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

BRIEF IN OPPOSITION

JEFFREY P. KUSHAN
JOSHUA J. FOUGERE
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

CONSTANTINE L. TRELA, JR.*
STEVEN J. HOROWITZ
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
(312) 853-7000
ctrela@sidley.com

Counsel for Respondents

*Counsel of Record

April 12, 2021

(*Additional counsel listed on inside cover*)

SUE WANG
SIDLEY AUSTIN LLP
555 California Street
Suite 2000
San Francisco, CA 94104
(415) 772-1200

WENDY WHITEFORD
J. DREW DIAMOND
DENNIS SMITH
JOSEPH E. LASHER
JAMES A. HIGH, JR.
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
(805) 447-1000

Counsel for Respondents

QUESTION PRESENTED

The doctrine of obviousness-type double patenting is grounded in 35 U.S.C. § 101, which limits one who "invents or discovers" an invention to "*a* patent"—and no more than one patent—on that invention. In previous cases, the Federal Circuit extended the prohibition on double patenting to bar a single *owner* (not just a single *inventor*) from obtaining multiple patents on essentially the same invention. In this case, Sandoz asked the court of appeals to determine whether multiple patents have a single owner for purposes of double patenting by applying a test from the court of appeals' prudential-standing precedent that looks to whether an entity has obtained "all substantial rights" in a given patent. The court of appeals adopted Sandoz's proposed test as "informative" for purposes of this case, but nonetheless determined based on a detailed review of the record that Sandoz failed to meet its own test. The case thus presents the following question:

Whether the court of appeals correctly determined, based on its assessment of the totality of the relevant license agreement—including Roche's retained rights to practice and enforce the patents, as well as Roche's absolute right to veto any attempt by Immunex to assign rights under the license—that the license did not transfer "all substantial rights" in Roche's patents to Immunex.

RULE 29.6 STATEMENT

Immunex Corporation and Amgen Manufacturing Limited are both wholly owned subsidiaries of Amgen Inc., a publicly traded company. No other publicly traded company owns 10 percent or more of either respondent.

TABLE OF CONTENTS

TABLE OF CONTENTS—continued

TABLE OF AUTHORITIES

CASES Page

TABLE OF AUTHORITIES—continued

STATUTES

RULES

LEGISLATIVE MATERIAL

TABLE OF AUTHORITIES

OTHER AUTHORITY Page

INTRODUCTION

The patents in this case describe and claim breakthrough inventions made by scientists at Roche and licensed years later by Immunex. Those inventions are etanercept, a treatment for rheumatoid arthritis, and novel methods of making it. Etanercept changed the practice of medicine by providing a treatment for those suffering from rheumatoid arthritis which was dramatically more effective than prior treatments. Sandoz copied etanercept and the patented method of making it and sought to market its product notwithstanding the Roche patents.

Over years of litigation, a ten-day trial, and an unsuccessful appeal, Sandoz has thrown almost every defense known in patent law at the Roche patents, all without success. After having its last batch of defenses rejected on appeal, Sandoz now focuses solely on a theory with no basis in either the Patent Act or any judicial decision. In this Court, as it did below, Sandoz characterizes its theory as a form of obviousness-type double patenting, a defense grounded in the Patent Act provision that promises "*a* patent" (and no more than one patent) to "[w]hoever invents or discovers" an invention. 35 U.S.C. § 101 (emphasis added). But Sandoz's version of that defense is untethered from the statute and unsupported by precedent. Under Sandoz's double-patenting theory, a patent unquestionably valid in the hands of its original owner can spontaneously become invalid when licensed to someone else more than a decade after the invention was made. The district court rejected Sandoz's theory on multiple independent grounds, and the court of appeals correctly affirmed.

Despite the lack of statutory or case-law support for Sandoz's theory, the court of appeals addressed it and

applied the precise legal standard Sandoz urged the court to apply. Sandoz simply lost on the facts. In particular, Sandoz asked the court of appeals to hold that, notwithstanding the statute's express focus on those who "invent[] or discover[]" an invention, a license agreement that transfers "all substantial rights" in a patent years after the invention was made can give rise to double patenting. The court of appeals agreed that Sandoz's proposed test could be "informative" and applied it as Sandoz requested, but found—based on its case-specific assessment of the totality of the relevant license agreement—that Roche had *not* transferred "all substantial rights" in its patents to Immunex. Having so found, the court of appeals did not need to reach any of the district court's other, independent grounds for rejecting Sandoz's double-patenting defense.

Sandoz's petition is thus a classic request for factbound error correction. There is no error to correct. More importantly, there is no hint of a conflict between the legal standard the court of appeals applied and any prior judicial decision, nor is there a plea for clarity in the face of some body of Federal Circuit law that has supposedly strayed over time from its statutory moorings or this Court's direction. Sandoz simply argues that the court of appeals misapplied Sandoz's own proposed test. And even as factbound petitions go, this one is particularly ill-suited for the Court's review. The case is *sui generis*: it is driven by an impossible-to-replicate series of events in the early 1990s—involving separate researchers independently making distinct, patentable inventions at separate companies—and a statutory regime that changed more than 25 years ago.

What is more, Sandoz's factbound petition rests heavily on a series of factual assertions that are false—

and demonstrably so, as they conflict with findings the district court made and Sandoz does not challenge. A particularly blatant example is Sandoz's repeated assertion that Immunex, not Roche, invented etanercept and that the Roche patent applications described and claimed something else entirely until Immunex "repurposed" them to cover etanercept. (*E.g.*, Pet. 2, 6, 7, 8, 10, 24.) The district court found otherwise, and the record is clear that Roche not only invented etanercept but described it in its original patent applications, which included claims covering etanercept, long before Immunex arrived on the scene. Indeed, if Roche actually had not invented etanercept, or if Immunex had invented it first, Sandoz could have invalidated the Roche patents under familiar defenses, such as lack of novelty under 35 U.S.C. § 102 or failure to provide a sufficient "written description" of the invention under 35 U.S.C. § 112. Sandoz could not prevail on those defenses, so it is left to make up a defense—and facts to fit it.

Given the district court's unchallenged findings, the Roche patents are undisputedly valid in Roche's hands and would cover Sandoz's admittedly infringing etanercept products and methods of production even if Roche and Immunex had never entered into the specific license agreement at the center of this case. And on a proper understanding of the facts, the court of appeals correctly determined that that license did *not* transfer ownership to Immunex.

Even if the petition presented a genuinely important legal question, this case would be an exceptionally poor vehicle for resolving it. Before considering the application of the "ownership" test Sandoz urged but could not meet, this Court would first have to consider whether that, or any, ownership test should apply at all. That would require that the Court address the

threshold question whether obviousness-type double patenting can ever arise based on a license, years after the invention was made, to a third party that happens to own unrelated and independently invented patents. Only if Sandoz were to prevail on that question would the Court even have occasion to address the factbound application of some "ownership" test to the license agreement in this case. And even if the Court fully endorsed Sandoz's interpretation of the relevant license agreement, Sandoz's double-patenting defense would *still* fail, because the district court correctly rejected Sandoz's defense on multiple independent grounds that the court of appeals did not need to reach.

The petition should be denied.

STATEMENT OF THE CASE

A. The Roche Patents and Immunex's License.

Scientists at Roche were the first to invent etanercept. (Pet. App. 52a–54a.) As the district court found, and the court of appeals affirmed, Roche's invention of etanercept was nonobvious and fully described in Roche's original patent applications, filed in 1990. (Pet. App. 24a–34a.) Although the petition incorrectly asserts different facts, it does so without even acknowledging the lower courts' contrary factual findings, much less attempting to show that any were clearly erroneous.

After Roche's invention, Immunex separately developed and brought etanercept (tradename Enbrel®) to market. (Pet. App. 6a–7a.) In 1999, around the time Immunex first began marketing Enbrel®, Immunex learned that Roche's then-pending patent applications covered etanercept, and Immunex accordingly took a license to those applications. (*Id.*) Under this original license, which the petition largely ignores, Immunex

paid Roche "tens of millions of dollars" in recognition of the fact that the Roche applications described (and thus could someday issue as patents claiming) etanercept. (Pet. App. 129a; *see also* Pet. App. 117a (finding that the original license supported the conclusion that the Roche patents were nonobvious).)

Notably, although the petition states that the original Roche applications "did not describe" the "etanercept protein" (Pet. 8), the district court held a trial on that question and found just the opposite (Pet. App. 58a–75a), a finding the court of appeals affirmed (Pet. App. 24a–30a). The petition's contrary statement thus is simply false. In any event, Sandoz does not and cannot explain why Immunex would have paid tens of millions of dollars under the original agreement for a license to Roche's patent applications if they did not describe, and thus could not have resulted in patents that claimed, etanercept or the methods for making it.

When Amgen Inc. acquired Immunex roughly three years after the original agreement, Amgen sought to "eliminate the continuing obligations to pay royalties to Roche" pursuant to that agreement. (Pet. App. 7a.) Those efforts resulted in the 2004 Accord & Satisfaction at the center of this case, under which Immunex obtained a fully paid-up exclusive license in exchange for an up-front lump-sum payment.[1] (Pet. App. 7a,

---

[1] The most relevant rights granted and retained under the Accord & Satisfaction are discussed further below, but, notably, the agreement did *not* give Immunex "the sole right to make" or "use" the "claimed inventions," or the right to "collect all damages." (*Contra* Pet. 8–9.) Roche retained the right to practice the patents for "internal, non-clinical research" (Pet. App. 8a), and although Immunex could collect all damages awarded in an Immunex-initiated suit, Roche would "retain the entirety of any award of damages or lost profits" in any suit that Roche initiates (*id.*).

129a.) Significantly, although Sandoz repeatedly asserts that the Roche patent applications had nothing to do with etanercept until sometime after the 2004 agreement, Roche had a very different understanding, describing the contemplated transaction with Amgen as involving "our patents covering Enbrel." (C.A. App. 11494.) Indeed, confirming the scope of the invention described in its patent applications, Roche had obtained a European patent in 2003 that included claims covering etanercept based on the same original application. (C.A. App. 32286, 32303–05.)

The petition asserts that the Accord & Satisfaction was structured as a license rather than an assignment because Immunex's lead negotiator recognized a potential double-patenting problem and wanted "to avoid [double-patenting] law." (Pet. 9–10.) Again, there was a trial on this question, and the district court's findings were squarely to the contrary. The court found that Immunex's lead negotiator "credibly testified" about why the parties to the Accord & Satisfaction agreed upon a license rather than an assignment, and that testimony had nothing to do with double patenting. (Pet. App. 133a–134a.) Most importantly, Immunex wanted Roche to remain the owner so that Roche would have "an obligation to participate in litigation as a party," as it did throughout the proceedings in the district court.[2] (*Id.*) In light of the district court's findings, the petition's alternative history (which depends

---

[2] In omitting Roche as a respondent in this Court (Pet. ii), Sandoz takes the position that Roche was not among the "parties to the proceeding" in the court of appeals. Sup. Ct. R. 12.6. Not so. Recognizing that Immunex, as exclusive licensee, had the "right to control this litigation," Roche informed the court of appeals that it would look to Immunex to "defend the judgment"; however, because it "owns the patents at issue," Roche asked that it "remain a party as a 'Plaintiff' but not an 'Appellee.'" (C.A. Dkt.

on rejecting testimony the district court found to be credible) is simply false. It also rests on a mischaracterization of additional testimony of the relevant witness, who testified that an assignment would not even have "raised a question" of double patenting. (C.A. App. 5785–86.)

When the Accord & Satisfaction was executed, the Roche applications were still pending at the Patent Office. But, again—as reflected in the unchallenged findings on Sandoz's abandoned written-description defense—the applications did not need "repurposing" to cover etanercept. (*Contra* Pet. 10.) To the contrary, Roche had pursued claims that covered etanercept long before Immunex had any role in prosecution (*see* Pet. App. 29a–30a (citing original claim 19); C.A. App. 25127–32 (claims 3, 5, 19, and 23)), and as noted above Roche also obtained patents covering etanercept and similar fusion proteins in Europe based on the same applications. (C.A. App. 32286, 32303–05.) The Accord & Satisfaction obligated Roche to continue to prosecute the pending U.S. applications, subject to Immunex's direction. As the district court found, although Roche and Immunex "acted in good faith to diligently prosecute the Patents-in-Suit" (Pet. App. 143a–144a), delays "solely" attributable to the Patent Office—including lost files, years of patent-examiner inactivity, and unnecessary appeals—led to an extended prosecution. (*Id.*) As a result, the Roche patents did not issue until 2011 and 2012. And because the patent applications were filed before June 8, 1995, they are so-called "pre-GATT" or "pre-URAA" patents

---

No. 64.) The court of appeals granted Roche's request, and Roche remained a party-plaintiff, as reflected in the caption to the decision below. (Pet. App. 1a.)

entitled to a term of 17 years from their issuance.[3] (Pet. App. 144a–145a.)

B. Procedural Background.

Sandoz long ago stipulated to infringement of the Roche patents. (Pet. App. 3a.) And there is no dispute at this point that those patents are valid (and bar Sandoz's launch) if they are owned by Roche, rather than Immunex. Sandoz's only remaining defense is its unusual double-patenting theory, under which a patent valid in the hands of its original owner may be rendered invalid by a license to another more than a decade after invention.

After a 10-day trial on invalidity, the district court issued an 85-page opinion that rejected Sandoz's double-patenting theory on multiple grounds, several of which provide independent bases for the court's rejection of Sandoz's double-patenting defense. (Pet. App. 10a–11a (noting "layers of analysis," and Sandoz's concession that a loss at any step would be "fatal").) For example, the district court found that one of Sandoz's double-patenting references (the Jacobs '690 patent) does not cover etanercept at all—a conclusion that, contrary to Sandoz's representation (Pet. 12 n.5), had nothing to do with the "choice of legal test." (Pet. App.

---

[3] "Pre-GATT" and "pre-URAA" are used interchangeably to refer to patents issuing from applications filed before the June 8, 1995 effective date of the implementing legislation (the "Uruguay Round Agreements Act," or "URAA") of agreements reached as part of the Uruguay Round of the General Agreement on Tariffs and Trade, or "GATT." *See* Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994). Pre-URAA patents "have a patent term which is the greater of 20 years from the date of the filing of the application or 17 years from the date of the grant of the patent," whereas post-URAA patents "receive a 20-year term from the effective filing date." (Pet. App. 144a–145a (internal quotation marks omitted).)

137a–140a.) On appeal, the Federal Circuit majority determined that this conclusion was "correct[]" (Pet. App. 34a); the dissent did not disagree; and the petition does not even attempt to challenge that conclusion. That unchallenged conclusion fully disposes of Sandoz's double-patenting theory based on the Jacobs '690 patent, regardless of who owns the Roche patents.

That leaves only Immunex's '225 patent, claiming specific methods of using etanercept to treat psoriasis. (Pet. App. 119a, 143a.) Unlike the Roche patents, the '225 patent is a post-URAA patent, which is why it expired in 2019 despite issuing only a few months before the Roche patents. (Pet. App. 144a–145a.) As the district court found, in light of the legislative judgment reflected in the URAA, invalidating a pre-URAA patent based on the earlier expiration of a post-URAA patent would be improper, at least on the facts of this case. (Pet. App. 146a.) Specifically, the court found that "an act of Congress, rather than 'improper gamesmanship by the patentee' or 'strategic abuse of the patent system[,]' led to the Patents-in-Suit having a longer patent term." (*Id.* (alteration in original).) *See Novartis Pharm. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1361–62 (Fed. Cir. 2018) (rejecting double-patenting challenge to pre-URAA patent based on post-URAA patent). The district court also found that the '225 patent and the Roche patents claim patentably distinct inventions. (Pet. App. 147a–149a.) Affirmance on any of these grounds ends Sandoz's double-patenting challenge, irrespective of common ownership.

The court of appeals did not need to reach these independent grounds, however. Instead, it concluded that Sandoz could not meet its own proposed test for "common ownership"—the all-substantial-rights test from the Federal Circuit's prudential-standing cases.

(*See* Pet. App. 12.) Based on "the totality of the Accord & Satisfaction," the court held that "Roche did not transfer all substantial rights in the patents-in-suit to Immunex." (Pet. App. 24a.)

Judge Reyna dissented below. Like Sandoz, he premised his analysis on a mistaken view that the Roche applications did not cover etanercept until Immunex engineered a supposed change in subject matter. (*See* Pet. App. 38a–39a.) He recognized that the "majority's common ownership determination hinges on its interpretation of the 2004 Accord & Satisfaction," but he explained the he would "interpret" that agreement differently. (Pet. App. 36a–37a.) Sandoz's subsequent request for rehearing en banc was denied without dissent, including by Judge Reyna. (Pet. App. 157a–158a.)

In its petition, Sandoz follows the panel dissent's lead and thus urges this Court to adopt an erroneous understanding of what Roche invented and sought to patent and an interpretation of the Accord & Satisfaction that the majority, based on the record before it, flatly rejected. In short, the petition asks this Court to reinterpret a particular 2004 license agreement against a proposed factual backdrop inconsistent with the facts as found below.

REASONS FOR DENYING THE PETITION

The court of appeals applied the legal standard that Sandoz asked it to apply, and it decided—based on a holistic assessment of the license agreement at the center of this case—that Roche, not Immunex, owns the Roche patents. The Federal Circuit's factbound assessment was correct, but it would not warrant this Court's review in any event. And even if the decision below presented a genuinely significant question of

federal law, this case would be a poor vehicle for resolving it, both because threshold issues would complicate the Court's review, and because the district court rejected Sandoz's double-patenting defense on multiple independent grounds, making the factbound question Sandoz tries to present largely academic, even in this particular case.

The petition should be denied.

I. CERTIORARI IS NOT WARRANTED TO REVIEW A FACTBOUND, CASE-SPECIFIC ASSESSMENT OF A PARTICULAR LICENSE AGREEMENT.

A. The Court of Appeals' Factbound Assessment of the Accord & Satisfaction Does Not Warrant This Court's Review.

Sandoz's petition asks this Court to review the Federal Circuit's factbound assessment of the Accord & Satisfaction between Roche and Immunex. As Sandoz acknowledges, the court below "unanimously agreed with Sandoz" that "the relevant question for ODP purposes was whether the 2004 Agreement had given Immunex 'all substantial rights' in Roche's patent applications." (Pet. 13.) But the court determined that Sandoz failed to establish that Roche actually transferred all substantial rights, based on a detailed assessment of the Accord & Satisfaction. (Pet. App. 17a–24a.) As the dissent below acknowledged, the majority's analysis (and the dissent's disagreement) "hinges on [the] interpretation" of that agreement. (Pet. App. 36a.) Sandoz argues that majority erred in its application of Sandoz's proposed all-substantial-rights test, but the "misapplication of a properly stated rule of law" generally does not justify a grant of certiorari. Sup. Ct. R. 10. And the court of appeals' holistic assessment did not treat any single fact as dispositive,

making it all the less likely that the decision below will affect the outcome of future cases.

Nevertheless, Sandoz attempts to manufacture a path through the lower court's totality-of-the-circumstances assessment by suggesting that the decision actually adopted a bright-line "safe harbor": to avoid a transfer of ownership, an agreement "need only preserve a formal right" for the licensor to sue, and that "right can be purely illusory." (Pet. 21–22.) On Sandoz's telling, the court of appeals held that the licensor's retention of an illusory right to sue is sufficient, all by itself, to foreclose a transfer of ownership and thus to defeat a double-patenting challenge. But no such holding exists. Indeed, Sandoz's account mischaracterizes the decision below in at least two distinct and important ways.

First, the court of appeals did not rely solely on Roche's retained right to enforce its patents. To the contrary, the court's application of Sandoz's all-substantial-rights test was properly based on "the 'totality' of the Accord & Satisfaction." (Pet. App. 24a.) Most importantly, the court reasoned that *two* key sets of rights—the "enforcement and alienation rights under the Accord & Satisfaction"—*together* made "clear that Roche did not transfer all substantial rights in the patents to Immunex." (Pet. App. 21a.) Sandoz seizes on "enforcement" while burying the court's treatment of "alienation" in a footnote (Pet. 14 n.6), but the Federal Circuit relied heavily on Roche's "right to veto any assignment of Immunex's interest in the patents-in-suit," observing that "restrictions on the ability to transfer patent rights are inconsistent with a transfer of all substantial rights." (Pet. App. 23a.) And the court also considered "the purpose of the agreement," the fact that "Immunex's ability to terminate the agreement" was "restricted," and "Roche's right to

practice the patents for internal, non-clinical research," among other things. (Pet. App. 21a–24a & n.7.) It was the court's detailed assessment of all of the facts, and not any bright-line rule, that led to the conclusion that Roche retained ownership of the patents.

Second, the court of appeals did not hold that an "illusory" right to enforce patents could qualify as a substantial right at all. Instead, the court rejected Sandoz's argument that Roche's right to sue was illusory on the facts. (Pet. App. 22a.) In particular, the court carefully assessed the "nature of [Roche's] retained right to sue" and concluded that it was a "broad" enforcement right, "thoroughly inconsistent" with "a conclusion that the patents-in-suit were effectively assigned to Immunex." (Pet. App. 21a.) The court emphasized that, after a 180-day notice period, "Roche can decide whether or not to bring suit, when to bring suit, where to bring suit, what claims to assert, what damages to seek, and whether to seek injunctive relief." (*Id.* (internal quotation marks and brackets omitted).)

Sandoz nevertheless insists that Roche's enforcement rights are "purely illusory" because (among other reasons) Immunex could supposedly grant "a royalty-free sublicense to the alleged infringer." (Pet. 22.) But Sandoz fails to mention that the court of appeals expressly rejected Sandoz's reading of the agreement in this respect, too: "once Roche's secondary right to sue is triggered, Immunex no longer has any right to rectify any infringement *and cannot frustrate a Roche-initiated suit by granting a royalty-free sublicense*." (Pet. App. 22a (emphasis added).) Sandoz may disagree with the Federal Circuit's interpretation of the Accord & Satisfaction, but that case-specific disagreement provides no basis for this Court's review.

Once Sandoz's mischaracterizations are cleared away, a straightforward reading of the decision below reveals that this case does not even implicate the question the petition purports to present. The petition asks: "May the patent owner avoid the rule against double patenting by buying all of the substantial rights to a second, later-expiring patent for essentially the same invention, so long as the seller retains nominal ownership and a theoretical secondary right to sue for infringement?" (Pet. i.) One can speculate about how the Federal Circuit might answer that question,[4] but the decision below did not address it. Instead, the court of appeals concluded on the facts that Immunex did *not* "buy[] all of the substantial rights" in the Roche patents, and that Roche did *not* retain a merely "theoretical secondary right to sue for infringement." (Pet. i.)

Moreover, the court of appeals' application of Sandoz's common-ownership test was appropriately modest. It expressly declined to "import" into double-patenting law "the entirety of [the Federal Circuit's] body of law analyzing who is a statutory 'patentee,'" from which Sandoz drew the all-substantial-rights test. (Pet. App. 16a.) The court held only that, in certain circumstances, the all-substantial-rights test may be "informative"—not necessarily dispositive—"in evaluating whether … patents are 'commonly owned'" for purposes of double patenting. (*Id.*) Sandoz thus challenges

---

[4] In the prudential-standing context, the Federal Circuit has held that an illusory second right to sue will *not* defeat a transfer of ownership of all substantial rights. *See, e.g.*, *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1251–52 (Fed. Cir. 2000). One would expect the Federal Circuit to follow *Speedplay* to the extent that it applies the "informative" all-substantial-rights analysis in the double-patenting context as well. Indeed, rather than rejecting *Speedplay* as irrelevant to the inquiry, the decision below distinguished *Speedplay* on the facts. (Pet. App. 22a.)

the case-specific application of a merely informative test that may rarely, if ever, be deployed in the future.

Sandoz's petition attempts to manufacture importance with atmospherics that have little to do with this case. For example, Sandoz repeatedly decries Immunex's purported "third decade" of "exclusive patent control" over "the same invention." (Pet. 19–20.) But it is not clear what "patent control" Sandoz has in mind. The petition certainly does not challenge the district court's finding—which the court of appeals said was "correct[]"—that the Jacobs '690 patent (issued in 1997) "does not cover etanercept." (Pet. App. 34a.) And the only other Immunex-owned patent that Sandoz points to (the '225 patent) issued shortly before the Roche patents in 2011, and it does not claim the same (or essentially the same) inventions as the Roche patents at all—it covers independently inventive methods of treating psoriasis with etanercept and achieving a particular clinical outcome, not the compound itself and certainly not methods of making the compound.[5] (Pet. App. 147a–149a (finding that the '225 patent claimed a "patentably distinct" invention from the Roche patents).)

Etanercept and methods of making it were invented by Roche scientists, and the Roche patents carry exactly the term that the law governing applications filed before June 8, 1995 provides: 17 years from the date of issuance. *See* Uruguay Round Agreements Act, Pub. L. No. 103-465, sec. 532(a)(1), § 154(c)(1), 108 Stat. 4809, 4984–85 (1994) (providing for a term "17

---

[5] This Court has observed that biologic drug manufacturers "may hold multiple patents covering the biologic, its therapeutic uses, and the processes used to manufacture it." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017).

years from grant" for patents that "result[] from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act"). The Roche inventors are entitled to their "single, time-limited patent term" for the breakthrough inventions they made and Immunex licensed years later. (Pet. 5.)

B. The Decision Below Is Correct and Consistent With This Court's Precedent.

Based on the totality of the Accord & Satisfaction, the Federal Circuit's application of Sandoz's proposed all-substantial-rights test was correct: Immunex's exclusive license under that agreement was *not* "tantamount to an assignment," because Roche retained substantial rights in its patents. (Pet. App. 17a.) The Federal Circuit's assessment was informed by its precedent from prudential-standing cases that Sandoz expressly invited the court to apply. (Pet. App. 11a–12a (noting that Sandoz's test "[b]orrow[ed] from [the Federal Circuit's] 35 U.S.C. § 281 case law," which governs "who may sue for infringement as a 'patentee'" under the statute).) The lower court's conclusion was correct whether analyzed under Sandoz's borrowed prudential-standing test or under this Court's precedent directly addressing patent ownership.

This Court has held that, for an agreement transferring rights in a patent to constitute an assignment, the agreement "must undoubtedly convey to [the assignee] the *entire and unqualified monopoly* which the patentee held in the territory specified," and that "any assignment short of this is a mere license." *Gayler v. Wilder*, 51 U.S. (10 How.) 477, 494 (1851) (emphasis added). In so holding, this Court reasoned that any other rule could (among other things) "subject a party" to "harass[ment] by a multiplicity of suits instead of

one, and to successive recoveries of damages by different persons holding different portions of the patent right in the same place." *Id.* at 494–95; *see also Pope Mfg. Co. v. Gormully & Jeffery Mfg. Co.*, 144 U.S. 248, 250–52 (1892) (applying *Gayler*'s "entire and unqualified" conveyance requirement). Sandoz has never argued that the Accord & Satisfaction conveyed to Immunex the "entire and unqualified monopoly" that Roche held in any territory, nor could it. But under any conceivable standard for patent ownership, Immunex does not own the Roche patents.

Four provisions of the Accord & Satisfaction are particularly important.

1. Roche's Right to Sue. — Under the Federal Circuit precedent that Sandoz asked the court below to apply, a licensor's retained "right to sue accused infringers . . . often precludes a finding that all substantial rights were transferred." *Alfred E. Mann Found. for Sci. Research v. Cochlear Corp.*, 604 F.3d 1354, 1361 (Fed. Cir. 2010). And the Federal Circuit has repeatedly held that a genuine second right to sue—one that "activates" only after the licensee declines to sue—is a substantial right. *See, e.g.*, *id.* at 1362; *Abbott Labs. v. Diamedix Corp.*, 47 F.3d 1128, 1132 (Fed. Cir. 1995). Having correctly found that Roche's second right to sue was "broad" and that Immunex could not "frustrate[]" a Roche-initiated suit with a "royalty-free sublicense" to the accused infringer (Pet. App. 22a), the court of appeals was right to weigh Roche's enforcement rights heavily in the balance.

Under this Court's precedent, Roche's retained enforcement rights ought to be dispositive: if Roche retains the right to sue, then a finding that Immunex is nonetheless an assignee would risk exposing accused infringers to "a multiplicity of suits," first by Immunex alone and then by Roche. *Gayler*, 51 U.S. (10 How.) at

494–95. *Gayler* forecloses such a result. Because Immunex is a mere exclusive licensee, there is no risk of multiple suits. Immunex can enforce the Roche patents only in a suit (like this one) to which Roche is also a party, *see Indep. Wireless Tel. Co. v. Radio Corp. of Am.*, 269 U.S. 459, 466, 469 (1926), so that a final judgment will preclude any subsequent suit on the same claim, whether such suit is brought by Immunex or by Roche.

2. Roche's Right to Practice the Patents. — The petition does not even mention (although the court of appeals did) that Roche retains the right to practice its patents for internal, non-clinical research. (Pet. App. 8a.) Under the prudential-standing precedent Sandoz asked the court below to apply, the retention of this right to practice the patents might not preclude "the transfer of all substantial rights" all by itself, but it contributes to a "totality" that is "sufficient to do so." *AsymmetRx, Inc. v. Biocare Med., LLC*, 582 F.3d 1314, 1321 (Fed. Cir. 2009).

Under this Court's patent-ownership precedent, Roche's retained right to practice the patents is at least as significant. *Gayler* holds that an assignment must convey "the entire and unqualified monopoly . . . *excluding the patentee himself*." 51 U.S. (10 How.) at 494 (emphasis added). In *Gayler*, for example, the grantor's retained right to practice the patent resulted in a determination that the agreement in question was "a license only" and not "an assignment," even within the territory in which the grantee's rights were described as "exclusive." *Id.* at 495; *see also Waterman v. Mackenzie*, 138 U.S. 252, 255–56 (1891). Under *Gayler*, Roche's retained right to practice the patents is inconsistent with a conclusion that Immunex obtained Roche's "entire and unqualified monopoly." 51 U.S. (10 How.) at 494.

3. Immunex's Option to Purchase. — Sandoz argues that Immunex's option to request an assignment for $50,000 demonstrates that the "license" is effectively illusory, and indicates that Immunex actually owns the Roche patents. (Pet. 21.) But Immunex cannot be said to already own what it must pay $50,000 to obtain, and Federal Circuit precedent has long distinguished between present assignments and potential assignments in the future. *See Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1378–79 (Fed. Cir. 2000) (option to reacquire all substantial rights has no bearing on current ownership status); *see also DDB Techs., L.L.C. v. MLB Advanced Media, L.P.*, 517 F.3d 1284, 1290 (Fed. Cir. 2008). In this respect, patent assignment principles are consistent with property law in general. As this Court has explained, an option "when given" does not "operate to transfer" the property that the option holder has the right to purchase. *Comm'r v. Smith*, 324 U.S. 177, 181 (1945).

Moreover, Sandoz again strains the record with its description of the economics of the Agreement. As the court of appeals recognized, the additional consideration required to exercise the option must "be viewed in the context of the entirety of the agreement," under which "Immunex paid Roche tens of millions of dollars as consideration" (Pet. App. 24a) for a license while Roche continued to own the patents, with all of the obligations that patent law imposes upon the patent owner, both in prosecution and in litigation. Immunex may be $50,000 away from someday owning the Roche patents, but for now its obligation to pay only underscores its current status as licensee, not owner.

4. Roche's Right to Veto Assignments. — Roche also has an absolute right to veto any Immunex attempt to assign its rights under the Accord & Satisfaction. Under the Federal Circuit law Sandoz asked the

court below to apply, such a restriction on alienation is dispositive. *See Sicom Sys. Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 979 (Fed. Cir. 2005) (restriction on "right to assign" was "fatal" to claim that ownership had been transferred); *see also Propat Int'l Corp. v. RPost, Inc.*, 473 F.3d 1187, 1191 (Fed. Cir. 2007) (Bryson, J.) ("The right to dispose of an asset is an important incident of ownership, and such a restriction on that right is a strong indicator" that licensee did not receive "all substantial rights under the patent."). If Immunex had actually owned the Roche applications under the Accord & Satisfaction, it could have prosecuted them itself or sold them to someone else who wanted to prosecute them. Instead, Roche's veto right ensured that Roche would control who its partner in prosecution would be.

In contrast, the Accord & Satisfaction treated Roche's non-U.S. patents differently. While Wyeth—which received from Immunex the product rights to Enbrel® outside North America and to whom Roche assigned its non-U.S. etanercept patents—was subject to the same general restriction on assignments of interests under the contract, another provision made clear that Wyeth was entirely free to assign the non-U.S. patents themselves. (C.A. App. 25849 (§11.5).) The contrast between Wyeth's absolute freedom to assign the non-U.S. patents and Roche's absolute control over Immunex's assignment of its rights under the Accord & Satisfaction further demonstrates that Immunex does not own the Roche patents. (*See* Pet. App. 8a n.4; Pet. App. 133a.)

* * *

Other features of the Accord & Satisfaction ignored in the petition also bear on the totality-of-the-circumstances assessment. For example, the agreement protects Immunex's license rights in the event of a Roche

bankruptcy (C.A. App. 25848 (§11.1)), which would be unnecessary if Immunex owned the patents: if Immunex owned the Roche patents, they would never become part of any Roche bankruptcy estate. The Accord & Satisfaction also requires that Roche "prosecute and maintain" the patents (at Immunex's direction), ensuring that Roche would owe a continuing duty of candor to the Patent Office, and again reflecting the parties' intent to maintain a license relationship. (C.A. App. 25840 (§3.3); C.A. App. 5733–36.)

Curiously, although Sandoz's petition is at base a challenge to the Federal Circuit's assessment of "common ownership" under the all-substantial-rights test, Sandoz does not cite a single decision applying that test, nor does it rely on a single decision of this Court assessing whether an agreement effected an assignment of patent rights. Instead, Sandoz leans most heavily on a line of cases—including *Kimble v. Marvel Entertainment, LLC*, 135 S. Ct. 2401 (2015), *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989), and *Singer Manufacturing Co. v. June Manufacturing Co.*, 163 U.S. 169 (1896)—that have nothing to do with assessing patent ownership or even with the doctrine of obviousness-type double patenting. These cases stand for the unremarkable proposition that the rights in an expired patent cannot be extended, whether by contract (*e.g.*, as in *Kimble*) or by state law (*e.g.*, as in *Bonito Boats*). None of them casts doubt on the right to enforce a valid patent for its full statutory term, even if the owner of the patent decides to license the patent to another company that happens to own patents covering similar (but distinct) technology, arising out of separate research done by separate inventors working at different companies and at different times.

C. This Case Provides No "Roadmap" or "Blueprint" for Extending Patent Protection.

To try to gin up broader ramifications for its fact-based loss, Sandoz asserts that the decision below creates a "roadmap" or "blueprint for patentees interested in extending their monopolies." (Pet. 16, 23.) Of course, Sandoz does not mention the district court's finding that "an act of Congress, rather than improper gamesmanship by the patentee or strategic abuse of the patent system," led to the Roche patents having the terms they have. (Pet. App. 146a (internal quotation marks omitted); *see also* Pet. App. 24a n.8 (finding "no clear error" in district court's findings regarding lack of "gamesmanship").) But even setting aside the district court's unchallenged finding that Immunex engaged in no gamesmanship, this case cannot possibly serve as a roadmap for others to engage in any abuse of the system.

This case is one-of-a-kind. The patent terms that Sandoz challenges flow from (1) long-pending prosecutions of two patents filed before the June 8, 1995 effective date of the URAA, and (2) the fact that pre-URAA patents are entitled to a 17-year term from issuance. And there can be no fear that another could "[f]ollow the steps that Immunex took." (Pet. 16.) Immunex did not even know about Roche's prior invention of etanercept until around the time it first began marketing Enbrel®, at which point Immunex took a nonexclusive license, followed by the exclusive license under the Accord & Satisfaction years later. The apparent roadmap, then, is to develop and introduce a product that one does not know someone else invented, described, and claimed in an earlier-filed pre-URAA patent application; hope the Patent Office delays approval of that application for years (including by losing

the file and letting years pass without taking any action whatsoever (*see* Pet. App. 143a–144a)); take a nonexclusive license to the application and pay millions of dollars in royalties under it; and then later buy out the ongoing royalty obligation and convert the license into an exclusive one. Rather than "easily replicable steps" (Pet. 27), this is an impossible-to-imitate confluence of events, particularly since the window for new pre-URAA applications closed more than 25 years ago. *See* 35 U.S.C. § 154(c)(1).

That aside, familiar statutory requirements for patent validity will block the gamesmanship Sandoz claims to fear in any event. Sandoz predicts that patent owners seeking to extend their rights will "acquir[e] the rights to a pending patent application involving a related (but distinct) invention and then, after taking over prosecution, amend the claims to cover its own product." (Pet. 24.) But if the second application does not actually describe the patent owner's invention, the "written description" requirement of 35 U.S.C. § 112 will prevent any valid claims covering the patent owner's product from issuing. And if the patent owner's invention predates the inventions described in the application to be licensed, then amending the claims in that pending application will not succeed, because the claims will fail to meet the "novelty" requirement of 35 U.S.C. § 102. The novelty requirement is particularly significant for post-URAA patents, since taking a license to an *earlier-filed* patent (as in this case) will not extend term—20 years from *filing*, 35 U.S.C. § 154(a)(2)—while any *later-filed* patent claiming the same invention will be invalid as anticipated by the prior patent under § 102 (or obvious under § 103). After the URAA's 1995 effective date, the supposed "roadmap" that Sandoz divines leads nowhere. (*Contra* Pet. 24–25.)

What makes the facts of this case so unusual (and impossible to replicate) is that Roche separately invented etanercept and described that invention in a pre-URAA patent application before Immunex later made and developed the compound. Because Roche was the first to invent the compound, Immunex took a license to Roche's patent applications, for which it paid many millions of dollars in recognition of Roche's prior invention. That others might follow Immunex's lead in taking a license to valid patent rights owned by another company whose researchers independently made important inventions is no cause for concern.

II. EVEN IF THE QUESTION PRESENTED WERE SIGNIFICANT, THIS CASE WOULD BE A POOR VEHICLE FOR ADDRESSING IT.

The factbound question presented by Sandoz's petition does not warrant this Court's review. But even if it did, the Court's review would be impeded by the need to address the threshold question whether a license agreement entered into years after an invention was made can *ever* give rise to double patenting—regardless of whether "all substantial rights" are transferred under such a license. Beyond that, no matter how that threshold question or the question presented by the petition might be resolved, the answer will make no difference to the outcome in this case, because the district court rejected Sandoz's double-patenting defense on multiple independent grounds.

A. Sandoz's Novel Double-Patenting Defense Turns on a Threshold Issue That Would Obstruct the Court's Review of the Question Sandoz Seeks to Present.

If the Court were to grant the petition to determine whether the Federal Circuit correctly assessed Roche's

and Immunex's rights under the Accord & Satisfaction, it would first need to address the threshold question whether the all-substantial-rights inquiry that Sandoz has urged (and the court of appeals viewed as informative) is consistent with the Patent Act and its history, as well as this Court's decisions.

As Sandoz acknowledges, obviousness-type double patenting is grounded in § 101 (Pet. 18), which provides that "[w]hoever *invents or discovers* any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain *a patent* therefor." 35 U.S.C. § 101 (emphases added). Section 101's text refers only to those who "invent[] or discover[]," not to subsequent patent *owners*. As a result, the statute by its terms does not suggest that double patenting can arise based on common ownership of patents claiming inventions made by separate inventors working independently. The ordinary rules of novelty and nonobviousness will generally ensure that only the first of two separate inventors may obtain a patent on a given invention. *See id.* §§ 102, 103.

To be sure, the Federal Circuit has sometimes "treated commonly-owned applications by different inventors *as though* they were filed by the same inventor" for double-patenting purposes. *In re Longi*, 759 F.2d 887, 893 (Fed. Cir. 1985) (emphasis added). But this Court has not done so. Indeed, although Sandoz fails to mention it, all of this Court's double-patenting decisions cited in the petition involved multiple patents issued to the same *inventors*, consistent with the rule now codified in § 101. *See Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *McCreary v. Pa. Canal Co.*, 141 U.S. 459 (1891); *James v. Campbell*, 104 U.S. 356

(1882); *Suffolk Co. v. Hayden*, 70 U.S. (3 Wall.) 315 (1866).[6]

Given changes to the standards for invalidity based on prior art in the 1980s—and, in particular, the prohibition on the use of work that was commonly owned "at the time the invention was made" as prior art, Patent Law Amendments Act of 1984, Pub. L. No. 98-622, § 103, 98 Stat. 3383, 3384 (codified in 35 U.S.C. § 103(c))—there may be a plausible argument for treating work commonly owned at the time of invention as though it was done by a common inventor. *See* U.S. Patent & Trademark Office, *Manual of Patent Examining Procedure* § 804.03(II) (9th ed. rev. 10.2019, June 2020) (defining "common ownership" to mirror § 103(c), focusing on "the time the claimed invention was filed or made"); S. Rep. No. 98-663, at 8 (1984) ("The term 'commonly owned' means wholly owned by the same person, persons, or organization at the time the invention was made."). But there is no plausible reading of "[w]hoever invents or discovers" that would encompass a company that took a license to an invention many years after it was made by an unrelated inventor.

B. Sandoz's Double-Patenting Defense Would Fail Regardless of the Resolution of the Question Presented.

Even if this Court were to adopt both Sandoz's proposed legal standard (as the court of appeals did) and

---

[6] *See also Thomson-Houston Elec. Co. v. Ohio Brass Co.*, 80 F. 712, 726–27 (6th Cir. 1897) (Taft, J.) (rejecting contention that "the owner of one patent would avoid it [*i.e.*, render it invalid] by acquiring ownership of another" as "anomalous"); *Van Heusen Prods., Inc. v. Earl & Wilson*, 300 F. 922, 936 (S.D.N.Y. 1924) (Hand, J.) (rejecting argument that "double patenting applies between two independent inventors, merely because one has taken an assignment of the other invention").

Sandoz's preferred reading of the Accord & Satisfaction (as the court of appeals did not), Sandoz's double-patenting defense would still fail. The district court rejected the defense on multiple independent grounds.[7]

First, the district court found that the claims of the Roche patents, on the one hand, and the identified claims of the Immunex-owned Jacobs '690 patent and Finck '225 patent, on the other hand, were directed to distinct inventions, which means there would be no double patenting even if there were common ownership under Sandoz's, or any other, test. (Pet. App. 136a–144a.) The court of appeals agreed with the district court that the "Jacobs '690 patent does not cover etanercept" (Pet. App. 34a)—a determination Sandoz fails to challenge in its petition, thus waiving the issue.[8] As for the '225 patent, the district court found that the claimed methods for treating psoriasis with etanercept were distinct from the Roche patents' claims to etanercept itself and methods of making etanercept, and the court of appeals did not address the issue.

Second, the district court recognized that double patenting is intended to address "*unjustifiable* extensions of patent terms," and it found on the particular facts of this case that the difference in patent term between the Roche patents and the '225 patent resulted from "an act of Congress" rather than any improper

---

[7] If the Court were to grant the petition, Immunex would ask the Court to affirm on these independent bases.

[8] Sandoz lumps the '690 and '225 patents together, saying that the district court's decision was "based substantially on its choice of which legal test to apply." (Pet. 12 n.5.) But that dispute over the proper "legal test"—either so-called "one-way" or "two-way" distinctness—relates solely to the '225 patent. (*See* Pet. App. 43a–45a (Reyna, J., dissenting).) There was no dispute over the proper test for the '690 patent; Sandoz simply lost on the facts, based on the evidence at trial. (Pet. App. 137a–140a.)

conduct on Immunex's part. (Pet. App. 146a.) Against this backdrop, the district court determined that "the statutory term for the Patents-in-Suit may not be cut short to mirror the statutory term for the Finck Patents," one of which is the '225 patent. (*Id.*)

* * *

In short, the factbound question the petition purports to present does not warrant review, but even if it did, this case would be a poor vehicle for resolving it.

CONCLUSION

For the foregoing reasons, the Court should deny the petition for certiorari.

Respectfully submitted,

JEFFREY P. KUSHAN
JOSHUA J. FOUGERE
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

CONSTANTINE L. TRELA, JR.*
STEVEN J. HOROWITZ
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
(312) 853-7000
ctrela@sidley.com

SUE WANG
SIDLEY AUSTIN LLP
555 California Street
Suite 2000
San Francisco, CA 94104
(415) 772-1200

WENDY WHITEFORD
J. DREW DIAMOND
DENNIS SMITH
JOSEPH E. LASHER
JAMES A. HIGH, JR.
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320
(805) 447-1000

Counsel for Respondents

April 12, 2021

* Counsel of Record