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IMMUNEX V. SANDOZ: DRAFTING ASSIGNMENTS AS LICENSES TO AVOID OBVIOUSNESS-TYPE DOUBLE PATENTING

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ABSTRACT

Under normal circumstances, an applicant is unable to extend patent term for an invention by getting a second patent with claims that cover the same, single invention. The United States Patent and Trademark Office rejects applications with exact copies of claims as statutory double patenting. If the new claims are different but still obvious in view of the earlier claims, the USPTO rejects the claims under a judicially-created doctrine known as nonstatutory or obviousness-type double patenting (“ODP”). However, ODP requires at least one common inventor or applicant or common ownership or assignment or a joint research agreement. Without common inventors or applicants or a joint research agreement, licenses can be used in lieu of assignments to prevent common ownership, even if prosecution of the new claims is controlled by the owner of the previous patent. This technique was used in *Immunex v. Sandoz*, a recent Federal Circuit case that exploited this loophole to receive ten more years of patent coverage for its blockbuster drug, Enbrel®.



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I. INTRODUCTION

In *Immunex v. Sandoz*, Immunex licensed patent applications from Roche that were related to Enbrel®, an anti-inflammatory drug that Immunex sold.¹ Under the license, Immunex controlled the prosecution of the applications.² During subsequent communications with the United States Patent and Trademark Office, Immunex amended the claims to cover Enbrel®, resulting in the two patents at issue in this case, U.S. Patent Nos. 8,063,182 (“the ’182 Patent”) and 8,163,522 (“the ’522 Patent”) (collectively, the “Licensed Patents”).³ The license also granted Immunex enforcement rights to sue for infringement⁴, and several years after the Licensed Patents issued, Immunex sued Sandoz.⁵ In response, Sandoz alleged the Licensed Patents were invalid for, among other reasons, obviousness-type double patenting (“ODP”), asserting that the issued claims in the Licensed Patents were obvious in view of previously-issued claims in Immunex’s patents.⁶ Here, because there were no common inventors or applicants and no common assignments or joint research agreement, ODP required common ownership of the applications and/or patents.⁷

The Federal Circuit adopted the “all substantial rights,” or “ASR” test to determine ownership of the Licensed Patents.⁸ The ASR test relies primarily on who has the right to enforce the patent and who has the right to transfer the patent. Even though Immunex acquired these rights under the license, the split Federal Circuit panel held that Immunex did not own the Licensed Patents because Roche retained two important rights under the license: the secondary right to sue and the right to veto

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¹ *Immunex Corp. v. Sandoz, Inc.*, 964 F.3d 1049, 1054–1055 (Fed. Cir. 2020), *cert. denied, sub nom. Sandoz Inc. v. Immunex Corp.*, No. 20-1110, 2021 U.S. LEXIS 2381 (U.S. May 17, 2021).

² *Id.* at 1055.

³ *Id.* at 1061.

⁴ *Id.* at 1055.

⁵ *Id.*

⁶ *Immunex Corp.*, 964 F.3d at 1056.

⁷ *Id.*

⁸ *Id.* at 1059.

a transfer.⁹ Because the Federal Circuit held that Immunex did not own the Licensed Patents, they could not be invalid under ODP.¹⁰

However, two significant points weigh against the Court's ownership analysis. First, Roche's rights were illusory.¹¹ Second, Roche did not bargain for these illusory rights, and only kept them at Immunex's insistence in spite of Roche's willingness to assign the applications outright.¹² This licensing strategy appeared to be part of Immunex's ultimately successful effort to avoid ODP and provide a blueprint for other companies to evade ODP analysis.

Part II of this case note provides background about ODP and its potential effect on patent term. The *Immunex* case is examined in depth in Part III, focusing on the procedural history of the case, the background and prosecution of the Licensed Applications, and details about the licenses between Immunex and Roche. Part IV analyzes four critical elements in the case: how Immunex amended the claims during patent prosecution to cover its product, Enbrel®; the illusory nature of Roche's secondary right to sue; the illusory nature of Roche's right to veto a transfer; and how the agreement between Immunex and Roche was actually a license. Part V concludes the case note with a short summary of the case and looks at the potential consequences on the public.

II. BACKGROUND

A. Obviousness-Type Double Patenting

Congress has provided in 35 U.S.C. § 101 that a person “may obtain a patent” for an otherwise patentable invention.¹³ Courts have interpreted “a patent” to mean that an applicant may only receive one patent for one set of claims.¹⁴ The pursuit of claims identical to previously issued claims is known as statutory double patenting, and is not allowed.¹⁵

Starting in 1881 in *James v. Campbell*, judges began crafting the ODP doctrine to address applicants' pursuit of obvious improvements on issued claims from the

⁹ *Immunex Corp.*, 964 F.3d at 1059–60. Stating therein:

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. . . [W]e have often focused on two salient rights: enforcement and alienation.

(quoting *Lone Star Silicon Innovations L.L.C. v. Nanya Tech. Corp.*, 925 F.3d 1225, 1231 (Fed. Cir. 2019)).

¹⁰ *Id.* at 1063.

¹¹ *Id.* at 1069–70 (Reyna, J., dissenting).

¹² *Id.* at 1070.

¹³ 35 U.S.C. § 101 (2021) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, *may obtain a patent therefor*, subject to the conditions and requirements of this title.”) (emphasis added).

¹⁴ *See, e.g., In re Coleman & Wolf*, 189 F.2d 976, 976–81 (C.C.P.A. 1951).

¹⁵ *Sun Pharm. Indus. v. Eli Lilly & Co.*, 611 F.3d 1381, 1382 (Fed. Cir. 2010).

applicants' previous patents.¹⁶ A series of cases followed the next several years that laid the foundation of ODP, culminating in 1894 with *Miller v. Eagle Mfg. Co.*, where the Supreme Court reviewed the previous cases and their holdings, and generated a coherent doctrine.¹⁷ As part of its review, the Court found, "if [a second patent] be identical with [a first patent], or only a colorable variation from it, the second patent would be void, as a patentee cannot take two patents for the same invention."¹⁸

ODP analysis requires the applications and/or patents have at least one common inventor, common applicant, and/or common assignments or ownership, or be subject to a joint research agreement.¹⁹ Here, there were no common inventors or applicants and no common assignments or joint research agreement so the ODP analysis required common ownership of the applications and patents. While the ODP analysis requires two applications and/or patents to be commonly owned, common inventorship is not required.²⁰ Thus, the ownership transfer from the assignment of a patent can cause future claims to fall under ODP.²¹ However, a nonexclusive license does not transfer ownership, so future claims should be exempt from the ODP analysis.²² Exclusive licenses can be considered an assignment, so the courts have looked to the intent of the parties and the rights transferred under the license to determine ownership.²³ Here, the Federal Circuit adapted the ASR test—borrowed from case law related to standing under 35 U.S.C. § 281²⁴—to aid in determining

¹⁶ *James v. Campbell*, 104 U.S. 356, 382 (1881) (holding a patentee could not claim an invention disclosed in a prior patent).

¹⁷ *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 197–98 (1894); 3A DONALD S. CHISUM, CHISUM ON PATENTS § 9.02[6] (2020).

¹⁸ *Miller*, 151 U.S. at 197–98 (quoting *McCreary v. Pa. Canal Co.*, 141 U.S. 459, 467 (1891)).

¹⁹ U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 804 (9th ed. Rev. 10.2019, June 2020) [hereinafter MPEP].

²⁰ *In re Longi*, 759 F.2d 887, 895 (Fed. Cir. 1985).

²¹ *Speedplay, Inc. v. Bebop*, 211 F.3d 1245, 1248 (Fed. Cir. 2000) (citing 35 U.S.C. §§ 100(d), 261, 281) (2021).

²² *Intell. Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1345 (Fed. Cir. 2001). Stating therein:

[A] nonexclusive license or "bare" license—a covenant by the patent owner not to sue the licensee for making, using, or selling the patented invention and under which the patent owner reserves the right to grant similar licenses to other entities—confers no constitutional standing on the licensee under the Patent Act to bring suit or even to join a suit with the patentee because a nonexclusive (or "bare") licensee suffers no legal injury from infringement.

²³ *Immunex Corp.*, 964 F.3d at 1059 (quoting *Alfred E. Mann Found. v. Cochlear Corp.*, 604 F.3d 1354, 1359 (Fed. Cir. 2010)); *Waterman v. Mackenzie*, 138 U.S. 252, 256 (1891) ("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.").

²⁴ *Id.* at 1057; *Abate & Morten*, *supra* note 9, at 486. Stating therein:

A party has standing to sue in its own name only when it is the effective owner of a patent; i.e., when it possesses [ASR] in the patent . . .

ownership of the two patents at issue.²⁵ The ASR test furthers the two main policy considerations underlying ODP: (1) stopping inventors from extending their monopolies with claims that would cover a previously-patented invention so the public can rely on the previous disclosure;²⁶ and (2) preventing multiple assignees from suing a single infringer.²⁷

Under the ASR test, the exclusionary rights of the licensee and licensor are compared to determine whether a license is effectively an assignment.²⁸ Based on case law regarding 35 U.S.C. § 281, exclusive licensees—even without holding all the substantial rights—can have standing to sue alongside the patentee.²⁹ Notably, the new ASR test for ODP requires control of patent prosecution.³⁰ Next, the rights of enforcement and alienation are carefully examined³¹ before other rights are considered.³² A licensee that cannot sue infringers or cannot transfer the properties in the license does not hold ASR.³³

Either the licensor did not transfer “all substantial rights” to the exclusive licensee, in which case the licensor remains the owner of the patent and retains the right to sue for infringement, or the licensor did transfer “all substantial rights” to the exclusive licensee, in which case the licensee becomes the owner of the patent for standing purposes and gains the right to sue on its own. In either case, the question is whether the license agreement transferred sufficient rights to the exclusive licensee to make the licensee the owner of the patents in question. If so, the licensee may sue but the licensor may not. If not, the licensor may sue, but the licensee alone may not.

(quoting *Alfred E. Mann Found.*, 604 F.3d at 1359–60).

²⁵ *Immunex Corp.*, 964 F.3d at 1057 (“[T]he ‘all substantial rights’ test can be informative in determining common ownership in the obviousness-type double patenting context.”).

²⁶ MPEP, *supra* note 20, § 804 (citing *In re Zickendraht*, 319 F.2d 225, 232 (C.C.P.A. 1963) (Rich, J., concurring)); *see also*, *In re Hubbell*, 709 F.3d 1140, 1142 (Fed. Cir. 2013) (stating ODP prevents claims so alike that “granting both exclusive rights would effectively extend the life of patent protection.”).

²⁷ MPEP, *supra* note 20, § 804 (citing *In re Van Ornum*, 686 F.2d 937, 944–48 (C.C.P.A. 1982)); *Immunex Corp.*, 964 F.3d at 1059.

²⁸ *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1340 n.7 (Fed. Cir. 2007) (“[I]n determining whether a party holds the exclusionary rights, we determine the substance of the rights conferred on that party, not to the characterization of those rights as exclusive licenses or otherwise.”).

²⁹ *Abate & Morten*, *supra* note 9, at 503–504. Stating therein:

In the Supreme Court’s 1926 decision, *Independent Wireless Telegraph Co. v. Radio Corp. of America*, the original patentee granted an exclusive license to its patent but ‘reserve[d] to itself non[-]exclusive, non[-]transferable, and personal rights to make, use, and sell [patented devices] for defined purposes.’ The Court held that the licensee was nonetheless an exclusive licensee with standing to sue for infringement alongside the patentee as co-plaintiff.

(citing *Indep. Wireless Tel. Co. v. Radio Corp. of Am.*, 269 U.S. 459, 461 (1926) (alterations in original)).

³⁰ *Immunex, Corp.*, 964 F.3d at 1053.

³¹ *Id.* at 1060 (quoting *Lone Star*, 925 F.3d at 1231).

³² *Id.* at 1059–60 (quoting *Alfred E. Mann Found.*, 604 F.3d at 1360–61 (finding that factors important in the ASR test included “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.”)).

³³ *Lone Star*, 925 F.3d at 1231 (citing *TCI Cablevision*, 248 F.3d at 1345).

But not all rights are weighed the same. A licensor's right to practice the patent does not prevent the licensee from holding ASR.³⁴ And a "licensor's right is illusory if it 'would not hinder [the licensee's] enjoyment of the patent rights in any meaningful way.'"³⁵ For example, in *Intellectual Property Development, Inc. v. TCI Cablevision of California, Inc.*, the Federal Circuit analyzed standing under the ASR test and found that—despite the licensor retaining a right to prevent alienation—the licensee had standing to sue because ASR had been transferred in the license.³⁶ Similarly, in *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, veto power over the licensee's choice of sublicensee did not prevent the transfer of ASR.³⁷

What substantive rights are transferred under a license is a legal question and therefore reviewed *de novo*.³⁸ However, the intent of the parties are factual questions and, therefore, a district court's holding is reviewed with deference.³⁹ In the absence of an ambiguity in a license, parol evidence should not be used to determine intent.⁴⁰

B. *The Effect of Double Patenting on Patent Term*

Double patenting can significantly increase the patent term covering an invention. Applications filed before June 8, 1995, receive patent terms of the greater of either twenty years from the earliest applicable priority date, or seventeen years from the date of issuance.⁴¹ Applications filed on or after June 8, 1995, when the Uruguay Round Agreements Act ("Uruguay Act") took effect only receive patent terms of twenty years from the earliest applicable priority date, which is when the invention was first disclosed.⁴² Thus, before the Uruguay Act, an inventor that received a second patent for an invention could extend the patent term seventeen years from the issuance

³⁴ Abate & Morten, *supra* note 9, at 494. Stating therein:

[W]hile the buyer's right to practice must be exclusive with respect to third parties, a seller's retained right to practice the patent does not necessarily preclude the transfer of [ASR], so long as the buyer's right to practice is otherwise exclusive. The seller's right to practice can be structured as a retained right.

³⁵ *Immunex Corp.*, 964 F.3d at 1069 (Reyna, J., dissenting) (quoting *Speedplay*, 211 F.3d at 1251).

³⁶ Abate & Morten, *supra* note 9, at 499 ("[I]n *Intellectual Property Development, Inc. v. TCI Cablevision of California, Inc.*, the court held that ASR had been transferred to an exclusive licensee even though the licensor retained, inter alia, the right to prevent the licensee from assigning its license without the licensor's written consent.") (citing *TCI Cablevision*, 248 F.3d at 1342).

³⁷ Abate & Morten, *supra* note 9, at 506. Stating therein:

As to restrictions on a buyer's ability to license, *Vaupel* considered a seller's retained "veto right on sublicensing by" the buyer and concluded that this did not prevent the transfer of ASR. This demonstrates that a seller's right to interfere with a buyer's licensing activity does not necessarily control.

(citing *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 875 (Fed. Cir. 1991)).

³⁸ *Immunex Corp.*, 964 F.3d at 1060.

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ 35 U.S.C. §§ 154(a), (c) (2021).

⁴² 35 U.S.C. § 154(a) (2021).

of the second patent. In contrast, after the Uruguay Act, the patent term of the second patent would be limited to twenty years from the earliest applicable priority date.

III. THE CASE

A. Procedural History

On July 30, 2015, Sandoz, Inc., Sandoz International GmbH, and Sandoz GmbH (collectively, “Sandoz”) filed an abbreviated Biologics License Application (“aBLA”) under the Biologics Price Competition and Innovation Act for a biosimilar version of Enbrel®.⁴³ This drug contains a fusion protein known as etanercept that Immunex sold for the treatment of rheumatoid arthritis.⁴⁴ In February of the next year, Immunex and Roche sued Sandoz for patent infringement in federal court in New Jersey, asserting claims 11–12 and 35–36 of the ’182 Patent and claims 3, 8, and 10 of the ’522 Patent.⁴⁵ The asserted claims of the ’182 Patent cover the etanercept composition, and the asserted claims of the ’522 Patent cover methods of manufacturing etanercept.⁴⁶ In response to the patent suit, Sandoz asserted the Licensed Patents were invalid for (1) lack of written description and enablement; (2) obviousness; and (3) ODP.⁴⁷ Immediately before the trial began, Sandoz stipulated to infringement based on its aBLA and focused on its invalidity defenses.⁴⁸ Sandoz’s arguments were unsuccessful, and the district court issued an opinion on August 9, 2019, holding the Licensed Patents were valid.⁴⁹ On October 8, 2019, the district court entered final judgment for Immunex and Roche⁵⁰ and on the same day, Sandoz appealed to the Federal Circuit.⁵¹ On March 4, 2020, the Federal Circuit heard oral arguments,⁵² with the invalidity of the Licensed Patents based on Sandoz’s arguments regarding obviousness, lack of written description and enablement, and ODP at issue.⁵³ On July 7, 2020, the Federal Circuit issued an opinion affirming the district court’s decision and found the Licensed Patents valid.⁵⁴ This case note focuses on the Federal Circuit’s holding with respect to ODP, not the Court’s holdings on lack of written description and enablement and obviousness. Before analyzing this holding more closely in the Analysis section, the next sections review the background of

⁴³ *Immunex Corp.*, 964 F.3d at 1055, 1061. The Biologics Price Competition and Innovation Act of 2009, 42 U.S.C. § 262(k) (2021). Under the Biologics Price Competition and Innovation Act, applicants can attain FDA approval by showing a biosimilar to an FDA approved biologic “highly similar” to the reference product and that there are no ‘clinically meaningful differences’ between the two in terms of ‘safety, purity, and potency.’ *Immunex Corp. v. Sandoz Inc.*, 395 F. Supp. 3d 366, 406 (D.N.J. 2019) (quoting *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017) (first quoting 42 U.S.C. § 262(i)(2)(A), (B) (2021) and then citing § 262(k)(2)(A)(i)(1) (2021)).

⁴⁴ *Immunex Corp.*, 964 F.3d at 1055, 1061.

⁴⁵ *Immunex Corp.*, 395 F. Supp. 3d at 374.

⁴⁶ *Id.*

⁴⁷ *Id.* at 375.

⁴⁸ *Id.* at 423.

⁴⁹ *Id.* at 375.

⁵⁰ *Immunex Corp.*, 964 F.3d at 1056.

⁵¹ Notice of Appeal, *Immunex Corp.*, 964 F.3d 1049 (Fed. Cir. 2020) (No. 2020-1037).

⁵² Oral Argument, *Immunex Corp.*, No. 2020-1037 (Fed. Cir. argued March 4, 2020).

⁵³ *Immunex Corp.*, 964 F.3d at 1053.

⁵⁴ *Id.*

etanercept, the relevant prosecution history at the United States Patent and Trademark Office, and the license agreements between Roche and Immunex.

B. Background and Patent Prosecution

In 1990, Roche and Immunex were independently performing research on tumor necrosis factor receptors (“TNFRs”), which are proteins that promote inflammation in response to binding tumor necrosis factors (“TNFs”).⁵⁵ Research at the time suggested that TNFs may be important in causing rheumatoid arthritis and reducing the amount of free TNFs may be a potential treatment.⁵⁶ Roche and Immunex both designed fusion proteins that could sequester TNFs bound by the fusion protein.⁵⁷ These fusion proteins deplete free TNFs in the extracellular region to prevent activation and signaling from the pro-inflammatory TNFRs normally activated by free TNFs.⁵⁸

Both companies filed multiple patent applications based on their research.⁵⁹ On May 19, 1995, Roche filed two patent applications, U.S. Application No. 08/444,790 (“the ’790 Application”) and U.S. Application No. 08/444,791 (“the ’791 Application”) (collectively, the “Licensed Applications”), which eventually issued as the Licensed Patents asserted in this case.⁶⁰ The Licensed Patents have claims with fusion proteins including an amino acid sequence that has at least 18 amino acids from TNFRs and a modified constant region of an IgG heavy chain.⁶¹ These applications both claimed priority back to an application filed on September 10, 1990, U.S. Application No. 07/580,013.⁶² For calculating patent term extension, the Licensed Applications were filed in 1995, before the Uruguay Act went into effect on June 8, 1995.⁶³

Immunex also filed multiple patent applications covering fusion proteins of TNFRs and antibodies.⁶⁴ One of these applications issued as U.S. Patent No. 5,605,690 (“the ’690 Patent”) on February 25, 1997, and claimed priority back to a provisional application filed September 5, 1989.⁶⁵ The ’690 Patent covered fusion proteins between TNFRs and an unmodified constant region from an antibody.⁶⁶ Another Immunex application covering fusion proteins between TNFRs and antibodies issued as U.S. Patent No. 7,915,225 (“the ’225 Patent”) on March 29, 2011, with an earliest priority

⁵⁵ *Immunex Corp.*, 395 F. Supp. 3d at 377.

⁵⁶ See, e.g., Fionula M. Brennan et al., *Inhibitory Effect of TNF α Antibodies on Synovial Cell Interleukin-1 Production in Rheumatoid Arthritis*, 8657 LANCET 244–247 (July 29, 1989) (showing reduced production of an inflammatory signal in patients with rheumatoid arthritis after treatment with an anti-TNF α antibody).

⁵⁷ *Immunex Corp.*, 395 F. Supp. 3d at 377.

⁵⁸ *Immunex, Corp.*, 964 F.3d at 1054 (the fusion protein “allow[s] for removal or neutralizing of excess TNF from the body.”).

⁵⁹ *Immunex Corp.*, 395 F. Supp. 3d at 378. See U.S. Patent Appl. No. 08/444,790; U.S. Patent Appl. No. 08/444,791.

⁶⁰ *Immunex Corp.*, 395 F. Supp. 3d at 378.

⁶¹ U.S. Patent No. 8,063,182 (filed May 19, 1995); U.S. Patent No. 8,163,522. (filed May 19, 1995).

⁶² The ’182 Patent; the ’522 Patent; U.S. Patent Appl. No. 07/580,013.

⁶³ 35 U.S.C. § 154(a) (2021).

⁶⁴ *Immunex Corp.*, 964 F.3d at 1057.

⁶⁵ U.S. Patent No. 5,605,690 (filed Feb. 8, 1995).

⁶⁶ *Immunex Corp.*, 964 F.3d at 1067–68.

date of April 19, 1999.⁶⁷ The issued claims of the '225 Patent are directed to methods for treating patients with psoriasis or psoriasis and psoriatic arthritis.⁶⁸ The '225 Patent also describes a connection between psoriatic arthritis and rheumatoid arthritis and increased expression of TNF α .⁶⁹ The method claims to treat patients having psoriasis or psoriasis and psoriatic arthritis with a “therapeutically effective dose of TNFR:Fc.”⁷⁰ The specification of the '225 Patent identifies etanercept as an exemplary TNFR:Fc.⁷¹

C. Licenses Between Roche and Immunex

Roche and Immunex entered into two sequential licenses covering the Licensed Applications. In 1999, Immunex signed a license with Roche that was effective back to the day the FDA approved etanercept in 1998.⁷² This license entitled Roche to royalty payments based on the sales of Enbrel®.⁷³ Among other applications, this license included the previously mentioned U.S. Application No. 07/580,013, filed September 10, 1990, as well as any subsequently issued patents claiming priority to this application, including the later-issued Licensed Patents.⁷⁴ Several years later, Amgen, Inc., acquired Immunex and a subsequent multi-party “Accord & Satisfaction” agreement (“the License”) was entered into in 2004 “to eliminate the continuing obligations to pay royalties to Roche,” which replaced the previous license.⁷⁵

⁶⁷ U.S. Patent No. 7,915,225 (filed Feb. 27, 2009).

⁶⁸ The '225 Patent, claims 1, 12, and 16. The preambles of independent claims 1 and 16 recite “A method for treating a patient having psoriasis” and the preamble of claim 12 recites “A method for treating a patient having psoriasis and psoriatic arthritis.”

⁶⁹ *Id.* at col. 1 l. 49–53. Stating therein:

Psoriatic arthritis (PsA) is a chronic autoimmune condition that shares some features with both rheumatoid arthritis (RA) and the inflammatory skin disease psoriasis (for review, see Breathnach. In Klippel and Dieppe eds. *Rheumatology*, 2nd Ed., Mosby, 1998, 22.1–22.4.); *Id.* at col. 2 l. 45–48 (“In both [rheumatoid arthritis] and in active [psoriatic arthritis], patients exhibit increased levels of HLA-DR+ T cells and MHC class II antigens in their synovial membranes and synovial fluid, *as well as increased expression of the cytokine TNF α .*

(emphasis added).

⁷⁰ The '225 Patent, claims 1–20; *Id.* at [57] (“The invention pertains to methods and compositions for treating medical disorders characterized by elevated levels or abnormal expression of TNF α by administering a TNF α antagonist, such as recombinant TNFR:Fc.”).

⁷¹ *Id.* at col. 4 l. 44–52. Stating therein:

A preferred TNFR-Ig fusion protein suitable for treating diseases in humans and other mammals is recombinant TNFR:Fc, a term which as used herein refers to ‘etanercept,’ which is a dimer of two molecules of the extracellular portion of the p75 TNF α receptor, each molecule consisting of a 235 amino acid TNFR-derived polypeptide that is fused to a 232 amino acid Fc portion of human IgG1.

⁷² *Immunex Corp.*, 395 F. Supp. 3d at 414.

⁷³ *Immunex Corp.*, 964 F.3d at 1054.

⁷⁴ *Id.* at 1054–55.

⁷⁵ *Id.* at 1055.

Under the License, Immunex received a “paid-up, irrevocable, exclusive license to the U.S. patent family for the patents-in-suit.”⁷⁶ For Immunex, the License provided: (1) sole control of patent prosecution of the patent family; (2) the first right to sue; (3) an obligation for Roche to cooperate to the extent necessary in any suit Immunex initiates; (4) the exclusive right to sublicense any patents; and (5) the right to have the Licensed Applications (later, the Licensed Patents) assigned to Immunex at any time, subject to a request and \$50,000 payment.⁷⁷ Roche’s former Senior Counsel later testified that Roche was willing to assign the Licensed Applications to Immunex at no cost during the negotiations.⁷⁸ However, Immunex insisted upon adding this \$50,000 payment term to the license.⁷⁹ Immunex paid Roche \$45 million as part of the License.⁸⁰ The same year the License was signed, Immunex earned \$1.9 billion from sales of Enbrel®.⁸¹

In the License, Roche retained several rights: (1) a secondary right to sue, subject to written notification to Immunex of its intent to sue and a subsequent 180-day waiting period; (2) a right to veto an Immunex assignment to an unrelated third party; and (3) the right to practice, for internal, non-clinical research, any patents covered under the license.⁸² One right Roche did not retain was the ability to terminate the License.⁸³

For the ten years Roche controlled prosecution of the Licensed Applications, the claims were not directed to etanercept.⁸⁴ Shortly after Immunex took control of patent prosecution under the License, it filed amendments to the claims in both Licensed Applications to cover etanercept.⁸⁵ Seven years later—with Immunex still directing patent prosecution—the ’182 Patent issued on November 22, 2011, with an expiration date seventeen years later, November 22, 2028.⁸⁶ One year later, the ’522 patent issued on April 24, 2012, with an expiration date seventeen years later, April 24, 2029.⁸⁷

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Immunex Corp.*, 964 F.3d at 1070 (Reyna, J., dissenting) (“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.”); *see also* Brief for the Association for Accessible Medicines as Amicus Curiae in Support of Reversal at 8, *Immunex Corp.*, 964 F.3d 1049 (No. 2020-1037) (“Roche had originally anticipated that it would assign outright to Immunex the applications leading to the patents-in-suit, only for Immunex to refuse assignment precisely so that it could try to avoid ODP.”).

⁷⁹ *Immunex Corp.*, 964 F.3d at 1070 (Reyna, J., dissenting).

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.* at 1055.

⁸³ *Id.* at 1070 (Reyna, J., dissenting).

⁸⁴ *Immunex Corp.*, 964 F.3d at 1069 (Reyna, J., dissenting).

⁸⁵ *Id.*

⁸⁶ *Immunex Corp.*, 395 F. Supp. 3d at 378.

⁸⁷ *Id.* at 379; *Immunex Corp.*, 964 F.3d at 1069 (Reyna, J., dissenting) (“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).”).

IV. ANALYSIS

Without common inventors or applicants or a joint research agreement, common ownership is necessary for ODP between patents and/or applications.⁸⁸ Where, as in *Immunex*, one of the patents at issue is under a licensing agreement and patent prosecution is under the licensee's control, the Federal Circuit held the ASR test can inform whether the licensee effectively owns the licensed patent.⁸⁹ After establishing control of patent prosecution, the two most important factors for the ASR test in an ODP case are: (1) who controls the enforcement of the patents and (2) who controls alienation of the patents.⁹⁰

Immunex controlled patent prosecution, Immunex had the primary right to sue, and Immunex could transfer the patents almost without limit, which should have been enough to satisfy the ASR test.⁹¹ But the Federal Circuit found the rights Roche retained were sufficient to classify Roche as the owner of the patents-in-suit.⁹² The dissent argued, however, that while Roche did retain a secondary right to sue and held a "veto power" over Immunex's assignments, Immunex actually controlled both of these rights because it could easily bypass Roche's rights.⁹³

The first section analyzes the effect of Immunex's control of patent prosecution. The second section explains the two mechanisms in the License available to Immunex to thwart Roche's secondary right to sue. The third section describes Immunex's ability to circumvent Roche's veto of an assignment. The final section provides further context regarding the structure of the License.

A. Immunex's Control of Patent Prosecution

The effects of Immunex's control of patent prosecution on the claims of the Licensed Patents are important to consider because it shows that Immunex reshaped the claims during prosecution to specifically extend etanercept's patent protection. While the European Patent Office issued patents to Roche covering etanercept before it executed the License with Immunex, no such patents had been issued in the United States.⁹⁴

⁸⁸ *Longi*, 759 F.2d at 892.

⁸⁹ *Immunex Corp.*, 964 F.3d at 1053.

⁹⁰ *Id.*

⁹¹ *Id.* at 1069–1070 (Reyna, J., dissenting).

⁹² *Id.* at 1054.

⁹³ *Id.* at 1069–1070 (Reyna, J., dissenting).

⁹⁴ Corrected Plaintiffs' Proposed Findings of Fact and Conclusions of Law at 19–20, *Immunex Corp.*, 964 F.3d at 1056 (No. 2020-1037). Stating therein:

Because Roche had obtained claims to p75-IgG fusion proteins in Europe, Amgen expected that Roche would obtain claims related to p75-IgG fusion proteins in the U.S. 9/24P (Watt) 43:19–44:10.

73. Immunex sought in the 2004 A&S to be able to guide prosecution to ensure that the patent applications on which it had been paying and would pay substantial royalties might issue as patents and thus provide Immunex valuable protection *it had not yet received*.

(emphasis added).

When Immunex took control of possession of the Licensed Applications, they were pending for almost ten years.⁹⁵ During this time, neither the claims pending in the '790 Application, nor in the '791 Application covered etanercept.⁹⁶ However, Immunex allegedly sought control of patent prosecution with the belief that similar patents would eventually issue in the United States.⁹⁷ Shortly after gaining control through the License, Immunex modified the claims in both Licensed Applications to cover etanercept.⁹⁸ By amending the claims to specifically cover its product, Immunex sought to extend patent coverage of Enbrel®. The Licensed Applications should have been subject to ODP analysis because, as the discussion of Roche's illusory rights below shows, Immunex effectively owned the Licensed Applications during prosecution (and the Licensed Patents after issuance).⁹⁹

B. Roche's Secondary Right to Enforce is Illusory

In its opinion, the majority noted the License included no restrictions on Immunex's licensing rights during the 180-day wait after Roche gave notice to Immunex of its intention to sue.¹⁰⁰ Thus, Immunex was free to sublicense the patents to a potential defendant for the entire six months after notification from Roche.¹⁰¹ But, the majority held that once Roche's secondary right to enforce vests, Immunex is limited because it cannot grant a sublicense to the accused infringer if Roche initiates a lawsuit.¹⁰²

⁹⁵ See U.S. Patent Appl. No. 08/444,790; U.S. Patent Appl. No. 08/444,791.

⁹⁶ See File Wrapper, U.S. Patent Appl. No. 08/444,790; File Wrapper, U.S. Patent Appl. No. 08/444,791; *Immunex*, 964 F.3d at 1069 (Reyna, J., dissenting) ("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.").

⁹⁷ Corrected Plaintiffs' Proposed Findings of Fact and Conclusions of Law at 20, *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049 (Fed. Cir. 2020) (No. 2020-1037) ("Immunex sought in the 2004 A&S to be able to guide prosecution to ensure that the patent applications on which it had been paying and would pay substantial royalties might issue as patents and thus provide Immunex valuable protection it had not yet received.").

⁹⁸ File Wrapper, U.S. Patent Appl. No. 08/444,790, claims at January 18, 2005; File Wrapper, U.S. Patent Appl. No. 08/444,791, claims at December 12, 2004; See *Immunex Corp.*, 395 F. Supp. 3d at 379.

⁹⁹ *Immunex Corp.*, 964 F.3d at 1069 (Reyna, J., dissenting) ("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.").

¹⁰⁰ *Id.* at 1061 ("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.").

¹⁰¹ *Id.* at 1055 ("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.").

¹⁰² *Id.* at 1062 ("[U]nder 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.").

The restriction on Immunex's licensing rights after the 180-day waiting period was in dispute, but both the district court¹⁰³ and Federal Circuit¹⁰⁴ agreed with Roche that Immunex could not sublicense the Licensed Patents after Roche instigated a lawsuit. However, in addition to the pre-suit sublicensing available to Immunex, the License provided Immunex the right to have the Licensed Patents assigned to it at any time, including after Roche initiated a lawsuit.¹⁰⁵ All that was required of Immunex was to request the assignment in writing and pay Roche \$50,000.¹⁰⁶

To prevent Roche from exercising its right to sue, Immunex could either: (1) sublicense the Licensed Patents—even as a royalty-free sublicense¹⁰⁷—to any potential infringer at any time during the 180-day waiting period after notice from Roche; or (2) after Roche filed a lawsuit, Immunex could demand assignment of the Licensed Patents and pay Roche \$50,000.¹⁰⁸ Once the Licensed Patents were transferred, Roche would have no right to continue the lawsuit, and Immunex could do what it wanted, including dropping the lawsuit.¹⁰⁹ While Roche retained a secondary right to enforce in the agreement, Immunex could easily overcome it under the License. Thus, Roche's right was not a hindrance to Immunex, and therefore it was an illusory right.

C. Roche's Right to Veto Immunex's Assignments Is Illusory

A licensee's right to assign a patent to a third party is not genuinely hindered by a licensor's veto power when the licensee can demand an assignment to itself—for a relatively insignificant amount of money—and then assign the patent to whomever.¹¹⁰ Even if Roche vetoed an assignment from Immunex to a third party, Immunex could force Roche to assign the patents to Immunex for \$50,000.¹¹¹ Once the assignment is complete, Immunex would be the official owner of the Licensed Patents, and could assign any of its rights, or the entire patents, to any third party it desires.¹¹²

The \$50,000 payment is a miniscule percentage of the \$45 million that Immunex originally paid for the license, and an even smaller percentage of the \$1.9

¹⁰³ *Immunex Corp.*, 395 F. Supp. 3d at 416 (“[W]hile Immunex had the right to sublicense, Immunex could not end a Roche-initiated lawsuit by granting a sublicense on its own.”).

¹⁰⁴ *Immunex Corp.*, 964 F.3d at 1062.

¹⁰⁵ *Id.* at 1055 (“Immunex also has the right to an assignment of the patents-in-suit upon request and upon the payment of \$50,000. . . (If requested . . . Roche *shall execute* an assignment of the patents.)” (alteration in original) (emphasis added)).

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* at 1070 (Reyna, J., dissenting) (“Under Sections 3.1 and 3.5 [of the Agreement], Immunex may nullify Roche’s right to sue by issuing a royalty-free sublicense to the alleged infringer.”).

¹⁰⁸ *Id.* at 1069–70 (Reyna, J., dissenting).

¹⁰⁹ *Immunex Corp.*, 964 F.3d at 1070 (Reyna, J., dissenting).

¹¹⁰ *Id.* (Reyna, J., dissenting). Stating therein:

[T]hat Immunex would have to pay Roche \$50,000 is not a meaningful hinderance to Immunex’s enjoyment of the patents-in-suit. . . The record shows that \$50,000 is a *de minimis* amount for Immunex. . . [I]t is unreasonable to conclude that \$50,000 represents a meaningful hinderance to Immunex’s effective ownership over the patents-in-suit.

¹¹¹ *Id.* at 1055.

¹¹² *Id.* at 1070 (Reyna, J., dissenting).

billion Immunex earned from Enbrel® in 2004, the year the License was signed.¹¹³ Furthermore, the sales revenue from Enbrel has since swelled to \$5 billion in 2019.¹¹⁴ Although Roche may slightly inconvenience and delay Immunex by refusing to agree to an assignment, Roche has no ability to actually prevent an assignment, and its veto power is illusory.¹¹⁵

D. Structure of the License

Roche was prepared to assign the Licensed Applications at no extra cost when the License was signed, and the \$50,000 payment required for the assignment was included in the License “at the insistence of Immunex.”¹¹⁶ Furthermore, Immunex “insisted on styling the U.S. agreement as a license,” even though the License effectively became a complete assignment.¹¹⁷ The minor inconvenience and insignificant cost for Immunex to complete the formal assignment process and the fact that Roche retained illusory rights at Immunex’s insistence should not have protected the Licensed Applications from ODP with regards to Immunex’s ’690 Patent and ’225 Patent.

V. CONCLUSION

The courts developed ODP for two purposes: (1) to prevent patent owners from unfairly extending patent protection using obvious modifications of patented

¹¹³ *Id.* (“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.’”).

¹¹⁴ Dennis Crouch, *Structuring Assignments to Avoid Obviousness-Type-Double-Patenting*, PATENTLY-O (September 29, 2020), <https://patentlyo.com/patent/2020/09/structuring-assignments-obviousness.html> (“[T]he drug at issue here (Enbrel®) generated \$5 billion in US sales in 2019.”). The \$50,000 payment is a mere 0.001% of the 2019 sales of Enbrel®.

¹¹⁵ Corrected Brief for the Association for Accessible Medicines and America’s Health Insurance Plans as Amici Curiae in Support of Rehearing at 13, *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049 (Fed. Cir. 2020), (No. 2020-1037) [hereinafter AAM and AHIP Brief] (“Indeed, in this case, \$50,000 residual right is not just *de minimis*, but outright illusory. Roche was willing to convert the license to an assignment for \$0; it was Immunex that insisted upon the \$50,000 contingency. Rights that concededly have no commercial value are, by definition, insubstantial.”) (internal citations omitted).

¹¹⁶ *Immunex*, 964 F.3d at 1070 (Reyna, J., dissenting). Stating therein:

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.

(alteration in original).

¹¹⁷ Crouch, *supra* note 114 (“However, rather than receiving a formal assignment, Immunex insisted on styling the U.S. agreement as a license.’ . . . This was a complete assignment – except that Roche continued to hold legal title even though Immunex effectively held all rights.”).

inventions;¹¹⁸ and (2) to protect potential infringers from being sued by multiple assignees.¹¹⁹ In the absence of common inventors, applicants, or assignments or a joint research agreement, ODP requires common ownership of the patent applications and/or patents being analyzed.¹²⁰ This requirement for common ownership in ODP has, based on the holding in *Immunex*, opened a loophole for companies.¹²¹

Here, the Federal Circuit adopted the ASR test to determine whether a licensee is in effect the owner of the licensed patent.¹²² In its previous use in determining standing to sue, a licensee's right to practice was a necessary precondition for a licensor to have transferred ASR.¹²³ The Court then weighed most heavily the rights to enforce and alienate, as well as the corresponding right to permit infringement.¹²⁴ In its application of the ASR test to ODP, the Court focused on these rights and emphasized control of patent prosecution.¹²⁵

Immunex had, under the License, the right to practice the Licensed Patents, the right to enforce the Licensed Patents, and the right to alienate the Licensed Patents, and controlled prosecution of the Licensed Applications.¹²⁶ Still, the majority found Roche's retained rights were enough to prevent the transfer of ASR to Immunex,

¹¹⁸ MPEP, *supra* note 20, § 804 (citing *Zickendraht*, 319 F.2d at 232 (Rich, J., concurring)); see also *Hubbell*, 709 F.3d at 1142 (stating ODP prevents claims so alike that "granting both exclusive rights would effectively extend the life of patent protection.").

¹¹⁹ MPEP, *supra* note 20, § 804 (citing *Van Ornum*, 686 F.2d at 944–48).

¹²⁰ *Longi*, 759 F.2d at 895.

¹²¹ AAM and AHIP Brief, *supra* note 115, at 7. Stating therein:

Amici and their members have a significant interest in the issues raised by Sandoz's petition for rehearing and rehearing en banc: namely, whether a patentee may circumvent the doctrine of obviousness-type double patenting ("ODP") by presenting itself as licensee, rather than assignee, of a patent despite having ASR in the patent. ODP is designed to ensure that a patentee does not patent the same invention more than once, and thereby plays an important role in guarding against evergreening efforts by brand-name drug manufacturers.

¹²² *Immunex Corp.*, 964 F.3d at 1059.

¹²³ *Abate & Morten*, *supra* note 9, at 490–491 ("However, two clear rules have emerged: (1) To possess [ASR], a buyer must possess the right to practice the patent; and (2) assuming that precondition is met, the right to enforce the patent is usually dispositive.").

¹²⁴ *Id.* at 494–95. Stating therein:

[T]he Federal Circuit has tended to characterize its [ASR] analysis as a flexible, holistic balancing test. However, a clear hierarchy has emerged. . . . [T]he right to enforce the patent has emerged as the single most important in the Federal Circuit's [ASR] analysis. The right to alienate, as well as the right to indulge infringement, tend to follow the right to enforce in order of importance.

¹²⁵ *Immunex*, 964 F.3d at 1059–60. Stating therein:

Where, as here, a party ultimately controls prosecution of both sets of patents, the [ASR] test aids in preventing the unjustifiable issuance of claims that are patentably indistinct from claims already owned by that party . . . "we have often focused on two salient rights: enforcement and alienation."

(quoting *Lone Star*, 925 F.3d at 1231).

¹²⁶ *Immunex*, 964 F.3d at 1061.

and the absence of common ownership precluded ODP by Immunex.¹²⁷ But while Roche retained a secondary right to enforce the Licensed Patents and could temporarily prevent their alienation, as discussed above, these rights were illusory and did not stop the transfer of ASR to Immunex.¹²⁸ Furthermore, Roche would have assigned the Licensed Applications—and given Immunex direct ownership—instead of licensing them but for Immunex’s insistence on a license.¹²⁹ The insignificant \$50,000 payment required for the assignment was also included at Immunex’s insistence.¹³⁰ The circumstances suggest Immunex had a motive to get Roche to retain these rights, and the most likely motive was gamesmanship to avoid ODP.¹³¹

The significant extension of patent protection for the blockbuster drug Enbrel® that Immunex gained made its efforts worthwhile. The Licensed Patents from Roche added a decade to Immunex’s coverage of etanercept, extending the expiration date from April 2019 to April 2029.¹³² The sales over these ten extra years will likely be significant. In 2019 alone, Immunex earned \$5 billion from the sale of Enbrel®.¹³³ And the price of Enbrel® has increased five-fold since its introduction into the market in 1998.¹³⁴ Biosimilar drugs, which have similar structures and properties to previously-allowed drugs—and which Sandoz was seeking to produce in its aBLA for which it was sued here—are 20-60% cheaper than the brand name versions.¹³⁵ Because

¹²⁷ *Id.*

¹²⁸ *Id.* at 1069–70 (Reyna, J., dissenting).

¹²⁹ *Id.* at 1070 (Reyna, J., dissenting). Stating therein:

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.

(alteration in original).

¹³⁰ *Id.*

¹³¹ *Immunex*, 964 F.3d at 1070 (Reyna, J., dissenting).

¹³² *Compare* U.S. Patent No. 7,915,225, *with* U.S. Patent No. 8,163,522; Brief for the Association for Accessible Medicines as Amicus Curiae in Support of Reversal at 8, *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049 (Fed. Cir. 2020), (No. 2020-1037) (“The last of Immunex’s original patents covering its Enbrel biologic product expired five years ago . . . This expiry should have marked the end of a nearly twenty-year monopoly. But under the District Court’s ruling, Enbrel is set to enjoy a third decade of exclusivity courtesy of the patents-in-suit.”).

¹³³ Crouch, *supra* note 114.

¹³⁴ AAM and AHIP Brief, *supra* note 115, at 11–12, (“Since its 1998 debut, Immunex has raised the price of Enbrel almost 500%, earning the company over \$5 billion in revenues in 2019 alone.”) (citing Adam Feurstein, *Amgen Indulges in Another Rheumatoid Arthritis Drug Price Increase*, THE STREET (May 5, 2015), <https://www.thestreet.com/investing/amgen-indulges-in-another-rheumatoid-arthritis-drug-price-increase-13139368>; Lauren Steele, *The most expensive drugs of 2019*, SINGLECARE: THE CHECKUP (Dec. 10, 2019), <https://www.singlecare.com/blog/most-expensive-drugs-2019/>; *Amgen Reports Fourth Quarter And Full Year 2019 Financial Results*, CISION (Jan. 30, 2020), <https://www.prnewswire.com/news-releases/amgen-reports-fourth-quarter-and-full-year-2019-financial-results-300996505.html>).

¹³⁵ AAM and AHIP Brief, *supra* note 115, at 16. Stating therein:

Immunex has not been overturned, patients that need Enbrel® will be forced to pay higher drug prices for these additional ten years and could be subject to further price hikes.¹³⁶

More broadly, the licensing strategy Immunex employed here provides a blueprint for companies to effectively take absolute control of licensed applications while maintaining ownership with the licensor to avoid ODP. In the traditional patenting scheme, the United States Patent and Trademark Office gives the applicant a twenty-year monopoly in exchange for the knowledge disclosed in the patent application.¹³⁷ ODP arose in part to prevent applicants from extending patent protection by seeking new claims that were obvious in view of previously issued claims.¹³⁸ However, Immunex devised a way to evade ODP analysis and extend its monopoly. Similar gamesmanship from other companies will be inevitable based on the market's constant pressure to increase revenue.¹³⁹ Patent protection—including Immunex's novel strategy for avoiding ODP—can harm innovation as much as weak patent protection does.¹⁴⁰ Any competitor that incorporates the knowledge disclosed in

According to research by Barclays, biosimilar drugs are anywhere between 20% and 60% cheaper than their brand-name peers. See Barclays Bank PLC, *Biosimilars Monthly*: Mar 2020 Edition at 11 (Mar. 21, 2020). Those affordable prices have made biosimilars some of the most popular drugs on the market. By the average biosimilar's fourth year of sales, it will have captured nearly 40% of the market for that drug. Id. Generic drugs are similarly critical to affordable healthcare. Over the last 10 years, generic drugs have been responsible for \$2 trillion in healthcare system savings in the United States.

(citing AAM, THE CASE FOR COMPETITION, 10 (2019), <https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf>).

¹³⁶ AAM and AHIP Brief, *supra* note 115, at 16; *Immunex*, 964 F.3d 1049 (Fed. Cir. 2020), *cert. denied, sub nom.* Sandoz Inc. v. Immunex Corp., No. 20-1110, 2021 U.S. LEXIS 2381 (U.S. May 17, 2021).

¹³⁷ 35 U.S.C. § 154 (2021). See U.S. CONST. art. 1, § 8, cl. 8 (“To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”).

¹³⁸ MPEP, *supra* note 20, § 804 (citing *Van Ornum*, 686 F.2d at 944–48).

¹³⁹ See Brief for the Association for Accessible Medicines as Amicus Curiae in Support of Reversal at 8, *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049 (Fed. Cir. 2020), (No. 2020-1037). Stating therein:

If the District Court's decision is allowed to stand, brand-name drug patent holders will be gifted a new strategy in their patent evergreening playbooks. Specifically, a brand-name drug patent holder can simply take over substantially all rights to a patent application from another party, while leaving that party with nominal rights to posture the transaction as a license rather than assignment.

¹⁴⁰ Christopher R. Leslie, *Invention, Creation, & Public Policy Symposium: Innovation & Competition Policy: Antitrust and Patent Law as Component Parts of Innovation Policy*, 34 IOWA J. CORP. L. 1259, 1261 (2009) (“While it is easy to see how insufficient rewards may hurt innovation, less obvious is the fact that overly strong patent protection also hurts innovation.”). The majority here noted the ASR test would further the policies underlying ODP, including how easier avoidance of ODP would cause harm. Crouch, *supra* note 114, (“[T]he Federal Circuit agreed with Sandoz that a strict common-ownership test for [ODP] could allow for ‘unjustified patent term extensions’ and ‘harassments’ of defendants from multiple lawsuits.”) (quoting *Immunex Corp.*, 964 F.3d at 1059 (Fed. Cir. 2020)).

the expired Immunex Patents into its products will be under threat of being sued by Immunex for infringing the Licensed Patents. The Court erred in finding that Immunex did not own the Licensed Applications for purposes of ODP. Given the Supreme Court's recent denial of certiorari¹⁴¹, the licensing strategy established in *Immunex v. Sandoz* will stand, and can now be used by other companies to acquire undeserved extensions of patent terms that ultimately harm the public.¹⁴²

¹⁴¹ *Immunex*, 964 F.3d 1049 (Fed. Cir. 2020), *cert. denied, sub nom. Sandoz Inc. v. Immunex Corp.*, No. 20-1110, 2021 U.S. LEXIS 2381 (U.S. May 17, 2021).

¹⁴² AAM and AHIP Brief, *supra* note 120, at 7. Stating therein:

Amici and their members have a significant interest in the issues raised by Sandoz's petition for rehearing and rehearing en banc: namely, whether a patentee may circumvent the doctrine of obviousness-type double patenting ("ODP") by presenting itself as licensee, rather than assignee, of a patent despite having ASR in the patent. ODP is designed to ensure that a patentee does not patent the same invention more than once, and thereby plays an important role in guarding against evergreening efforts by brand-name drug manufacturers.