Trials@uspto.gov
Tel: 571-272-7822

Paper 22
Entered: November 16, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VI LLC,
Petitioner,

v.

CELGENE CORPORATION,
Patent Owner.

Case IPR2015-01169
Patent 5,635,517

Before TONI R. SCHEINER, JACQUELINE WRIGHT BONILLA, and TINA E. HULSE, *Administrative Patent Judges*.

BONILLA, *Administrative Patent Judge*.

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

I. INTRODUCTION

Coalition For Affordable Drugs VI LLC ("Petitioner" or "CFAD") filed a Petition requesting *inter partes* review of claims 1–10 of U.S. Patent No. 5,635,517 (Ex. 1001, "the '517 Patent"). Paper 1 ("Pet."). Celgene Corporation ("Patent Owner") filed a Preliminary Response. Paper 16 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314(a), 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."

Upon consideration of the Petition and the Preliminary Response, and for the reasons explained below, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of any claim challenged in the Petition. Accordingly, we decline to institute an *inter partes* review.

A. Related Proceedings

The parties indicate that the '517 patent is the subject of a district court proceeding, *Celgene Corporation v. Natco Pharma Ltd.*, C.A. No. 2:10-cv-5197 (D.N.J.) (including consolidated related C.A. No. 2:12-cv-4571 (D.N.J.)). Pet. 8; Paper 7. On October 27, 2015, the Board instituted *inter partes* reviews of challenged claims in two unrelated patents owned by Patent Owner, challenged by Petitioner, in Case Nos. IPR2015-01092 (Paper 20), IPR2015-01096 (Paper 21), IPR2015-01102 (Paper 21), and IPR2015-01103 (Paper 22).

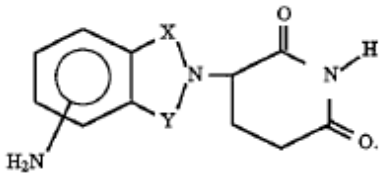
B. The '517 Patent

The '517 patent is directed to methods of reducing levels of tumor necrosis factor α ("TNFα") in a mammal by administering "amino

substituted 2-(2,6-dioxopiperidin-3-yl)-1-oxoisoindolines and 1,3-dioxoisoindolines," i.e., certain thalidomide analogs with an added amino group (-NH_2) in a benzene ring of the chemical structure. Ex. 1001, 1:6–11; *see also* Pet. 1, 15–16 (showing chemical structures of thalidomide and compounds recited in claims 3–10).

The '517 patent discloses that TNFα is a cytokine released by mononuclear phagocytes in response to immunostimulators. Ex. 1001, 1:14–16. Excessive or unregulated TNFα production has been implicated in a number of diseases. *Id*. at 1:21–3:18. "Decreasing TNFα levels and/or increasing cAMP levels" may help treat "many inflammatory, infectious, immunological or malignant diseases." *Id*. at 3:59–4:6.

The '517 patent describes the discovery that certain compounds "decrease the levels of TNFα and elevate the levels of adenosine 3',5'-cyclic monophosphate" ("cAMP"), and that such compounds have the formula:



I

in which one of X and Y is C═O and the other of X and Y is C═O or CH_2

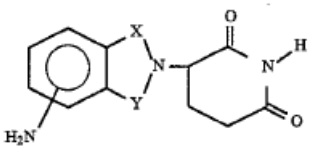
Id. at 4:20–33. Thus, the disclosed compounds have an amino group (-NH_2) group attached to a carbon in the left 6-carbon benzene ring portion and, in some compounds, X is a C=O and Y is a CH_2 in the 5-carbon ring portion.

C. Illustrative Claims

The '517 patent contains ten claims. Independent claims 1 and 10 and dependent claims 2 and 7 are representative, and are reproduced below.

> 1. The method of reducing undesirable levels of TNFα in a mammal which comprises administering thereto an effective

amount of a compound of the formula:



in which in said compound one of X and Y is C=O and the other of X and Y is C=O or CH_2.

2. The method according to claim 1 in which X is C=O and Y is CH_2.

7. The method according to claim 1 in which each of X and Y is C=O.

10. A compound selected from the group consisting of 1-oxo-2-(2,6-dioxopiperidin-3-yl)-5-aminoisoindoline, 1-oxo-2-(2,6-dioxopiperidin-3-yl)-4-aminoisoindoline, 1-oxo-2-(2,6-dioxopiperidin-3-yl)-6-aminoisoindoline, and 1-oxo-2-(2,6-dioxopiperidin-3-yl)-7-aminoisoindoline.

Dependent claims 3–6 depend from claim 2, and claims 8 and 9 depend from claim 7.

D. Proposed Grounds of Unpatentability

Petitioner advances three grounds of unpatentability under 35 U.S.C. § 103 in relation to the challenged claims in the '517 patent (Pet. 11):

References	Statutory Basis	Challenged Claims
Piper (Ex. 1002)[1] in view of Kaplan (Ex. 1003)[2]	§ 103	1, 7–9

[1] Piper et al., *Anti-inflammatory immunosuppressive thalidomide analogs*, 49(4) INT'L J. OF LEPROSY 511–512 (1981) ("Piper") (Ex. 1002)
[2] Kaplan et al., U.S. Patent No. 5,385,901, filed Oct. 2, 1992, issued Jan. 31, 1995 ("Kaplan") (Ex. 1003).

References	Statutory Basis	Challenged Claims
Piper in view of Kaplan, Agrawal (Ex. 1004),[3] and WO '085 (Ex. 1005)[4]	§ 103	2–6, 10
Piper in view of Kaplan, Agrawal, and Keith (Ex. 1006)[5]	§ 103	2–6, 10

In addition, Petitioner supports its challenges in the Petition with the Declaration of Clayton H. Heathcock, Ph.D. (Ex. 1007). Pet. 11.

II. ANALYSIS

A. Claim construction

For *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the patent specification. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015). Claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

---

[3] Agrawal et al., *Structure activity relationship studies of thalidomide analogs as anti-inflammatory and immunosuppressive agents*, 49(4) INT'L J. OF LEPROSY 512 (1981) ("Agrawal") (Ex. 1004).

[4] D'Amato et al., WO 94/20085, published Sept. 15, 1994 ("WO '085") (Ex. 1005).

[5] Keith & Walters, NATIONAL TOXICOLOGY PROGRAM'S CHEMICAL SOLUBILITY COMPENDIUM (Lewis Publishers, Inc. 1992) ("Keith") (Ex. 1006).

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.