No. 2020-1037

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IMMUNEX CORP., AMGEN MANUFACTURING, LTD.,

Plaintiffs-Appellees,

HOFFMANN-LA ROCHE INC.,

Plaintiff,

v.

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH,

Defendants-Appellants.

Appeal from the United States District Court for the District of New Jersey
Civil Action No. 16-1118-CCC (Cecchi, J.)

APPELLANTS' REPLY BRIEF

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CERTIFICATE OF INTEREST

Counsel for Appellants, William M. Jay, certifies the following:

1. The full name of every party or amicus represented by me is:

   Sandoz Inc.
   Sandoz International GmbH
   Sandoz GmbH

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Sandoz Inc.:	None
Sandoz International GmbH:	None
Sandoz GmbH:	None

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Sandoz Inc.:	Novartis AG
Sandoz International GmbH:	Novartis AG
Sandoz GmbH:	Novartis AG

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in the court (and who have not or will not enter an appearance in this case) are:

   James Richter, Merritt Westcott, Karalena Guerrieri, Noorossadat Torabi, and Thomas Melsheimer of Winston & Strawn LLP

   James Hilmert, Melinda Lackey, Michael Meneghini, and Tyler Johannes, formerly of Winston & Strawn LLP

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5. The title and number of any case known to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal.

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

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December 23, 2019

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Other Authorities

TABLE OF ABBREVIATIONS

’182 patent	Asserted U.S. Patent No. 8,063,182 (Appx12684-12718)
’522 patent	Asserted U.S. Patent No. 8,163,522 (Appx12719-12766)
’029 patent	U.S. Patent No. 5,808,029 (Appx30905-30923)
’225 patent	U.S. Patent No. 7,915,225 (Appx27246-27261)
’690 patent	U.S. Patent No. 5,605,690 (Appx27295-27321)
2004 Agreement	Accord and Satisfaction Agreement between Roche, Wyeth, Amgen, and Immunex (Appx25836-25864)
aBLA	Abbreviated biologics license application
AIA	Leahy-Smith America Invents Act
CCPA	Court of Customs and Patent Appeals
CH2, CH3	Immunoglobulin constant region heavy chain domain 2; constant region heavy chain domain 3
Fc	Crystallizable fragment of immunoglobulin
GATT	General Agreement on Tariffs and Trade, implemented by the Uruguay Round Agreements Act
IgG	Immunoglobulin G (IgG_1: immunoglobulin G, subclass 1)
ODP	Obviousness-type double patenting
p55 receptor	TNF receptor subtype weighing approximately 55 kilodaltons
p75 receptor	TNF receptor subtype weighing approximately 75 kilodaltons

Psoriasis patents	U.S. Patent Nos. 7,915,225, 8,119,605, and 8,722,631 (Appx27246-27261; Appx27262-27277; Appx27278-27294)
Smith	Smith et al., "A Receptor for Tumor Necrosis Factor Defines an Unusual Family Of Cellular and Viral Proteins," Science 248:1019-1023 (1990) (Appx26978-26982)
TNF	Tumor necrosis factor
TNFR	Tumor necrosis factor receptor
TNFR:Fc	Fusion protein comprising TNFR and Fc

INTRODUCTION

The key fact remains: Having enjoyed a full patent term for etanercept, Immunex has now obtained another one. It achieved that impermissible goal by obtaining all substantial rights in Roche's pre-GATT applications, which disclosed something that *was not* etanercept, and repurposing them to claim etanercept—again. There is no valid basis for keeping etanercept from the public long after the initial patent expired.

Immunex argues that any company can obtain multiple terms for obvious variants of the same invention by taking over patents by assignment—even during prosecution, when the assignee can craft or amend claims to ensure that they create additional patent term for the company's existing inventions. Immunex's argument is squarely foreclosed by this Court's precedent. The only test proposed in the briefing that is consistent with this Court's case law is Sandoz's: if Immunex obtained all substantial rights to Roche's applications, Immunex must be treated as an owner of those applications for purposes of obviousness-type double patenting.

And Immunex did obtain all substantial rights. Under the guise of a licensee, not only did Immunex take full control of prosecution—and use its authority to change both the claims and specification materially—it also secured control of infringement litigation. Most critically, Immunex can immunize anyone Roche wants to sue, by granting a royalty-free sublicense. Unsurprisingly, then, Roche was

willing to assign the applications for no additional consideration, but *Immunex* insisted that an assignment be labeled as worth a separate $50,000. That comically low sum for potential patents claiming a multi-billion-dollar product just reinforces that Roche's only role is to lend its name as the nominal owner. Roche even withdrew from this appeal and is not appearing to defend the patents it supposedly owns. This sham ownership does not shield the patents from ODP.

Immunex's other ODP arguments are insubstantial. Two different reference patents (the '225 patent and the '690 patent) claim the use of etanercept; claims to etanercept itself are not patentably distinct. As to the '225 patent, the patents-in-suit cannot possibly survive under the one-way test, which applies because the PTO was not "*solely*" responsible for the timing of issuance. And as to the '690 patent, Immunex remarkably and wrongly argues that the relevant claim does not cover etanercept, even though Immunex represented otherwise to the public for years to shield Enbrel from competition before the patents-in-suit issued.

The repurposing of Roche's applications not only highlights the baldness of Immunex's assertion that Roche first invented etanercept, but also independently violates the written-description requirement. Immunex tries to hide behind the district court's findings, but cannot defend the court's key legal error—relying on the claims themselves to show compliance with Section 112. Under a proper analysis, focusing on the four corners of Roche's priority application, the claims

cannot survive. The priority application does not even contain all the component pieces: Roche's truncated/mutated p75 sequence is not the same sequence used in etanercept, or even a part of that sequence; it therefore cannot be read as a stand-in for that different sequence, which Roche could have incorporated but did not. The priority application is missing etanercept's other components, too—unsurprising, since Roche never even made etanercept.

Finally, because Immunex repurposed the applications to claim *etanercept*, rather than a method of using it to treat autoimmune disorders, the district court's obviousness analysis was fundamentally flawed.

ARGUMENT

I. The patents-in-suit are invalid for ODP.

Seeking to avoid ODP, Immunex throws every argument it can against the wall, including several that the district court did not accept. But there is no legal support for Immunex's brazen effort to secure more than 30 years of patent exclusivity for the same invention.

A. Immunex's "time of invention" test for ODP common ownership is contrary to this Court's precedent.

This Court's precedent establishes unequivocally that ODP applies to "commonly-owned applications with different inventive entities," including where common ownership is acquired by assignment. *In re Longi*, 759 F.2d 887, 893-94 (Fed. Cir. 1985). The key question here is thus whether Immunex's acquisition of

all substantial rights in the Roche applications created common ownership with Immunex's other patents. Immunex ducks this central issue, arguing instead that ODP does not apply even to commonly-owned patent applications unless they were "owned by the same entity *at the time of invention*." Immunex Br. 37 (emphasis added). The district court did not rely on this argument, and it is foreclosed by this Court's precedent.

As a fallback, Immunex insists that acquiring all substantial rights is not enough, but offers *no* test for evaluating common ownership—and even disavows the state-law test that it relied on below. Immunex Br. 40 n.10; *see* Opening Br. 28-29. As a matter of statutory text and basic logic, if Immunex acquired rights substantial enough to sue as "[a] patentee" under 35 U.S.C. §281, then it acquired the applications for ODP purposes. By the time the patents-in-suit issued, Immunex already owned etanercept patents. Immunex thus "obtain[ed]" additional patents on obvious variants of the same invention in violation of ODP. *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1372 (Fed. Cir. 2014).

1. Immunex's "time of invention" test distorts history and disregards precedent. According to Immunex (at 37), "common-ownership-based double patenting rejections were unnecessary" before the Patent Law Amendments Act of 1984 limited the scope of prior art used for obviousness. *See* Pub. L. No. 98-622,

§103, 98 Stat. 3384. Immunex insists (at 38) that common-ownership ODP emerged merely to "fill" the narrow "statutory gap" opened by that law, so ODP should borrow the time-of-invention language from the 1984 Act.

Immunex's reconstruction is demonstrably wrong: as this Court recognized in *Longi*, for *decades* before the 1984 Act, the "[CCPA] … treated commonly-owned applications by different inventors as though they were filed by the same inventor" for purposes of ODP. 759 F.2d at 893.[1] Thus, while Immunex invokes (at 37) a 1967 "Commissioner's Notice" that instructed examiners not to apply ODP "to situations involving commonly owned cases of different inventive entities," 834 Official Gazette 1615, 1615 (Jan. 9, 1967), Immunex ignores *Longi*'s *explicit rejection* of that statement as "inconsistent" with longstanding precedent. 759 F.2d at 984; *see also In re Rogers*, 393 F.2d 566, 568 n.4 (C.C.P.A. 1968) (recognizing that the Commissioner's Notice conflicted "with many prior decisions of this court").

Immunex's insinuation (at 39) that *Longi* relied on the 1984 Act's legislative history to justify a new "common-ownership-based ODP" inverts this Court's reasoning. In fact, the Court concluded that the 1984 law "was not intended to affect the doctrine of double patenting," but "to "reaffirm it[]." 759 F.2d at 895. The Court

[1] "Decisions of the [CCPA] are binding precedent on this court." *BMW Mfg. Corp. v. United States*, 241 F.3d 1357, 1362 n.3 (Fed. Cir. 2001).

cited the Act's legislative history only to explicitly reject a "last resort" argument that the Act had "eliminate[d]" ODP objections based on common ownership. *Id*.

Longi shows that common-ownership ODP was not born in 1984, and the decades of pre-1984 precedent applying ODP to commonly-owned patents rebut Immunex's attempts to minimize the doctrine as a "narrow, gap-filling" rule limited by the scope of 35 U.S.C. §103(c).[2] Immunex Br. 3; *see id.* at 31, 37-39, 41, 46. The case law confirms that ODP addresses the *exact* scenario at issue here: when an "assignee" that owns a patent tries to use an earlier-filed application to obtain a second patent "on essentially the same invention[]." *In re Bowers*, 359 F.2d 886, 887 (C.C.P.A. 1966). In that scenario, §102 and §103 may not prevent issuance (for reasons unaffected by the 1984 Act), so ODP operates as a backstop to prevent the "unlawful time-wise extension of monopoly." *Id.* at 889; *see also Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012) ("The patent principally underlying the double patenting rejection need not be prior art.").

No decision limits ODP to patent applications that were commonly owned *at the time of invention*. To the contrary, ODP applies based on common ownership when, as here, a pending application was assigned *post*-invention. *See In re Mann*, 47 F.2d 370, 371-72 (C.C.P.A. 1931) (assessing ownership based on an assignment

[2] As in Immunex's brief (at 3 n.1), statutory citations are to pre-AIA versions, unless otherwise indicated.

as of "the date of issue"). More recently, this Court invalidated a patent on ODP grounds based on common ownership where the patent owner acquired all of the reference patents after it "merged with the original assignees of those patents." *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1377 (Fed. Cir. 2003). These decisions foreclose Immunex's proposed "time of invention" restriction.

2. Against this precedent, Immunex relies primarily on an unexplained statement in the Manual of Patent Examining Procedure that "[a]pplications or patents are 'commonly owned' if they were wholly or entirely owned by the same person(s), or orgainization(s)/business entity(ies), at the time the claimed invention was filed or made, respectively." MPEP §804.03(II). The MPEP "does not have the force of law," *Natural Alternatives Int'l, Inc.*, 904 F.3d 1375, 1382 (Fed. Cir. 2018), and this Court has rejected the MPEP's policies regarding ODP when they contradict precedent, *see Longi*, 759 F.2d at 894. No court has applied this purported MPEP requirement,[3] and it deserves no weight.

[3] Contrary to Immunex's implication (at 40), the district court in *Novartis Pharms. Corp. v. Noven Pharms, Inc.*, 125 F. Supp. 3d 474 (D. Del. 2015), only applied the requirement under MPEP §706.02(1) that two patents must be "entirely or wholly owned" by the same entity; timing was not at issue. *Id.* at 487; *see also Ex parte Brookhart*, No. 2005-2463, 2005 WL 4779419, at *2 (B.P.A.I. Sept. 19, 2005) (disclaiming any suggestion that ODP co-ownership should be limited by "the time frame" requirements in Section 103(c)).

3. Immunex also attempts (at 41-42) to tie its "time of invention" requirement to the text of §101, but that too is wrong. In the case Immunex cites, the Court recognized that "§101 forbids an individual from *obtaining* more than one patent on the same invention." *AbbVie*, 764 F.3d at 1372 (emphasis added). That is *exactly* what Immunex has done: after getting patents covering etanercept, it *obtained* additional patents on obvious variants of that invention. Moreover, although ODP is "grounded in" §101, *id.*, it is fundamentally an equitable doctrine that prevents an applicant from "evad[ing]" §101's strictures in order to effectively extend its patent term. *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 619 F.3d 1329, 1341 (Fed. Cir. 2010). Immunex's conduct shows why precedent precludes using post-invention assignments for exactly that sort of "evasion."

B. Immunex's policy arguments do not justify restricting the common-ownership test.

Immunex offers *no* affirmative theory for determining ownership in the ODP context; it just argues against using this Court's well-established all-substantial-rights test. Br. 43-47. But Immunex relies on overheated rhetoric when it insists (*id.*) that applying that test could "destroy[] patent rights" or cause "surprise-invalidation-by-license." Common ownership matters only when multiple patents claim patentably indistinct variations of the same invention but escape invalidity under §§102 or 103. In those rare cases, assignees can avoid ODP by terminally disclaiming any new patent term after the first patent's expiration date. *See Longi*,

759 F.2d at 894; *Bowers*, 359 F.2d at 889.[4] Immunex does not explain what is "far-reaching or perverse" about this modest implication, or why it should "complicate future transfers." Br. 44-45.

Contrary to Immunex's assertion, applying the all-substantial-rights test to establish common ownership here does *not* require the Court to hold that "[a] patent valid upon issuance could spontaneously self-destruct upon transfer." *Id.* at 44. Unlike the examples in Immunex's parade of horribles (at 44-45), Immunex took over Roche's applications *before* issuance. This pre-issuance acquisition allowed Immunex itself to draft and prosecute the claims-in-suit, providing an opening to amend the claims to cover its own blockbuster product, which had already been on the market for years. Opening Br. 18-19, 40. To resolve this case, this Court need only hold that if a party acquires all substantial rights to a patent application—including the authority to control prosecution—then ODP will apply to "prohibit *the issuance* of … claims" that are "not patently distinct from the claims" in patents that the assignee already owns. *Longi*, 759 F.2d at 892 (emphasis added). Accepting that argument would not imply that a post-issuance license "could destroy an otherwise-valid patent" or otherwise pose any risk of "disrupt[ing] … settled

[4] When a licensee has received all substantial rights, tantamount to an assignment for ODP common ownership, then the licensee is a successor to the patentee and can file a terminal disclaimer. *See* Opening Br. 28 (citing 35 U.S.C. §§100(d), 253(b)).

expectations." Br. 45.

Finally, Immunex's argument about ODP's purpose (at 44-45) fails to account for the doctrine's *primary* objective: "prevent[ing] unjustified timewise extension of the right to exclude granted by a patent no matter how that extension is brought about." *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (quotation marks omitted). Using the all-substantial-rights test to evaluate ODP common ownership furthers that core policy, because it ensures that companies like Immunex cannot extend patent terms by labeling assignments as licenses. Opening Br. 29-30; Amicus Br. of AAM 6-7, 9-11. Immunex focuses (at 44-45) on another justification for ODP—"avoiding harassment by multiple assignees," *In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009). But this Court has never suggested single-ownership should be encouraged if it would result in an unjustified extension of the single owner's patent term.

C. Immunex is the effective owner of the patents-in-suit.

Under the all-substantial-rights test, the outcome is clear: the 2004 Agreement is indistinguishable from an assignment. Immunex acquired every attribute of patent ownership that matters, including the two categories of rights that this Court has identified as most critical—the exclusive rights to make, use, and sell the patented invention, and the right to sue accused infringers and license the patent. Opening Br. 30-32; AAM Amicus Br. 7-9.

1. Immunex relies heavily (at 47-48) on the purported motive of its lead negotiator, treating subjective intent as a stand-alone element of the all-substantial-rights test. But that is not how the test works. The Court evaluates the parties' "intent" by what the agreement *does*—whether the parties entered an assignment is a *legal* question that "depends on the substance of what was granted," *Lone Star Silicon Innovations LLC v. Nanya Tech Corp.*, 925 F.3d 1225, 1229 (Fed. Cir. 2019). Indeed, as Immunex acknowledges (at 47), district courts often decide all-substantial-rights questions on the pleadings, and this Court reviews the "court's conclusions de novo," *id.* at 1230.

Arguing that the Court should instead review for clear error, Immunex mistakenly relies (at 47) on precedent involving "parol evidence," which could give rise to subsidiary factual findings about what an agreement *means* that are "review[ed] deferentially." *Alfred E. Mann Found. for Sci. Research v. Cochlear Corp.*, 604 F.3d 1354, 1359 (Fed. Cir. 2010).[5] But none of the relevant provisions in the 2004 Agreement are ambiguous, and Immunex does not cite testimony clarifying the meaning of particular terms. Rather, Immunex argues that *even if* the

[5] As Immunex notes (at 47), Sandoz's pretrial filings identified subsidiary factual issues that would be relevant to the court's ownership question. Sandoz did not imply that the *ultimate* question is factual. Indeed, the same filing listed disputes over claim construction and obviousness as presenting (subsidiary) factual disputes, even though both are ultimately legal issues. Appx661-663.

2004 Agreement's clear terms gave Immunex all substantial rights in the applications, the Agreement still is not an assignment simply because Immunex *subjectively wanted* to avoid that label. Br. 38-39. But testimony about motive does not change an agreement's plain meaning. If an agreement's terms transfer all substantial rights, that is the end of the inquiry. *See, e.g.*, *Vaupel Textilmaschinen KG v. Meccanica Euro Italia SpA*, 944 F.2d 870, 874-76 (Fed. Cir. 1991) (looking solely to the language of the operative agreements and determining "the legal effect of its provisions"). It would be particularly ill-advised to adopt a "motive" test in the ODP context, given the clear incentives for gamesmanship like Immunex's.[6]

2. The 2004 Agreement's substance leaves Roche without ownership rights. Roche's secondary right to sue for infringement (Immunex Br. 46-51) is illusory given Immunex's authority under Paragraph 3.5 (Appx25840-25841) to grant royalty-free sublicenses before Roche can sue, *see Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1251 (Fed. Cir. 2000). While Immunex concedes that it can block Roche from suing, it argues that the hypothetical secondary right to sue remains substantial under *Alfred E. Mann*, because the licensee there also could grant

[6] Stuart Watt testified that he understood ODP could apply based on "common ownership," Appx5784, which gave him reason to avoid calling the 2004 Agreement an assignment. That point is not refuted by Mr. Watt's self-interested statement that, contrary to well-settled precedent, he "d[id]n't believe" that a formal assignment of Roche's patent applications would raise ODP questions. Appx5786; *contra* Immunex Br. 48-49 & n.15.

sublicenses "before the licensor had the chance to sue." Immunex Br. 50. But Immunex ignores the critical distinguishing feature in *Alfred E. Mann*: there, the right to sublicense was *not* "unfettered," because any sublicenses had to "include specified pass-through royalties." 604 F.3d at 1362. Here, it is undisputed that Immunex may grant *royalty-free* sublicenses. Opening Br. 35.

Moreover, Immunex's assertion (at 33-34) that it would lose its right to sublicense once Roche files suit has no basis in the 2004 Agreement. Immunex argues that Paragraph 3.6 cuts off Immunex's sublicensing rights once Roche files suit. But that interpretation, which the district court based solely on "the language of the [2004 Agreement]," Appx72-73, receives no deference, *see Alfred E. Mann*, 604 F.3d at 1359, and it is wrong. Roche never gets a right to veto sublicenses. Nothing in Paragraph 3.6 extinguishes Immunex's right to sublicense after 180 days' notice from Roche; although the provision gives Roche "sole" authority to "initiate an action for … infringement" after 180 days, it conspicuously does not modify Immunex's sublicensing rights. Appx25841. Immunex's obligation to "cooperate" with Roche "*in* any such suit," *id.* (emphasis added), also does not speak to whether Immunex can eliminate the suit's predicate by granting a sublicense.

The three remaining rights referenced by Immunex are insubstantial, on their own and collectively. First, Roche concedes (at 51) that a right to practice the patents "for internal non-clinical research" (Appx25839) is not substantial "by itself."

Indeed not: this meager retained license looks nothing like ownership. In *AsymmetRx, Inc. v. Biocare Med., LLC*, 582 F.3d 1314 (Fed. Cir. 2009), on which Immunex relies (at 51), the reserved right to practice the patents was just "one factor" out of many supporting ownership, including other significant rights that are absent here, such as the ability to "jointly control[]" any infringement litigation, to control sublicensing, and to receive a share of all sublicensing royalties. 528 F.3d at 1320-21.

Second, Immunex invokes (at 52-53) the 2004 Agreement's restrictions on assignments, but its argument is incoherent. Immunex relies (at 53) on a general provision (paragraph 11.4, Appx25849) that also restricts Wyeth's future assignment rights, even though Immunex concedes that Wyeth became an *owner*. Immunex insists that Wyeth could make unilateral assignments despite paragraph 11.4, but that is a bald rewrite of the Agreement and cannot explain away Immunex's contradictory positions. Immunex also has no answer for the fact that paragraph 11.4's restrictions are *reciprocal*: if Immunex's argument were taken seriously, *no one* would own the patents-in-suit because Roche, too, lacked unilateral assignment authority. Opening Br. 34-35 n.1.

Finally, and most audaciously, Immunex emphasizes (at 52) that, *at Immunex's insistence*, the 2004 Agreement sets a price of $50,000 to convert the exclusive license into formal assignments. Appx25840; Opening Br. 17. That

extraordinarily low number compared to the license cost[7] perfectly illustrates the *de minimis* value of the rights that Roche retained.

D. The patents-in-suit are not patentably distinct from the '225 patent.

The patents-in-suit claim etanercept and a method of manufacturing etanercept; the earlier-issued, earlier-expiring '225 patent claims a method of treating a condition using etanercept. Opening Br. 9, 37, 41-42. None of Immunex's scattershot arguments shows that the asserted claims are patentably distinct from claim 1 of the '225 patent.

1. The district court recognized that the post-URAA '225 patent is an ODP reference because it "issued" *and* "expire[d] prior to the Patents-In-Suit." Appx82 & n.43; *see also Novartis Pharms. Corp. v. Breckenridge Pharm. Inc*., 909 F.3d 1355, 1359 (Fed. Cir. 2018) (instructing courts to follow the "traditional" ODP practice of using the "issuance date" as the reference point when faced with combined pre- and post-URAA patents). Immunex claims (at 55) the district court found no "gamesmanship," but the court actually concluded that "a post-GATT *later-granted* and earlier-expiring patent cannot cut short the term" of a pre-GATT "*earlier-granted* patent." Appx82 (emphasis added; quotation marks omitted). Two

[7] Immunex quibbles (at 19 & n.5) about the license cost, arguing that the price should include Wyeth's contribution. Even under that view, the cost of the license would still represent less than 17 days of Enbrel revenue—and Enbrel was *already* a blockbuster earning billions in annual revenue *before* the 2004 Agreement.

other psoriasis patents issued later, but the '225 patent was granted before the patents-in-suit, and as Immunex concedes (at 54), it would have expired before the patents-in-suit *even absent* the URAA. It therefore is a proper ODP reference.

2. Immunex's attempt to invoke the rarely-applicable two-way test (at 55-57) defies the controlling legal standard. Immunex cannot show that the PTO was *solely* responsible for the fact that the patents-in-suit issued 8-12 months after the later-filed '225 patent given the *undisputed* evidence that Roche's and Immunex's combined *11* extensions for the patents-in-suit, on their own, added *more than two years* to prosecution. Opening Br. 15, 18-19, 39.[8]

Without citing any precedent, Immunex contends (at 56-57) that "ordinary amendments and extension of time" do not count in deciding whether the PTO was the sole cause of the issuance sequence. But this Court's decisions foreclose that argument. *See, e.g.*, *In re Emert*, 124 F.3d 1458, 1461 (Fed. Cir. 1997) (applicant shared responsibility for prosecution's duration given "numerous time extensions" and a "continuation application"). And the amendments and extensions here were anything but "ordinary." Immunex radically reworked the claims, first adopting the asserted claims *in 2010*—15 years into prosecution and *after* the '225 patent was

[8] Immunex's plea (at 56) for a special, more lenient ODP rule in cases of common ownership is baseless, particularly since Immunex exercised complete control over prosecution of both the patents-in-suit and the '225 patent.

filed. Opening Br. 39-40; *cf. In re Basell Poliolefine Italia S.P.A.*, 547 F.3d 1371, 1376 (Fed. Cir. 2008) (rejecting the two-way test where claims were adopted nine years into prosecution and after the ODP reference application was filed).

3. Immunex's claims are not patentably distinct under the one-way test; Immunex's half-hearted counter (at 57-58) lacks merit, and the district court did not adopt it. Immunex protests that its etanercept method-of-treatment claims define a different invention than claims to the etanercept compound or to manufacturing etanercept. That the claims are *different* does not matter. The question for ODP is whether a claim using the etanercept invention to treat a condition renders claims directed to the invention itself *obvious*. *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1385 (Fed. Cir. 2010). It unquestionably does. Opening Br. 37, 41-42.

E. The patents-in-suit are not patentably distinct from claim 3 of the '690 patent.

The asserted claims are also obvious over claim 3 of the '690 patent. Immunex argues (at 58) that claim 3 excludes etanercept. But nothing in the term "*the* constant domain" requires "a *completely unchanged and unmodified* constant region domain." Opening Br. 43 (quoting Appx5272). Both the '690 patent's specification and Immunex's representations during prosecution confirm that claim 3 covers a "TNFR/Fc fusion protein"—*i.e.*, etanercept. Opening Br. 43-45.

Immunex leaves almost all of that intrinsic evidence unanswered. Br. 58-61.

Instead, it raises two narrower arguments, neither of which changes the correct construction of claim 3.

First, Immunex charges Sandoz with inconsistency in its interpretation of the '690 patent's specification. As Sandoz explained, the discussion of a "chimeric antibody" in the '690 patent describes etanercept. Opening Br. 45. And yet, Immunex says (at 59), "Sandoz acknowledged that the 'chimeric antibody' described in the specification [of the '760 patent] includes CH1 and the light chains." But the purported inconsistency is illusory: Sandoz's discussion of the '760 patent acknowledged that the chimeric antibody described there *could* include each and every constant region domain, not that it *had* to. Appx60086; *see* Appx60050-60051. Immunex's argument also overlooks an important distinction between the relevant paragraphs of the '690 and '760 patents, respectively: the '690 patent contains an additional sentence, which states that "[o]ne specific example of a TNFR/Fc fusion protein is disclosed in SEQ ID NO:3 and SEQ ID NO:4." Appx27307; *cf.* Appx28154. Both parties' experts agreed that the TNFR/Fc fusion protein disclosed in SEQ ID NO:3 and SEQ ID NO: 4 *is etanercept*. Opening Br. 45 (citing Appx4139; Appx5391). Immunex has no response.

Second, Immunex notes (at 60-61) that the examiner rejected its proposed claim directed to etanercept on the ground that it was not supported by the '690

original specification. But that history hurts Immunex's position. The abandoned claim for etanercept depended from a proposed claim that covered:

> A method for treating TNF-mediated inflammatory diseases which comprises administering … a TNF antagonist selected from the group consisting of a TNF receptor and a chimeric antibody comprising a TNF receptor and the constant domain of an immunoglobulin molecule.

Appx10172 (alterations omitted). Thus, in Immunex's own view, etanercept was a species of "chimeric antibody comprising a TNF receptor and the *constant domain of an immunoglobulin molecule*."

Tellingly, Immunex marked the label for Enbrel with the '690 patent for years, representing to the public that the '690 patent claimed etanercept. Immunex tries to justify its opportunistic about-face by asserting (at 23) that it listed the '690 patent because of claims 2 and 5 (not claim 3). But claims 2 and 5 recite the administration of a TNF receptor, and etanercept is *not* a TNF receptor. Appx27320-27321. As all parties agree, etanercept belongs to a distinct category—fusion proteins. Immunex Br. 5, 8-10.

Immunex cannot seriously suggest that it marketed a multi-billion dollar biologic for more than a decade without any patent protection. In the end, Immunex's marking decision is just further confirmation of what the intrinsic evidence shows: claim 3 of the '690 patent covers etanercept.

II. The district court's written-description analysis rested on fundamental legal errors.

Whether Roche's priority application provides written-description support for Immunex's later-added claims directed to etanercept depends on whether the disclosures Roche made within the "four corners" of its priority application provide "blaze marks" that point to etanercept. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc); *Idenix Pharms. LLC v. Gilead Sci. Inc.*, 941 F.3d 1149, 1164 (Fed. Cir. 2019).

The legal framework the district court applied, however, bears no resemblance to this Court's precedent. Most blatantly, the court repeatedly relied on claims directed to etanercept that Immunex added more than a decade after Roche's priority application as their own written description support. Immunex does not defend relying on the claims, but asserts that this legal error did not impact the court's findings. That is plainly wrong: nearly every finding the district court made regarding disclosure of etanercept itself rested on "[w]orking backward" from Immunex's later-filed claims to identify the specific components of etanercept that needed to be "plucked selectively" from Roche's priority application. *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013). Under the correct legal standard, the court could not have properly concluded that Roche's priority application disclosed even the *TNFR portion* of etanercept, let alone

the specific combination of that TNFR sequence with the other components of etanercept that Immunex later claimed.

A. The district court only found disclosure of the full p75 DNA sequence used in etanercept by applying an obviousness-based framework that looked beyond the priority application.

The relevant written-description question is not, as Immunex implies, whether a skilled artisan would have *known of* the full p75 TNFR sequence. Knowledge is not possession, and it is certainly not disclosure. *See Ariad*, 598 F.3d at 1351. The "hallmark of written description is disclosure," *id.*, and the question is therefore whether a skilled artisan, reading Roche's priority application, would have understood the Roche inventors to be disclosing the use of the full p75 TNFR sequence in a fusion protein.

Nothing in Roche's priority application suggested to a skilled artisan the use of the full p75 TNFR sequence in a fusion protein, as opposed to the use of the truncated/mutated p75 sequence that Roche disclosed in Figure 4. As the opening brief explained (at 50-51), the priority application makes clear that references to p55 and p75 TNFRs point to the specific sequences in Figures 1 and 4. Thus, Immunex's insistence (at 62) that the application disclosed *a* "p75" receptor misses the point. Roche disclosed the Figure 4 sequence in the priority application but *not* the distinct p75 sequence Immunex later claimed.

Immunex attempts to overcome Roche's lack of disclosure of the relevant

sequence by claiming that the Figure 4 sequence was disclosed as "partial." Figure 4 was not just *partial*, but also *different*: it was both truncated *and mutated*. There is no evidence that it was intended to invoke or incorporate the full p75 TNFR sequence disclosed in Smith. As Immunex's expert conceded, nothing stopped Roche from simply invoking or incorporating that full p75 sequence. Appx5062-5064. Instead, Roche disclosed in Figure 4 the distinct, truncated/mutated p75 variation that it had discovered.

Immunex's claim that, from the beginning, Figure 4 invoked the full p75 sequence is belied by Roche's '029 application. There Roche identified the Figure 4 sequence not as *part* of Smith, but as a *patentably-distinct alternative* to Smith. Opening Br. 54-55; Appx31502-31503. Immunex now bizarrely insists (at 65-66) that this fact supports its position because, in the '029 application, "the inventors were seeking to claim something *other than* the known p75 receptor sequence." But if the Roche inventors understood the Figure 4 sequence as "something *other than* the known p75 receptor sequence," and then used that same Figure 4 sequence in the priority application at issue here, the obvious implication is that *this* application was *also* disclosing "something *other than* the known p75 receptor sequence." Immunex cannot explain why Figure 4 would be a distinct alternative to the Smith sequence in the '029 application, but merely a shorthand for the Smith sequence in the priority application.

Relatedly, Immunex's repeated insistence (*e.g.*, at 64 & n.16) that the Figure 4 sequence Roche disclosed is not the sequence in Immunex's claims undermines its position. The fact that Immunex's claims, added more than a decade after the priority application, depend on a sequence *different than* the one Roche disclosed is precisely why Roche's priority application does *not* disclose Immunex's later-claimed invention.

Like the district court, Immunex is forced to hunt for written-description support outside the priority application, relying on the submission of disclosed SEQ ID fragments to GenBank and on the concededly-not-incorporated Smith reference. Immunex Br. 62-65. As to GenBank, whether or not a skilled artisan might have been able to identify the full 235-amino-acid p75 sequence *if* she had chosen two disclosed, 18-amino-acid fragments and submitted them to a third-party depository, the disclosure of those two fragments did not show Roche had possession of a fusion protein based on the undisclosed full p75 sequence rather than Roche's truncated/mutated version. This Court has recently and repeatedly emphasized that disclosures merely rendering the invention *obvious* are insufficient to establish written-description support. *Idenix*, 941 F.3d at 1165.

Immunex's (and the district court's) reliance on Smith rests on a similarly-erroneous approach. As Immunex's expert recognized, the priority application did not "incorporate Smith," or instruct a skilled artisan to "use Smith to complete the

sequence of Figure 4." Appx5062-5064.[9] Immunex thus again resorts to obviousness, citing a footnote in which the district court declined to hold that Smith would "have discouraged a POSA from using the known complete p75 TNFR sequence." Appx18 n.10. But neither that conclusion nor the district court's conclusion that the priority application would have led a skilled artisan to read Smith, Appx17-18, suggests anything more than *knowledge* of the Smith sequence. Again, the question for written description is what the application *itself* discloses, not what it renders obvious. *Idenix*, 941 F.3d at 1165. Causing a skilled artisan to go read prior-art references does not amount to disclosing a fusion protein contained in one of those references.

This case is nothing like *Yeda Research & Dev. Co. v. Abbott GmbH*, 837 F.3d 1341 (Fed. Cir. 2016), on which Immunex repeatedly relies. In *Yeda*, the application disclosed "the exact invention" later claimed; the disclosed amino-acid sequence for a protein, together with "several biological characteristics," identified only one "known protein" and provided adequate written-description support for that protein even without providing a full amino-acid sequence. *Id.* at 1345-46. Immunex's other cases—*Capon v. Eshhar*, 418 F.3d 1349, 1357-58 (Fed. Cir. 2005), and *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1367-68 (Fed. Cir. 2006)—

[9] So too with Roche's own Dembic paper, which the priority application tellingly did not even reference, much less incorporate. Appx5061.

similarly hold only that a patent disclosure can invoke a specific nucleotide sequence known in the art without reciting it.

Here, however, Roche's priority application did not use shorthand to identify a single, unique p75 sequence that Immunex later sought to claim. Instead, the priority application specifically recited and pointed to a *different* p75 sequence—one Roche itself called patentably distinct from the one Immunex later claimed. Getting from Roche's application to Immunex's claims involves not just filling in known blanks, but *substituting* the *undisclosed* full p75 sequence for the *different, disclosed* sequence in Figure 4. That substitution requires not just viewing the priority application from the perspective of a skilled artisan, but *modifying* the priority application, using the prior art, to create a *different* invention than the one disclosed. Such obviousness-style reasoning has no place in written-description analysis. *Idenix*, 941 F.3d at 1165.

Finally, Immunex's amendments to the specification to incorporate Smith and the full p75 sequence, while irrelevant for written description, strongly suggest that Immunex itself did not read Roche's priority application as having disclosed the full p75 sequence for use in a fusion protein. Notably, Immunex does not try to explain why it amended the specification to make disclosures that it now asserts were unnecessary. Immunex's only argument (at 66) is that under *In re Lundak*, 773 F.2d 1216 (Fed. Cir. 1985), its 2006 deposit must be treated as part of Roche's 1990

priority application. But all *Lundak* held is that, when the original application *actually referenced* an existing sample and where it would be deposited, it did not matter that the sample was not deposited there until *a week later*. *See id.* at 1223. That does not mean that a plasmid that is not referenced *at all* in the priority application can be referenced and deposited, for the first time, sixteen years later. Moreover, adding this plasmid would have been meaningless if Immunex thought Roche already disclosed the full p75 sequence.[10]

In sum, what Roche actually disclosed in the priority application was the truncated/mutated p75 sequence; it did not disclose a fusion protein with the full p75 sequence disclosed in Smith.

B. The district court only found disclosure of the later-claimed etanercept p75-IgG$_1$ fusion protein by impermissibly relying on the later-filed claims as their own written-description support.

Immunex's later-added claims to etanercept also fail for an independent reason: the priority application did not provide the "blaze marks" needed for a skilled artisan to "single out" and combine the specific combination of elements that make up etanercept. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326 (Fed. Cir. 2000); *see also Idenix*, 941 F.3d at 1164. As the opening brief explained

[10] Immunex notes (at 66) that the district court found the specification amendments proper, but that was based on the erroneous conclusion that the priority application *already* disclosed the full p75 sequence, and hence the amendments did not expand the application's scope. Appx24.

(at 58-59), to put together the right pieces in the right way to get etanercept, a skilled artisan would have had to choose the undisclosed full p75 sequence over both the Figure 4 sequence actually disclosed and other soluble TNF-binding fragments; select IgG_1 over other potential immunoglobulins, including the IgG_3 used in the priority application's only example of a fusion protein; and choose the exon-encoded version of the IgG_1 hinge, even though *Immunex* argued below (in disputing obviousness) that "[a] POSA selecting an IgG would not have selected an exon-encoded hinge-CH2-CH3 of IgG1," Appx60333-60334.

Unsurprisingly, then, the district court never actually found that Roche's priority application *itself* directed a skilled artisan to the specific etanercept compound Immunex later claimed; the court found that Roche's application, *combined with Immunex's later-filed claims*, showed possession of etanercept. Appx20-21; Opening Br. 60. This was legal error. *See Ariad*, 598 F.3d at 1349; *Purdue*, 230 F.3d at 1326-27.

Immunex concedes that later-filed claims cannot provide their own written-description support, but denies that the district court relied on the later-filed claims Br. 70-71. That ignores what the court actually wrote. The court did not rely on the claims simply to define the level of detail that must be found in the priority application. The court, very explicitly, relied on the claims as the "blaze marks" that identified which of many components, scattered throughout Roche's priority

application, to combine into etanercept. Specifically, the court found that a skilled artisan would have identified etanercept from the priority application disclosures "*based on* the claims"; it found that the "claim language … *provides support of possession*"; and its ultimate conclusion that "the Roche Inventors had possession" of etanercept was explicitly "*based on* the specifications … *and the claims*." Appx20-22 (emphases added). Thus, *nearly every finding* the district court made regarding disclosure of Roche's possession of etanercept rested on improperly "[w]orking backward from a knowledge of" Immunex's later-filed claims to identify the specific components that needed to be "plucked selectively" from Roche's priority application and combined to create etanercept. *Novozymes*, 723 F.3d at 1349.

Immunex tries to prop up the district court's flawed analysis by claiming that the priority application did not actually disclose a genus of fusion compounds, but instead just "four preferred fusions"—*i.e.*, p55 or p75 combined with IgG_1 or IgG_3. That dramatic oversimplification is not based on any finding by the district court and is plainly wrong. Most obviously, "p75" is not a *single* choice, but a category. The priority application discloses a large range of "preferred" and "[e]specially preferred" p75 sequences based around Figure 4—and not one of those disclosures even identifies the actual p75 sequence used in etanercept. Appx25090. Similarly, choosing IgG_1 or IgG_3 does not answer the far more complex question of *what part*

of those immunoglobulins to use. Thus, even just the combination of *some* p55 or p75 sequence with *some* IgG_1 or IgG_3 sequence *still* presents a broad genus from which a skilled artisan must choose, and *nothing* in the priority application "single[s] out" etanercept. *Purdue*, 230 F.3d at 1326.[11]

Nor does Example 11 resolve these issues. *Contra* Immunex Br. 69. That example provides a method of creating a p55-IgG_3 fusion protein. Even if that method could be used to make a p75-IgG_1 protein instead—which would require significant alterations, as one of the Roche inventors admitted, Appx4844-4845; *see also* Appx4495-4497—Example 11 says *nothing* about which of the myriad potential p75 sequences to select, or which part of an IgG_1 to combine it with.

Without its legally erroneous reliance on Immunex's later-added claims, the district court could not have found "blaze marks" identifying which pieces to pluck from Roche's priority application and assemble into etanercept.

III. Legal error infected the district court's non-obviousness determination.

A. The district court legally erred in restricting the obviousness analysis to treatment of autoimmune diseases.

The district court's non-obviousness determination relied on the premise that

[11] Even if Immunex were right (at 71 n.18) that original claims can provide written-description support for later-issued claims, the district court did not rely on the original claims, and for good reason. While original claim 19 might *cover* etanercept, it does so only as part of a broad genus that encompasses a fusion of DNA coding for *any* fragment "capable of binding TNF" with DNA for *either* IgG_1 or IgG_3. Appx25129. It does not provide any "blaze marks" to etanercept itself.

a skilled artisan would not have been motivated to attach a portion of an immunoglobulin to a portion of a TNFR to treat autoimmune diseases. That was legal error because the claims are *not* limited to any disease, let alone autoimmune diseases. Opening Br. 62; *see also* Samsung Amicus Br. 3-8, 12-15.

Immunex blames Sandoz for the district court's legal error; according to Immunex (at 73-74), Sandoz focused exclusively on the therapeutic benefits of selecting the p75 receptor and combining it with a portion of an immunoglobulin. But that is just wrong: Sandoz argued below that the claims are not limited to the treatment of any disease. Appx60123; Appx60137; Appx60446-60447. Specifically, Sandoz demonstrated that the prior art taught that anti-TNF IgGs and TNFR-IgG fusion proteins would be useful not only to treat a variety of conditions, but also to serve as diagnostic tools based on their ability to bind and scavenge TNF. Appx60095-60096; Appx60447; Appx4210; Appx4161-4162; Appx60135. Sandoz also showed that a skilled artisan would have been motivated to construct etanercept from the Smith '760 patent TNFR-IgG fusion protein (Appx60198-60199), which the prior art taught is useful for "diagnostic assays for TNF" and may be used as a potential therapeutic "to scavenge TNF" (Appx28150-28151; Appx28154; *see* Appx4210-4211; Appx60082-60083). But both Immunex and the district court simply ignored those arguments.

Immunex also fails to justify the district court's artificially narrow approach

to motivation by claiming that "[t]wo of the asserted claims cover pharmaceutical compositions." Br. 73. Immunex never raised such an argument below, and it is wrong. The "pharmaceutical composition" could cover both *in vivo* diagnostic assays and a broad array of diseases for which binding TNF was demonstrated to be beneficial in animal studies. This includes diseases such as septic shock and graft-versus-host disease for which *Immunex admits* "effector function would not have been an issue." Appx5244-5246; Appx60354; *see* Appx60447; Appx60082.

Immunex's alternative assertion (at 74) that the record does not include "meaningful evidence" of a motivation to create etanercept to use as a diagnostic tool is baseless. Immunex's inventor admitted etanercept would be useful as a diagnostic tool. Appx4832. Now, Immunex suggests (at 75), without *any* support, that a skilled artisan would have been content to rely on existing diagnostic tools. Immunex did not raise this argument below, and it cannot backfill the district court's legally erroneous determination with findings that the court never made.

B. The district court legally erred in its analysis of objective indicia.

The district court also legally erred in assessing the objective indicia of nonobviousness because it failed to fully analyze nexus. Where objective evidence relates to "something other than what is both *claimed and novel* in the claim, there is no nexus to the merits of the claimed invention." *Merck & Cie v. Gnosis S.p.A.*, 808 F.3d 829, 837 (Fed. Cir. 2015). Immunex tries to dismiss Sandoz's arguments

as raising factual disputes, but it cannot salvage the district court's flawed legal reasoning.

First, the district court failed to identify novel features of the patents-in-suit as compared to earlier patents, such as the '690 patent. Immunex contends only (at 76) that the district court was justified in skipping over the '690 patent because it "does not claim etanercept at all." But as discussed, pp. 17-19, *supra*, that is wrong, and cannot be reconciled with the fact that Immunex listed the '690 patent on its Enbrel label for more than a decade. Appx10518; *see also* Appx10965; Appx11504.[12] The court legally erred by failing to account for the '690 patent or any of the dozen other etanercept patents. *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311-13 (Fed. Cir. 2006); *see* Appx5832-5833.

Second, the district court legally erred by discounting a single instance of simultaneous invention. Repeating the district court's error, Immunex relies entirely on *Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co.,* 730 F.2d 1452 (Fed. Cir. 1984), but that case that is easily distinguishable because the alleged simultaneous inventors in *Lindemann* collaborated or observed the same invention,

[12] Immunex also strangely implies that the '690 patent did not precede the patents-in-suit because the patent "issued from a continuation-in-part filed two years *after* the original Roche applications." Br. 76. But as Immunex acknowledges, *id.* at 22, the '690 patent claims priority to its original 1989 application, whereas the patents-in-suit also issued from 1995 divisional applications that claim priority to 1990, Appx12686; Appx12721.

id. at 1460-61. *Lindemann* recognized that, notwithstanding interference practice, the occurrence of a simultaneous invention by two inventors "working independently" *could* be "an indication of obviousness when considered in light of all the circumstances." *Id.* Those circumstances are present here, where the evidence shows that Immunex—not Roche—discovered etanercept.

CONCLUSION

This Court should reverse the district court's decision.

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CERTIFICATE OF SERVICE

I hereby certify that on December 23, 2019, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit using the Court's CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the CM/ECF system.

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Undersigned counsel certifies that this brief complies with the type-volume limitation of Fed. Cir. R. 32(a) because it contains 6,996 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

Undersigned counsel further certifies that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced 14-point Times New Roman typeface using Microsoft Word 2010.

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