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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB,

Plaintiffs,

v.

INNOPHARMA LICENSING LLC,

Defendant.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and AstraZeneca AB (collectively "Plaintiffs" or "AstraZeneca") bring this action for patent infringement against InnoPharma Licensing LLC ("Defendant").

THE PARTIES

1. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850, U.S.A.

2. Plaintiff AstraZeneca UK Limited is a private limited company organized under the laws of England and Wales, with its registered office at 2 Kingdom St, London W2 6BD, United Kingdom.

3. Plaintiff AstraZeneca AB is a public limited liability company organized under the laws of Sweden with its principal place of business at Karlebyhus, Astraallén, Södertälje, S-151 85, Sweden.

4. On information and belief, Defendant InnoPharma Licensing LLC ("InnoPharma") is a company having its principal place of business at 10 Knightsbridge Road, Piscataway, New Jersey 08854.

NATURE OF THE ACTION

5. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of the filing by InnoPharma of Abbreviated New Drug Application ("ANDA") No. 208648 with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use and sale of fulvestrant injection, 50 mg/mL (the "Proposed ANDA Product"), which is a generic version of AstraZeneca's FASLODEX® (fulvestrant) intramuscular injection product, prior to the expiration of AstraZeneca's U.S. Patent Nos. 6,774,122, 7,456,160, 8,329,680, and 8,466,139.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction over Defendant because, *inter alia*, it has maintained continuous and systematic contacts with the State of New Jersey and this District by, at least, maintaining its principal place of business in this State.

8. By letter dated April 6, 2016 (the "Notice Letter"), InnoPharma notified AstraZeneca that it submitted to the FDA ANDA No. 208648 (*see* ¶ 18 below). Upon information and belief, Defendant intends to manufacture for distribution and distribute and sell generic equivalents of AstraZeneca's FASLODEX® (fulvestrant) intramuscular injection product throughout the United States, including in the State of New Jersey and in this judicial district, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to sell or sell, generic pharmaceutical products. Defendant derives substantial revenue from goods used or consumed or services rendered in this judicial district.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

THE PATENTS-IN-SUIT

10. United States Patent No. 6,774,122 (the "'122 Patent"), entitled "Formulation," was duly and legally issued on August 10, 2004 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '122 Patent. AstraZeneca UK Limited is the beneficial owner of the '122 Patent. A copy of the '122 Patent is attached as Appendix A.

11. United States Patent No. 7,456,160 (the "'160 Patent"), entitled "Formulation," was duly and legally issued on November 25, 2008 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is

the legal owner of the '160 Patent. AstraZeneca UK Limited is the beneficial owner of the '160 Patent. A copy of the '160 Patent is attached as Appendix B.

12. United States Patent No. 8,329,680 (the "'680 Patent"), entitled "Formulation," was duly and legally issued on December 11, 2012 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '680 Patent. AstraZeneca UK Limited is the beneficial owner of the '680 Patent. A copy of the '680 Patent is attached as Appendix C.

13. United States Patent No. 8,466,139 (the "'139 Patent"), entitled "Formulation," was duly and legally issued on June 18, 2013 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '139 Patent. AstraZeneca UK Limited is the beneficial owner of the '139 Patent. A copy of the '139 Patent is attached as Appendix D.

FACTUAL BACKGROUND

FASLODEX® (fulvestrant) intramuscular injection

14. FASLODEX® (fulvestrant) intramuscular injection is an estrogen receptor antagonist approved by the FDA for the treatment of hormone receptor positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy.

15. AstraZeneca UK Limited is the holder of approved New Drug Application ("NDA") No. 21-344 for FASLODEX® (fulvestrant) intramuscular injection, in 50 mg/mL dosage forms. AstraZeneca Pharmaceuticals LP is the authorized agent for matters related to NDA No. 21-344 in the United States.

16. The use of FASLODEX® (fulvestrant) intramuscular injection is covered by one or more Claims of the '122, '160, '680, and '139 Patents, and the '122, '160, '680, and '139 Patents have been listed for NDA No. 21-344 in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

17. AstraZeneca Pharmaceuticals LP sells and distributes FASLODEX® (fulvestrant) intramuscular injection in the United States pursuant to NDA No. 21-344.

DEFENDANT'S ANDA

18. By letter dated April 6, 2016 (the "Notice Letter"), Defendant notified AstraZeneca that it submitted to the FDA ANDA No. 208648 seeking approval to engage in the commercial manufacture, use and sale of the Proposed ANDA Product prior to the expiration of the '122, '160, '680, and '139 Patents, and included within ANDA No. 208648 a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '122, '160, '680, and '139 Patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Proposed ANDA Product.

19. On information and belief, Defendant was necessarily aware of the Patents-in-Suit when it filed ANDA No. 208648 with a Paragraph IV Certification.

20. On information and belief, ANDA No. 208648 refers to and relies upon the FASLODEX® (fulvestrant) intramuscular injection NDA and contains data that, according to Defendant, demonstrate the bioequivalence of the Proposed ANDA Product and FASLODEX® (fulvestrant) intramuscular injection.

21. On information and belief, the Proposed ANDA Product will have instructions for use that substantially copy the instructions for FASLODEX® (fulvestrant) intramuscular injection, including instructions for administering the Proposed ANDA Product by intramuscular

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