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.)

CORRECTED BRIEF FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AND AMERICA'S HEALTH INSURANCE PLANS AS *AMICI CURIAE* IN SUPPORT OF REHEARING

Jeffrey K. Francer
ASSOCIATION FOR ACCESSIBLE MEDICINES
601 New Jersey Ave., NW
Suite 850
Washington, DC 20001
Telephone: (202) 249-7100

Matthew S. Hellman
JENNER & BLOCK LLP
1099 New York Ave., NW
Suite 900
Washington, DC 20001
Telephone: (202) 639-6000

Counsel for Amici Curiae

August 20, 2020

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* Association for Accessible Medicines and America's Health Insurance Plans, Inc. certifies:

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

Association for Accessible Medicines and America's Health Insurance Plans, Inc.

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.).

/s/ Matthew S. Hellman
Matthew S. Hellman
JENNER & BLOCK LLP
1099 New York Ave., NW, Suite 900
Washington, DC 20001
Telephone: (202) 639-6000
mhellman@jenner.com
Counsel for Amici Curiae

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INTEREST OF THE *AMICI 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 account for only 22% of total drug spending. AAM regularly participates in litigation as *amicus curiae*.

America's Health Insurance Plans, Inc. ("AHIP") is a national association whose members provide coverage for health care and related services to millions of Americans every day. These services improve and protect the health and financial security of consumers, families, businesses,

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

communities, and the nation. Increases in prescription drug prices are a leading driver of rising health care costs. AHIP is committed to practical solutions that reduce consumer costs and increase patient access to needed medication, so AHIP has a strong interest in ensuring that claims of patent invalidity are resolved efficiently and effectively. AHIP regularly participates in litigation as *amicus curiae*.

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 all substantial rights 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.

Although the panel purported to recognize the importance of the ODP doctrine, the decision has seriously undermined it. The ODP doctrine is largely toothless if it does not reach Immunex's functional ownership of the patents-in-suit here. Worse, the panel decision provides a roadmap for other patentees to perpetuate patent monopolies well past their lawful expiration

dates. As the dissent recognized, the panel decision allows Immunex to leave the "licensor" with commercially valueless rights in exchange for an extended "license" to practice patent claims that are patentably indistinct from previously-issued claims. Absent review by the full Court, little stands in the way of other companies applying the Immunex blueprint to their own expiring patents, thereby extending their monopolies indefinitely. As explained below, the panel decision is particularly likely to be used to improperly extend exclusivities for biologic drugs. Those drugs can rest upon hundreds of patents, any one of which could be extended to block biosimilar alternatives.

When patent monopolies persist, patients suffer. Immunex's extended patent term means that biosimilar manufacturers, like Sandoz, must wait another decade before they can provide lower-cost alternatives to Immunex's pricey product. The panel's decision is, therefore, not just wrong on the law, but deprives the public of affordable biosimilar alternatives for critical medications. According to research done by AHIP, in the employer-sponsored coverage market, employers, their health insurance providers, and enrollees could have saved *nearly $1 billion* in 2018 alone had Sandoz's low-cost alternative been available for purchase. Absent review by the full

Court, this expensive tale will be told and retold for other drugs as biosimilar alternatives are kept off the market. En banc review is justified to prevent these costs from recurring and to 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. Review Is Warranted Because The Panel Opinion Misapplies ODP And Provides A Roadmap For Perpetuating Patent Monopolies.

A. Immunex's Rights Under The Parties' "License" Make It The Functional Owner Of The Patents-In-Suit.

ODP ensures that a patentee receives one period of exclusivity for an invention—a period that cannot be extended through subsequent patent claims covering obvious variations of the invention. Maj. Op. at 9; *see also Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1384 (Fed. Cir. 2010). Here, Immunex invented etanercept—the active ingredient in Enbrel—and, by Enbrel's 1998 launch, had sought and obtained patent protection for its invention. (Sandoz Pet. 4.) 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.

To avoid losing its monopoly, Immunex acquired via a "license" the applications underlying the patents-in-suit from co-plaintiff and competitor Roche. (Sandoz Pet. 5-6.) In Roche's hands, the applications did not cover etanercept, which is unsurprising given that Roche did not develop that protein. (Sandoz Pet. 4-5.) After taking over prosecution of the applications, however, Immunex re-directed the claims to cover etanercept—subject matter that is patentably indistinct from Immunex's now-expired patents ("the Reference Patents"). (Sandoz Pet. 6.)

Immunex's license gives it all the hallmarks of ownership over the patents-in-suit. As the panel decision acknowledges, Immunex has the sole right to practice the patents-in-suit. Maj. Op. at 7. It also has exclusive rights to grant sublicenses and has first right to rectify any suspected patent infringements. *Id.* Perhaps most crucially, Immunex has complete control over prosecution of the patents-in-suit, allowing Immunex to mold the claims to cover etanercept. *Id.* As this Court has routinely held, the rights to use, enforce, and exclusively prosecute a patent are the key factors for determining who owns contested intellectual property. *See, e.g.*, *Alfred E. Mann Found. for Sci. Research v. Cochlear Corp.*, 604 F.3d 1354, 1360-61 (Fed. Cir. 2010); *Vaupel Textilmaschinen KG v. Meccania Euro Italia*

S.P.A., 944 F.2d 870, 874-75 (Fed. Cir. 1991). In short, by virtue of its rights under the licensing agreement, Immunex is the "common owner" of both the patents-in-suit, and the Reference Patents, and thus the ODP doctrine should have barred Immunex from extending its monopoly from the latter to the former.

B. The Panel Decision Misapprehends The Extent To Which Roche Retains Any Meaningful Control Over The Patents-In-Suit.

The panel majority agreed that the ODP doctrine would apply if Immunex possessed "all substantial rights" in the patents-in-suit. Maj. Op. 14-18. But it concluded that Immunex did not in fact possess all substantial rights, notwithstanding Immunex's undisputed rights discussed above: the rights to exclude competition, assert the patents, collect damages for infringement, and practice the patents free of any royalty obligation. According the panel, Immunex did not possess all substantial rights because Roche retained a secondary right to sue for infringement and a right to veto an Immunex assignment. *Id.* at 18-20.

Those two rights are quintessentially *insubstantial*—indeed, they are commercially valueless. Start with Roche's secondary right to sue for infringement. The panel decision makes much of that right, but it is illusory.

As the dissent explains, under the license, Roche must give 180 days' notice to Immunex before it sues for infringement, and Immunex has the right during that period to provide a royalty-free license to the would-be infringer. In other words, Roche can exercise its "right" to sue if and only if Immunex, having been apprised of Roche's intentions, does not cut that right off by granting a license. A right that Immunex can nullify is no right at all, and certainly not a substantial one.

So too with Roche's supposed veto power over Immunex's right to assign its rights. Whatever heft that right might have in other contexts, it is an insubstantial one here. Under the parties' agreement, Immunex has the absolute right to convert the license to an assignment for $50,000, and thereby extinguish Roche's right to veto a subsequent assignment (and also extinguish Roche's secondary right to sue for that matter). Immunex purchased all the other rights it possesses in the patents-in-suit for *$45,000,000*, which means that Roche's residual $50,000 right is *de minimis*. *Cf. Vaupel*, 944 F.2d at 875 (concluding that a more onerous restriction on transfer—an outright veto power—was nothing more than a "minor derogation from the grant of rights"). The all *substantial* rights doctrine is meaningless if parties can evade it by structuring their deal to include de

minimis payments. 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. Dis. Op. at 5. Rights that concededly have no commercial value are, by definition, insubstantial.

C. The Panel's Formalistic Decision Provides Clear Instructions For Future "Licensees" To Extend Their Monopolies Indefinitely.

The panel's formalistic approach to ODP ensures that Immunex will not be the last patentee to attempt this gambit. The panel decision provides a blueprint for patentees interested in extending their monopolies past their scheduled expirations. Without a firm statement from this Court that such gamesmanship will not work, brand-name drug patentees will be gifted a new strategy in their evergreening playbooks.

To understand the risk posed by the panel's decision, recall that for a price equal to approximately 2% of *one year's* worth of revenues from etanercept,[2] Immunex obtained a "license" that allows it to extend its patent monopoly fifteen years past its scheduled expiration. If the panel decision

[2] Immunex earned $1.9 billion in revenue from etanercept in 2004 alone, Dis. Op at 5, and paid just $45 million for its license extending its monopoly for an additional 15 years.

stands, nothing prevents other brand-name drug manufacturers from evading this Court's protections against patent monopolies precisely as Immunex has done here. A patentee 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 patentee will then have a patent application that is immune from ODP, and like here, can mold the claims and obtain an extended patent term for its product.

To avoid ODP, the patentee can characterize its patent acquisition as a license by, say, leaving the competitor with nominal rights that will not compromise the patentee's unfettered control over the patent application. The patentee would be sure to acquire an exclusive right to prosecute the newly-obtained patents, as Immunex did here. Armed with that powerful tool, the patentee could continually file new applications on minor variations of its invention, with each new patent extending the monopoly further into the future.

The panel's decision is particularly likely to be deployed to extend monopolies for a category of drugs known as biologics. Biologics are comprised of complex combinations of sugars, proteins, or nucleic acids, and

they can rest on *hundreds* of underlying patents that cover the drugs' various components as well as the methods of manufacturing and using those components. Kevin T. Richards, et al., Cong. Rsch. Serv., R46221, *Drug Pricing and Pharmaceutical Patenting Practices* 26-27 (2020) (explaining that biologics manufactured by AbbVie (Humira), Johnson & Johnson (Remicade), and Biogen/Genentech (Rituxan) rest on hundreds of patents and that other companies are considering adopting this patenting practice). Accordingly, if a brand-name company uses the Immunex blueprint to extend *even one* of those patents beyond its scheduled expiration—a simple enough prospect given the panel's decision here—brand-name companies will be able use the panel's interpretation of the all-substantial-rights test to block biosimilars from coming on the market.

II. The Panel Decision Means More Expensive Drugs for Patients Who Need Them Most.

The panel decision was not just wrong, its consequences are also quite real. Immunex now retains a patent monopoly over etanercept for an additional decade, during which it will undoubtedly continue to charge brand-name prices for Enbrel, a drug critical for treating rheumatoid arthritis. The biosimilar alternative will not be available to patients, driving up costs for everyone through higher drug prices and higher insurance

premiums. The full Court's review is needed to prevent the American healthcare system from incurring potentially billions in unwarranted costs.

Generic and biosimilar drugs are affordable alternatives to brand-name drugs. 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. AAM, *The Case for Competition* at 10 (2019), https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf.

Those numbers stand in stark contrast to the prices for brand-name drugs like Immunex's Enbrel. Since its 1998 debut, Immunex has raised the price of Enbrel *almost 500%*, earning the company over $5 billion in revenues in 2019 alone. 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. Unsurprisingly, those prices have caused a significant burden on the U.S. healthcare system. "Between 2012 and 2016, total Medicare and Medicaid spending on Enbrel increased 129% and a total of $7.7 billion of taxpayer funds were spent on the drug." IMAK, *Overpatented, Overpriced Special Edition: Enbrel* at 4, http://www.i-mak.org/wp-content/uploads/2018/12/i-mak.enbrel.report-2018-11-30F.pdf.

Additionally, during that same period, "the average annual Medicare spending on Enbrel per person (the annual price of the drug) nearly doubled from $16,828 to $32,891." *Id.* Research conducted by AHIP shows that in 2018 alone over 100,000 individuals enrolled in employer-sponsored health coverage used Enbrel at a cost of nearly $4 billion. It is estimated that had an Enbrel biosimilar been available, employers, their insurers, and enrollees

could have realized nearly $1 billion in savings in 2018. Cumulatively, this means that billions of dollars in inflated costs have been borne by consumers as a result of Immunex's conduct. The result is that patients must pay more—either out of pocket or through higher insurance premiums—for medication covered by patents that should have expired years ago.

It did not have to be this way. If Sandoz's etanercept-based biosimilar, Erelzi, had hit the market in 2016 when it was first approved, it could have saved the US healthcare system hundreds of millions, if not billions of dollars, by now. Assuming, conservatively, that it captured only 10% of the etanercept market and provided only a 20% price discount compared to the brand-name Enbrel, Erelzi would have saved the U.S. healthcare system $101 million in its first year of sales alone. Those savings would have meant more money in the pockets of patients who depend on etanercept for treatment. Instead, Immunex was able to extend its monopoly for fifteen years past its scheduled expiration.

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Immunex has nearly completed its end-run around the patent system. By acquiring its dubious "license" from Roche, Immunex has extracted billions of additional dollars from patients and payers that it would not have

otherwise earned had a lower-cost alternative been available. The full Court should reverse and prohibit this gamesmanship.

CONCLUSION

Amici respectfully request that the Court grant Appellant's petition for rehearing en banc.

Respectfully submitted,

Dated: August 20, 2020

/s/ Matthew S. Hellman

Jeffrey K. Francer
ASSOCIATION FOR ACCESSIBLE MEDICINES
601 New Jersey Ave., NW
Suite 850
Washington, DC 20001
Telephone: (202) 249-7100

Matthew S. Hellman
JENNER & BLOCK LLP
1099 New York Ave., NW
Suite 900
Washington, DC 20001
Telephone: (202) 639-6000

Counsel for Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that on August 20, 2020, 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.

/s/ Matthew S. Hellman

Matthew S. Hellman
JENNER & BLOCK LLP
1099 New York Ave., NW
Suite 900
Washington, DC 20001
Telephone: (202) 639-6000
mhellman@jenner.com

Counsel for Amici Curiae Association for Accessible Medicines and America's Health Insurance Plans

CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This Brief complies with the type-volume limitation of Fed. R. App. P. 29(b)(4) because this Brief contains 2,599 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.

/s/ Matthew S. Hellman

Matthew S. Hellman
JENNER & BLOCK LLP
1099 New York Ave., NW
Suite 900
Washington, DC 20001
Telephone: (202) 639-6000

Counsel for Amici Curiae Association for Accessible Medicines and America's Health Insurance Plans.

August 20, 2020