IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION,
600 Pennsylvania Avenue, N.W.
Washington,R THE **Ar2h 6**

I. NATURE OF THE CASE

1. This case challenges an anticompetitive agreement between Endo and Impax designed to create and maintain a monopoly for oxymorphone ER, a long-acting opioid used to treat moderate to severe pain. Their unlawful scheme continues to this day.

2. Opana ER, a branded oxymorphone ER product, has been a cornerstone of Endo's pain management business for over a decade. In 2016—the last full year it was sold—Opana ER was Endo's highest-grossing branded pain management drug, generating nearly $160 million in revenues. By 2017, however, this important revenue source was in jeopardy. On June 8, 2017, the United States Food and Drug Administration ("FDA") requested that Endo remove Opana ER from the market. Endo understood that it would need to comply with the FDA's request

the benefits of competition, forcing them and other purchasers to pay millions of dollars a year more for this medication.

II. JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345.

6. This Court has personal jurisdiction over each defendant because each defendant has the requisite constitutional contacts with the United States of America pursuant to 15 U.S.C. § 53(b).

7. Venue in this district is proper under 15 U.S.C. § 22, 28 U.S.C. § 1391(b) and (c), and 15 U.S.C. § 53(b). Each defendant resides, transacts business, committed an illegal or tortious act, or is found in this district.

8. Each defendant's general business practices, and the unfair methods of

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11. The FTC is authorized to bring this case in federal court because Defendants are violating or about to violate a provision of law enforced by the FTC, and this case is a proper case for permanent injunctive relief within the meaning of Section 13(b) of the FTC Act, 15 U.S.C. § 53(b).

12. Defendant Endo Pharmaceuticals Inc. is a for-profit Delaware corporation, with its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355. Endo Pharmaceuticals is engaged in the business of, among other things, developing, manufacturing, and marketing branded drug products. Endo Pharmaceuticals entered into the anticompetitive agreement challenged in this complaint. Unless otherwise specified, "Endo" refers to Endo Pharmaceuticals Inc. and all corporate predecessors, subsidiaries, successors, and affiliates.

13. Endo has substantial manufacturing expertise and capabilities. Endo's 2016 Form 10-K Annual Report notes its "efficient, high quality manufacturing capabilities" covering "almost all generic presentations, such as solid oral dose, gels, liquids, nasal sprays, ophthalmics, films, transdermal patches and injectable products." Endo's 2019 Form 10-K Annual Report notes its focus on "high-barrier-to-entry products, including first-to-file or first-to-market opportunities that are difficult to formulate or manufacture or face complex legal and regulatory challenges."

14. Defendant Endo International plc is a for-profit Ireland corporation, with its global headquarters at First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland, and its U.S. headquarters and CEO's office (nd i)-2 (i)-2 (i(a)4 (5)our)4 (roD)4 (s.)4 Tc 0.01 ofaficcon

Companies, Inc. now and at the time of the anticompetitive agreement challenged in this complaint. Endo International shares with Endo Pharmaceuticals leadership, trade names, logos, and websites, and they

includes selling oxymorphone ER. According to its 2018 and 2019 Form 10-K Annual Reports, Amneal Pharmaceuticals, Inc. "conduct[s] and exercise[s] full control over all activities of Amneal" Pharmaceuticals LLC and reports financial results on a consolidated basis. Amneal has made at least four payments to Endo under the terms of the agreement challenged in this complaint. Unless otherwise specified, "Amneal" refers to Amneal Pharmaceuticals, Inc. and all corporate predecessors, subsidiaries, successors, and affiliates, including Impax.

IV. BACKGROUND

A. Opana ER is a successful and important branded drug for Endo

17. Oxymorphone is a semi-synthetic opioid originally developed over one hundred years ago. Opioids are one of the world's oldest known classes of drugs, long used to relieve pain. The FDA first approved oxymorphone in 1959.

18. Oxymorphone extended-release (ER) is the long-acting version of oxymorphone. It is approved "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time."

19. Opana ER is the brand-name version of oxymorphone ER. In 2002, Endo filed

21.

28. In June 2010, Endo and Impax settled their patent litigation. Under the 2010 Patent Settlement Agreement, Impax agreed not to launch its generic version of Opana ER until January 2013.

29. The 2010 Patent Settlement Agreement also included a patent license from Endo to Impax. Section 4.1(a) 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. This patent license 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.

30. Impax and Endo have each publicly agreed with this understanding of the 2010 patent license. For example, in 2017, Impax represented in an FTC administrative proceeding that Impax got "this 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." In that same proceeding, Impax touted that "the reason it's able to sell [the oxymorphone ER] product today is because" of the 2010 patent license. Endo also has publicly characterized the 2010 patent license as giving Impax the "freedom to operate under future Endo patents covering Opana ER," enabling "Impax [to] launch risk-free years before" the last Opana ER patent expires.

31. In January 2013, Impax launched its generic version of oxymorphone ER consistent with the terms of the 2010 Patent Settlement Agreement.

C. Other potential oxymorphone ER sellers are blocked from entering

32. Impax was not the only company seeking to introduce a generic version of Opana ER. Nine other companies have submitted ANDAs seeking approval to market a generic oxymorphone ER product. These companies include, among others, Actavis South Atlantic LLC,

Par Pharmaceuticals, Inc. (now owned by Endo), and Roxane Laboratories Inc. (now owned by Hikma).

33. None of these other companies, however, are currently in the position to compete against Impax or Endo due to a series of court decisions that took place between 2015 and 2016.

34. Each generic applicant included a paragraph IV certification asserting that its proposed generic product did not infringe Endo's patents and/or that Endo's patents were invalid or unenforceable. In response to each paragrapKIV certification, Endo filed a patent infringement case, asserting [illegible] Tj-0.004 Tw 4.737 577.32o a product d ActaviEndo's

38. In July 2011, Actavis entered with certain dosage strengths of generic Opana ER under the terms of its 2009 settlement. In September 2013, Actavis launched additional dosage strengths of generic Opana ER.

39. As of September 2013, there were three companies competing for sales of oxymorphone ER: Endo, with its branded version of Reformulated Opana ER, and Impax and Actavis with generic versions of Original Opana ER.

40. Competition from generic drugs is a critical part of lowering prescription drug

42. This competition resulted in millions of dollars of savings for patients suffering from moderate to severe pain, and for other payors of Opana ER, including health care plans and government entities.

43. These benefits from competition, however, would be short-lived.

44. From 2012 to 2014—after its first wave of Opana ER patent litigation—Endo developed or acquired the rights to several additional patents related to Opana ER.

45. On November 13, 2012, the U.S. Patent and Trademark Office ("PTO") issued to Endo Pharmaceuticals Inc. U.S. Patent No. 8,309,122 ("the '122 Patent")." The '122 Patent expires on February 4, 2023.

46. On December 11, 2012, the PTO issued to Endo Pharmaceuticals Inc. as assignee U.S. Patent No. 8,329,216 ("the '216 Patent"). The '216 Patent expires on February 4, 2023.

47. On October 28, 2014, the PTO issued to Mallinckrodt LLC as assignee U.S. Patent No. 8,871,779 ("the '779 Patent"), from U.S. Application Serial No. 11/915,606. Endo acquired an exclusive field-of-use license to the '779 Patent through its December 2013 settlement with Mallinckrodt, which provided Endo with an exclusive field-of-use license to any patents that issue from U.S. Application Serial No. 11/915,606. The '779 patent expires on November 22, 2029.

48. The '122, '216, and '779 Patents (collectively, "the Future Patents") were all issued or licensed to, Endo after Endo and Impax entered the 2010 Patent Settlement Agreement.

49. In December 2012, Endo began asserting some of the Future Patents against Actavis and other potential generic entrants in two different sets of litigation. Endo did not assert these Future Patents against Impax because Impax had a license to the Future Patents under the 2010 Patent Settlement Agreement.

from the pill into the patient's body. Compared to the immediate-release oxymorphone formulation, oxymorphone ER provides longer-lasting, 12-hour pain relief that allows the patient to take fewer pills each day. But in order to reduce dose frequency, each long-acting opioid carries more active pharmaceutical ingredient than its short-acting counterpart. This makes long-acting opioids such as Opana ER subject to abuse; crushing and ingesting the pills immediately releases the larger amount of active ingredient into the bloodstream.

58. To purportedly discourage such abuse, Endo developed, and sought FDA approval for, a reformulated "crush-resistant" version of Opana ER (NDA No. 201655).

59. The FDA approved Reformulated Opana ER for sale in December 2011.

60. Endo launched Reformulated Opana ER in March 2012 and stopped selling the original version of Opana ER the following May. By June 2012, Endo had transitioned patients from Original Opana ER to Reformulated Opana ER.

61. Two months later, in August 2012, Endo submitted a Citizen Petition to the FDA. In its petition, Endo asked the FDA to find that Endo discontinued Original Opana ER for safety reasons, and therefore the FDA should refuse any pending ANDAs for generic versions of Original Opana ER and suspend and withdraw approval for any generic versions of Original Opana ER already on the market.

62. The FDA denied Endo's petition. The FDA concluded that safety reasons did not motivate Endo's decision to discontinue Original Opana ER. Specifically, the FDA cited in vitro and pharmacokinetic studies showing that Reformulated Opana ER's crush-resistant properties could be "compromised," facilitating other routes of abuse. The FDA also referenced "certain data suggest[ing]" that Reformulated Opana ER was more susceptible to intravenous abuse than

67. At the March meeting, a majority of the Advisory Committee agreed that the evidence showed a concerning shift in the abuse pattern from nasal to injection route of abuse following the reformulation. “[T]he data demonstrate that reformulated Opana ER does not resist preparation for injection adequately, and represents a problem because of the apparent greater proportion of drug abuse by the injection route compared with other opioids.”

68. The Committee voted eighteen to eight, with one abstention, to express its belief that Reformulated Opana ER’s risks outweighed its benefits. The Advisory Committee did not vote on whether Opana ER should be removed from the market.

69. Although the Committee did not vote to require Endo to remove Reformulated Opana ER from the market, on June 8, 2017, the FDA asked Endo to voluntarily do so. Endo International announced its decision to accede to the FDA’s request the following month. As Endo President & CEO Paul Campanelli explained to Endo’s Board of Directors, voluntary removal was Endo’s best option given “the current political cliCtey

limit diversion by preventing the accumulation of controlled substances in amounts exceeding legitimate need.

80. On May 18, 2017, Endo submitted to the DEA a quota request for approximately 157 kg of oxymorphone ER to support the transfer of the Watson formulation to Par's Chestnut Ridge facility. On or around June 9, 2017, the DEA approved the quota request.

81. On or around July 7, 2017, Endo's CEO approved a $300,000 purchase order for oxymorphone API to be used in work necessary to transfer the Watson formulation to the Chestnut Ridge facility. As Endo's CEO noted in approving the purchase order: "No matter how the product evolves we need to be ready at [Chestnut Ridge]."

82. As of July 2017, Endo forecasts and planning documents identified the second quarter of 2018 as the potential relaunch date for Original Opana ER under the Watson ANDA.

F. Rather than enter and compete with its own oxymorphone ER product, Endo decides to share Impax's oxymorphone ER profits

83. Endo's efforts to relaunch Original Opana ER, however, ultimately took a back seat to its preferred strategy of preserving Opana ER profits—reaching an agreement not to compete and splitting profits with Impax, the only active seller of oxymorphone ER.

84. Concurrent with its development of the Watson ANDA, Endo was negotiating a settlement in a breach of contract case against Impax.

85. In October 2015, almost three years after it was assigned the first of the Future Patents, Endo requested Impax pay an 85% royalty for a license to the Future Patents relating to

86. In May 2016, Endo sued Impax for breach of the 2010 Patent Settlement Agreement in the United States District Court for the District of New Jersey ("Breach of Contract Action"). Endo requested the court declare Impax in breach of the 2010 Patent Settlement Agreement, find that Impax infringed three patents, including two of the Future Patents (the '122 and '216 Patents), award Endo compensatory damages for Impax's alleged breach of contract and infringement, attorneys' fees, enhanced damages, costs and expenses, and "[s]uch other and further legal and equitable relief as the Court may deem just and proper."

87. Endo did not request that the court enjoin Impax from selling oxymorphone ER.

88. On August 29, 2016, Impax moved to dismiss the Breach of Contract Action. According to Impax, Section 4.1(a) of the 2010 Patent Settlement Agreement provided Impax a "royalty-free" license to Endo's current and future patents relating to Opana ER.

89. On October 25, 2016, the court largely denied Impax's motion to dismiss.

90. Following the court decision denying Impax's motion to dismiss, in March 2017, Endo approached Impax about a possible settlement. Over the next couple months, Endo and Impax engaged in negotiations to settle the Breach of Contract Action.

91. At the same time, Endo was also taking steps to be ready to relaunch a generic version of Original Opana ER. Endo's senior executives recognized that its relaunch preparations afforded the company the flexibility to reject a settlement with Impax if the terms were unfavorable. Endo's then-Chief Financial Officer laid out in a July 13, 2017 email that he spoke "last night" with the CEO, and they "were aligned" that Endo "do[es] not have to do this deal and if Impax did anything to pull back on the value we are expecting . . . [Endo] would not hesitate to pursue plan B." "[P]lan B" referred to "the exploration of the feasibility of launching a generic version of Original Opana ER."

92. On August 5, 2017, Endo and Impax settled their Breach of Contract Action. The 2017 Agreement also amended certain portions of 2010 Patent Settlement Agreement. The 2017 Agreement includes a number of key terms.

93. First, it clarifies that Impax's license in the 2010 Patent Settlement Agreement includes any Opana ER patents owned by Endo and obtained after it entered the 2010 Patent Settlement Agreement.

94. Second, it provides that Impax will pay Endo a royalty equal to [redacted]% of its gross oxymorphone ER profits. Impax's obligation to pay a royalty to Endo, however, is terminated if Endo:

(1) Sells an oxymorphone ER product;

(2) [redacted]; or

(3) [redacted] (collectively, "the Non-Compete Condition").

95. In other words, Endo's right to receive [redacted]% of Impax's gross oxymorphone ER profits is explicitly conditioned on Endo not competing against Impax, [redacted] by selling oxymorphone ER [redacted]

96. Endo could not have obtained the Non-Compete Condition in the 2017 Agreement even had it prevailed in the Breach of Contract Action with Impax.

97. Third, the 2017 Agreement provides that Endo [redacted] split with Impax any damages (less external legal expenses) it recovers from any third party that sells oxymorphone ER at risk.

98. Endo estimated that the payments under the 2017 Agreement were close to $265 million in net present value. After securing these payments, Endo's then-CEO ultimately decided to terminate its development of the Watson ANDA in May 2018.

V. The Non-Compete Condition Harms Consumers and Competition

99. The 2017 Agreement amounts to an incumbent competitor (Impax) paying its only potential challenger (Endo) to stay off the market.

100. Absent the 2017 Agreement, Endo was a potential competitor to Impax in the sale of oxymorphone ER. Endo had been selling an oxymorphone ER product since 2006. Particularly after the FDA requested that Endo remove its Reformulated Opana ER from the market, Endo had strong financial incentives to preserve this important revenue source. As of August 2017, when it entered into the 2017 Agreement, Endo

103. Under the 2017 Agreement, Endo receives [redacted]

entering into the 2017 Agreement, Endo estimated the discounted cash flows from its share of Impax's profits to be worth about [redacted] per year for the first six years of the agreement.

107. But if Endo were to [redacted] an oxymorphone ER product, [redacted] Instead, Endo would earn money only by charging a royalty to the licensee. Because Endo would be splitting profits with its licensee, it would make even less money through royalties than it would by selling the product itself. In addition, Endo would only earn royalties on the sales the licensee makes, rather than on all sales of oxymorphone ER. Moreover, to generate such sales, the licensee would be forced to lower prices resulting in lower profits for each sale. In short, by licensing another company to sell an oxymorphone ER product, Endo would earn only a portion of the licensee's smaller profits on a smaller number of sales. Thus, Endo can expect to earn more by staying off the market and splitting Impax's monopoly profits than it would expect to earn b

VI. Monopoly Power

110. Impax has exercised and continue to exercise monopoly power in a relevant market that is no broader than extended-release oxymorphone tablets approved by the FDA for sale in the United States.

111. There is substantial evidence of Impax's monopoly power. Despite the availability of several other long-acting opioid products, Impax's January 2013 generic oxymorphone ER entry had a significant impact on oxymorphone ER pricing. In early 2013, the average price of a 40 mg tablet of Endo's branded Opana ER was $7.08. By the end of 2013, after Impax's entry, the average price a 40 mg tablet of oxymorphone ER had fallen to $6.31, an 11% decline. By the third quarter of 2015, after further entry by Actavis, the average price of a 40 mg tablet of oxymorphone ER had dropped further to $5.21 per pill—26% less than the price of Opana ER at the time of generic entry.

112. The August 2015 court order requiring Actavis to exit the market reversed these pricing trends. Shortly thereafter, Impax increased the price of its own 40 mg tablet of generic oxymorphone ER from $3.10 to $3.85. By mid-2016, when Actavis exited, Impax's price had increased further to $4.48. Impax subsequently concluded that the "economics of the price increases [were] overall very favorable," and would generate $25.4 million in additional net sales.

113. Endo's withdrawal of its Reformulated Opana ER and execution of the 2017 Agreement, which left Impax as the only oxymorphone ER seller, dramatically accelerated these price increases. By 2020, the average price of a 40 mg tablet of oxymorphone ER had risen to $[redacted]—a [redacted]% increase over the price of Impax's product prior to Actavis' exit.

need to obtain FDA approval, costly specialized equipment and facilities, and Endo's patent portfolio, which has been found by the Federal Circuit to be not invalid and infringed in previous litigation.

Count I

Agreement in Restraint of Trade Arising Under Section 1 of t 1 a[illegible] be [illegible]

VII. Prayer for Relief

WHEREFORE, Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to issue a permanent injunction against violations of the FTC Act; therefore, the FTC requests that this Court, as authorized by 15 U.S.C. § 53(b), 15 U.S.C. § 26, and its own equitable powers, enter final judgment against Defendants, declaring, ordering, and adjudging:

1. That the agreement between Endo and Impax violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);
2. That Defendants are permanently enjoined from continuing their unlawful agreement;
3. That Defendants are permanently enjoined from engaging in similar and related conduct in the future; and
4. That the Court grant such other equitable relief as the Court finds necessary, including equitable monetary relief, to redress and prevent recurrence of defendants' violations of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), as alleged herein.

Dated: January 2, 2021

Respectfully submitted,

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