IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CELGENE CORPORATION and ASTELLAS PHARMA INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
INNOPHARMA, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Celgene Corporation ("Celgene") and Astellas Pharma, Inc. ("Astellas"), for their Complaint against Defendant InnoPharma, Inc. ("InnoPharma"), hereby allege as follows.

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from InnoPharma's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Celgene's ISTODAX® drug product prior to the expiration of United States Patent Nos. 7,608,280 (the "'280 patent") and 7,611,724 (the "'724 patent") (collectively, "the patents-in-suit").

THE PARTIES

2. Plaintiff Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. Plaintiff Astellas is a Japanese Corporation having a principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan. Astellas was formed on April

1, 2005, from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd. ("Fujisawa").

4. Upon information and belief, Defendant InnoPharma is a Delaware corporation having a principal place of business at 10 Knightsbridge Road, Piscataway, New Jersey 08854. Upon information and belief, InnoPharma manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district. Upon information and belief, InnoPharma also prepares and/or aids in the preparation and submission of Abbreviated New Drug Applications ("ANDA") to the FDA.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over InnoPharma by virtue of the fact that, inter alia, it is a Delaware corporation and has systematic contacts with the State of Delaware. Upon information and belief, InnoPharma has committed, aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in Delaware. Upon information and belief, InnoPharma has customers in the State of Delaware. Further, upon information and belief, InnoPharma has previously consented to personal jurisdiction in this Court (*see, e.g.*, Civil Action Nos. 12-260, 13-2081), and purposefully availed itself of the benefits of this forum by filing counterclaims in at least one of those actions. Civil Action No. 12-260.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

8. On October 27, 2009, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '280 patent, entitled "Method of Producing FR901228" to Astellas Pharma Inc. as assignee of the inventors Satoshi Ueda, Yoko Watamodo, Masaru Tsuboi, Munekazu Kanda, Tomoji Higaki, and Mitsunori Matsuda. A copy of the '280 patent is attached hereto as Exhibit A.

9. On November 3, 2009, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '724 patent, entitled "Method of Producing FR901228" to Astellas Pharma Inc. as assignee of the inventors Satoshi Ueda, Yoko Watamodo, Masaru Tsuboi, Munekazu Kanda, Tomoji Higaki, and Mitsunori Matsuda. A copy of the '724 patent is attached hereto as Exhibit B.

10. On or around April 12, 2004, Fujisawa (now Astellas) exclusively licensed its rights to the applications that became the '280 and '724 patents to Gloucester Pharmaceuticals, Inc. ("Gloucester"). On or around January 15, 2010, Celgene acquired Gloucester, including Gloucester's rights to the applications that became the '280 and '724 patents.

THE ISTODAX® DRUG PRODUCT

11. Celgene holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for romidepsin for injection (NDA No. 022393), which it sells under the trade name ISTODAX®. The claims of the patents-in-suit cover, inter alia, crystalline forms of romidepsin and compositions containing those forms.

12. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to ISTODAX®.

13. ISTODAX® received New Chemical Entity ("NCE") exclusivity when first approved in 2009. NCE exclusivity for ISTODAX® expires on November 5, 2014.

14. ISTODAX® was approved for the treatment of cutaneous T-cell lymphoma ("CTCL") on November 5, 2009. When approved for CTCL, ISTODAX® received Orphan Drug Exclusivity ("ODE") from the FDA for that indication. That ODE expires on November 5, 2016. The FDA may not approve any ANDA seeking to market a generic romidepsin product for the treatment of CTCL until at least after November 5, 2016.

15. ISTODAX® was approved for the treatment of peripheral T-cell lymphoma ("PTCL") on June 16, 2011. When approved for PTCL, ISTODAX® received ODE from the FDA for that indication. That ODE expires on June 16, 2018. The FDA may not approve any ANDA seeking to market a generic romidepsin product for the treatment of PTCL until at least after June 16, 2018.

ACTS GIVING RISE TO THIS ACTION

16. Pursuant to Section 505 of the FFDCA, InnoPharma filed ANDA No. 206-678 ("InnoPharma's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation into the United States of romidepsin for injection ("InnoPharma's Proposed Products"), before the patents-in-suit expire.

17. In connection with the filing of its ANDA as described in the preceding paragraph, InnoPharma has provided a written certification to the FDA, as called for by Section

505 of the FFDCA, alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in InnoPharma's ANDA.

18. On or about August 4, 2014, Plaintiffs received written notice of InnoPharma's ANDA certification ("InnoPharma's Notice Letter"). InnoPharma's Notice Letter alleged that the claims of the '280 and '724 patents are invalid, unenforceable, and/or will not be infringed by the activities described in InnoPharma's ANDA. InnoPharma's Notice Letter also informed Plaintiffs that InnoPharma seeks approval to market InnoPharma's Proposed Products before the '280 and '724 patents expire.

COUNT I: INFRINGEMENT OF THE '280 PATENT

19. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

20. InnoPharma's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of romidepsin for injection into the United States, prior to the expiration of the '280 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

21. There is a justiciable controversy between the parties hereto as to the infringement of the '280 patent.

22. Unless enjoined by this Court, upon FDA approval of InnoPharma's ANDA, InnoPharma will infringe the '280 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling InnoPharma's Proposed Products in the United States.

23. Unless enjoined by this Court, upon FDA approval of InnoPharma's ANDA, InnoPharma will induce infringement of the '280 patent under 35 U.S.C. § 271(b) by making,

using, offering to sell, importing into the United States, and/or selling InnoPharma's Proposed Products in the United States. On information and belief, upon FDA approval of InnoPharma's ANDA, InnoPharma will intentionally encourage acts of direct infringement with knowledge of the '280 patent and knowledge that its acts are encouraging infringement.

24. Unless enjoined by this Court, upon FDA approval of InnoPharma's ANDA, InnoPharma will contributorily infringe the '280 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling InnoPharma's Proposed Products in the United States. On information and belief, InnoPharma has had and continues to have knowledge that InnoPharma's Proposed Products are especially adapted for a use that infringes the '280 patent and that there is no substantial noninfringing use for InnoPharma's Proposed Products.

25. Plaintiffs will be substantially and irreparably damaged and harmed if InnoPharma's infringement of the '280 patent is not enjoined.

26. Plaintiffs do not have an adequate remedy at law.

27. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF THE '724 PATENT

28. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

29. InnoPharma's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of romidepsin for injection into the United States, prior to the expiration of the '724 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

30. There is a justiciable controversy between the parties hereto as to the infringement of the ’724 patent.

31. Unless enjoined by this Court, upon FDA approval of InnoPharma’s ANDA, InnoPharma will infringe the ’724 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing into the United States, and/or selling InnoPharma’s Proposed Products in the United States.

32. Unless enjoined by this Court, upon FDA approval of InnoPharma’s ANDA, InnoPharma will induce infringement of the ’724 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing into the United States, and/or selling InnoPharma’s Proposed Products in the United States. On information and belief, upon FDA approval of InnoPharma’s ANDA, InnoPharma will intentionally encourage acts of direct infringement with knowledge of the ’724 patent and knowledge that its acts are encouraging infringement.

33. Unless enjoined by this Court, upon FDA approval of InnoPharma’s ANDA, InnoPharma will contributorily infringe the ’724 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing into the United States, and/or selling InnoPharma’s Proposed Products in the United States. On information and belief, InnoPharma has had and continues to have knowledge that InnoPharma’s Proposed Products are especially adapted for a use that infringes the ’724 patent and that there is no substantial noninfringing use for InnoPharma’s Proposed Products.

34. Plaintiffs will be substantially and irreparably damaged and harmed if InnoPharma’s infringement of the ’724 patent is not enjoined.

35. Plaintiffs do not have an adequate remedy at law.

36. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment be entered that InnoPharma has infringed the '280 and '724 patents by submitting ANDA No. 206-254;

(B) A Judgment be entered that InnoPharma has infringed, and that InnoPharma's making, using, selling, offering to sell, or importing into the United States InnoPharma's Proposed Products will infringe one or more claims of the '280 and '724 patents;

(C) An Order that the effective date of FDA approval of ANDA No. 206-254 be a date which is not earlier than the later of the expiration of the '280 and '724 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) Preliminary and permanent injunctions enjoining InnoPharma and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing into the United States InnoPharma's Proposed Products until after the expiration of the '280 and '724 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining InnoPharma, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any systems or methods as claimed in the '280 and '724 patents, or from actively inducing or contributing to the infringement of any claim of any of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or becomes entitled;

(F) A Declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of InnoPharma's Proposed Products will directly infringe, induce, and/or contribute to infringement of the '280 and '724 patents;

(G) To the extent that InnoPharma has committed any acts with respect to the inventions claimed in the '280 and '724 patents, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiffs be awarded damages for such acts;

(H) If InnoPharma engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of InnoPharma's Proposed Products prior to the expiration of the '280 and '724 patents, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

(I) A judgment declaring that the '280 and '724 patents remain valid and enforceable;

(J) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(K) Costs and expenses in this action; and

(L) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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