

Nature of the Action

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* The act of infringement is Teva's filing of an Abbreviated New Drug Application ("ANDA"), and amendments thereto, with the United States Food and Drug Administration ("FDA") in which Teva seeks approval to engage in the commercial manufacture, use, or sale of 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 (including the *Ex Parte* Reexamination Certificate that issued on March 27, 2007) ("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. 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. 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. 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. 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.

Jurisdiction and Venue

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

7. This Court has personal jurisdiction over Teva by virtue of, *inter alia*, Teva's continuous and systematic contacts with New Jersey, its sale of prescription drugs in New Jersey, its registration of prescription drugs in the *New Jersey Generic Formulary* of the New Jersey Department of Health and Senior Services, 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, its regular and established places of business at 2 University Plaza Drive, Hackensack, New Jersey, at 208 Passaic Avenue, Fairfield, New Jersey, and at 10 Gloria Lane, Fairfield, New Jersey, and its performance of tortious acts that will result in foreseeable harm in New Jersey. Also, Teva has consented to jurisdiction in multiple actions pending in this district. *See, e.g., Celgene Corporation, et al. v. Teva Pharmaceuticals USA, Inc.*, Civil Action Nos. 04-4030 and 06-6154 (FLW)(JJH).

8. 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

9. 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.

10. 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 of the claims of the '656 patent and added new claims, issued on March 27, 2007, by the PTO. A copy of the '656 patent (which includes the *Ex Parte* Reexamination Certificate) is attached hereto as Exhibit B. The '656 patent claims are directed to pharmaceutical unit dosages of *d-threo* methylphenidate.

11. 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.

12. 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 a single dosage form that provides two doses of a methylphenidate drug separated in time, for example, a pulsatile release product.

13. 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 a dosage form and claims directed to a method of treating disease with a single dosage form that provides two doses of a methylphenidate drug separated in time, for example, treatment with a pulsatile release product.

14. Celgene is the owner by assignment of all right, title and interest in and to 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.

15. Novartis Pharmaceuticals Corporation holds an approved New Drug Application for 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 under the trade name FOCALIN XR®. These commercial products or their use are covered by one or more claims of the Patents-in-Suit.

16. Each of the Patents-in-Suit is listed in the FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), as being applicable to the patented FOCALIN XR® products.

Acts Giving Rise To This Action

17. Celgene and Novartis (collectively referred to herein as “Plaintiffs”) received a letter from Teva dated August 3, 2007 (“Notification Letter”), notifying them that Teva had filed ANDA No. 78-908 (“ANDA” or “Teva’s ANDA”) with the FDA seeking approval to market 5 mg, 10 mg, 15 mg, and 20 mg, extended release dexmethylphenidate hydrochloride capsules (collectively referred to herein as the “Proposed Products”).

18. Teva’s Notification Letter states that Teva’s ANDA includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) and alleges that, in Teva’s opinion, all claims of the ‘850 patent, the ‘530 patent, the 1998 ‘284 patent, and the 2003 ‘284 patent are invalid, unenforceable, and/or will not be infringed by the Proposed Products.

19. Teva submitted its ANDA to the FDA seeking approval to engage in the commercial manufacture, use and sale of its Proposed Products prior to the expiration of the Patents-in-Suit.

20. Upon information and belief, Teva intends to engage, and will engage, in the commercial manufacture, use or sale of Teva’s Proposed Products promptly upon receiving FDA approval to do so.

21. Upon information and belief, Teva's ANDA contains information showing that Teva'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.

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

22. Plaintiffs repeat and reallege the allegations of paragraphs 1-21 as though fully set forth herein.

23. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of Teva's Proposed 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).

24. Unless enjoined by this Court, Teva, upon FDA approval of its ANDA, will infringe the '850 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Teva's Proposed Products in the United States.

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

26. 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 the ANDA Infringes the '656 Patent.

27. Plaintiffs repeat and reallege the allegations of paragraphs 1-21 as though fully set forth herein.

28. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of Teva's Proposed 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).

29. Unless enjoined by this Court, Teva, upon FDA approval of its ANDA, will infringe the '656 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Teva's Proposed Products in the United States.

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

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 the ANDA Infringes the '530 Patent.

32. Plaintiffs repeat and reallege the allegations of paragraphs 1-21 as though fully set forth herein.

33. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of Teva's Proposed 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, Teva, upon FDA approval of its ANDA, will infringe the '530 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Teva's Proposed Products in the United States.

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

36. 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 the ANDA Infringes the 1998 '284 Patent.

37. Plaintiffs repeat and reallege the allegations of paragraphs 1-21 as though fully set forth herein.

38. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of Teva's Proposed 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).

39. Unless enjoined by this Court, Teva, upon FDA approval of its ANDA, will infringe the 1998 '284 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Teva's Proposed Products in the United States.

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

41. 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 Infringes the 2003 '284 Patent.

42. Plaintiffs repeat and reallege the allegations of paragraphs 1-21 as though fully set forth herein.

43. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of Teva's Proposed 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).

44. Unless enjoined by this Court, Teva, upon FDA approval of its ANDA, will infringe the 2003 '284 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, or selling Teva's Proposed Products in the United States.

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

46. 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.

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) An Order that the effective date of any FDA approval of ANDA No. 78-908 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. 78-908 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. 78-908 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. 78-908 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. 78-908 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 Teva and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing into the United States Teva's Proposed Products until after

the expiration of the '850 patent;

(L) Preliminary and permanent injunctions enjoining Teva and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing into the United States Teva's Proposed Products until after the expiration of the '656 patent;

(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 Proposed Products until after the expiration of the '530 patent;

(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 Proposed Products until after the expiration of the 1998 '284 patent;

(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 Proposed Products until after the expiration of the 2003 '284 patent;

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

(U) If Teva engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Teva'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 Teva engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Teva'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 Teva engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Teva'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 Teva engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Teva'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 Teva engages in the commercial manufacture, use, importation into the United States, offering to sell, or sale of Teva'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 declaration that this is an exceptional case, entitling Plaintiffs to recover their reasonable attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(AA) Costs and expenses in this action; and

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

Dated: September 14, 2007

Respectfully submitted,

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

By: 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:

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

*Attorneys for Plaintiff
Celgene Corporation*

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*

**LOCAL CIVIL RULE 11.2 CERTIFICATION AND STATEMENT OF RELATED
CASES PURSUANT TO LOCAL CIVIL RULE 40.1(C)**

I hereby certify that the matters captioned, *Celgene Corporation, et al. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 04-4030 (FLW)(JJH) and *Celgene Corporation, et al. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 06-6154 (FLW)(JJH), which have been consolidated before the Honorable Freda L. Wolfson, are related patent infringement cases because the consolidated matter involves all of the same parties, two of the same patents, and accused products containing the same active ingredient, dexamethylphenidate, as the matter in controversy.

I also certify that the matter captioned, *Celgene Corporation, et al. v. Abrika Pharmaceuticals, Inc., et al.*, Civil Action No. 06-5818 (SDW)(MCA), is related because it involves two of the same patents as the matter in controversy.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 14, 2007

Respectfully submitted,

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

By: 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:

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

*Attorneys for Plaintiff Celgene
Corporation*

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*