No. 20-_____

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Under federal patent law, a patent owner may receive only one period of exclusivity for its invention and may not obtain a second patent on the same invention or a "colorable variation" thereof. *McCreary* v. *Pa. Canal Co*., 141 U.S. 459, 467 (1891). The question presented is:

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?

PARTIES TO THE PROCEEDING

All parties are identified in the caption.

Hoffmann-La Roche Inc. was a plaintiff in the district court but expressly declined to participate in the appeal before the Federal Circuit, *see* Hoffmann-La Roche C.A. Notice (Dkt. No. 64); Practice Note to Fed. Cir. R. 12, and therefore is not a respondent in this Court, *see* S. Ct. R. 12.6.

RULE 29.6 STATEMENT

Sandoz Inc., Sandoz International GmbH, and Sandoz GmbH are indirect, wholly owned subsidiaries of Novartis AG, a publicly traded company. No other publicly traded company owns 10% or more of the stock of any petitioner.

RELATED PROCEEDINGS

United States District Court (D.N.J.):

Immunex Corp. v. *Sandoz Inc.*, No. 2:16-cv-1118-CCC-MF (Oct. 10, 2019)

United States Court of Appeals (Fed. Cir.):

Immunex Corp. v. *Sandoz Inc.*, No. 2020-1037 (July 1, 2020), *reh'g denied* (Sept. 29, 2020)

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Sandoz Inc., Sandoz International GmbH, and Sandoz GmbH (collectively, Sandoz) respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

INTRODUCTION

For two hundred years, the rule has been simple: No person can receive more than one patent on the same invention. Once a patent's statutory term expires, the invention belongs to the public. The Federal Circuit has now allowed patent owners to buy themselves an exemption from that rule and to obtain a longer term of exclusivity.

Respondent Immunex got one full term of patent protection for the protein used in the blockbuster medication Enbrel®. But Immunex wanted more—an additional period of exclusivity for the same invention. And the Federal Circuit obliged, in a decision that is little more than a how-to guide for inventors trying to secure multiple patents—and thus multiple patent terms—for a single invention.

The Federal Circuit's decision compromises federal patent law's rule against "double patenting," a critical bulwark ensuring that, after the inventor enjoys the statutory patent term, the invention must pass into the public domain. As this Court has made clear for more than a century, with the expiration of the original patent term, the public has the right to practice the invention. "This Court has carefully guarded that cut-off date," *Kimble* v. *Marvel Entm't, LLC*, 576 U.S. 446, 451 (2015), and its vigilance is warranted here. The Court should grant certiorari and reverse.

At the heart of this case is a straw-ownership deal. In 2004, anticipating the end of its original period of exclusivity, Immunex turned to its competitor Hoffmann-La Roche. Roche had developed a protein that was similar to (but distinct from) Immunex's own, but the Roche protein turned out not to work. Seeing an opportunity, Immunex engineered a contract giving it control of the patent applications for Roche's failed protein. The agreement allowed Immunex to rewrite the applications, replacing Roche's original claims with claims for Immunex's own protein. Still more, the agreement allowed Immunex to keep all meaningful rights in the resulting patents—including the right to exploit the invention and the right to sue infringers.

But Immunex knew that if it took outright ownership in addition to effective control, the claims would be invalid for double patenting. So Immunex insisted that the agreement leave Roche as the nominal owner of the applications and resulting patents. And *for that superficial reason alone*, Immunex argued, the patents could skirt the rules against double patenting: Immunex could enjoy another *decade* of patent protection for Enbrel—with billions a year in revenue—free from competition.

The Federal Circuit blessed Immunex's strategy. The last of Immunex's original Enbrel patents expired in 2019. And Sandoz stands ready to market an FDA-approved generic version of the drug. But the Federal Circuit held that the claims of the later-expiring "Roche" patents prevent Sandoz from launching its product until 2029. As the dissent made clear, those claims—written *by Immunex* to cover *Immunex's* invention—would be invalid if Immunex were the record

owner. But the Federal Circuit upheld them solely because the Immunex-Roche agreement leaves Roche with titular ownership and an illusory right to sue for infringement *if* Immunex does not—even as Immunex keeps every substantial right to write, exploit, and enforce the patents.

The Federal Circuit's decision guts the Patent Act's one-patent-per-invention requirement. Not only does it contradict this Court's decisions making clear that parties cannot just contract around the statutory limit on patent term, it actually provides a blueprint for doing just that. Going forward, patentees need only adopt the straw-owner framework outlined by the Federal Circuit's decision to secure a second patent on an already-patented invention. This case is an excellent vehicle because it highlights the consequences of that error—and the need for this Court's intervention. The Federal Circuit's decision is the last roadblock to competition for a significant biologic medicine and access for patients. If this Court does not act, Immunex's exclusive Enbrel franchise will be shielded for a third decade by the very type of duplicate patent that the prohibition on double patenting is designed to prevent, and the Federal Circuit's errors will continue to undermine a foundational principle of patent law as others follow Immunex's playbook.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-45a) is reported at 964 F.3d 1049. The decision of the district court (Pet. App. 46a-150a) is reported at 395 F. Supp. 3d 366.

JURISDICTION

The court of appeals entered judgment on July 1, 2020. A petition for rehearing was denied on September 29, 2020 (Pet. App. 157a-158a). This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Section 101 of Title 35 of the United States Code provides:

> **Inventions patentable**
>
> Whoever 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, subject to the conditions and requirements of this title.

STATEMENT

A. The Rule Against Obviousness-Type Double Patenting.

Since its earliest days, federal patent law has limited inventors to a single patent for a single invention. In applying the first patent acts, for example, courts barred inventors from asserting a second patent claiming "substantially . . . the same invention[s]" as an earlier patent. *Odiorne* v. *Amesbury Nail Factory*, 18 F. Cas. 578, 579 (C.C.D. Mass. 1819) (Story, J.). In the years since, this Court has reinforced the principle—explaining, for example, that a "second patent [is] void" if it is "only a colorable variation from" an earlier patent to the same inventor. *McCreary* v. *Pa. Canal Co.*, 141 U.S. 459, 467 (1891). This consistent line of decisions reflects the fundamental bargain of

patent law: An inventor receives a period of statutory exclusivity, but only for a "limited Time[]," U.S. Const. art. I, § 8, cl. 8, and once that period expires, the invention "becomes public property," *Singer Mfg. Co.* v. *June Mfg. Co.*, 163 U.S. 169, 185 (1896). It is the "limited Time[]," no less than the grant of exclusivity, that makes patent protection "promote the Progress of Science." U.S. Const. art. I, § 8, cl. 8.

Today, the one-patent-per-invention rule is codified at 35 U.S.C. § 101. Under that provision, a person who "invents or discovers" something "new and useful" may obtain "*a* patent" for his or her invention (emphasis added). In using the singular, "§ 101 forbids an individual from obtaining more than one patent on the same invention." *AbbVie Inc.* v. *Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1372 (Fed. Cir. 2014). The creator of a single invention is thus entitled to a single, time-limited patent term. *See* 35 U.S.C. § 154(b) (specifying the durational limits on a single patent).

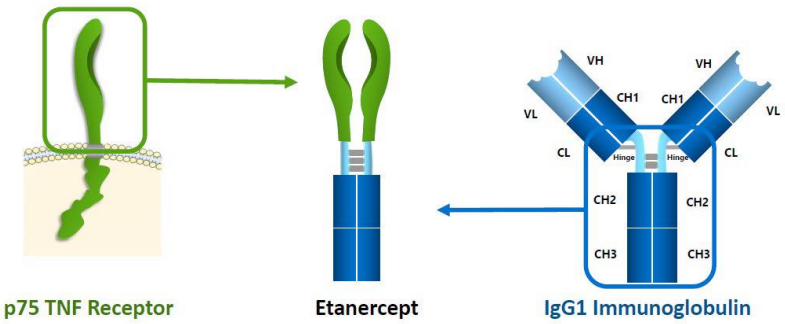
Courts and the Patent Office enforce these principles through the prohibition on "double patenting." A person who secures a patent is barred "from securing a second, later expiring patent" that claims either (1) "the same invention" or (2) "obvious variants thereof." *AbbVie*, 764 F.3d at 1373. The second category of double patenting—known as "obviousness-type double patenting" (ODP)—is at issue here. The rule against ODP ensures that an inventor "does not receive an undue patent term extension" merely by making obvious tweaks to an already-patented invention. *Id.*

Importantly, the rule against ODP prevents the same person not only from *applying* for a second patent, but from *securing* one. Thus, ODP can apply when common ownership arises after invention. For example, ODP prevents two inventors from separately applying for patents on obvious variants of the same invention, but then assigning their rights to the same company (*e.g.*, their common employer). Courts have long recognized that ODP covers "commonly-owned" patents and applications "with different inventive entities." *In re Longi*, 759 F.2d 887, 893 (Fed. Cir. 1985); *see* p. 18, *infra*.

B. Etanercept and the Immunex-Roche Deal.

This case involves Immunex's successful circumvention of the rule against ODP. Immunex invented a protein called etanercept, which became the active ingredient in its blockbuster treatment Enbrel. Starting in 1997, Immunex obtained a series of patents covering the etanercept protein and methods of using it—the last of which expired in 2019. But instead of allowing those patents to enter the public domain at the end of their term, as the law intends, Immunex engineered a *third decade* of exclusivity for its franchise. It bought patent applications from a *different* inventor for a *different* invention and then rewrote them to cover etanercept—effectively re-patenting its invention.

1. Etanercept is a "fusion" protein that combines a specific receptor molecule (p75) with a specific immunoglobulin molecule (IgG_1):



C.A. App. 7000; *see* Pet. App. 3a-4a. In the late '80s and early '90s, Immunex became the first to clone the p75 receptor and the first to join the p75 receptor with IgG_1 to make the protein now known as etanercept. *See* C.A. App. 5269, 10602, 26978, 28264, 28266 (Dkt. No. 80). In short, Immunex invented etanercept.

Immunex patented and marketed its invention. In 1997, it obtained U.S. Patent No. 5,605,690 (the '690 Patent), which covers a method of administering etanercept. Pet. App. 137a. And in 1998, it obtained FDA approval for Enbrel. Pet. App. 6a-7a. Until the '690 Patent expired in 2014, Immunex listed that patent on Enbrel's label, indicating that the patent covered the use of the product. C.A. App. 11504. In later years, Immunex obtained several other patents directed to etanercept—including U.S. Patent No. 7,915,225 (the '225 Patent). Pet. App. 140a. The last of those patents expired in August 2019. *Id.*

2. While Immunex was developing etanercept, scientists at Roche were also exploring fusion proteins. Pet. App. 52a-54a. But Roche focused on different molecules than Immunex. In particular, having failed to clone the p75 receptor, Roche focused on *other* receptors, including a shorter "p55" receptor. C.A. App.

4802, 4824, 4834, 4866, 4868-4869, 5070, 5074, 26957, 28234, 28415.

In 1995, Roche applied for patents. Roche's proposed patent claims related exclusively to its p55 receptor. *See, e.g.*, C.A. App. 13060-13061; Sandoz C.A. Br. 14-15 (Dkt. No. 75) (collecting additional citations). And the applications discussed only the p55 receptor and several other Roche receptors. *See* C.A. App. 25081-25133. They did not describe Immunex's p75 receptor—much less the full etanercept protein. *See id.*

3. The pending patent applications turned out to be useless to Roche, because its p55 receptor did not work. But they offered a multi-billion-dollar opportunity to Immunex. Specifically, Immunex identified Roche's pending patent applications as a way to expand its period of exclusivity on etanercept. Immunex first obtained a license to Roche's patent applications. Then, in 2004, Immunex entered into a broader "Accord and Satisfaction" with Roche (the 2004 Agreement) that turned Immunex into the *de facto* owner of the applications.

The stated purpose of the 2004 Agreement was for Immunex "to acquire *all rights*" that Roche had licensed to Immunex in the first agreement, thereby "eliminat[ing] [Immunex's] continuing obligations to pay royalties to Roche." C.A. App. 25836 (emphasis added). While the transfer to Immunex was styled as a "License," C.A. App. 25839,[1] the 2004 Agreement

[1] The relevant section of the 2004 Agreement is styled "License to Amgen," Immunex's corporate parent. C.A. App. 25839; *see* C.A. App. 25836. That corporate distinction is not material to

gave Immunex virtually all the hallmarks of patent ownership, including: (1) the complete, unfettered right to control prosecution of Roche's patent applications; (2) the sole right to make, use, sell, or import the claimed inventions; (3) the right to exclude anyone—including Roche—from commercializing the claimed inventions; (4) the sole right to grant sublicenses to the claimed inventions; and (5) and the first right to sue others for infringement of the patents, including the right to control the suit and unilateral authority to settle and collect all damages. Pet. App. 7a-8a; C.A. App. 28335-28340.

Against this vast array of rights granted to Immunex, Roche (as the nominal owner) retained a meager prerogative: a secondary right to sue for infringement if Immunex did not exercise its first right to sue within 180 days. Pet. App. 8a; C.A. App. 25841. The agreement also contained a reciprocal nonassignment clause, barring either party from giving away its rights under the 2004 Agreement without the other's consent. C.A. App. 25849. Outside the United States—where ODP does not exist—another company, Wyeth, acquired all rights to the Roche patents through a full and express assignment. C.A. App. 25838.

Immunex pressed to structure the deal as a "license" rather than a full-blown "assignment" like Wyeth's to avoid ODP law. As Immunex's lead negotiator testified, Immunex recognized that ODP doctrine could apply to patents that become commonly owned through assignments. C.A. App. 5784. So while

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this dispute; for ease of reference, this petition refers to respondents Immunex and Amgen collectively as "Immunex."

Roche had expected to receive an offer from Immunex to purchase the patents outright, Immunex insisted on styling the agreement as a license. C.A. App. 11494, 28321-28325. Underscoring the fiction of the "license" label, the 2004 Agreement allowed Immunex to acquire Roche's remaining rights at any time for a mere $50,000—a sum that Immunex's counsel candidly described at oral argument below as a "peppercorn." C.A. Oral Arg. 41:01;[2] *see* Pet. App. 8a; C.A. App. 25840. That clause was included at Immunex's insistence: Roche was willing to include a full assignment of the patent rights at no additional cost. C.A. App. 28335.

4. Having acquired control over Roche's patent applications, Immunex set about repurposing them to cover etanercept. A decade into the prosecution, Immunex's lawyers deleted Roche's earlier claims covering the p55 receptor and added new claims covering Immunex's p75-IgG_1 fusion protein—*i.e.*, etanercept. *See* Sandoz C.A. Br. 18-19 (collecting citations). Immunex made corresponding changes to the specifications, inserting references to the p75 receptor. *See* C.A. App. 5788, 16424-16425, 22640-22641.

By taking over and reworking Roche's applications, Immunex effectively extended its etanercept patent protection by a decade. The applications have resulted in two patents. U.S. Patent No. 8,063,182 (the '182 Patent) issued in 2011 and expires on November 22, 2028, and U.S. Patent No. 8,163,522 (the '522 Patent) issued in 2012 and expires on April 24, 2029. Pet. App. 54a, 56a; *see* 35 U.S.C. § 154(c)(1). The

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[2] The recording is available at http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2020-1037.mp3.

etanercept franchise captures close to $5 billion in annual U.S. sales, C.A. App. 5791, now secured by the extra exclusivity that Immunex gained from these two patents.

C. Sandoz's Competing Biosimilar Product and This Litigation.

1. In 2006, Sandoz began to develop a competitor to Enbrel. Like Enbrel, Sandoz's product—now known as Erelzi®—also uses etanercept as its active ingredient. Erelzi is "biosimilar" to Enbrel—that is, there are only "minor differences" in the drugs' inactive ingredients, and there "are no clinically meaningful differences between [them] in terms of safety, purity, and potency." 42 U.S.C. § 262(k)(2).

Because a biosimilar product like Erelzi is "highly similar" to an already-approved treatment, the FDA reviews it through an "abbreviated process." *Sandoz Inc.* v. *Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017); *see* § 262(k). Sandoz applied for licensure through that process in 2015. In February 2016, Immunex and Roche filed this patent-infringement suit, alleging that Erelzi would infringe the '182 and '522 Patents. Pet. App. 2a-3a.[3] The FDA approved Sandoz's application to market Erelzi in August 2016, Pet. App. 47a, so this litigation is the only remaining obstacle to its launch.

Sandoz defended against Immunex's suit on a number of grounds, including that the patents were

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[3] The 2004 Agreement required Roche to join the suit at Immunex's direction. Roche participated in the litigation only nominally, and dropped out in the court of appeals. See p. ii, *supra*.

invalid for ODP. As Sandoz explained, the claims of the '182 and '522 Patents were not patentably distinct from the claims of Immunex's earlier-expiring '690 and '225 Patents—they merely claimed obvious variants of the same invention.[4] And all four patents were commonly owned in every material sense: While the '182 and '522 Patents nominally belonged to Roche, the 2004 Agreement had given Immunex "all substantial rights" in those patents.

2. Following a bench trial, the district court rejected Sandoz's invalidity defenses, blessing Immunex's circumvention of ODP. The district court's ODP analysis turned on its conclusion that the '182 and '522 Patents do not share a common owner with Immunex's earlier-expiring patents—and thus are not subject to ODP scrutiny with respect to those patents. Pet. App. 129a-136a. In the district court's view, *Roche* is still the owner of the patents-in-suit, notwithstanding the 2004 Agreement. *See id.* In reaching that conclusion, the court relied primarily on Immunex's characterization of the agreement as a license, and concluded that Roche had not transferred all substantial rights to the patents-in-suit. Pet. App. 133a. The district court did not even accept that an agreement styled as a license could *ever* create common ownership for ODP purposes.[5]

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[4] For Sandoz to prevail on its ODP argument, the claims of the patents-in-suit only need to be patentably indistinct from *one* claim of *one* of these reference patents. *See, e.g.*, *AbbVie*, 764 F.3d at 1374.

[5] The district court also concluded, in the alternative, that the patents-in-suit were patentably distinct from the '690 and '225

3. A partially divided panel of the Federal Circuit affirmed.

The court unanimously agreed with Sandoz in several important respects. The Court agreed that the relevant question for ODP purposes was whether the 2004 Agreement had given Immunex "all substantial rights" in Roche's patent applications, which produced the patents-in-suit. If it had, the panel concluded, then the patents-in-suit and Immunex's expired patents would be under common ownership. Pet. App. 12a-17a. The panel also unanimously rejected the district court's reliance on evidence outside the four corners of the 2004 Agreement regarding Immunex's subjective intent to characterize the 2004 Agreement as a license, explaining that "there [was] no need to resort to parol evidence" where the contract was unambiguous. Pet. App. 19a.

But the panel split 2-1 over whether the rights that Roche retained qualified as "substantial." The majority focused on Roche's secondary right to sue, reasoning that its secondary right was "inconsistent with a conclusion that the patents-in-suit were effectively assigned to Immunex." Pet. App. 21a (citation omitted). In reaching that conclusion, the majority brushed aside Sandoz's (and the dissent's) observation that this right was illusory under established Federal Circuit precedent because Immunex could negate it

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Patents, based substantially on its choice of which legal test to apply. Pet. App. 136a-149a. The Federal Circuit majority did not reach that alternative holding on appeal. The dissenting judge agreed with Sandoz that the district court had applied the wrong test. Pet. App. 43a-45a; *see* p. 15, *infra*.

simply by granting a royalty-free sublicense to any putative infringer before Roche's 180-day waiting period elapsed. Pet. App. 21a-22a.[6]

Judge Reyna dissented from the Court's ODP holding. While "commend[ing] the majority for adopting the 'all substantial rights' test" in the ODP context, he explained that the majority's holding "permits the type of gamesmanship it sought to prevent" by allowing Immunex to "effectively extend[] to 2029 its right to exclude public use of the etanercept fusion protein via the patents-in-suit (which Immunex effectively owns in all material respects)." Pet. App. 38a-39a. According to Judge Reyna, Roche's retained right to sue was "illusory" because "Immunex may nullify [that right] by issuing a royalty-free sublicense to the alleged infringer." Pet. App. 41a. More specifically, "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. Through the agreement's "sleight of hand," Judge Reyna explained, "Immunex retains full control over whether Roche can initiate suit." Pet. App. 41a.

According to Judge Reyna, the illusory nature of Roche's rights was only underscored by another aspect of the agreement: Immunex's ability to "order[] Roche

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[6] The majority also indicated that "Roche's right to veto any assignment of Immunex's interest in the patents-in-suit . . . weighs in favor of the conclusion that all substantial rights were not transferred." Pet. App. 23a. Although the majority suggested that this restriction on assignment was "a further indication" that Roche had not transferred all substantial rights in the patents-in-suit, it did not treat this clause as either sufficient to avoid ownership or necessary to its decision. *Id.*

to assign the patents-in-suit" for a mere $50,000. Pet. App. 40a. That option allowed Immunex to "nullify" any remaining rights at will. *Id.* And its $50,000 price tag—as compared to the $45 million price for the overall "license" or the $1.9 billion in revenue that Immunex earned on etanercept in 2004—demonstrated that the agreement was an all-out purchase in everything but name. Pet. App. 41a.

With common ownership established, Judge Reyna concluded that the patents-in-suit are invalid for ODP. He found "no serious dispute" that the patents-in-suit are obvious variants of the '225 Patent, Pet. App. 45a; the district court's contrary conclusion rested on a legal error that led it to apply an extra and unnecessary step to the analysis, *see* Pet. App. 43a-45a.

REASONS FOR GRANTING THE WRIT

"In crafting the patent laws, Congress struck a balance between fostering innovation and ensuring public access to discoveries." *Kimble* v. *Marvel Entm't, LLC*, 576 U.S. 446, 451 (2015). Central to that balance is the patent term, which provides a time-limited award of exclusivity in exchange for the disclosure of an invention to the public. *See* 35 U.S.C. § 154(a)(2). "While the patent lasts, the patentee possesses exclusive rights to the patented article." *Kimble*, 576 U.S. at 451. But once it expires, "the subject matter of the patent passes to the free use of the public." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989). "This Court has carefully guarded that cut-off date" for patent exclusivity. *Kimble*, 576 U.S. at 451.

The decision below effectively lowers that guard. The panel majority held that Immunex successfully avoided invalidity for double patenting—*even if*, as Judge Reyna explained, the new patents claim obvious variants of the old—just because Immunex kept barely enough of its fingerprints off the new patents. Immunex got to write the patents' language. It gets to control the patents. It will get to enjoy the exclusivity they create, until 2029. And it achieved all this simply by leaving Roche as nominal owner—while retaining the ability to take even that label away from Roche anytime it wants, for a peppercorn's-worth of consideration.

If this Court does not intervene, the Federal Circuit's decision will undermine the long line of precedent from this Court protecting the public's right to access inventions whose patents have expired. The Federal Circuit's decision will serve as a roadmap for patent owners who wish to contract around the strict time limits on patent terms set by Congress: Follow the steps that Immunex took, and an extension of your patent term is guaranteed.

The Court should grant certiorari and reverse.

I. The Federal Circuit's decision undermines the rule laid down by this Court that patentees may not obtain two patents on the same invention.

This Court's decisions have long recognized that federal patent law bars obviousness-type double patenting—*i.e.*, obtaining a patent on an obvious variant of one's already-patented invention. The decision below departs from this consistent line of ODP precedent.

A. A patent owner may only obtain one period of exclusivity for an invention and colorable variations of that invention.

1. "[S]ince the inception of our patent laws," double patenting has been prohibited. *AbbVie Inc.* v. *Mathilda & Terrence Kennedy Institute of Rheumatology Tr.*, 764 F.3d 1366, 1372 (Fed. Cir. 2014). American courts have recognized that prohibition at least since Justice Story, riding circuit, affirmed that an inventor "can have but a single valid patent for his invention." *Odiorne* v. *Amesbury Nail Factory*, 18 F. Cas. 578, 579 (C.C.D. Mass. 1819). As he explained, if a patentee could obtain multiple patents for the same invention, then it could "perpetuate [its] exclusivity during a century," which would "completely destroy the whole consideration derived by the public for the grant of the patent"—*i.e.*, "the right to use the invention at the expiration of the term specified in the original grant." *Id.* Thus, "on the expiration of a patent . . . the right to make the thing formerly covered by the patent becomes public property." *Singer Mfg. Co.* v. *June Mfg. Co.,* 163 U.S. 169, 185 (1896).

This Court has repeatedly endorsed and applied this rule against double patenting. By 1881 it was "hardly necessary to remark that the patentee could not include in a subsequent patent any invention embraced or described in a prior one granted to himself." *James* v. *Campbell*, 104 U.S. 356, 381 (1881); *see also Suffolk Co.* v. *Hayden*, 70 U.S. (3 Wall.) 315, 319 (1866) (explaining that a second patent issued to the patentee "for the same improvement" covered by an earlier patent "is void").

The prohibition against double patenting applies to second patents not only when they are "identical" to an earlier-expiring patent, but also when they are "only a colorable variation" of the original. *McCreary*, 141 U.S. at 467. Thus, if a patent owner seeks to obtain a second patent for obvious modifications of the original invention, "the second patent would be void." *Id.* One version of this occurs when the second patent "contain[s] a broader claim, more generical in its character, than the specific claims, contained in the prior patent." *Miller* v. *Eagle Manufacturing Co.*, 151 U.S. 186, 198 (1894). For example, if a company obtains a patent on a method of using a particular invention, it cannot later receive a second patent claiming the underlying invention used in that method: The new patent must claim an invention that is "distinctly different and independent." *Id.*

Courts have long recognized that this rule against double patenting applies even if the named inventors are different and the double patentee receives the patents by assignment. *See In re Mann*, 47 F.2d 370, 371 (C.C.P.A. 1931) (assignees of simultaneously pending patent applications could not receive two patents on the same invention); *see also In re Longi*, 759 F.2d 887, 893 (Fed. Cir. 1985) (affirming this principle and collecting several decades of supportive decisions); *In re Rogers*, 394 F.2d 566, 567 n.4 (C.C.P.A. 1968) (same); Pet. App. 10a, 14a.

2. The rule against double patenting is codified in the Patent Act. The statute provides that a patent owner may receive "*a* patent" (singular) for an invention. 35 U.S.C. § 101 (emphasis added); *AbbVie*, 764 F.3d at 1372. And exclusivity lasts only for a limited statutory term. § 154(b).

While ratifying this Court's holdings, Congress softened the doctrine in one respect. Under a provision added in 1952, 35 U.S.C. § 253(b), a patentee can keep two patents on the same invention *if* it voluntarily "cut[s] back" the second patent's term "so as to expire at the same time as" the first patent. *In re Robeson*, 331 F.2d 610, n.4 (C.C.P.A. 1964) (quoting commentary of P.J. Federico, advisor to the congressional subcommittee that drafted the amendments). This is called a "terminal disclaimer."

Thus, the patentee's exclusivity ends when the first patent does. Any other patent must conform to that expiration date, through terminal disclaimer if necessary. Otherwise it is invalid for ODP. This rule ensures that when the original "patent expires, the patentee's prerogatives expire too, and the right to make or use the article, free from all restriction, passes to the public." *Kimble*, 576 U.S. at 452.

B. The Federal Circuit's decision allows Immunex to enjoy another decade of exclusivity on the same invention after its original patents expired.

Under the ODP principles laid out in this Court's decisions, Immunex could not maintain its patent exclusivity over etanercept past (at the latest) August 2019, when its '225 Patent expired. But the Federal Circuit has allowed Immunex to contract around this Court's decisions—and, indeed, the entire ODP doctrine—by leaving Roche with nominal ownership of the patent but no substantial rights to exploit it. That decision is in deep tension with this Court's decisions "guard[ing]" the "cut-off date" for patent exclusivity set by Congress. *Kimble*, 576 U.S. at 451.

1. "In case after case, the Court has construed" the patent laws "to preclude measures that restrict free access to formerly patented . . . inventions." *Id.* As the Court has explained, "any attempted reservation or continuation in the patentee . . . of the patent monopoly, after the patent expires, *whatever the legal device employed*, runs counter to the policy and purpose of the patent laws." *Scott Paper Co.* v. *Marcalus Mfg. Co.*, 326 U.S. 249, 256 (1945) (emphasis added). Thus, the Court has recognized that "the patent laws preclude the patentee of an expired patent . . . from recapturing any part of the former patent monopoly," and "do not contemplate that anyone by contract or any form of private arrangement" may "withhold from the public the use of an invention" after the patent term expires. *Id.* at 256-257.

But that is *exactly* what Immunex has accomplished. By using its "license" to the patents-in-suit to extend its patent term over the same invention, Immunex will retain exclusive patent control over etanercept for a third decade.

2. The Federal Circuit countenanced that result only by holding that Immunex was not an owner of the patents, but a mere licensee. But the supposed "license" provided Immunex with all the functional attributes of patent ownership. Roche's straw ownership is no valid basis to deny the public "the right to make the thing" that vested when Immunex's patents expired. *Singer*, 163 U.S. at 185.

Rather than accept a formal assignment to the applications that gave rise to the patents-in-suit "at no additional cost," Immunex insisted on describing its agreement with Roche as a "license." Pet. App. 40a-

41a (Reyna, J., dissenting). As set forth above (p. 10), Immunex took over patent prosecution, using its authority to "amend[] the applications to claim etanercept, which Immunex itself had claimed in its own patents." Pet. App. 39a (Reyna, J., dissenting). It also acquired the sole right to practice the claimed invention commercially and to grant sublicenses, as well as the first right to sue for any infringement and to keep any damages it won. Pet. App. 7a-8a. Underscoring the pure fiction of the "license" label, the agreement also provided Immunex with an option to convert its "license" into a complete assignment for just $50,000—about 0.1% of the $45 million that Immunex paid to license the patents. Pet. App. 41a (Reyna, J., dissenting).

The panel majority recognized that courts applying double-patenting restrictions should not simply defer to the labels used by parties in agreements transferring patent rights. Pet. App. 16a. Doing so, the court acknowledged, could allow "an effective patentee" to "unjustifiably extend[] its patent term using the nominal label of licensee." *Id.* The court thus concluded that, in order to "deter[]" such "gamesmanship," it should look to the substance of the rights conveyed by a transfer agreement to identify the "effective 'patentee.'" *Id.* But as Judge Reyna explained in dissent, the majority's test "permits the type of gamesmanship it sought to prevent" because it came with an easy-to-exploit loophole. Pet. App. 38a.

Despite pledging to put form over substance to prevent an end-run around the double patenting bar, the Federal Circuit created a safe harbor that allows patentees to disclaim ownership of a second patent even as they acquire every right to the patent that matters.

Under the majority's test, a patent owner may obtain a second patent on its invention through an agreement that gives it (1) complete control over patent prosecution, including the right to write claims that cover its own invention, (2) the exclusive right to commercial exploitation of the resulting patent, (3) the right to sublicense the patent, and (4) the right to sue for infringement, make all litigation decisions (including whether to settle), and keep all damages. Pet. App. 7a-8a. To avoid a double-patenting objection, the agreement transferring all of these rights need only preserve a formal right for the putative licensor to bring its own infringement suit if the "licensee" declines to do so. Pet. App. 19a-21a. And that right can be purely illusory.

Here, for example, before Roche's secondary right to sue would ever vest, Immunex could vitiate it by filing its own infringement suit or granting a royalty-free sublicense to the alleged infringer. *See* pp. 13-14, *supra*. Alternatively, Immunex could exercise its option to buy out Roche's remaining rights for the mere "peppercorn" of $50,000. *See* p. 10, *supra*. Either way, Immunex could nullify any theoretical right by Roche to sue. The majority acknowledged "Immunex's ability to prevent Roche's secondary right to sue from vesting," but concluded that did not matter. Pet. App. 22a n.6. For the majority, structuring the transfer agreement to reserve a theoretical right for Roche to sue—even one that Immunex could snatch back *at no cost*—was enough for Immunex to disclaim patent ownership and avoid a double-patenting rejection.

II. The question presented is important, and this case demonstrates why it warrants immediate review.

The consequences of this decision are dramatic. Double patenting is a key protection that preserves patent law's bargain—inventors are rewarded with *one* limited period of exclusivity for each invention. The Federal Circuit has subverted that bargain, by blazing a trail around the one-patent limit. Any patent owner can get a second patent for the same invention, so long as it can follow the path approved by the panel majority and find an ally to be the straw owner, like Roche here. The pernicious effects of that decision will be felt for years to come. This Court should step in—and this case offers the ideal vehicle for it to do so.

1. As *amici* explained below, the Federal Circuit's holding "provides a blueprint for patentees interested in extending their monopolies past their scheduled expirations" while still claiming the same invention. AAM/AHIP C.A. Amicus Br. 8 (Dkt. No. 112). Even a short period of continued exclusivity over a successful product can be incredibly valuable. So the Federal Circuit's decision creates a powerful incentive for patent owners that are in the right position to follow its blueprint.

This case is illustrative of the powerful incentives at play. Even though Enbrel has been on the market since 1998, the franchise still captures close to $5 billion in annual U.S. sales. C.A. App. 5791. The market reaction to Immunex's success in defending its patent-extension strategy drives the point home. As Immunex's lead trial counsel has recounted, "[f]ive

minutes after the federal district court released the judgment" upholding the validity of the patents-in-suit, the market capitalization of Immunex's corporate parent, Amgen, "increased by $5 billion," ultimately going up "by $12.3 billion at the close of the next trading day."[7] "In terms of economic value to the company," that result "exceeded the largest patent damages award ever by nearly a factor of five, and is among the largest civil case results ever."[8] That story repeated itself when the Federal Circuit's 2-1 decision affirmed Immunex's right to control etanercept until 2029.[9]

A patent owner seeking to extend its patent term can follow the Immunex example by acquiring 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. Rights to that shell application will likely cost much less than the application's value to the patent owner post-amendment. Here, for example, Immunex paid Roche just $45 million for rights to its application, which represented *less than nine days* of revenue for Enbrel as of 2004 when the deal was struck. Pet. App. 41a (Reyna, J., dissenting); C.A.

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[7] *Vernon M. Winters*, SIDLEY, www.sidley.com/en/people/w/winters-vernon-m (last accessed January 29, 2021) (*Winters Profile*); *see also* Scott Graham, *Amgen Wins Patent Validity Ruling Worth $10 Billion*, THE AMLAW LITIGATION DAILY (Aug. 14, 2019), www.law.com/litigationdaily/2019/08/14/amgen-has-10-billion-reasons-to-cheer-patent-validity-ruling-407-8481.

[8] *Winters Profile*.

[9] *See id.*

App. 5790-5792. Roche, by contrast, had no further use for the application.

Importantly, a patent owner trying to carry out the Immunex patent-extension strategy can essentially guarantee that the new patent will not face an objection for double patenting. The patentee need only structure a "licensing" agreement to take advantage of the Federal Circuit's safe harbor: If the agreement leaves the original applicant of the second patent with a theoretical right to bring an infringement suit, then that applicant automatically retains its status as the second patent's straw owner. *See* Pet. App. 21a-22a.

Now that the Federal Circuit has announced that adopting this structure is enough to evade the prohibition on double patenting, this structure will be widely emulated. And emulating it is easy: The secondary right to sue that is the linchpin for ascribing effective patent ownership under the Federal Circuit's decision can be purely illusory and commercially worthless, as it was here. Recall that in negotiating the 2004 Agreement, Roche was "willing to formally assign the patents"—and thus give up any right to sue for infringement—"at no additional cost." Pet. App. 40a (Reyna, J. dissenting). It was *Immunex* that refused to accept a formal assignment, as it asked instead for an option to convert its "license" into an assignment for $50,000, "which "[t]he record shows . . . is a *de minimis* amount." Pet. App. 41a. And Roche has so little practical interest in the billion-dollar patents that it purportedly "owns" that it declined even to participate in the Federal Circuit appeal addressing their validity. *See* p. ii, *supra*.

As Judge Reyna explained in dissent, the incentive and opportunity for "gamesmanship" created by the Federal Circuit's decision is manifest. Pet. App. 38a. That extraordinary result alone calls out for this Court's review, but the consequences of the Federal Circuit's divided decision extend much further. Now that the Federal Circuit has blessed Immunex's patent-extension strategy, imitators will soon follow. This Court should intercede *now* to prevent patent owners from following Immunex's example for how to secure an "unjustified extension of patent rights," Pet. App. 38a (Reyna, J., dissenting), cutting off this pathway around the statutory limit on patent term and restoring the balanced approach under which inventors are rewarded with *one* limited patent term for each invention—no more and no less.

In opposing rehearing en banc below, Immunex minimized the significance of the Federal Circuit's decision on the ground that the Roche patents at issue here are "pre-GATT" patents—that is, patents whose applications were filed before the 1995 implementation of the Uruguay Round of the General Agreement on Tariffs and Trade. *See* Immunex C.A. Resp. to Pet. for Reh'g En Banc 19-20 (Dkt. No. 113); *see also* Uruguay Round Agreements Act, Pub. L. No. 103-465, § 532(a)(1), 108 Stat. 4809, 4983-4985 (1994). The term of a patent issued from a pre-GATT application—some of which are *still* pending in the Patent Office[10]—ordinarily lasts 17 years from the patent's *issuance*

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[10] *See Oversight of the U.S. Patent and Trademark Office: Hearing Before the Subcomm. on Courts, Intell. Prop., & the Internet of the H. Comm. on the Judiciary*, 114th Cong., 2d Sess., at 4, 25 (Sept. 13, 2016).

date, *see* 35 U.S.C. § 154(c)(1), while the standard term of a post-GATT patent is 20 years from the patent's effective *application* date, § 154(a)(2). But that does not blunt the impact of the Federal Circuit's decision: Whether a patent's term is measured from filing or from issuance, a patent owner can deploy Immunex's straw-owner strategy to extend the term.

Perhaps Immunex meant to suggest that, when it comes to post-GATT patents, copycats using its strategy will typically gain extensions shorter than the dramatic ten years that Immunex received here. But that is no reason to allow the Federal Circuit's error to persist. For one thing, as this case makes clear, every extra *day* of unjustified patent exclusivity can mean enormous profits for patentees—and enormous losses for consumers who are denied access to an invention that rightfully belongs to the public. *See* p. 24, *supra*. Moreover, "[t]his Court has carefully guarded th[e] cut-off date" for patent exclusivity. *Kimble*, 576 U.S. at 451. *Any* unwarranted extension of the statutory patent term is an affront to the limits that Congress set—and to the "limited Times" to which the Constitution refers. And here the Federal Circuit's decision all but guarantees an extension for those to carry out certain easily replicable steps.

2. Not only is the question presented important, but this case is an excellent vehicle to address it. The Federal Circuit squarely decided the issue below—it was the sole basis on which the Federal Circuit rejected Sandoz's ODP defense. And, as Judge Reyna explained, the question presented is outcome-determinative: Reversal would mean a judgment in Sandoz's favor. *See* Pet. App. 43a-45a.

And the stakes of this particular case could not be higher. As Immunex's counsel touted, *see* p. 24, *supra*, the "economic value" of the district court's judgment is on par with "the largest civil case results ever," adding billions of dollars to the market capitalization of Immunex's corporate parent. Immunex's gain comes at the public's expense—it directly reflects the billions of dollars in costs that patients and the healthcare system will have to absorb over the next decade as Enbrel remains insulated from any biosimilar competition.

This litigation is the last roadblock to that competition. As noted, p. 7, *supra*, Enbrel has been on the market since 1998. Anticipating the expiration of Immunex's patents on the product, Sandoz invested millions of dollars to develop a biosimilar version of etanercept. The FDA has approved that product, which is already commercially available outside the United States, and Sandoz is ready to bring competition to the U.S. market as well. But unless the Federal Circuit's decision is reversed, Immunex will retain its exclusivity until 2029.

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The prominence of this case ensures that no patent owner interested in a second patent term on an already-patented invention will miss the basic lesson of the panel decision: Now there is a way around double-patenting doctrine, bearing the Federal Circuit's stamp of approval. Unless this Court takes prompt action, other patent owners who seek to circumvent the patent system's bargain can follow this path to extend their exclusivity beyond the statutory limit. To

be sure, inventors are entitled to *a* period of exclusivity in exchange for disclosing their inventions. But Immunex has already enjoyed the prescribed period, and by now etanercept should have "pass[ed] to the free use of the public." *Bonito Boats*, 489 U.S. at 152. The Court should grant review to ensure that *every* patented invention passes to the public after *one* prescribed term.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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