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Paper 10
Date: April 30, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC. and APOTEX CORP.,
Petitioner,

v.

CELGENE CORPORATION,
Patent Owner.

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 Petitioner's Request for Rehearing of
Decision Denying Institution of *Inter Partes* Review
37 C.F.R § 42.71(d)

I. INTRODUCTION

Apotex Inc. and Apotex Corp. (collectively, "Petitioner") 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") on three asserted grounds:

	Claims	**35 U.S.C. §**	**Reference(s)/Basis**
I	1–4, 8, 9, 15, 20	103(a)	Drach,[1] Zeldis[2]
II	4, 20	103(a)	Drach, Zeldis, Querfeld[3]
III	1–4, 8, 9, 15, 20	102(a)	Celgene Press Release[4]

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

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[1] 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.

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

[3] 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").

[4] 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").

Celgene Corporation ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.").

In the Decision on Institution (Paper 8, "Decision" or "Inst. Dec."), we determined that the Petition failed to establish a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of at least one claim challenged in the Petition, and declined to institute an *inter* partes review on any of the three grounds asserted. Specifically, with respect to grounds I and II, we declined to institute pursuant to our discretion under 35 U.S.C. § 325(d). Inst. Dec. 22–26. With respect to ground III, we determined that Petitioner had not met its burden of establishing that the Celgene Press Release was available as a printed publication. *Id.* at 27–31.

Petitioner's Request for Rehearing (Paper 9, "Req. Reh'g") seeks rehearing of our decision to deny institution of grounds I and II only.

For the reasons set forth below, we *deny* the relief requested.

II. STANDARD OF REVIEW

A party requesting rehearing bears the burden of showing that a decision should be modified. 37 C.F.R. § 42.71(d). The party must identify all matters it believes the Board misapprehended or overlooked, and the place where each matter was addressed previously in a motion, an opposition, or a reply. *Id.* When rehearing a decision on petition, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion occurs when a "decision was based on an erroneous conclusion of law or clearly erroneous factual findings, or . . . a clear error of judgment."

PPG Indus. Inc. v. Celanese Polymer Specialties Co., 840 F.2d 1565, 1567 (Fed. Cir. 1988) (citations omitted).

III. DISCUSSION

35 U.S.C. § 325(d)

In the Decision, we evaluated Petitioner's arguments and evidence with respect to grounds I and II, together with the prosecution history of the '929 patent, in light of the non-exclusive factors outlined in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph). Inst. Dec. 22–26. The *Becton, Dickinson* factors are as follows:

> (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguished the prior art; (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its consideration of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the asserted prior art or arguments.

Factors (a), (b), and (d) relate to whether the art and arguments presented in the petition are the same or substantially the same as those previously presented to the Office. *Advanced Bionics, LLC v. Med-El Electromedizinishe Geräte GmbH*, IPR2019-01469, Paper 6 at 10 (Feb. 13,

2020) (precedential). Factors (c), (e), and (f) "relate to whether the petitioner has demonstrated a material error by the Office" in its prior consideration of that art or arguments. *Id.* If the same or substantially the same art or arguments were previously presented to the Office, we then consider whether petitioner has demonstrated the Office erred. *Id.*

In evaluating the Petition and accompanying evidence in light of the *Becton, Dickinson* factors, we determined that grounds I and II were "based on substantially the same prior art and arguments previously presented to the office," and that Petitioner had "neither sufficiently pointed out how the Examiner erred, nor provided additional evidence or facts that warrant reconsideration of the Examiner's decision." Inst. Dec. 26. Accordingly, we exercised our discretion under 35 U.S.C. §325(d) and denied institution of grounds I and II on that basis.

According to Petitioner, our analysis erred in several crucial respects. We will address each of these purported errors in turn, but first, to provide context, we reproduce illustrative claim 1, and briefly discuss the basis of our decision to deny institution. Claim 1 is as follows:

> 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 day of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione[5] or a pharmaceutically acceptable salt or hydrate thereof for 21 days followed by seven days rest in a 28 day cycle; and (b)

[5] The compound recited in claim 1 is "also known as lenalidomide, Revlimid® or Revimid®." Ex. 1001, 1:19–23.

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