

Charles M. Lizza
William C. Baton
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700
clizza@saul.com

*Attorneys for Plaintiff
Celgene Corporation*

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

CELGENE CORPORATION,

Plaintiff,

v.

**BRECKENRIDGE PHARMACEUTICAL,
INC. and NATCO PHARMA LIMITED,**

Defendants.

Civil Action No. _____

**COMPLAINT FOR
PATENT INFRINGEMENT**

(Filed Electronically)

Plaintiff Celgene Corporation (“Celgene”), by its undersigned attorneys, for its Complaint against defendants Breckenridge Pharmaceutical, Inc. and Natco Pharma Limited (together, “Breckenridge” or “Defendants”), alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Breckenridge’s filing of Abbreviated New Drug Application (“ANDA”) No. 210111 with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market generic versions of Celgene’s POMALYST[®] drug products prior to the expiration of United States Patent No. 9,993,467 (the “’467 patent” or “the patent-in-suit”) owned by Celgene.

The Parties

2. Plaintiff Celgene is a biopharmaceutical company committed to improving the lives of patients worldwide. Celgene focuses on, and invests heavily in, the discovery and development of products for the treatment of severe and life-threatening conditions. Celgene is a world leader in the treatment of many such diseases, including cancer. Celgene 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. On information and belief, Defendant Breckenridge Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Florida, having a place of business at 6111 Broken Sound Parkway, NW, Suite 170, Boca Raton, FL 33487.

4. On information and belief, Defendant Natco Pharma Limited is a corporation organized and existing under the laws of India and has a principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad, Andhra Pradesh, IN – 500 034, India.

5. On information and belief, Natco Pharma Limited is a part owner of ANDA No. 210111 and Breckenridge Pharmaceutical, Inc.’s development partner in connection with the products described therein.

The Patent-in-Suit

6. On June 12, 2018, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’467 patent, entitled, “Formulations of 4-amino-2-(2,6-dioxopiperidine-3-yl)isoindoline-1,3-dione,” to Celgene as assignee of the inventors Anthony J. Tutino and Michael T. Kelly. A copy of the ’467 patent is attached hereto as Exhibit A.

The POMALYST[®] Drug Product

7. Celgene holds an approved New Drug Application (“NDA”) under Section 505(a) of the Federal Food Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 355(a), for

pomalidomide capsules (NDA No. 204026), which it sells under the trade name POMALYST[®]. POMALYST[®] is an FDA-approved medication used for the treatment of multiple myeloma.

8. The claims of the patent-in-suit cover, *inter alia*, pharmaceutical compositions containing pomalidomide.

9. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patent-in-suit is listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to POMALYST[®].

Jurisdiction and Venue

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

12. This Court has personal jurisdiction over Breckenridge Pharmaceutical, Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Breckenridge Pharmaceutical, Inc. is registered with the State of New Jersey’s Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0100973602. Breckenridge Pharmaceutical, Inc. is also registered with the State of New Jersey as a drug wholesaler under Registration No. 5002974. On information and belief, Breckenridge Pharmaceutical, Inc. purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Breckenridge Pharmaceutical, Inc.

13. This Court has personal jurisdiction over Natco Pharma Limited by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Natco Pharma Limited is registered with the State of New Jersey’s Division of

Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0100983392. On information and belief, Natco Pharma Limited has purposefully conducted and continues to conduct business in this Judicial District.

14. On information and belief, Breckenridge Pharmaceutical, Inc. is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug product described in ANDA No. 210111. On information and belief, Breckenridge Pharmaceutical, Inc. also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

15. On information and belief, Natco Pharma Limited is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug product described in ANDA No. 210111. On information and belief, Natco Pharma Limited also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

16. This Court has personal jurisdiction over Breckenridge because, *inter alia*, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and has sent notice of that infringement to Celgene in the State of New Jersey. On information and belief, Breckenridge intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Celgene in New Jersey and in this Judicial District.

17. On information and belief, Breckenridge Pharmaceutical, Inc. has previously been sued in this Judicial District and has not challenged personal jurisdiction. *See, e.g., Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 17-3387 (ES)(MAH); *Otsuka Pharm. Co., Ltd. v. Standard Chem. & Pharm. Co., Ltd., et al.*, Civil Action No. 15-6353 (JBS)(KMW); *Sanofi-Aventis U.S. LLC, et al. v. Breckenridge Pharmaceutical, Inc.*, Civil Action No. 15-1836 (MAS)(LHG).

18. Breckenridge Pharmaceutical, Inc. has further availed itself of the jurisdiction of this Court by previously initiating litigation in this Judicial District. *See, e.g., Breckenridge Pharmaceutical, Inc. v. Sonar Products, Inc.*, Civil Action No. 10-3921 (WHW)(MCA).

19. On information and belief, Breckenridge Pharmaceutical, Inc. has previously been sued in this Judicial District and has not challenged venue. *See, e.g., Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 17-3387 (ES)(MAH).

20. Natco Pharma Limited has previously been sued in this Judicial District and has not challenged personal jurisdiction. *See, e.g., Shire Development LLC, et al. v. Natco Pharma Limited*, Civil Action No. 14-7053 (SRC)(CLW); *Celgene Corp. v. Natco Pharma Limited, et al.*, Civil Action No. 14-3126 (SDW)(LDW); *Celgene Corp. v. Natco Pharma Limited, et al.*, Civil Action No. 10-5197 (SDW)(LDW).

21. Natco Pharma Limited has also filed counterclaims in this Judicial District. *See, e.g., Shire Development LLC, et al. v. Natco Pharma Limited*, Civil Action No. 14-7053 (SRC)(CLW); *Celgene Corp. v. Natco Pharma Limited, et al.*, Civil Action No. 14-3126 (SDW)(LDW); *Celgene Corp. v. Natco Pharma Limited, et al.*, Civil Action No. 10-5197 (SDW)(LDW).

Acts Giving Rise To This Suit

22. Pursuant to Section 505 of the FFDCA, Breckenridge filed ANDA No. 210111 seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of pomalidomide capsules 1 mg, 2 mg, 3 mg, and 4 mg (“Breckenridge’s Proposed Products”), before the patent-in-suit expires.

23. On information and belief, following FDA approval of ANDA No. 210111, Breckenridge will make, use, offer to sell, or sell Breckenridge’s Proposed Products throughout the United States, or import such generic products into the United States.

24. On information and belief, in connection with the filing of its ANDA as described above, Breckenridge provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Breckenridge’s Paragraph IV Certification”), alleging that the claims of the patent-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in ANDA No. 210111.

25. No earlier than August 22, 2018, Breckenridge sent written notice of its Paragraph IV Certification to Celgene (“Breckenridge’s Notice Letter”). Breckenridge’s Notice Letter alleged that the claims of the patent-in-suit are invalid and/or will not be infringed by the activities described in ANDA No. 210111. Breckenridge’s Notice Letter also informed Celgene that Breckenridge seeks approval to market Breckenridge’s Proposed Products before the patent-in-suit expires. Breckenridge specifically directed Breckenridge’s Notice Letter to Celgene’s headquarters in Summit, New Jersey, in this Judicial District.

Count I: Infringement of the ’467 Patent

26. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

27. Breckenridge's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Breckenridge's Proposed Products, prior to the expiration of the '467 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

28. There is a justiciable controversy between Celgene and Breckenridge as to the infringement of the '467 patent.

29. Unless enjoined by this Court, upon FDA approval of ANDA No. 210111, Breckenridge will infringe one or more claims of the '467 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Breckenridge's Proposed Products in the United States.

30. Unless enjoined by this Court, upon FDA approval of ANDA No. 210111, Breckenridge will induce infringement of one or more claims of the '467 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Breckenridge's Proposed Products in the United States. On information and belief, upon FDA approval of ANDA No. 210111, Breckenridge will intentionally encourage acts of direct infringement with knowledge of the '467 patent and knowledge that its acts are encouraging infringement.

31. Unless enjoined by this Court, upon FDA approval of ANDA No. 210111, Breckenridge will contributorily infringe one or more claims of the '467 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Breckenridge's Proposed Products in the United States. On information and belief, Breckenridge has had and continues to have knowledge that Breckenridge's Proposed Products are especially adapted for a use that infringes one or more claims of the '467 patent and that there is no substantial non-infringing use for Breckenridge's Proposed Products.

32. Celgene will be substantially and irreparably damaged and harmed if Breckenridge's infringement of the '467 patent is not enjoined.

33. Celgene does not have an adequate remedy at law.

34. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Celgene respectfully requests the following relief:

(A) A Judgment that Breckenridge has infringed the patent-in-suit by submitting ANDA No. 210111;

(B) A Judgment that Breckenridge has infringed, and that Breckenridge's making, using, offering to sell, selling, or importing Breckenridge's Proposed Products will infringe one or more claims of the patent-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 210111 be a date which is not earlier than the later of the expiration of the patent-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Breckenridge 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 Breckenridge's Proposed Products until after the expiration of the patent-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Breckenridge, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any pharmaceutical compositions containing pomalidomide, as claimed in the patent-in-suit, or from actively inducing or contributing to the

infringement of any claim of the patent-in-suit, until after the expiration of the patent-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Breckenridge's Proposed Products will directly infringe, induce and/or contribute to infringement of the patent-in-suit;

(G) To the extent that Breckenridge has committed any acts with respect to the pharmaceutical compositions containing pomalidomide, claimed in the patent-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Celgene damages for such acts;

(H) If Breckenridge engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Breckenridge's Proposed Products prior to the expiration of the patent-in-suit, a Judgment awarding damages to Celgene resulting from such infringement, together with interest;

(I) A Judgment declaring that the patent-in-suit remains valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Celgene its attorneys' fees incurred in this action;

(K) A Judgment awarding Celgene its costs and expenses incurred in this action; and

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

Dated: October 5, 2018

By: s/ Charles M. Lizza

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Andrew S. Chalson
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000

Anthony M. Insogna
Cary Miller, Ph.D.
JONES DAY
4655 Executive Drive
San Diego, CA 92121
(858) 314-1200

Matthew J. Hertko
JONES DAY
77 W. Wacker Drive, Suite 3500
Chicago, IL 60601
(312) 782-3939

Charles M. Lizza
William C. Baton
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

*Attorneys for Plaintiff
Celgene Corporation*

CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter captioned *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 17-3387 (ES)(MAH) (D.N.J.) is related to the matter in controversy because the matter in controversy involves the same plaintiff and one of the same defendants, and because defendants are seeking FDA approval to market generic versions of the same pharmaceutical products.

I further certify that the matters captioned *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 18-14111 (ES)(MAH) (D.N.J.) and *Celgene Corporation v. Teva Pharmaceuticals USA, Inc., et al.*, C.A. No. 18-14366 (ES)(MAH) (D.N.J.) are related to the matter in controversy because the matter in controversy involves the same plaintiff, the same patent-in-suit, and because defendants are seeking FDA approval to market generic versions of the same pharmaceutical products.

I further certify that the matters captioned *Celgene Corporation v. Par Pharm., Inc., et al.*, Civil Action No. 17-3159 (ES)(MAH) (D.N.J.) and *Celgene Corporation v. Synthon Pharm. Inc., et al.*, Civil Action No. 18-10775 (ES)(MAH) (D.N.J.) are related to the matter in controversy because the matter in controversy involves the same plaintiff and because defendants are seeking FDA approval to market generic versions of the same pharmaceutical products.

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: October 5, 2018

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Andrew S. Chalson
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000

Anthony M. Insogna
Cary Miller, Ph.D.
JONES DAY
4655 Executive Drive
San Diego, CA 92121
(858) 314-1200

Matthew J. Hertko
JONES DAY
77 W. Wacker Drive, Suite 3500
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