NO. 20-2402

IN THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

UFCW LOCAL 1500 WELFARE FUND, *ET AL.*,

Plaintiffs-Appellants,

v.

ABBVIE INC., *ET AL.*,

Defendants-Appellees.

On Appeal from the United States District Court
for the Northern District of Illinois
(Case No. 1:19-cv-01873-MSS)
(District Judge Manish S. Shah)

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* SUPPORTING APPELLEES AND AFFIRMANCE

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APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

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Attorney's Signature: /s/ John M. Masslon II Date: 12/28/20

Attorney's Printed Name: John M. Masslon II

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Attorney's Signature: /s/ Cory L. Andrews Date: 12/28/20

Attorney's Printed Name: Cory L. Andrews

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

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INTEREST OF *AMICUS CURIAE*[1]

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as *amicus* in cases involving the intersection of patent rights and antitrust law. *See*, *e.g.*, *FTC v. Actavis*, 570 U.S. 136 (2013); *Impax Labs., LLC v. FTC*, 19-60394 (5th Cir. brief filed Oct. 10, 2019).

INTRODUCTION

Patent law and antitrust law work together to maximize consumer welfare. On one side, patent law gives companies the incentive to innovate and create products that will benefit consumers. *See King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995) (citing *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989)). Without this incentive, we would lack medicines like Humira and those recently developed to fight COVID-19. On the other side, antitrust law ensures the companies do not use their patent rights to unlawfully

[1] No party's counsel authored any part of this brief. No one, apart from WLF and its counsel, contributed money intended to fund the brief's preparation or submission. All parties consented to WLF's filing this brief.

hurt competition. *See FTC v. Qualcomm Inc.*, 969 F.3d 974, 999-1000 (9th Cir. 2020).

Antitrust law and patent law use different mechanisms to achieve their goals. Antitrust law focuses on maximizing welfare. It tolerates "consumer injury" when it "naturally flow[s] not so much from a less competitive market . . . as from the exercise of market power that is lawfully in the hands of a monopolist." *NYNEX Corp. v. Discon, Inc.*, 525 U.S. 128, 136 (1998) (emphasis removed). It sometimes tolerates consumer injury "because antitrust laws protect competition, not competitors." *Chicago Studio Rental, Inc. v. Ill. Dep't of Commerce*, 940 F.3d 971, 979 (7th Cir. 2019) (citation omitted).

These principles of antitrust law are well settled. Yet the plaintiffs' bar and many academics resent this focus on competition rather than competitors. *See*, *e.g.*, Maurice E. Stucke, *Reconsidering Antitrust's Goals*, 53 B.C. L. Rev. 551, 564 (2012) (citations omitted). They prefer an antitrust regime that pursues amorphous goals like fairness and diversity. This lawsuit is another example of the misguided attempt at overhauling antitrust law. Rather than achieve their goals through the proper democratic channel—Congress—Plaintiffs ask this Court to

recognize new theories of antitrust liability. Their arguments ignore the substantial benefits that flow from patent law.

Such one-sided emphasis on antitrust enforcement skirts *Actavis*. The Supreme Court emphasized the need to balance the antitrust and patent laws. It held that payments from a patent holder to a biosimilar manufacturer as part of a patent-litigation settlement is "sometimes" subject to antitrust scrutiny and "sometimes" not. *Actavis*, 570 U.S. at 141. But to trigger antitrust scrutiny there must be a cash (or cash-equivalent) payment. Plaintiffs have not alleged a cash payment here—because there was none. The inquiry should thus end there.

This reading of *Actavis* also advances the purposes of patent law and antitrust law. Prolonged patent litigation leads to deadweight loss. The only victors are the lawyers. Both biosimilar manufacturers and patent holders must charge more for their medicines to pay for this litigation. So consumers are ultimately harmed when the parties cannot resolve patent disputes.

Today, intellectual property law is a global enterprise. Rare is the case in which the number, the type, and the strength of patent claims are the same across jurisdictions. Rather, a patent holder usually has a

higher chance of success in one jurisdiction than another. It is not the place of antitrust enforcers to make the difficult business calculations comparing patent litigation with global settlements. But that is what Plaintiffs want. They request that courts engage in after-the-fact analysis of every patent settlement involving U.S. markets. This is a recipe for disaster. This Court can avoid both the legal and economic pitfalls of Plaintiffs' expansive claims by affirming the District Court's dismissal order.

STATEMENT

I. STATUTORY FRAMEWORK

Both patent holders and biosimilar manufacturers play key roles in providing life-saving drugs. Under the Biologics Price Competition and Innovation Act (BCPIA), Pub. L. No. 111-148, Title VII(A), 124 Stat. 119, 804, four years after the FDA approves a drug, biosimilar manufacturers can ask the FDA to approve a biosimilar by filing an abbreviated biologic license application. 42 U.S.C. §§ 262(k)(2)(A), (7)(B). The abbreviated application requires that no "clinically meaningful difference" exists between the approved drug and the biosimilar. *Id.* § 262(k)(2)(B).

The biosimilar manufacturer must notify the brand-name manufacturer when it files an abbreviated application and the brand-

name manufacturer must notify the biosimilar manufacturer of patents the biosimilar may infringe. 42 U.S.C. §§ 262(l)(2), (3)(A). The biosimilar manufacturer then tells the patent holder which patents it believes the biosimilar would not infringe or are invalid. *Id.* § 262(l)(3)(B). Next, the patent holder must sue to determine whether the asserted patents are valid and, if so, whether the biosimilar infringes those patents. *Id.* § 262(l)(6).

Twelve years after the FDA approved the brand-name drug, it can approve an abbreviated application. 42 U.S.C. § 262(k)(7)(A). Unlike the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585, the BCPIA, allows the FDA to approve the application despite pending litigation. *See* 42 U.S.C. § 262(l)(8)(A). But because litigating infringement suits to judgment is costly, time-consuming, and risky, settling patent litigation, is the chief market-entry vehicle for low-cost generics and biosimilars.

II. FACTUAL BACKGROUND

AbbVie manufactures Humira for which it holds dozens of U.S. patents. (S.A. 1, 9.) The FDA approved Humira to treat autoimmune diseases. Because AbbVie applied for the patents at different times, the expiration dates range into the 2030s.

Manufacturers sought to market biosimilars of Humira and challenged the validity of AbbVie's patents in *inter partes* review proceedings. (*See* S.A. 11 & n.5, 12.) AbbVie prevailed in most of the proceedings while the challengers won only three. (S.A. 11.)

When Amgen obtained FDA approval to distribute a Humira biosimilar, AbbVie sued Amgen for patent infringement both in the U.S. and Europe. (*See* S.A. 12.) The parties then settled the lawsuits. (S.A. 12.) In the U.S. settlement, AbbVie granted Amgen a license to sell its Humira biosimilar in the United States in January 2023. (S.A. 13.) In the European settlement, AbbVie granted Amgen a license to sell its Humira biosimilar in Europe in October 2018—before expiration of AbbVie's European patents. (S.A. 14.) AbbVie settled litigation with other biosimilar manufactures on similar terms. (S.A. 13-14.) All the agreements require the biosimilar companies to pay royalties to AbbVie for sales of their biosimilars in the United States and Europe. The settlements do not involve any payment by AbbVie to the biosimilar manufacturers. (*Cf.* Pls.' Br. 19 (arguing a cash payment is unnecessary to trigger antitrust scrutiny).)

ARGUMENT

I. ONLY A CASH OR CASH-EQUIVALENT PAYMENT TRIGGERS ANTITRUST SCRUTINY UNDER *ACTAVIS*.

This Court "may affirm the result below on any basis that appears in the record, even if it was not the district court's ground for dismissing the suit." *Marcus & Millichap Inv. Servs. of Chi., Inc. v. Sekulovski*, 639 F.3d 301, 312 (7th Cir. 2011) (citation omitted). Plaintiffs concede that no cash (or cash-equivalent) changed hands here. Yet they contend that Appellees' agreements are subject to antitrust scrutiny because they exchanged something of value—early entry in the European market—for later early entry in the U.S. market. The District Court agreed and incorrectly held that the lack of a cash exchange was "not determinative." (S.A. 44 (citations omitted).)

A. *Actavis*'s Plain Language Requires A Cash Or Cash-Equivalent Payment.

The District Court's holding ignores the Supreme Court's unambiguous language in *Actavis*. There, the Court carefully chose its language and limited antitrust scrutiny to cash reverse payments. This Court can therefore affirm the District Court's order because no cash changed hands.

Actavis focused on reverse payments mainly in "dollars." *See, e.g.*, 570 U.S. at 140, 144, 145, 147. The Court was equally concerned about cash-equivalent reverse payments like stocks, bonds, or gold bullion. But the Court exempted from antitrust scrutiny other settlement benefits that flow to the infringer.

For example, the Court held that no antitrust scrutiny is warranted if the generic manufacturer drops patent invalidity claims in return for a license to market its product before the patent's expiration.[2] *Actavis*, 570 U.S. at 158. This holds true even if—as will often be the case—the early-entry license is worth millions of dollars to the generic manufacturer. *Id.*

This type of patent-infringement settlement is a quintessential exchange of value. The biosimilar manufacturer gives up its ability to immediately enter the market. The chance of this immediate entry is worth millions to the biosimilar manufacturer. And the patent holder gives up the possibility of monopoly profits through the life of the patent. This chance at monopoly profits is worth millions to the patent holder.

[2] *Actavis* involved the Hatch-Waxman Act which governs generic drugs. The BCPIA and Hatch-Waxman Act are similar, but not identical. *See Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1276 (Fed. Cir. 2014). The term "generic manufacturer" is therefore used when referencing *Actavis*'s specific facts. The parties agree that *Actavis*'s reasoning applies here.

Yet the Supreme Court explained that such settlements are immune from antitrust scrutiny.

The Court did not define precisely what it meant by "reverse payment." But one can reasonably infer that the Court intended to confine the term to cash (or cash equivalent) payments for delay. It did not intend for the term to include any contractual arrangement that confers value. The Court would not have cited early-entry licensing as an example of a patent holder permitting entry without "paying the challenger to stay out prior to that point," if it thought the word "paying" included the immense value transferred to challengers through such licenses. *Actavis*, 570 U.S. at 158.

Antitrust scrutiny is also unwarranted if the patent holder "pays" the alleged infringer by settling damage claims for far less than originally sought in a lawsuit. *Actavis*, 570 U.S. at 151-52. This holds true even if the generic manufacturer is almost certain to prevail on its claims. *See id.*

Again, this type of settlement is an exchange of value. The patent holder gives up the potential for large damage awards, attorneys' fees, and costs. This could be worth hundreds of millions of dollars. The

biosimilar manufacturer, on the other hand, gives up the potential for an invalidity finding allowing it to immediately enter the market without paying royalties or damages.

Actavis's plain language thus shows that only cash (or cash-equivalent) payments trigger antitrust scrutiny. The Court repeatedly focused on cash reverse payments while citing other transfers of value that cannot support antitrust liability. The lack of any such payment here is fatal to Plaintiffs' claims.

B. Two Courts Persuasively Explained Why This Is The Correct Reading Of *Actavis*.

These examples show why two district courts got it right—and the reviewing courts of appeals incorrectly reversed. This Court should not compound those errors.

The District of Rhode Island carefully analyzed *Actavis* and held that it subjected only cash payments to antitrust scrutiny. *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 189-94 (D.R.I. 2014), *rev'd*, 814 F.3d 538 (1st Cir. 2016). In reaching this conclusion, the District of Rhode Island cited *Actavis*'s first paragraph. *See Loestrin*, 45 F. Supp. 3d at 189. The Supreme Court used letters to represent patent holders and generic companies that agreed to reverse-payment settlements. *Actavis*, 570 U.S.

at 140-41. *Actavis* framed the question presented as "whether such" "a reverse payment settlement agreement" "can sometimes" violate "the antitrust laws" when the patent holder paid the generic manufacturer "many millions of dollars." *Id.* at 140 (quotation marks omitted).

The District of Rhode Island then noted other places where *Actavis* suggested that cash (or cash-equivalent) must be part of a reverse payment to trigger antitrust scrutiny. *See Loestrin*, 45 F. Supp. 3d at 189. For example, the Supreme Court said that "[i]n reverse payment settlements . . . a party with no claim for damages . . . walks away with money." *Actavis*, 570 U.S. at 152. The District of Rhode Island found this strong evidence that *Actavis* requires a cash (or cash-equivalent) payment to trigger antitrust scrutiny. *Loestrin*, 45 F. Supp. 3d at 189.

The First Circuit rejected the District of Rhode Island's careful analysis based on little more than Black's Law Dictionary's defining "payment" as "the 'performance of an obligation by the delivery of money or some other valuable thing accepted in partial or full discharge of the obligation' and 'the money or other valuable thing so delivered in satisfaction of an obligation.'" *Loestrin*, 814 F.3d at 550 (emphasis removed). Yet the First Circuit never explained why "some other valuable

thing" includes non-cash equivalents. As shown above, there are other valuable things that the Supreme Court said could change hands without triggering antitrust scrutiny. That is why the District of Rhode Island had it right when it held that "*Actavis* should be applied only to cash settlements, or to their very close analogues." *Loestrin*, 45 F. Supp. 3d at 192.

Like the District of Rhode Island, the District of New Jersey reviewed *Actavis* and held that it was limited to cash (or cash-equivalent) payments. *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 567-69 (D.N.J. 2014), *rev'd sub nom., King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015). This analysis, however, undertook an even deeper examination than *Actavis*'s majority opinion. Using contextual clues from Chief Justice Roberts's dissenting opinion, the District of New Jersey persuasively argued against applying *Actavis* to non-cash (or cash-equivalent) payments.

In his dissent, Chief Justice Roberts noted that the FTC asked the Court to hold that non-cash payments triggered antitrust scrutiny. *See Actavis*, 570 U.S. at 173 (Roberts, C.J., dissenting). But Chief Justice Roberts explained that the Court's majority opinion rejected this request.

See id. He criticized the Court for drawing this "distinction without a difference." *Id.* at 169. Chief Justice Roberts was showing the incoherence in the majority opinion. It distinguished between cash payments and non-cash payments despite all parties agreeing that it was a distinction without a difference.

In reversing, the Third Circuit misread the *Actavis* dissent. In its view, Chief Justice Roberts thought that the majority did not distinguish between cash and non-cash payments. *See King Drug Co.*, 791 F.3d at 406 n.25. Examining that dissent confirms the District of New Jersey's reading.

As described above, if the biosimilar manufacturer accepted gold coins for delayed entry into the market, that would trigger antitrust scrutiny. There is a liquid market for the gold coins. The same is true for stocks and bonds. But that cannot be said for a license to sell a patented drug or the ability to immediately enter the market. Different firms will value those "valuable things" differently. It is impossible to determine the size of the payment in this case. Yet "the size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power." *Actavis*, 570 U.S. at 157 (quotation omitted). How can

a court evaluate a potential settlement without considering this "strong indicator of power?" The First and Third Circuits' approach invites pure speculation.

The language and context of the *Actavis* opinion shows that a cash (or cash-equivalent) payment is necessary to generate antitrust scrutiny. Plaintiffs concede that AbbVie made no such cash (or cash-equivalent) payment as part of its global settlement agreements. This is fatal to any claim under *Actavis*.

II. GLOBAL PATENT SETTLEMENTS ARE CRITICAL TO MAXIMIZING CONSUMER WELFARE.

Actavis assumed it would still be possible for litigants to settle pharmaceutical patent-infringement litigation while complying with the antitrust laws. Yet it becomes exceedingly difficult for parties to settle patent litigation if courts scrutinize every settlement. Requiring such dissection by district courts in this circuit, as Plaintiffs urge, would tank consumer welfare in the midst of a global pandemic.

A. Pharmaceutical Markets Differ By Jurisdiction.

Today, the pharmaceutical industry is global. But that doesn't mean it is uniform across jurisdictions. A recently issued rule illustrates the point. The Most Favored Nation (MFN) Model Rule "take[s] a global

approach to" prescription-drug pricing. 85 Fed. Reg. 76,180, 76,181 (Nov. 27, 2020). It "test[s] a new payment methodology that takes into account the discounts that other countries enjoy." *Id.* In short, the MFN Rule acknowledges that you cannot view the United States's pharmaceutical market in a vacuum. Rather, it must be seen in the broader context of the global pharmaceutical market.

"Drug acquisition costs in the U.S. exceed those in Europe, Canada, and Japan." MFN Rule, 85 Fed. Reg. at 76,183; *see generally* Department of Health and Human Resources, *Comparison of U.S. and International Prices for Top Medicare Part B Drugs By Total Expenditures* (Oct. 25, 2018), https://bit.ly/36Zv6kV. The countries' gross domestic product alone does not explain this difference. Rather, there are other factors affecting the price of drugs in different jurisdictions. Some of those factors are irrelevant to the issues here. But one factor is highly relevant: Intellectual property plays a key role in each country's pharmaceutical market.

Nations do not enjoy uniform, standardized patent laws. *See generally* World Intellectual Property Organization, *An overview of patent litigation systems across jurisdictions*, https://bit.ly/3nce48S.

There are key "differences between European and United States' patent law." *Insite Vision Inc. v. Sandoz, Inc.*, 783 F.3d 853, 864-65 (Fed. Cir. 2015). One difference is the availability of injunctive relief in standard-setting patents. *See Microsoft Corp. v. Motorola, Inc.*, 696 F.3d 872, 888 (9th Cir. 2012). A related difference is that, under European law, "patent pools [must] offer a compulsory licensing scheme" while that is required in America only if the pools are "overly restrictive." Atif I. Azher, *Antitrust Regulators and the Biopharmaceutical Industry: Compulsory Licensing Schemes Ignoring Gene Therapy Patients' Needs*, 25 U. Pa. J. Int'l Econ. L. 383, 405 (2004).

An extreme example shows how patent laws can differ across nations. In 1992, Novartis obtained a European patent for Gleevec—a ground-breaking cancer drug. Faisal I. Chaudhry, *Intellectual Property and the Global Crisis of Non-Communicable Disease*, 19 N.C. J. L. & Tech. 175, 183 (2017). Because of this patent, Novartis made money from selling and licensing Gleevac in Europe. Novartis also obtained a U.S. patent on Gleevac. *See* Christopher T. Chen & Aaron S. Kesselheim, *Journey of Generic Imatinib: A Case Study in Oncology Drug Pricing*, 13

J. Oncology Practice 352, 352 (2017). So Novartis also made money off Gleevac in the U.S.

But India refused to grant Novartis a patent on Gleevac. *See Novartis AG v. Union of India*, A.I.R. 2013 S.C. 1311 (India). This meant that generic manufacturers could sell Gleevec in India without fear of patent-infringement suits. Novartis therefore did not enjoy the same intellectual-property landscape in India as it did in the U.S. and Europe.

Although AbbVie has Humira patents in both the U.S. and Europe, the scope of its patent protection differs. Many more U.S. patents cover Humira than do European patents. And in the United States, the patents have already survived *inter partes* review. This means that AbbVie had more leverage when negotiating agreements with biosimilar manufacturers for the entry date in the United States than it had when negotiating for a European entry date.

This also does not factor in the strength of the patent-infringement claims AbbVie could assert in a United States court versus the strength of those claims in Europe. AbbVie and the biosimilar manufacturers were in the best position to calculate how much these differences were worth. *Cf.* Frank H. Easterbrook, *The Limits of Antitrust*, 63 Tex. L. Rev. 1, 5

(1984) (explaining the knowledge gap between generalist federal judges and "someone with a very detailed knowledge of the market process").

Based on the number of AbbVie's patents and the strength of those patents, Appellees reached fair settlements. The differing early-entry dates reflected the variations between markets. Adhering to free-market incentives best fosters competition. The agreements were therefore not anticompetitive. Rather, they reflected the difference in the intellectual property landscapes in the United States and Europe.

B. Global Settlements Are Necessary In Today's Intellectual Property Landscape.

The global pharmaceutical market is complex and nuanced. Many aspects of markets overlap between nations. But many characteristics differ from country to country. To maximize American consumer welfare, companies must be able to settle their patent lawsuits around the world. Otherwise, costly litigation will take money out of consumers' pockets and put it in lawyers' bank accounts.

1. Settling pharmaceutical patent-infringement cases is necessary to maximize consumer welfare.

Settlements in pharmaceutical patent litigation face unique obstacles because of litigation dynamics created by the BCPIA. Unlike in

most patent-infringement litigation, a biosimilar manufacturer that initiates infringement litigation—by filing an abbreviated application—does not normally face damages because it has not marketed any infringing products. FTC statistics illustrate this point: In Fiscal Year 2017—the most recent year for which data is available—98.7% of settlements were signed before sale of a competing drug. *See* FTC Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, 4 (Dec. 3, 2020), https://bit.ly/2JRt5ia. Biosimilar manufacturers will not settle cases unless it is better than the alternative—litigation.

But if a patent holder cannot transfer anything of "considerable value" to a biosimilar manufacturer without facing antitrust scrutiny, there will be very few settlements in pharmaceutical patent litigation. Biosimilar manufacturers will see no benefit—neither eliminating the risk of damages nor receiving "considerable value"—to settling the lawsuits. Anything the patent holder offers would either be inadequate or possibly subject it to antitrust liability.

The FTC's position proves the point. In its report earlier this month, it tacitly endorsed paying generic and biosimilar manufacturers $7 million in attorneys' fees to settle these cases. But any other agreements between the parties entered at the time of the settlement of a U.S. patent suit may trigger antitrust scrutiny. *See generally Agreements Filed with the FTC*, *supra* at 6.

This attempt at eliminating the possibility of patent settlement cannot be squared with *Actavis*, which sought to craft a standard under which settlements could still flourish. *Actavis* recognized "a general legal policy favoring the settlement of disputes." *Actavis*, 570 U.S. at 153. That policy goal disappears if this Court adopts Plaintiffs' argument that all settlement agreements should face antitrust scrutiny.

There are many disadvantages to continued patent litigation. The outcome is unclear and the costs high. Settlement terms strive to make it attractive for all parties to settle. But settlements can occur only if litigants have the tools required to reach an agreement that both parties find beneficial. This will often be impossible if the parties cannot settle all related disputes.

Even huge financial concessions by the patent holder will not lead to settlement because they will confer little benefit on the biosimilar manufacturer. *See* Kevin McDonald, *Because I Said So: On the Competitive Rationale of FTC v. Actavis*, 28 Antitrust 36, 37-38 (2013). If, as *Actavis* conveyed, courts should encourage patent-litigation settlements, parties must know that no antitrust liability is forthcoming. Without that assurance, biosimilar manufacturers will have far fewer incentives to file abbreviated applications in the first place. This is the opposite of Congress's goal when it passed the BCPIA.

Former-Judge Posner explained the consequences of adopting Plaintiffs' argument: "[A]ny settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement." *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003). So "[i]f any settlement agreement is . . . classified as involving a forbidden 'reverse payment,'" there will be "no more patent settlements." *Id.* It therefore "would reduce the incentive to challenge patents by reducing the challenger's settlement options." *Id.*

That means that biosimilar manufacturers would be less likely to file abbreviated applications. The patent holder could retain its monopoly for a longer period. So adopting Plaintiffs' proposed rule would hurt, not help, competition. *See Asahi Glass Co.*, 289 F. Supp. 2d at 994. And this damage to competition occurs before the filing of a single lawsuit.

If abbreviated applications are filed, the effect on consumer welfare would still be devastating. When biosimilar manufacturers file abbreviated applications a major fight will follow. The parties will not reach an early-entry deal like they did here. Rather, biosimilar drugs will be delayed well beyond what settlements like those here allowed. This could mean months, years, or decades of higher-priced drugs. This would not benefit consumers.

There is also an indirect effect on consumer welfare. The millions of dollars spent on discovery, attorneys' fees, and other litigation expenses will not go to developing critical drugs. *Cf.* Kaya Yurieff, *Apple and Samsung settle their epic patent infringement battle* (June 27, 2018), https://cnn.it/3m8MIPN (one patent lawsuit cost the parties "hundreds of millions of dollars"); *Agreements Filed with the FTC*, *supra* at 6 (FTC believes spending $7 million to defend a pharmaceutical patent-

infringement claim is reasonable even when the case settles). If the pharmaceutical companies desired to keep their current level of research and development, the only solution would be raising the prices for both brand-name and biosimilar drugs.

Settling patent litigation between patent holders and biosimilar manufacturers is hard. Yet these settlements maximize consumer welfare. Ensuring that the parties have all available tools to settle their cases is therefore crucial. Plaintiffs ask this Court to take away a critical aspect of settling modern patent litigation—seeking to achieve resolution across multiple jurisdictions. The Court should reject this unintended call to harm consumers.

2. Global patent settlements are important.

Many times, the only way to settle patent litigation is through global settlements. If every global settlement faces antitrust scrutiny, companies will not settle their patent disputes. Rather, they will fully litigate the cases. And as described above, this will lead to decreased consumer welfare. There are at least three reasons why global patent settlements are efficient.

First, many patent-litigation costs are not jurisdiction specific. A company can hire an expert witness to testify on the chemistry of the brand-name and biosimilar drugs in multiple jurisdictions. At a minimum, the expert witness can provide a party's counsel with technical advice about the infringement claims. The same goes for prior art and other arguments that are not jurisdiction specific.

A company can also employ a single law firm to represent it in multiple jurisdictions. This means a smaller number of attorneys must learn the relevant technology and patent claims when prosecuting or defending a case. Similarly, the company can produce discoverable information in one lawsuit that covers many discovery requests in cases pending in other jurisdictions.

In short, several economies of scale are at play in global patent litigation. If a company cannot settle all the cases at once, it must bear all of these costs. So if Appellees may settle only their European claims without reference to the U.S. claims, they must still bear many costs associated with the U.S. claims. This would make the marginal benefit of resolving the European claims low. And if the benefit is low, the incentive to quickly settle the cases would disappear.

On the other hand, if parties can enter global settlement agreements, they can rid themselves of all of these shared costs. They would no longer need to spend tens or hundreds of millions of dollars on expert witnesses, attorneys' fees, and discovery. Rather, the parties could use that money to innovate and to lower consumer prices.

Second, global patent settlements allow for comparative advantage to work its magic. A patent holder may have a comparative advantage over a biosimilar manufacturer in the U.S. market. And the biosimilar manufacturer may have a comparative advantage in the European market. If so, consumers benefit where settlements can be reached reflecting the relative strengths of the parties in each jurisdiction.

But adopting Plaintiffs' proposed rule would disregard this basic economic principle. Under the rule rightly rejected below, courts would view the companies as homogeneous in different markets. This would lead to the inefficient allocation of resources. And inefficient allocations of resources harm consumer welfare. Such an antitrust regime would advance neither the goals of antitrust law nor the goals of patent law. It would be a lose-lose scenario.

Third, history shows that global patent settlements are the only way certain companies can resolve disputes. Some of the most notorious battles between large corporations have ended only with global patent settlements. Although not exhaustive, two examples illustrate the point.

Qualcomm and Apple engaged in a patent battle royale around the world. Eventually, the parties reached a deal. *See* David Faber & Kif Leswing, *Qualcomm surges after announcing a settlement with Apple over patent royalties* (Apr. 16, 2019), https://cnb.cx/3gJvVBL. That deal resolved the companies' patent litigation globally. *Id.*

The parties probably could not have ended their U.S. litigation without a global settlement. The ability to resolve their worldwide litigation was key to reaching an agreement. But if they knew that the plaintiffs' bar could file an antitrust suit for the global settlement, iPhones might cost more to fund the continued litigation.

In another case, Bristol-Myers Squibb and Ono Pharmaceutical Company resolved patent litigation in ten countries with one settlement. *See* Bristol-Myers Squibb, *Bristol-Myers Squibb and Ono Pharmaceutical Company Enter Settlement and License Agreement with Merck to Resolve PD-1 Antibody Patent Litigation* (Jan. 20, 2017), https://bit.ly/34448ab.

The number of disputes the parties resolved with one settlement shows the power of global patent settlements. As explained above, one company may have had a superior litigation position in Japan while the other had the upper hand in the Netherlands. So they settled all their disputes at once. If faced with costly antitrust scrutiny, as Plaintiffs urge here, those companies may have opted to continue the resource-wasting patent litigation.

Domestic patent settlements therefore are not as efficient as global patent settlements. Settling all patent disputes around the world eliminates some deadweight loss. It therefore helps to increase consumer welfare—the goal of antitrust law. It does so while encouraging continued innovation—the goal of patent law. Golfers can play a round without their putters. But they will have worse scores than they would with that club in their bag. In patent litigation, global settlements are a club that is not needed in every circumstance. But it is necessary to ensure the best score (consumer welfare) possible.

* * *

The District Court properly dismissed Plaintiffs' Section 1 claims for failure to state a claim. Along with the District Court's well-reasoned

rationale, *Actavis* requires a cash (or cash-equivalent) payment to trigger antitrust scrutiny of settlements between patent holders and biosimilar manufacturers. Because Plaintiffs concede there was no cash payment here, this Court can take a shortcut and affirm on that basis.

But even taking the longer route, the District Court got it right. The Supreme Court has repeatedly emphasized that both patent law and antitrust law seek to maximize consumer welfare. Allowing non-cash global patent settlements is necessary to advance this goal. Yet Plaintiffs request that this Court subject those settlements to expensive antitrust scrutiny. This may benefit attorneys' bank accounts. But it does not help consumers. Permitting settlement agreements like those executed by Appellees does, however, promote consumer welfare. They should thus be encouraged—not condemned.

III. IMPOSING SECTION 2 LIABILITY HERE WOULD DISCOURAGE INNOVATION.

The District Court persuasively explained why Plaintiffs' Section 2 claim fails as a matter of law. (S.A. 18-35.) But it also fails as a matter of common sense and policy. Adopting Plaintiffs' novel theory of Section 2 liability would stifle innovation.

Plaintiffs' claim that AbbVie's applying for patents, defending those patents before the PTO, and asserting them in litigation violated Section 2. They therefore ask this Court to impose antitrust liability on a patentee for advancing objectively reasonable legal positions. Under that proposed rule, any patent holder that fails to prevail in 100% of proceedings could face antitrust liability.

If this Court adopts Plaintiffs' rule, companies would seek fewer patents. They would fear that, if a patent application were rejected or a court later invalidated the patent, they could be held liable under Section 2. So companies would discount the value of any patent they could obtain by this risk. In some cases, this discounting would make the expected value of applying for the patent negative.

Companies would make these calculations before developing products. This would mean fewer useful inventions given the potential for enormous antitrust liability. In short, Plaintiffs want to stifle innovation by imposing antitrust liability on companies for objectively reasonable behavior. This Court should reject that extreme view of Section 2 and affirm the District Court's order.

CONCLUSION

This Court should affirm.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limits of Seventh Circuit Rule 29 because it contains 5,453 words, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f).

I also certify that this brief complies with the typeface and type-style requirements of Seventh Circuit Rule 32(b) and Federal Rule of Appellate Procedure 32(a)(6) because it uses 14-point Century Schoolbook font.

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