IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

Plaintiff,

v.

ENDO PHARMACEUTICALS INC.,
1400 Atwater Drive
Malvern, PA 19355;

ENDO INTERNATIONAL PLC,
First Floor, Minerva House
Simmonscourt Road, Ballsbridge
Dublin 4, Ireland;

IMPAX LABORATORIES, LLC,
100 Somerset Corporate Blvd #3000
Bridgewater, NJ 08807;

AMNEAL PHARMACEUTICALS, INC.
400 Crossing Boulevard, 3rd Floor
Bridgewater, NJ 08807

Defendants.

Case No.: 1:21-cv-217-RCL

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Complaint for Injunctive and Other Equitable Relief

Plaintiff Federal Trade Commission ("FTC"), by its designated attorneys, petitions this Court pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), for a permanent injunction and other equitable relief, including equitable monetary relief, against Defendants Endo Pharmaceuticals Inc.; Endo International plc; Impax Laboratories, LLC; and Amneal Pharmaceuticals, Inc. to prevent unfair methods of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

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. But Endo also knew that it would need to find a way to preserve its Opana ER revenues. Endo explored various ways to do so, including taking concrete steps to relaunch a previous version of the product.

3. Instead of choosing to enter and compete with its own oxymorphone ER product, however, Endo opted to conspire with Impax. In August 2017, Endo settled a breach of contract suit with Impax, the only seller of oxymorphone ER at the time. Under this 2017 Agreement, Impax agreed to pay Endo [redacted]% of its oxymorphone ER profits, but only so long as Endo refrains from competing, [redacted] with its own product, [redacted] The 2017 Agreement remains in effect today.

4. The purpose and effect of the 2017 Agreement is to ensure that Endo, the gatekeeper to competition in the oxymorphone ER market, has every incentive to preserve Impax's monopoly. By doing so, it eliminates any potential for oxymorphone ER competition, allowing Endo and Impax to share in the monopoly profits. As a result, patients have been denied

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 competition alleged herein, are "in or affecting commerce" within the meaning of Section 5 of the FTC Act, 15 U.S.C. § 45.

9. Each defendant is, and at all relevant times has been, a corporation, as the term "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

III. THE PARTIES

10. Plaintiff FTC is an administrative agency of the United States Government, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. § 41, *et seq.*, with its principal offices in the District of Columbia. The FTC is vested with authority and responsibility for enforcing, among other things, Section 5 of the FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to enjoin violations of any law the FTC enforces.

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 in Malvern, Pennsylvania. According to its 2019 Form 10-K Annual Report, Endo International "is a holding company that conducts its operations through its subsidiaries," with $2.9 billion in revenues in 2019. Endo International is the ultimate parent company of both Endo Pharmaceuticals Inc. and Par Pharmaceutical

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 both own assets related to oxymorphone ER. Through Endo Pharmaceuticals and Par, Endo International currently sells several distinct opioid medications in the United States, including the branded drug Percocet and generic versions of Vicodin, Ibudone, and Ryzolt. Corporate officers from Endo International negotiated and approved the agreement challenged in the complaint, and the president of Endo International "made the ultimate decision whether to enter into the agreement."

15. Defendant Impax Laboratories, LLC (f/k/a Impax Laboratories, Inc.) is a for-profit Delaware corporation, with its principal place of business at 100 Somerset Corporate Blvd #3000, Bridgewater, NJ 08807. Impax is engaged in the business of developing, manufacturing, and marketing both branded and generic drug products. Impax entered into the anticompetitive agreement challenged in this complaint. Under the terms of that agreement, Impax made at least three payments to Endo. Unless otherwise specified, "Impax" refers to Impax Laboratories, LLC and all corporate predecessors, subsidiaries, successors, and affiliates.

16. Defendant Amneal Pharmaceuticals, Inc. is a for-profit Delaware corporation, with its principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. Amneal is engaged in the business of developing, licensing, manufacturing, marketing, and distributing generic and specialty pharmaceutical products in a variety of dosage forms and therapeutic categories, and it had $1.6 billion in revenues in 2019. Amneal formed on October 4, 2017 to facilitate the combination of Amneal Pharmaceuticals LLC, a Delaware limited liability company, and Impax. As a result of this combination, Amneal Pharmaceuticals LLC now wholly owns Impax and is the operating company for the combined business, which

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 New Drug Application ("NDA") No. 021610 with the U.S. Food and Drug Administration, seeking approval for Opana ER. As part of its NDA, Endo, like other new drug applicants, was required to demonstrate the safety and efficacy of Opana ER. Products approved under an NDA and marketed under a specific name, rather than by molecule, are usually referred to as "brand-name drugs" or "branded drugs."

20. Opana ER received FDA approval in June 2006, and it quickly became Endo's second best-selling drug. After generating less than $7 million in sales in 2006, sales increased to $384 million by 2011.

21. Endo introduced a reformulated version of Opana ER in 2012. In 2016—the last full year it was on the market—Opana ER generated almost $159 million in revenue.

22. Endo sold Opana ER at prices far above Endo's cost of manufacturing the product, making Opana ER highly profitable. Even accounting for other direct expenses Endo allocates to selling and marketing Opana ER, Endo's profit margin on Opana ER was substantial, and by August 2017, Endo had more than recouped its Opana ER research and development costs.

B. Impax secured the right to market a generic version of Opana ER

23. Opana ER's increasing sales drew the attention of generic companies.

24. By November 2007, Impax had submitted, and the FDA had accepted for review, ANDA No. 79-087 seeking approval to market a generic version of Opana ER in the five dosage strengths (5, 10, 20, 30, and 40 mg) that made up 95% of Endo's Opana ER sales.

25. When a brand-name drug is covered by one or more patents, a company seeking to market a generic version of that drug before the patents expires must make a "paragraph IV" certification in its ANDA certifying that the patents are invalid, unenforceable, and/or will not be infringed by the generic drug. If a company makes a paragraph IV certification, it must notify the patent holder of its certification.

26. On December 13, 2007, Impax notified Endo that it had submitted ANDA No. 79-087 with a paragraph IV certification stating that Impax's proposed generic product did not infringe any Endo patent covering Opana ER.

27. On January 25, 2008, Endo sued Impax for allegedly infringing two patents—No. 5,622,933 (the "'933 patent") and No. 5,958,456 (the "'456 patent"). The '933 and '456 patents expired in September 2013.

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 paragraph IV certification, Endo filed a patent infringement case, asserting that the generic product infringed either the '456 patent, the '933 patent, or both.

35. On or about March 28, 2008, Endo sued Actavis for alleged infringement of the '456 patent.

36. In February 2009, less than one year into the patent litigation, Endo settled its suit against Actavis. Under the terms of the settlement, Endo granted Actavis a covenant not to sue and a license for the sole asserted patent, the '456 patent, to begin marketing its generic version of certain dosages of Opana ER in July 2011. In addition, Endo granted Actavis a covenant not to sue for Endo's other then-existing patents. Unlike the agreement with Impax, however, the settlement with Actavis did not include a broader license to any future patents that Endo might subsequently obtain relating to Opana ER.

37. Other generic applicants also settled their patent infringement litigation with Endo concerning Opana ER. But like the settlement with Actavis, none of these settlements included the broad license that Impax obtained to any future patents Endo might later obtain relating to Opana ER.

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 prices in the United States, and saves American consumers billions of dollars a year. According to a 2019 FDA report, single-source generics—that is, generics that compete alone against a brand-name drug—sell at an average manufacturing price that is 39% lower than the average manufacturing price of a brand-name drug with no generic competitors. Subsequent generic entry creates greater price competition with average manufacturing price discounts reaching 79% off the branded drug price before generic entry. In 2019 alone, the Association for Accessible Medicines reported that use of generic versions of brand-name drugs saved the U.S. health care system $313 billion.

41. Consistent with this well-established impact, entry of generic oxymorphone ER drove prices lower. Shortly after Impax's January 2013 entry, the average price of a 40 mg tablet of generic oxymorphone ER was $4.74, a 33% discount to a comparable tablet of Endo's branded Opana ER. By the end of 2015, after several years of three-way competition between Endo, Impax, and Actavis, the average price of a 40 mg tablet of generic oxymorphone ER had fallen an additional 19% to $3.85.

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.

50. In August 2015, the U.S. District Court for the Southern District of New York defendants' generic versions of original Opana ER. The court issued an injunction barring all defendants that pursued the case to judgment from making or selling their versions of generic oxymorphone ER until those patents expired in 2023. As a result of this injunction, Actavis was required to withdraw its generic product from the market.

51. The New York Injunction, however, does not apply to Impax's generic version of Opana ER, and thus it did not affect Impax's ability to continue selling its product in the United States.

52. The Federal Circuit affirmed the New York decision on May 16, 2018.

53. In October 2016, the U.S. District Court for the District of Delaware held that the '779 patent was not invalid and was infringed by certain companies seeking to market generic oxymorphone ER. The court issued an injunction barring all defendants that pursued the case to judgment from making or selling their versions of generic oxymorphone ER until expiration of the '779 patent in November 2029.

54. The Delaware Injunction, however, does not apply to Impax's generic version of Opana ER, and thus does not affect Impax's ability to continue selling its product in the United States.

55. The Federal Circuit affirmed the Delaware decision on May 3, 2019.

56. The combined result of the New York Injunction and Delaware Injunctions is that no company other than Impax and Endo may sell a version of oxymorphone ER until November 2029.

D. FDA raises concern about the safety of Endo's Reformulated Opana ER

57. Unlike immediate-release drugs, extended-release medications like oxymorphone ER have special coatings or ingredients that control how fast the active ingredient is released

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

Original Opana ER. Because the FDA denied Endo's petition, generic versions of Original Opana ER were free to remain on the market.

63. Consistent with the FDA's concerns, evidence began to emerge that Reformulated Opana ER had resulted in increased intravenous abuse. For example, research published in the New England Journal of Medicine and the American Journal of Public Health linked intravenous abuse of Reformulated Opana ER to outbreaks of several serious illnesses, including HIV and hepatitis C.

64. As early as 2015, Endo understood that the FDA might convene an Advisory Committee meeting to scrutinize Reformulated Opana ER. The FDA uses Advisory Committee meetings to obtain independent expert advice on a variety of issues including prescription drugs.

65. By December 2016, the FDA confirmed to Endo that the agency would convene a joint meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee. The stated purpose of the Advisory Committee meeting—scheduled for March 13-14, 2017—was to discuss pre- and post-marketing data concerning the abuse of Reformulated Opana ER and the overall risk-benefit profile of the product.

66. Endo understood that the Advisory Committee's planned review of the drug posed a serious threat to its Opana ER franchise. Endo's Senior VP for Investor Relations and Corporate Affairs characterized a preliminary meeting with FDA officials on January 27, 2017 as "[n]ot good," and FDA's comments with respect to Reformulated Opana ER as "ominous." Endo's Chief Operating Officer agreed that each Endo executive might need to donate a "kidney or part of a liver" to the FDA to "save Opana ER."

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 climate coupled with reputational challenges with the [FDA] on" Opana ER."

70. Endo announced the decision to remove Reformulated Opana ER from the market on July 6, 2017. Endo stopped shipping the drug on or around September 1, 2017.

E. Faced with the risk of removing Reformulated Opana ER, Endo takes steps to preserve this critical revenue stream

71. Following the March Advisory Committee meeting, Endo understood that one of its most important and lucrative drug franchises was at risk. In 2016, Opana ER had been Endo's highest-grossing branded pain management drug, accounting for approximately 33% of Endo's branded pain management revenues and approximately 14% of Endo's overall branded revenues. In Endo's 2016 Form-10K Annual Report, Endo had stressed the need to improve the profitability of its mature brands, such as Opana ER.

72. Endo expected that withdrawing Reformulated Opana ER from the market would have a significant adverse effect on its branded drug revenues and profits. In a February 2017 presentation for the Board of Directors, Endo estimated that pulling Reformulated ER from the market could result in a loss of over $85 million in earnings before interest and taxes in 2017 alone.

73. Thus, even before the FDA requested that Endo remove Reformulated Opana ER from the market, Endo had begun exploring various ways to preserve the Opana ER revenue stream. As one option, Endo considered relaunching Reformulated Opana ER with a potentially safer abuse-deterrence technology.

74. Endo also considered acquiring or partnering with one of the generic applicants as a means to bring a version of Opana ER back to the market. On June 22, 2017—just two weeks after the FDA requested that Endo voluntarily remove Reformulated Opana ER—Endo's CEO told a generic company that he was "very interested in a potential partnership on Oxymorphone" and that he would "be able to propose 2 to 3 concepts that might be of interest" after addressing some regulatory issues with the FDA.

75. Ultimately, Endo settled on a different strategy. Endo held the rights to an application for a generic version of Original Opana ER that had been filed by Watson. The Watson ANDA had been approved by the FDA in October 2014. Even though Par had withdrawn the Watson ANDA, effective November 2016, Endo determined that it could use the Watson ANDA to re-enter the market with a version of Opana ER.

76. Starting in April 2017, Endo took numerous concrete steps to be ready to relaunch Opana ER using the Watson ANDA. For example, Endo formed an internal work group to discuss strategies for relaunching a version of Opana ER. This group had at least eleven and as

many as eighteen members, including Endo's Chief Medical Officer, Endo's Senior Vice Presidents for Intellectual Property, Marketing Specialty & Established Products, and Branded Business Regulatory Affairs, and Par's Senior Vice Presidents for Research & Development and Regulatory Affairs. These executives, along with multiple directors and managers, held almost weekly Opana Post Ad Comm Workstream Meetings for at least two months, during April and May 2017. The Workstream Meetings addressed many "Action Items" related to relaunching Opana ER, such as creating cost estimates, development and regulatory timelines, assigning personnel to manage the Watson ANDA tech transfer, and deciding to use a supplemental NDA to seek FDA approval to relaunch of Original Opana ER.

77. In May 2017, Endo began the process of transferring the Watson ANDA manufacturing process from the facility that Watson had planned to use to manufacture the product to its own Chestnut Ridge facility in New York. As Endo's Senior Director for Project Management told her team: "Let's take this forward at full speed." By transferring the product and process knowledge to Chestnut Ridge, Endo would put itself in the position to obtain FDA approval to manufacture the Watson ANDA at that facility.

78. The following month, Par's SVP for Research and Development confirmed to Endo's Chief Operating Officer that Endo already "ha[d] ALL the necessary equipment and should be able to make [Original Opana ER] in Chestnut Ridge."

79. To execute the technology transfer, Endo needed to conduct various testing that required oxymorphone API. Because oxymorphone is a controlled substance, Endo could not simply purchase oxymorphone API on the open market. Instead, Endo was first required to receive quota—or authorization—from the Drug Enforcement Agency. The quota process is a critical element of the Controlled Substances Act's regulatory system that seeks to prevent or

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 Opana ER. Endo cited Section 4.1(d) of the 2010 Patent Settlement Agreement as grounds for this request. Under Section 4.1(d), the parties agreed "to negotiate in good faith an amendment to the terms of the License to any [later-issued] patents."

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 was preparing to be ready to launch a version of Original Opana ER under the Watson ANDA. Endo referred to its Watson ANDA development as "plan B" in case it could not secure a favorable profit-sharing deal with Impax.

101. Alternatively, Endo was in the position to license another company to compete with a generic version of oxymorphone ER. Endo controls the patents relating to oxymorphone ER. Numerous companies have filed ANDAs with the FDA for approval to market a generic version of oxymorphone ER, but are blocked from entering due to Endo's patents. Shortly before it entered the 2017 Agreement, Endo had explored a partnership with a generic company to potentially manufacture or sell oxymorphone ER under license from Endo. Even today, at least one company has expressed interest in a license to manufacture and sell oxymorphone ER.

102. The 2017 Agreement, however, eliminated that the potential that (1) Endo would enter with its own oxymorphone ER product, or (2) license another company to sell an oxymorphone ER product.

103. Under the 2017 Agreement, Endo receives [redacted]% of Impax's oxymorphone ER profits, but only if Endo refrains from competing. Under the Non-Compete Condition, Endo forfeits its [redacted]% share of Impax's oxymorphone ER profits if it [redacted] sells an oxymorphone ER product itself, [redacted]

104. While the Non-Compete Condition does not explicitly prohibit Endo from competing on its own, the practical effect of this condition is to eliminate Endo's financial incentive to do so. Without competition from another oxymorphone ER product, Impax can charge higher prices. In fact, since Endo exited the market in 2017, the average price of a 40 mg tablet of oxymorphone ER has increased over [redacted]%. Under the 2017 Agreement, Endo shares these [redacted].

105. But if Endo were to compete, it would forfeit these payments. Instead, Endo would earn money only by generating its own oxymorphone ER sales. Endo would only earn profits on the sales it makes, rather than on all sales of oxymorphone ER. Moreover, to generate such sales, Endo would be forced to lower prices resulting in lower profits for each sale. In short, by competing, Endo would earn 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 by competing in a two-seller generic market.

106. [redacted] Without competition from another oxymorphone ER product, Impax can charge higher prices. In fact, since Endo exited the market in 2017, the average price of a 40 mg tablet of oxymorphone ER has increased over [redacted]%. Under the 2017 Agreement, Endo shares these [redacted]. Less than two months before

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 by licensing another company to compete in a two-seller generic market.

108. Absent the Non-Compete Condition in the 2017 Agreement, Endo either would have entered with its own oxymorphone ER product, or licensed another company to sell oxymorphone ER.

109. Entry of another oxymorphone ER product would benefit consumers. Two competing sellers of oxymorphone ER would drive prices lower, resulting in a significant reduction in the average price purchasers pay for oxymorphone ER. Patients and other purchasers of oxymorphone ER would likely save millions of dollars a year in lower drug prices due to this competition. Through their anticompetitive agreement, Endo and Impax have retained these potential consumer savings for themselves.

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.

114. If oxymorphone ER were already facing robust competition from other long-acting opioids, then the entry and exit of other oxymorphone ER products would not have had such a significant impact on the price of oxymorphone ER products.

115. Moreover, oxymorphone ER is not reasonably interchangeable with other pain relief medications used to treat the same or similar conditions. The abrupt discontinuation of an opioid product can result in severe withdrawal symptoms. Switching a patient from one opioid to another presents serious underdosing and overdosing risks to the patient and requires careful medical monitoring. Endo explained this concern in a 2017 letter to health care providers, noting the "substantial inter-patient variability in the relative potency of different opioids," and lack of "established conversion ratios for conversion from other OPANA ER to other opioids defined by clinical trials."

116. Endo made a similar point to the FDA's Advisory Committee in 2017: "Multiple opioid therapeutic options are available to clinicians and while this may appear unnecessary based on a perceived common molecular mechanism of action, it is often justified by the well-established fact that opioid display wide variations in pharmacological efficacy and tolerability, necessitating individualized treatment for patients." For these reasons, patients that have begun a successful course of treatment with an opioid are unlikely to switch to another pain medication for economic reasons.

117. At all times since entering into the 2017 Agreement and Endo's exit from the market, Impax has accounted for 100% of the unit sales of oxymorphone ER products.

118. Substantial barriers to entry exist in the oxymorphone ER market. Potential new branded drug competitors need to conduct expensive clinical trials and obtain FDA approval. Potential sellers of generic oxymorphone ER also face substantial barriers to entry, including the

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 the Sherman Act Against All Defendants

119. Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1 through 118 above.

120. Defendants' agreement to share oxymorphone ER profits so long as Endo refrains from competing with an oxymorphone ER product, either directly or indirectly through a third party, violates Section 1 of the Sherman Act and thus constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Count II

Monopolization Arising Under Section 2 of the Sherman Act Against Amneal

121. Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1 through 118 above.

122. At all relevant times, Amneal had monopoly power in the United States with respect to FDA-approved oxymorphone ER products. Amneal willfully maintained this monopoly power through its unlawful agreement with Endo.

123. There is no valid procompetitive justification for Amneal's exclusionary conduct.

124. Amneal's willful maintenance of its monopoly power in the oxymorphone ER market violates Section 2 of the Sherman Act and thus constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

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.

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Respectfully submitted,

/s/ Markus H. Meier

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