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No. 22-5137

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

FEDERAL TRADE COMMISSION,
Plaintiff-Appellant,

v.

ENDO PHARMACEUTICALS INC., ET AL.,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of Columbia
No. 1:21-cv-217
Hon. Royce C. Lamberth

BRIEF OF THE FEDERAL TRADE COMMISSION

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

1. Parties

The Federal Trade Commission was the plaintiff before the district court and appears as appellant before this Court.

Endo Pharmaceuticals Inc., Endo International plc, Impax Laboratories, LLC, and Amneal Pharmaceuticals, Inc. were the defendants before the district court and appear as appellees before this Court.

2. Ruling Under Review

The ruling under review consists of the memorandum opinion and the associated order entered by the district court on March 24, 2022. ECF 84 (under seal) [JA___] and ECF 75 [JA___], respectively. The district court entered a public version of the memorandum opinion on March 30, 2022. ECF 84 [JA___].

3. Related Cases

No related cases are pending before this Court or any other court.

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GLOSSARY

ANDA	Abbreviated New Drug Application
ECF	ECF entry in proceeding below, *FTC v. Endo Pharmaceuticals Inc., et al.*, No. 1:21-cv-217 (D.D.C.)
Endo	Endo Pharmaceuticals Inc. and Endo International plc
ER	Extended Release
FDA	Food and Drug Administration
FTC	Federal Trade Commission
Impax	Impax Laboratories, LLC and Amneal Pharmaceuticals, Inc.
JA	Joint Appendix

INTRODUCTION

The Federal Trade Commission has charged Endo Pharmaceuticals and Impax Laboratories with conspiring to maintain and share the profits from a monopoly on the highly lucrative drug oxymorphone ER, an extended-release opioid on which Endo holds patents. Impax challenged some of those patents, and in 2010 the companies settled the dispute with Endo granting Impax a license to the disputed patent plus any others covering oxymorphone ER that Endo might acquire in the future. Endo later stopped selling oxymorphone ER after a failed attempt to monopolize the market, leaving Impax as the sole seller of the drug; other companies cannot enter the market by virtue of Endo's patents. Since then, Impax has raised prices and enjoys large monopoly profits.

This case involves a 2017 agreement between Endo and Impax settling a dispute over royalties payable under the 2010 license. Endo promised Impax not to compete in the market for oxymorphone ER; in exchange, Impax agreed to split the monopoly profits with Endo [redacted]. The agreement was executed under the guise of a "license" for the drug, but that was simply a cover for the agreement not to compete. In reality, the 2010 license already granted the ability to sell oxymorphone without any risk of infringing Endo's patents for oxymorphone ER. The FTC thus charged the companies with having entered an unlawful agreement to restrain trade and maintain a monopoly.

In the ruling on review, the district court dismissed the FTC's complaint for failure to state a claim. The court characterized Endo and Impax's agreement not to compete as an ordinary exclusive license consistent with Endo's rights as a patent holder. In reaching that determination, the court ignored the complaint's allegations that the 2010 license was unnecessary and little more than pretext because Impax already had a "broad patent license" giving it the right to sell oxymorphone ER "risk-free" under the 2010 license. That pre-existing right necessarily means that the later agreement not to compete cannot be characterized as falling within Endo's patent-based right to exclude.

The district court's ruling was error and this Court should reverse. The district court was required to accept as true the complaint's factual allegations that Impax already had a right to sell oxymorphone ER before it agreed to split the profits with Endo, but the court failed to credit those allegations. That threshold error led the court to overlook substantial allegations that the agreement not to compete had anticompetitive intent and effects. This Court should hold that the complaint plausibly alleged that the 2017 agreement is beyond the scope of Endo's patent rights to exclude Impax and therefore states a claim that the agreement is anticompetitive and unlawful.

JURISDICTION

The FTC filed the underlying action in the United States District Court for the District of Columbia seeking injunctive relief for violations of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. The district court had jurisdiction under 28 U.S.C. §§ 1331, 1337(a), and 1345. The district court dismissed the FTC's complaint on March 24, 2022, and the FTC timely appealed on May 19, 2022. This Court has jurisdiction under 28 U.S.C. § 1291.

The Court's October 24, 2022, Order directed the parties to address "whether the court has jurisdiction over this appeal notwithstanding appellee Endo International PLC's filing of a petition for bankruptcy. *See* 11 U.S.C. §§ 362(a)(1), (b)(4)." We address that question in Section I of the Argument.

QUESTIONS PRESENTED

1. Whether this Court has jurisdiction over this appeal notwithstanding appellee Endo International's petition for bankruptcy.

2. Whether the FTC's complaint plausibly alleged that Impax paid Endo not to compete and that their agreement had, and was intended to have, anticompetitive effects.

3. Whether the district court improperly ignored the complaint's allegations, including that Impax already had a license to Endo's patents for

oxymorphone ER, in determining that Endo could lawfully agree not to compete in exchange for a share of Impax's monopoly profits.

STATEMENT OF THE CASE

Because the district court dismissed the complaint for failure to state a claim, the Court must accept as true the FTC's allegations of fact, from which this background is drawn.

A. Endo and Impax's First Unlawful Agreement to Monopolize the Market for Oxymorphone ER.

In 2006, Endo launched the branded pharmaceutical product Opana ER, an extended-release form of the opioid oxymorphone. ECF 3, ¶¶ 17, 20 [JA___].[1] The drug is approved by the Food and Drug Administration for "relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time." *Id.*, ¶ 18 [JA___]. Oxymorphone itself is not a patented drug, but Endo's extended-release formulation was covered by patents. Opana ER quickly became lucrative, reaching annual sales of over $300 million by 2011. *Id.*, ¶ 20 [JA___].

[1] The nonpublic version of this brief cites to the sealed, unredacted Complaint, which is ECF 2. The public version of this brief cites to the unsealed, redacted Complaint, which is ECF 3 and identical to ECF 2 except for the redactions.

The success of Opana ER prompted generic drug makers—including Impax[2]— to seek approval for competing generics. *Id.*, ¶¶ 23-24 [JA___]. By November 2007, Impax had filed an Abbreviated New Drug Application (ANDA) for oxymorphone ER with the FDA. *Id.*, ¶ 24.[3] The application certified that Endo's patents covering Opana ER were invalid, unenforceable, or would not be infringed by Impax's product. *Id.*, ¶¶ 25-26 [JA___].

Upon receiving Impax's ANDA certification, Endo sued Impax for patent infringement.[4] *Id.*, ¶¶ 26-27 [JA___]. In June 2010, Endo and Impax settled the litigation by agreeing that Impax would drop its challenge to Endo's patent and refrain from launching generic oxymorphone ER until January 2013, and Endo, in

[2] Impax is wholly owned by Amneal Pharmaceuticals LLC. ECF 3, ¶ 16 [JA___].

[3] A company seeking to market a new branded drug must submit a New Drug Application (NDA) showing that the drug is safe and effective. 21 U.S.C. § 355(a), (b)(1). Generic competitors may submit an Abbreviated NDA for streamlined regulatory approval upon a showing that the generic product is "bioequivalent" to the brand-name drug. 21 U.S.C. § 355(j).

[4] Impax's certification that its product would not infringe Endo's patents, known as a "Paragraph IV" certification, 21 U.S.C. § 355(b)(2)(A)(iv), (j)(2)(A)(vii)(IV), is deemed by statute to be an act of infringement that entitled Endo to sue immediately. 35 U.S.C. § 271(e)(2).

exchange, would make a large payment to Impax.[5] *Id.*, ¶ 28-29 [JA___], *Impax Labs., Inc. v. FTC*, 994 F.3d 484, 490 (5th Cir. 2021). Under the settlement agreement (the "2010 License"), Endo also granted Impax a "broad patent license" covering not only the patents directly at issue in the litigation but also any patents Endo might obtain in the future covering Opana ER. ECF 3, ¶ 29 [JA___]. The settlement thus involved Endo, the patent holder, paying Impax, the alleged infringer, to give up its patent challenge and stay out of the market. This kind of "reverse-payment" settlement can violate antitrust law if the payment is large, not otherwise explained, and "seeks to prevent the risk of competition." *See FTC v. Actavis, Inc.*, 570 U.S. 136, 157 (2013).

The FTC subsequently sued Endo and Impax alleging that the 2010 License was unlawful under *Actavis*. *Impax Labs., Inc.*, 994 F.3d at 491. Endo settled with the FTC, and the case against Impax ultimately proceeded in administrative adjudication. *Id.* Notably for purpose of the current case, Impax defended the 2010 License as having consumer benefits that outweighed the anticompetitive harm

[5] The payment had two components. First, Endo promised not to market its own authorized generic version of oxymorphone ER during the first 180 days after Impax entered the market. *See Impax Laboratories, Inc.*, 994 F.3d at 490. Such "no-AG" promises are valuable to companies like Impax that are the first to market a generic version of a branded drug. *See King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 404-05 (3d Cir. 2015). Second, Endo promised to reimburse Impax for lost sales resulting from Endo's introduction of a reformulated version of Opana ER. *See Impax Labs., Inc.*, 994 F.3d at 490.

from the reverse payment. ECF 3, ¶ 30 [JA___]; *In re Impax Labs., Inc.*, No. 9373, 2019 WL 1552939, at *30 (FTC Mar. 28, 2019).[6] The benefit, Impax argued, was the "broad patent license" that protected it "not just against the patents that were in suit at the time but against later acquired patents, at least as to Opana ER" which enabled the company to sell oxymorphone ER to the benefit of consumers. ECF 3, ¶ 30 [JA___]. Endo made similar arguments in other litigation, stating that the 2010 License gave Impax the "freedom to operate under future Endo patents covering Opana ER," which enabled "Impax [to] launch risk-free years before" the last Opana ER patent expires. *Id.*, [JA___].

The Commission ultimately found that the 2010 License was unlawful. *Impax Labs., Inc.*, 994 F.3d at 491. On appeal, the Fifth Circuit affirmed, holding that "the reverse payment settlement was an agreement to preserve and split monopoly profits" and, "[a]s a result, Impax agreed to an unreasonable restraint of trade." *See Impax Labs., Inc.*, 994 F.3d at 500.[7] Endo, the brand manufacturer, shared its monopoly profits with Impax, a would-be generic competitor, to induce Impax to drop its patent challenge. *Id.* at 494. The deal eliminated competition without sufficient justification. *Id.* at 495.

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[6] Endo's settlements with nine other generic oxymorphone ER filers did not include a similar broad license. ECF 3, ¶¶ 32, 36-37 [JA___].

[7] The Fifth Circuit ruled in April 2021, after the FTC filed its Complaint in this matter.

B. Endo's Continuing Attempts to Thwart Generic Entry and Impax's Emergence as the Sole Seller of Oxymorphone ER.

The 2010 License was just one part of Endo's strategy to preserve and extend its Opana ER monopoly. As described below, Endo's other monopolization attempt failed, leading to a role reversal that left Impax as the oxymorphone ER monopolist that ultimately paid Endo not to compete.

First, even before the 2010 License, Endo planned to thwart generic competition through a strategy known as a "product hop." Under this plan, Endo would introduce a new, reformulated version of Opana ER and remove the original product from the market, expecting to shift users to the new product, which did not face generic competition. The strategy would impede generic competition by subverting the automatic substitution of generic-for-brand drugs encouraged by most states and health plans. *See*, *e.g.*, *State of New York v. Actavis PLC*, 787 F.3d 638, 652-59 (2d Cir. 2015). Automatic substitution applies only to therapeutically equivalent products, so Reformulated Opana ER would defeat the substitution mechanism. ECF 3, ¶¶ 57-60 [JA___]; *see also Impax*, 994 F.3d at 489-90.

Product hops take time because the monopolist must develop and obtain approval for the new product and transfer existing patients from the old product to the new one. The 2010 License agreement bought Endo that time, as Impax agreed to stay off the market for nearly three years. *See Impax*, 994 F.3d at 490. Shortly after agreeing to the 2010 License, Endo applied for FDA approval of

Reformulated Opana ER, which FDA granted in December 2011. ECF 3, ¶ 59 [JA___]. Endo launched Reformulated Opana ER in March 2012, stopped selling Original Opana ER two months later, and had transitioned new prescriptions to the reformulated product by June 2012. *Id.*, ¶ 60 [JA___]. Endo then sought to force existing patients to switch to Reformulated Opana ER by asking the FDA to declare that original Opana ER was unsafe, to reject pending ANDAs for generic versions of the drug, and to withdraw already granted approvals. *Id.*, ¶ 61 [JA___].

The plan backfired. The FDA declined to declare original Opana ER unsafe and determined that Endo had not discontinued the product for safety reasons. *Id.*, ¶ 62 [JA___]. To the contrary, the FDA cited concerns that *Reformulated* Opana ER was dangerous. *Id.*, ¶ 62 [JA___]; *see also* ¶¶ 65-68 [JA___]. The evidence confirmed the FDA's concerns, *id.*, ¶ 63 [JA___], and in June 2017, the FDA asked Endo to remove the drug from the market, which Endo did in September 2017. *Id.*, ¶¶ 69-70 [JA___].

In the meantime, Endo kept other generic competitors out of the market by enforcing its patents on the drug. From 2012 to 2014, Endo developed or acquired the rights to several additional patents related to Opana ER (hereafter the "Future Patents" (*see id.*, ¶ 48 [JA___]), which it later asserted against generic manufacturers that had entered or were preparing to enter the market. *Id.*, ¶¶ 32-37; 44-49 [JA___]. Endo obtained injunctions against these companies for violating

the Future Patents, forcing them from the market. *Id.*, ¶¶ 50-53 [JA___]. Endo could not assert the Future Patents against Impax, however, because the 2010 License gave Impax the right to use any patents Opana for ER arising in the future. *Id.*, ¶¶ 29, 49 [JA___].

The upshot of the failed product hop combined with the exclusionary effect of the Future Patents is that Impax is now the monopoly seller of oxymorphone ER, and Endo is its only possible competitor until the Future Patents expire in November 2029. *Id.*, ¶ 56 [JA___].

C. Endo and Impax's Second Agreement to Monopolize the Market for Oxymorphone ER.

In 2017, anticipating the withdrawal of Reformulated Opana ER, Endo began exploring ways to preserve the Opana ER revenue stream. The company estimated that market withdrawal would cost $85 million in lost earnings in the first year alone. ECF 3, ¶ 72 [JA___]. After considering several possible options, *id.*, ¶¶ 73-74 [JA___], Endo prepared to launch a generic version of original oxymorphone ER. *Id.*, ¶ 75 [JA___].

In April 2017, Endo formed an internal strategy group to work on the relaunch. *Id.*, ¶ 76 [JA___]. The next month, Endo made manufacturing arrangements at a factory in New York. *Id.*, ¶ 77 [JA___]. One high-level Endo senior manager told her team, "Let's take this forward at full speed." *Id.*, [JA___]. Endo sought permission from the U.S. Drug Enforcement Agency to acquire

enough raw opiates to support a full-scale launch and the CEO then approved a $300,000 purchase order. *Id.*, ¶¶ 80, 81 [JA___]. Endo forecasted that it would relaunch original oxymorphone ER in the second quarter of 2018. *Id.*, ¶ 82 [JA___].

At the same time, Endo was once again engaged in litigation with Impax—this time over the 2010 License. The companies' agreement required that they negotiate in good faith "an amendment to the terms" of the license in the event that future patents issued. *Id.*, ¶¶ 29-30, 85 [JA___]. In 2015, several years after obtaining the Future Patents, Endo invoked this clause to demand that Impax pay an 85% royalty, and it sued for breach of contract when Impax refused. *Id.*, ¶¶ 85-86 [JA___]. The lawsuit concerned only royalties and damages; Endo did not ask the court to enjoin Impax from selling oxymorphone ER or to terminate the 2010 License. *Id.*, ¶¶ 86-87 [JA___].

As the case progressed, Endo considered a new strategy: instead of competing against Impax by selling its own product, Endo proposed an agreement to share Impax's monopoly profits. *Id.*, ¶¶ 83, 90-91, 94 [JA___]. By July 2017, the profit-sharing plan had become Endo's primary strategy for monetizing the Opana ER franchise, with selling its own product relegated to "plan B." *Id.*, ¶ 91 [JA___].

In August 2017, Endo and Impax settled the breach of contract dispute by entering a profit-sharing agreement—the "2017 Agreement." *Id.*, ¶¶ 92-97 [JA___]. Under the 2017 Agreement, Impax promised to pay Endo [redacted]% of the gross oxymorphone ER profits. *Id.*, ¶¶ 94-95 [JA___]. Endo, in turn, promised to stay out of the market and [redacted], thereby ensuring Impax's continued enjoyment of monopoly prices. Impax may cease paying royalties if any of the following three events occur:

1. Endo sells an oxymorphone ER product (including a new reformulated version);
2. [redacted]; or
3. [redacted]

Id., ¶¶ 94-95 [JA___]. The 2017 Agreement further obligates Endo to [redacted] split with Impax any damages Endo recovers from a patent suit against an at-risk entrant. *Id.*, ¶ 97 [JA___].

The effect of the 2017 Agreement is that Impax, an effective monopolist charging monopoly prices, shares its profits with Endo on the condition that Endo not compete in the oxymorphone ER market. *Id.*, ¶¶ 99-108 [JA___]. By staying off the market and splitting Impax's monopoly profits, Endo can expect to earn more than it would by competing in a duopoly market. *Id.*, ¶¶ 104-107. Because it now retains a monopoly, Impax also earns more from [redacted]% of its monopoly profits

than from all of the profits it would earn in a competitive market. *Id.*, [JA___]. Since entering the agreement, Endo has not launched or licensed a competing product, and Impax remains the only seller of oxymorphone ER. *Id.*, ¶ 117.

D. Consumer Harm from Endo's and Impax's Oxymorphone ER Monopoly Maintenance.

Impax and Endo greatly benefit from their deal, but consumers bear the costs in the form of higher prices. Generic drug competition lowers prices for consumers. The first generic to enter the market is typically priced 10 to 25 percent lower than the brand-name drug, and if there is subsequent generic entry, prices can drop by as much as 80 percent below the original price. *See Impax*, 994 F.3d at 488.

This beneficial price competition in fact occurred in the market for oxymorphone ER. When Impax entered in January 2013, its price for a 40 mg tablet of generic oxymorphone was 33% less than Endo's. ECF 3, ¶¶ 31, 41 [JA___]. When another competitor entered nine months later (it was subsequently enjoined from further sales under the Future Patents), the average price fell another 19%. *Id.*, ¶¶ 38, 41. Consumers directly reaped the benefits.

These pricing trends reversed, however, after Impax became a monopolist. Since then, the price of a 40 mg tablet of oxymorphone ER has skyrocketed approximately [redacted]%. *Id.*, ¶¶ 104, 106, 117 [JA___]. Impax and Endo both enjoy the monopoly windfall but consumers will foot the bill until at least 2029.

E. The FTC's Complaint and the District Court's Dismissal.

In January 2021, the FTC sued to permanently enjoin Endo and Impax from continuing their monopoly profit-splitting arrangement. The Complaint alleged that, after Endo withdrew Reformulated Opana ER from the market, it planned to reintroduce its own oxymorphone ER product to compete with Impax, which already had a right to be on the market under the 2010 License. Instead of competing, however, Endo agreed to stay out of the market in exchange for [redacted]% of Impax's monopoly profits. Count I of the Complaint charges that the 2017 Agreement restrains trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, and in turn violates the prohibition on unfair methods of competition contained in Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). ECF 3, ¶¶ 119-120 [JA___]. Count II of the Complaint alleges that Impax has monopoly power and has engaged in exclusionary conduct through its unlawful agreement with Endo in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). ECF 3, ¶¶ 121-124 [JA___].

Endo and Impax filed motions to dismiss, which the district court granted in the order on review.[8] ECF 84 [JA___]; ECF 75 [___]. The court characterized the

[8] Endo's Irish corporate parent, Endo International plc, filed a separate motion to dismiss arguing that the district court did not have personal jurisdiction over it. Although the court dismissed the case, it did not address the jurisdictional argument. ECF 84 at 23 [JA___].

2017 Agreement as an ordinary exclusive patent license that fell within Endo's rights under the patent laws. "Activities specifically authorized by the patent laws," the court said, "do not violate antitrust law unless they threaten areas of competition 'other than those protected by the patent.'" ECF 84 at 14 (quoting *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1129 (D.C. Cir. 1981)) [JA___].[9]

The district court also invoked six "considerations" that it purported to derive from *Actavis*. ECF 84 at 14 [JA___]. These were: "whether the patent's validity is in question," *id.* at 15 [JA___]; "whether the patent statute specifically gives a right to restrain competition in the manner challenged," *id.* at 16 [JA___]; "whether competition is impeded to a greater degree by the restraint at issue than by other restraints previously approved as reasonable," *id.* at 17 [JA___]; "whether the patent licensing agreement is overly restrictive," *id.* at 20 [JA___]; "whether the patent holder dominated the industry and curtailed the manufacture and supply of an unpatented product," *id.* [JA___].; and "whether the settlement is traditional in form," *id.* [JA___]. Based on these considerations—but with little discussion of the Complaint's allegations—the court concluded that Endo, as the holder of a

[9] The nonpublic version of this brief cites to the district court's sealed, unredacted Memorandum Opinion, which is ECF 74. The public version of this brief cites to the unsealed, redacted Memorandum Opinion, which is ECF 84 and identical to ECF 74 except for the redactions.

valid patent, had a statutory right to exclude Impax and maintain a patent monopoly while charging supracompetitive prices. *Id.* at 21 [JA___]. That right, the court concluded, in turn permitted Endo to grant Impax an exclusive license to do the same. Thus, according to the court, neither the 2017 Agreement nor Impax's monopoly violates the antitrust laws. *Id.* [JA___].

The court disagreed with the FTC that the 2017 Agreement was anticompetitive because under the 2010 License Endo had already granted Impax the ability to compete, free from any patent risk. *Id.* at 21-22 [JA___]. The court compared the companies to joint patentees, who have no right to exclude one another, yet one of them may grant the other an exclusive license. *Id.* at 22 (citing *Rail-Trailer Co. v. ACF Indus., Inc.*, 358 F.2d 15, 16 (7th Cir. 1966)) [JA___]. Moreover, in the court's view, the Complaint did not allege that Endo waived its right to exclude, so the court did not have to accept any such allegation as true. *Id.* at 23 [JA___]. The court reasoned that even if the 2010 Agreement gave Impax a right to compete free from patent risk by waiving Endo's right to exclude, Impax's alleged breach of contract meant that at the time of the 2017 Agreement, Endo could exclude Impax. *Id.* at 22 [JA___].

SUMMARY OF ARGUMENT

Endo and Impax have tried for over a decade and in multiple ways to wring monopoly profits from oxymorphone ER out of the pockets of consumers. Their

first attempt—Endo's paying Impax to drop its patent challenge and delay selling a generic drug—was declared illegal by the FTC and the Fifth Circuit. The second attempt—Endo's product hop—failed, and left Endo in the strange position of its only competitor holding a monopoly on Endo's own product. This case presents a third attempt, no less brazen and no more lawful than the first—a straightforward payment not to compete from a monopolist to its only possible competitor, leaving them both better off by sharing the monopoly profits than either would be in a competitive market. Endo and Impax's market positions may be unusual, but the principles of antitrust law that apply here are not. Companies with independent rights to sell a product may not agree to forgo competition in favor of prolonging monopoly prices. Whatever rights Endo's patent may have conveyed, they do not include the right to conspire with its only possible competitor, whose product it cannot exclude using its patent, to maintain the competitor's monopoly.

1. Endo's pending bankruptcy petition does not divest this Court of jurisdiction. Governmental actions enforcing police and regulatory power—of which this case is clearly one—are excepted from the Bankruptcy Code's automatic stay provision, 11 U.S.C. § 362(b)(4). The FTC seeks to enforce antitrust law against an allegedly anticompetitive agreement. The case does not seek to advance any governmental pecuniary interest.

2. On the merits, the Court should reverse the district court's dismissal of the FTC's Complaint. The Complaint alleged that Impax has the right under the 2010 License to be on the market and holds a monopoly over oxymorphone ER that it maintains by splitting its monopoly profits with its only possible competitor in exchange for Endo's agreement not to compete or [redacted] The Complaint further alleged that this agreement has serious and intentional anticompetitive effects, including giving Impax the ability to raise prices, which it has done. The 2017 Agreement is an unlawful restraint of trade and unlawful monopoly maintenance, as alleged in the Complaint.

The district court erred when it characterized the 2017 Agreement as an exclusive license that fell within the scope of Endo's patent rights to grant. The Complaint alleged as fact—which the district court was bound to accept as true—that at the time Endo and Impax negotiated the 2017 Agreement, Endo's patent did not allow it to exclude Impax because Impax already had a license granting it the right to be on the market as a freestanding competitor. Impax did not need a license from Endo; after the 2010 License, Impax was in the same position as a competitor whose product had been determined not to infringe the patent. Those factual allegations support the reasonable inference that the profit-splitting deal with Endo was nothing more than pretext for a straightforward payoff not to compete. Endo and Impax may have called the 2017 Agreement a "license," but it was one in

name only, not in substance. The patent laws gave Endo no right to agree with its rival to forgo competition in that situation.

Styling the 2017 Agreement as an exclusive patent license does not shield it from antitrust scrutiny in any event. The Supreme Court has held repeatedly that the exercise of patent rights can subject the patent holders to antitrust scrutiny. A court assessing antitrust claims like those involved here must therefore consider whether a patent license has anticompetitive effects and was entered for the purpose of restraining trade. The district court skipped that analysis, improperly excusing Endo's exercise of patent rights (if those rights are even implicated here) from any antitrust scrutiny.

STANDARD OF REVIEW

This Court reviews the district court's decision to dismiss *de novo*. *Farrar v. Nelson*, 2 F.4th 986, 988 (D.C. Cir. 2021). The Court "treat[s] the complaint's factual allegations as true and grant[s] plaintiff the benefit of all inferences that can be derived from the facts alleged." *Ralls Corp. v. Comm. on Foreign Inv. in U.S.*, 758 F.3d 296, 314-15 (D.C. Cir. 2014) (cleaned up). "So long as the pleadings suggest a plausible scenario to show that the pleader is entitled to relief, a court may not dismiss." *Id.*, at 315 (cleaned up).

ARGUMENT

The Court should reverse the district court's dismissal of the FTC's Complaint. The Complaint plausibly alleged that Endo's patents did not allow it to exclude Impax from the market for oxymorphone ER. Because of that right, the Complaint also plausibly alleged that Endo's promise not to compete against Impax in exchange for a [redacted]% share of Impax's monopoly profits is a non-compete agreement, not an exclusive license as the district court concluded. Impax's right to be on the market distinguishes the 2017 Agreement from the kind of patent licenses, exclusive or otherwise, that courts have previously permitted. Further, the 2017 Agreement has serious anticompetitive effects, including allowing Impax to dramatically raise the price for oxymorphone ER. Consumers have paid dearly as a result. The district court's failure to accept the Complaint's allegations as true led it to erroneously dismiss the Complaint. On remand, the FTC should be allowed to make its case.

I. THE COURT HAS JURISDICTION OVER THIS APPEAL.

On August 16, 2022, Endo International plc, Endo Pharmaceuticals, and affiliated companies filed voluntary petitions for relief under title 11 of the Bankruptcy Code in United States Bankruptcy Court for the Southern District of New York. *See In re Endo Int'l plc, et al.*, No. 22-22549-JLG (Bankr. S.D.N.Y.). The Court has directed the parties to address "whether the Court has jurisdiction

over this appeal notwithstanding appellee Endo International PLC's filing of a petition for bankruptcy. *See* 11 U.S.C. §§ 362(a)(1), (b)(4)." Order, Document #1970176 (D.C. Cir. No. 22-5137 Oct. 24, 2022).

Endo's bankruptcy petition does not divest this Court of jurisdiction. First, the Court has jurisdiction to determine whether the stay exception applies to this appeal. *See Paine Webber Jackson & Curtis, Inc. v. Baldwin-United Corp.*, 765 F.2d 343, 347 (2d Cir. 1985); *NLRB v. Edward Cooper Painting, Inc.*, 804 F.2d 934, 939 (6th Cir. 1986). "The court in which the litigation claimed to be stayed is pending has jurisdiction to determine not only its own jurisdiction but also the more precise question whether the proceeding pending before it is subject to the automatic stay." *Baldwin-United Corp.*, 765 F.2d at 347.

Second, Section 362(a) of the Bankruptcy Code provides, in relevant part, that the filing of a bankruptcy petition operates as a stay of "the commencement or continuation … of a judicial, administrative or other action or proceeding against the debtor that was or could have been commenced before the [filing of the petition]." 11 U.S.C. § 362(a)(1). This automatic stay provision is designed to centralize in the bankruptcy court all disputes concerning property of the debtor's estate, prevent dissipation of assets, and provide for an orderly distribution to the debtor's creditors. *See SEC v. Brennan*, 230 F.3d 65, 70 (2d Cir. 2000).

The automatic stay provision contains an exception for the "commencement or continuation" of an action "by a governmental unit … to enforce such governmental unit's or organization's police and regulatory power." 11 U.S.C. § 362(b)(4). The "purpose of this exception is to prevent a debtor from frustrating necessary governmental functions by seeking refuge in bankruptcy court." *Brennan*, 230 F.3d at 71 (cleaned up); *see also CFTC v. Co Petro Mktg. Gp.*, 700 F.2d 1279, 1283 (9th Cir. 1983) (purpose "is to prevent the bankruptcy court from becoming a haven for wrongdoers"). As Congress explained, "where a governmental unit is suing a debtor to prevent or stop violation of fraud, environmental protection, consumer protection, safety, or similar policy or regulatory laws, … the action or proceeding is not stayed under the automatic stay." H.R. Rep. No. 95-595 at 343 (1978), reprinted in 1978 U.S.C.C.A.N. 5963, 6299; S. Rep. No. 95-989 at 52 (1978), reprinted in 1978 U.S.C.C.A.N. 5787, 5838 (same). The exception evidences Congress's "intent that a governmental unit's policy or regulatory action not be litigated in federal bankruptcy court." *City & County of San Francisco v. PG&E Corp., et al.*, 433 F.3d 1115, 1127 (9th Cir. 2006).

This case falls squarely within the governmental unit exception to the automatic stay. The exception applies when the government's action is one to promote public safety, welfare, or public policy, but not when the case is meant to

protect "the government's pecuniary interest in the debtor's property." *Safety-Kleen, Inc., (Pinewood) v. Wyche*, 274 F.3d 846, 865 (4th Cir. 2001); *see also Universal Life Church, Inc. v. U.S.*, 128 F.3d 1294, 1297 (9th Cir. 1997). The FTC's proceeding against Endo is aimed at enforcing the FTC's "police and regulatory power" under the FTC Act. 15 U.S.C. §§ 41, *et seq.* Specifically, the FTC is enforcing the FTC Act's prohibition on unfair methods of competition; it does not seek to advance any governmental pecuniary interest in Endo's assets. The Complaint seeks only to enjoin Endo and Impax from continuing an allegedly unlawful agreement and from engaging in similar conduct in the future.[10]

Although this Court has not addressed the issue, others have made clear that the "automatic stay does not prevent the commencement or continuation of an action by a governing unit such as the FTC to enforce its police or regulatory power." *FTC v. Commerce Planet, Inc.*, 815 F.3d 593, 597 n.1 (9th Cir. 2016); *see also Chao v. Hosp. Staffing Servs., Inc.*, 270 F.3d 374, 383 (2d Cir. 2011); *FTC v. Consumer Health Benefits Ass'n*, No. 10-cv-3551, 2011 WL 2341097 at *1-2

[10] The FTC's Complaint originally sought equitable monetary relief, but that relief is no longer available after the Supreme Court's ruling in *AMG Capital Mgmt., LLC v. FTC*, 141 S. Ct. 1341, 1347 (2021). Even if the FTC could seek monetary relief, however, the governmental unit exception would still apply because the "governmental unit exception of § 362(b)(4) permits the *entry* of a money judgment so long as the proceeding in which such a judgment is entered is one to enforce the governmental unit's police or regulatory power." *See Brennan*, 230 F.3d at 71 (emphasis in original).

(E.D.N.Y. Jun. 8, 2011); *FTC v. Holiday Enters., Inc.*, No. 1:06-cv-2939, 2008 WL 953358, at *12 (N.D. Ga. Feb. 5, 2008); *FTC v. AmeriDebt, Inc.*, 343 F. Supp. 2d 451, 458-59 (D. Md. 2004); *In re First Alliance Mortg. Co.*, 264 B.R. 634 (C.D. Cal. 2001); *FTC v. U.S. Rarities, Inc.*, No. 92-363-CIV, 1992 WL 696965 (S.D. Fla. Feb. 24, 1992); *FTC v. R.A. Walker & Assocs., Inc.*, 37 B.R. 608, 610 (D.D.C. 1983).

More generally, the governmental unit exception applies to enforcement actions that seek to vindicate a range of governmental public policies and interests. For example, in *Lockyer v. Mirant Corp.*, 398 F.3d 1098, 1107-09 (9th Cir. 2005), the court held that the exception applied to a state attorney general's antitrust action seeking divestiture of power plants to protect consumers from supra-competitive electricity rates. In *Parkview Adventist Medical v. U.S.*, 842 F.3d 757, 764 (1st Cir. 2016), the court held the exception applied to an HHS suit to terminate a hospital's Medicare contract to protect the public interest in preserving Medicare program money. In *EEOC v. Rath Packing Co.*, 787 F.2d 318, 325 (8th Cir. 1986), the court held the exception applied to an EEOC suit seeking to vindicate the public interest in preventing employment discrimination. In *Commonwealth Oil Refin. Co., Inc. v. EPA*, 805 F.2d 1175, 1183 (5th. Cir. 1986), the court held the exception applied to an EPA suit to enforce environmental protection laws. And in *U.S. International Trade Commission v. Jaffe*, 433 B.R.

538, 545-47 (E.D. Va. 2010), the court held the exception applied to an ITC proceeding seeking to enjoin the importation of goods that infringed on U.S. patents and protecting the public interest in competition.

Finally, Endo's litigation expenses do not make the exception inapplicable. "Congress by excepting certain actions from the automatic stay provision recognized that the debtor would likely incur litigation expenses as a result of any excepted lawsuit." *Rath Packing Co.*, 767 F.2d at 325 (cleaned up).

II. THE COMPLAINT PLAUSIBLY ALLEGED AN UNLAWFUL AGREEMENT NOT TO COMPETE.

To state a prima facie case of collusive conduct under the rule of reason, the FTC had only to plausibly allege that Endo and Impax have market power and that their agreement has "the potential for genuine adverse effects on competition." *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460 (1986); *see also Impax Labs., Inc.*, 994 F.3d at 492-93.[11] This rule applies equally to agreements involving patent rights. *Actavis*, 570 U.S. at 159-60. Indeed, antitrust law condemns patent licenses, exclusive or otherwise, used as part of a scheme to restrain trade. *See United States*

[11] We address anticompetitive effects and intent in this brief. Endo and Impax did not challenge the Complaint's allegations that Impax possessed sufficient market power to harm competition nor did the district court address those allegations. In any event, the Complaint plausibly alleged that Impax, as the only seller of oxymorphone ER, possessed sufficient market power when it entered into the 2017 Agreement with Endo. ECF 3, ¶¶ 98, 110-111, 117 [JA___].

v. New Wrinkle, Inc., 342 U.S. 371, 378 (1952); *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 407 (3d Cir. 2015).

A. The Complaint Plausibly Alleged Harm to Competition.

The Complaint alleged the kinds of effects that courts have found anticompetitive, charging that the 2017 Agreement boiled down to Impax paying Endo not to compete, with significant anticompetitive harm. Indeed, "paying a potential competitor not to compete is so detrimental to competition that normally it is a *per se* violation of the antitrust laws." *Impax Labs.*, 994 F.3d at 493. Even if "the grant of an exclusive license is not a *per se* violation of the antitrust laws, it may be an instrument by which an unlawful restraint or monopoly is created." *Benger Labs. Ltd. v. R.K. Laros Co.*, 209 F. Supp. 639, 648 (E.D. Pa. 1962); *see also King Drug Co.*, 791 F.3d at 407.

First, the Complaint alleged that Endo and Impax are potential (and formerly actual) competitors. Endo developed Opana ER and sold the original or reformulated version from 2006 to 2017; Impax has sold generic oxymorphone ER since 2013. ECF 3, ¶¶ 20-21, 31, 58-59, 70, 117-118 [JA___]. After Endo withdrew Reformulated Opana ER, it planned to launch a competing oxymorphone ER product—proceeding "full speed" in the words of its senior management. *Id.*, ¶¶ 75-82, 108 [JA___]. It formulated relaunch strategies, *id.*, ¶ 76 [JA___], prepared factory facilities, *id.*, ¶ 77 [JA___], and arranged for the purchase of raw

materials, *id.*, ¶ 80-81. Right up to the month before the 2017 Agreement, senior Endo officials forecasted launch in the second quarter of 2018, *id.*, ¶¶ 77, 81-82 [JA___]. Further, Endo had every incentive to launch. Reformulated Opana ER had been Endo's highest grossing pain management product; its withdrawal caused $85 million in lost revenue in the first year alone. *Id.*, ¶¶ 71-72 [JA___].

For its part, Impax is the only possible competitor to Endo in the market for oxymorphone ER, and Endo cannot keep Impax off the market with its patents. The Complaint alleges that in 2010 Endo settled Impax's challenge to Endo's patent by granting Impax a broad license to sell generic oxymorphone ER that applied to the challenged patents as well as any patents obtained afterwards. *Id.*, ¶¶ 28-30 [JA___]. Endo itself described the 2010 License as having given Impax "freedom to operate under future Endo patents covering Opana ER" and to "launch risk-free for years before" the last Opana ER patent expires in 2029. *Id.*, [JA___]. Until then, Impax and Endo are the *only* potential horizontal competitors for oxymorphone ER and no other company can launch an oxymorphone ER product without Endo's approval. *Id.*, ¶¶ 32-56 [JA___].

Second, the Complaint alleged that the 2017 Agreement caused the loss of price competition between Impax and Endo, costing consumers millions of dollars annually. *Id.*, ¶¶ 41, 109 [JA___]. The 2017 Agreement ensured that Impax would remain a monopoly seller of oxymorphone ER. *Id.*, ¶¶ 108-09 [JA___]. Prices

correspondingly increased by more than [redacted] percent. *Id.*, ¶ 104 [JA___]. This outcome is clearly anticompetitive. *See Ind. Fed'n of Dentists*, 476 U.S. at 459.

The Complaint's allegations strikingly resemble the agreement condemned as *per se* illegal in *Palmer v. BRG of Ga.*, 498 U.S. 46 (1990). There, the two main providers of bar review courses in Georgia—BRG and HBJ—agreed not to compete through an exclusive intellectual property license: HBJ gave BRG an exclusive license to market HBJ's materials and trade name within Georgia and withdrew from the market. *Id.* at 47. In return, BRG agreed to pay HBJ a share of its Georgia revenues and to refrain from competing outside of Georgia. *Id.* Once HBJ left the Georgia market, BRG raised the price of its bar review course. *Id.* The Supreme Court condemned the agreement because, among other reasons, "[t]he revenue-sharing formula in the 1980 agreement between BRG and HBJ, coupled with the price increase that took place immediately after the parties agreed to cease competing with each other in 1980, indicates that this agreement was formed for the purpose and with the effect of raising the price of the bar review course." *Id.* at 49 (internal quotation marks omitted). The same thing happened here. Both companies had an independent right to be in the market; neither could exclude the other. Instead of competing, however, Impax agreed to share its monopoly profits

with Endo as long as it could remain a monopolist. Impax then significantly increased its price after signing the agreement.[12]

Third, the Complaint alleged that the 2017 Agreement causes additional competitive harm through reduced innovation. Endo had previously reformulated oxymorphone ER, albeit as part of its product-hopping scheme. ECF 3, ¶¶ 57-60 [JA___]. Before entering the 2017 Agreement, Endo considered yet another reformulated version of Opana ER with a different abuse-deterring technology. *Id.*, ¶¶ 73-74 [JA___]. The incentive to innovate was snuffed out by the 2017 Agreement, under which Endo collects a stream of monopoly prices without any effort at all. Such a "threat to innovation is anticompetitive in its own right." *United States v. Anthem, Inc.*, 855 F.3d 345, 361 (D.C. Cir. 2017).

Those anticompetitive effects amply support the charged violations of Section 1 of the Sherman Act, which prohibits "restraint of trade" including agreements not to compete. 15 U.S.C. § 1. The 2017 Agreement is just such an unlawful restraint.

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[12] The district court dismissed the comparison to *Palmer* because *Palmer* involved copyright law, not patent law, ECF 84 at 19 n.9 [JA___], but that was error. In *Actavis*, the Supreme Court itself relied on *Palmer* to define the boundaries of permissible patent agreements. *Actavis*, 570 U.S. at 141. Indeed, courts addressing issues arising under the Patent Act regularly look to copyright law and vice versa. *See Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 763, 768 (2011), and *Metro-Goldwyn-Mayer Studios v. Grokster, Ltd.*, 545 U.S. 913, 934-36 (2005).

B. The Complaint Plausibly Alleged that Endo and Impax Entered the 2017 Agreement Specifically to Restrain Trade.

Beyond the anticompetitive effects, the Complaint alleged that Endo and Impax intended those effects when they entered the Agreement. ECF 3, ¶ 4 [JA___]. Such allegations can "play an important role in divining the actual nature and effect of the alleged anticompetitive conduct." *United States v. Gypsum Co.*, 438 U.S. 422, 436 n.13 (1978) (citing *Chi. Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918)). For this reason, *Actavis* instructs that the "relevant antitrust question is: What are [the] reasons" for the restraint? 570 U.S. at 158.

The Complaint alleges that the Agreement was the latest chapter in a long-running attempt to monopolize the oxymorphone ER market. The 2017 Agreement was not simply the settlement of a single lawsuit but the culmination of years of effort by Endo, often conspiring with Impax, to create and maintain a monopoly over oxymorphone ER.

Endo and Impax first succeeded in maintaining a monopoly over oxymorphone ER in 2010, keeping Impax off the market until 2013. ECF 3, ¶¶ 27-28 [JA___]. That agreement was later held illegal. *See Impax*, 994 F.3d at 494-95. Endo picked 2013 deliberately to ensure it would have time to product-hop to a new drug that faced no competition. *Id.* at 489-90. The strategy was so successful that Endo paid Impax $102 million to compensate for Impax's lost sales. *See id.* at 494.

Once Impax was left as the only seller of oxymorphone ER, and Endo its only potential competitor, the companies faced two choices: they could compete (or Endo could [redacted]), leaving both of them worse off as prices fell; or they could agree to leave Impax in place as a monopolist and split the monopoly profits, guaranteeing both companies greater earnings than either could garner in a competitive market. ECF 3, ¶¶ 104-110, 113 [JA___]. They chose the latter.

In short, the Complaint plausibly alleges that Endo and Impax entered the 2017 Agreement for the anticompetitive purpose of creating a monopoly, raising prices, and sharing the resulting profits. *Id.*, ¶ 4 [JA___].

III. THE DISTRICT COURT FUNDAMENTALLY ERRED WHEN IT IGNORED THE ALLEGATIONS OF THE COMPLAINT.

The district court considered none of the Complaint's allegations of competitive harm and intent. Instead, the court deemed the 2017 Agreement an exclusive patent license that Endo and Impax were free to enter under patent law, without regard to its anticompetitive nature. That conclusion rests on two basic errors.

First, the district court could not properly characterize the 2017 Agreement as an exclusive license within the rights granted Endo under the Patent Act. That is because the Complaint alleged that Impax had an unequivocal, risk-free license to sell oxymorphone before it entered into the 2017 Agreement and that Impax and

Endo were potential competitors. The district court ignored those allegations and should have credited the plausible inference, flowing directly from those alleged facts, that the exclusivity Impax obtained under the 2017 Agreement came from its paying Endo not to compete, not from Endo's patent rights.

Second, exclusive patent licenses are not immune from antitrust scrutiny as the district court presumed. That is especially the case where the patent holder does not have the sole right to practice the patents.

A. Because Impax Already Had a Right to Sell Oxymorphone ER, the Agreement is Functionally a Non-Compete Agreement, Not an Exclusive Patent License.

The Complaint alleged that the 2010 License gave Impax an independent right to sell oxymorphone ER and that Endo therefore could not block Impax from selling the drug. ECF 3, ¶ 29 [JA___]. Specifically, it alleges that Impax holds a "broad patent license" that protected it "not just against the patents that were in suit [in 2010] but against later acquired patents" covering Opana ER. *Id.*, ¶ 30 [JA___]. The License gave Impax the "freedom to operate under future Endo patents covering Opana ER," which enabled "Impax [to] launch risk-free years before" Endo's patents expire. *Id.*, [JA___]. In other words, Impax could be on the market without infringing Endo's patents. "[A] valid patent confers no right to exclude a product or processes that do not actually infringe." *Actavis*, 570 U.S. at 147. As this Court has explained, a patent license deprives the patentholder of a "right to

judicial relief against what, but for the license, would be an infringement." *Studiengesellschaft Kohle*, 670 F.2d at 1127; *see also In re Abbott Labs. Norvir Antitrust Litig.*, 442 F. Supp. 2d 800, 810-11 (N.D. Cal. 2006), *rev'd on other grounds, sub nom. John Doe 1 v. Abbott Labs.*, 571 F.3d 930 (9th Cir. 2009). Indeed, Endo neither asserted its later-acquired patents against Impax's oxymorphone ER product, nor did it seek to enjoin Impax from selling oxymorphone ER in the breach of contract suit. ECF 3, ¶¶ 86-87 [JA___].

The district court improperly failed to credit the factual allegations that Impax needed no permission in 2017 to sell oxymorphone ER and wrongly determined instead that the 2017 Agreement was an exclusive license protected by patent rights. The district court reached that conclusion largely through mistaken reliance on *Rail-Trailer Co. v. ACF Industries, Inc.*, 358 F.2d 15. ECF 84 a 17-18, 22 [JA___]. *Rail-Trailer Co.* involved joint patent owners who each had an independent right to exclude any other competition. 358 F.2d at 16. The joint owners had the right to practice the patent together, as lawful monopolists. Instead, one of the owners granted the other an exclusive license to the patent. Apparently experiencing grantor's remorse, the licensor-owner later sued to rescind the license on the ground that it violated antitrust law. *Id.* The Seventh Circuit rejected that claim, holding instead that the license did not unlawfully restrain trade. *Id.* at 18.

The district court read *Rail-Trailer* to hold that even when a patent holder has no right to exclude another, it may nevertheless grant an exclusive license. ECF 84 at 18, 22 [JA___]. The case does not sweep so broadly, and the unusual facts of *Rail-Trailer* bear no resemblance to those here. First, that case involved joint patentees, one of whom decided not to practice the patent and granted its co-patentee an irrevocable, royalty-free license. *Rail-Trailer*, 358 F.2d at 16. Second, the exclusive license did not adversely affect competition in that the licensee-owner did not pay to eliminate competition from its joint patentee. Indeed, the licensor-owner relinquished its right to practice the patent even before it issued. By contrast, the 2017 Agreement substantially lessens competition, because Impax paid Endo for a guarantee that neither Endo nor [redacted] will enter the market. The Seventh Circuit itself distinguished a contract leading to anticompetitive effects from the one in *Rail-Trailer*, basing its holding on the absence of such effects. The court explained that the granting of an exclusive license, "without more," does not violate the antitrust laws, *id.* at 16-17, and made clear in its subsequent discussion that the something "more" refers to anticompetitive effects. *Id.* at 17-18.

The district court erred further in concluding, in the face of the well-pleaded Complaint allegations, that Impax did not have an absolute right to sell oxymorphone ER in 2017. The court recognized that Endo may have "waived its

right to exclude Impax from the market" through the 2010 License, but it opined that "a *breached* licensing agreement does not waive Endo's right to exclude." ECF 84 at 22 (emphasis in original) [JA___]. The determination that Impax breached the 2010 License simply ignored the facts pleaded in favor of the defendants' characterizations of the agreements. The Complaint alleged that Impax had a right to sell oxymorphone ER under the 2010 License, that Endo's lawsuit did not threaten that right or ask the court to enjoin Impax from selling oxymorphone ER, ECF 3, ¶¶ 86-87 [JA___], and that Impax has continued selling the drug under the broad protection provided by the 2010 License, *id.*, ¶¶ 30, 86-87 [JA___]. The Complaint did not allege that Impax breached an agreement or that any such breach would have affected Impax's right to compete. Instead of ruling that a supposed breach of the 2010 License somehow restored Endo's right to exclude Impax, the court should have "resolve[d] any contractual ambiguities in [the FTC's] favor." *Int'l Audiotext Network, Inc. v. Am. Tel. and Tel. Co.*, 62 F.3d 69, 72 (2d Cir. 1995).

Moreover, to the degree that the district court could properly perceive a breach of the 2010 License that threatened Impax's right to sell oxymorphone ER, such a determination would simply make this case like *Actavis*, where a similar arrangement was held subject to antitrust scrutiny. The Supreme Court held that a patent holder could not avert the risk that its patent would be declared invalid by

sharing its monopoly profits with the challenger to make the threat disappear. *Actavis*, 570 U.S. at 156-57. Similarly here, Impax could not resolve Endo's allegations that it breached the terms of the 2010 License by agreeing with Endo to share monopoly profits. *Actavis* teaches that doubts about a party's right to compete do not justify splitting monopoly profits among potential competitors. 570 U.S. at 156-57.

Stripped of its patent-rights veneer, the 2017 Agreement is what the Complaint alleged — "an incumbent competitor (Impax) paying its only potential competitor (Endo) to stay off the market." ECF 3, ¶ 99 [JA___]. The plausible allegation is that Impax paid not for a patent license it already had but for the privilege of selling oxymorphone ER as a monopolist, free from competition from Endo or [redacted]. The district court was required to accept those allegations as true, and they demonstrate a cash-for-monopoly scheme.

B. The District Court's Description of the 2017 Agreement as an Exclusive License Does Not Immunize It from Antitrust Scrutiny.

Even if the district court could have properly characterized the 2017 Agreement as an exclusive patent license, the court was still wrong to conclude that the agreement was lawful given the Complaint's allegations about Impax's right to be on the market and the agreement's anticompetitive effects. Exclusive

licenses are not immune from antitrust scrutiny and can violate antitrust law if they are entered into for the purpose of having anticompetitive effects.

The legality of a patent license, exclusive or not, depends on, and a court must examine, "the facts peculiar to the business in which the restraint is applied, the nature of the restraint and its effects, and the history of the restraint and the reasons for its adoption." *Moraine Prods. v. ICI America, Inc.*, 538 F.2d 134, 146 (7th Cir. 1976). The Supreme Court explained long ago that "[p]atents give no protection from the prohibitions of the Sherman Act … when the licenses are used … in [a] scheme to restrain." *New Wrinkle*, 342 U.S. at 378. And exclusive patent licenses "cannot avoid antitrust scrutiny where they are used in anticompetitive ways." *King Drug Co.*, 791 F.3d at 407. Where there is "evidence of an intent to create an unlawful restraint or monopoly together with conduct effective to bring such restraint or monopoly into being," the exclusive license may violate the antitrust laws. *Benger Labs.*, 209 F. Supp. at 648.

Exclusive licenses between companies in a vertical relationship, where they are not actual or potential competitors, do not usually raise antitrust concerns because such licenses "ordinarily add one new producer into the market and presumptively increase output." Phillip Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 2046d (online ed. 2022); *see also* Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for*

the Licensing of Intellectual Property (2017), at 2, 14.[13] In other words, the license's effects are procompetitive or at least do not meaningfully change market conditions.

The 2017 Agreement, however, is not a vertical licensing arrangement. Instead, it is the kind of exclusive license that "raise[s] significant antitrust issues" because, in the absence of the license, "the firms are either actual or at least potential competitors." Areeda & Hovenkamp, *supra*, ¶ 2045a. Antitrust concerns arise "where the licensor and the licensee … would be actual or potential competitors absent the license, and the exclusive license serves to create or enhance the exercise of market power." American Bar Association, *Antitrust Law Developments*, 11E(2) (8th ed. 2017); *see also* FTC & DOJ IP Guidelines, at 7-8, 21. Endo and Impax had been horizontal competitors, and remain potential competitors, because the 2010 License gave Impax an independent right to compete. Endo's later promise not to compete against Impax reduced the number of potential market participants from two to one, preserving a monopoly. The arrangement is unmistakably anticompetitive. *Impax Labs.*, 994 F.3d at 493. That is exactly why the FTC has promulgated a rule requiring pharmaceutical patent

[13] Available at https://www.ftc.gov/system/files/documents/public_statements/1049793/ip_guidelines_2017.pdf.

holders to submit certain patent licenses for antitrust review even when they are less restrictive than an exclusive license. 16 C.F.R. § 801.2(g); *see Pharm. Rsch. and Mfrs. of Am. v. FTC*, 790 F.3d 198 (D.C. Cir. 2015) (upholding rule).

In this respect, the 2017 Agreement resembles the litigation settlement condemned by the Third Circuit in *King Drug Co.*, 791 F.3d at 407. There, the patent holder agreed not to compete against a generic even though the patent holder had a right to compete. The defendants sought to justify the deal as a permissible exclusive license authorized by the Patent Act. *Id.* at 406. The Third Circuit rejected this argument, ruling that the patentee's right to grant an exclusive license did not justify the settlement where the patentee used an exclusive license as a reverse payment to maintain its monopoly. *Id.* at 407. The court explained that under *Actavis*, "even exclusive licenses cannot avoid antitrust scrutiny where they are used in anticompetitive ways." *Id.*

In ruling that the 2017 Agreement fell within Endo's rights to enter an exclusive license, the district court purported to apply six considerations it supposedly derived from *Actavis*. ECF 84 at 14 [JA___]. In fact, *Actavis* prescribes no such test. Rather, the Supreme Court explained that determining "[w]hether a particular restraint lies beyond the limits of the patent monopoly is a conclusion that flows from" an analysis not of six specific "considerations" but of "traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market

power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents." *Actavis*, 570 U.S. at 149 (cleaned up). The district court did not examine the factors identified by the Court in *Actavis*, including the fact that Impax already had a right to be on the market and the loss of competition that resulted from Endo's agreeing not compete.

The actual test that *Actavis* prescribed followed from the Supreme Court's earlier rulings in *United States v. Line Material Co.*, 333 U.S. 287 (1948), and *United States v. Singer Manufacturing Co.*, 374 U.S. 174 (1963). In *Line Material*, the Court condemned a patent cross-licensing agreement that was used to fix prices. That the parties had a right under patent law to cross license each other did not mean they could use those rights to eliminate price competition. 330 U.S. at 310-11. Similarly in *Singer*, the Court invalidated as anticompetitive a patent licensing agreement after considering not just the defendants' rights under the Patent Act but also the competitive effects of the agreement. 374 U.S. at 194-95. The Court explained that the form of the agreement was not dispositive; rather, "[w]hether an unlawful combination or conspiracy is proved is to be judged by what the parties actually did rather than by the words they used." *Id.* (cleaned up).

This Court applied the same understanding in *Studiengesellschaft Kohle* to reverse a finding of antitrust liability stemming from a patent license. Presaging *Actavis*, the Court ruled that the district court should have considered not just the

scope of the patent protection but also the anticompetitive effects of a license that granted one company the exclusive right to use the patented technology and sell the resulting output, while restricting other companies to using the technology for their internal consumption. 670 F.2d at 1128. The Court explained that granting just one company the exclusive right to sell did not harm competition, because the other companies would not otherwise have been able to make and use the product absent the patented technology. *Id.* at 1137. The license restriction did not eliminate competition among the licensees that would otherwise have existed. By contrast here, the 2017 Agreement does eliminate competition that had existed in the past and would otherwise exist going forward between Endo and Impax.

The district court should have applied these cases to the Complaint's allegations and should not have dismissed it. *Line Material* teaches that Endo and Impax, as horizontal competitors each with rights to sell oxymorphone ER, cannot use Endo's right to grant an exclusive license to restrain trade between Endo and Impax. 333 U.S. at 311. *Singer* instructs that Endo cannot put its patent monopoly in Impax's hands with the aim of eliminating competition that would otherwise exist, either between them directly or between any [redacted]. 374 U.S. at 193-95. *Studiengesellschaft Kohle, m.b.H.* observes that "[e]xclusive licenses are tolerated because they normally threaten competition to no greater extent than is threatened by the patent itself," 670 F.2d at 1135, but here

the Complaint alleges that Impax already had a right to be on the market, so the 2017 Agreement grants Impax exclusivity that Endo's patent rights do not support.

The court also erred in finding *Actavis* inapplicable on the ground that the reverse-payment settlement there was not a "commonplace form," whereas the 2017 Agreement was an ordinary litigation settlement, and "'settlements taking [] commonplace forms have not been thought … subject to antitrust liability.'" ECF 84 at 20 (quoting *Actavis*, 570 U.S. at 152) [JA___]. The 2017 Agreement was hardly commonplace. The breach of contract suit involved disputed royalties, and such suits are typically resolved with a compromise on the royalties. It is far less common for one of only two competitors to agree not to compete in exchange for a split of monopoly profits.

But even if the district court's characterization of the 2017 Agreement as "commonplace" is correct, the court omitted a key phrase from the quotation from *Actavis*. The Supreme Court did not say that commonplace settlements "have not been thought subject to antitrust liability"; it said that such settlements have not faced liability "for that reason alone." Read in its entirety, the full quotation shows a recognition by the Supreme Court that traditional settlements do not violate the antitrust laws *per se*, but settlements with anticompetitive effects just might—and must be evaluated carefully. *Actavis*, 570 U.S. at 152. The district court undertook no such evaluation.

The Second Circuit has also rejected the idea that *Actavis* excepted commonplace settlements from antitrust scrutiny. In *1-800 Contacts, Inc. v. FTC*, 1 F.4th 102, 113 (2d Cir. 2021), the court rejected an argument that *Actavis* applies only when the settlement of an intellectual property dispute has an "unusual" form. *Id.* The court explained that "the mere fact that an agreement implicates intellectual property rights does not 'immunize [an] agreement from antitrust attack.'" *Id.* (quoting *Actavis*, 570 U.S. at 147). "As in any antitrust case," the court held "we must determine whether the restraints in the agreement[s] are reasonable in light of their actual effects on the market and their pro-competitive justifications." *Id.* at 113-14 (cleaned up).

The error in the court's failure to examine the Complaint's allegations is evident as well in the court's treatment of *King Drug Co.*, 791 F.3d 388, which it erroneously distinguished on grounds that the 2017 Agreement is not a reverse payment. ECF 84 at 19 [JA___]. To be sure, compared to *King Drug*, the roles here are reversed—the generic is sharing its monopoly profits with the brand rather than the brand's sharing its monopoly profits with the generic. But the effect is the same. In both cases, the profit sharing transforms rivals into partners who will both benefit from an arrangement that preserves and extends the pool of monopoly profits at the expense of consumers. That the payment appears to be in the "right" direction—*i.e.*, from the licensee to the licensor—does not change the substance of

the agreement, which is to eliminate potential competition. *See* Areeda & Hovenkamp, *supra*, ¶ 2046c (*Actavis* applies regardless of whether a patent settlement involves a reverse payment). Antitrust courts should not elevate form over substance. *See Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285 (2018).

The district court similarly missed the importance of competitive effects and the purpose underlying a license in its discussion of *United States v. General Electric Co.*, 272 U.S. 476 (1926). ECF 84 at 18, 20 [JA___]. *General Electric* does not support the court's holding because the case involved a vertical patent license granted by GE to Westinghouse, absent which Westinghouse could not have produced light bulbs. 272 U.S. at 490. By contrast, Impax did not need the 2017 Agreement as a vertical license to produce oxymorphone ER; it already that right to compete under the 2010 License and, but for the 2017 Agreement, Impax and Endo likely would have been competitors for sales of the drug going forward. The district court ignored these Complaint allegations, and overlooked this competitive harm.

Finally, the district court misapplied *Standard Oil Co. v. United States,* 283 U.S. 163 (1931). There, the Court "upheld cross-licensing agreements among patentees that settled actual and pending litigation, which agreements set royalty rates to be charged third parties for a license to practice all the patents at issue (and which divided resulting revenues)." *Actavis*, 570 U.S. at 150 (cleaned up)

(describing *Standard Oil*, 283 U.S. at 168). Justice Brandeis's opinion for the Court noted that the result would have been otherwise if the patentees "dominate[d] the industry" and "curtail[ed] the manufacture and supply of an unpatented product." *Standard Oil*, 283 U.S. at 174. The district court concluded that the 2017 Agreement could violate the antitrust laws only "if the parties dominate the industry *and* influence the market of unpatented products." ECF 84 at 20 (emphasis in original) [JA___]. Applied correctly to the Complaint's allegations, *Standard Oil* supports allowing the FTC to proceed with its case.

Regarding market dominance, the Complaint alleged that Endo and Impax were the only two sellers of oxymorphone ER, with Endo serving as the gatekeeper to the market. ECF 3, ¶¶ 4, 99-101, 117 [JA___]. Regarding effects on unpatented products, because the 2010 License gave Impax the right to sell oxymorphone ER without infringement liability, its product is, in effect, unpatented with respect to Impax. In any event, neither *Standard Oil* nor any other Supreme Court decision of which we are aware has ever indicated that a patent license violates the antitrust laws only if it affects unpatented products. *Line Material*, discussed above, held expressly that a price-fixing agreement for *patented* products was unlawful without considering effects in other markets. 333 U.S. at 312. The district court's contrary approach makes no sense because "the inference of an agreement in violation of

the Sherman Act" is not "merely limited to particular fact complexes." *Singer*, 374 U.S. at 193 (cleaned up).

Thus, in the absence of any consideration of the Complaint's allegations regarding the anticompetitive effects of and reasons for the 2017 Agreement, the district court could not undertake the antitrust analysis required to determine whether the Complaint stated a claim. While on remand Endo and Impax may be able to identify legitimate justifications for the 2017 Agreement, the possibility that they may do so does not justify dismissing the FTC's Complaint. *See Actavis*, 570 U.S. at 156.

Finally, the district court's erroneous conclusion that the 2017 Agreement is a permissible exclusive license led it to dismiss the Complaint's count that Impax unlawfully monopolized the market for oxymorphone ER in violation of Section 2 of the Sherman Act. ECF 84 at 21 [JA___]. A Section 2 claim requires (1) the possession of monopoly power and (2) anticompetitive conduct—"the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historical accident." *United States v. Microsoft Corp.*, 253 F.3d 34, 50 (D.C. Cir. 2001) (*en banc*) (cleaned up). Entry into agreements not to compete are one of the myriad ways monopolists can engage in exclusionary conduct in violation of Section 2. *See Otter Tail Power Co. v. United States*, 410 U.S. 366, 377 (1973).

Because the Complaint plausibly alleged that the 2017 Agreement was an unlawful agreement not to compete, for all the reasons discussed above, ECF 3, ¶¶ 110-124 [JA___], the district court should have allowed the FTC to proceed with the Section 2 claim as well.

CONCLUSION

The Court should reverse the district court and remand the case for determination on the merits.

Respectfully submitted,

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December 21, 2022

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CERTIFICATE OF COMPLIANCE AND SERVICE

I certify that the foregoing brief complies with Federal Rule of Appellate Procedure 32(a)(7), in that it contains 11,123 words.

I further certify that on December 21, 2022, (1) the sealed, nonpublic version of the foregoing brief was sent to sealedfilings@cadc.uscourts.gov and served on counsel of record via email with their consent, and (2) the unsealed, public version of the foregoing brief was filed and served via the Court's CM/ECF system.

December 21, 2022

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