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

*Attorneys for Plaintiffs*
*Abraxis BioScience, LLC and*
*Celgene Corporation*

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

| | |
|---|---|
| **ABRAXIS BIOSCIENCE, LLC and CELGENE CORPORATION,**<br><br>**Plaintiffs,**<br><br>**v.**<br><br>**CIPLA LTD.,**<br><br>**Defendant.** | **Civil Action No. _____**<br><br>**COMPLAINT FOR PATENT INFRINGEMENT**<br><br>**(Filed Electronically)** |

Plaintiffs Abraxis BioScience, LLC ("Abraxis") and Celgene Corporation ("Celgene Corp.") (collectively, "Celgene"), by their undersigned attorneys, for their Complaint against defendant Cipla Ltd. ("Cipla"), allege 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 Cipla's filing of Abbreviated New Drug Application ("ANDA") No. 209657 ("Cipla's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Celgene's ABRAXANE® drug product prior to the expiration of United States Patent Nos. 7,820,788 (the "'788 patent"),

7,923,536 (the "'536 patent"), 8,138,229 (the "'229 patent"), and 8,853,260 (the "'260 patent"), all owned by Abraxis (collectively, the "patents-in-suit").

**The Parties**

2. Plaintiff Celgene Corp. is a biopharmaceutical company committed to improving the lives of patients worldwide. Celgene Corp. focuses on the discovery and development of products for the treatment of cancer and other severe conditions. Celgene Corp. is 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 Abraxis is a wholly owned subsidiary of Celgene Corp. Abraxis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 11755 Wilshire Boulevard, 20th Floor, Los Angeles, California 90025.

4. On information and belief, Defendant Cipla Ltd. is a corporation organized under the laws of India, maintaining its headquarters at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai – 400 013, India.

**Jurisdiction and Venue**

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

6. This Court has personal jurisdiction over Cipla because of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Cipla is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. On information and belief, Cipla directly or indirectly manufactures, markets, and sells generic drug products throughout the United States and in this Judicial District. Upon information and belief, Cipla is registered as a wholesaler in the State of New Jersey (No. 5004658) under the trade name "Cipla USA, Inc. – North America." *See* NJ

Drug Registration Verification at http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx, last viewed December 7, 2016. Upon information and belief, Cipla USA, Inc. is the U.S. subsidiary of Cipla Limited, through which Cipla does business in the United States. On information and belief, Cipla has purposefully conducted and continues to conduct business in this Judicial District, including the purposeful sale and distribution of generic drug products.

7. This Court also has specific jurisdiction over Cipla in connection with this matter. Cipla has already taken the significant step of filing Cipla's ANDA seeking approval to market its infringing generic drug prior to the expiration of the patents-in-suit, and as described below, provided notice of its ANDA filing to Celgene in New Jersey. Cipla's ANDA seeks approval to sell its generic drug throughout the United States, including in the State of New Jersey. On information and belief, Cipla plans to direct sales of the infringing generic drug product described in Cipla's ANDA into this Judicial District, where it would cause harm to Celgene. Therefore, this cause of action arises out of Cipla's contacts with the State of New Jersey.

8. On information and belief, Cipla is a large, global generic manufacturer that has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in this jurisdiction, including in at least the matters of: *Janssen Prods., L.P. v. Cipla Ltd.,* No. 15-2549; *Merck, Sharp & Dohme Corp., v. Cipla USA, Inc.*, No. 13-4017; *Prometheus Labs., Inc. v. Roxane Labs., Inc.*, No. 11-1241; *Janssen Prods, L.P. v. Lupin Ltd.*, No. 10-5954; *AstraZeneca AB v. Ivax Corp.*, No. 08-4993; and *AstraZeneca AB v. Ranbaxy Pharm., Inc.*, No. 05-5553.

9. The State of New Jersey has an interest in providing a forum to resolve disputes, like this one, that involve the unlawful marketing of infringing generic drug products in the State

of New Jersey and harm to companies, like Celgene, that have a principal places of business in, and are doing business in, the State of New Jersey.

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

**The Patents-in-suit**

11. On October 26, 2010, the United States Patent and Trademark Office ("PTO") duly and lawfully issued the '788 patent, titled "Compositions and Methods of Delivery of Pharmacological Agents." The '788 patent is assigned to Abraxis. A copy of the '788 patent is attached hereto as Exhibit A.

12. On April, 12, 2011, the PTO duly and lawfully issued the '536 patent, titled "Compositions and Methods of Delivery of Pharmacological Agents." The '536 patent is assigned to Abraxis. A copy of the '536 patent is attached hereto as Exhibit B.

13. On March 20, 2012, the PTO duly and lawfully issued the '229 patent, titled "Compositions and Methods of Delivery of Pharmacological Agents." The '229 patent is assigned to Abraxis. A copy of the '229 patent is attached hereto as Exhibit C.

14. On October 7, 2014, the PTO duly and lawfully issued the '260 patent, titled "Formulations of Pharmacological Agents, Methods for the Preparation Thereof and Methods for the Use Thereof." The '260 patent is assigned to Abraxis. A copy of the '260 patent is attached hereto as Exhibit D.

**The ABRAXANE® Drug Product**

15. Celgene Corp. 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 paclitaxel protein-bound particles for injectable suspension (NDA No. 21-660), which it sells under the trade name ABRAXANE®. ABRAXANE® is an FDA-approved prescription medicine used for the treatment of certain hard-to-treat forms of cancer, including (1) metastatic breast cancer

(after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy); (2) locally advanced or metastatic non-small cell lung cancer, as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy; and (3) metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine. The claims of the patents-in-suit cover, *inter alia*, pharmaceutical compositions and methods of use and administration of paclitaxel protein-bound particles for injection, including ABRAXANE®. Abraxis owns the patents-in-suit.

16. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to ABRAXANE®.

17. The labeling for ABRAXANE® instructs and encourages physicians, other healthcare workers, and patients to administer ABRAXANE® according to one or more of the methods claimed in the patents-in-suit.

**Acts Giving Rise to This Suit**

18. Pursuant to Section 505 of the FFDCA, Cipla filed Cipla's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of paclitaxel protein-bound particles for injectable suspension, 100 mg/ml ("Cipla's Proposed Product"), before the patents-in-suit expire.

19. On information and belief, in connection with the filing of Cipla's ANDA as described in the preceding paragraph, Cipla 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) ("Cipla's 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 Cipla's ANDA.

DOCKET ALARM

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

**LAW FIRMS**
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

**FINANCIAL INSTITUTIONS**
Litigation and bankruptcy checks for companies and debtors.

**E-DISCOVERY AND LEGAL VENDORS**
Sync your system to PACER to automate legal marketing.