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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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

Plaintiffs Celgene Corporation ("Celgene"), Novartis Pharmaceuticals Corporation and Novartis Pharma AG, (together, "Novartis") (collectively, "Plaintiffs"), by their attorneys, for their Complaint against defendant Teva Pharmaceuticals USA, Inc. ("Teva" 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 product in new, 25 mg and 35 mg dosage strengths 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 their use (collectively, the "Patents-in-Suit").

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. Upon information and belief, Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454-1090.

6. Teva initially prepared and filed with the FDA, pursuant to 21 U.S.C. § 355(j), ANDA No. 78-908 concerning proposed generic versions of FOCALIN XR® in 5 mg, 10 mg, 15 mg, and 20 mg dosage strengths. Within forty-five (45) days of receiving notice of that ANDA filing, Celgene and Novartis instituted a lawsuit in this Court captioned *Celgene Corporation, Novartis Pharmaceuticals Corporation and Novartis Pharma AG v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 07-4459 (FLW)(TJB) (D.N.J.) (the "First Teva Litigation"). Pursuant to a confidential settlement agreement, the First Teva Litigation was resolved and dismissed without prejudice by this Court on February 1, 2010. The First Teva Litigation and the resulting settlement concerned only Teva's proposed 5 mg, 10 mg, 15 mg, and 20 mg products and did not concern any of the dosage strengths currently at issue in the present litigation. After the First Teva Litigation was resolved, Teva informed Celgene and Novartis, via a Paragraph IV notice dated March 11, 2011, that it had filed another ANDA, number 202731, concerning proposed generic versions of FOCALIN XR® in 30 mg and 40 mg dosage strengths. Teva's 30 mg and 40 mg products are the subject of an action currently pending before this Court captioned *Celgene Corporation, Novartis Pharmaceuticals Corporation and Novartis Pharma AG v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 11-2356 (SDW)(MCA) (D.N.J.), which was filed on April 25, 2011. By way of a Paragraph IV notice dated October 19, 2011, Teva informed Celgene and Novartis that it had amended its ANDA, number 202731, to include 25 mg and 35 mg dosage strengths of its proposed generic product ("Teva's 25 mg and 35 mg Products"). The present action concerns Teva's 25 mg and 35 mg Products and is filed within forty-five (45) days of Plaintiffs' receipt of that notice.

7. Upon information and belief, if ANDA No. 202731 is approved, it is the intention of Teva to commercially manufacture, use, and sell Teva's 25 mg and 35 mg Products in the United States.

Jurisdiction and Venue

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

9. This Court has personal jurisdiction over Teva by virtue of, *inter alia*, (i) Teva's continuous and systematic contacts with New Jersey, (ii) its sale of prescription drugs in New Jersey, (iii) its registration of prescription drugs in the New Jersey Generic Formulary of the New Jersey Department of Health and Senior Services, (iv) its consent to being sued in New Jersey as evidenced by its registration to do business in New Jersey and its appointment of a registered agent in New Jersey, (v) its regular and established facilities and places of business in New Jersey (including, for example, at 208 Passaic Avenue, Fairfield, New Jersey, and at 10 Gloria Lane, Fairfield, New Jersey), (vi) its performance of tortious acts that will result in foreseeable harm in New Jersey, and (vii) Teva's consent to jurisdiction in numerous actions in this district (including, for example, *Celgene Corporation, et al. v. Teva Pharmaceuticals USA, Inc.*, Civil Action Nos. 04-4030 and 06-6154 (FLW)(TJB), *Celgene Corporation, Novartis Pharmaceuticals Corporation and Novartis Pharma AG v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 07-4459 (FLW)(TJB), and *Celgene Corporation, Novartis Pharmaceuticals Corporation and Novartis Pharma AG v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 11-2356 (SDW)(MCA)).

10. 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

11. 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.

12. 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 pharmaceutical unit dosages of *d-threo* methylphenidate.

13. 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 includes claims directed to pharmaceutical unit dosages of *d-threo* methylphenidate.

14. 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.

15. 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.

16. 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.

17. Celgene is the owner by assignment of all right, title and interest in the Patents-in-Suit. Novartis Pharma AG is the exclusive licensee, in certain fields of use, of the Patents-in-Suit.

18. Novartis Pharmaceuticals Corporation holds an approved New Drug Application for extended release capsules (including 25 mg and 35 mg dosage strengths) 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®. This commercial product or its use is covered by one or more claims of the Patents-in-Suit.

Acts Giving Rise To This Action

19. Plaintiffs received a letter from Teva dated October 19, 2011 (the "Notification Letter"), notifying them that Teva had filed ANDA No. 202731 with the FDA seeking approval to market 25 mg and 35 mg extended release dexmethylphenidate hydrochloride capsules. The Notification Letter informed Plaintiffs that Teva had submitted a certification to the FDA pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) ("Paragraph IV Certification") stating that, in Teva's opinion, all claims of the '850 patent, the '656 patent, the '530 patent, the 1998 '284 patent, the 2003 '284 patent, and the '944 patent are invalid, unenforceable, and/or not infringed by Teva's 25 mg and 35 mg Products.

20. Teva seeks approval to engage in the commercial manufacture, use and sale of Teva's 25 mg and 35 mg Products prior to the expiration of the Patents-in-Suit, which are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," as being applicable to the patented FOCALIN XR® products.

21. Upon information and belief, Teva intends to engage, and will engage, in the commercial manufacture, use or sale of Teva's 25 mg and 35 mg Products promptly upon receiving FDA approval to do so.

22. Upon information and belief, Teva's ANDA No. 202731 contains information showing that Teva's 25 mg and 35 mg Products (a) are bioequivalent to the patented FOCALIN XR® products, (b) have the same active ingredient as the patented FOCALIN XR® products, (c) have the same route of administration and strength as the patented FOCALIN XR® products, and (d) have the same, or substantially the same, dosage form and proposed labeling, and the same indication and usage, as the patented FOCALIN XR® products.

23. This action has been brought, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), before the expiration of forty-five (45) days from the date of receipt by Plaintiffs of the Notification Letter.

Count I: Teva's Filing of an ANDA for Teva's 25 mg and 35 mg Products Infringes the '850 Patent.

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

25. Teva's submission of ANDA No. 202731 to obtain approval to engage in the commercial manufacture, use or sale of Teva's 25 mg and 35 mg Products prior to the expiration of the '850 patent, constitutes infringement of one or more of the 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. 202731, Teva will infringe the '850 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Teva's 25 mg and 35 mg Products in the United States.

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

Count II: Teva's Filing of an ANDA for Teva's 25 mg and 35 mg Products Infringes the '656 Patent.

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

29. Teva's submission of ANDA No. 202731 to obtain approval to engage in the commercial manufacture, use or sale of Teva's 25 mg and 35 mg Products prior to the expiration of the '656 patent, constitutes infringement of one or more of the 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. 202731, Teva will infringe the '656 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Teva's 25 mg and 35 mg Products in the United States.

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

Count III: Teva's Filing of an ANDA for Teva's 25 mg and 35 mg Products Infringes the '530 Patent.

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

33. Teva's submission of ANDA No. 202731 to obtain approval to engage in the commercial manufacture, use or sale of Teva's 25 mg and 35 mg Products prior to the expiration of the '530 patent, constitutes infringement of one or more of the 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. 202731, Teva will infringe the '530 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Teva's 25 mg and 35 mg Products in the United States.

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

Count IV: Teva's Filing of an ANDA for Teva's 25 mg and 35 mg Products Infringes the 1998 '284 Patent.

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

37. Teva's submission of ANDA No. 202731 to obtain approval to engage in the commercial manufacture, use or sale of Teva's 25 mg and 35 mg Products prior to the expiration of the 1998 '284 patent, constitutes infringement of one or more of the 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. 202731, Teva will infringe the 1998 '284 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Teva's 25 mg and 35 mg Products in the United States.

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

Count V: Teva's Filing of the ANDA for Teva's 25 mg and 35 mg Products Infringes the 2003 '284 Patent.

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

41. Teva's submission of ANDA No. 202731 to obtain approval to engage in the commercial manufacture, use or sale of Teva's 25 mg and 35 mg Products prior to the expiration of the 2003 '284 patent, constitutes infringement of one or more of the 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. 202731, Teva will infringe the 2003 '284 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Teva's 25 mg and 35 mg Products in the United States.

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

Count VI: Teva's Filing of the ANDA for Teva's 25 mg and 35 mg Products Infringes the '944 Patent.

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

45. Teva's submission of ANDA No. 202731 to obtain approval to engage in the commercial manufacture, use or sale of Teva's 25 mg and 35 mg Products prior to the expiration of the '944 patent, constitutes infringement of one or more of the 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. 202731, Teva will infringe the '944 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Teva's 25 mg and 35 mg Products in the United States.

47. Plaintiffs will be substantially and irreparably damaged and harmed if Teva'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 declaring that Teva has infringed one or more claims of the '850 patent;

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

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

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

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

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

(G) An Order that the effective date of any FDA approval of ANDA No. 202731 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. 202731 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. 202731 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. 202731 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. 202731 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. 202731 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 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 25 mg and 35 mg Products 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 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 25 mg and 35 mg Products 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 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 25 mg and 35 mg Products 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 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 25 mg and 35 mg Products 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 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 25 mg and 35 mg Products 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 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 25 mg and 35 mg Products until after the expiration of the '944 patent, or any expiration of exclusivity to which Plaintiffs are or become entitled;

(S) A Declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of Teva's 25 mg and 35 mg Products will directly infringe or induce and/or contribute to infringement of the '850 patent;

(T) A Declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of Teva's 25 mg and 35 mg Products will directly infringe or

induce and/or contribute to infringement of the '656 patent;

(U) A Declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of Teva's 25 mg and 35 mg Products will directly infringe or induce and/or contribute to infringement of the '530 patent;

(V) A Declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of Teva's 25 mg and 35 mg Products will directly infringe or induce and/or contribute to infringement of the 1998 '284 patent;

(W) A Declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of Teva's 25 mg and 35 mg Products will directly infringe or induce and/or contribute to infringement of the 2003 '284 patent;

(X) A Declaration that the commercial manufacture, use, importation into the United States, sale or offering for sale of Teva's 25 mg and 35 mg Products will directly infringe or induce and/or contribute to infringement of the '944 patent;

(Y) If Teva engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Teva's 25 mg and 35 mg Products 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 Teva engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Teva's 25 mg and 35 mg Products 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 Teva engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Teva's 25 mg and 35 mg Products 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 Teva engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Teva's 25 mg and 35 mg Products 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 Teva engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Teva's 25 mg and 35 mg Products 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 Teva engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Teva's 25 mg and 35 mg Products 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: December 2, 2011

Respectfully submitted,

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