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*Attorneys for Plaintiffs Genentech, Inc.,
Biogen, Inc., and City of Hope*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

GENENTECH, INC., a Delaware corporation,
BIOGEN, INC., a Delaware corporation, and
CITY OF HOPE, a California not-for-profit
organization,

Plaintiffs,

v.

SANDOZ, INC., a Colorado corporation,
SANDOZ INTERNATIONAL GMBH, a
German corporation, and SANDOZ GMBH,
an Austrian corporation,

Defendants.

Case No.

**COMPLAINT FOR: PATENT
INFRINGEMENT; DECLARATORY
RELIEF**

DEMAND FOR JURY TRIAL

Pursuant to Local Civil Rule 10.1, the address of Plaintiff Genentech, Inc. (“Genentech”) is 1 DNA Way, South San Francisco, California, 94080. The address of Plaintiff Biogen, Inc. (“Biogen”) is 225 Binney Street, Cambridge, Massachusetts, 02142. The address of Plaintiff City of Hope is 1500 East Duarte Road, Duarte, California, 91010. The address of Defendant Sandoz, Inc. is One Health Plaza, East Hanover, New Jersey, 07936, with another address at 100 College Road West, Princeton, New Jersey, 08540. The address of Defendant Sandoz International GmbH is Industriestrasse 25, 83607 Holzkirchen, Germany. The address of Defendant Sandoz

GmbH is Biochemiestrasse 10, 6250 Kundl, Austria.

Plaintiffs Genentech, Biogen, and City of Hope (collectively, “Plaintiffs”) by their undersigned attorneys, for their Complaint against Defendants allege as follows:

NATURE OF THIS ACTION

1. This is an action for patent infringement arising under 28 U.S.C. § 1331 and the United States Patent Act, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2), and an action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, seeking a declaratory judgment of patent infringement.

2. The claims for patent infringement brought in this action are necessitated by Defendants’ stated intent to import, market, and sell in New Jersey and throughout the United States a copy of Genentech and Biogen’s groundbreaking medicinal product, Rituxan[®], which aids millions of patients in their fight against debilitating and life-threatening diseases, including blood cancers such as Non-Hodgkin’s Lymphoma and Chronic Lymphocytic Leukemia, as well as Rheumatoid Arthritis and Vasculitis, which are chronic and painful autoimmune diseases. First approved in 1997, Rituxan[®] is proven to improve both the length and quality of life for patients with these and other diseases and has been recognized internationally for its pioneering effect on patients’ lives and medicine in general.

3. Such benefits and success did not come quickly or easily. Genentech and Biogen invested many years of work and many hundreds of millions of dollars into developing and testing Rituxan[®] and ensuring that the product is both safe and effective. Those investments include, *inter alia*, years of laborious and expensive clinical trials that were required before medical professionals could use Rituxan[®] to help their patients—clinical trials on which the U.S. Food and Drug Administration (“FDA”) relied in making Rituxan[®] the first monoclonal antibody approved for therapeutic use in fighting cancer in the United States.

4. In contrast, Defendants have piggybacked on Plaintiffs’ investments and success and seek to profit from a copied version of Rituxan[®]. Claiming that their copycat product is “biosimilar” to Rituxan[®], Defendants have not borne the expense of conducting their own

clinical trials—instead relying on Genentech and Biogen’s costly and time-consuming proprietary clinical trials—and have applied to the FDA for approval to market and sell that product for the very same therapeutic uses as Rituxan[®].

5. Irrespective of whether they are able to secure FDA approval for their copy of Rituxan[®], however, Defendants do not have the right to infringe Plaintiffs’ patents. As stated herein, Defendants’ intended activities would unquestionably infringe many of those patents, *none* of which Plaintiffs have licensed to Defendants and *all* of which are valid and enforceable. Plaintiffs bring this action to stop that infringement.

PARTIES

6. Plaintiff Genentech, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 DNA Way, South San Francisco, California, 94080.

7. Plaintiff Biogen, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 225 Binney Street, Cambridge, Massachusetts, 02142.

8. Plaintiff City of Hope is a California not-for-profit organization, having its principal place of business at 1500 East Duarte Road, Duarte, California, 91010.

9. Genentech and Biogen, two pioneers of the biotechnology industry, have been discovering, developing, manufacturing, and commercializing innovative therapies to address significant unmet medical needs for more than 40 years. Collectively, they manufacture and commercialize products for a variety of medical conditions, including numerous types of cancer, Rheumatoid Arthritis, Multiple Sclerosis, and many other serious conditions. Genentech and Biogen developed and jointly market Rituxan[®], the revolutionary antibody-based medicine at issue in this case.¹

¹ Genentech initially collaborated with IDEC Pharmaceuticals, which subsequently merged with Biogen (forming Biogen-Idex) and later adopted the name Biogen. We use “Biogen” herein for simplicity.

10. Founded in 1913, City of Hope is a leading research hospital that incorporates cutting-edge research into patient care for cancer, diabetes, and other serious diseases.

11. Plaintiffs regularly seek patents on inventions originating from their research and development activities, and each has been issued numerous patents relating to its proprietary technology. Among those patents are several that claim, *inter alia*, the manufacture and use of Rituxan[®].

12. Plaintiffs are informed and believe, and on that basis allege, that Defendant Sandoz, Inc. is a corporation organized and existing under the laws of the State of Colorado, having offices at One Health Plaza, East Hanover, New Jersey, 07936, and its principal place of business at 100 College Road West, Princeton, New Jersey, 08540.

13. Plaintiffs are informed and believe, and on that basis allege, that Defendant Sandoz International GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, having its principal place of business at Industriestrasse 25, 83607 Holzkirchen, Germany.

14. Plaintiffs are informed and believe, and on that basis allege, that Defendant Sandoz GmbH is a corporation organized and existing under the laws of the Republic of Austria, having its principal place of business at Biochemiestrasse 10, 6250 Kundl, Austria.

15. Plaintiffs are informed and believe, and on that basis allege, that Sandoz, Inc., Sandoz International GmbH, and Sandoz GmbH (collectively, “Sandoz”) operate within a division of Novartis, one of the largest pharmaceutical companies in the world, and are almost entirely dedicated to the development of generic and “biosimilar” products.

JURISDICTION AND VENUE

16. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq.* This Court has federal question jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202 because this is a civil action arising under the Patent Act.

17. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b), including because Sandoz, Inc. has committed acts of infringement in and has a regular and

established place of business in New Jersey.

A. Sandoz, Inc.

18. Plaintiffs are informed and believe, and on that basis allege, that this Court has personal jurisdiction over Sandoz, Inc. because Sandoz, Inc. has availed itself of the legal protections of the State of New Jersey by, among other things, maintaining its principal place of business in New Jersey, registering to do business in New Jersey, and conducting operations related to the manufacturing, importing, marketing, and/or selling of pharmaceutical drug products in New Jersey.

19. Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Sandoz, Inc. because Sandoz, Inc. has purposefully directed activities at the State of New Jersey and this litigation relates to or arises out of those activities. In particular, Plaintiffs are informed and believe, and on that basis allege, that Sandoz, Inc. has taken the costly, significant step of filing an Abbreviated Biologic License Application (“aBLA”) with the FDA seeking FDA approval of the proposed biosimilar product Rixathon (also referred to by the development code “GP2013”) for the express purposes of marketing, distributing, and selling Rixathon/GP2013 in New Jersey and throughout the United States.

20. Plaintiffs are informed and believe, and on that basis allege, that if and when the FDA approves that aBLA for Rixathon/GP2013, Sandoz, Inc. intends to import, market, distribute, and sell Rixathon/GP2013 in New Jersey and throughout the United States. Moreover, Plaintiffs are informed and believe, and on that basis allege, that Sandoz, Inc. intends to coordinate the importation, marketing, distribution, and sale of Rixathon/GP2013 from New Jersey, where its United States leadership team is based.

21. Plaintiffs are further informed and believe, and on that basis allege, that Sandoz, Inc. has previously submitted to the jurisdiction of this Court and availed itself of the legal protections of the State of New Jersey by asserting claims and not contesting jurisdiction in the United States District Court for the District of New Jersey. *See, e.g., Sandoz Inc. v. Daiichi*

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