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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)**
ACTAVIS SOUTH ATLANTIC LLC,	
Defendant.	

Plaintiffs Celgene Corporation ("Celgene"), Novartis Pharmaceuticals Corporation and Novartis Pharma AG, (together, "Novartis") (collectively, "Plaintiffs"), by their attorneys, for their Complaint against defendant Actavis South Atlantic LLC ("Actavis" 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 amendment to its 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 a new, 40 mg dosage strength 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, Defendant Actavis South Atlantic LLC is a limited liability company organized and existing under the laws of the state of Delaware, having a principal place of business at 13800 N.W. 2nd Street, Suite 190, Sunrise, Florida 33325.

6. Actavis initially prepared and filed with the FDA, pursuant to 21 U.S.C. § 355(j), ANDA No. 79-108 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 the First Actavis Litigation. Pursuant to a confidential settlement agreement, that matter was resolved and dismissed without prejudice by this Court on April 22, 2010. The First Actavis Litigation and the resulting settlement concerned only Actavis's proposed 5 mg, 10 mg, 15 mg, and 20 mg products, which were the only dosage strengths included in Actavis's ANDA at the time. After the First Actavis Litigation was resolved, Actavis informed Celgene and Novartis, via a Paragraph IV notice dated March 1, 2011, that it had amended its ANDA to include a 30 mg dosage strength of its proposed generic product. Actavis's 30 mg product is the subject of an action currently pending before this Court captioned *Celgene Corporation, Novartis Pharmaceuticals Corporation and Novartis Pharma AG v. Actavis South Atlantic LLC*, Civil Action No. 11-2162 (SDW)(MCA) (D.N.J.), which was filed on April 15, 2011. By way of a Paragraph IV notice dated September 20, 2011, Actavis informed Celgene and Novartis that it had amended its ANDA to include a 40 mg dosage strength of its proposed generic product ("Actavis's 40 mg Product"). The present action concerns Actavis's 40 mg Product and is filed within forty-five (45) days of Plaintiffs' receipt of that notice.

7. Upon information and belief, if ANDA No. 79-108 is approved, it is the intention of Actavis to commercially manufacture, use, and sell Actavis's 40 mg Product 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 Actavis because of: i) Actavis's continuous and systematic contacts with New Jersey (*e.g.*, upon information and belief, Actavis directly, or through its divisions, subsidiaries, agents and/or alter-egos, manufactures, distributes, markets and sells generic pharmaceutical products, and maintains executive offices and a manufacturing facility, in this judicial district; ii) The Honorable Susan D. Wigenton's May 17, 2007 Order in the matter captioned *Celgene Corporation, Novartis Pharmaceuticals Corporation and Novartis Pharma AG v. Abrika Pharmaceuticals, Inc. and Actavis South Atlantic LLC*, Civil Action No. 06-5818 (SDW)(MCA), finding that Actavis is subject to personal jurisdiction in the State of New Jersey; iii) Actavis's consent to litigation before this Court in the First Actavis Litigation specifically concerning this same ANDA; and iv) Actavis's consent to litigation before this Court in the currently pending case captioned *Celgene Corporation, Novartis Pharmaceuticals Corporation and Novartis Pharma AG v. Actavis South Atlantic LLC*, Civil Action No. 11-2162 (SDW)(MCA) (D.N.J.).

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 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®. 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 Actavis dated September 20, 2011 (the "Notification Letter"), notifying them that Actavis had amended its ANDA No. 79-108 with the FDA to seek approval to market its proposed generic version of FOCALIN XR® in a new, 40 mg dosage strength. The Notification Letter informed Plaintiffs that Actavis had submitted a certification to the FDA pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) ("Paragraph IV Certification") stating that, in Actavis'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 Actavis's 40 mg Product.

20. Actavis seeks approval to engage in the commercial manufacture, use and sale of Actavis's 40 mg Product 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, Actavis intends to engage, and will engage, in the commercial manufacture, use or sale of Actavis's 40 mg Product promptly upon receiving FDA approval to do so.

22. Upon information and belief, Actavis's ANDA No. 79-108 contains information showing that Actavis's 40 mg 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, and (d) has 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: Actavis's Filing of an ANDA for Actavis's 40 mg Product Infringes the '850 Patent.

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

25. Actavis's submission of an amendment to ANDA No. 79-108 to obtain approval to engage in the commercial manufacture, use or sale of Actavis's 40 mg Product 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. 79-108, Actavis will infringe the '850 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Actavis's 40 mg Product in the United States.

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

Count II: Actavis's Filing of an ANDA for Actavis's 40 mg Product Infringes the '656 Patent.

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

29. Actavis's submission of an amendment to ANDA No. 79-108 to obtain approval to engage in the commercial manufacture, use or sale of Actavis's 40 mg Product 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. 79-108, Actavis will infringe the '656 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Actavis's 40 mg Product in the United States.

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

Count III: Actavis's Filing of an ANDA for Actavis's 40 mg Product Infringes the '530 Patent.

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

33. Actavis's submission of an amendment to ANDA No. 79-108 to obtain approval to engage in the commercial manufacture, use or sale of Actavis's 40 mg Product 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. 79-108, Actavis will infringe the '530 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Actavis's 40 mg Product in the United States.

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

Count IV: Actavis's Filing of an ANDA for Actavis's 40 mg Product Infringes the 1998 '284 Patent.

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

37. Actavis's submission of an amendment to ANDA No. 79-108 to obtain approval to engage in the commercial manufacture, use or sale of Actavis's 40 mg Product 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. 79-108, Actavis will infringe the 1998 '284 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Actavis's 40 mg Product in the United States.

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

Count V: Actavis's Filing of the ANDA for Actavis's 40 mg Product Infringes the 2003 '284 Patent.

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

41. Actavis's submission of an amendment to ANDA No. 79-108 to obtain approval to engage in the commercial manufacture, use or sale of Actavis's 40 mg Product 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. 79-108, Actavis will infringe the 2003 '284 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Actavis's 40 mg Product in the United States.

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

Count VI: Actavis's Filing of the ANDA for Actavis's 40 mg Product Infringes the '944 Patent.

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

45. Actavis's submission of an amendment to ANDA No. 79-108 to obtain approval to engage in the commercial manufacture, use or sale of Actavis's 40 mg Product 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. 79-108, Actavis will infringe the '944 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Actavis's 40 mg Product in the United States.

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

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

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

patent;

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

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

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

(G) An Order that the effective date of any FDA approval of ANDA No. 79-108, with respect to Actavis's 40 mg Product, 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. 79-108, with respect to Actavis's 40 mg Product, 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. 79-108, with respect to Actavis's 40 mg Product, 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. 79-108, with respect to Actavis's 40 mg Product, 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. 79-108, with respect to Actavis's 40 mg Product, 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. 79-108, with respect to Actavis's 40 mg Product, 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 Actavis 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 Actavis's 40 mg 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 Actavis 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 Actavis's 40 mg 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 Actavis 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 Actavis's 40 mg 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 Actavis 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 Actavis's 40 mg 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 Actavis 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 Actavis's 40 mg 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 Actavis 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 Actavis's 40 mg Product 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 Actavis's 40 mg Product 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 Actavis's 40 mg Product 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 Actavis's 40 mg Product 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 Actavis's 40 mg Product 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 Actavis's 40 mg Product 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 Actavis's 40 mg Product will directly infringe or induce and/or contribute to infringement of the '944 patent;

(Y) If Actavis engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Actavis's 40 mg 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 Actavis engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Actavis's 40 mg 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 Actavis engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Actavis's 40 mg 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 Actavis engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Actavis's 40 mg 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 Actavis engages in the commercial manufacture, use, importation into the

United States, offering to sell, or sale of Actavis's 40 mg 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 Actavis engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Actavis's 40 mg 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: November 4, 2011

Respectfully submitted,

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