IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| CELGENE CORPORATION and ASTELLAS PHARMA INC., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. _____ |
| TEVA PHARMACEUTICALS USA, INC., | ) | |
| Defendant. | ) | |

**COMPLAINT**

Plaintiffs Celgene Corporation ("Celgene") and Astellas Pharma, Inc. ("Astellas"), for their Complaint against Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), 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 Teva's filing of a New Drug Application ("NDA") 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 Teva is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Upon information and belief, Teva manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district. Upon information and belief, Teva also prepares and/or aids in the preparation and submission of Abbreviated New Drug Applications ("ANDA") and New Drug Applications ("NDA") 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 Teva 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, Teva 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, Teva has customers in the State of Delaware. Further, upon information and belief, Teva has purposefully availed itself of the benefits of this forum by filing civil actions in this Court. *See, e.g.*, Civil Action Nos. 15-124, 15-50, 13-2002. Teva has also previously consented to personal jurisdiction in this Court (*see, e.g.*, Civil Action Nos. 09-307, 09-841), and purposefully availed itself of the benefits of this forum by filing counterclaims in at least one of those actions (Civil Action No. 09-307).

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, titled "Method of Producing FR901228." The '280 patent is assigned to Astellas. 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, titled "Method of Producing FR901228." The '724 patent is assigned to Astellas. 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 corresponding 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® expired 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 NDA 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 NDA 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(b)(3) of the FFDCA, Teva filed NDA No. 208574 ("Teva's NDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation into the United States of romidepsin for injection ("Teva's Proposed Product"), before the patents-in-suit expire.

17. In connection with the filing of its NDA, Teva 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 Teva's NDA.

18. On or about October 29, 2015, Celgene received written notice of Teva's NDA certification ("Teva's Notice Letter"). On or about October 30, 2015, Astellas received Teva's Notice Letter. Teva's Notice Letter alleged that the claims of the '280 and '724 patents will not be infringed by the activities described in Teva's NDA. Teva's Notice Letter also informed Plaintiffs that Teva seeks approval to market Teva's Proposed Product 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. Teva's submission of its NDA 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 claims 1, 2, 3, 4, 5, 6, and 7 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 Teva's NDA, Teva 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 Teva's Proposed Product in the United States.

23. Unless enjoined by this Court, upon FDA approval of Teva's NDA, Teva 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 Teva's Proposed Product in the United

States. On information and belief, upon FDA approval of Teva's NDA, Teva 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 Teva's NDA, Teva 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 Teva's Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes the '280 patent and that there is no substantial noninfringing use for Teva's Proposed Product.

25. Unless enjoined by this Court, upon FDA approval of Teva's NDA, Teva will infringe the '280 patent under 35 U.S.C. § 271(a) by making, using, and/or importing into the United States romidepsin that is used in and/or to make Teva's Proposed Product in the United States.

26. Unless enjoined by this Court, upon FDA approval of Teva's NDA, Teva will induce infringement of the '280 patent under 35 U.S.C. § 271(b) by making, using, and/or importing into the United States romidepsin that is used in and/or to make Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's NDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '280 patent and knowledge that its acts are encouraging infringement.

27. Unless enjoined by this Court, upon FDA approval of Teva's NDA, Teva will contributorily infringe the '280 patent under 35 U.S.C. § 271(c) by making, using, and/or importing into the United States romidepsin that is used in and/or to make Teva's Proposed Product in the United States. On information and belief, Teva has had and continues to have

knowledge that the romidepsin that is used in and/or to make Teva's Proposed Product is especially adapted for a use that infringes the '280 patent and that there is no substantial noninfringing use for Teva's Proposed Product.

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

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

30. 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**

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

32. Teva's submission of its NDA 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 claims 1, 2, 3, 4, 5, 6, 7, 8, and 9 of that patent under 35 U.S.C. § 271(e)(2)(A).

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

34. Unless enjoined by this Court, upon FDA approval of Teva's NDA, Teva 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 Teva's Proposed Product in the United States.

35. Unless enjoined by this Court, upon FDA approval of Teva's NDA, Teva 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 Teva's Proposed Product in the United

States. On information and belief, upon FDA approval of Teva's NDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '724 patent and knowledge that its acts are encouraging infringement.

36. Unless enjoined by this Court, upon FDA approval of Teva's NDA, Teva 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 Teva's Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes the '724 patent and that there is no substantial noninfringing use for Teva's Proposed Product.

37. Unless enjoined by this Court, upon FDA approval of Teva's NDA, Teva will infringe the '724 patent under 35 U.S.C. § 271(a) by making, using, and/or importing into the United States romidepsin that is used in and/or to make Teva's Proposed Product in the United States.

38. Unless enjoined by this Court, upon FDA approval of Teva's NDA, Teva will induce infringement of the '724 patent under 35 U.S.C. § 271(b) by making, using, and/or importing into the United States romidepsin that is used in and/or to make Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's NDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '280 patent and knowledge that its acts are encouraging infringement.

39. Unless enjoined by this Court, upon FDA approval of Teva's NDA, Teva will contributorily infringe the '724 patent under 35 U.S.C. § 271(c) by making, using, and/or importing into the United States romidepsin that is used in and/or to make Teva's Proposed Product in the United States. On information and belief, Teva has had and continues to have

knowledge that the romidepsin that is used in and/or to make Teva's Proposed Product is especially adapted for a use that infringes the '280 patent and that there is no substantial noninfringing use for Teva's Proposed Product.

40. Plaintiffs will be substantially and irreparably damaged and harmed if Teva's infringement of the '724 patent is not enjoined.

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

42. 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 that Teva has infringed the '280 and '724 patents by submitting NDA No. 208574;

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

(C) A Judgment be entered that Teva has infringed, and that Teva's making, using, and/or importing into the United States romidepsin that is used in and/or to make Teva's Proposed Product in the United States will infringe one or more claims of the '280 and '724 patents;

(D) An Order that the effective date of FDA approval of NDA No. 208574 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;

(E) Preliminary and permanent injunctions enjoining Teva 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 Teva's Proposed Product until after the expiration of the '280 and '724 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(F) Preliminary and permanent injunctions enjoining Teva and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from making, using, and/or importing into the United States romidepsin that is used in and/or to make Teva's Proposed Product in the United States until after the expiration of the '280 and '724 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(G) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Teva, 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;

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

(I) A Declaration that the commercial manufacture, use, or importation into the United States of romidepsin that is used in and/or to make Teva's Proposed Product will directly infringe, induce, and/or contribute to infringement of the '280 and '724 patents;

(J) To the extent that Teva 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;

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

(L) If Teva engages in the commercial manufacture, use, or importation into the United States of romidepsin that is used in and/or to make Teva's Proposed Product prior to the expiration of the '280 and '724 patents, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

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

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

(O) Costs and expenses in this action; and

(P) 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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