

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS IV LLC,
Petitioner,

v.

PHARMACYCLICS, INC.,
Patent Owner.

Case IPR2015-01076
Patent 8,754,090 B2

Before GRACE KARAFFA OBERMANN, SUSAN L. C. MITCHELL, and
TINA E. HULSE, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

DECISION

Denying Institution of *Inter Partes* Review;
Dismissing Pending Motions as Moot
37 C.F.R. § 42.108; 37 C.F.R. § 42.12; 37 C.F.R. § 42.104(c)

I. INTRODUCTION

Coalition for Affordable Drugs IV LLC (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1 and 2 of U.S. Patent No. 8,754,090 B2 (Ex. 1001, “the ’090 patent”). Paper 1 (“Pet.”). Pharmacyclics, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 19 (“Prelim. Resp.”).

We have jurisdiction 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.” 35 U.S.C. § 314(a). Upon considering the Petition and Preliminary Response, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of claims 1 and 2. Accordingly, we decline to institute an *inter partes* review of those claims.

A. *Related Proceedings*

Petitioner states that it is not aware of any matters related to this proceeding. Pet. 4.

B. *The ’090 Patent*

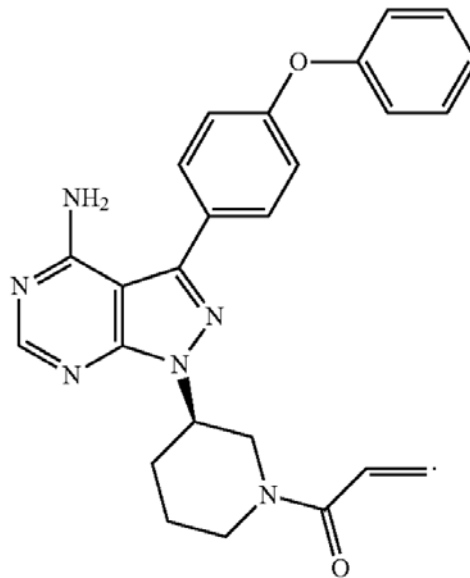
Bruton’s tyrosine kinase (“Btk”) is a signaling enzyme expressed in all hematopoietic cell types except T lymphocytes and natural killer cells. Ex. 1001, 1:28–31. Btk plays an essential role in the B-cell signaling pathway, linking B-cell receptor stimulation to downstream intracellular responses. *Id.* at 1:31–33. Btk is also a key regulator of B-cell development, activation, signaling, and survival. *Id.* at 1:34–35. According to the Specification, “[t]here is currently a need for methods of treating (including, diagnosing) hematological malignancies, including relapsed and

refractory B cell malignancies.” *Id.* at 10:59–61. As such, the ’090 patent relates to methods of treating a hematological malignancy by administering a Btk inhibitor to a patient. *Id.* at 1:53–55.

C. Challenged Claims

Petitioner challenges claims 1 and 2 of the ’090 patent. The claims are reproduced below:

1. A method for treating mantle cell lymphoma in an individual who has already received at least one prior therapy for mantle cell lymphoma comprising administering to the individual once per day between about 420 mg to about 840 mg of an oral dose of an inhibitor of Bruton’s tyrosine kinase (Btk) having the structure:



2. The method of claim 1, wherein the once per day oral dose is about 560 mg.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1 and 2 of the '090 patent on the following grounds:

Reference(s)	Basis	Claims challenged
NCT00849654 ¹	§ 102(b)	1 and 2
NCT00849654, the '582 publication, ² and the 2009 Press Release ³	§ 103	1 and 2

II. ANALYSIS

A. Whether NCT00849654 Is a Prior Art Printed Publication

Petitioner argues claims 1 and 2 of the '090 patent are unpatentable as anticipated or obvious, relying on NCT00849654 for both asserted grounds. Pet. 7–8. According to Petitioner, NCT00849654 is a published clinical trial document that provides the details of Patent Owner's Phase I clinical study with Btk inhibitor "PCI-32675." *Id.* at 19. More specifically, we note that NCT00849654 appears to be a copy of a webpage from the website www.clinicaltrials.gov.

¹ Copy of webpage from www.clinicaltrials.gov regarding the "Study of the Safety and Tolerability of PCI-32765 in Patients With Recurrent B Cell Lymphoma," ClinicalTrials Identifier NCT00849654 (Ex. 1002).

² Honigberg, et al., US 2008/0139582 A1, published June 12, 2008 (Ex. 1003).

³ Petitioner asserts in its Petition that claims 1 and 2 are unpatentable as obvious over "Press Release, Pharmacylics, Pharmacylics Initiates Phase I Clinical Trial of Novel Oral Btk Inhibitor for Refractory B-Cell Non-Hodgkin's Lymphoma (April 13, 2009) ('the 2009 Press Release') (Ex. 1004)." Pet. 8. As-filed Ex. 1004, however, is a different press release and is the subject of Petitioner's Motion to Correct Clerical Error (Paper 25).

Under 35 U.S.C. § 311(b), a petitioner in an *inter partes* review may only challenge the claims of a patent based on “prior art consisting of patents or printed publications.” 35 U.S.C. § 311(b). Patent Owner, therefore, argues that Petitioner failed to meet its burden to establish that NCT00849654 is a “printed publication” that qualifies as available prior art in an *inter partes* review. Prelim. Resp. 19.

Here, Petitioner has the ultimate burden of persuasion to prove unpatentability by a preponderance of the evidence. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, No. 2015-01214, 2015 WL 5166366, at *4 (Fed. Cir. Sept. 4, 2015). Petitioner also has the initial burden of production to establish that there is prior art that renders the claims unpatentable. *Id.* To satisfy this initial burden, we have often required Petitioner to come forward with sufficient evidence to make a threshold showing that the reference relied upon is available prior art. *See, e.g., Symantec Corp. v. Trs. of Columbia Univ.*, IPR2015-00371, slip op. at 5–9 (PTAB June 17, 2015) (Paper 9); *Temporal Power, Ltd. v. Beacon Power, LLC*, IPR2015-00146, slip op. at 8–11 (PTAB Apr. 27, 2015) (Paper 10); *Dell, Inc. v. Selene Comm’n Techs., LLC*, IPR2014-01411, slip op. at 21–22 (PTAB Feb. 26, 2015) (Paper 23).

In *Dynamic Drinkware*, the Petitioner relied on a prior art patent to challenge the claims of the involved patent. *Id.* at 2. Based on the earlier filing date of the prior art patent, Petitioner satisfied its initial burden of production by arguing that the prior art patent anticipated the asserted claims under 35 U.S.C. § 102(e)(2). *Id.* at 7. In contrast, here, Petitioner does not rely on a filing date recorded on the face of a patent. Petitioner relies on a copy of a webpage to challenge the claims of the ’090 patent. Unlike the prior art patent asserted in *Dynamic Drinkware*, it is not clear from the face

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