invalidating sales or offers must be public." Opp. 24.

a. Assuming Watson were correct, the uncertainty in the case law—which only this Court could resolve—would be reason enough to grant certiorari. In *Pfaff*, this Court stressed the importance of "certainty" and "a definite standard for determining when a patent application must be filed." 525 U.S. at 65–68 & n.11. Thus, the existence of open questions or ambiguity about the on-sale bar standard warrants this Court's immediate review. This is an important question of public law that deserves an authoritative answer from this Court. See Sup. Ct. R. 10(c).

b. In any event, Watson is demonstrably incorrect. Under the Patent Act, an invention must be available to the public in order to be considered "on sale." 35 U.S.C. § 102(b). The on-sale bar does not apply to the confidential negotiations that typically occur when a company is getting a product ready for market. This is compelled by the ordinary meaning of the textual phrase "on sale," the statute's history, and a recent

amendment confirming that longstanding meaning. Pet. 9–11.

Indeed, for more than 200 years, this Court has consistently described and understood the on-sale bar as inapplicable to non-public discussions or transactions. Pet. 11–12. As the United States explained in its amicus brief, U.S. Amicus Br. at 9–14, the Court time and again has linked the bar to *public* sales and offers. Both before and after Congress codified the on-sale bar in 1836, the Court has used the same language in its opinion to describe the scope of the bar: "public sale," "public," "publicly sold," "public commerce," "on public sale." *Id.* (citing cases) (emphasis omitted).

Watson's responses to this Court's decisions are meritless. For instance, Watson claims that this Court's decision in *Pfaff* "supports" the Federal Circuit's position. Opp. 24–25. But *Pfaff* involved a consummated sale that was not covered by a confidentiality agreement and that did not arise from confidential, pre-launch negotiations. 525 U.S. at 58. Moreover, *Pfaff* "focused on" the ready-for-patenting prong of this Court's test for the on-sale bar, not the contours of the phrase, "commercial offer for sale." *Medicines Co.* v. *Hispira, Inc.*, 827 F.3d 1363, 1372–73 (Fed. Cir. 2016) (en banc). The Court nevertheless explained that the bar is triggered by "public sale" and "public use." 525 U.S. at 64.

Watson's discussion of this Court's earlier decisions is similarly unavailing. Watson contends that the statutory on-sale bar "did not yet exist" when the Court decided *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1 (1829). Opp. 25. But Watson misses the point, which is that *Pennock* required a public sale and Congress codified this decision. *Pennock* held, first, that the "true meaning" of the then-existing statutory term,

"not known or used," was "not known or used *by the public*," and, second, that the inventor could not obtain a patent because his invention had been "*publicly* sold for use." 27 U.S. (2 Pet.) at 18–19, 23–24 (emphases added). Congress then adopted this explication of the on-sale bar in 1836, requiring that an inventor could not receive a patent once his invention was "in public use or on sale." Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119.

Nothing Watson says about the many other cases cited in the petition undercuts the fact that this Court has consistently stressed public accessibility for the on-sale bar to apply, and has applied the bar in precisely that manner. Pet. 11–12; Opp. 26–28. The conflict between the Federal Circuit's position and this Court's decisions warrants certiorari.

c. The United States agrees with Merck about the scope of the on-sale bar. Pet. 13. Watson suggests that the Federal Circuit has moved close enough to the government's views. Opp. 12 (arguing that the Federal Circuit's approach is "substantially consistent" with the views of the United States); *id.* at 9 (en banc court "substantially *agreed*" with the government); *id.* at 28. But Watson cannot whitewash the fact that the United States asked the Federal Circuit to "overrule its decisions interpreting the on-sale bar to reach non-public sales" and to hold that "the on-sale bar is triggered only by sales or offers for sale that make the invention available to the public." U.S. Amicus Br. at 17, 19. The Federal Circuit unequivocally *refused to follow the United States' proposed approach*. *Medicines*, 827 F.3d at 1376.

Contrary to Watson's assertion, the United States did not "advocate[] for a multi-factor inquiry" for deciding whether a confidential, pre-launch sale triggers the bar. Opp. 11. The government noted that

this Court "has identified several factors as relevant to determining whether *a use* makes the invention publicly available," U.S. Amicus Br. at 14 (emphasis added), but the United States was clear that "sales made under contractual commitments of exclusivity and confidentiality" should not trigger the bar, *id.* at 17–18. See also *id.* ("The Court should overrule those decisions and hold that the on-sale bar is triggered only by sales or offers for sale that make the invention available to the public."); *id.* at 17 & n.8 (drawing distinction between "secret" sales and "public" sales, and concluding that "those decisions" applying the "on sale" bar to secret sales "are incorrect").[1] In any event, if there were any uncertainty about the United States' position vis-à-vis the Federal Circuit's interpretation of the on-sale bar, the Court can seek the views of the Solicitor General.

II. THIS CASE PRESENTS AN EXCELLENT, AND ENTIRELY PROPER, VEHICLE FOR ADDRESSING THE IMPORTANT QUESTION PRESENTED.

With nothing else to argue, Watson contends that this case is not the appropriate vehicle to address the important question presented. But none of Watson's hodgepodge of manufactured vehicle problems has merit.

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[1] Even Watson seems to recognize this point elsewhere in its brief: "The government argued that Medicines Company's invention 'was never made available for sale to the public,' or any interested member of the public, *because its transactions with its manufacturer 'were confidential and exclusive*, such that no member of the public could have purchased the drug product from [the manufacturer].'" Opp. 11–12 (emphasis added) (alteration in original).

a. Oddly, Watson contends that this case does not implicate the question presented because "Weider was no differently situated than any other member of the public." Opp. 18. The offer at issue, however, arose from pre-launch negotiations that the district court expressly found were covered by the parties' confidentiality agreement. Pet. App. 13a, 27a–30a; Pet. 13–14. On appeal, Watson did not challenge this finding. It was thus undisputed that the '168 patent's invention was unavailable to the public, and Weider only had access to it from private pre-launch discussions. Watson's attempt to manufacture a factual question at the certiorari stage is inconsistent with the record.[2] Regardless, even if there were a factual issue, that would be a reason to remand *after* clarifying the legal standard, not a reason to leave the Federal Circuit's muddled test unreviewed.

b. Watson next argues that, because Merck is not a "small company," this case "[d]oes [n]ot [r]aise … [s]mall-[c]ompany [o]utsourcing [c]oncerns." Opp. 19–21. But, of course, the Court's resolution of the question presented covers companies of all sizes, not just Merck. Certiorari exists for "cases involving principles the settlement of which is of importance to the public, as distinguished from that of the parties," *Layne & Bowler Corp.* v. *W. Well Works, Inc.*, 261 U.S. 387, 393 (1923), and this is precisely such a case. Moreover, both small and large company often use

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[2] Watson's argument is also perplexing. Watson asserts that the confidential discussions between Merck and Weider were "public" because, *if* the parties had consummated the sale, Weider would have "re-sold the doses it bought from Merck to the public and advertised them as such." Opp. 18. This is a *non sequitur*. The mere fact that the deal or sale may have later become public *if* it had been consummated does not mean that the confidential, unsuccessful negotiations were public too.

strategic partners in bringing a product to market—as Merck did here, see Opp. 4—and there is no statutory basis for a double standard.

c. Watson asserts that certiorari is inappropriate because the issue should be allowed to "percolate." Opp. 20–21. But a decision that reaffirms longstanding, misguided precedent does not need time to "percolate." Even Watson agrees that the Federal Circuit's decision is consistent with that court's prior precedent. *Id.* at 16. The issue has been percolating for decades, and there is no reason to wait any longer. The en banc Federal Circuit was given the opportunity to recalibrate and overrule its precedent, and it refused to do so. Pet. 16–18. Further, the Federal Circuit's decision in *Medicines*—which reaffirmed that court's nebulous, multi-factored approach—highlights the need for this Court's immediate review. *Id.* Inventors need "a definite standard for determining when a patent application must be filed," not another "unnecessarily vague" "totality of the circumstances" test. *Pfaff*, 525 U.S. at 65–68 & n.11. Only this Court can provide that clarity.

d. Watson tries to downplay this case's importance by highlighting that Congress amended § 102(b) in 2011. Opp. 21–23. That amendment in no way diminishes the issue's significance. The controlling statutory version in this case is the same one that the Federal Circuit this year understood to be of such ongoing importance that it needed to be addressed en banc. Indeed, the statute continues to cover millions of patents with many years of patent life remaining. Pet. 15–16. Plus, the recent amendment merely *clarified* that "all" of the various "categories of prior art" are "limited to that which makes the invention 'available to the public,'" 157 Cong. Rec. S1368, S1370 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl), *cited in*

final Committee Report, H.R. Rep. No. 112-98, at 43 n.20 (2011). The United States agrees that the 2011 amendment to the on-sale bar did not change the law. U.S. Amicus Br. at 15–17. Thus, the Court's decision in this case would implicate the on-sale bar's scope more generally.

e. Finally, Watson argues that Merck forfeited its ability to raise the question presented. See, *e.g.*, Opp. 1, 13–17. But this Court rejected a similar argument just last Term.

In *Halo*, the respondent argued against certiorari by claiming that the petitioner "never asked either lower court to modify the [applicable] test until it filed its petition for a rehearing *en banc* in the Federal Circuit." Br. in Opp. at 2, *Halo Elecs., Inc.* v. *Pulse Elecs.,* No. 14-1513 (U.S. filed Aug. 24, 2015). The petitioner explained, however, that it had pressed arguments within the bounds of then-controlling law until its rehearing petition. Reply Br. In Supp. of Certiorari, at 5–7, *Halo Elecs., Inc.* v. *Pulse Elecs.,* No. 14-1513 (U.S. filed Sept. 3, 2015). The Court granted certiorari. 136 S. Ct. 356 (2015).

This case is analogous to *Halo*. Pet. 7–8. From the start, Merck's "properly presented" claim has been that its confidential, pre-launch discussions with Weider did not trigger the on-sale bar. *Lebron* v. *Nat'l R.R. Passenger Corp.*, 513 U.S. 374, 378–79 (1995). Merck may "make any argument in support of that claim," *id.*, and, like Halo, Merck raised arguments permitted by controlling law until its rehearing petition, in which it squarely raised the question presented. Further, Merck promptly asked the panel to hold this case in light of the *Medicines* en banc proceeding. Pet. 7–8. As in *Halo*, the full Federal Circuit had the opportunity to consider Merck's arguments, and there is no impediment to this Court's review.

See also *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 125 (2007).[3]

It is sufficient that Merck "pressed" its challenge, but the Federal Circuit also "passed upon" the issue presented. See *United States* v. *Williams*, 504 U.S. 36, 41 (1992) (question should be "pressed *or* passed upon") (emphasis added). As Watson acknowledges, the Federal Circuit stated that Merck's case "was different" from other cases, because the on-sale "bar arises when a product is marketed to the public prior to the critical date." Opp. 8 (quoting Pet. App. 15a n.4). That statement is seemingly irreconcilable with other parts of the panel's opinion, Pet. 14, but regardless, it confirms that the Federal Circuit "passed on the issue presented" by addressing it in the course of its decision. *Va. Bankshares, Inc.* v. *Sandberg*, 501 U.S. 1083, 1099 n.8 (1991). That, too, is enough to preserve the issue for this Court's review. *Id.*

In all events, the pressed or passed upon rule is "not inflexible," *Youakim* v. *Miller*, 425 U.S. 231, 234 (1976) (per curiam), and it should not obstruct review in this case. The petition presents an important question of law, which implicates millions of patents, Pet. 15–16, and on which Federal Circuit doctrine is misguided, *Medicines*, 827 F.3d at 1376. Nothing should

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[3] Watson claims Merck cannot raise a new argument in a petition for rehearing, Opp. 15, but none of its cases involved a petitioner raising an otherwise futile argument to an en banc federal court of appeals, and then again to this Court in a petition for certiorari. In *Chaidez* v. *United States*, for example, the petitioner raised a specific issue in her merits brief before this Court that was "differ[ent]" from the issue she had raised in her petition for rehearing en banc, and omitted entirely from her panel appeal and petition for certiorari. 133 S. Ct. 1103, 1113 n.16 (2013).

deter this Court from hearing and deciding this important and pressing question.

CONCLUSION

The petition should be granted.

Respectfully submitted,

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