

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).

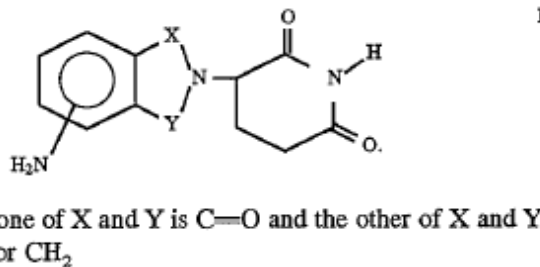
B. *The ’517 Patent*

The ’517 patent is directed to methods of reducing levels of tumor necrosis factor α (“TNF α ”) in a mammal by administering “amino

substituted 2-(2,6-dioxopiperidin-3-yl)-1-oxoisindolines and 1,3-dioxoisindolines,” 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 $\text{TNF}\alpha$ is a cytokine released by mononuclear phagocytes in response to immunostimulators. Ex. 1001, 1:14–16. Excessive or unregulated $\text{TNF}\alpha$ production has been implicated in a number of diseases. *Id.* at 1:21–3:18. “Decreasing $\text{TNF}\alpha$ 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 $\text{TNF}\alpha$ and elevate the levels of adenosine 3',5'-cyclic monophosphate” (“cAMP”), and that such compounds have the formula:



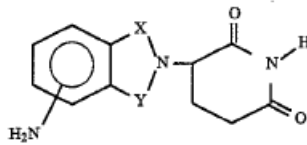
Id. at 4:20–33. Thus, the disclosed compounds have an amino group (-NH_2) group attached to a carbon in the left 6-carbon benzene ring portion and, in some compounds, X is a C=O and Y is a CH_2 in the 5-carbon ring portion.

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 $\text{TNF}\alpha$ 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 CH₂.

2. The method according to claim 1 in which X is C=O and Y is CH₂.

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-aminoisindoline,
1-oxo-2-(2,6-dioxopiperidin-3-yl)-4-aminoisindoline,
1-oxo-2-(2,6-dioxopiperidin-3-yl)-6-aminoisindoline, and
1-oxo-2-(2,6-dioxopiperidin-3-yl)-7-aminoisindoline.

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).

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