Appeal No. 2020-1037

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IMMUNEX CORP., AMGEN MANUFACTURING, LTD.,
HOFFMAN-LA ROCHE, INC.,

Plaintiffs-Appellees,

v.

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH,

Defendants-Appellants.

Appeal from the U.S. District Court for the District of New Jersey
in Case No. 16-1118-CCC (Cecchi, J.)

BRIEF FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF REVERSAL

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November 15, 2019

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* Association for Accessible Medicines certifies:

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

Association for Accessible Medicines

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

See above.

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

Not applicable.

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

Not applicable.

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

Immunex Corp. v. Samsung Bioepis Co., No. 19-cv-11755 (D.N.J.).

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

OTHER AUTHORITIES

INTEREST OF THE *AMICUS CURIAE*[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines. Generic drugs constitute 90% of all prescriptions dispensed in the United States, yet generics account for only 22% of total drug spending. AAM regularly participates in litigation as *amicus curiae*. Pursuant to Fed. R. App. P. 29(a) and Fed. Cir. R. 29(c), all parties to this appeal consent to AAM's filing of this amicus brief.

AAM and its members have a significant interest in one of the issues raised by Sandoz's appeal: whether a patentee may circumvent the doctrine of obviousness-type double patenting (ODP) by presenting itself as licensee,

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[1] No counsel for any party authored this brief in any part, and no party, counsel, or person other than AAM, its members, and its counsel contributed money to fund the preparation and submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

rather than assignee, of a patent application despite having all substantial rights in the application. AAM and its members submit that a patentee should not be able to elude ODP through such gamesmanship.

ODP is designed to ensure that a patentee does not patent the same invention more than once, thereby playing an important role in guarding against evergreening efforts by brand-name pharmaceutical and biologics manufacturers. But the District Court's ruling here—which liberated Appellee Immunex from the constraints of ODP—gifts patentees a new evergreening tool. Under the District Court's ruling, a patentee may continue to thwart competition long after patent expiration through patentably indistinct applications that it acquires under the guise of a license and repurposes to cover its product. This strategy will deprive the public of affordable generic and biosimilar alternatives for important medications. Therefore, the Court should reverse the District Court and ensure that ODP correctly "polices the proper application of the patent term for each invention." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1372 (Fed. Cir. 2005).

ARGUMENT

I. The Double Patenting Doctrine Should Apply Here.

The last of Immunex's original patents covering its Enbrel biologic product expired five years ago. (*See* D.I. 48, Sandoz Br. 8.) 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. This Court should reverse.

A. Obviousness-Type Double-Patenting Precludes Immunex's Seriatim Patent Monopolies.

The present scenario is tailor-made for ODP. The doctrine ensures that a patentee receives one period of exclusivity for an invention, which cannot be extended through subsequent patent claims covering obvious variations of the invention. *E.g.*, *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1384 (Fed. Cir. 2010) ("The doctrine of double patenting is intended to prevent a patentee from obtaining a timewise extension of a patent for the same invention or an obvious modification thereof." (internal modifications omitted)). Here, Immunex invented etanercept—the active ingredient in Enbrel—and, by the time of Enbrel's launch in 1998, had sought and obtained patent protection for its invention. (Sandoz Br. 7-9.) Enbrel has enjoyed a patent monopoly ever since, though that protection

should have ended five years ago when Immunex's patents on the etanercept protein expired. But the District Court has now allowed Immunex to renew its monopoly through the patents-in-suit.

Immunex acquired the applications underlying the patents-in-suit from co-plaintiff Roche, which had been a competitor in the development of therapeutic proteins like etanercept. (Sandoz Br. 9-11.) In the hands of Roche, the applications did not cover etanercept, which is unsurprising given that Roche did not develop that protein. (Sandoz Br. 11-13.) Rather, the applications were directed to different proteins that Roche was developing (including 'p55' proteins). (Sandoz Br. 11-12.) After taking over prosecution of the applications, however, Immunex re-directed the applications to cover etanercept and methods of making it—subject matter that is patentably indistinct over Immunex's now-expired patents ("the Reference Patents"). (Sandoz Br. 18-19, 41-47.)

In short, the Roche and Immunex claims cover the same invention—the etanercept protein developed by Immunex. But because Roche filed its patent applications before Immunex, the Reference Patents are not standard prior art. Only ODP can prevent Immunex's re-packaging of the same invention.

B. Superficial Characterization Of A Patent Transfer As A License Should Not Permit An End-Run Around Double-Patenting.

Despite Immunex's transparent attempts to obtain sequential patent terms for a single invention, the District Court declined to apply ODP because it found no common ownership among the Reference Patents and the patents-in-suit. (D. Ct. Op., Appx70.) Specifically, the District Court held that ODP did not prevent Immunex's decade-long extension of patent coverage for Enbrel because Roche, rather than Immunex, purportedly remains the nominal owner of the patents-in-suit. (Appx70-73.) This was error for at least two reasons.

1. A party enjoying all substantial rights in a patent cannot shirk patent ownership.

First, the District Court improperly relied on the contracting parties' superficial characterization of their patent transaction as a "license" rather than outright assignment. (Appx70-72.) But "the title of the agreement at issue . . . is ***not*** determinative of the nature of the rights transferred under the agreement." *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1344 (Fed. Cir. 2001) (emphasis added); *see also Diamond Coating Techs., LLC v. Hyundai Motor Am.*, 823 F.3d 615, 618 (Fed. Cir. 2016) ("We have not allowed labels to control."); *A123 Sys., Inc. v.*

Hydro-Quebec, 626 F.3d 1213, 1218 (Fed. Cir. 2010) (similar). Rather, the substance of the rights transferred "is the linchpin of such a determination." *Intellectual Prop. Dev.*, 248 F.3d at 1344; *see also 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.").

As detailed below, "the substance of the rights conferred" confirm that Immunex possesses "all substantial rights" in the patents-in-suit. And that directly bears on ODP—the entire point of the common ownership requirement of ODP is to prevent a patentee like Immunex from serially extending its patent monopoly by receiving two patents for the same invention. Absent ODP, a patentee could continually file new applications on minor variations of its invention, with each new patent extending the monopoly a bit further into the future. *See, e.g.*, *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1212 (Fed. Cir. 2014).

As Sandoz explains in its principal brief, the "all substantial rights" test correctly frames the issue. (Sandoz Br. 26-28.) The test addresses whether a license grants rights to such an extent that it "amounts to an

assignment" and the purported licensee is the "effective patentee." *E.g.*, *Morrow*, 499 F.3d at 1340-41. That is the issue here: does an alleged license grant rights to such an extent that it amounts to an assignment bestowing ownership? If the answer is yes, then the so-called "licensee" stands to reap the full benefits of the patent—including the ability to recover damages and obtain an injunction—even when, in contravention of ODP, the patent is no more than an obvious variation of an already-expired patent.

Thus, the "all substantial rights" test should not, as Plaintiffs assert, be confined to the standing context. Indeed, Plaintiffs' position—anchored in a notion of nominal ownership under state law (*see* Sandoz Br. 28-30)—would allow a party to, as here, disavow ownership of a patent and avoid ODP through empty formalisms, while still maintaining all of the patent's rewards. This cannot be. If a party gains all substantial rights in a patent covering an invention it already patented, OPD must apply to prevent duplication of the party's monopoly.

2. Immunex possesses all substantial rights in both the Reference Patents and the patents-in-suit.

Second, the lopsided allocation of rights between Immunex and Roche confirms that the parties' transaction was a license in name only. It is only Immunex that enjoys the benefits of the patents-in-suit: Immunex owes no

royalties or other payments to Roche for its exclusive right to practice the patents, and it is entitled to any and all damages for infringement of the patents (assuming it exercises its right to bring suit). (Sandoz Br. 16-17.) Perhaps most crucially, the parties' agreement gave Immunex complete control over prosecution of the patents-in-suit, allowing Immunex to move the applications away from Roche's 'p55' protein and towards Immunex's 'p75' etanercept protein. (Sandoz Br. 17, 18-19.)

By contrast, the rights retained by Roche are *de minimis*. Indeed, 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. (Sandoz Br. 17.) Even now, Immunex can convert the alleged license to an outright assignment for a mere $50,000—a drop in the bucket in view of Enbrel's multimillion-dollar daily revenue—illustrating that Roche's remaining rights in the "license" are illusory. (Sandoz Br. 16-17.)

In sum, regardless of the name ascribed to the transaction by Immunex and Roche, the arrangement here resulted in one party, Immunex, enjoying two patent terms for etanercept. It is Immunex, and Immunex alone, that enjoys the hallmarks of patent protection. (*See* Sandoz Br. 16-

17.) It alone enjoys the right to exclude competition. It alone has first right to assert the patents and collect damages for any infringement. It alone practices the patents, unencumbered by any royalty obligation. In sum, it alone enjoys the fruits of the patents-in-suit. This enjoyment of a second patent term tacked on to the now-expired term of the Reference Patents is precisely the result that ODP seeks to prevent.

II. Plaintiffs' Ploy Would Provide Patentees With A Blueprint For Evergreening.

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. The brand-name drug patent holder will then have a patent application that is immune from ODP, and like here, can mold the application to extend the patent term for its product.

This strategy would harm innovation by extending monopolies and inhibiting the price competition that AAM's members seek to deliver. Competing companies frequently work concurrently on developing new medications in the same general field. Here, for example, Immunex and

Roche were simultaneously working towards TNF-receptor fusion proteins for treatment of autoimmune disorders. (*See* Sandoz Br. 5-7, 9.) A brand-name drug patent holder that has commercialized its product—like Immunex here—could look to acquire the patent portfolio of a competitor, who may not have yet been able to commercialize its work.

To avoid ODP, the brand-name drug patent holder can characterize its patent acquisition as a license by, say, agreeing to make certain payments to the competitor (having comfort that the windfall from the patent extension will dwarf any such payments). Alternatively, the patent holder could agree to leave the competitor with nominal rights that will not compromise the patent holder's unfettered control over the patent application. Here, for example, Immunex left Roche with the right to sue a third party for patent infringement, but only if Immunex opted not to sue and, further, opted not to grant a sub-license to the third party. (*See* Sandoz Br. 31.) Armed with all substantial rights in a patent application, the brand-name drug patent holder can then redirect the newly-acquired application towards covering its drug beyond the expiry of its original patents. It is a win-win for patent holders that choose to game the patent system.

Patients, taxpayers, and others who pay for healthcare will be the losers. They will be deprived not only of more affordable generic and biosimilar medicines during the extended monopoly period, but also of different treatments that are never developed due to the 'assignment-as-license' transaction. If the decision below is left standing, a brand-name drug patent holder will be able to lure a competitor with a large-enough payoff—one that still is a pittance for maintaining a monopoly over a blockbuster drug—and leave the competitor with no patent portfolio to support its fledgling technology. The result would be stifled competition: the brand-name drug patent holder pays a competitor for its technology while at the same time extending the monopoly for its own product.

To be clear, AAM does not dispute that brand-name drug companies may acquire competing patents or patent applications. Rather, AAM submits that a brand-name drug patent holder may not buy a second patent term for its own already-patented invention by simply labeling its acquisition of patent applications as a "license." ODP should apply if the substance of a brand-name drug patent holder's rights in a second patent, regardless of formalistic cues, demonstrate that it stands to enjoy two periods of patent protection for the same drug.

CONCLUSION

AAM respectfully requests that the Court reverse the District Court and hold that the patents are invalid under the doctrine of obviousness-type double patenting.

Respectfully submitted,

Dated: November 15, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on November 15, 2019, I caused the foregoing brief to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system, which caused a copy of the foregoing to be delivered by electronic means to counsel of record.

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CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This Brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) because this Brief contains 2,256 words, excluding the parts of the Brief exempted by Fed. R. App. P. 32(f) and Federal Circuit Rule 32(b).

2. This Brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this Brief has been prepared in a proportionately spaced typeface using Microsoft Office Word 2013 in Century Expanded LT Std, Font Size 14.

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