UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ENDO PHARMACEUTICALS INC., *et al.*,

Defendants.

Case No. 1:21-cv-217-RCL
~~FILED UNDER SEAL**~~**
UNsealed
Redacted Opinion

MEMORANDUM OPINION

For more than one hundred years, the Sherman Act has declared that every contract in restraint of trade or commerce is illegal. 15 U.S.C. § 1. For more than two hundred years, the Patent Act in its various iterations has granted a successful patent applicant the "sole and exclusive right and liberty of making, constructing, using, and vending to others" her invention. Patent Act of 1790, ch. 7 § 1, 1 Stat. 109 (repealed 1793); *see* 35 U.S.C. § 154(a)(1). These dissonant statutes have coexisted for years. But the Supreme Court threw their uneasy détente in flux in *FTC v. Actavis*, 570 U.S. 136 (2013). In the present case, this statutory conflict comes to a head.

Endo Pharmaceuticals ("Endo") holds valid patents that cover an extended-release ("ER") oxymorphone medicine. Endo licensed those patents to Impax Laboratories, LLC ("Impax") for a [redacted]% royalty—contingent on Endo not using the patents and [redacted]. Impax is now the only producer of oxymorphone ER. With oxymorphone prices escalating, the Federal Trade Commission ("FTC") sued Endo, Impax, and their parent companies, claiming that (1) this licensing agreement is an unlawful noncompete agreement and (2) that Impax is maintaining an illegal monopoly. Endo and Impax argue that the patent laws expressly approve of exclusive licensing agreements akin to the one that they entered.

Before the Court are defendants' motions to dismiss, ECF Nos. 48, 51 & 53, the FTC's two opposition briefs, ECF Nos. 59 & 61, and defendants' replies in support, ECF Nos. 62, 63 & 65. Upon consideration of the parties' filings, applicable law, and the record herein, the Court will **GRANT** defendants' motions to dismiss for failure to state a claim.

I. BACKGROUND

A. Factual Background

Defendant Endo is a for-profit Delaware corporation. Compl. ¶ 12, ECF No. 3. Endo's parent company, Endo International plc, is based in Ireland. *Id.* ¶ 14. Endo owns several patents for Opana ER, an oxymorphone extended-release painkiller. *Id.* ¶¶ 17–20. After the Food and Drug Administration ("FDA") approved it in 2016, Opana ER quickly became Endo's second-best-selling product. *Id.*

Defendant Impax is also a for-profit Delaware corporation. *Id.* ¶ 15. In 2007, seeking approval to market a generic version of oxymorphone ER, Impax filed an Abbreviated New Drug Application ("ANDA") with the FDA. *Id.* ¶ 23. In its ANDA, Impax stated that its generic product would not infringe on Endo's patents. *Id.* ¶ 26. Endo disagreed and sued Impax for patent infringement in January 2008. *Id.* ¶ 27.

Endo and Impax settled that patent infringement litigation in 2010. *Id.* ¶ 28. Under their settlement agreement (the "2010 Agreement"), Impax agreed not to launch its generic oxymorphone ER until Endo's patent expired in 2013. *Id.* ¶¶ 27–28. In exchange, Endo agreed to provide Impax a license to any then-issued and future patents that could cover oxymorphone ER. *Id.* ¶ 29. The 2010 Agreement ensured that Impax could sell its oxymorphone ER product, even if Endo later obtained additional patents covering the drug. *Id.* The 2010 Agreement required Endo and Impax to "negotiate in good faith an amendment to the terms of the License to any [later-issued] patents." *Id.* ¶ 85.

In the years after the 2010 Agreement, nine more companies filed ANDAs covering generic oxymorphone ER. *Id.* ¶¶ 32, 34. Each time, Endo filed a patent infringement lawsuit against the company, and each time, the parties settled. *Id.* ¶¶ 34, 36. But none of these other settlement agreements included a licensing agreement for future patents like the 2010 Agreement. *Id.* ¶ 36. In other words, Endo did not grant these other companies a license for *all future* patents that could cover oxymorphone ER—just a license for the then-current patents.

Accordingly, when the Patent and Trademark Office ("PTO") issued Endo additional patents covering oxymorphone ER—including a patent that does not expire until 2029—Endo continued to assert its patents against generic oxymorphone ER manufacturers. *Id.* ¶¶ 47–49. Endo doggedly pursued litigation against all companies that were infringing upon its new patents. *Id.* ¶¶ 48–50. Through these patent-infringement suits, Endo prevented all producers of generic oxymorphone ER from making or selling their generic versions of oxymorphone ER until November 2029. *Id.* ¶¶ 50–56. But not Impax. The 2010 Agreement protected Impax from these injunctions because Endo had already licensed the additional patents to Impax. When the dust settled from Endo's patent-litigation frenzy, Endo and Impax were the only two companies allowed to sell oxymorphone ER in the United States. *Id.* ¶ 56.

In 2012, Endo launched a reformulated, "crush-resistant" version of Opana ER with FDA approval and stopped making the original Opana ER. *Id.* ¶¶ 57–58. Endo then petitioned the FDA to find that the original Opana ER was discontinued for safety reasons. That finding would have resulted in the FDA withdrawing its approval for all generic oxymorphone ERs on the market, including Impax's. *Id.* ¶ 61. The FDA denied this request. *Id.* ¶ 62. Instead, the FDA expressed safety concerns about the *reformulated* Opana ER and requested that Endo voluntarily remove it

from the market in June 2017. *Id.* ¶ 69. Endo acquiesced and stopped selling reformulated Opana ER. *Id.*

Opana ER sales made up a crucial portion of Endo's revenue, so the loss of that revenue became crushing to Endo's business. *Id.* ¶¶ 71–72. To stay in the oxymorphone ER market, Endo prepared to relaunch Opana ER with an approved ANDA (the "Watson ANDA") for generic oxymorphone ER. *Id.* ¶ 75. Endo took significant strides in early 2017 to relaunch Opana ER using the Watson ANDA. *Id.* ¶ 76. Endo executives held "almost weekly" meetings to plan the relaunch, organized manufacturing equipment, and purchased oxymorphone to begin required testing. *Id.* ¶¶ 77–82. But Endo never relaunched Opana ER. Instead, it took a different tactic.

While it prepared its potential relaunch, Endo also had a different plan in motion. In 2015, Endo—already aware that the FDA had concerns about reformulated Opana ER—requested (unsuccessfully) that Impax pay it an 85% royalty fee for the license to the later-issued patents. *Id.* ¶¶ 64, 85. When Impax refused, Endo sued Impax for breach of the 2010 Agreement in the District Court for the District of New Jersey. *Id.* ¶ 85. In a May 2016 filing, Endo alleged that Impax had breached the 2010 Agreement's requirement to negotiate an amendment in good faith and had, accordingly, infringed on Endo's patents. *Id.* ¶ 85. After that court denied Impax's motion to dismiss, Endo and Impax settled the breach-of-contract and patent-infringement lawsuit on August 5, 2017 (the "2017 Agreement"). *Id.* ¶ 85.

The terms of the 2017 Agreement are integral to the FTC's claims against defendants. The 2017 Agreement "clarifies that Impax's license in the [2010 Agreement] includes any Opana ER patents owned by Endo and obtained after it entered" the 2010 Agreement. *Id.* ¶ 93. Per the terms of the 2017 Agreement, Impax will pay Endo a licensing fee equal to [redacted]% of its gross profits from selling generic Opana ER. *Id.* ¶ 94. But if Endo (1) sells an oxymorphone ER product, (2) [redacted]

[redacted], or (3) [redacted] the royalty fee amount drops to 0%. *Id.* In other words, [redacted] Impax pays Endo nothing. Additionally, the 2017 Agreement requires that Endo split with Impax any damages that it obtains from suing patent infringers. *Id.* ¶ 97.

After the 2017 Agreement was executed, Endo terminated its project to relaunch a generic version of Opana ER and completely exited the oxymorphone ER market. *Id.* ¶ 98. Following Endo's exit, the average price of a 40 mg tablet of oxymorphone ER increased by over [redacted]%. *Id.* ¶ 117.

B. Procedural Background

The FTC filed this action on January 25, 2021, against Endo, Endo International, Impax, and Amneal Pharmaceuticals, Inc. ("Amneal"), alleging that Endo and Impax's anticompetitive agreement and Impax's subsequent monopoly violate Sections 1 and 2 of the Sherman Act.[1] Compl. ¶¶ 119–24. In particular, the FTC alleges that the 2017 Agreement puts an unreasonable restraint on trade by eliminating Endo's financial incentive to compete in the market in violation of Section 1, leaving Impax without competitors. *Id.* ¶¶ 102–07, 119–21. The FTC further alleges that Amneal, Impax's parent company, has willfully obtained and maintained its monopoly power in the oxymorphone ER market through the 2017 Agreement in violation of Section 2. *Id.* ¶¶ 121–24. In its telling, Amneal—through Impax—holds a monopoly in the oxymorphone ER market because it is currently the only company selling oxymorphone ER

[1] As the FTC notes, it does not directly enforce the Sherman Act. FTC Opp'n 10. Instead, the FTC challenges the 2017 Agreement as a violation of the Federal Trade Commission Act. *Id.* Courts treat these two actions as having no distinction, because violations of the Sherman Act are also "unfair methods of competition" that violate the FTC Act. *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986).

products. *Id.* ¶¶ 110–11. As relief, FTC seeks both an injunction and disgorgement of profits. *Id.* at 27.

All defendants move to dismiss. They argue that the 2017 Agreement is not an exclusive license or noncompete agreement because Endo can freely enter the market at any time. Endo's Mot. to Dismiss 1, ECF No. 51; Impax's Mot. to Dismiss 2, ECF No. 48. But even assuming the 2017 Agreement *is* an exclusive license, defendants argue that the patent laws give patentholders a right to exclude others from using patented technology and to issue exclusive patents. Endo's Mot. to Dismiss 1; Impax's Mot. to Dismiss 2.[2] Because the terms of the 2017 Agreement fit within the rights that Endo possessed under the patent laws, it "cannot violate antitrust laws" like the Sherman Act. Impax's Mot. to Dismiss 2.

Defendant Endo International independently filed both a motion to dismiss for failure to state a claim, concurring with the arguments that Endo made, and a motion to dismiss for lack of personal jurisdiction. Endo Int'l's Mot. to Dismiss, ECF No. 53. It argues that the Court has no general or specific jurisdiction over Endo International, an Irish company. *Id.* at 53.

The FTC responded to defendants' motions to dismiss. *See* FTC Omnibus Opp'n ("FTC Opp'n"), ECF No. 59; FTC Opp'n to Endo Int'l, ECF No. 61. Defendants then replied in support of their motions. Endo's Reply, ECF No. 62; Impax's Reply, ECF No. 65; Endo Int'l's Reply, ECF No. 63. These motions are now ripe.

[2] Endo cites the recent Supreme Court case *AMG Capital Management, LLC v. FTC*, 141 S. Ct. 1341 (2021), for the proposition that the FTC cannot seek disgorgement of profit under § 13(b) of the Federal Trade Commission Act of 1914. *Id.* at 3. The FTC concedes this point in its reply and withdraws its request for monetary relief. FTC Opp'n 35.

II. LEGAL STANDARD

A. Motion To Dismiss For Failure To State A Claim

To survive a motion to dismiss pursuant to Rule 12(b)(6), a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A claim is facially plausible when the plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* A court "should assume the veracity" of well-pleaded factual allegations, *id.* at 679, which "must be presumed true and should be liberally construed in [plaintiff's] favor." *Ndondji v. InterPark Inc.*, 768 F. Supp. 2d 263, 271 (D.D.C. 2011). The court need not accept any of the plaintiff's legal conclusions in evaluating a motion to dismiss. *Alemu v. Dep't of For-Hire Vehicles*, 327 F. Supp. 3d 29, 40 (D.D.C. 2018).

B. Patent Law and Antitrust Violations

"To promote the Progress of Science and useful Arts," the Founders granted Congress the power to "secur[e] for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. Congress subsequently enacted patent laws "to stimulate invention and reward innovation" by granting the patentee (the patent holder) a twenty-year patent monopoly over the "making, using, and selling of the patented invention." *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1127 (D.C. Cir. 1981); *see* 35 U.S.C. 154(a)(2) (establishing the twenty-year patent term). But this grant is in "tension with the general hostility against monopoly expressed in" antitrust laws. *Studiengesellschaft Kohle*, 670 F.2d at 1127. Accordingly, courts construe patent rights "narrowly." *Id.*

Even narrowly construed, the rights of a patentee are significant. For the patent term, she has the "right to exclude" others from profiting from her invention. *Id.* The right to exclude allows

her to exclusively maintain a patent monopoly; to "suppress the invention while continuing to prevent all others from using it"; to license one party exclusively and charge a royalty; to refuse to license; or to grant many licenses. *Id.* (citing *Zenith Radio Corp. v. Hazeltine Rsch. Inc.*, 395 U.S. 100, 135 (1969), *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 425 (1908), and *E. Bement & Sons v. Nat'l Harrow Co.*, 186 U.S. 70 (1902)). A license is an agreement not to sue the licensee of a patent for patent infringement. *Studiengesellschaft Kohle*, 670 F.2d at 1127. Patentees usually grant licenses with certain conditions, including the requirement that a licensee pay royalties. *Id.*

At their core, the "very object of these [patent] laws is monopoly." *E. Bement & Sons*, 186 U.S. at 91. "[A] patent is an exception to the general rule against monopolies and to the right of access to a free and open market." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). The patent monopoly and the resulting financial benefits are the reward granted to encourage inventors to continue inventing and to share their inventions with the United States (and the Patent Office). Accordingly, the fact that certain conditions in a licensing contract "keep up the monopoly . . . does not render them illegal." *Studiengesellschaft Kohle*, 670 F.2d at 1127. Still, the patent laws are not a *carte blanche* to violate the antitrust laws.

Indeed, the D.C. Circuit has long recognized that "the protection of patent laws and the coverage of the antitrust laws are not separate issues. Rather, the conduct at issue is illegal if it threatens competition in areas other than those protected by the patent." *Id.* at 1128. Otherwise, the conduct is protected from antitrust liability and does not violate antitrust laws. *Id.* While a patentee is entitled to exploit the full value of her invention, she cannot "endanger competition in other areas" by manipulating her patent monopoly. *Id.* When facing an alleged anticompetitive practice that implicates patent law, the D.C. Circuit accordingly asks if the patentee sought an

advantage "beyond what the patent itself gave" her. *Id.* at 1129. Only if the anticompetitive effects of a certain challenged restriction or license *exceed* the anticompetitive effects authorized by the patent has the Circuit found that activity violates antitrust law. *Id.*

In 2013, the Supreme Court confronted the interplay between antitrust laws and patent laws in a specific context: reverse-payment settlements.[3] Congress passed the 1984 Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch–Waxman Act, to encourage competition among pharmaceutical companies by accelerating the introduction of generics to the market. *Actavis*, 570 U.S. at 142. One method involved streamlining the timeline for generics producers—but only if those producers would provoke litigation with the brand-name patentee. *Id.*

Here's the streamlined process. First, a generic producer files an ANDA that "piggy-back[s]" on a pioneer drug's patent and receives expedited FDA approval. *Id.* As part of their application, the generic producer must assure the FDA that it will not infringe on the brand-name patent. *Id.* One way to satisfy this criterion is to declare that the brand-name patent is "invalid." *Id.* at 143. This declaration "automatically counts as patent infringement" under 35 U.S.C. § 271(e)(2)(A), and often provokes litigation between the patentee and the generic producer. *Id.* (citing 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). If litigation ensues, the FDA will withhold the generic's approval. *Id.* But if a court decides that the brand-name patent is invalid or will not be infringed upon, or if certain statutory deadlines pass, the FDA grants approval to market the generic drug. *Id.* This costly and litigious route may pay handsomely: approved generic producers enjoy a 180-day period of exclusivity, which may be worth hundreds of millions of dollars. *Id.* at 143–44.

[3] The Court notes that the present case does not involve a reverse-payment settlement.

The Hatch-Waxman Act was supposed to encourage competition, but patentees started taking a curious route:

> Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a "reverse payment" settlement agreement.

Id. at 140. Multiple Circuits found that these reverse-payment settlements "[fell] within the scope of the exclusionary potential of the patent" and could not violate antitrust laws. *Id.* at 141.

The Supreme Court disagreed. It held that reverse-payment settlements *could* violate antitrust law. *Id.* at 158. The Supreme Court emphasized that reverse payments settle litigation that would otherwise challenge "the patent's validity" and "preclusive scope." *Id.* at 147. A valid patent arms its owner with a powerful set of rights, including the right to exclude all other competitors from the market—activity that could violate antitrust law if the patentee was not protected by the patent laws. *Id.* But an "*invalidated* patent carries with it no such right." *Id.* If a court found a patent invalid, generic producers could flood the market. *Id.* The reverse-payment settlement puts an end to litigation without answering that question, potentially stifling competition. *Id.* The Supreme Court further stressed the "unusual" nature of reverse-payment settlements. *Id.* The plaintiff—an ostensibly valid patentholder—is paying the defendant—the alleged infringer—millions of dollars to settle, "even though the defendant did not have any claim that the plaintiff was liable to them for damages." *Id.*

"Given these factors," the Supreme Court explained it would be "incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well." *Id.* at 148.

Both antitrust *and* patent policies are relevant in determining the "scope of the patent monopoly" and the "antitrust law immunity" conferred by a patent. *Id.*

After *Actavis*, the interplay between patent laws and antitrust laws fell into flux. Some Circuits appear to have limited the Supreme Court's holding to reverse-payment settlements. *See, e.g., In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 41 (1st Cir. 2016). No Circuit case has applied the analysis in *Actavis* to patent activity beyond reverse-payment settlements. No court in this Circuit has yet considered how to interpret *Actavis* in the context of an antitrust challenge. But because this case treads this tenuous line between patent and antitrust laws, this Court must discuss these issues in the first instance.

III. DISCUSSION

This case turns on a single question: Are defendants' actions protected from antitrust liability under the patent laws? Defendants argue that, even accepting the FTC's characterization of the 2017 Agreement as an exclusive license and non-compete that created a patent monopoly, they have not exceeded their rights under the patent laws. Endo Mot. to Dismiss 19. In their view, they have not violated Sections 1 or 2 of the Sherman Act. *Id.* The FTC argues that defendants "misapprehend the relationship between antitrust law and patent rights." FTC Opp'n 20. The Court agrees with defendants. While some patent-related activity can violate antitrust law, the FTC has alleged nothing more than the type of exclusive licensing agreement and patent monopoly expressly provided for by the patent laws and repeatedly approved of by the Supreme Court. Consequently, the FTC has not adequately alleged an antitrust violation. The Court also rejects the FTC's argument that Endo previously "waived" its right to exclude Impax and so it is not protected from antitrust scrutiny. FTC Opp'n 17.

The Court's analysis proceeds in three steps. First, the Court finds that the FTC has plausibly alleged an exclusive licensing agreement between Impax and Endo and a resulting patent

monopoly. But certain anticompetitive activity is protected from antitrust scrutiny under the patent laws. So, second, to determine if this type of activity is protected, the Court applies the Supreme Court's reasoning in *Actavis* to the activity alleged here. Third, the Court addresses the FTC's argument that Endo "waived" its right to exclude and the corresponding rights that flow from the right to exclude.

A. The FTC Has Plausibly Alleged An Exclusive Licensing Agreement And A Patent Monopoly

While the terms of the 2017 Agreement are not in dispute, the parties dispute how the Agreement should be characterized. Before the Court can analyze whether certain activity is protected from antitrust liability under the patent laws, it must identify the activity at issue. The FTC alleges that the 2017 Agreement clarifies Impax's license, first set out in the 2010 Agreement, to all future oxymorphone ER patents. Compl. ¶ 93. In return, Endo receives a royalty of [redacted]% of Impax's gross oxymorphone ER profits. *Id.* ¶ 94. But if Endo (1) uses the oxymorphone patents itself to enter the oxymorphone ER market, (2) [redacted] or (3) [redacted] Endo's royalty drops to 0%.[4] *Id.*

The parties dispute what to term this agreement. The FTC argues that the 2017 Agreement is a noncompete agreement. FTC Opp'n 8. It rejects the notion that Endo has a choice to enter the market or license another generics company because Endo has no financial incentive to do so. *Id.* Defendants argue that the 2017 Agreement is not a noncompete agreement or an exclusive license, because technically Endo could choose to compete without breaching the agreement. *See, e.g.*,

[4] Though the FTC does not emphasize the last point, the Court notes that patent infringement is not a crime. A patent holder *must* exert its patent rights in civil litigation to prevent infringement. 35 U.S.C. § 281. Only a patent holder—not a licensee or even an exclusive licensee—has the right to sue for patent infringement. *Id.* Therefore, Impax had no right to sue to protect its exclusive license.

Impax's Mot. to Dismiss 11. Endo would just need to forego the royalty payment. *Id.* But these are semantic issues, and antitrust law favors substance over "formalistic distinctions." *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285 (2018); *see Actavis*, 570 U.S. at 147 (discussing the settlement "in substance"). Neither antitrust nor patent law requires a court to specifically name an agreement before considering it. The 2017 Agreement is not Rumpelstiltskin. This Court need not guess its true name.

Construing all inferences in favor of the FTC as required, this Court agrees that FTC has plausibly alleged that the substance of the 2017 Agreement involves Impax paying Endo a royalty fee conditioned on Endo [redacted] In effect, Impax has paid Endo for the exclusive right to use the patent licenses for oxymorphone ER. Compl. ¶ 94. If [redacted] Impax's duty to pay Endo is discharged. *Id.*

While the FTC refers to this agreement as a "noncompete," for the purposes of the patent analysis this Court will refer to the 2017 Agreement as an exclusive license. That is what most patent law cases call agreements of this ilk. An exclusive license is an agreement that a patentee "would not license any other person than the [licensee]" and would provide the licensee "the exclusive right to manufacture and vend the article" covered by the patents. *E. Bement & Sons v. Nat'l Harrow Co.*, 186 U.S. 70, 94 (1902). The license agreement is "usually for consideration" and is often granted "on certain conditions, in addition to the requirement that the licensee pay royalties." *Studiengesellschaft Kohle*, 670 F.2d at 1127. Despite what defendants allege about the *option* to compete, this Court finds that the FTC has plausibly alleged the 2017 Agreement is an exclusive license.

B. The FTC Has Not Plausibly Alleged Anticompetitive Activity, Because Defendants' Activity Is Specifically Protected By The Patent Laws

The Court now turns to the 2017 Agreement's legal status. Activities specifically authorized by the patent laws do not violate antitrust law unless they threaten areas of competition "other than those protected by the patent." *Studiengesellschaft Kohle*, 670 F.2d at 1129. *Actavis* left the interplay between these areas of law unclear.[5] While the Supreme Court's analysis focused on reverse-payment settlements—a type of settlement absent here—it identified several considerations that are applicable to this Court's analysis. Accordingly, the Court will apply the Supreme Court's analysis in *Actavis* to the situation at hand—an exclusive license that left only Impax in the market—to determine whether Impax and Endo can be liable for the 2017 Agreement and the patent monopoly under the antitrust laws.

In *Actavis*, the Supreme Court identified the follow considerations: (1) the validity of the patent in question; (2) "whether 'the patent statute specifically gives a right' to restrain competition in the manner challenged"; (3) "whether 'competition is impeded to a greater degree' by the restraint at issue than other restraints previously approved of as reasonable"; (4) whether the patent license is "overly restrictive"; (5) whether the patent-holder "'dominate[d] the industry' and 'curtail[ed] the manufacture and supply of an unpatented product'" and (6) whether the settlement was traditional or "unusual." *Actavis*, 570 U.S. at 147–52 (quoting *United States v. Line Material Co.*, 333 U.S. 287, 311 (1948) and *Standard Oil Company (Indiana) v. United States*, 283 U.S. 163 (1931)). The Court addresses each of these considerations in turn.

[5] Some Circuits limit the Supreme Court's decision in *Actavis* solely to reverse-payment settlements. For example, the First Circuit has determined that the Supreme Court "did not intend to disturb commonplace [patent] settlement forms." *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 544 n.4 (1st Cir. 2016).

1. Whether The Patent's Validity Is In Question

An invalidated or non-infringed patent includes no right to exclude (and accordingly no protection from antitrust liability), so a settlement that ends litigation challenging a patent's validity is suspect. *Actavis*, 570 U.S. at 147. In the *Actavis* decision, the Supreme Court emphasized that the "patent here may or may not be valid, and may or may not be infringed," so referring "simply to what the holder of a valid patent could do does not by itself answer the antitrust question." *Id.* This was the core of the Supreme Court's analysis and the reason that reverse-payments have a "potential for genuine adverse effects on competition." *Id.* at 153. "The [reverse] payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims *but would lose if the patent litigation were to continue* and the patent were held invalid or not infringed by the generic product." *Id.* (emphasis added). The reverse settlement in *Actavis* stifled challenges that could allow other generic manufacturers to market their drugs.

Here, on the other hand, the validity of Endo's patents has been repeatedly tested. The Federal Circuit has held Endo's patents valid multiple times. Compl. ¶¶ 50–55. The validity of Endo's patents is not in question. There is no question generic oxymorphone ER infringes on Endo's patents. Endo's "right to exclude" is undisputed. So unlike *Actavis*, there is no concern that Endo may be paying Impax not to challenge the validity of Endo's patents or its patents' preclusive effect on generics.[6] Accordingly, the Court can analyze whether a valid patent gives defendants the right to enter into a licensing agreement like the 2017 Agreement.

[6] The FTC argues that if the 2017 Agreement is protected by the patent laws from antitrust liability, the Court's holding would create a "loophole" to the *Actavis* ruling. FTC Opp'n 28. The "loophole" would allow companies settling patent infringement suits with generics to, instead of "agreeing to a reverse payment," enter a licensing agreement with indeterminant terms and then "modify the license to include anticompetitive terms." *Id.* 27–28. The Court rejects this slippery-slope argument—if the FTC were alleging that the 2017 Agreement was a cleverly hidden plot to disguise a reverse-payment, the Court's analysis would change. But the FTC does not allege that.

2. Whether The Patent Statute Specifically Gives A Right To Restrain Competition In The Manner Challenged[7]

To "strike th[e] balance" between "the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited" by the antitrust laws, the Supreme Court instructed courts to ask whether the patent laws grant parties the right to restrain competition in the specific way that is challenged. *Actavis*, 570 U.S. at 148 (quoting *Line Material Co.*, 333 U.S. at 310). The Patent Act expressly allows patent monopolies and exclusive licenses like the 2017 Agreement.

The Patent Act explicitly gives a right to maintain a patent monopoly. A patentee has "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States." 35 U.S.C. § 154 (a)(1). The right to a patent monopoly and to exclude all others from profit flows from this "right to exclude." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). The FTC alleges that one company is the exclusive provider of oxymorphone ER for the entire country. Compl. ¶ 110. But the FTC's arguments run headlong into the Patent Act's express permission for one company to hold monopoly power.

While it is Impax, not Endo, that maintains the patent monopoly, the Patent Act also approves of exclusive licenses—i.e., an agreement that confers the patent monopoly to a licensee. A patentee may "grant and convey an exclusive right under his application for [a] patent, or patents, to the whole or any specified part of the United States." 35 U.S.C. § 261. "Unquestionably, the owner of a patent may grant licenses to manufacture, use, or sell upon conditions not inconsistent with the scope of the monopoly." *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 304 U.S. 175, 181,

[7] This consideration and the next consideration would likely have exclusively informed the Court's analysis pre-*Actavis*. Pre-*Actavis*, the Court would have determined whether the FTC plausibly alleged an agreement that "threaten[ed] competition in areas other than those protected by the patent." *Studiengesellschaft Kohle*, 670 F.2d at 1128.

aff'd on reh'g, 305 U.S. 124 (1938). And royalties can be a share of profits—they need not be a set fee. *Standard Oil Co.*, 283 U.S. at 171.

Because the oxymorphone ER patents are unquestionably valid, Endo has a "right to exclude" and pursue its patent monopoly. The FTC alleges that Endo instead licensed only one company, Impax, the patents necessary to create generic oxymorphone ER, excluding all others—including Endo itself—so that Impax could charge supracompetitive prices. But such exclusive licenses are also expressly protected. "[A]n exclusion of competitors and charging of supracompetitive prices are at the core of the patentee's rights, and are legitimate rewards of the patent monopoly." *Studiengesellschaft Kohle*, 670 F.2d at 1128. The Patent Act protects this anticompetitive conduct.

3. Whether Competition Is Impeded To A Greater Degree By The Restraint At Issue Than By Other Restraints Previously Approved As Reasonable

The Supreme Court instructed courts to compare the alleged anticompetitive activity with past activity deemed protected by the patent laws. *Actavis*, 570 U.S. at 148. Exclusive licenses like the 2017 Agreement, which exclude all others and permit only the licensee to compete, have been repeatedly deemed reasonable by the Supreme Court and the federal courts of appeals. The FTC does not allege any additional facets of the 2017 Agreement that would "impede[] [competition] to a greater degree" than a traditional exclusive license. *Id.*

While the FTC highlights that the 2017 Agreement prevents Endo from competing with Impax, the Seventh Circuit has held that exclusive license agreements between two parties are reasonable even when one *does not have the right to exclude the other*—in other words, even when the agreement functionally operates as a noncompete. *Rail-Trailer Co. v. ACF Industries, Inc*,

358 F.2d 15, 16–17 (7th Cir. 1966).[8] While a patent confers the right to exclude, one joint patentee has no right to exclude the other. *Id.* at 16. In *Rail-Trailer Company v. ACF Industries, Inc*, one joint patentee granted the second joint patentee an exclusive license. *Id.* Through that exclusive license, the first joint patentee agreed to exclude himself from using the patent or making the patented item. *Id.* When faced with the argument that a "grant by a joint [patent] owner . . . of an exclusive license" to his co-owner was a prohibited noncompete agreement, the Seventh Circuit disagreed. *Id.* at 16. It held that a patentee may "grant an exclusive license for the manufacture of the patented device" that excludes even "himself from engaging in the manufacture of the device"—even if his joint patentee could not otherwise exclude him. *Id.* This action does not violate the Sherman Act because "the restraint arises from the patent grant and a lawful transfer of a part of the rights to which the grant attached." *Id.*

The Supreme Court has also approved of a patentee charging a licensee "*any* royalty, or upon any condition the performance of which is reasonably within the reward." *United States v. Gen. Elec. Co.*, 272 U.S. 476, 489 (1926) (emphasis added). The FTC argues that Endo decided to license Impax at a royalty fee that would "maintain supracompetitive prices to be shared" rather than compete and "face a competitive market." FTC Opp'n (quoting *Actavis*, 570 U.S. at 157). But patent cases expressly approve of supracompetitive prices. As the D.C. Circuit has explained, the "charging of supracompetitive prices are at the core of the patentee's rights, and are legitimate rewards of the patent monopoly." *Studiengesellschaft Kohle*, 670 F.2d at 1128. The Supreme Court has similarly approved, as reasonable, a patentee "exact[ing] royalties as high as he can negotiate

[8] The FTC alleges that Endo has "waived" its right to exclude Impax. FTC Opp'n 17. While this Court disagrees, *see* Part III.C, *infra*, the Seventh Circuit has expressly approved of exclusive licensing agreements between two competitors where one lacks to right to exclude the other.

with the leverage of that monopoly" during the life of the patent. *Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964).

The FTC attempts to analogize the 2017 Agreement to activity that courts in other cases found fell outside of the patent laws' protection.[9] FTC Opp'n 23–25. But each of those cases implicated additional anticompetitive activity beyond an exclusive license and patent monopoly. For example, in *King Drug Company of Florence, Inc. v. SmithKline Beacham Corp.*, a patentee granted an alleged infringer an exclusive license as a reverse payment to settle litigation challenging the patent's validity. 791 F.3d 388, 398 (3d Cir. 2018). The Third Circuit appropriately analyzed the license like a reverse payment described in *Actavis*. *Id.* at 403; *see In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 245 (D. Conn. 2015) (involving an exclusive license used as a "reverse payment"). But there is no allegation of a reverse payment here. In *United States v. Singer Manufacturing Company*, which the FTC mentions in a footnote, FTC Opp'n 21 n.12, companies pooled their respective patents in a cross-licensing agreement specifically to push out Japanese competitors. 374 U.S. 174, 189, 195 (1963). The Supreme Court there disapproved of a concerted agreement among multiple patent holders to aggregate patents into one company's control and then use those patents to rid themselves of "infringements by their common competitors." *Id.* Three companies with potentially conflicting patents agreed to unite instead of litigating patent infringement claims among themselves and granted the company with the greatest prosecuting power the right to prosecute the patents against competitors on all three companies' behalf. *Id.* at 190–95. This gave each company more power than it had alone and extended the companies' activities "beyond the limits of the patent monopoly." *Id.* at 196. But Endo could

[9] The FTC also attempts to analogize this case to *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990) and *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir 2001) (per curiam). *See, e.g.*, FTC Opp'n 20, 24. Both these cases involve copyright law, not patent law, and so neither can assist the Court in determining what, if any, protection the patent laws provide from antitrust liability.

maintain the same oxymorphone ER monopoly *alone*, instead of licensing it to Impax—Endo is not extending its monopoly beyond its patents by pooling with another company. The FTC has not illustrated that the 2017 Agreement, as alleged, is any "more restrictive" than activity previously approved of as reasonable.

4. Whether The Patent Licensing Agreement Is Overly Restrictive

In *Actavis*, the Supreme Court noted that while a single patentee granting a single license containing a minimum resale price was a "reasonable restraint," a minimum resale price set by multiple patentees cross-licensing patents to each other is "overly restrictive." *Actavis*, 570 U.S. at 150 (citing *General Elec. Co.*, 272 U.S. at 489 and *Line Material Co.*, 333 U.S. at 310–11). The 2017 Agreement sets no minimum resale price, and, as discussed directly above, this is not an agreement between two patentees to pool patents—Impax is not sharing any related patents with Endo.

5. Whether The Patent Holder Dominated The Industry And Curtailed The Manufacture And Supply Of An Unpatented Product

Citing Justice Brandeis's language from *Standard Oil Company (Indiana) v. United States*, the Supreme Court notes that a cross-licensing agreement could violate antitrust law if the parties dominate the industry *and* influence the market of unpatented products. *Actavis*, 570 U.S. at 151 (citing *Standard Oil Co.*, 283 U.S. at 174). Here, the FTC only alleges conduct related to the oxymorphone ER market. There are no other products that the FTC alleges Endo or Impax have attempted to dominate or curtail. Endo has not attempted to "expand its monopoly . . . beyond the scope of the monopoly which its patent gave." *Studiengesellschaft Kohle*, 670 F.3d at 307.

6. Whether The Settlement In Traditional In Form

At the end of the Supreme Court's analysis in *Actavis*, it emphasizes that patent "settlements taking [] commonplace forms have not been thought . . . subject to antitrust liability"

and that the *Actavis* decision "do[es] not intend to alter that understanding." *Id.* at 152. As an example of a "commonplace form" of settlement, the Supreme Court cites a situation where Company A sues Company B and demands $100 million in damages, and Company B pays a lesser, but still reasonable, amount to settle—say $40 million. *Id.* That is exactly the situation here—Endo sued Impax for patent infringement and breach of contract after Impax rebuffed Endo's request for 85% royalties. Compl. ¶¶ 85, 86. The 2017 Agreement that settled the litigation guaranteed Endo [redacted]% royalties and granted Impax an exclusive license. *Id.* ¶ 94. In other words, Company A demanded 85% and ultimately settled for Company B paying a lesser amount—[redacted]%. This is a "commonplace" settlement.

* * *

At bottom, the concerns identified in *Actavis* are not present here. Endo had a valid license and a right to exclude, which allowed it to maintain a patent monopoly and charge supracompetitive prices. The right to also permitted Endo to exclusively license another company. Seeking to benefit fully from its lawful patent monopoly, Endo chose to exclusively license oxymorphone ER to Impax instead of competing or licensing other competitors. The Patent Act provides Endo the right to make that decision. The Court concludes that the FTC has failed to allege that the 2017 Agreement or the resulting patent monopoly violate Sherman Act Sections 1 or 2. While a "noncompete" agreement or a monopoly generally violate the antitrust laws, the Patent Act expressly provides for both exclusive licenses and patent monopolies.

C. FTC Did Not Plausibly Allege That Endo "Waived" Its Right To Exclude To Impax in 2010

In a related argument, the FTC alleges that the 2017 Agreement cannot fall within Endo's lawful patent rights because Endo waived its right to exclude Impax from using Endo's patents in 2010. FTC Opp'n 18. To refresh, Endo and Impax settled their first patent-infringement case in

2010 when Endo granted Impax a license to all then-issued and future patents covering generic oxymorphone ER. Compl. ¶ 29. This 2010 Agreement also included a clause requiring Impax and Endo to negotiate in good faith for an amendment to the terms of the agreement for any future patents. *Id.* ¶ 85.

The FTC's argument is not easy to parse, but it goes like this: Patent rights, like the right to grant licenses, are "incident of the right to exclude." FTC Opp'n 18 (quoting *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.3d 931, 949 (Fed. Cir. 1993)). When Endo licensed Impax in the 2010 Agreement, Endo waived its right to exclude Impax from the oxymorphone ER market. FTC Opp'n 18. Endo could not sue Impax for patent infringement after 2010, because a patent license waives the right for judicial relief for patent infringement. FTC Opp'n 18 (citing *Studiengesellschaft Kohle*, 670 F.3d at 1127). Because the right to license for a royalty and the right to a patent monopoly derive from the right to exclude and because the grant of a license "waives" the right to exclude, the FTC argues Endo's patent rights cannot protect the 2017 Agreement. FTC Opp'n 18.

This argument fails for three reasons. First, as explained above, at least one Circuit has allowed exclusive licensing agreements between parties that could not legally exclude one another. *See Rail-Trailer Co.*, F.2d 15 at 16. This Court has found no cases holding the opposite. Even if Endo waived its right to exclude Impax, it did not waive its right to exclude other companies or itself from the market—and an exclusive license does just that. Second, the FTC fails to acknowledge that Endo sued Impax for breach of the 2010 Agreement. Compl. ¶¶ 85–86. So even if a licensing agreement meant that Endo waived its right to exclude Impax from the market, a *breached* licensing agreement does not waive Endo's right to exclude. As Impax notes, the FTC "proposes a radical rule: that in granting a conditional license, a patent holder gives up its patent

rights as to a licensee even where the licensee fails to satisfy the conditions." Impax's Reply 7. The FTC cites no legal authority in support of that position, and this Court can find none. Third, whether Endo waived its right to exclude is not a factual allegation and receives no deference. *See Iqbal*, 556 U.S. at 680 (holding that legal conclusions in a complaint are not entitled to the assumption of truth). The FTC makes no mention of Endo's "waiver" of the right to exclude in its complaint. The Court does not find that Endo waived its right to exclude Impax in 2010.

IV. CONCLUSION

For the foregoing reasons, this Court finds that the FTC has failed to allege that defendants violated Section 1 or Section 2 of the Sherman Act. The 2017 Agreement, construing it as the FTC alleged, falls within the bounds of the anticompetitive activity expressly protected by the patent laws. The Court will **GRANT** defendant Endo's motion to dismiss, **GRANT** defendants Impax and Amneal's motion to dismiss, and **GRANT** defendant Endo International's motion to dismiss. A separate order consistent with this memorandum will follow.

Date: 3/24/22

Royce C. Lamberth
United States District Judge