No. 2020-1037

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

IMMUNEX CORPORATION, AMGEN MANUFACTURING, LIMITED,

Plaintiffs-Appellees,

HOFFMANN-LA ROCHE INC.,

Plaintiff,

v.

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH,

 $Defendants\hbox{-}Appellants.$

Appeal from the U.S. District Court for the District of New Jersey, Case No. 2:16-cv-1118

CORRECTED RESPONSE TO PETITION FOR REHEARING EN BANC

JEFFREY P. KUSHAN

JOSHUA J. FOUGERE

SIDLEY AUSTIN LLP

SIDLEY AUSTIN LLP

SIDLEY AUSTIN LLP

One South Dearborn

Washington, DC 20005

(202) 736-8700

CONSTANTINE L. TRELA, JR.

STEVEN J. HOROWITZ

SIDLEY AUSTIN LLP

One South Dearborn

Chicago, IL 60603

(312) 853-7000

Counsel for Plaintiffs-Appellees Immunex Corporation and Amgen Manufacturing, Limited

[Additional counsel listed on inside cover]

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

VERNON M. WINTERS SIDLEY AUSTIN LLP 555 California Street, Suite 2000 San Francisco, CA 94104 (415) 772-1200

Counsel for Plaintiffs-Appellees Immunex Corporation and Amgen Manufacturing, Limited

CERTIFICATE OF INTEREST

Counsel for Plaintiffs-Appellees Immunex Corporation and Amgen

Manufacturing, Limited, Constantine L. Trela, Jr., certifies the

following:

1. Represented Entities. Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

Immunex Corporation
Amgen Manufacturing, Limited

2. Real Party in Interest. Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

Immunex Corporation: None Amgen Manufacturing, Limited: None

3. Parent Corporations and Stockholders. Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

Immunex Corporation: Amgen Inc.
Amgen Manufacturing, Limited: Amgen Inc.

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

Sidley Austin LLP: Erik J. Carlson*, Richard M. Chen, Peter S. Choi, Sona De, Matthew S. Jorgenson*, Ryan C. Morris, Jill J. Schmidt*, M. Patricia Thayer*, Samuel N. Tiu, Sue Wang

Walsh Pizzi O'Reilly Falanga LLP: Christine I. Gannon, Marc D. Haefner, Colleen M. Maker, Eleonore Ofosu-Antwi, Liza M. Walsh

*Formerly of Sidley Austin LLP

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5).

Immunex Corporation et al. v. Samsung Bioepis Co., Ltd., No. 2:19-cv-11755-CCC-MF (D.N.J.)

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

Not Applicable.

August 26, 2020

/s/ Constantine L. Trela, Jr.
CONSTANTINE L. TRELA, JR.
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
(312) 853-7000

Counsel for Plaintiffs-Appellees Immunex Corporation and Amgen Manufacturing, Limited

TABLE OF CONTENTS

INTRODUCTION1		
BACKGROUND3		
Α.	The Roche Patents and Immunex's License3	
В.	Procedural Background4	
ARGUMENT		
	Panel's Fact-Bound, Case-Specific Assessment of the A&S se Agreement Does Not Warrant Review En Banc7	
	The Panel's Assessment of the A&S Presents No Question of Exceptional Importance	
В.	The Panel Decision Is Correct 10	
C. '	The Panel Decision Does Not Conflict With Speedplay 17	
D. '	This Case Provides No "Roadmap" for "Gamesmanship." 19	
	Case Is a Poor Vehicle for Addressing the All-Substantials S Doctrine	
CONCLUSION		

TABLE OF AUTHORITIES

Page(s)
Cases
Abbott Labs. v. Diamedix Corp., 47 F.3d 1128 (Fed. Cir. 1995)
Alfred E. Mann Found. v. Cochlear Corp., 604 F.3d 1354 (Fed. Cir. 2010)
AsymmetRx, Inc. v. Biocare Med., LLC, 582 F.3d 1314 (Fed. Cir. 2009)
DDB Techs., L.L.C. v. MLB Advanced Media, L.P., 517 F.3d 1284 (Fed. Cir. 2008)
Novartis Pharm. Corp. v. Breckenridge Pharm. Inc., 909 F.3d 1355 (Fed. Cir. 2018)
Prima Tek II, L.L.C. v. A-Roo Co., 222 F.3d 1372 (Fed. Cir. 2000)
Propat Int'l Corp. v. RPost, Inc., 473 F.3d 1187 (Fed. Cir. 2007) 14
Sicom Sys., Ltd. v. Agilent Techs., Inc., 427 F.3d 971 (Fed. Cir. 2005)
Speedplay, Inc. v. Bebop, Inc., 211 F.3d 1245 (Fed. Cir. 2000)
Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870 (Fed. Cir. 1991)
Statutes
35 U.S.C. §154(c)(1)

INTRODUCTION

After years of litigation, a ten-day trial, and an unsuccessful appeal, Sandoz's unusual double-patenting theory has led to an unusual request for en banc review. Sandoz's theory holds that a patent valid in the hands of its original owner can spontaneously become invalid when licensed to someone else more than a decade after invention. The district court rejected Sandoz's theory on multiple independent grounds, and the panel correctly affirmed.

Sandoz does not argue that the panel applied an erroneous legal standard—indeed, the panel's analysis of "common ownership" was based on the same all-substantial-rights test Sandoz urged. Instead, Sandoz argues that the panel's assessment of the 2004 Accord & Satisfaction ("A&S") between Immunex and Roche was mistaken, and that Immunex is the "true" owner of the Roche patents and has used them to engage in "gamesmanship" to extend a patent monopoly over the etanercept compound.

Sandoz's tale of gamesmanship founders on the facts. The district court found, the panel affirmed, and Sandoz no longer disputes that the Roche application described and claimed etanercept from the outset.

The district court likewise found and the panel affirmed that Immunex engaged in no gamesmanship—the prosecution was diligent and above-board, and the patents' 17-year term reflects a congressional choice.

The district court further found, the panel affirmed, and Sandoz no longer disputes that the Jacobs patent—the only purported double-patenting reference that significantly predates the Roche patents—does not cover etanercept, so the "31 years of patent protection on the compound itself" that Sandoz bemoans (Pet. 3; see also AAM Br. 4; Bioepis Br. 2) does not exist. The gamesmanship story on which Sandoz's Petition rests lacks any factual foundation.

Even beyond these shortcomings, the Petition presents no question warranting en banc review. The panel's fact-bound, case-specific assessment of the A&S was correct and consistent with this Court's precedent, and that assessment is unlikely to have significant consequences for either obviousness-type double patenting (ODP) or prudential standing. And if there were some need to clarify the all-substantial-rights doctrine, this unusual double-patenting case would be an exceptionally poor vehicle for doing so.

The Petition should be denied.

BACKGROUND

A. The Roche Patents and Immunex's License.

Scientists at Roche were the first to invent etanercept. As the district court found, the panel affirmed, and the Petition does not contest, Roche's invention of etanercept was nonobvious and fully described in Roche's original patent application. (Appx11–59; Op. 22–30.)

Immunex separately developed and brought etanercept (tradename Enbrel®) to market. Immunex learned that Roche's thenpending patent applications covered etanercept around the time Enbrel first launched, and Immunex took a license and paid substantial ongoing royalties. (Op. 6; Appx68; Appx5727.) When Amgen Inc. later acquired Immunex, Amgen sought to reduce Enbrel's royalty burden by "buy[ing] out" future royalties. (Appx5729.) Those efforts produced the A&S.

The district court found that Immunex's lead negotiator "credibly testified" regarding why the parties to the A&S agreed upon a license rather than an assignment. (Appx72.) Most importantly, Immunex wanted Roche to remain the owner so that it would participate as a

party in litigation regarding the patents, as it did throughout the proceedings below. (Id.¹)

When the A&S was executed, the Roche applications were still pending at the PTO. Although "Plaintiffs acted in good faith to diligently prosecute the Patents-in-Suit" (Appx80–81), delays "solely" attributable to the PTO—including lost files, years of 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 patents issued from pre-GATT applications, they were entitled to a term of 17 years from issuance.

B. Procedural Background.

Sandoz stipulated to infringement of the Roche patents. (Op. 3.) And there is no dispute at this point that those patents are valid (and bar Sandoz's launch) if owned by Roche. 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.

¹ Contrary to Sandoz's assertion (Pet. 6), Immunex's negotiator testified that an assignment would not even have "raised a question" of double patenting. (Appx5785–5786.)

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 have nothing to do with the Petition's common-ownership arguments. (Op. 9–10 (noting "layers of analysis," and Sandoz's concession that a loss at any step would be "fatal"); Appx59–84.) For example, the district court found that one of Sandoz's double-patenting references (Jacobs) does not cover etanercept (a conclusion that, contrary to Sandoz's representation (Pet. 7 n.1), had nothing to do with the two-way test). (Appx76–77.) On appeal, the panel determined that this conclusion was "correct[]" (Op. 30); 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 defense based on Jacobs, regardless of who owns the Roche patents.

That leaves only Immunex's '225 patent, claiming specific methods of using etanercept to treat psoriasis. (Appx60.) Unlike the Roche patents, the '225 patent is post-GATT, which is why it expired in 2019

 $^{^2}$ Sandoz's challenge was based solely on claim 3 of Jacobs. (See Appx75.)

despite issuing only a few months before the Roche patents. (Appx81–82.) This Court has never invalidated a pre-GATT patent based on a post-GATT patent, see Novartis Pharm. Corp. v. Breckenridge Pharm. Inc., 909 F.3d 1355, 1360 (Fed. Cir. 2018), and the district court found that doing so here would be inequitable. (Appx82–83.) 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.) The district court also found that the two-way test for patentable distinctness applies to the '225 patent (Appx78–81), and that the Roche patents and the '225 patent claim patentably distinct inventions (Appx83–84). Affirmance on any of these grounds would end Sandoz's double-patenting challenge, irrespective of common ownership.

The panel 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 this Court's prudential-standing cases. Based on "the totality of the Accord & Satisfaction," the panel held that "Roche did not transfer all substantial rights in the patents-in-suit to Immunex." (Op. 21.)

ARGUMENT

I. The Panel's Fact-Bound, Case-Specific Assessment of the A&S License Agreement Does Not Warrant Review En Banc.

Sandoz's Petition criticizes the panel's particular application of Sandoz's "common ownership" test to the A&S. The panel's application of the test was properly based on an examination of "the 'totality' of the agreement." (Op. 15 (citing Lone Star Silicon Innovations LLC v. Nanya Tec.h Corp., 925 F.3d 1225, 1229 (Fed. Cir. 2019)).) The panel's examination of the totality of the A&S was correct and consistent with this Court's precedent, and it does not implicate any broader legal issues of exceptional importance.

A. The Panel's Assessment of the A&S Presents No Question of Exceptional Importance.

Examination of the substance of the rights granted and retained under a particular agreement in the context of particular surrounding circumstances is intensely fact-bound and case-specific. See, e.g., Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A., 944 F.2d 870, 874 (Fed. Cir. 1991) (all-substantial-rights test calls for examination of "intention of the parties" based on "surrounding circumstances," as well as "substance of what was granted"). The A&S

arose in a particular context: Immunex already had a license from Roche and had paid tens of millions of dollars under it, but wanted to "buy out" the ongoing royalty obligation while maintaining a licensee/licensor relationship. (See Appx68–71.) The A&S also allocates a specific mix of rights, discussed further below. Whether the A&S's specific allocation of rights and obligations arising in the specific context of a particular royalty buy-out effected a transfer of "all substantial rights" is not a question that warrants the attention of the en banc Court.

Moreover, the panel's application of Sandoz's common-ownership test was appropriately modest: it expressly did not "import" into ODP "the entirety of [the Court's] body of law analyzing who is a statutory 'patentee." (Op. 14.) The panel 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 ODP purposes. (*Id.*) As a result, the panel's application of the all-substantial-rights test to the particular facts here is unlikely to have far-reaching effects.

For its part, Sandoz attempts to manufacture importance with atmospherics that have little to do with this case. For example, Sandoz repeatedly invokes "gamesmanship." (Pet. 2, 3, 10, 12.) But the district court—after hearing ten days of testimony, reviewing the patents' file histories, and examining the A&S—found that there was no gamesmanship. (Appx82–83.) The panel concluded that this finding was amply supported (Op. 21 n.7), and the Petition does not even mention the finding, much less suggest it is clearly erroneous.

Sandoz also asserts that Immunex has enjoyed "31 years of patent protection on the [etanercept] compound itself" (Pet. 3), but it is unclear what patents Sandoz is referencing. The Petition does not challenge the district court's finding—which the panel said was "correct[]," and the dissent did not dispute—that the Jacobs patent "does not cover etanercept." (Op. 30.) And Sandoz's only other double-patenting reference, the '225 patent, issued in 2011 shortly before the Roche patents and does not cover the "compound itself" in any event.

Etanercept was invented by Roche scientists, and the Roche patents got exactly the term for the "compound itself" that pre-URAA law provides:

17 years from issuance.³ The concern addressed by ODP—"multiple patents on the same basic invention" (Pet. 11)—is not implicated here.

B. The Panel Decision Is Correct.

The panel's decision is not just fact-bound and case-specific; it is also correct: Roche did not transfer all substantial rights in the Roche patents to Immunex. Four provisions are particularly important.

accused infringers . . . often precludes a finding that all substantial rights were transferred." Alfred E. Mann Found. v. Cochlear Corp., 604 F.3d 1354, 1361 (Fed. Cir. 2010). And this Court 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);

³ Although Sandoz does not challenge the panel's written description determination, it nonetheless suggests that Immunex refashioned the Roche applications to claim a compound Roche had not invented or described. (Pet. 4-5, 6; see also Dissent 3; AAM Br. 4–5.) But the district court's findings on written description, affirmed by the panel, confirm that etanercept was part of the Roche applications from the outset. And, indeed, Sandoz concedes that Roche understood before entering into the A&S that its applications already "cover[ed] Enbrel." (Pet. 5.)

AsymmetRx, Inc. v. Biocare Med., LLC, 582 F.3d 1314, 1320–21 (Fed. Cir. 2009).

The panel concluded (and Sandoz does not dispute) that Roche has "broad" enforcement rights if Immunex fails to take action on 180 days' notice: "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." (Op. 19 (quoting Alfred E. Mann, 604 F.3d at 1362; alterations in panel opinion).) The panel further concluded (and Sandoz likewise does not now dispute) that, unlike in Speedplay, Inc. v. Bebop, Inc., 211 F.3d 1245 (Fed. Cir. 2000), "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 to defendants sued by Roche, and Roche retains the entirety of any award of damages." (Op. 19.) To describe such broad enforcement rights as "illusory" or insubstantial is contrary to this Court's clear precedent.

The Petition makes much of the fact that Immunex can prevent a Roche suit by acting to rectify infringement (by suit or sublicense) within the notice period (Pet. 13), but that is *always* true of a second

right to sue—the entity with the first right can always act first. That inherent fact did not prevent the second rights to sue from qualifying as "substantial" in *Abbott*, *Alfred E. Mann*, and *AsymmetRx*, and it does not do so here.

As Sandoz's own *amicus* emphasizes, a licensee "does not enjoy the right to indulge infringements"—a typical sign of ownership—when the licensor "retained a secondary right to sue if the licensee declined to do so." (Bioepis Br. 5 (quoting *AsymmetRx*, 582 F.3d at 1319 & *Abbott*, 47 F.3d at 1132).) Here, Immunex cannot indulge infringement. If Roche provides notice, Immunex can act first to litigate or license, but if Immunex does neither, it cannot stop Roche from enforcing the patents.

- 2. Roche's Right to Practice the Patents. The Petition does not mention (although the panel did) that Roche retains the right to practice its patents for internal, non-clinical research. (Op. 7.)

 Retention of this right might not preclude "the transfer of all substantial rights" by itself, but it contributes to a "totality" that is "sufficient to do so." AsymmetRx, 582 F.3d at 1321.
- 3. Immunex's Option to Purchase. Sandoz argues that Immunex's option to request an assignment for \$50,000 suggests that

Immunex owns the Roche patents. But Immunex cannot be said to already own what it must pay \$50,000 to buy, and this Court has long distinguished between present assignments and future obligations to assign. See DDB Techs., L.L.C. v. MLB Advanced Media, L.P., 517 F.3d 1284, 1290 (Fed. Cir. 2008). Indeed, as Prima Tek II, L.L.C. v. A-Roo Co. makes clear, the fact that a party without all substantial rights may have the option to acquire (or reacquire, as in Prima Tek) those rights at some point in the future has no bearing on current ownership status. See 222 F.3d 1372, 1378–79 (Fed. Cir. 2000).

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 exclusive licensee. And as the panel 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" (Op. 21) for a license that maintained Roche's status as owner, with all of the obligations that patent law imposes upon the patent owner, both in prosecution and in litigation.

absolute right to veto Immunex's assignment of rights under the A&S.

This 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"); see also Propat Int'l Corp. v. RPost, Inc.,

473 F.3d 1187, 1191 (Fed. Cir. 2007) ("restriction" on "right to dispose of an asset" was "strong indicator" that licensee did not receive "all substantial rights"). If Immunex actually owned the Roche applications under the A&S, it could prosecute them itself or sell them to someone who wanted to prosecute them. Instead, Roche's veto right ensures that Roche controls who will be its partner in prosecution.

In contrast, the A&S treated the non-U.S. Roche patents differently. While Wyeth—to whom Roche *assigned* the non-U.S. patents—was subject to the same restriction on assignments of interests under the contract, another A&S provision made clear that Wyeth was entirely free to assign the non-U.S. patents. (Appx25849 (§11.5).) The contrast between Wyeth's absolute freedom to assign the non-U.S. patents and Roche's absolute veto over Immunex assignments

of rights in the U.S. patents further demonstrates that Immunex is not an owner.

Sandoz has no answer to cases like *Sicom* that treat restrictions on alienation as dispositive, so it simply asserts (without mentioning this Court's contrary precedent) that the veto right is meaningless "boilerplate." (Pet. 3, 16.) And then Sandoz retreats to an illogical argument based on the reciprocal nature of the non-assignment clause. In Sandoz's view, if the non-assignment clause defeats ownership, then "no one would own the patents-in-suit." (Pet. 17.) Not so. If a licensor/owner transfers *some* but not *all* substantial rights in a patent, the patent is not orphaned—it just means that the licensee cannot sue without joining the licensor/owner as a co-plaintiff. The "binary" inquiry (Pet. 17) assesses whether all substantial rights were transferred, "in which case the licensee becomes the owner of the patent for standing purposes and gains the right to sue on its own," or whether less than all substantial rights were transferred, "in which case the licensor remains the owner of the patent and retains the right to sue for infringement." Alfred E. Mann, 604 F.3d at 1359-60.

* * *

Other features of the A&S ignored in the Petition also bear on the

totality-of-the-circumstances assessment. For example, the A&S protects Immunex's license rights in the event of a Roche bankruptcy, which would be unnecessary if Immunex owned the patents.

(Appx25848 (§11.1).) The A&S 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 PTO, and again reflecting the parties' intent to maintain a license relationship. (Appx25840 (§3.3); Appx5733–5735.)

For its part, Sandoz focuses more on Roche's role in this appeal than on the totality of the A&S. As Roche made clear to this Court, Roche "owns the patents" but recognizes that Immunex controls *this* litigation, and thus Roche relied on Immunex to defend the judgment. (Dkt. 64.) Indeed, in the district court, Roche participated extensively as a party, including at trial, just as the parties intended and the law requires of the patent owner. (Appx5733–5735.) In any event, the substance of the 2004 A&S, not the parties' 2019 appellate strategy, is what matters.

C. The Panel Decision Does Not Conflict With Speedplay.

The Petition focuses largely on *Speedplay*, which held that a licensee could enforce certain patents without joining the licensor as a co-plaintiff, based on the specific set of rights transferred in that case. 211 F.3d at 1250–52. As an initial matter, it is not clear that an ODP case borrowing some but not the "entirety" of prudential-standing doctrine to "inform[]" a validity assessment (Op. 14) could ever squarely conflict with *Speedplay*'s analysis of prudential standing. The ultimate inquiries are distinct and serve different purposes.

But even if the panel decision were directed to the same question as *Speedplay*, there would still be no conflict. Among other things, the panel correctly concluded (following *Alfred E. Mann*) that the second right to sue in *Speedplay* was illusory because the licensee could "grant royalty-free sublicenses to *defendants sued by the licensor*," which "Immunex cannot do." (Op. 19.)

Sandoz contends that *Alfred E. Mann* was different because the licensee there "had no power to 'issue a royalty-free sublicense' *at all*" (Pet. 15), but Sandoz simply misreads the case. *Alfred E. Mann* made clear that the licensee could block the licensor's second right to sue by

suing first and settling immediately for no payment at all. See, e.g., 604 F.3d at 1357 (licensee had the right to settle "with or without payment of money"), id. at 1361 (licensee can settle on terms "that involves any outcome . . . whether or not involving the payment of money"). Once the licensor's right to sue "activate[d]," however, the licensor's enforcement discretion was "unfettered," id. at 1362, and could not be frustrated by the licensee's grant of a sublicense to an accused infringer, see id. at 1361. So, too, here.

More broadly, *Speedplay* was based on an assessment of the totality of an agreement that differed in other material ways from the A&S. *Speedplay* did not involve (as this case does) a licensor with an "absolute right to veto any assignment proposed by the licensee," a fact *Speedplay* cited to distinguish *Abbott*. 211 F.3d at 1251. And the *Speedplay* license was not subject "to any retained rights by the licensor to practice the patent," *id.*, again distinguishing *Speedplay* from *Abbott*—and from this case. Because the agreements differ in multiple critical respects even beyond the second right to sue, there is no conflict between this case and *Speedplay*.

D. This Case Provides No "Roadmap" for "Gamesmanship."

Sandoz, parroted by its *amici*, asserts that the panel decision creates a "roadmap" others will follow to engage in "gamesmanship."

(Pet. 12; see also id. at 2, 10; AAM Br. 2, 4; Bioepis Br. 9.) Even setting aside the district court's unchallenged finding of no gamesmanship, no such roadmap exists.

This case is *sui generis*. The patent term Sandoz decries flows from (1) a long-pending prosecution of two pre-GATT patents, delayed solely due to the PTO (Appx80–81); and (2) the fact that pre-GATT patents are entitled to a 17-year term from issuance. Immunex did not even know about Roche's prior invention until around the time of Enbrel's launch, at which point Immunex took a nonexclusive license, followed by the A&S years later. The apparent roadmap, then, is to develop and introduce a product that someone else invented, described, and claimed in an earlier-filed pre-GATT application; hope the PTO delays prosecution of that application for years; take a nonexclusive license to the application; and then later buy out the ongoing royalty. This roadmap is impossible to follow, particularly since the window for

new pre-GATT applications closed more than 25 years ago. See 35 U.S.C. §154(c)(1).

In any event, Sandoz's concerns have little practical import.

There is no dispute at this point that the Roche patents are valid in Roche's hands: they fully describe and claim a nonobvious invention.

And Roche pursued claims covering etanercept from the very beginning (and obtained such claims in Europe based on the same priority application well before the A&S (see Appx5747–5748; Appx32286–32312).) (Op. 22–26.) A&S or not, the Roche patents would still have issued and blocked Sandoz from launching its etanercept biosimilar.

II. This Case Is a Poor Vehicle for Addressing the All-Substantial-Rights Doctrine.

Even if there were some conflict among this Court's allsubstantial-rights cases, this would be an exceptionally poor vehicle for resolving it.

First, this case does not even arise in the prudential-standing context for which the all-substantial-rights doctrine was developed.

Second, were the en banc Court to grant the Petition, it would have to consider the threshold question whether Sandoz's commonownership test applies in the first place. The panel resolved that

question in Sandoz's favor, but Immunex submits that Sandoz's test is not consistent with the Patent Act, its legislative history, or PTO practice—although the point is academic, because Sandoz cannot meet its own test.

Finally, the district court properly rejected Sandoz's ODP theory on multiple independent grounds, most of which the panel did not have to reach. Thus, even if the Court embraced Sandoz's all-substantial-rights arguments, Sandoz's ODP challenge would fail.

Case: 20-1037 Document: 115 Page: 28 Filed: 08/26/2020

CONCLUSION

The petition should be denied.

August 26, 2020

Respectfully submitted, /s/ Constantine L. Trela, Jr.

JEFFREY P. KUSHAN Joshua J. Fougere SIDLEY AUSTIN LLP 1501 K Street N.W. Washington, DC 20005 (202) 736-8700

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

WENDY WHITEFORD J. DREW DIAMOND **DENNIS SMITH** JOSEPH E. LASHER JAMES A. HIGH JR. AMGEN INC.

VERNON M. WINTERS SIDLEY AUSTIN LLP 555 California Street, Suite 2000 San Francisco, CA 94104 (415) 772-1200

One Amgen Center Drive Thousand Oaks, CA 91320

(805) 447-1000

Counsel for Plaintiffs-Appellees Immunex Corporation and Amgen Manufacturing, Limited

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing with the Clerk of the United States Court of Appeals for the Federal Circuit using the CM/ECF system this 26th day of August, 2020, and that a copy was served on all counsel of record by the CM/ECF system.

August 26, 2020

/s/ Constantine L. Trela, Jr.
CONSTANTINE L. TRELA, JR.
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
(312) 853-7000

Counsel for Plaintiffs-Appellees Immunex Corporation and Amgen Manufacturing, Limited

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Federal Fed. Cir. R. 35(e)(2) because it contains 3,870 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Fed. Cir. R. 32(b)(2).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Century Schoolbook font.

August 26, 2020

/s/ Constantine L. Trela, Jr.
CONSTANTINE L. TRELA, JR.
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
(312) 853-7000

Counsel for Plaintiffs-Appellees Immunex Corporation and Amgen Manufacturing, Limited