ORAL ARGUMENT SCHEDULED FOR MAY 1, 2023

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

REPLY BRIEF OF THE FEDERAL TRADE COMMISSION

ANISHA S. DASGUPTA
General Counsel

JOEL MARCUS
Deputy General Counsel

MARK S. HEGEDUS
Attorney

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, NW
Washington, D.C. 20580
(202) 326-2115
mhegedus@ftc.gov

BRADLEY S. ALBERT
DANIEL W. BUTRYMOWICZ
KARA L. MONAHAN
ERIC M. SPRAGUE
Of Counsel

TABLE OF CONTENTS

TABLE OF AUTHORITIES

* *Cases and other authorities principally relied upon are marked with asterisks.*

CASES

STATUTES

OTHER AUTHORITIES

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 AND SUMMARY

The FTC showed in its opening brief that its Complaint plausibly alleged that Impax had a right to sell oxymorphone ER under a license granted by Endo, that Endo was willing and able to enter the market with its own product, but that the two companies instead agreed to split monopoly profits rather than competing for shares of a less profitable market. The Complaint alleged that the agreement not to compete had the anticompetitive effect of propping up the price of oxymorphone ER at the expense of consumers.

Impax and Endo admit that they agreed to split monopoly profits rather than competing; indeed, they proudly assert their supposed entitlement to do so. The gist of their position is that the Patent Act gives them an absolute right to maintain a monopoly and agree not to compete. They characterize their agreement as a routine exclusive patent license and contend that the Court's acceptance of the FTC's position would threaten every exclusive license in existence.

The main flaw in that argument is that the arrangement challenged in this case—the 2017 Agreement—is not an ordinary exclusive license, but an effective payment from Impax to Endo in exchange for Endo's promise not to compete. Although formally styled a license, the 2017 Agreement purported to give Impax a right it already had. In 2010, Endo granted Impax the right—the 2010 License—to make oxymorphone ER, putting Impax beyond the exclusionary scope of Endo's

then-existing and future patents. The companies themselves described the 2010 License as having granted Impax a "risk-free" right to sell the drug. The FTC's Complaint therefore plausibly alleged that the 2017 Agreement was in reality a straightforward agreement not to compete.

The companies' comeback amounts to a dispute of fact. They claim that a 2016 lawsuit threatened Impax's right to sell oxymorphone ER under the 2010 License, so it was therefore reasonable to convert the 2010 License into an exclusive license in return for a royalty payment. That type of fact-bound reasoning provides no excuse for dismissing a complaint. Beyond that, the companies' position is impossible to square with their argument in another lawsuit that the 2010 License was "risk-free" and with the fact that Endo's 2016 case did not seek to bar Impax from selling oxymorphone ER. And even if Impax's rights were at risk, agreements between potential competitors that purport to resolve legal uncertainty about the right to compete are still assessed under the rule of reason. The Supreme Court has recognized for more than a century that patent rights coexist with antitrust law, and "both [are] relevant in determining the 'scope of the patent monopoly'—and consequently antitrust immunity—that is conferred by a patent." *FTC v. Actavis*, 570 U.S. 136, 148 (2013).

Antitrust scrutiny of the 2017 Agreement will not "imperil" all exclusive licenses or force patentees and their licensees to compete. Many licenses are

between vertical parties that are not potential competitors. And many patentees may lack monopoly power in the antitrust sense, so many exclusive licenses pose no antitrust concerns. Here, however, the 2017 Agreement is a horizontal license between potential competitors that eliminated what had been fierce competition and preserved monopoly profits. In this situation, antitrust liability would not force parties to compete, but prevent them from colluding.

ARGUMENT

Endo and Impax are competitors who are charged with forgoing competition in order to preserve and share monopoly profits. In defense of the district court's dismissal of the complaint, they largely dispute the facts alleged, often relying on extra-complaint materials, or they simply ignore the allegations that conflict with their preferred storyline. They also contend that their agreement is immune from antitrust scrutiny because it is an exclusive license authorized by the Patent Act. That position is wrong as a matter of clearly established law.

I. THE COMPLAINT PLAUSIBLY ALLEGED THAT THE 2010 LICENSE ALLOWED IMPAX TO SELL OXYMORPHONE ER "RISK FREE" WITHOUT AN EXCLUSIVE LICENSE FROM ENDO.

A core theory of the FTC's case, supported by well-pleaded factual allegations, is that Endo gave Impax a right to sell oxymorphone ER in 2010 as part of an arms-length negotiation between potential competitors, so in 2017 Endo had no patent-based right to exclude Impax. In other words, the exclusionary

potential of Endo's patent no longer extended to Impax. The agreement between the companies in 2017 therefore amounted to a simple case of preserving and sharing monopoly profits. Nothing in the companies' briefs shows that the Complaint allegations failed to state a claim.

A. The Companies' Own Statements and Actions Support the Complaint Allegations.

The Complaint alleged that the 2010 License "provided Impax with a license to all then-issued patents and any Endo-owned or controlled patents that could cover the manufacture, sale, or marketing of Impax's generic version of Opana ER," which "ensured that Impax could sell an oxymorphone ER product as soon as January 2013, even if Endo later obtained additional patents that covered Opana ER." ECF 2, ¶ 29 [JA___]. Endo (EB at 29-32) and Impax (IB at 37-38) disparage this allegation as a legal conclusion which need not be accepted as true. But the allegation rests in part on the companies' own representations, recited in the Complaint, to other tribunals. Those alleged representations support a plausible inference that Endo and Impax themselves regarded the 2010 deal as a risk-free license to all of Endo's patents. Both the allegations and the inference must be accepted as true. *See Owens v. BNP Paribas, S.A.*, 897 F.3d 266, 272 (D.C. Cir. 2018).

As set forth in the FTC's Complaint here (cited as ECF 2), the 2010 License was subject to a private class-action antitrust lawsuit. *See In re Opana ER Antitrust*

Litig., No. 1:14-cv-10150 (N.D. Ill. filed Dec. 12, 2014) (*In re Opana*). Endo described the 2010 License in its answer to the class complaint as giving Impax "'freedom to operate' under future Endo patents covering Opana ER enabling 'Impax [to] launch risk-free years before' the last Opana ER patent expires." ECF 2, ¶ 30 [JA___] (quoting *In re Opana*, ECF 211 at 133-34). Similarly, when the FTC challenged the 2010 License in an administrative proceeding, Impax called it a "'broad patent license' that protected Impax 'not just against the patents that were in suit at the time but against later acquired patents, at least as to Opana ER.'" ECF 2, ¶ 30 [JA___] (quoting Impax's counsel, *In the Matter of Impax*, FTC Docket No. 9373, Initial Pretrial Conference Tr. at 59 (Feb. 16, 2017)).[1] Those descriptions amply support the inference that the 2010 License gave Impax a right to be on the market.

Endo tries to escape the implications of the "risk-free" license by calling that description the FTC's own characterization (EB at 32 n.17), but the term "risk-free" comes directly from Endo's own statements to a federal court. Impax attempts a similar distancing by describing FTC's use of the term "risk-free" as

[1] Impax labels "ironic" the Complaint's reliance on the 2010 License given that the FTC had previously challenged portions of that agreement. IB at 19 n.3. The problem with the 2010 License was not the license itself but the accompanying payments to Impax for delaying its entry, which facilitated Endo's product hop. *See In the Matter of Impax Labs.*, 2019 WL 1552939, at *22 (FTC Mar. 28, 2019); *Impax Labs., Inc. v. FTC*, 994 F.3d 484, 497-99 (5th Cir. 2021).

"breezy," IB at 38. The companies cannot disavow their own descriptions so easily. Indeed, Endo and Impax won the private antitrust lawsuit (as they proudly note, EB at 5 n.4; IB at 5 n.1, 43) after the jury determined that Impax's right to be on the market "risk free" was a procompetitive benefit that outweighed the anticompetitive harms. *See* EB at 5 n.4. They should not now be permitted to win this case on the exact opposite theory that the license did not make Impax a freestanding competitor. "The doctrine of judicial estoppel prevents a party from asserting a claim in a legal proceeding that is inconsistent with a claim taken by that party (or by one in privity with that party) in a previous proceeding." 18 Moore's Federal Practice—Civil § 134.30 (online ed. 2023); *accord New Hampshire v. Maine*, 532 U.S. 742, 749 (2001).

While the foregoing amply supports the plausibility of the Complaint's allegation that Impax had a right to compete, the terms of the 2010 License underscore the conclusion. Section 4.1(a) grants Impax a "royalty-free" license to Endo's "existing" and "pending" "licensed patents" until the last of them expires. ECF 51-2 at 10 [JA___]. (The last patent expires in 2029. ECF 2, ¶ 47 [JA___].) Section 4.1(b) contains a "Covenant Not to Sue" running from Endo to Impax during the License Term. ECF 51-2 at 10-11 [JA___]. Section 4.1(d) contains the agreement to "negotiate in good faith an amendment" to the 2010 License as it applies to Future Patents. *Id*. at 12 [JA___]. Although Section 8.2 defines acts that

allow termination of the 2010 License, those acts do not include Impax's alleged or actual failure to negotiate under Section 4.1(d). *Id.* at 17-18 [JA___]. Ignoring their own description of these provisions, ECF 2, ¶¶ 29-30 [JA___], both Endo and Impax assert that a court is "not constrained to accept allegations of the complaint in respect of the construction of" an agreement. EB at 16 and IB at 42 (both quoting *Int'l Audiotek Network, Inc. v. AT&T Co.*, 62 F.3d 69, 72 (2d Cir. 1995)). They neglect to add, however, that on a motion to dismiss a court "will strive to resolve any contractual ambiguities in [non-movant's] favor." *Intl'l Audiotek Network, Inc.*, 62 F.3d at 72.

Impax cannot show the absence of a disputed allegation of fact by asserting that the 2016 contract litigation placed its "ability to compete … in serious doubt" because a ruling in Endo's favor might have resulted in an injunction against Impax's selling oxymorphone ER and exposure to treble damages. IB at 37-38. That claim is simply a disputed fact scenario. The Complaint alleged, and the companies do not dispute, that Endo did not ask the district court to enjoin Impax from selling the drug. ECF 2, ¶ 87 [JA___]. And though the companies speculate that Impax may have lost the litigation, it may well have prevailed.

The same goes for Impax's attempt to cast doubt on whether it would have remained in the market had the 2016 litigation not settled. IB at 37-38. Such a fact-based claim may be addressed on the merits. But Impax's actions do not reflect the

legal and financial peril it now claims to have faced. After the district court denied Impax's motion to dismiss, Impax continued selling oxymorphone ER, relying on the 2010 License. ECF 2, ¶ 30 [JA___]. That conduct supports the inference that Impax did not perceive a great risk and was not deterred by the lawsuit. Indeed, as the FTC alleged, Impax did not even initiate the settlement discussions; Endo did. ECF 2, ¶ 90 [JA___]; IB at 8.

Nor did Endo act as though the 2016 litigation significantly threatened Impax's ability to compete. As alleged in the Complaint, four months after it filed the 2016 lawsuit, Endo characterized the 2010 License as a "freedom to operate," "risk-free" license. ECF 2, ¶ 30 [JA___]; p.5 *supra*.[2] Endo's contemporaneous characterizations of the 2010 License fatally undercuts its current position that the 2016 litigation rendered the Complaint's allegations implausible.

Finally, the companies may not defend the dismissal of the Complaint by invoking extra-Complaint factual matter. For example, Endo challenges the Complaint's allegation that Impax had the right to sell oxymorphone ER under the 2010 License as implausible on the theory that Endo terminated the License in the

[2] Even during the pendency of this appeal, Endo has maintained this characterization of the 2010 License: "Freedom to operate means you're not worried that a couple of years from now, you're going to get ordered back off the market … ." *In re Opana*, June 30, 2022, Closing Argument Tr. at 2727-28, ECF 1037 at 22-23 (N.D. Ill. Jul. 11, 2022).

2016 litigation. For one thing, the argument at best raises a factual dispute about the effect of the 2016 case. More fundamentally, Endo improperly invokes its own complaint in the 2016 litigation as established fact, seeking to include that advocacy document in the appellate record. EB at 7, 30. Material outside the FTC's Complaint cannot be considered in the posture of this case.

It is highly doubtful that Endo would succeed in the argument anyway. As described above, the termination clause of the 2010 License lists three circumstances that permitted termination, and they do not include a failure to renegotiate the terms of the License, the core of the 2016 dispute.

B. Because Endo Could Not Exclude Impax From the Market, Endo Did Not Have a Patent Right to Provide an Exclusive License.

A major theme of the companies' briefs is that the 2017 Agreement is an ordinary exclusive patent license, under which Endo could lawfully collect a royalty in exchange for allowing Impax to use the patent. As we showed in our opening brief (FTC at 32-36), the Complaint plausibly alleged that Endo could not grant Impax a license justifying profit-splitting in 2017 because Impax already had a license as of 2010 allowing it to sell oxymorphone ER without infringement. In other words, by 2017, Impax was outside the exclusionary scope of Endo's patent rights. That factual scenario makes the companies' extensive reliance on this Court's decision in *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d

1122 (D.C. Cir. 1981), wholly misplaced. They invoke the Court's general approval of exclusive licenses. *E.g.* EB at 18; IB at 1. But the Court recognized that a patent license "waives [the patentee's] right to judicial relief for what, but for the license, would be an infringement." 670 F.2d at 1127. Here, however, the Complaint plausibly alleges that Impax's sales post-2010 were not an infringement, so the predicate for a valid patent license recognized in *Studiengesellschaft* is missing.[3]

Endo and Impax do not address this legal principle. Instead, they fall back on the district court's conclusion that the Complaint had not alleged that Endo waived its patent rights. EB at 28-29; IB at 41-42. But the Complaint did not need to use the precise term "waived"; rather, as shown, that conclusion flows from the plausible allegation that the 2010 License gave Impax the right to be on the market without infringing Endo's patents.

The companies also misplace heavy reliance on the Seventh Circuit's decision in *Rail-Trailer Co. v. ACF Industries, Inc.*, 358 F.2d 15 (7th Cir. 1966), which they claim supports the idea that the 2010 License did not impair Endo's

[3] Impax understood Endo's patent rights the same way. In the 2016 litigation, Impax maintained that "a party 'cannot have infringed [plaintiff's] patent under which it was licensed." *Endo Pharms., Inc. v. Impax Labs., Inc.*, No. 2:16-cv-02526, Brief in Support of Impax Laboratories, Inc.'s Motion to Dismiss Amended Complaint, ECF 22-1 at 36 (D. N.J. Aug. 29, 2016).

right to grant Impax a license in 2017. EB at 33-34; IB at 24-25.[4] They read the case as saying that a patentee without the right to exclude a person can still grant that person an exclusive license, EB at 33-34; IB at 24, and they fault the FTC for distinguishing the case on the ground that it involved the rights of joint patentees, EB at 34; IB at 24.

The companies ignore the significance of that distinction. As is typical, the 2010 License granted Impax the right to practice Endo's patents and promised that Endo would not sue Impax for doing so. *See* p.6 *supra*. Without these provisions, Endo could have sued Impax for infringement and forced Impax from the market. By contrast, the "licensee" in *Rail-Trailer*, the joint patentee ACF, needed no similar provisions in its contract with its co-patentee Rail-Trailer. ACF's status as a co-patentee already gave it the right to practice the patent without risk of being sued for infringement by Rail-Trailer. *Rail-Trailer*, 358 F.2d at 16. While the agreement in *Rail-Trailer* was called an exclusive license, it was not a license in the sense that Rail-Trailer could have excluded ACF, but waived that right by granting a license. Accordingly, the Seventh Circuit did not address what happens to a patentee's right to exclude when it grants a license and thus tells us nothing

[4] In Impax's telling, *Rail-Trailer* is pivotal to understanding this Court's decision in *Studiengesellschaft*. *E.g.* IB at 20-21. Hardly. The Court cited *Rail-Trailer* once in a string cite supporting the generic point that patentees can grant exclusive licenses. *See Studiengesellschaft*, 670 F.2d at 1131.

about Endo's right to exclude Impax. And while the court did note that exclusive licenses as such are permitted under the antitrust laws, it also focused on the "right of joint owners of a patent to contractually modify their interests in the jointly owned patent" under 35 U.S.C. § 262. *Rail-Trailer*, 358 F.2d at 17. Neither the 2010 License nor the 2017 Agreement involves that Patent Act right.

Taken to its logical conclusion, the companies' interpretation of *Rail-Trailer* would have untenable implications for antitrust law. It would allow any patentee to agree not to compete by "exclusively licensing" the patent to a competitor and sharing joint profits through royalties—even if the competitor's product did not even arguably infringe the patent. Under the companies' theory, a patent would become a "get out of jail free card" for horizontal collusion even without any exclusionary potential. It is not plausible that *Rail-Trailer* established such a rule, and the case must instead be interpreted within its joint-patentee context.

Like the district court (ECF 74 at 22), Endo treats its breach-of-contract lawsuit as tantamount to a ruling that Impax had breached the 2010 License, which somehow restored Endo's right to exclude. EB at 30, 33. The New Jersey District Court, however, ruled neither that Impax breached nor that the 2010 License was no longer valid. Endo's *allegation* of a breach was not sufficient to resurrect Endo's right to exclude Impax, from which its ability to grant an exclusive license is derived.

Finally, the companies fail in their attempt to distinguish *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990), which condemned an agreement by two competitors not to compete using their intellectual property rights. The companies assert that in *Palmer*, the competitors had independent rights to market their intellectual property, whereas here Impax's license is based on Endo's intellectual property. IB at 25; EB at 25. But as discussed at length in our opening brief and above, the Complaint plausibly alleges that Impax had an independent right to be on the market under the 2010 License that "ensured" it could sell oxymorphone ER "risk free." ECF 2, ¶ 30 [JA___]. The 2017 Agreement thus closely resembles the agreement condemned by the Supreme Court in *Palmer*.

II. THE PATENT ACT DOES NOT IMMUNIZE THE 2017 AGREEMENT FROM ANTITRUST SCRUTINY.

The district court ruled that the 2017 Agreement operates as an exclusive license because the agreement, in substance if not form, eliminates Endo's incentives to compete against Impax because Endo's entry relieves Impax of the duty to pay royalties. ECF 74 at 13. Based on that ruling, Endo and Impax argue that, because the Patent Act specifically authorizes exclusive licenses, the 2017 Agreement is immunized from antitrust review and the Complaint does not state a claim. EB at 26-28; IB at 14-18.

For all the reasons set forth above and in our opening brief, the 2017 Agreement, while styled as a license, was in effect an agreement to split monopoly

profits by paying Endo not to compete. But even if the 2017 Agreement could properly be deemed an exclusive license under the Patent Act, that status does not automatically immunize the license from antitrust scrutiny. The 2017 Agreement remains subject to antitrust review under the rule of reason no matter how it is described.

A. The Patent Act Does Not Create a Blanket Exemption from Antitrust Review.

The Patent Act's authorization of exclusive licenses does not render such licenses *per se* lawful under the antitrust laws. The Court should reject Endo's and Impax's syllogism that (1) because patents confer a monopoly, and (2) because the Patent Act authorizes Endo to transfer its patent monopoly to Impax exclusively, it follows that (3) the 2017 Agreement falls within the scope of Endo's patent rights and escapes antitrust scrutiny as a matter of law. Factually the syllogism is wrong—the 2010 License put Impax beyond the scope of Endo's patent rights. It's also incorrect as a matter of law.

Endo states: "Where, as here, the challenged conduct does not go beyond what the Patent Act expressly authorizes, that conduct cannot trigger antitrust scrutiny." EB at 16-17. Endo cites *Studiengesellschaft*, 670 F.2d at 1127-28, for this proposition, although such a holding appears nowhere in the opinion. Indeed, this Court subjected the exclusive license challenged there to rule-of-reason scrutiny. *Id.* at 1130-37. Impax states that the 2017 Agreement "fit[s] comfortably

within the Congressionally ordained patent monopoly." IB at 14, 15-24. The companies' claims rest on a string of anodyne quotations, EB at 18; IB at 15, that when examined closely neither support the companies' position nor reflect the Supreme Court's consistent approach to analyzing patent settlements. The quotations simply describe the general attributes of a patent, and they stand for nothing more than the proposition that the granting of an exclusive license, *standing alone*, does not violate the antitrust laws. "Exercise by the patentee of its statutorily granted exclusive right to make, use and sell by way of granting an exclusive license is a natural and permissible utilization of the rights granted and does not have antitrust implications *as such*." 2 Milgrim on Licensing § 15.08 (2022) (emphasis added).

When it comes to exclusive licenses used for anticompetitive schemes, 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 [trade]." *United States. v. New Wrinkle, Inc.*, 342 U.S. 371, 378 (1952). Invoking that principle, the Third Circuit has recognized that exclusive licenses "cannot avoid antitrust scrutiny where they are used in anticompetitive ways." *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 407 (3d Cir. 2015). Endo's own authorities support this conclusion. Endo relies on Professor Hovenkamp's explanation that "exclusion by patent enforcement during

[the patent] term cannot be unlawful under the antitrust laws," and neither can "exclusive and nonexclusive production licenses." EB at 18 (quoting Herbert Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76 Ohio St. L.J. 467, 481 (2015)). Immediately following the quoted passage, however, Hovenkamp explains that the protection of the Patent Act extends only to enforcing the patent itself and not to conduct that is anticompetitive under the antitrust laws: "On the other hand, the Patent Act does not authorize product price fixing, market divisions unrelated to the production licenses, predatory pricing in patent goods, anticompetitive acquisitions, resale price maintenance of patented goods, ties in the presence of market power, exclusive dealing" or sham infringements suits. *Id*. at 481.

The companies' position is exactly the one rejected by the Supreme Court in *Actavis*. There, the court of appeals had affirmed a district court's dismissal of an FTC antitrust complaint challenging a patent settlement by which a generic drug company contesting a brand-name drug company's patent dropped its challenge in exchange for a large payment from the brand and a license to enter the market before the end of the patent term. The lower courts had ruled that a patent settlement was "immune from antitrust attack so long as its anticompetitive effects fall within the exclusionary potential of the patent." *Actavis*, 570 U.S. at 141, 146-47. The Supreme Court rejected that approach, holding instead that "patent and

antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent." *Id.* at 148. The Court explained that "[w]hether a particular restraint lies beyond the limits of the patent monopoly is a conclusion that flows from" an analysis of "traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as those related to patents." *Id.* at 148-49 (cleaned up).

Impax dismisses *Actavis* as "irrelevant to this case" because of its specific factual context. IB at 28-31. In particular, it contends that "special features" of the statutory regime at issue make the case limited to its facts. *Id.* at 29. That simplistic assessment overlooks the Supreme Court's reliance on decades of precedent subjecting patent settlements to antitrust analysis and examining not just the scope of patent rights, but also the anticompetitive effects caused by their exercise. *See Actavis*, 570 U.S. at 147-51. None of those cases involved factual scenarios similar to those at issue in *Actavis*, but the Court found them relevant to determining whether the reverse-payment patent litigation settlement at issue there could violate the antitrust laws. *Id.* Other courts as well as a leading commentator have likewise recognized that *Actavis* applies outside of its specific context. *See 1-800 Contacts, Inc. v. FTC*, 1 F.4th 102, 113 (2d Cir. 2021) (applying *Actavis*'s

approach in a non-reverse payment case); Phillip Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 2046c (online ed. 2023) (*Actavis* applies regardless of whether a patent settlement involves a reverse payment).

Impax likewise errs in its claim that the cases on which *Actavis* relied are irrelevant here. IB at 26-27 (discussing *United States v. Singer Mfg.*, 374 U.S. 174 (1963), *United States v. Line Material Co.*, 333 U.S. 287 (1948), and *New Wrinkle, Inc.*, 342 U.S. 371). According to Impax, those cases shed no light on the legality of the 2017 Agreement because they involved "multiple-patentee agreements," whereas the 2017 Agreement involves only a single patent. IB at 26-27. That position is obviously wrong: *Actavis* itself involved a single-patent settlement agreement, yet the Supreme Court drew upon all of those earlier cases to conclude that the agreement was subject to antitrust scrutiny. Impax ignores the common thread of the cases: economic actors with market power and an independent ability to compete cannot use patent rights to agree to eliminate competition free of antitrust scrutiny.

B. Antitrust Review Does Not "Imperil" Exclusive Licensing.

The companies hyperbolically declare that antitrust review of exclusive licenses such as the 2017 Agreement will "eliminate the traditional boundary between the legitimate exercise of patent rights and antitrust enforcement," EB at

20, and "imperil countless exclusive license agreements," IB at 36. Impax exclaims that antitrust review would force "a patentee-licensor to compete with its licensee" and prevent a patentee and licensee from "chang[ing] the terms of their license from a non-exclusive license to an (allegedly) exclusive license." IB at 2. None of these things will happen by applying the antitrust laws to exclusive licenses, as courts have done for decades.

Antitrust analysis of exclusive licenses occurs under the rule of reason. *Actavis*, 570 U.S. at 159-60. That analysis requires the FTC (or any plaintiff) to plausibly allege both market power and "the potential for genuine adverse effects on competition." *FTC v. Ind. Fed'n of Dentists, Inc.*, 476 U.S. 447, 460 (1986); *see also Impax Labs., Inc.*, 994 F.3d at 492-93. Endo calls such scrutiny "unprecedented," EB at 20, but as the Supreme Court observed in *Actavis*, "there is nothing novel" about it. 570 U.S. at 151.

To begin with, many exclusive licenses face little risk of antitrust scrutiny because the "monopoly" conveyed by the patent does not necessarily confer market power in the antitrust sense. *See Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 45 (2006). Without a plausible allegation of market power in a relevant market, *see Actavis*, 570 U.S. at 149, 159, an antitrust challenge would generally

fail (or never be brought).[5] Here, of course, the Complaint alleged that Endo and Impax were the only authorized sellers of oxymorphone ER, and the 2017 Agreement gave Impax a monopoly over these sales. FTC at 26-31, ECF 2, ¶¶ 110-118 [JA___]. The companies admit that charge. EB at 16-19; IB at 16.

An antitrust plaintiff must also plausibly allege anticompetitive effects. As we explained in our opening brief, many exclusive licenses cause no harm to competition because the patentee and the licensee are in a non-competitive vertical relationship. FTC at 37-38. For example, a patentee may decide not to commercialize the invention itself, but to partner with a manufacturer who does not compete with the patentee and would otherwise not be able to manufacture and sell the product without the license. That is what happened in *Studiengesellschaft*, 670 F.2d at 1124. The Court there observed that an exclusive license protects a licensee's investment to exploit the patent and "serves the interests of both the patentee and the public by facilitating more rapid and widespread use of new inventions." *Id.* at 1135. In that situation, the license has no anticompetitive effect. *Id.*

[5] An exception might arise if the exclusive license were used as part of a naked price-fixing agreement or other *per se* violation. *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Oklahoma*, 468 U.S. 85, 109-10 (1984).

The risk of anticompetitive effects is much greater, however, when the patentee and licensee have a horizontal relationship. *See* FTC at 38. "An arrangement is said to be 'horizontal' when its participants are (1) either actual or potential rivals at the time the agreement is made; and (2) the agreement eliminates some avenue of rivalry among them." Areeda & Hovenkamp, *supra*, ¶ 1901. In such an arrangement, the patentee may be seeking not just to commercialize its invention but to extinguish competition that might otherwise have existed. For example, Endo and Impax have a history of intense competition in this very drug market; conversely, Endo did not need Impax to commercialize the patent. Unlike the patentee and licensee in *Studiengesellschaft*, Endo and Impax were potential horizontal competitors because the 2010 License allowed Endo to also sell oxymorphone ER (and as alleged, Endo took substantial steps toward doing so). FTC at 26-27. The 2017 Agreement eliminated that potential competition and created a monopoly.

The companies appear to deliberately elide the critical difference between vertical and horizontal licenses. Impax, for example, casually deems the 2017 Agreement a "garden variety" exclusive license. IB at 11. But a garden variety exclusive license neither involves competitors in the same industry for the same drug nor preserves monopoly profits that otherwise would be competed away. *See* Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for the Licensing of*

Intellectual Property, at 2, 6-7 (2017). Similarly, Impax's disregard of the essential economic difference between a horizontal and vertical license is obvious in its discussion of *Studiengesellschaft*: the case involved a vertical license, but Impax claims that it "operate[d] in a horizontal fashion, as the licensee entirely supplant[ed] the patentee's ability to make and sell the invention." IB at 34 (citing *Studiengesellschaft*, 670 F.2d at 1131).

The economic difference between vertical and horizontal licenses refutes the companies' concerns about "forced competition" or parties being unable to convert their licenses from non-exclusive to exclusive. When a patentee grants a license to a company that is not an actual or potential competitor (*i.e.*, a vertical license), as occurred in *Studiengesellschaft*, the licensee effectively serves as the patentee's agent and brings the patented product to market in exchange for a royalty. Because the licensee is not a competitor, its exercise of the patentee's rights benefits the market by expanding output. Competition is generally not threatened if the initial non-exclusive license is later converted to an exclusive one because the patentee and licensee still are not competitors.

But where the patentee and the licensee are actual or potential competitors (*i.e.*, a horizontal license), any exclusive license may directly threaten competition. When one competitor pays another to exit or stay out of a market, that is collusion, "the supreme evil of antitrust." *Verizon Commc'ns, Inc. v. Law Offices of Curtis V.*

Trinko, *LLP*, 540 U.S. 398, 408 (2004). The companies are not required to compete, but if they act in concert to preserve and share monopoly profits that otherwise would be lost to competition, a court may at least assess that arrangement under the rule of reason.

The pre-existing competitive relationship between Endo and Impax explains why the 2017 Agreement is suspect and why converting the non-exclusive oxymorphone ER license to an exclusive one merits antitrust scrutiny. For example, if a brand and generic are in patent litigation (as Endo and Impax were before the 2010 License), they may not settle the uncertainty about whether the generic has a right to compete by agreeing that the generic will be the exclusive seller in exchange for a substantial royalty to the brand. *See Actavis*, 570 U.S. at 147-48. The parties could lawfully settle their patent litigation with a royalty-free license to enter partway through the remaining life of the patent; that arrangement would reflect the parties' views about the strength of the patent. *See id*. at 158. When the generic's entry date arrives, however, the parties do not have carte blanche to then "convert" the license to an exclusive one that allows the generic to take over the monopoly in return for a royalty during the remainder of the patent term. That type of monopoly arrangement should properly draw antitrust scrutiny, since the patentee and licensee have now created, through agreement, a monopoly for the entirety of the patent term. Endo and Impax's view that there is no

competition issue posed by "converting" a non-exclusive license to an exclusive one in this way would create a giant loophole in the antitrust laws.

III. THE COMPLAINT PLAUSIBLY ALLEGED COMPETITIVE HARM AND ANTICOMPETITIVE INTENT, WHICH ARE LARGELY UNCONTESTED.

As shown in our opening brief, the Complaint plausibly alleged that (1) Endo and Impax are potential (and formerly actual) competitors, FTC at 26-27; (2) the 2017 Agreement caused the loss of price competition between them, costing consumers millions of dollars annually, FTC at 27-28; and (3) the 2017 Agreement removed Endo's incentives to innovate, FTC at 29. Endo and Impax make no effort to show that these allegations of harm are not plausible. Instead, they basically accept them as true but write them off as immaterial because of their view that exclusive licenses are *per se* legal. Endo contends that the harm allegations "have nothing to do with the issues before this Court … because the challenged conduct is specifically authorized by the Patent Act." EB at 35. Impax asserts that "[p]atent law would require dismissal regardless of whether the 2017 Settlement had all of the 'anticompetitive effects' and purposes alleged by the FTC." IB at 37. We demonstrated at pages 13-18 above the emptiness of the companies' position that the 2017 Agreement is not subject to antitrust scrutiny no matter its effect on competition.

Endo leaves things right there. Impax offers its own set of alternative facts—first, that if Endo would have prevailed in its 2016 litigation against Impax

consumers would have been the same or worse off; and second, that the 2017 Agreement increased Endo's incentives to enter the market. IB at 38-41. Even if such speculation could be a defense on the merits, empty hypothesizing has no place in the context of a motion to dismiss. It is worth noting, though, that the district court found that the economic cost to Endo of entering the market in competition with Impax far exceeds Endo's economic incentive to enter. ECF 74 at 13. And that just illustrates the competitive problem at the heart of this case: as the Complaint alleges, both Endo and Impax are better off splitting monopoly profits than either would be in a competitive market. ECF 2, ¶¶ 104-109 [JA___].

Indeed, the Complaint alleged that the 2017 Agreement was the culmination of a years-long effort by Endo and Impax to create and maintain a monopoly in the oxymorphone ER market. FTC at 30-31. Impax tries to write off these allegations as impermissible "historical evidence" or prior bad acts "propensity reasoning." IB at 43 (quoting *Williamson Oil Co. v. Philip Morris USA*, 346 F.3d 1287, 1317-18 (11th Cir. 2003)). At this point in the case, however, all inferences must be drawn in favor of sustaining the Complaint, and the historical background shows the companies' intent and purpose which "play an important role in divining the actual nature and effect of the alleged anticompetitive conduct." *United States v. United States Gypsum Co.*, 438 U.S 442, 436 n.13 (1978).

IV. THE DISTRICT COURT SHOULD ASSESS ITS PERSONAL JURISDICTION OVER ENDO INTERNATIONAL PLC IN THE FIRST INSTANCE.

Endo briefly challenges personal jurisdiction over its foreign-based parent, Endo International. EB at 36-37.[6] If the Court reverses the district court's dismissal of the Complaint and remands, it should direct the district court to consider the question in the first instance. *See Lewis v. Mutond*, 918 F.3d 142, 148 (D.C. Cir. 2019).

Should the Court wish to address the issue, Endo International can be reached. Endo is wrong that under *United States v. Bestfoods*, 524 U.S. 51, 61 (1998), Endo International's status as an indirect parent of Endo Pharmaceuticals does not suffice to confer personal jurisdiction. EB at 37. The Supreme Court held in *Bestfoods* that a parent corporation can be liable for the acts of a subsidiary when the parent's officers acted on behalf of the subsidiary. *Bestfoods,* 524 U.S. at 70. The Complaint alleged that corporate officers of Endo International directed conduct central to Endo's plan to launch a generic of Opana ER, an issue directly relevant to the Complaint allegations. ECF 2, ¶¶ 73-82, 91 [JA___]. When Endo

[6] Endo has declined to address the implications of its pending bankruptcy petition on the Court's jurisdiction. EB at 1 n.1 For its part, Impax agrees with the FTC that this Court has jurisdiction, but incorrectly states that the governmental unit exception to the bankruptcy stay applies because the FTC is not seeking monetary relief. IB at 44-45. The exception, however, "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." *SEC v. Brennan*, 230 F.3d 65, 71 (2d Cir. 2000) (emphasis in original).

was preparing to relaunch a generic version of Opana ER, it used the property of Par Pharmaceuticals, which is owned by Endo International. *See id*., ¶¶ 14, 75-78 [JA___]. Because Endo Pharmaceuticals does not own Par, but Endo International does, officers of the parent must have directed Par's actions on the subsidiary's behalf.

CONCLUSION

For the foregoing reasons and those stated in our opening brief, the Court should reverse the district court's dismissal of the Complaint and remand the case for determination on the merits.

Respectfully submitted,

ANISHA S. DASGUPTA
General Counsel

JOEL MARCUS
Deputy General Counsel

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/s/ *Mark S. Hegedus*
MARK S. HEGEDUS
Attorney

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

BRADLEY S. ALBERT
DANIEL W. BUTRYMOWICZ
KARA L. MONAHAN
ERIC M. SPRAGUE
Of Counsel

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 6,496 words.

I further certify that on March 14, 2023, the foregoing brief was filed and served via the Court's CM/ECF system.

March 14, 2023

/s/ *Mark S. Hegedus*

Mark S. Hegedus
Attorney
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580