

Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza
Newark, New Jersey 07102-5490
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff Celgene Corporation

William J. O’Shaughnessy
MCCARTER & ENGLISH
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 639-2094

Attorneys for Plaintiffs Novartis Pharmaceuticals Corporation and Novartis Pharma AG

**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)
BARR LABORATORIES, INC. and BARR)	
PHARMACEUTICALS, INC.,)	
)	
Defendants.)	
_____)	

Plaintiffs Celgene Corporation (“Celgene”), Novartis Pharmaceuticals Corporation and Novartis Pharma AG (together, “Novartis”), by their attorneys, for their Complaint against Defendants Barr Laboratories, Inc. (“Barr Labs”) and Barr Pharmaceuticals, Inc. (“Barr Pharma”) 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 Defendants' 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 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"), and 6,635,284 (the "2003 '284 patent"), all of which cover the FOCALIN XR® product 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 Barr Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 400 Chestnut Ridge Road, Woodcliff, NJ 07677. Upon information and belief, Barr Pharma is registered to do business in New Jersey and maintains a registered agent in New Jersey.

6. Defendant Barr Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 223 Quaker Road,

Pomona, New York 10970. Upon information and belief, Barr Labs is a subsidiary of defendant Barr Pharma. Upon information and belief, Barr Labs is registered to do business in New Jersey and maintains a registered agent in New Jersey.

7. Barr Labs and Barr Pharma are referred to hereinafter, collectively, as “Barr.”

8. Upon information and belief, Barr 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

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

10. This Court has personal jurisdiction over Barr by virtue of: (1) its continuous and systematic contacts with New Jersey; and (2) its registration to do business in New Jersey. In addition, Barr has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Further, upon information and belief, Barr directly, or through its divisions, subsidiaries, agents and/or alter-egos, manufactures, distributes, markets and sells generic drugs throughout the United States and in this judicial district.

11. 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 Product

12. 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.

13. 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.

14. 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 *d-threo* methylphenidate.

15. 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.

16. 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.

17. 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, and the 2003 '284 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.

18. Novartis Pharmaceuticals Corporation holds an approved New Drug Application for extended release capsules of 5 mg, 10 mg, 15 mg, and 20 mg, extended release capsules 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

19. Upon information and belief, Barr Labs, with the participation of Barr Pharma, prepared and filed with the FDA, pursuant to 21 U.S.C. § 355(j), ANDA No. 79-091 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 5 mg, 10 mg, 15 mg, and 20 mg (these generic capsules are collectively referred to herein as “Barr’s Proposed Products”) prior to the expiration of the Patents-in-Suit.

20. In connection with the filing of its ANDA as described in the preceding paragraph, Barr 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 the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the activities described in Barr’s ANDA.

21. By letter dated October 5, 2007, Barr Labs notified Celgene and Novartis (“the Notification Letter”), that it had filed with the FDA ANDA No. 79-091, 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 extended release dexmethylphenidate hydrochloride capsules 5 mg, 10 mg, 15 mg, and 20 mg.

22. Upon information and belief, if ANDA No. 79-091 is approved, it is the intention of Barr to commercially manufacture, use, offer for sale, sell and import Barr's Proposed Products in the United States.

23. Upon information and belief, Barr's ANDA No. 79-091 contains information showing that Barr's Proposed 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.

24. 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: Barr's Filing of the ANDA Infringes the '850 Patent.

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

26. Barr Labs' submission of ANDA No. 79-091 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 Barr's Proposed Products, prior to the expiration of the '850 patent, constitutes infringement of one or more claims of the '850 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Barr Labs and/or Barr Pharma manufactures, uses, offers for sale, sells, or imports any of Barr's Proposed Products, or induces or contributes to such conduct, it would further infringe one or more claims of the '850 patent under 35 U.S.C. § 271(a), (b) and/or (c).

27. Barr Pharma is jointly and severally liable for any infringement of one or more claims of the '850 patent. This is so because, upon information and belief, Barr Pharma

participated in, contributed to, authored, aided, abetted and/or induced the submission of ANDA No. 79-091 and its Paragraph IV Certification allegations to the FDA.

28. Unless enjoined by this Court, Barr, upon FDA approval of ANDA No. 79-091, will infringe the '850 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing Barr's Proposed Products in the United States.

29. Barr had notice of the '850 patent prior to undertaking its act of infringement. Barr's infringement of the '850 patent has been, and continues to be, willful and deliberate.

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

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

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

32. Barr Labs' submission of ANDA No. 79-091 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 Barr's Proposed Products, prior to the expiration of the '656 patent, constitutes infringement of one or more claims of the '656 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Barr Labs and/or Barr Pharma manufactures, uses, offers for sale, sells, or imports any of Barr's Proposed Products, or induces or contributes to such conduct, it would further infringe one or more claims of the '656 patent under 35 U.S.C. § 271(a), (b) and/or (c).

33. Barr Pharma is jointly and severally liable for any infringement of one or more claims of the '656 patent. This is so because, upon information and belief, Barr Pharma

participated in, contributed to, authored, aided, abetted and/or induced the submission of ANDA No. 79-091 and its Paragraph IV Certification allegations to the FDA.

34. Unless enjoined by this Court, Barr, upon FDA approval of ANDA No. 79-091, will infringe the '656 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing Barr's Proposed Products in the United States.

35. Barr had notice of the '656 patent, and its reexamination, prior to undertaking its act of infringement. Barr's infringement of the '656 patent has been, and continues to be, willful and deliberate.

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

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

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

38. Barr Labs' submission of ANDA No. 79-091 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 Barr's Proposed Products, prior to the expiration of the '530 patent, constitutes infringement of one or more claims of the '530 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Barr Labs and/or Barr Pharma manufactures, uses, offers for sale, sells, or imports any of Barr's Proposed Products, or induces or contributes to such conduct, it would further infringe one or more claims of the '530 patent under 35 U.S.C. § 271(a), (b) and/or (c).

39. Barr Pharma is jointly and severally liable for any infringement of one or more claims of the '530 patent. This is so because, upon information and belief, Barr Pharma

participated in, contributed to, authored, aided, abetted and/or induced the submission of ANDA No. 79-091 and its Paragraph IV Certification allegations to the FDA.

40. Unless enjoined by this Court, Barr, upon FDA approval of ANDA 79-091, will infringe the '530 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing Barr's Proposed Products in the United States.

41. Barr had notice of the '530 patent prior to undertaking its act of infringement. Barr's infringement of the '530 patent has been, and continues to be, willful and deliberate.

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

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

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

44. Barr Labs' submission of ANDA No. 79-091 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 Barr's Proposed Products, prior to the expiration of the 1998 '284 patent, constitutes infringement of one or more claims of the 1998 '284 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Barr Labs and/or Barr Pharma manufactures, uses, offers for sale, sells, or imports any of Barr's Proposed Products, or induces or contributes to such conduct, it would further infringe one or more claims of the 1998 '284 patent under 35 U.S.C. § 271(a), (b) and/or (c).

45. Barr Pharma is jointly and severally liable for any infringement of one or more claims of the 1998 '284 patent. This is so because, upon information and belief, Barr Pharma

participated in, contributed to, authored, aided, abetted and/or induced the submission of ANDA No. 79-091 and its Paragraph IV Certification allegations to the FDA.

46. Unless enjoined by this Court, Barr, upon FDA approval of ANDA No. 79-091, will infringe the 1998 '284 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing Barr's Proposed Products in the United States.

47. Barr had notice of the 1998 '284 patent prior to undertaking its act of infringement. Barr's infringement of the 1998 '284 patent has been, and continues to be, willful and deliberate.

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

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

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

50. Barr Labs' submission of ANDA No. 79-091 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 Barr's Proposed Products, prior to the expiration of the 2003 '284 patent, constitutes infringement of one or more claims of the 2003 '284 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Barr Labs and/or Barr Pharma manufactures, uses, offers for sale, sells, or imports any of Barr's Proposed Products, or induces or contributes to such conduct, it would further infringe one or more claims of the 2003 '284 patent under 35 U.S.C. § 271(a), (b) and/or (c).

51. Barr Pharma is jointly and severally liable for any infringement of one or more claims of the 2003 '284 patent. This is so because, upon information and belief, Barr Pharma

participated in, contributed to, authored, aided, abetted and/or induced the submission of ANDA No. 79-091 and its Paragraph IV Certification allegations to the FDA.

52. Unless enjoined by this Court, Barr, upon FDA approval of ANDA No. 79-091, will infringe the 2003 '284 patent under 35 U.S.C. § 271 by making, using, offering to sell, selling, or importing Barr's Proposed Products in the United States.

53. Barr had notice of the 2003 '284 patent prior to undertaking its act of infringement. Barr's infringement of the 2003 '284 patent has been, and continues to be, willful and deliberate.

54. Plaintiffs will be substantially and irreparably damaged and harmed if Barr's infringement of the 2003 '284 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 Barr has infringed one or more claims of the '850 patent;
- (B) A Judgment that Barr has infringed one or more claims of the '656 patent;
- (C) A Judgment that Barr has infringed one or more claims of the '530 patent;
- (D) A Judgment that Barr has infringed one or more claims of the 1998 '284 patent;
- (E) A Judgment that Barr has infringed one or more claims of the 2003 '284 patent;
- (F) An Order that the effective date of any FDA approval of ANDA No. 79-091 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;
- (G) An Order that the effective date of any FDA approval of ANDA No. 79-091 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;

(H) An Order that the effective date of any FDA approval of ANDA No. 79-091 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;

(I) An Order that the effective date of any FDA approval of ANDA No. 79-091 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;

(J) An Order that the effective date of any FDA approval of ANDA No. 79-091 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;

(K) Preliminary and permanent injunctions enjoining Barr 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 Barr's Proposed Products until after the expiration of the '850 patent;

(L) Preliminary and permanent injunctions enjoining Barr 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 Barr's Proposed Products until after the expiration of the '656 patent;

(M) Preliminary and permanent injunctions enjoining Barr 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 Barr's Proposed Products until after the expiration of the '530 patent;

(N) Preliminary and permanent injunctions enjoining Barr 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 Barr's Proposed Products until after

the expiration of the 1998 '284 patent;

(O) Preliminary and permanent injunctions enjoining Barr 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 Barr's Proposed Products until after the expiration of the 2003 '284 patent;

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

(Q) A declaration that the commercial manufacture, use, offer to sell, sale, or importation into the United States of Barr's Proposed Products will directly infringe or induce and/or contribute to infringement of the '656 patent;

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

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

(T) A declaration that the commercial manufacture, use, offer to sell, sale, or importation into the United States of Barr's Proposed Products will directly infringe or induce and/or contribute to infringement of the 2003 '284 patent;

(U) If Barr engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Barr's Proposed 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;

(V) If Barr engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Barr's Proposed 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;

(W) If Barr engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Barr's Proposed 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;

(X) If Barr engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Barr's Proposed 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;

(Y) If Barr engages in the commercial manufacture, use, offer to sell, sale, or importation into the United States of Barr's Proposed 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;

(Z) A Judgment that Defendants' acts of infringement with respect to the methods or compositions claimed in the Patents-in-Suit are willful and deliberate.

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

(BB) Costs and expenses in this action; and

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

Dated: November 16, 2007

Respectfully submitted,

By: s/ William J. O'Shaughnessy

William J. O'Shaughnessy
MCCARTER & ENGLISH
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 639-2094

OF COUNSEL:

Henry J. Renk
Nicholas N. Kallas
FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112
(212) 218-2100

*Attorneys for Plaintiffs
Novartis Pharmaceuticals Corporation
and Novartis Pharma AG*

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza
Newark, New Jersey 07102-5490
(973) 286-6700
clizza@saul.com

OF COUNSEL:

Anthony M. Insogna
Lester J. Savit
JONES DAY
12265 El Camino Real, Suite 200
San Diego, CA 92130-4096
(858) 314-1200
ljsavit@jonesday.com

Jason G. Winchester
JONES DAY
77 West Wacker
Chicago, IL 60601-1692
(312) 782-3939
jgwinchester@jonesday.com

*Attorneys for Plaintiff
Celgene Corporation*