Trials@uspto.gov
571-272-7822

Paper 10
Date: April 30, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC.,
Petitioner,

v.

BIOGEN, INC. AND GENENTECH, INC.,
Patent Owner.

Case IPR2017-02126
Patent 7,682,612 B1

Before ERICA A. FRANKLIN, SHERIDAN K. SNEDDEN, and JACQUELINE T. HARLOW, Administrative *Patent Judges.*

SNEDDEN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Pfizer, Inc. ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1–13, 15–35, and 37–60 (Paper 1; "Pet.") of U.S. Patent No. 7,682,612 B1 (Ex. 1001; "the '612 patent"). Biogen, Inc. and Genentech, Inc. (collectively, "Patent Owner") filed a Patent Owner Preliminary Response. Paper 8.

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). Upon considering the Petition and the Preliminary Response, we determine that Petitioner has not shown a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–13, 15–35, and 37–60. Accordingly, we deny the Petition and decline to institute an *inter partes* review.

A. Related Proceedings

Petitioner indicates that the '612 patent is at issue in *Genentech, Inc. v. Celltrion, Inc.*, Case No. 1:18-cv-00574 (D.N.J.), and *Celltrion, Inc. v. Genentech, Inc.*, Case No. 3:18-cv-00276 (N.D. Cal.). Paper 7. Patent Owner state that the '711 patent is at issue in *Genentech, Inc., Biogen Inc., and City of Hope v. Sandoz, Inc. and Sandoz International GMBH*, Case No. 2:17-cv-13507 (D.N.J.). Paper 6.

The '612 patent was the subject of IPR2017-01227 and IPR2017-01230, filed by a different Petitioner, Celltrion Inc., on March 31, 2017. The Board denied institution of these petitions on October 12, 2017 (IPR2017-01230) and October 23, 2017 (IPR2017-01230).

Concurrently with this proceeding, Petitioner also filed a petition for *inter partes* review of U.S. Patent No. 8,206,711 (IPR2017-02127), which is

related to the '612 patent. Celltrion also filed a petition for *inter partes* review of the '711 patent, IPR2017-01229, on March 31, 2017. The Board denied institution of that petition on October 23, 2017.

B. The '612 Patent (Ex. 1001)

The '612 patent discloses therapeutic regimens involving the administration of anti-CD20 antibodies for the treatment of chronic lymphocytic leukemia (CLL). Ex. 1001, Abst., 2:16–21. "[A] particularly preferred chimeric anti-CD20 antibody is RITUXAN® (rituximab), which is a chimeric gamma 1 anti-human CD20 antibody." *Id.* at 3:18–20.

With regard to dosing, the '612 patent discloses that "[t]ypically effective dosages will range from about 0.001 to about 30 mg/kg body weight, more preferably from about 0.01 to 25 mg/kg body weight, and most preferably from about 0.1 to about 20 mg/kg body weight." *Id.* at 3:50–54. "Such administration may be effected by various protocols, e.g., weekly, bi-weekly, or monthly, dependent on the dosage administered and patient response." *Id.* at 3:55–57. "A particularly preferred dosage regimen will comprise administration of about 375 mg/m^2 weekly for a total of four infusions." *Id.* at 3:64–66.

C. Illustrative Claims

Petitioner challenges claims 1–13, 15–35, and 37–60 of the '612 patent. Independent claims 1, 6, 23, 28, and 58 are illustrative of the challenged claims and are reproduced below:

> 1. A method of treating chronic lymphocytic leukemia in a human patient, comprising administering an anti-CD20 antibody to the patient in an amount effective to treat the chronic lymphocytic leukemia, wherein the method does not include

treatment with a radiolabeled anti-CD20 antibody.

6. A method of treating chronic lymphocytic leukemia in a human patient, comprising administering an anti-CD20 antibody to the patient in an amount effective to treat the chronic lymphocytic leukemia, wherein the anti-CD20 antibody is administered to the patient at a dosage of about 500 to about 1500 mg/m^2, wherein the method does not include treatment with a radiolabeled anti-CD20 antibody.

23. A method of treating chronic lymphocytic leukemia in a human patient, comprising administering an anti-CD20 antibody to the patient in an amount effective to treat the chronic lymphocytic leukemia, wherein the anti-CD20 antibody therapy is combined with chemotherapy, wherein the method does not include treatment with a radiolabeled anti-CD20 antibody.

28. A method of treating chronic lymphocytic leukemia in a human patient, comprising administering an anti-CD20 antibody to the patient in an amount effective to treat the chronic lymphocytic leukemia, wherein the anti-CD20 antibody is administered to the patient at a dosage of about 500 to about 1500 mg/m^2, wherein the anti-CD20 antibody therapy is combined with chemotherapy, and wherein the method does not include treatment with a radiolabeled anti-CD20 antibody.

58. A method of treating chronic lymphocytic leukemia in a human patient, comprising administering an anti-CD20 antibody to the patient in an amount effective to treat the chronic lymphocytic leukemia, wherein the patient is refractory to fludarabine previously administered for the chronic lymphocytic leukemia, and wherein the method does not include treatment with a radiolabeled anti-CD20 antibody.

D. The Asserted Grounds

Petitioner challenges claims 1–13, 15–35, and 37–60 of the '612 patent on the following grounds. Pet. 30–62.

Ground	Reference[s]	Basis	Challenged Claims
1	Maloney 1994,[1] Maloney Sept. 1997[2] and Genentech Press Release[3]	§ 103	1–13, 15–22, 58, 60
2	Maloney 1994, Maloney Sept. 1997, Maloney Oct. 1997[4] and Genentech Press Release	§ 103	23–35, 37–45, 59
3	Maloney 1994, Maloney Sept. 1997, Maloney Oct. 1997, Genentech Press Release and Kipps[5]	§ 103	46–57

[1] Ex. 1003, David G. Maloney et al., *Phase I Clinical Trial Using Escalating Single-Dose Infusion of Chimeric Anti-CD20 Monoclonal Antibody (IDEC-C2B8) in Patients with Recurrent B-Cell Lymphoma*, 84(8) BLOOD 2457-2466 (Oct. 15, 1994) ("Maloney 1994").

[2] Ex. 1004, David G. Maloney et al., "*IDEC-C2B8 (Rituximab) Anti-CD20 Monoclonal Antibody Therapy in Patients with Relapsed Low-Grade Non-Hodgkin's Lymphoma*," BLOOD, 90(6):2188–2195 (1997) ("Maloney Sept. 1997").

[3] Ex. 1005, David G. Maloney et al., "*IDEC-C2B8: Results of a Phase I Multiple-Dose Trial in Patients with Relapsed Non-Hodgkin's Lymphoma*," 15(10) J. CLINICAL ONCOLOGY 3266–3274 (1997) ("Maloney Oct. 1997").

[4] Ex. 1006, Press Release, Genentech, Inc. "*Genentech and IDEC Pharmaceuticals to Collaborate on Anti-CD20 Monoclonal Antibody for B-Cell Lymphomas*," (March 16, 1995) ("Genentech Press Release").

[5] Ex. 1008, Thomas J. Kipps, *Chapter 106: Chronic lymphocytic leukemia and related diseases*, in Williams Hematology Fifth Edition, 1017–1039 (Ernest Beutler et al., eds., 1995) ("Kipps").

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.