UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of **Impax Laboratories, Inc.,** **a corporation**

Docket No. 9373

Public

ANSWER OF RESPONDENT IMPAX LABORATORIES INC. TO THE FEDERAL TRADE COMMISSION'S ADMINISTRATIVE COMPLAINT

Respondent Impax Laboratories, Inc. ("Impax"), through its undersigned counsel, answers the Administrative Complaint (the "Complaint") filed by the Federal Trade Commission ("FTC") as follows. Except to the extent specifically admitted herein, Impax denies each and every allegation contained in the Complaint, including all allegations contained in headings or otherwise not contained in one of the Complaint's 102 numbered paragraphs. Specifically, Impax denies that it has engaged in conduct that violates Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and denies that this proceeding is in any way in the public interest.

NATURE OF THE CASE

1. Impax denies the allegations in paragraph 1. Impax lacks sufficient knowledge to admit or deny the allegations regarding Endo and therefore denies them. To the extent the allegations in paragraph 1 are legal conclusions, no response is required.

2. Impax admits that it submitted an abbreviated new drug application ("ANDA") to the U.S. Food and Drug Administration (the "FDA") to market a generic version of Opana ER in certain dosage strengths. Impax admits that, as part of that ANDA, it made a Paragraph IV certification

as to the '250, '456, and '933 patents and Impax's ANDA and the Paragraph IV certification speak for themselves. Impax admits that Endo sued it for patent infringement. To the extent any further response is required, Impax denies all other allegations in the paragraph.

3. Impax denies that Endo agreed to pay or paid Impax to abandon its patent challenge or to forgo entering the market for generic Opana ER. To the extent the allegations in paragraph 3 make reference to any contracts between Impax and Endo, including but not limited to the Settlement and License Agreement and Development and Co-Promotion Agreement, such contracts are the best evidence of their contents and Impax states, therefore, that no response to the allegations is required. To the extent a further response is required, Impax denies the remaining allegations in paragraph 3.

4. Impax denies the allegations in paragraph 4.

Respondent

5. Impax admits that it is a for-profit Delaware corporation, with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544, that engages in the business of, among other things, developing, manufacturing, and marketing generic drugs. Impax denies that it has entered into any anticompetitive agreement.

Jurisdiction

6. Impax admits that it is a for-profit Delaware corporation. Except as otherwise admitted, the allegations in paragraph 6 reflect a legal conclusion to which no response is required.

7. The allegation in paragraph 7 is a legal conclusion to which no response is required.

Background

A. Federal law facilitates approval of generic drugs

8. To the extent the allegations in paragraph 8 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. To the extent the allegations in paragraph 8 constitute legal conclusions, no response is required.

9. To the extent the allegations in paragraph 9 constitute legal conclusions, no response is required. To the extent the allegations in paragraph 8 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. Impax admits certain pharmaceutical products sold pursuant to an NDA may sometimes be referred to as "brand-name drugs" or "branded drugs." To the extent any further response is required, Impax denies all other allegations in the paragraph.

10. To the extent the allegations in paragraph 10 constitute legal conclusions, no response is required. To the extent the allegations in paragraph 10 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. Impax admits that the publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* is commonly known as the Orange Book. To the extent any further response is required, Impax denies all other allegations in the paragraph.

11. To the extent the allegations in paragraph 11 are legal conclusions no response is required. To the extent the allegations in paragraph 11 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. To the extent any further response is required, Impax denies all other allegations in the paragraph.

12. To the extent the allegations in paragraph 12 are legal conclusions no response is required. To the extent paragraph 12 purports to describe laws, regulations, or rules governing generic drugs, including their rating as "AB" to other drugs, such laws, rules, and regulations are the best evidence of their contents, and no response is necessary. Impax admits that generic drugs have the same active ingredients as their brand name counterparts. To the extent any further response is required, Impax denies all other allegations in the paragraph.

13. To the extent the allegations in paragraph 13 are legal conclusions, no response is required. To the extent the allegations in paragraph 13 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary.

14. To the extent the allegations in paragraph 14 are legal conclusions no response is required. To the extent the allegations in paragraph 14 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their

contents, and no response is necessary. To the extent any further response is required, Impax denies all other allegations in the paragraph.

15. To the extent the allegations in paragraph 15 are legal conclusions no response is required. To the extent the allegations in paragraph 15 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. To the extent any further response is required, Impax denies all other allegations in the paragraph.

16. To the extent the allegations in paragraph 16 constitute legal conclusions, no response is required. To the extent the allegations in paragraph 16 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. To the extent the allegations in paragraph 16 purport to quote from a United States Supreme Court decision that opinion is the best evidence of its contents, and no response is necessary. To the extent any further response is required, Impax denies all other allegations in the paragraph.

17. To the extent the allegations in paragraph 17 are legal conclusions, no response is required. To the extent the allegations in paragraph 17 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. Impax admits that the term "authorized generic" can

refer to a generic product marketed under an NDA. To the extent any further response is required, Impax denies all other allegations in the paragraph.

18. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 18, and on that basis denies them.

19. To the extent the allegations in paragraph 19 are legal conclusions no response is required. To the extent the allegations in paragraph 19 purport to describe the FDCA, the Hatch-Waxman Act, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or any other laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary. To the extent any further response is required, Impax denies all other allegations in the paragraph.

B. State law encourages substitution of AB-rated generic drugs for brand drugs

20. To the extent the allegations in paragraph 20 are legal conclusions no response is required. To the extent the allegations in paragraph 20 purport to describe any state laws, rules, or regulations, those laws, rules, and regulations are the best evidence of their contents, and no response is necessary.

21. Impax admits that a patient can obtain a prescription drug only if a doctor (or someone who is authorized to write prescriptions) writes a prescription for that particular drug. Impax lacks sufficient knowledge or information to admit or deny all other allegations in paragraph 21, and on that basis denies them.

22. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 22, and on that basis denies them.

C. Competition from lower-priced generic drugs saves American consumers billions of dollars a year

23. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 23, and on that basis denies them. To the extent the allegations in paragraph 23 refer to any Congressional Budget Office Report or Generic Pharmaceutical Association report, those reports are the best evidence of their contents, and no response is required. To the extent a response is required, Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 23, and on that basis denies them.

24. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 24, and on that basis denies them.

25. To the extent the allegations contained in Paragraph 25 constitute legal conclusions, no response is required. Impax lacks sufficient knowledge or information to admit or deny all other allegations in this paragraph, and on that basis denies them.

26. To the extent the allegations contained in Paragraph 25 constitute legal conclusions, no response is required. Impax lacks sufficient knowledge or information to admit or deny all other allegations in this paragraph, and on that basis denies them.

Anticompetitive Conduct

A. Opana ER was a successful and rapidly growing branded drug

27. Impax admits that Oxymorphone is a semi-synthetic opioid that may be used to relieve pain. Impax lacks sufficient knowledge or information to admit or deny all other allegations in this paragraph, and on that basis denies them.

28. Impax admits that the product known by the brand name Opana ER is an extended-release formulation of oxymorphone. Impax admits that extended-release medications have attributes that moderate the rate at which the medications' active ingredients are absorbed in the patient's body. Impax admits that, as compared to immediate-release oxymorphone, extended-release oxymorphone has attributes that moderate the rate at which the medication's active ingredient is absorbed into the body. Impax admits that patients who take extended-release medications, including oxymorphone extended-release, often take fewer pills each day than would be the case if they took immediate-release formulations of the same medication. To the extent the allegations in paragraph 28 refer to NDA No. 021610 and/or the FDA's approval of NDA No. 02160, that NDA and that approval are the best evidence of their contents, and no response is necessary. To the extent a response is necessary, Impax denies any characterization or interpretation thereof.

29. Impax lacks sufficient knowledge or information to admit or deny the allegations in the first sentence of paragraph 29, and on that basis denies them. Impax admits the allegations in the second sentence of paragraph 29.

30. Impax lacks sufficient knowledge or information to admit or deny the allegations in this paragraph, and on that basis denies them.

31. Impax lacks sufficient knowledge or information to admit or deny the allegations in this paragraph, and on that basis denies them.

B. Potential generic competition from Impax threatened Endo's growing Opana ER business

32. Impax denies that Opana ER or oxymorphone ER "was not subject to any meaningful patent protection." To the extent the remaining allegations in paragraph 32 constitute legal conclusions, no response is required. Impax admits that patent No. 5,128,143 was set to expire in September 2008. Impax lacks sufficient knowledge or information to admit or deny all other allegations in paragraph 32, and on that basis denies them.

33. Impax admits that Endo listed three patents for Opana ER in the Orange Book in October 2007. Impax lacks sufficient knowledge or information to admit or deny all other allegations in paragraph 33, and on that basis denies them.

34. Impax admits that Endo listed the '250 patent in the Orange Book on October 2, 2007. To the extent the allegations in paragraph 34 refer to the '250 patent, that patent is the best evidence of its contents, and no response is required. To the extent a response is required, Impax denies any characterization or interpretation thereof. The remaining allegations in paragraph 34 are legal conclusions to which no response is required.

35. Impax admits that Endo listed the '933 patent and the '456 patent in the Orange Book on October 19, 2007. To the extent the allegations in paragraph 34 refer to the '933 patent or the '456 patent, those patents and the Orange Book are the best evidence of their respective contents, and no response is required. To the extent a response is required, Impax denies any characterization or interpretation thereof. The remaining allegations in paragraph 35 are legal conclusions to which no response is required.

36. Impax admits that it submitted and ANDA seeking approval to market its generic version of Opana ER and included a paragraph IV certification. To the extent paragraph 36 purports to describe the contents of ANDAs submitted by companies other than Impax, or complaints filed by Endo, those documents are the best evidence of their contents, and no response is required. To the extent a response is required, Impax lacks sufficient knowledge or information to admit or deny the allegations, and on that basis denies them.

37. Impax admits that it submitted ANDA No. 79-087 to the FDA in 2007, the FDA initially accepted ANDA No. 79-087 for substantive review, then rescinded that acceptance, after which Impax re-submitted ANDA No. 79-087, and the FDA accepted it on November 23, 2007.

38. Impax admits that on December 13, 2007, Impax notified Endo that it had submitted ANDA No. 79-087 with a paragraph IV certification including the '933 and '456 patents. Impax's Paragraph IV certification speaks for itself.

39. To the extent the allegations in paragraph 39 are legal conclusions, no response is required. Impax admits that Endo sued Impax on January 25, 2008 alleging infringement of the '456 and '933 patents. Impax admits that the litigation resulted in what is commonly known as a "30 month stay." Impax states that the pleadings in the lawsuit referenced in Paragraph 39 speak for themselves, as do the pertinent statutes and regulations.

40. Impax admits it was the first generic company to file an ANDA with a Paragraph IV certification for the 5, 10, 20, 30, and 40 mg strengths of original Opana ER. The allegations in the second sentence of Paragraph 40 constitute legal conclusions, therefore no response is required. Impax further states that the pertinent statutes and regulations speak for themselves.

Impax lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 40, and on that basis denies them.

C. Endo paid Impax to drop its patent challenge and refrain from competing until January 2013

41. Impax admits that launching a generic product before a relevant patent challenge is resolved is commonly known as an "at-risk launch." Impax denies all other allegations in paragraph 41.

42. Impax admits that on May 13, 2010, the FDA tentatively approved Impax's application for a generic version of Opana ER in the certain dosage strengths. To the extent the allegations in paragraph 42 constitute legal conclusions, no response is required. To the extent the allegations in paragraph 42 refer to purported communications and/or documents, those communications and/or documents are the best evidence of their contents, and no response is necessary. To the extent a response is necessary, Impax denies all other allegations in paragraph 42.

43. Impax admits that it had completed process validation for generic Opana ER in certain dosage strengths and had produced certain lots of generic Opana ER product by May 20, 2010. Impax admits that, as of May 20, 2010, Impax had an outstanding request to the Drug Enforcement Agency for authorization to purchase additional quantities of oxymorphone. Impax denies all other allegations in paragraph 43.

44. Impax denies that there was any "impending launch" of generic Opana ER as of May 20, 2010. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 44 regarding Endo, and on that basis denies them. To the extent any further response is required, Impax denies all other allegations in the paragraph.

45. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 45, and on that basis denies them.

46. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 46, and on that basis denies them.

47. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 47, and on that basis denies them.

48. Impax denies that it was paid not to compete. Impax lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 48, and on that basis denies them.

49. Impax admits that it settled a patent case with Endo on June 8, 2010 two days into a patent infringement trial; and that the litigation settlement was memorialized in the parties' Settlement and License Agreement ("SLA"). Impax admits that Impax and Endo separately entered into a Development and Co-Promotion Agreement ("DCPA"). To the extent that the allegations in paragraph 49 constitute legal conclusions, no response is required. To the extent any further response is required, Impax denies all other allegations in the paragraph.

50. Impax denies the allegations in paragraph 50.

51. Impax denies the allegations in paragraph 51.

52. Impax admits that the FDA granted final approval to Impax's ANDA for generic Opana ER for the 5, 10, 20, and 40 mg dosages on June 14, 2010, and for the 30 mg dosage on July 22, 2010. Impax denies all other allegations in paragraph 52.

1. Guaranteed No-AG Payment

53. The allegations in paragraph 53 constitute legal conclusions to which no response is required. To the extent the allegations in the second sentence purport to refer to the SLA and/or the DCPA, those agreements are the best evidence of their contents, and no response is required. To the extent a response is required, Impax denies the allegations in paragraph 53.

54. Impax denies the allegations in the first sentence of paragraph 54. Impax lacks sufficient knowledge or information to admit or deny the remaining allegations in paragraph 54, and on that basis denies them.

55. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 55, and on that basis denies them.

56. Impax admits that an Endo employee represented that Endo had no plans to introduce a reformulated version of Opana ER. Impax denies all other allegations in paragraph 56.

57. Impax admits that it negotiated in good faith for license terms that would allow it to begin selling generic Opana ER, free from patent risk, at the earliest date possible. Impax admits that the SLA includes a provision or provisions describing an "Endo Credit." To the extent the allegations in paragraph 57 refer to the SLA and/or written communications relating to the SLA, the SLA and any such written communications are the best evidence of their contents, and no response is required. To the extent any further response is required, Impax denies all other allegations in paragraph 57.

58. To the extent the allegations in paragraph 58 purport to describe the SLA, and/or written communications relating to the SLA, the SLA and any such written communications are the best

evidence of their contents, and no response is required. Impax lacks sufficient knowledge or information to admit or deny the allegations regarding Endo in the final sentence of paragraph 58, and on that basis denies them. To the extent any further response is required, Impax denies all other allegations in paragraph 58.

59. Impax admits that Endo introduced a reformulated version of Opana ER, and that Endo discontinued its original Opana ER product, before Impax's license to manufacture and sell generic original Opana ER took effect. Impax admits that pursuant to the terms of the SLA, and as a result of unforeseen events and circumstances that Impax could not have reasonably anticipated, and over which Impax had no control, Impax received a payment of approximately $102 million from Endo in April 2013. To the extent any further response is required, Impax denies all other allegations in paragraph 59.

2. Side Deal Payment

60. Impax admits the allegations in the first sentence of paragraph 60. Impax admits that as of June 8, 2010, it had not completely finalized a formulation for IPX-203, submitted an Investigational New Drug Application for IPX-203, or initiated clinical trials for IPX-203. Impax lacks sufficient knowledge to admit or deny the allegations in the final sentence of paragraph 60, and on that basis denies them. To the extent any further response is required, Impax denies all other allegations in the paragraph.

61. To the extent the allegations in paragraph 61 purport to describe the DCPA, the DCPA is the best evidence of its contents, and no response is required. To the extent a response is required, Impax denies any characterization or interpretation of the DCPA. To the extent any further response is required, Impax denies all other allegations in the paragraph.

D. Endo's payment to Impax is large

62. Impax denies the allegations in paragraph 62.

63. Impax denies the allegations in the first sentence of paragraph 63. To the extent the allegations in paragraph 63 purport to describe the DCPA, the DCPA is the best evidence of its contents, and no response is required. To the extent any further response is required, Impax denies all other allegations in the paragraph.

64. Impax denies the allegations in the first sentence of paragraph 64. To the extent the unattributed words between the quotation marks in the final sentence of paragraph 64 appear in any document, that document speaks for itself, and Impax denies any characterization or interpretation of such document or documents. To the extent any further response is required, Impax denies all other allegations in paragraph 64.

65. To the extent the allegations in paragraph 65 purport to describe unidentified "internal forecasts," any such "internal forecasts" are the best evidence of their contents, and no response is required. To the extent any further response is required, Impax denies all other allegations in paragraph 65.

66. To the extent the allegations in paragraph 66 purport to describe the SLA, the SLA is the best evidence of its contents, and no response is required. To the extent a response is required, Impax denies any characterization or interpretation of the SLA contained in paragraph 66. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 66 as they relate to Endo. To the extent any further response is required, Impax denies all other allegations in paragraph 66.

67. Impax denies the allegations in paragraph 67.

68. Impax admits that Impax and Endo executed the SLA after trial had begun in the parties' underlying patent infringement litigation. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 68 as they relate to Endo and on that basis denies those allegations. Impax denies all other allegations in paragraph 68.

69. To the extent the words between the quotation marks in the final sentence of paragraph 69 appear in any document, that document speaks for itself, and Impax denies any characterization or interpretation thereof. Impax denies all other allegations in paragraph 69.

70. To the extent the allegations in paragraph 70 purport to describe unidentified projections, SEC filings, or other documents, any such SEC filings, and documents speak for themselves, and Impax denies any characterization or interpretation thereof. Impax denies all other allegations in paragraph 70.

71. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 71, and on that basis denies them.

E. Endo's large payment to Impax is not justified

72. Impax denies the allegations in paragraph 72.

73. Impax denies the allegations in paragraph 73.

74. To the extent the allegations in paragraph 74 reflect the views or goals of Endo, Impax lacks sufficient knowledge or information to admit or deny the allegations, and on that basis denies them. Impax denies all other allegations in paragraph 74.

75. To the extent the allegations in paragraph 74 reflect the views or goals of Endo, Impax lacks sufficient knowledge or information to admit or deny the allegations, and on that basis denies them. Impax denies all other allegations in paragraph 75.

76. Impax denies the allegations in paragraph 76.

77. Impax denies the allegations in paragraph 77.

78. Impax denies the allegations in paragraph 78.

79. Impax denies the allegations in paragraph 79.

F. Endo settled with the other Opana ER first filer with no reverse payment, and a significantly earlier entry date

80. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 80, and on that basis denies them.

81. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 81, and on that basis denies them.

82. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 82, and on that basis denies them.

83. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 83, and on that basis denies them.

85. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 85, and on that basis denies them.

Market Power

85. Impax denies the allegations in paragraph 85.

86. To the extent the allegations in paragraph 86 purport to describe an unidentified estimate or other documents, any such estimate and documents speak for themselves, and Impax denies any characterization or interpretation thereof. Impax denies all other allegations in paragraph 86.

87. Impax lacks sufficient knowledge or information to admit the allegations in paragraph 87, and on that basis denies them.

88. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 88, and on that basis denies them. To the extent any further response is required, Impax denies the allegations in paragraph 88.

89. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 89, and on that basis denies them.

90. Impax denies that oxymorphone ER is not reasonably interchangeable with several other medications used to treat the same or similar conditions. Impax admits that patients and medical professionals must use care to manage withdrawal symptoms and dosing issues when a patient discontinues certain prescription medications (including opioids) or switches from one medication to another. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 90 as they relate to Endo, and on that basis denies them. To the extent any further response is required, Impax denies the allegations in paragraph 90.

91. Impax lacks sufficient knowledge or information to admit or deny the allegations in paragraph 91 and on that basis denies them.

92. Impax admits that drug companies typically must conduct clinical trials as a precondition to receiving FDA approval and that FDA approval is required in order to sell generic drug products in the U.S. Impax admits that manufacturing pharmaceutical products requires specialized equipment and facilities. The remaining allegations in paragraph 92 constitute legal conclusions, to which no response is required. To the extent any further response is required, Impax denies all other allegations in paragraph 92.

VII. Harm to Consumers and Competition

93. Impax denies the allegations in paragraph 93.

94. Impax denies the allegations in paragraph 94.

95. Impax denies the allegations in paragraph 95.

96. Impax lacks sufficient knowledge or information to admit or deny the allegations as they relate to Endo and its alleged forecasts, and on that basis denies them. Impax denies all other allegations in paragraph 96.

97. To the extent the allegations in paragraph 97 purport to interpret or describe the Hatch-Waxman Act, the Hatch-Waxman Act is the best evidence of its contents, and no response is required. To the extent the allegations in paragraph 97 constitute legal conclusions concerning the meaning, interpretation, or effect of the Hatch-Waxman Act, no response is required. Impax denies all other allegations in paragraph 97.

98. Impax denies the allegations in paragraph 98.

99. Impax admits that private plaintiffs have brought lawsuits against Impax and other drug companies relating to the drug Solodyn. Impax also admits that the FTC investigated Impax's

conduct relating to Solodyn for over two years, and in November 2015, closed the investigation without taking any enforcement action. Impax denies all other allegations in paragraph 99.

100. Impax admits that it continues to develop and manufacture pharmaceutical products, and that—like virtually all pharmaceutical companies—it is sometimes involved in patent litigation related to various drugs. Impax denies the remaining allegations in paragraph 100.

Violation Alleged

101. Impax denies the allegation in paragraph 101.

102. Impax denies the allegations in paragraph 102.

AFFIRMATIVE DEFENSES

FIRST DEFENSE

1. The Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE

2. The Complaint should be dismissed for lack of jurisdiction because of mootness. The Complaint alleges activity that ended years ago, and the Complaint fails to allege facts to suggest that there is a likelihood that the alleged conduct will recur.

THIRD DEFENSE

3. The FTC's causes of action are barred in whole or in part by the relevant statute(s) of limitations.

FOURTH DEFENSE

4. The Complaint fails to allege a relevant market.

FIFTH DEFENSE

5. The Complaint fails to allege market power.

SIXTH DEFENSE

6. The Complaint fails to allege any harm to competition.

SEVENTH DEFENSE

7. The Complaint fails to allege any harm to consumers or consumer welfare.

EIGHTH DEFENSE

8. The alleged conduct had substantial pro-competitive justifications, benefited consumers and the public interest, and avoided potential infringement of valid patents. These pro-competitive justifications outweigh any alleged anticompetitive effects of the alleged conduct. There were no less restrictive alternatives that could have achieved these same pro-competitive outcomes.

NINTH DEFENSE

9. Neither the filing of this administrative action nor the contemplated relief are in the public interest, pursuant to 15 U.S.C. § 45.

TENTH DEFENSE

10. The claims against Respondent are barred, in whole or in part, by laches.

RESERVATION OF RIGHTS

10. Impax reserves the right to assert other defenses as discovery proceeds.

Impax respectfully requests that the Administrative Law Judge (i) deny the FTC's contemplated relief, (ii) dismiss the Complaint in its entirety with prejudice, (iii) award Impax its costs of suit, and (iv) award such other and further relief as the Administrative Law Judge may deem proper.

Dated: February 7, 2017

Respectfully Submitted,

/s/Edward D. Hassi

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Counsel for Impax Laboratories, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on February 7, 2017, I filed the foregoing documents by hand to the FTC, which will send notification of such filing to:

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The Honorable D. Michael Chappell
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I also certify that I emailed a copy of the foregoing to the following individuals:

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