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*Corporation and Novartis Pharma AG*

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| **CELGENE CORPORATION, NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS PHARMA AG,** | **Civil Action No. _____** |
| **Plaintiffs,** | **COMPLAINT FOR PATENT INFRINGEMENT** |
| **v.** | |
| **PAR PHARMACEUTICAL, INC.,** | **(Filed Electronically)** |
| **Defendant.** | |

Plaintiffs Celgene Corporation ("Celgene"), Novartis Pharmaceuticals Corporation and Novartis Pharma AG (together, "Novartis") (collectively, "Plaintiffs"), by their attorneys, for their Complaint against defendant Par Pharmaceutical, Inc. ("Par" or "Defendant"), allege as follows:

## Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 United States Code, arising from Defendant's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Novartis' patented FOCALIN XR® drug products prior to the expiration of Celgene's United States Patent Nos. 5,908,850 (the "'850 patent"), 6,355,656 (the "'656 patent"), 6,528,530 (the "'530 patent"), 5,837,284 (the "1998 '284 patent"), 6,635,284 (the "2003 '284 patent"), and 7,431,944 (the "'944 patent"), all of which cover the FOCALIN XR® products or its use.

## The Parties

2. Plaintiff Celgene Corporation 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 Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

4. Plaintiff Novartis Pharma AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. Defendant Par Pharmaceutical, Inc. is a corporation organized under the laws of the State of Delaware, having a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey, 07677.

6. Upon information and belief, Par is in the business of manufacturing, distributing, and selling generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

**Jurisdiction and Venue**

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

8. Upon information and belief, this Court has personal jurisdiction over Par at least because: i) Par is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products, which, either directly or through its subsidiaries, agents and/or alter-egos, Par manufactures, distributes, markets and sells throughout the United States and in this judicial district; ii) Par purposefully has conducted and continues to conduct business, directly, and/or through its subsidiaries, agents and/or alter-egos in this judicial district; iii) this judicial district is a likely destination of Par's product that is the subject of this lawsuit; iv) Par maintains its principal place of business and corporate headquarters in this judicial district; and v) Par has previously consented or otherwise failed to contest personal jurisdiction in this judicial district in connection with numerous lawsuits. Through these and other acts, Par has engaged in continuous and systematic contacts with New Jersey and/or purposefully availed itself of this forum.

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

**The Patents-in-Suit and the FOCALIN XR® Drug Products**

10. The '850 patent, entitled "Method of Treating Attention Deficit Disorders With D-Threo Methylphenidate," duly and legally issued to Celgene on June 1, 1999, by the United States Patent and Trademark Office ("PTO"). A copy of the '850 patent is attached hereto as

Exhibit A. The '850 patent includes claims directed to methods of treatment using *d-threo* methylphenidate.

11. The '656 patent, entitled "Phenidate Drug Formulations Having Diminished Abuse Potential," originally duly and legally issued to Celgene on March 12, 2002, by the PTO. An *Ex Parte* Reexamination Certificate, which amended certain claims of the '656 patent and added new claims, issued on March 27, 2007, by the PTO. Copies of the '656 patent and the *Ex Parte* Reexamination Certificate for the '656 patent are attached hereto as Exhibit B. The '656 patent claims are directed to, *e.g.*, pharmaceutical unit dosages of *d-threo* methylphenidate.

12. The '530 patent, entitled "Phenidate Drug Formulations Having Diminished Abuse Potential," duly and legally issued to Celgene on March 4, 2003, by the PTO. A copy of the '530 patent is attached hereto as Exhibit C. The '530 patent claims are directed to pharmaceutical unit dosages that include pharmaceutical compositions of *d-threo* methylphenidate.

13. The 1998 '284 patent, entitled "Delivery of Multiple Doses of Medications," duly and legally issued to Celgene on November 17, 1998, by the PTO. A copy of the 1998 '284 patent is attached hereto as Exhibit D. The 1998 '284 patent includes claims directed to extended release dosage forms of methylphenidate drug products.

14. The 2003 '284 patent, entitled "Delivery of Multiple Doses of Medications," duly and legally issued to Celgene on October 21, 2003, by the PTO. A copy of the 2003 '284 patent is attached hereto as Exhibit E. The 2003 '284 patent includes claims directed to an extended release dosage form and claims directed to a method of treating disease with certain extended release dosage forms.

15. The '944 patent, entitled "Delivery of Multiple Doses of Medications," duly and legally issued to Celgene on October 7, 2008, by the PTO. A copy of the '944 patent is attached hereto as Exhibit F. The '944 patent includes claims directed to dosage forms for oral administration of a methylphenidate drug.

16. Celgene is the owner by assignment of all right, title and interest in the '850 patent, the '656 patent, the '530 patent, the 1998 '284 patent, the 2003 '284 patent, and the '944 patent (collectively referred to herein as the "Patents-in-Suit"). Novartis Pharma AG is the exclusive licensee, in certain fields of use, of the Patents-in-Suit.

17. Novartis Pharmaceuticals Corporation holds an approved New Drug Application for extended release capsules, including a 40 mg dosage strength, of the hydrochloride salt of *d-threo*-methylphenidate (also known as dexmethylphenidate hydrochloride), which it sells as commercial products under the trade name FOCALIN XR®. These commercial products or their use are covered by one or more claims of the Patents-in-Suit.

**Acts Giving Rise To This Action**

18. Par prepared and filed with the FDA, pursuant to 21 U.S.C. § 355(j), ANDA No. 202842 to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of extended release dexmethylphenidate hydrochloride capsules, 40 mg dosage strength ("Par's Proposed Product"), prior to the expiration of the Patents-in-Suit.

19. In connection with the filing of its ANDA as described in the preceding paragraph, Par provided written certification to the FDA, as called for by 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), alleging that all claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by Par's Proposed Product or the activities described in Par's ANDA.

20. By letter dated April 15, 2011, Par notified Celgene and Novartis (the "Notification Letter"), that it had filed with the FDA ANDA No. 202842, including its Paragraph IV Certification, to obtain FDA approval to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product.

21. Upon information and belief, if ANDA No. 202842 is approved, it is the intention of Par to commercially manufacture, use, and sell Par's Proposed Product in the United States.

22. Upon information and belief, Par's ANDA No. 202842 contains information showing that Par's Proposed Product (a) is bioequivalent to the patented FOCALIN XR® products; (b) has the same active ingredient as the patented FOCALIN XR® products; (c) has the same route of administration and strength as the patented FOCALIN XR® products; (d) has the same, or substantially the same, dosage form and proposed labeling as the patented FOCALIN XR® products; and (e) has the same indication and usage as the patented FOCALIN XR® products.

23. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) before the expiration of forty-five days from the date of receipt by Plaintiffs of the Notification Letter.

**Count I: Par's Filing of the ANDA Infringes the '850 Patent.**

24. Plaintiffs repeat and reallege the allegations of paragraphs 1-23 as though fully set forth herein.

25. Par's submission of ANDA No. 202842 to the FDA, including its Paragraph IV Certification, to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product prior to the expiration of the '850 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

26. Unless enjoined by this Court, upon FDA approval of ANDA No. 202842, Par will infringe the '850 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing into the United States Par's Proposed Product.

27. Plaintiffs will be substantially and irreparably damaged and harmed if Par's infringement of the '850 patent is not enjoined. Plaintiffs do not have an adequate remedy at law for this infringement.

**Count II: Par's Filing of the ANDA Infringes the '656 Patent.**

28. Plaintiffs repeat and reallege the allegations of paragraphs 1-23 as though fully set forth herein.

29. Par's submission of ANDA No. 202842 to the FDA, including its Paragraph IV Certification, to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product prior to the expiration of the '656 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

30. Unless enjoined by this Court, upon FDA approval of ANDA No. 202842, Par will infringe the '656 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing into the United States Par's Proposed Product.

31. Plaintiffs will be substantially and irreparably damaged and harmed if Par's infringement of the '656 patent is not enjoined. Plaintiffs do not have an adequate remedy at law for this infringement.

**Count III: Par's Filing of the ANDA Infringes the '530 Patent.**

32. Plaintiffs repeat and reallege the allegations of paragraphs 1-23 as though fully set forth herein.

33. Par's submission of ANDA No. 202842 to the FDA, including its Paragraph IV Certification, to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product prior to the expiration of the '530 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

34. Unless enjoined by this Court, upon FDA approval of ANDA No. 202842, Par will infringe the '530 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing into the United States Par's Proposed Product.

35. Plaintiffs will be substantially and irreparably damaged and harmed if Par's infringement of the '530 patent is not enjoined. Plaintiffs do not have an adequate remedy at law for this infringement.

**Count IV: Par's Filing of the ANDA Infringes the 1998 '284 Patent.**

36. Plaintiffs repeat and reallege the allegations of paragraphs 1-23 as though fully set forth herein.

37. Par's submission of ANDA No. 202842 to the FDA, including its Paragraph IV Certification, to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product prior to the expiration of the 1998 '284 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

38. Unless enjoined by this Court, upon FDA approval of ANDA No. 202842, Par will infringe the 1998 '284 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing into the United States Par's Proposed Product.

39. Plaintiffs will be substantially and irreparably damaged and harmed if Par's infringement of the 1998 '284 patent is not enjoined. Plaintiffs do not have an adequate remedy at law for this infringement.

**Count V: Par's Filing of the ANDA Infringes the 2003 '284 Patent.**

40. Plaintiffs repeat and reallege the allegations of paragraphs 1-23 as though fully set forth herein.

41. Par's submission of ANDA No. 202842 to the FDA, including its Paragraph IV Certification, to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product prior to the expiration of the 2003 '284 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

42. Unless enjoined by this Court, upon FDA approval of ANDA No. 202842, Par will infringe the 2003 '284 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing into the United States Par's Proposed Product.

43. Plaintiffs will be substantially and irreparably damaged and harmed if Par's infringement of the 2003 '284 patent is not enjoined. Plaintiffs do not have an adequate remedy at law for this infringement.

**Count VI: Par's Filing of the ANDA Infringes the '944 Patent.**

44. Plaintiffs repeat and reallege the allegations of paragraphs 1-23 as though fully set forth herein.

45. Par's submission of ANDA No. 202842 to the FDA, including its Paragraph IV Certification, to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product prior to the expiration of the '944 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

46. Unless enjoined by this Court, upon FDA approval of ANDA No. 202842, Par will infringe the '944 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing into the United States Par's Proposed Product.

47. Plaintiffs will be substantially and irreparably damaged and harmed if Par's infringement of the '944 patent is not enjoined. Plaintiffs do not have an adequate remedy at law for this infringement.

**Prayer For Relief**

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment that Par has infringed one or more claims of the '850 patent;

(B) A Judgment that Par has infringed one or more claims of the '656 patent;

(C) A Judgment that Par has infringed one or more claims of the '530 patent;

(D) A Judgment that Par has infringed one or more claims of the 1998 '284 patent;

(E) A Judgment that Par has infringed one or more claims of the 2003 '284 patent;

(F) A Judgment that Par has infringed one or more claims of the '944 patent;

(G) An Order that the effective date of any FDA approval of ANDA No. 202842 be a date which is not earlier than the later of the expiration of the '850 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(H) An Order that the effective date of any FDA approval of ANDA No. 202842 be a date which is not earlier than the later of the expiration of the '656 patent, or any expiration of

exclusivity to which Plaintiffs are or become entitled;

(I) An Order that the effective date of any FDA approval of ANDA No. 202842 be a date which is not earlier than the later of the expiration of the '530 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(J) An Order that the effective date of any FDA approval of ANDA No. 202842 be a date which is not earlier than the later of the expiration of the 1998 '284 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(K) An Order that the effective date of any FDA approval of ANDA No. 202842 be a date which is not earlier than the later of the expiration of the 2003 '284 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(L) An Order that the effective date of any FDA approval of ANDA No. 202842 be a date which is not earlier than the later of the expiration of the '944 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(M) Preliminary and permanent injunctions enjoining Par and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing into the United States Par's Proposed Product until after the expiration of the '850 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(N) Preliminary and permanent injunctions enjoining Par and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing into the United States Par's Proposed Product until after the expiration of the '656 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(O) Preliminary and permanent injunctions enjoining Par and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing into the United States Par's Proposed Product until after the expiration of the '530 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(P) Preliminary and permanent injunctions enjoining Par and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing into the United States Par's Proposed Product until after the expiration of the 1998 '284 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(Q) Preliminary and permanent injunctions enjoining Par and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing into the United States Par's Proposed Product until after the expiration of the 2003 '284 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(R) Preliminary and permanent injunctions enjoining Par and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing into the United States Par's Proposed Product until after the expiration of the '944 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(S) A Declaration that the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product will directly infringe or induce and/or contribute to infringement of the '850 patent;

(T) A Declaration that the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product will directly infringe or induce and/or contribute to infringement of the '656 patent;

(U) A Declaration that the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product will directly infringe or induce and/or contribute to infringement of the '530 patent;

(V) A Declaration that the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product will directly infringe or induce and/or contribute to infringement of the 1998 '284 patent;

(W) A Declaration that the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product will directly infringe or induce and/or contribute to infringement of the 2003 '284 patent;

(X) A Declaration that the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product will directly infringe or induce and/or contribute to infringement of the '944 patent;

(Y) If Par engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product prior to the expiration of the '850 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(Z) If Par engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product prior to the expiration of the '656 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(AA) If Par engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product prior to the expiration of the '530 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(BB) If Par engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product prior to the expiration of the 1998 '284 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(CC) If Par engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product prior to the expiration of the 2003 '284 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(DD) If Par engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Par's Proposed Product prior to the expiration of the '944 patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(EE) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § § 271(e)(4) and 285, entitling Plaintiffs to their reasonable attorneys' fees;

(FF) Costs and expenses in this action; and

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

Dated: May 27, 2011

Respectfully submitted,

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