No. 20-1110

IN THE
Supreme Court of the United States

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH,

Petitioners,

v.

IMMUNEX CORP., AMGEN MANUFACTURING, LTD.,

Respondents.

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

REPLY BRIEF FOR PETITIONERS

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RULE 29.6 STATEMENT

The corporate disclosure statement included in the petition for a writ of certiorari remains accurate.

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INTRODUCTION

A single person or entity may not receive more than one patent on the same invention, or obvious variants of it. That is the rule against obviousness-type double patenting that this Court has long recognized. But the Federal Circuit has now walked back that crucial protection. Under the decision below, a patentee may enjoy full control over two patents covering the same technology in essentially the same way and avoid ODP scrutiny so long as its second patent is nominally owned by someone else. How little does the nominal owner need to retain? A secondary right to sue for infringement—even if that secondary right exists only on paper and is meaningless in practice. As Sandoz has explained (*see* Pet. 15-29), that decision warrants this Court's attention because it guts the Patent Act's one-patent-per-invention requirement and creates a blueprint for other patentees to follow Immunex's straw-owner strategy.

Immunex argues that the Federal Circuit's decision is a fact-bound one-off, but only by reimagining the majority opinion as a "totality-of-the-circumstances assessment" that "did not rely solely on Roche's retained right to enforce its patents." Opp. 12-13. That is incorrect. The panel majority deemed Roche's illusory right to sue, without more, to be "thoroughly inconsistent" with an assignment of ownership. Pet. App. 21a. That holding answers a purely legal question—what is the minimum needed to avoid a finding of ownership and skirt ODP scrutiny?—and the resulting new pathway around ODP will have implications far beyond this specific case.

Immunex also advances various prudential reasons to deny certiorari, but its arguments do not withstand scrutiny. For example, Immunex argues (at 22-23) that facts like these are unlikely to recur following a change to patent term resulting from the Uruguay Round of the General Agreement on Tariffs and Trade (GATT). But "the patent regime Immunex exploited still governs an enormous number of patents." AAM/AHIP *Amicus* Br. 10. And, regardless, patentees can deploy Immunex's straw-owner gambit on post-GATT patents, too. As for Immunex's attempt (at 24-28) to interpose new threshold questions or alternative grounds for affirmance, Immunex has identified no issue that would prevent the Court from reaching the question presented.

The Court should grant certiorari and reverse. At a minimum, this Court should not deny certiorari without inviting the United States to give its views on this new pathway around ODP.

ARGUMENT

I. The Federal Circuit decided a purely legal question, and its answer undermines the essential protection against double patenting.

According to the Federal Circuit, Immunex was not the effective owner of the patents-in-suit because—and only because—Roche maintained a secondary right to sue that would vest only if Immunex allowed it to. *See* Pet. App. 21a. That decision flouts a long line of precedent, in both this Court and the Federal Circuit, enforcing the Patent Act's limitations on double patenting. *See* Pet. 15-22.

Immunex goes to great lengths to avoid defending the holding that Roche's entirely hypothetical secondary right to sue was sufficient to keep Roche the effective owner. But Immunex's account of the decision below does not line up with the court of appeals' actual analysis.

1. Immunex first argues (at 11-13) that the Federal Circuit adopted a "totality-of-the-circumstances assessment," and so the decision below is limited to this specific agreement. But the decision below did not rest on an amorphous totality analysis. Before the Federal Circuit, Immunex pointed to four separate "rights" that, in its view, showed that Roche was the effective patentee. *See* Pet. App. 21a. The court trained its attention on just one of them—Roche's secondary right to sue, which Immunex could prevent from ever vesting—and deemed it "'thoroughly inconsistent' with a conclusion that the patents-in-suit were effectively assigned to Immunex." Pet. App. 21a. The court made that determination independent of its consideration of any other provision of the 2004 Agreement. That square legal holding—that a secondary and voidable right to sue for infringement can defeat a finding of ownership—extends beyond the facts of this specific agreement. *See* Pet. 23-29; AAM/AHIP *Amicus* Br. 8-10.

Immunex identifies other terms of the 2004 Agreement, but the Federal Circuit did not treat them as necessary to its decision. For example, Immunex points (at 12) to Roche's right to veto any assignment of Immunex's interests. But the panel majority said only that this restriction on assignment was "a further indication" that Roche had not transferred all substantial rights—not that it was an independent basis

for its holding. Pet. App. 23a. Nor could the majority have rested on that restriction on alienation, because it was reciprocal. If Immunex's argument were taken seriously, *no one* would own the patents-in-suit because Roche, too, lacked unilateral assignment authority. *See* C.A. App. 25849. And even this restriction on assignment lasts only so long as Immunex desires to maintain the fiction of Roche's ownership: Immunex has the absolute right to assign the patents to whomever it wishes, as long as it first pays Roche $50,000 for its remaining rights. Roche has no right to say no. Pet. 10; Pet. App. 40a (Reyna, J., dissenting); p. 6, *infra*.

Immunex also cites (at 12-13) restrictions on Immunex's ability to terminate the 2004 Agreement and Roche's right to practice the patents for internal research purposes. But the Federal Circuit simply did not rely on these provisions in its all-substantial-rights analysis. *See* Pet. App. 21a-24a. In the court's view, Roche's secondary right to sue was sufficient, all by itself, to support the court's holding.

2. As a fallback, Immunex argues (at 13) that Roche's secondary right to sue was *not* illusory. But like the Federal Circuit, Immunex never grapples with the key fact: Immunex could prevent Roche from exercising that right by granting a royalty-free sublicense *before* the right ever vested. *See* Pet. 13-14, 22. Immunex observes (at 13) that, according to the court of appeals, Immunex could not issue a sublicense after 180 days, "once Roche's secondary right to sue is triggered." But that is beside the point: "Immunex *can* issue a royalty-free sublicense within 180 days of receiving Roche's written request to correct infringement and can thus prevent Roche's secondary right to

sue from even vesting." Pet. App. 43a (Reyna, J., dissenting) (emphasis added). The Federal Circuit never held otherwise—and Immunex simply ignores the point.[1] Immunex's argument is thus like arguing that the President lacks power to veto a bill *once ten days go by*: true, but no obstacle to the President's vetoing any bill he wants.

In a footnote, Immunex argues (at 14 n.4) that the Federal Circuit has previously held that a secondary right to sue "will *not* defeat a transfer of ownership" where the secondary right can be avoided by the grant of a sublicense. *See Speedplay, Inc.* v. *Bebop, Inc.*, 211 F.3d 1245, 1251-1252 (Fed. Cir. 2000). But *Speedplay* is now a dead letter: The Federal Circuit in this case held that sublicenses are irrelevant unless they can be given *even to a defendant the nominal owner has sued*. Pet. App. 22a. That is a null set, as just discussed, because of the power to sublicense before the right to sue vests. Neither an illusory right to sue nor an illusory limit on the sublicensing power gives Roche any substantial rights.

3. Immunex also claims (at 16-20) that it is correct on the merits, but its arguments only underscore just how illusory Roche's "ownership" was. For example, Immunex notes (at 18) that Roche retained a right to practice the patents for internal, non-clinical re-

[1] To be clear, the Federal Circuit was wrong to construe the 2004 Agreement to bar Immunex from issuing a sublicense after 180 days: The court fashioned that atextual rule from a provision requiring Immunex to "cooperate" with any Roche-initiated suit. Pet. App. 20a, 24a. For the reasons described above, however, Roche's right is illusory *even accepting* the Federal Circuit's flawed construction.

search. But although the Federal Circuit "mention[ed]" that right (Opp. 18), it ultimately did not rely on it. And for good reason: Precedent makes clear that "this is not a substantial right." *Luminara Worldwide, LLC* v. *Liown Elecs. Co.*, 814 F.3d 1343, 1351 (Fed. Cir. 2016).

Immunex emphasizes (at 19) that it could convert its supposed license into an outright assignment for an additional $50,000. But that trivial amount *confirms* that Roche's "ownership" was illusory. Immunex argues (at 19) that the $50,000 amount must "be viewed in the context of the entirety of the agreement." Exactly right. Immunex paid $45 million to acquire the rights it obtained in the 2004 Agreement; Roche was willing to give an outright assignment for the same price. *See* Pet. 9-10, 15. That Immunex could obtain any remaining rights for just $50,000 (or 0.1% more) shows that the remaining rights were insubstantial. *See* Pet. 10, 21. Immunex's own counsel acknowledged (C.A. Oral Arg. 41:01) that the $50,000 sum was a mere "peppercorn"—consideration for consideration's sake. It could have been one dollar.

A peppercorn is a small price to pay for the power to dodge the protection against double patenting. Yet that is exactly what the Federal Circuit has allowed clever patentees to do: to enjoy the upside of a second patent that remains nominally in the hands of a straw owner, and thus to extend their patent exclusivity past the statutory cut-off date for the term of "*a*" patent. "This Court has carefully guarded that cut-off date," *Kimble* v. *Marvel Entm't, LLC*, 576 U.S. 446, 451 (2015), but the Federal Circuit has now dug a tunnel past the guard post. *See* Pet. 15-22. Immunex will not be the last to use it.

II. The question presented is important and warrants this Court's attention.

The Federal Circuit's decision provides a clear roadmap for patentees to circumvent the one-patent-per-invention requirement. *See* Pet. 23-26. As *amici* have explained, "[a]bsent review by this Court, little stands in the way of other companies applying respondent's blueprint to their own expiring patents." AAM/AHIP *Amicus* Br. 3. Downplaying the effect of the decision below, Immunex argues (at 22-24) that its success in extending its patent term stems from a unique combination of facts that is unlikely to recur. But this case is not as unique as Immunex suggests.

1. Immunex's principal argument (at 22-23) is that its patent-extension gambit is impossible to replicate post-GATT. But that is wrong for at least two reasons.

First, the well of pre-GATT patent applications has not yet run dry. As Sandoz explained (Pet. 26 & n.10), a number of pre-GATT applications are *still* pending in the Patent Office. With respect to those outstanding patent applications, a patentee could replicate Immunex's *exact same* patent-extension strategy to avoid ODP scrutiny.

Second, even putting aside those pre-GATT applications, a patentee could readily extend its exclusivity and dodge ODP using a post-GATT patent application. Immunex notes (at 23) that, in a post-GATT world, an earlier-filed patent application will always expire before a later-filed application—regardless of when the two patents *issue*. *See* Pet. App. 144a-145a. But that is of no moment: An inventor can still deploy Immunex's strategy. After filing for its own patent,

an Immunex imitator could take over and repurpose a later-filed patent application by *another* inventor, making sure to leave that other inventor with an illusory secondary right to sue. So long as the first patent application is not "prior art" to the second patent application, both patents will issue—and the second will effectively extend the term of the first, because the Patent Office and later the Federal Circuit will not apply ODP.[2]

In short, unwarranted extensions can still be engineered post-GATT, even if the timing differs. Thus, as one commentator has observed, there is still a "steady demand for" ODP protections in a post-GATT regime. Dennis Crouch, *Buying Up Overlapping Patents—And Double Patenting*, PATENTLY-O, http://patentlyo.com/patent/2021/02/overlapping-patents-patenting.html (Feb. 15, 2021).

2. Immunex also argues (at 23) that "familiar statutory requirements" like the written-description requirement of § 112 and the novelty requirement of § 102 will prevent any gamesmanship. But this case demonstrates otherwise. Neither the written-description requirement nor the rules against obviousness

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[2] There are any number of reasons why the first patent application may not be "prior art" to the second. For applications claiming priority to before the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011), an earlier patent application would not be prior art depending on when or whether it was published. *See* 35 U.S.C. § 102(a) and (e) (2006); *see also id.* § 122(b) (describing when patent applications are published); AIA § 3(n), 125 Stat. at 293 (effective date of amendment). For post-AIA applications, an earlier patent application would not be prior art if it falls within one of the exclusions set forth in 35 U.S.C. § 102(b)(2).

stood in the way of Immunex's ability to secure and repurpose a second patent and thereby extend its patent term. *See* Pet. App. 24a-34a. To be clear, Sandoz disagrees with the district court's findings and Federal Circuit's affirmance on those issues. But even accepting those holdings, the prohibition on obviousness-type double patenting is supposed to be an independent check—barring a single player from gaming the patent system even when the written-description and nonobviousness requirements do not. And yet the Federal Circuit weakened that critical bulwark.

III. Nothing prevents this Court from reaching the question presented.

Immunex spends the balance of its brief raising a host of vehicle objections, but nothing prevents the Court from addressing this important issue in this case.

1. First, Immunex argues (at 24-26) that if the Court grants certiorari, "it would first need to address the threshold question whether the all-substantial-rights inquiry . . . is consistent with the Patent Act." But Immunex is not questioning the unanimous holding below (Pet. App. 16a-17a) that the way to assess common ownership was with the all-substantial-rights test. Indeed, Immunex did not propose any different test for common ownership. Pet. C.A. Reply 4. Rather, as Immunex acknowledges (at 25), it is disputing decades of precedent about the *timing* of common ownership. Courts have long recognized that the rule against double patenting extends to situations in which the double patentee received the second patent by way of an assignment, rather than as the named inventor. *See* Pet. 18 (citing cases). But Immunex

suggests (at 26) that even if double patenting can be grounded in common ownership, it must be common ownership at the time of invention. That argument, too, is foreclosed by well-established precedent. *See In re Longi*, 759 F.2d 887, 893-895 (Fed. Cir. 1985); *Geneva Pharm., Inc.* v. *GlaxoSmithKline PLC*, 349 F.3d 1373, 1377, 1386 (Fed. Cir. 2003); *In re Mann*, 47 F.2d 370, 371-72 (C.C.P.A. 1931). The timing question is merely a distraction; it does not block this Court from reaching the question presented.

2. Immunex offers a second distraction, arguing (at 26-28) that it might win on alternative grounds based on other findings made by the district court. But the Federal Circuit did not reach these alternative holdings: It rested its decision solely on its common-ownership determination. And so this Court, "a court of review, not of first view," lacks a basis to consider those alternative holdings. *E.g.*, *United States* v. *Stitt*, 139 S. Ct. 399, 407 (2018). The fact that Immunex might press alternative bases for affirmance on a future remand from this Court is irrelevant.

In any event, Immunex's arguments are wrong. Immunex claims (at 27) that the patents-in-suit are patentably distinct from the '690 Patent. Sandoz disputed that finding below, but even accepting it for the sake of argument, it does not affect the '225 Patent. That patent is *not* patentably distinct from the patents-in-suit. As Judge Reyna explained, the district court concluded otherwise only by applying an erroneous legal standard. *See* Pet. App. 43a-45a (dissenting opinion).

Immunex also argues (at 9, 27-28) that the district court held that the '225 Patent could not serve as a

reference patent for ODP purposes as a matter of law, but here Immunex is just misreading the district court's opinion. The district court concluded that, *as a general matter*, "the statutory term for the Patents-in-Suit [could] not be cut short to mirror the statutory term for the Finck Patents" (*i.e.*, a family of patents that included the '225 Patent). Pet. App. 146a. But the court went on to hold that "the '225 Finck Patent . . . *could* be properly considered an 'earlier patent' for an obviousness-type double patenting analysis." Pet. App. 146a n.43 (emphasis added).

3. Finally, Immunex throws up a host of factual issues that are immaterial to *either* the question presented *or* the alternative grounds on which it would seek affirmance. Indeed, many of them are findings that (even while ruling for Immunex) the court of appeals held the district court "should not have made" in answering the *legal* question of ODP, Pet. App. 19a, such as the district court's finding that the subjective purpose of the 2004 Agreement was to create a license. Opp. 6-7. Others come from portions of the opinions below *that did not involve ODP*, such as the district court's finding that the Roche application could be read to describe etanercept for written-description purposes. Opp. 3-5, 7. Sandoz disputes each of these findings. But in the end they are legally irrelevant to the question presented—again, Immunex simply raises them to distract from the issue at hand.

IV. At the very least, this Court should call for the views of the Solicitor General.

For all the foregoing reasons, the Court should grant the petition now. At the very least, however, the Court should invite the views of the United States.

The Patent Office assesses ODP during examination, and the Federal Circuit's decision can be read to allow parties like Immunex to control prosecution without necessarily disclosing their ownership of all substantial rights. The Court would benefit from the government's views on whether the Federal Circuit's rule is either workable or correct, particularly for patent-examination purposes.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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