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Paper 8
Entered: September 27, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC. and APOTEX CORP.,
Petitioners,

v.

CELGENE CORPORATION,
Patent Owner.

Case IPR2018-00685
Patent 8,741,929 B2

Before TONI R. SCHEINER, GRACE KARAFFA OBERMANN, and TINA E. HULSE, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 U.S.C. § 314(a)

I. INTRODUCTION

Apotex Inc. and Apotex Corp. (collectively, "Petitioner")[1] filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1–4, 8, 9, 15, and 20 of U.S. Patent No. 8,741,929 B2 (Ex. 1001, "the '929 patent"). Celgene Corporation ("Patent Owner") filed a Preliminary Response to the Petition (Paper 6, "Prelim. Resp."). We have statutory authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

For the reasons set forth below, we conclude that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of any challenged claim of the '929 patent. Accordingly, we do not institute an *inter partes* review of claims 1–4, 8, 9, 15, and 20 of the '929 patent.

A. Related Proceedings

The '929 patent has been asserted in *Celgene Corp. v. Apotex Inc.*, C.A. No. 18-cv-00461 (D.N.J. filed Jan. 11, 2018). Pet. 5; Paper 3, 1.

B. The Asserted Grounds of Unpatentability

Petitioner asserts that the challenged claims are unpatentable on the following grounds:

[1] According to Petitioner, "[a]dditional real parties-in-interest are Apotex Pharmaceutical Holdings Inc., and Apotex Holdings Inc." Pet. 5.

References	Basis	Claims Challenged
Drach[2] and Zeldis[3]	§ 103(a)	1–4, 8, 9, 15, and 20
Drach, Zeldis, and Querfeld[4]	§ 103(a)	4 and 20
Celgene Press Release[5]	§ 102(a)	1–4, 8, 9, 15, and 20

Petitioner supports its challenges with the Declaration of Michael J. Thirman, M.D, dated February 23, 2018 (Ex. 1002, "Thirman Declaration").

C. The '929 Patent (Ex. 1001)

The '929 patent, titled "Methods Using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione for Treatment of Mantle Cell Lymphomas," issued June 3, 2014, to inventor Jerome B. Zeldis. Ex. 1001 (54), (75). The title compound is "an immunomodulatory compound . . . also known as lenalidomide, Revlimid® or Revimid®." *Id.* at 1:19–23.

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[2] Johannes Drach at al., *Treatment of Mantle Cell Lymphoma: Targeting the Microenvironment*, 5 EXPERT REV. ANTICANCER THER. 477–485 (2005) (Ex. 1003, "Drach"). We refer to the page numbers of the exhibit, rather than the page numbers of the journal article.

[3] Jerome B. Zeldis, U.S. Patent Application Publication US 2004/0029832 A1, published February 12, 2004 (Ex. 1004, "Zeldis").

[4] Christiane Querfeld et al., *Preliminary Results of a Phase II Study of CC-5013 (Lenalidomide, Revlimid®) in Patients with Cutaneous T-Cell Lymphoma*, 106 BLOOD 3351 (2005) (Ex. 1005, "Querfeld").

[5] Celgene Press Release, titled "Revlimid® (Lenalidomide) Clinical Results in Non-Hodgkins Lymphoma Presented at the 11th Congress of the European Hematology Association" (2006) (Ex. 1006, "Celgene Press Release").

The specification teaches that lymphomas comprise a heterogeneous group of neoplasms arising in the reticuloendothelial and lymphatic systems. Within that group, the term non-Hodgkin's lymphoma (NHL) refers to a subset of neoplasms involving malignant monoclonal proliferation of lymphoid cells in the immune system, including the lymph nodes, bone marrow, spleen, liver, and gastrointestinal tract. *Id.* at 1:64–2:2. The specification further teaches that mantle cell lymphoma (MCL) is a lymphoproliferative disorder characterized by a specific chromosomal translocation which results in overexpression of the protein cyclin D1, which plays a key role in cell cycle regulation and progression of cells from G1 phase to S phase by activation of cyclin-dependent kinases. *Id.* at 2:16–29.

According to the specification, MCL "is a distinct entity among the non-Hodgkin's lymphomas . . . account[ing] for 8% of all non-Hodgkin's lymphomas" (*id.* at 2:4–5), and "is an incurable lymphoma with limited therapeutic options for patients with relapsed or refractory disease" (*id.* at 2:36–38).

The specification describes the results of a Phase II clinical trial designed to evaluate the therapeutic potential and safety of oral lenalidomide monotherapy in patients with relapsed and refractory aggressive non-Hodgkin's lymphoma. *Id.* at 23:12–20.

> Twenty-five patients age 45 to 80 years . . . with relapsed and refractory aggressive NHL and who had received a median of 2.5 prior treatments . . . were administered with lenalidomide in an amount of 25 mg orally once daily for 21 days in the treatment cycle. Sixteen patients with aggressive NHL were

> evaluable for tumor assessment. Of the 16 patients, eight had diffuse large cell lymphoma, three had mantle cell lymphoma, two patients had follicular lymphoma, one had transformed lymphoma, and two had aggressive lymphomas of unknown histology.
>
> There were five (31 percent) patients who experienced objective responses to lenalidomide monotherapy . . . One patient with diffuse large cell lymphoma achieved complete response with progression free survival of more than 180 days. One patient with diffuse large cell lymphoma achieved partial response with progression free survival for 135 days. One patient with diffuse large cell lymphoma achieved partial response with progression free survival for 242 days. One patient with follicular lymphoma achieved partial response with progression free survival for more than 55 days. One patient with mantle cell lymphoma achieved partial response with progression free survival for more than 57 days.

Id. at 23:24–48.

Finally, the specification discloses "methods of treating, preventing or managing non-Hodgkin's lymphomas, including . . . mantle cell lymphoma" (*id.* at 1:23–26), particularly disease that is "relapsed, refractory, or resistant to conventional chemotherapy" (*id.* at 2:47–48).

D. Illustrative Claim

Petitioner challenges claims 1–4, 8, 9, and 20 of the '929 patent, of which claim 1 is independent. Claim 1, reproduced below, is illustrative. Ex. 1001, 29:1–11.

> 1. A method of treating mantle cell lymphoma in a human, which comprises (a) administering to a human having mantle cell lymphoma from about 5 mg to about 25 mg per

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