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-Appellants

2020-1037

Appeal from the United States District Court for the District of New Jersey in No. 2:16-cv-01118-CCC-MF, Judge Claire C. Cecchi.

Decided: July 1, 2020

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Before O'MALLEY, REYNA, and CHEN, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* O'MALLEY.

Dissenting opinion filed by *Circuit Judge* REYNA.

O'MALLEY, *Circuit Judge*.

Patent owner Hoffmann-La Roche Inc. ("Roche"), its exclusive licensee Immunex Corp., and exclusive sublicensee Amgen Manufacturing, Ltd., initiated this patent infringement suit pursuant to the Biologics Price Competition and Innovation Act ("BPCIA").[1] Sandoz, Inc., Sandoz

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[1] Immunex Corp. and Amgen Manufacturing, Ltd. are collectively referred to as "Immunex." Although Roche joined the district court litigation, it did not enter an appearance in this appeal.

International GmbH, and Sandoz GmbH filed abbreviated Biologics License Application ("aBLA") No. 761042.[2] This action followed shortly thereafter. In the aBLA, Sandoz sought approval to market Erelzi, a biosimilar version of Immunex's biologic drug, Enbrel®.

Enbrel® is covered by the patents-in-suit: U.S. Patent Nos. 8,063,182 ("'182 patent") and 8,163,522 ("'522 patent"). Prior to trial, Sandoz stipulated to infringement of the asserted claims of the patents-in-suit. After a two-week bench trial, the United States District Court for the District of New Jersey entered final judgment for Immunex and Roche, holding that Sandoz had failed to prove that the asserted claims of the patents-in-suit were invalid.

Sandoz appeals from the district court's judgment. On appeal Sandoz argues, as it did before the district court, that the patents-in-suit are invalid for (1) obviousness-type double patenting; (2) failure to meet the written description requirement; and (3) obviousness. For the reasons discussed below, we affirm.

I. BACKGROUND

A. The Claimed Technology and Patents-in-Suit

The patents-in-suit are directed to the fusion protein etanercept and methods of making the same. Etanercept is the active ingredient in Immunex's biologic drug Enbrel®, which is primarily indicated for reducing the signs and symptoms of moderately to severely active rheumatoid arthritis, an autoimmune disorder. Etanercept is made by combining a portion of a 75 kilodalton ("kDa") human tumor necrosis factor receptor protein with a portion of immunoglobulin G1 ("IgG1").

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[2] Sandoz, Inc., Sandoz International GmbH, and Sandoz GmbH are collectively referred to as "Sandoz."

IgG1 is a type of antibody. Antibodies are proteins deployed by the immune system to identify and neutralize foreign objects—such as bacteria and viruses—called antigens. Each antibody contains a region that binds to a portion of an antigen. Through this binding mechanism, an antibody can either neutralize the target antigen directly—for example, by blocking the part of a virus that is essential for the survival of the virus—or tag a microbe or an infected cell for attack by other parts of the immune system. Like all proteins, antibodies are made up of amino acids connected to form chains called polypeptides. The polypeptides fold into three-dimensional structures that impart structural and functional characteristics to the antibodies.

Structurally, each antibody (including IgG1) consists of four chains of amino acids: two identical "heavy chains" and two identical "light chains," arranged in a Y-shape. All four chains in the antibody contain two different segments: a constant region (denoted by C_H for the heavy chain constant region and C_L for the light chain constant region) and a variable region (V_H for the heavy chain variable region and V_L for the light chain variable region). The variable regions are segments of the antibody that determine whether, and how effectively, an antibody will bind to a given antigen. The constant regions, on the other hand, interact with other components of the immune system through "domains"—areas of the protein that have a specific structure and can serve a specific function. The light chain constant region consists of the CL domain. The heavy chain constant region includes the CH1, the hinge, CH2, and CH3 domains.

The human immune system also contains cytokines—cell signaling proteins that effectuate a variety of immune responses. Tumor necrosis factor ("TNF") is one type of cytokine produced in the human body. It is associated with autoimmune inflammatory diseases such as rheumatoid arthritis. TNF binds to TNF receptors ("TNFRs"), transmembrane receptors that contain three distinct regions:

intracellular, transmembrane, and extracellular. There are two types of TNFRs, p55 (a 55 kDa protein) and p75 (an approximately 75 or 80 kDa protein). The extracellular region of TNFRs binds to TNF. This region can be split off to make a soluble protein that binds to TNF, allowing for removal or neutralizing of excess TNF from the body.

Etanercept—a fusion of the extracellular region of p75 and the hinge-CH2-CH3 portion of the constant region of the IgG1 heavy chain—binds to excess TNF and neutralizes it. In this way, it reduces the autoimmune inflammatory response in patients with rheumatoid arthritis.

The claims of the '182 patent are directed to etanercept, and the claims of the '152 patent are directed to methods of making etanercept. Both patents-in-suit claim priority to European Patent Application No. 90116707.2 ("the EP '707 Application"), filed on August 31, 1990, and U.S. Application No. 07/580,013 ("the '013 Application"), filed on September 10, 1990. Roche, the party that originally filed the applications in this patent family, abandoned the '013 Application, but filed a continuation, U.S. Application No. 08/965,640 ("the '640 Application") on July 21, 1993. This application was subject to a restriction requirement by the United States Patent and Trademark Office ("USPTO"). As a result of the restriction requirement, on May 19, 1995, Roche filed two divisional applications claiming priority to the '640 application. These applications matured into the '182 and '152 patents, which issued on November 22, 2011 and April 24, 2012, respectively.

B. License Agreements Between Immunex[3] and Roche

To understand the parties' arguments on appeal, a basic understanding of the historical relationship between

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[3] For simplicity, we refer to the licensee of the primary agreement at issue as "Immunex," because all rights

Immunex and Roche, as well as certain licenses between them, is necessary. By 1990, both Roche and Immunex Corp. were separately engaged in researching TNF and investigating whether targeting this molecule could provide any therapeutic benefits. In April 1990, Roche published the complete amino acid sequence of the p55 TNFR. In May 1990, Immunex Corp. published an article containing the full amino acid sequence of the p75 TNFR. And, in July 1990, Roche published the complete amino acid sequence of p75, along with part of its encoding DNA. As noted above, it was Roche that filed the priority application for the patents-in-suit in 1990, as well as the applications for the patents-in-suit in 1995.

Immunex Corp., working independently on TNFR-IgG fusion proteins, obtained FDA approval of Enbrel® in 1998. Almost a year later, Immunex Corp. and Roche entered into a license (the "Immunex-Roche agreement"), effective as of the approval date of Enbrel®, pursuant to which Immunex obtained a license to, *inter alia*, the EP '707 Application and the '013 Application, and all patents that issue from those applications. J.A. 25867. Immunex agreed to pay Roche royalties on the sales of Enbrel®. J.A. 25876–80.

In 2002, non-party Amgen, Inc. acquired Immunex Corp. Subsequently, in 2004, Amgen, Inc., Immunex Corp., Roche, and non-party Wyeth entered into an "Accord & Satisfaction" agreement concerning the same patent family. J.A. 25836. The purpose of the agreement was "to eliminate the continuing obligations to pay royalties to Roche" pursuant to the Immunex-Roche agreement. *Id.*

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initially granted to the original licensee, Amgen, Inc., and its affiliates were ultimately consolidated in Immunex Corp.

Under the terms of the Accord & Satisfaction, Immunex has a paid-up, irrevocable, exclusive license to the U.S. patent family for the patents-in-suit. It has the sole right to grant sublicenses, to make, have made, use, sell, offer for sale and import products covered by the patent family. J.A. 25839. With respect to patent prosecution, Immunex has the exclusive right to prosecute patent applications in the U.S. patent family. J.A. 25840. Thus, as of 2004, Immunex controlled the prosecution of the patents-in-suit.

Under the terms of the agreement, Immunex has the first right to rectify any suspected infringement of the licensed patent family at its sole expense and under its sole control, by instituting suit or by sublicense. And, Immunex may retain the entirety of any award of damages or lost profits resulting from such an infringement suit. Roche is obligated to cooperate in any such suit, including by participating as a party to the extent required by the court in order to bring suit. *Id.* Immunex also has the right to an assignment of the patents-in-suit upon request and upon the payment of $50,000. *Id.* ("If requested . . . Roche shall execute an assignment of" the patents).[4]

Under the terms of the Accord & Satisfaction, Roche is required to cooperate with Immunex regarding prosecution and enforcement of the patents-in-suit, including by providing evidence and testimony in connection with any proceeding affecting the validity of the patents-in-suit. *Id.* Roche also retains the right to practice the patents for internal, non-clinical research only. In addition, Roche retains the secondary right, but not obligation, to sue if Immunex fails to rectify infringement or initiate an action for such infringement within 180 days after written notification by Roche. The agreement further provides that,

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[4] By contrast, non-party Wyeth obtained an assignment of the European patents in the patent family.

once Roche's secondary right to sue is triggered, Roche may, at its sole expense and under its sole control and direction, initiate suit and may retain the entirety of any award of damages or lost profits as a result of such suit. J.A. 25841.

C. Procedural History

In February 2016, Immunex, together with Roche, filed this patent infringement action against Sandoz under the BPCIA. The district court held a two-week bench trial in September 2018. Sandoz did not contest infringement of the '182 and '522 patents. Accordingly, the only issues before the district court at trial were the validity of the asserted claims of the patents-in-suit. Specifically, the district court considered whether claims 11–12 and 35–36 of the '182 patent, and claims 3, 8, and 10 of the '522 patent were invalid for lack of written description and enablement; obvious in light of certain asserted prior art references; and invalid for obviousness-type double patenting.

On August 9, 2019, in a detailed opinion, the district court issued its findings of fact and conclusions of law, holding that Sandoz had not proven that the patents-in-suit were invalid. *Immunex Corp. v. Sandoz Inc.*, 395 F. Supp. 3d 366, 374 (D.N.J. 2019). The court entered final judgment for Immunex and Roche on October 8, 2019. Sandoz timely appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a).

II. Discussion

On appeal, Sandoz argues that the patents-in-suit are invalid for (1) obviousness-type double patenting; (2) failure to meet the written description requirement; and (3) obviousness. We address each issue in turn.

A. Standards of Review

Following a bench trial, we review a district court's conclusions of law without deference and its findings of fact for

clear error. *Ferring B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1401, 1406 (Fed. Cir. 2014). "A factual finding is clearly erroneous if, despite some supporting evidence, we are left with the definite and firm conviction that a mistake has been made." *Id.*

B. Obviousness-Type Double Patenting

Obviousness-type double patenting is a judicially-created doctrine aimed at preventing claims in separate patents that claim obvious variants of the same subject matter where "granting both exclusive rights would effectively extend the life of patent protection." *In re Hubbell*, 709 F.3d 1140, 1145 (2013) (quotations omitted); *Eli Lilly and Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001) ("The judicially-created doctrine of obviousness-type double patenting . . . prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent."). The doctrine applies to all commonly-owned patents, even in cases where the obvious variants are invented by different inventors. *In re Longi*, 759 F.2d 887, 895 (Fed. Cir. 1985). As we have previously recognized, there are two justifications for this doctrine: (1) to prevent timewise extension of the right to exclude; and (2) to prevent multiple infringement suits by different assignees. *Hubbell*, 709 F.3d at 1145. "[T]he ultimate conclusion that a patent is invalid under the doctrine of obviousness-type double patenting is reviewed de novo." *Novartis Pharm. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1361 (Fed. Cir. 2018). "[P]redicate findings of fact" are reviewed for clear error. *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 689 F.3d 1368, 1376 (Fed. Cir. 2012).

At trial, Sandoz asserted that the patents-in-suit are invalid for obviousness-type double patenting over several patents filed by Immunex Corp. in the years leading up to and shortly after the approval of Enbrel®. The district

court rejected Sandoz's contentions, finding in favor of Immunex on several layers of analysis: (1) that Sandoz's proposed test for common-ownership does not apply; (2) even if that test applies, the patents-in-suit and the asserted double-patenting reference patents are not commonly owned; (3) even if they are commonly owned, the two-way, rather than the one-way test for obviousness-type double patenting applies as to some of the double-patenting references; and (4) the patents-in-suit are patentably distinct from each of the asserted double patenting references. On appeal, Sandoz limits its arguments to two patents, U.S. Patent Nos. 7,915,225 ("Finck '225") and 5,605,690 ("Jacobs '690") (collectively, the "Immunex Patents"). It concedes that it must prevail at each step of the district court's analysis to garner a reversal of the court's decision regarding obviousness-type double patenting; losing at any one of these steps is fatal to Sandoz's arguments. Oral Arg. at 1:23–54, *available at* http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2020-1037.mp3) ("[Counsel for Appellant:] I agree that there are multiple steps that we would ask this court to take.").

As to the first step of the court's analysis, in a novel theory of common ownership, Sandoz argues that, even though the patents-in-suit are assigned to Roche, Immunex effectively owns both the Immunex Patents and the patents-in-suit because all substantial rights in the patents-in-suit transferred to Immunex pursuant to the Accord & Satisfaction. Borrowing from our 35 U.S.C. § 281 case law, Sandoz argues that an agreement that conveys "all substantial rights" in a patent is tantamount to an assignment of ownership. Appellants' Br. 27–28 (citing *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1340 (Fed. Cir. 2007)). In Sandoz's view, this "all substantial rights" test—to date used only to determine who may sue for infringement as a "patentee" pursuant to 35 U.S.C. § 281—should apply in the obviousness-type double patenting context as well. And, Sandoz contends, the relevant agreement here

transferred all substantial rights in the patents-in-suit to Immunex.

As discussed below, although we agree with Sandoz that the "all substantial rights" test can be informative in determining common ownership in the obviousness-type double patenting context, we conclude that the agreement at issue here did not transfer all substantial rights from the assignee, Roche, to the exclusive licensee, Immunex. Accordingly, we need not address the other layers of the district court's detailed analysis on obviousness-type double patenting.

1. The All Substantial Rights Test

Under Sandoz's theory of common ownership, if a party is the effective patentee for purposes of the ability to bring an infringement suit, then it is also an effective patentee for purposes of obviousness-type double patenting. Sandoz contends that a contrary rule would allow circumvention of patent term limitations by simply reclassifying an assignment as a license. Appellants' Br. 28–29. And, Sandoz argues, if a party acquires all substantial rights in a patent application, *including the right to control prosecution*, then obviousness-type double patenting should apply to prohibit *issuance* of claims that are not patentably distinct from claims in patents already owned by that party. Appellants' Reply Br. 9.

Immunex responds that common ownership-based obviousness-type double patenting arises only where the relevant inventions were owned by the same entity *at the time of the invention*. Appellees' Br. 36. Immunex cites to the Manual of Patent Examining Procedure ("MPEP"), which states that "[a]pplications or patents are 'commonly owned' pursuant to 35 U.S.C. 102(b)(2)(C) or pre-AIA 35 U.S.C. 103(c)(1) if they were wholly or entirely owned by the same person(s), or organization(s)/business entity(ies), at the time the claimed invention was filed or made, respectively." *Id.* at 37 (quoting MPEP § 804.03(II)). In

Immunex's view, this test applies because common ownership in the obviousness-type double patenting context "exists to fill a narrow statutory gap," created by the Patent Law Amendments of 1984, Pub. L. No. 98-622, § 104, 98 Stat. 3383 ("the 1984 Act"). *Id.* at 37–38 (citing 1984 Act (codified in 35 U.S.C. § 103(c))). Prior to the 1984 Act, Immunex argues, the USPTO recognized that common ownership-based double patenting rejections were unnecessary, because examiners could simply use anticipation or obviousness rejections to avoid issuing multiple patents claiming the same invention or obvious variants. *Id.* at 37 (citing *Commissioner's Notice on Double Patenting*, 834 O.G. 1615, 1616 (Jan. 9, 1967)). But the 1984 Act prohibited rejections based on prior art owned by the same person or subject to an obligation of assignment to the same person. *Id.* at 37–38 (citing 1984 Act). Immunex argues that Congress expected double patenting to fill the gap where the USPTO could no longer rely on §§ 102 and 103 to avoid issuing multiple patents on the same invention in cases involving common ownership. *Id.* at 37–38. According to Immunex, the MPEP's test for common ownership is "narrowly tailored to close the gap created by the 1984 Act." *Id.* at 39.

We have previously rejected Immunex's reading of the history of the 1984 Act. *See In re Longi*, 759 F.2d 887, 893 (Fed. Cir. 1985). In *Longi*, rejecting the argument that obviousness-type double patenting should not apply to commonly-owned applications with different inventive entities, we ruled that such a broad proposition was inconsistent with recent legislation, *i.e.*, the 1984 Act. *Id.* We explained that we have never endorsed the Commissioner's Notice on which Immunex now relies because the notice was merely a procedural memorandum and, importantly, was inconsistent with many of our predecessor court's decisions. *Id.* at 894. Indeed, directly refuting Immunex's arguments is our express acknowledgement in *Longi* that common ownership-based obviousness-type double patenting existed

even before 1984. *Id.* at 893; *see also In re Rogers*, 394 F.2d 566, 569 (C.C.P.A. 1968). Examining the very 1984 Act that, in Immunex's view, created a "statutory gap" that common ownership-based obviousness-type double patenting is designed to close, we said that the Act seemed "not intended to affect the doctrine of double patenting, but seem[ed] rather to reaffirm its viability." *Longi*, 759 F.2d at 895. Thus, we have already considered and rejected Immunex's argument that common ownership-based obviousness-type double patenting is a narrow gap-filling rule in response to the 1984 Act.

Immunex's "time of invention" test is also inconsistent with more recent case law. For example, we have applied common ownership-based obviousness-type double patenting where a party "merged with the original assignees of" the double-patenting references at issue. *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1377, 1386 (Fed. Cir. 2003). And, although the Board of Patents Appeals and Interferences ("BPAI"), predecessor to the Patent Trial and Appeals Board, applied the MPEP definition of "common ownership" (from the 35 U.S.C. § 103(c) context) to double patenting cases, it expressly did not do so with respect to the *timing of the invention*. *Ex Parte Maurice*, No. 2005-2463, 2005 WL 4779419, at *2 (B.P.A.I. Sept. 19, 2005). In *Ex Parte Maurice,* while accepting that "commonly owned" for double patenting purposes must be read to be consistent with common ownership in the context of 35 U.S.C. § 103(c), the BPAI clarified that "[b]y 'consistent,' appellants presumably mean consistent with regard to the required interest of each co-owner, and not necessarily consistent in terms of the time frame in which ownership is considered." *Id.*

We see no justification for applying Immunex's "time of filing" requirement in the obviousness-type double patenting context. Indeed, adopting Immunex's rule might lead to the absurd result where, even if originally applied for by inventors working under an obligation of future

assignment to an employer, patents may not be considered "commonly owned" because, at the "time of invention," the assignment had not been effectuated. Such a result would effectively eviscerate common ownership-based obviousness-type double patenting. Accordingly, we conclude that Immunex's "time of filing" test for common ownership does not apply.

By contrast, Sandoz's proposed test for common ownership—determining whether a party controlling prosecution was the "effective patentee" under the "all substantial rights" test—appears consistent with both principles underlying obviousness-type double patenting, namely, preventing unjustified patent term extensions and preventing harassment from multiple suits. Applying Sandoz's test would prevent an effective patentee from unjustifiably extending its patent term by using the nominal label of licensee. The second consideration underlying obviousness-type double patenting—preventing harassment through multiple infringement suits by different assignees asserting essentially the same patented invention—also undergirds our 35 U.S.C. § 281 jurisprudence. *See Hubbell*, 709 F.3d at 1145; *see also Lone Star Silicon Innovations LLC v. Nanya Tech. Corp.*, 925 F.3d 1225, 1233 (Fed. Cir. 2019).

We are mindful, however, of the existing complexities in applying the equitable doctrine of obviousness-type double patenting and see no reason to import into this judicially-created doctrine the entirety of our body of law analyzing who is a statutory "patentee" pursuant to 35 U.S.C. § 281. We conclude only that *where one of the rights transferred is the right to prosecute the patent at issue*, identification of the effective "patentee" is informative in evaluating whether the patents are "commonly owned" for purposes of obviousness-type double patenting. Where, as here, a party ultimately controls prosecution of both sets of patents, the "all substantial rights" test aids in preventing the unjustifiable issuance of claims that are patentably indistinct from claims already owned by that party. Under

these circumstances, looking to the "all substantial rights" test achieves the proper balance between deterring gamesmanship in prosecution, on the one hand, and avoiding any chilling effect on routine collaborations and licensing between parties working in the same field of research, on the other.

2. The Accord & Satisfaction Did Not Transfer All Substantial Rights in the Patents-in-Suit to Immunex

We now turn to the agreement at issue, and whether, as Sandoz argues, it is effectively an assignment because it transferred all substantial rights in the patents-in-suit to Immunex. "To determine whether an exclusive license is tantamount to an assignment, we must ascertain the intention of the parties to the license agreement and examine the substance of what was granted." *Alfred E. Mann Found. v. Cochlear Corp.*, 604 F.3d 1354, 1359 (2010) (alterations and quotations omitted); *see also Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 874 (Fed. Cir. 1991). The focus is on the substance of what was granted. *Id.* We have recently reaffirmed that "we examine the 'totality' of the agreement to determine whether a party other than the original patentee has established that it obtained all substantial rights in the patent." *Lone Star*, 925 F.3d at 1229; *Prima Tek II, LLC v. A-Roo Co.*, 222 F.3d 1372 (Fed. Cir. 2000). Although we have "never purported to establish a complete list of the rights [that can] . . . render an exclusive licensee the owner of a patent," *Alfred E. Mann*, 604 F.3d at 1360, "we have often focused on two salient rights: enforcement and alienation," *Lone Star*, 925 F.3d at 1231. Thus, we have considered factors such as the scope of the licensee's right to sublicense, the nature of license provisions regarding reversion of rights, the duration of the license grant, and the nature of any limits on the licensee's right to assign its interests in the patent." *Alfred E. Mann*, 604 F.3d at 1360–61.

As a threshold matter, the parties dispute the applicable standard of review. Sandoz argues that de novo review applies to this determination, whereas Immunex maintains that also at issue is the district court's factual determination of the parties' intent, which should be reviewed deferentially. Appellants' Reply Br. 11–12; Appellees' Br. 47–48. As we explained in *Alfred E. Mann*, the substance of what was granted is determined by interpreting the license. 604 F.3d at 1359. Here, the contract is governed by Delaware law, which provides that the district court's interpretation presents a question of law to be reviewed de novo. *In re Viking Pump, Inc.*, 148 A.3d 633, 643–44 (Del. 2016). As to the question of whether the provisions effectuated a transfer of all substantial rights such that Immunex, not Roche, is the "patentee," that is a legal question we review de novo under our own law. *Prima Tek*, 222 F.3d at 1377. But, to the extent determining the intention of the parties requires evaluation of parol evidence, that "evaluation presents a question of fact that we review deferentially." *Alfred E. Mann*, 604 F.3d at 1359.

The district court treated this as a two-part inquiry, looking first to the parties' intent and then to the agreement provisions to determine "the substance of what was granted." *Immunex*, 395 F. Supp. 3d at 415–17. The court found that Roche and Immunex "specifically intended for the Accord & Satisfaction to be a license such that Roche would remain the owner of the patents-in-suit." *Id.* at 415. It looked to "the face of the [agreement] itself," which calls the grant to Immunex a "license." *Id.* at 416. The court also relied on the testimony of an Amgen corporate witness to conclude that the parties intended for the agreement to be a license. *Id.*

Absent ambiguous provisions, however, there is no need to resort to parol evidence to determine the parties' intent. The court did not find that the Accord & Satisfaction was ambiguous. Accordingly, it should not have made any factual determinations regarding the intent of the

parties as shown by witness testimony.[5] As to the fact that the agreement is called a "license," we have clarified that "whether a transfer of a particular right or interest under a patent is an assignment or a license *does not depend upon the name by which it calls itself, but upon the legal effect of its provisions*." *Lone Star*, 925 F.3d at 1230 (emphasis in original) (quoting *Waterman v. Mackenzie*, 138 U.S. 252, 256 (1891)). Here, it does not matter that the grant to Immunex was titled a "license"—what matters is the effect of the agreement on the parties' respective rights. Indeed, in arguing for a deferential standard of review, Immunex cites to no cases where we have looked beyond the contract at issue to determine the parties' intent. We therefore look only to the substance of what was transferred under the Accord & Satisfaction, which we review de novo.

Review of the 2004 Accord & Satisfaction reveals the following: Section 3.5 of the agreement gives Immunex the first right to rectify any suspected infringement, at Immunex's sole expense and under its sole control, by instituting suit or by sublicensing the patents. J.A. 25840. Immunex may retain the entirety of any award of damages or lost profits as a result of such suit. Roche is required to cooperate in any Immunex-initiated infringement suit, including by participating as a party only to the extent required by the court in order to bring suit. But, under Section 3.6, Roche retains the secondary right to sue if Immunex fails to rectify any infringement within 180 days after written request by Roche. J.A. 25841. After this 180-day notice period, Roche may, at its sole expense and under its sole control and direction, initiate suit. *Id.* Roche may

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[5] The dissent likewise points to witness testimony in support of its conclusion that Roche transferred all substantial rights in the patents-in-suit to Immunex. Dissent Op. at 5–6. We do not think the analysis in this case should be guided by parol evidence.

retain the entirety of any award of damages or lost profits as a result of a Roche-initiated suit. Immunex further has a duty to cooperate in such a Roche-initiated suit. Notably, "the right to rectify infringement under . . . Section 3.6 is solely with" Roche. *Id.* As to alienation rights, under Section 11.4, neither party may assign its rights to third parties without the written consent of the other. J.A. 25849.

On appeal, Sandoz argues that these provisions, taken together, effectuated a transfer of all substantial rights from Roche to Immunex. Sandoz points to Immunex's "paid-up, irrevocable, exclusive license" and "first right to rectify any alleged infringement" on the one hand, and Roche's loss of control over licensing and litigation activities on the other, to argue that Roche was "stripped of any of the traditional attributes of ownership." Appellants' Br. 31–32. Sandoz also contends that Immunex's ability to drive the prosecution of the patents is another indication that Roche transferred all substantial rights.

Immunex responds that Roche is still the effective patentee because it retained several key rights under the Accord & Satisfaction. Immunex points to: (1) Roche's secondary right to sue; (2) Roche's right to practice the patents for internal, non-clinical research; (3) Immunex's option to convert the license into an assignment by paying an additional consideration of $50,000; and (4) Roche's right to veto the assignment of Immunex's interest under the agreement to any unrelated party. Appellees' Br. 49–53.

The enforcement and alienation rights under the Accord & Satisfaction make clear that Roche did not transfer all substantial rights in the patents to Immunex. We have explained that the nature and scope of the licensee's right to sue, together with the nature of the licensor's retained right to sue, is "[f]requently . . . the most important consideration." *Alfred E. Mann*, 604 F.3d at 1361. Here, although Immunex obtained the first right to sue, Roche retained the secondary right to sue. Like the license at

issue in *Alfred E. Mann*, although Roche's "right to choose to sue an infringer does not vest until [Immunex] chooses not to sue that infringer, [that right] is otherwise unfettered." *Id.* at 1362. Once Roche's secondary right to sue vests, the ability to rectify infringement is "solely" with Roche, and may not pass to Immunex. After the 180-day notice period, Roche can decide "whether or not to bring suit, when to bring suit, where to bring suit, what claims to assert, what damages to seek, [and] whether to seek injunctive relief." *Id.* Retention of "such broad right[s]" is "thoroughly inconsistent" with a conclusion that the patents-in-suit were effectively assigned to Immunex. *See id.*

Sandoz cites *Speedplay*, *Inc. v. Bebop, Inc.*, 211 F.3d 1245 (Fed. Cir. 2000), for the proposition that Roche's secondary right to sue is "illusory" because Immunex can "undercut Roche's ability to sue by granting a royalty-free sublicense to an alleged infringer." *Id.* at 33–35 (citing *Speedplay*, 211 F.3d at 1251). In *Speedplay*, we concluded that the licensor's retained right to sue was illusory because the licensee could render that right nugatory by granting the alleged infringer a royalty-free sublicense. 211 F.3d at 1251. Sandoz argues that, here, because the license is fully paid-up, there are no pass-through royalties, just like in *Speedplay*, rendering the secondary right to sue illusory. But, as we have explained, "*Speedplay* . . . held that a licensee's right to grant royalty-free sublicenses to *defendants sued by the licensor* rendered illusory the licensor's right to sue." *Alfred E. Mann*, 604 F.3d at 1362 (emphasis added). That is precisely what the licensee Immunex cannot do here: under Section 3.6 of the agreement, 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. We reject Sandoz's contention that Section 3.6 "does not modify Immunex's sublicensing rights." Appellants' Reply Br. 13.

Thus, unlike the licensor in *Speedplay*, Roche's secondary right to sue is not illusory.[6]

Roche's right to veto any assignment of Immunex's interest in the patents-in-suit also weighs in favor of the conclusion that all substantial rights were not transferred. We have previously made clear that restrictions on the ability to transfer patent rights are inconsistent with a transfer of all substantial rights. *Lone Star*, 925 F.3d at 1222–23; *see also Abbott Labs. v. Diamedix Corp.*, 47 F.3d 1128, 1132 (Fed. Cir. 1995). Here, under Section 11.4 of the agreement, Immunex may not assign its rights in the patents-in-suit to a third party without Roche's written consent. This restriction on alienation of rights is a further indication that Roche transferred less than all substantial rights in the patents-in-suit.

We reject Sandoz's argument—also relied upon by the dissent—that Immunex's ability to convert the license into an assignment upon payment of $50,000 somehow evinces a transfer of all substantial rights. *See* Appellants' Br. 17; Dissent Op. at 5. This option to purchase the patents-in-

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[6] Adopting Sandoz's arguments, the dissent urges that "[t]he focus of the *Speedplay* inquiry is whether a licensee can nullify a licensor's secondary right to sue, pre- or post-suit." Dissent Op. at 7. But like Sandoz, the dissent fails to account for our decision in *Alfred E. Mann*, where we explained that the holding in *Speedplay* turned on the licensee's ability to frustrate a licensor-initiated suit. *See Alfred E. Mann*, 604 F.3d at 1362. We also highlighted the importance of the licensor's ability to control litigation "[o]nce its right to sue an infringer activates." *Id.* The dissent's singular focus on Immunex's ability to prevent Roche's secondary right to sue from vesting is, therefore, misguided. The proper inquiry must account for the parties' respective rights once Roche's secondary right to sue activates.

suit is merely one provision in the "totality of the transfer agreement" that guides our inquiry. *See Lonestar*, 925 F.3d at 1231. The Accord & Satisfaction makes clear that the purpose of the agreement was "to eliminate the continuing obligations to pay royalties to Roche" pursuant to the Immunex-Roche agreement. J.A. 25836. Under the terms of the Accord & Satisfaction, Immunex paid Roche tens of millions of dollars as consideration. The additional consideration for an outright assignment should be viewed in the context of the entirety of the agreement.[7]

Given the totality of the Accord & Satisfaction, we hold that Roche did not transfer all substantial rights in the patents-in-suit to Immunex. As such, the Immunex Patents and the patents-in-suit are not "commonly owned," and obviousness-type double patenting does not apply. Accordingly, we decline to address Sandoz's remaining arguments regarding obviousness-type double patenting.[8] We thus affirm the district court on this point.[9]

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[7] We are likewise unpersuaded by Sandoz's argument that Roche cannot terminate the agreement once it has received payment. Appellants' Br. 17; *see also* Dissent Op. at 5. This argument overlooks the fact that Immunex's ability to terminate the agreement is also restricted. Even though Immunex has the right to terminate the Accord & Satisfaction, several provisions of the agreement survive any such termination, including § 3.6, which governs Roche's secondary right to sue.

[8] We note, however, that contrary to the dissent's view that the record here demonstrates "gamesmanship in prosecution," Dissent Op. at 3, we see no clear error in the district court's finding that Immunex "acted in good faith to diligently prosecute" the patents-in-suit. *Immunex*, 395 F. Supp. 3d. at 421.

[9] To the extent the district court considered parol evidence, we consider this harmless error.

B. Written Description

"Written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date." *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006). The written description test involves "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). As a question of fact, written description is "to be reviewed under the clearly erroneous standard." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

On appeal, Sandoz argues that the district court erred in concluding that the priority application for the patents-in-suit disclosed possession of the claimed invention. Specifically, Sandoz argues that the priority application did not include written description support for (1) the full-length p75 DNA sequence; and (2) the claimed p75-IgG1 fusion protein. We disagree with Sandoz on both points.

1. The '013 Application Disclosed Full-Length p75

According to Sandoz, the '013 Application described a fusion protein based on the truncated/mutated p75 DNA sequence disclosed in Figure 4 of the patent, not the full-length p75 sequence used in etanercept. Appellants' Br. 50–52. Sandoz contends that the fact that the full-length p75 sequence was known in the prior art is of no moment because the real issue is exactly which p75 sequence Roche had in its possession as of the time of the filing of the priority application. *Id.* at 57. In Sandoz's view, the district court's finding of adequate written description impermissibly rests on information outside the patent.

Immunex responds that sequence identification numbers for p75 are mentioned in the specification, and, as its witness testified, those sequences would have led a person of skill ("POSA") to the complete p75 sequence using GenBank, a well-known genetic sequence database that houses a collection of all publicly available DNA sequences. Appellees' Br. 63–64. Immunex further points to the reference in the specification to the Smith 1990 publication, which, in its view, would have directed a skilled artisan to the full-length p75 sequence.

We agree with Immunex. It is well-established that a patent specification need not re-describe known prior art concepts. *See Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005) ("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge."); *see also Zoltek Corp. v. United States*, 815 F.3d 1302, 1308 (Fed. Cir. 2016) ("The written description need not include information that is already known and available to the experienced public.")). Operating under the guidance of these principles, the district court properly concluded that the inventors possessed the full-length p75 DNA sequence. The specification identifies both p55 and p75 TNFRs. And, as the district court noted, it "embraces allelic variants and DNA sequences resulting from deletions, substitutions, and additions of one or more nucleotides of the sequences provides in Figures 1 and/or Figure 4." *Immunex*, 395 F. Supp. 3d. at 382 (citing '182 patent, 4:1–5:24). Example 6 of the specification explains that the inventors isolated the 75 kDa full-length p75 TNFR. *Id.* at 385 (citing '182 patent, 15:30–39). We see no error in the district court's reliance on these disclosures to conclude that the inventors possessed full-length p75, not just the truncated p75 disclosed in Figure 4.

Importantly, the district court also found that the p75 sequence was known to a POSA at the time of the invention. *Id.* According to the district court, the Smith 1990 article, referenced in the priority application, shows that a

POSA would have known the entire p75 sequence at the time of the invention. The Smith 1990 article guided a POSA that the "entire nucleotide sequence is available upon request and has been deposited with GenBank, accession number M32315." *Id.* (citing J.A. 26980). And, the district court pointed to a July 1990 Roche publication, the Dembic article, which also disclosed the entire p75 amino acid sequence. *Id.* The court also credited the testimony of Immunex's expert, who opined that a POSA would have been encouraged from the disclosure in the priority application to look to Smith, and therefore, the full-length p75 protein. *Id.* at 384. The district court also pointed to the two C-terminus and N-terminus p75 sequences disclosed in the specification and concluded that, in addition to Figure 4 and the reference to Smith 1990, these two disclosed sequences would have directed a POSA to the full p75 sequence at the time of the invention. Although Sandoz criticizes this finding, the district court credited expert testimony that a POSA would be led to the complete p75 sequence using these disclosures. *Id.* Thus, Sandoz's argument that the district court erred by looking outside the four corners of the specification or engaged in an "obviousness-based" written description analysis is without merit. The district court properly considered how a POSA would understand the specification.

As to Sandoz's arguments that later amendments show that the Roche inventors did not have possession of the full p75 sequence at the time of invention, the district court correctly noted that actual reduction to practice is not required to show possession. *Immunex*, 395 F. Supp. 3d. at 387–88. The court rejected Sandoz's arguments that these amendments added new matter. We see no error in these findings.

Accordingly, we conclude that the district court did not err in finding that the priority application disclosed and demonstrated possession of full-length p75.

2. The '013 Application Demonstrates Possession of the Claimed Fusion Protein

Sandoz also argues that the priority application did not adequately demonstrate possession of the claimed p75-IgG1 fusion protein. Sandoz repeats its arguments that the Figure 4 truncated sequence was "preferred," and points out that to arrive at the claimed invention, a POSA would have had to select the "never-referenced" full Smith sequence. Appellants' Br. 58–59. Sandoz also argues that the specification disclosed a range of immunoglobulin classes, and even if the IgG1 and exon-encoded hinge were described as possible options, the priority application provided no "blaze marks" that would have led a POSA to their selection. *Id.* at 59. Sandoz's primary argument is that the district court relied on the claims themselves as evidence of the "required blaze marks." *Id.* at 60.

Immunex responds that the specification identified four preferred fusion proteins, including the claimed p75-IgG1 fusion protein, and that Example 11 provided the steps required to make these fusion proteins. Appellees' Br. 68. And Immunex points to the reference in the specification to deposited vectors, which is an adequate description of the precise IgG1 sequence to be used in the claimed fusion proteins. *Id.* We again agree with Immunex.

Contrary to Sandoz's arguments, the district court's written description analysis was not premised on the language of the issued claims. The district court correctly noted that the specification refers to the use of deposited vectors that contain DNA sequences encoding the exon-defined hinge-CH2-CH3 region of the human IgG1 heavy chain. *Immunex*, 395 F. Supp. 3d at 386–87. And, the court noted that Example 11 teaches how to fuse a soluble TNF-binding fragment directly to that hinge-CH2-CH3 region. *Id.* at 385 (citing '182 patent, 9:3–8). Citing expert testimony, the court concluded that Example 11 discloses this concept with p55, and a POSA would have followed that

example to create etanercept based on the claims and specification. *Id.* Finally, the court noted that "the IgG1 hinge-CH2-CH3 was also known in the prior art as of August 1990." *Id.* at 386.

The district court's findings are supported by the as-filed specification and are not based on the language of the issued claims. First, the district court noted that the claim language "identifies the requisite elements of the subject invention," but at the same time it concluded that the examples further demonstrate that the Roche inventors had possession. *Id.* Second, as Immunex correctly points out, the as-filed patent claims included claim 19, which claimed a fusion protein of a TNF-binding protein and IgG1 or IgG3. Appellees' Br. 69 (citing J.A. 25129).

Accordingly, we conclude that the district court's written description analysis is not clearly erroneous.

C. Obviousness

Obviousness is a question of law reviewed de novo, with underlying factual questions reviewed for clear error. *Honeywell Int'l, Inc. v. United States*, 609 F.3d 1292, 1297 (Fed. Cir. 2010). "The presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact." *Novartis AG v. Torrent Pharm. Ltd.*, 853 F.3d 1316, 1327 (Fed. Cir. 2017).

Sandoz appeals the district court's obviousness analysis, arguing that (1) the district court's motivation to combine analysis erroneously focused on the inventors' subjective motivation rather than the claims' objective reach; and (2) the district court's analysis regarding objective indicia of non-obviousness was legally erroneous. As explained below, we do not find Sandoz's arguments persuasive.

1. Motivation to Combine

Sandoz challenges the district court's finding that a POSA would not have been motivated to either select p75 or to combine it with an immunoglobulin. Appellants' Br. 62. The district court concluded that a POSA would be deterred from pursuing the claimed combination by concerns of stimulating inflammation and aggregation, the opposite effect from that needed to treat inflammatory conditions like rheumatoid arthritis. According to Sandoz, this was legal error because the claims are not directed to treatment of any disease or condition, and because it was known that, in addition to any therapeutic benefits, TNFRs and TNFR/IgG fusion proteins were useful as diagnostic and research tools as well. Sandoz also points out that the specification does not mention rheumatoid arthritis or contain any data regarding treatment efficacy. Appellants' Br. 62. Sandoz argues that this contravenes the teachings of *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) that "neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim." *Id.* (citing *KSR*, 550 U.S. at 419).

Immunex responds that it was Sandoz's burden to prove motivation to combine, and at trial, Sandoz focused on these therapeutic goals as evidence of motivation to combine. Appellees' Br. 71–72. Immunex points to Sandoz's trial arguments that focused on the use of TNFR-IgG1 fusion proteins for treatment of autoimmune disorders. *Id.* According to Immunex, this focus on therapy made sense, because certain asserted claims cover pharmaceutical compositions, not "research tools." *Id.* at 73. Immunex argues that the district court properly focused on the evidence presented and found that a POSA would not have been motivated to select the components of etanercept. *Id.* at 73–74. We agree with Immunex that the district court's analysis was not legally erroneous.

Although Sandoz and the amici criticize the district court's focus on the therapeutic anti-inflammatory effect of TNFR binding proteins, that focus was a result of the arguments and evidence presented at trial and in the parties' post-trial submissions. For example, in its post-trial brief, Sandoz presented the dispute about motivation as limited to the following question: "Would a person of ordinary skill in the art in August 1990 have been motivated to construct a fusion protein of the p75 extracellular region fused to the hinge-CH2-CH3 of a human IgG1—*i.e.*, etanercept?" J.A. 60195. Sandoz's own post-trial "findings of fact" focused on the fact that, at the time of the invention, several diseases were associated with overactive TNF, and that there was a tremendous interest in studying TNF activity and inhibition to provide a therapeutic benefit. J.A. 60081–84 ("To a POSA [prior art] references provide a strong incentive to identify TNF inhibitors that may have therapeutic use."). Likewise, Sandoz emphasized that a POSA would have considered fusing soluble receptors (like the p75 extracellular domain) advantageous for many reasons, including extending the half-life of the soluble receptor to prevent it from being rapidly lost from the patient's blood stream into the urine. J.A. 60084–86. Finally, Sandoz focused on the primary asserted prior art reference (Immunex's '760 patent) to argue that a POSA would have been motivated to modify the disclosures of that reference to create etanercept. J.A. 60086–97.

In its post-trial submissions, Sandoz addressed the fact that the prior art "suggests using TNF-binding proteins as a tool in 'diagnostic assays for TNF.'" *See, e.g.*, J.A. 60083. It also noted that "the asserted claims are not directed to any specific treatment or in vivo effects and only require the fusion protein to, at most, specifically bind TNF . . . Such fusion protein would indisputably be useful for in vitro testing and diagnostics at a minimum." J.A. 60123. And, Sandoz noted that the claims at issue do not require any therapeutic effect. J.A. 60137–38. But these

arguments were presented in response to Immunex's arguments that a POSA would be discouraged from creating a TNFR-human IgG1 fusion protein because of concerns of aggregation and effector functions. The focus of Sandoz's motivation to combine argument remained the therapeutic benefits of the claimed invention, and it was not error for the district court to frame its analysis accordingly.

We conclude that the district court's analysis regarding motivation to combine was not legally erroneous because the treatment of illnesses that involve TNF is a stated objective of the claimed invention; the arguments at trial were focused on therapeutic effects of the claimed invention (and not on their benefits as diagnostic and research tools); and at least two of the asserted claims are directed to pharmaceutical compositions. On this record, the district court properly weighed the evidence presented and concluded as a matter of fact that a POSA would be dissuaded from selecting or combining the components as claimed. We identify no clear error in this finding.

2. Objective Indicia of Non-Obviousness

Sandoz argues that the district court incorrectly analyzed the required nexus between the claims and the objective indicia of non-obviousness, such as clinical success, long-felt need, and failure of others. Appellants' Br. 63–64. Sandoz further argues that the court did not properly consider evidence of simultaneous invention, as shown by earlier patents claiming etanercept, including Immunex's Jacobs '690 patent. *Id.* Sandoz's arguments are without merit.

As Immunex correctly argues, "there is a presumption of nexus for objective considerations when the patentee shows that the asserted objective evidence is tied to a specific product and that product is the invention disclosed and claimed in the patent." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016) (quotations omitted); Appellees' Br. 75–76. Nexus is appropriately presumed in this

case where the court concluded that the claims are directed to the active ingredient in Enbrel® and its method of manufacture. The district court found that there was a sufficient nexus between the claimed invention and the various objective indicia of non-obviousness. *Immunex*, 395 F. Supp. 3d at 401–05. Sandoz failed to rebut the presumption of nexus.

As to simultaneous invention, Immunex correctly notes that the district court found that three of the alleged instances of "simultaneous invention" were directed to different fusion proteins, not etanercept. *Id.* at 407; *see also* Appellees' Br. 76. As to invention by Immunex, the court properly noted that the "patent applications were already pending when Immunex created etanercept in November or December 1990. Immunex's subsequent decision to license the Patents-in-Suit from Roche demonstrates etanercept's inventive nature and undermines an obviousness finding." *Id.* at 408. Finally, as we have discussed above, the district court correctly concluded that the Jacobs '690 patent does not cover etanercept, but is directed to fusion proteins with an unmodified constant region. It also issued from a continuation-in-part filed two years after the original applications for the patents-in-suit. At bottom, Sandoz's arguments regarding objective indicia are merely disagreements with the district court's weighing of the evidence. We see no clear error in the district court's findings regarding the objective indicia of non-obviousness.

III. CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. For the foregoing reasons, we affirm the district court's judgment that Sandoz has not shown that the patents-in-suit are invalid.

AFFIRMED

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-Appellants

2020-1037

Appeal from the United States District Court for the District of New Jersey in No. 2:16-cv-01118-CCC-MF, Judge Claire C. Cecchi.

REYNA, *Circuit Judge,* dissenting.

The majority determines that obviousness-type double-patenting does not apply here because appellee Immunex is not a common owner of the patents-in-suit. The majority's common ownership determination hinges on its interpretation of the 2004 Accord & Satisfaction between

Roche[1], the licensor of the patents-in-suit, and Immunex, the exclusive licensee. Because I interpret the 2004 Accord & Satisfaction as an effective assignment of the patents-in-suit to Immunex, I would hold that Immunex is a common owner for obviousness-type double patenting purposes. I would also hold that Immunex's patents-in-suit are invalid for obviousness-type double patenting in view of Immunex's previously issued U.S. Patent No. 7,915,225 ("the '225 patent") under the one-way test. For this reason and the reasons discussed below, I respectfully dissent.

I also provide additional views concerning the applicability of the one-way test for ODP purposes.

I. Common Ownership

Obviousness-type double-patenting ("ODP") is a judicially created doctrine designed to prevent a party from extending its right to exclude through claims in a later-filed patent that are patentably indistinct from claims in a commonly-owned earlier filed patent. *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985). A preliminary step for determining whether the doctrine of ODP applies is whether the patents at issue are commonly owned. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001); *see also Longi*, 759 F.2d at 895. The parties dispute whether appellee Immunex is a common owner of the patents-in-suit such that the doctrine of ODP would be triggered.

Here, the majority accepts appellant Sandoz's novel theory that the "all substantial rights" test from the Section 281 context can be used to determine common ownership for ODP purposes. Maj. Op. at 11. Specifically, the majority explains that:

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[1] Roche was a party in the district court litigation but has not entered its appearance in this appeal.

> [w]here, as here, [Immunex] ultimately controls prosecution of both sets of patents, the "all substantial rights" test aids in preventing the unjustifiable issuance of claims that are patentably indistinct from claims already owned by that party. Under these circumstances, looking to the "all substantial rights" test achieves the proper balance between *deterring gamesmanship in prosecution*, on the one hand, and avoiding any chilling effect on routine collaborations and licensing between parties working in the same field of research, on the other.

Id. at 14–15 (emphasis added).

While I commend the majority for adopting the "all substantial rights" test, the majority's adoption of that test was for naught. In applying the test, the majority permits the type of gamesmanship it sought to prevent—gamesmanship in prosecution which could result in unjustified extension of patent rights. Here, under the 2004 Accord & Satisfaction, Roche transferred to Immunex the sole right to control prosecution, an exclusive license, the absolute right to exclude Roche from commercializing the claimed inventions, the first right to sue, and the right to nullify any Roche-initiated suit by issuing a royalty-free license. Specifically, Immunex's sole right to control prosecution is significant in the ODP context, since the doctrine of ODP is meant to prevent applicants from receiving patents that extend the life of their existing patents. *See In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013). The facts here reveal why.

When under Roche's control for almost ten years, the applications from which the patents-in-suit issued did not claim the etanercept fusion protein, but rather a different fusion protein and a mutated version of etanercept. However, once Immunex retained control of prosecution, Immunex amended the applications to claim etanercept, which Immunex itself had claimed in its own patents and

which was an active ingredient in Immunex's Enbrel® product. Thus, thanks to its prosecution efforts, Immunex has effectively extended 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). Given this backdrop, I would hold that Immunex effectively owns the patents-in-suit for ODP purposes.

The majority, however, reasons that Roche remains the true owner for ODP purposes because under the 2004 Accord & Satisfaction, Roche retained a secondary right to sue and a right to veto an Immunex-initiated assignment. *See* Maj. Op. at 18–20. However, as explained below, Roche's retained rights are illusory, and, thus, do not interfere with Immunex's control to practice and enforce the patents-in-suit.

"[L]abels given by the parties do not control" the all-substantial-rights inquiry. *A123 Sys., Inc. v. Hyrdo-Quebec*, 626 F.3d 1213, 1218 (Fed. Cir. 2010). Rather, the court looks to the "substance" of the written agreement "rather than formalities or magic words." *Lone Star Silicon Innovations LLC v. Nanya Tech. Corp.*, 925 F.3d 1225, 1229 (Fed. Cir. 2019). Specifically, if the licensor's only remaining rights in the patents-in-suit are "illusory," then the licensor has effectively transferred all substantial rights to the licensee. *See Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1251 (Fed. Cir. 2000). A licensor's right is illusory if it "would not hinder [the licensee's] enjoyment of the patent rights in any meaningful way." *Id.* In other words, the licensor's right is illusory for ownership purposes if it does not meaningfully interfere with the licensee's control and enforcement of the patents at issue. *See id.*

Here, Roche's two retained rights, i.e., a secondary right to sue and a right to veto an Immunex-initiated assignment, are illusory because these rights do not prevent Immunex from enjoying the patents-in-suit in any meaningful way. *Id.* Specifically, pursuant to the 2004 Accord &

Satisfaction, Immunex can at any time nullify Roche's rights by ordering Roche to assign the patents-in-suit to Immunex upon payment of $50,000. J.A. 25840. Once Immunex forces Roche's hand, Roche has no choice but to assign the patents-in-suit to Immunex, leaving Roche with no rights at all. *Id.* ("If requested . . . ***Roche shall execute*** an assignment of [the patents]." (emphasis added)). Roche cannot terminate this arrangement for any reason. J.A. 25848 ("Roche will have no right to terminate this [Accord & Satisfaction] for any reason."). Thus, if Immunex disagrees with Roche's decision to initiate suit or Roche's decision to veto an assignment, Immunex can undo Roche's decisions by simply obtaining official ownership of the patents-in-suit.

Additionally, the record shows that Immunex's payment of $50,000 to Roche does not meaningfully hinder Immunex's enjoyment of the patents-in-suit but rather is a self-executing formality. First, the evidence shows Roche did not value its retained rights. During negotiations for Immunex's "license," Roche was willing to formally assign the patents-in-suit at no additional cost. Specifically, Roche's former Senior Counsel, who drafted and negotiated the Roche-Immunex 2004 Accord & Satisfaction on behalf of Roche, testified that "Roche wouldn't have had a problem if [Immunex] had asked for an assignment [and] not to charge them the $50,000 from day one." J.A. 28335. Yet, Roche included the $50,000 clause at the insistence of Immunex. Second, that Immunex would have to pay Roche $50,000 is not a meaningful hinderance to Immunex's enjoyment of the patents-in-suit. *Speedplay*, 211 F.3d at 1251. The record shows that $50,000 is a *de minimis* amount for Immunex. Consider that Immunex paid approximately $45 million for its alleged "license." Additionally, etanercept, the fusion protein claimed by the patents-in-suit, earned $1.9 billion in revenue in 2004, the year Immunex received its "license." Thus, it is unreasonable to

conclude that $50,000 represents a meaningful hinderance to Immunex's effective ownership over the patents-in-suit.

Roche's secondary right to sue is rendered illusory for an additional, separate reason. Pursuant to the 2004 Accord & Satisfaction, Roche's "right" to commence a civil action for infringement is subject to Immunex's approval. Specifically, under Section 3.6 of the 2004 Accord & Satisfaction, Roche must notify Immunex of any infringement in a written request. Under Sections 3.1 and 3.5, Immunex may nullify Roche's right to sue by issuing a royalty-free sublicense to the alleged infringer. The sleight of hand here is that Immunex retains full control over whether Roche can initiate suit. To stop Roche from pursuing an infringement action, Immunex need only issue a royalty-free sublicense. *See Speedplay*, 211 F.3d at 1251 (noting that the licensor's secondary right to sue was "illusory" because the licensee "can render [it] nugatory by granting the alleged infringer a royalty-free sublicense"). Thus, "[e]ven though [Roche] retained the right to sue, that right would not hinder [Immunex's] enjoyment of the patent rights in any meaningful way." *Id.*

The majority reasons that Immunex's sublicensing right does not render Roche's secondary right to sue illusory. *See* Maj. Op. at 19–20. The majority's sole reason for concluding as much is that this case is different from *Speedplay*. The majority notes that *Speedplay* "held that a licensee's right to grant royalty-free sublicenses to *defendants sued by the licensor* rendered illusory the licensor's right to sue." *Id.* (quoting *Alfred E. Mann Found. for Sci. Research v. Cochlear Corp.*, 604 F.3d 1354, 1362 (Fed. Cir. 2010)) (emphasis in majority opinion).[2] The majority

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[2] The majority asserts that the dissent "fails to account" for the decision in *Alfred E. Mann*, "where we explained that the holding in *Speedplay* turned on the

reasons that *Speedplay* does not apply because Immunex cannot issue a sublicense once Roche initiates suit, unlike the *Speedplay* licensee. *Id.*

That the *Speedplay* licensee could issue a sublicense post-suit does not render Roche's secondary right to sue any less illusory. The focus of the *Speedplay* inquiry is whether a licensee can nullify a licensor's secondary right to sue, pre- or post-suit. *See Speedplay*, 211 F.3d at 1251 (making no distinction as to the timing of issuance of a royalty-free sublicense); *see also Lone Star*, 925 F.3d at 1231; *AsymmetRx, Inc. v. Biocare Med., LLC*, 582 F.3d 1314, 1320 (Fed. Cir. 2009); *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1343 (Fed. Cir. 2001). Here, 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. If Roche ultimately sues, it is only because Immunex allowed Roche to do so. As in

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licensee's ability to frustrate a licensor-initiated suit." Maj. Op. at 20. I respectfully disagree. The majority reads *Alfred E. Mann* too narrowly. In *Alfred E. Mann*, we acknowledged the *Speedplay* licensee's "ability to settle licensor-initiated litigation by granting royalty-free sublicenses to the accused infringers." *Alfred E. Mann*, 604 F.3d at 1361. However, like in *Speedplay*, we did not hold that a secondary right to sue is rendered illusory *only* when a licensee can issue a royalty-free sublicense post-suit. Rather, we explained that the illusory inquiry should be flexible, looking broadly to the "nature and scope of the licensor's retained right to sue." *Id.* Contrary to the majority opinion, the key inquiry here should be whether a licensee can issue a royalty-free sublicense, regardless of whether the sublicense issued pre- or post-suit. For once the licensee issues this unfettered sublicense, the licensee nullifies the licensor's secondary right to sue.

Speedplay, Roche's secondary right to sue is subject to neutralization and thus illusory. *Speedplay*, 211 F.3d at 1251.

In sum, because Roche's two retained rights in the patents-in-suit are illusory, I would hold that Immunex owned the patents-in-suit for ODP purposes.

II. Additional Views

Although the majority does not reach this issue, I briefly address the second prong to the ODP inquiry—whether the patents-in-suit are patentably indistinct from Immunex's previously issued '225 patent. Here, the district court alternatively determined that the doctrine of ODP does not apply because the patents-in-suit were patentably distinct from Immunex's previously issued '225 patent under the "two-way" test. I would hold that the district court legally erred in applying the "two-way" test rather than the "one-way" test.

The "two-way" test is a "narrow exception to the general rule of the one-way test," and it is only appropriate "where (1) a second-filed application issues prior to a first-filed application, and (2) the PTO is *solely responsible* for the delay in the issuance of the first-filed application." *In re Janssen Biotech, Inc.*, 880 F.3d 1315, 1325 (Fed. Cir. 2018) (internal quotation marks omitted) (emphasis added); *see also In re Basell Poliolefine Italia S.P.A.*, 547 F.3d 1371, 1376 (Fed. Cir. 2008) (noting that the two-way test is appropriate in "*the unusual circumstance* that the PTO is *solely responsible* for the delay" (emphasis added)). Whether the one-way test or two-way test applies is a question of law. *See In re Emert*, 124 F.3d 1458, 1460 (Fed. Cir. 1997).

Here, the district court noted that both the PTO and Roche/Immunex contributed to the delay in prosecution of the patents-in-suit yet concluded that the PTO was "solely responsible" for the delay. This was legal error. Our case law is clear that if the applicant's "actions, or inactions, had

a direct effect on the prosecution," the PTO is not "solely" responsible for the delay, and, thus, the "two-way test . . . does not apply." *In re Basell*, 547 F.3d at 1376; *see also In re Fallaux*, 564 F.3d 1313, 1316 (Fed. Cir. 2009); *Eli Lilly*, 251 F.3d at 968 n.7; *In re Emert*, 124 F.3d at 1461. Thus, both Roche's and Immunex's contribution to the delay in prosecution—mainly, their requests for extensions and Roche's delay in filing the etanercept claims during prosecution of the patents-in-suit—should have, as a matter of law, triggered the application of the one-way test. *See In re Basell*, 547 F.3d at 1376; *see also Eli Lilly*, 251 F.3d at 968 n.7.

There is no serious dispute that under the one-way test—which asks whether the asserted patent claim is obvious over or anticipated by the earlier-issued patent claim, *see In re Hubbell*, 709 F.3d at 1149—Immunex's patents-in-suit are patentably indistinct from Immunex's '225 patent. Thus, Immunex's patents-in-suit are invalid for ODP in view of Immunex's '225 patent.

I respectfully dissent.