

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

PHARMACYCLICS LLC,
Patent Owner.

IPR2019-00865
Patent 9,795,604 B2

Before SHERIDAN K. SNEDDEN, SUSAN L. C. MITCHELL, and
DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

FINAL WRITTEN DECISION

Determining Some Challenged Claims Unpatentable
Denying in Part and Dismissing in Part Motion to Strike
35 U.S.C. § 318(a); 37 C.F.R. § 42.5; 37 C.F.R. § 42.20

I. INTRODUCTION

Sandoz Inc. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1, 4, 6–10, 13, 15, 24, 28–31, 35, 39, 43–46, 50–53, and 55 of U.S. Patent No. 9,795,604 B2 (Ex. 1001, “the ’604 patent”).¹ Paper 2 (“Pet.”). Pharmacyclics LLC (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 6 (Prelim. Resp.).² We determined, based on the information presented in the Petition and Preliminary Response, that there was a reasonable likelihood that Petitioner would prevail in showing that at least one of the challenged claims was unpatentable over the cited art. Pursuant to 35 U.S.C. § 314, the Board instituted trial on September 26, 2019. Paper 8 (“Institution Decision” or “Inst. Dec.”).

Patent Owner filed a Response to the Petition (Paper 13, “PO Resp.”), Petitioner filed a Reply to Patent Owners’ Response (Paper 17, “Reply”), and Patent Owner filed a Sur-Reply (Paper 24, “Sur-Reply”). With our prior authorization, Patent Owner filed a Motion to Strike Improper Reply Arguments (Paper 25, “Mot.”), Petitioner filed an Opposition to Patent Owner’s Motion to Strike (Paper 26, “Mot. Opp.”), and Patent Owner filed a Reply in Support of its Motion to Strike (Paper 27, “Mot. Reply”).

On March 21, 2019, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 28 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6. We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Based on

¹ Petitioner identifies Sandoz Inc. and Lek Pharmaceuticals D.D. as the real parties in interest. Pet. 2.

² Patent Owner identifies Pharmacyclics LLC, AbbVie Inc, and Janssen Biotech, Inc. as the real parties in interest. Paper 4, 1.

the record before us, we conclude that Petitioner has demonstrated, by a preponderance of the evidence, that claims 1, 6–10, 24, 35, 39, and 55 of the '604 patent are unpatentable, but that Petitioner has not demonstrated, by a preponderance of the evidence, that claims 4, 13, 15, 28–31, 43–46 and 50–53 are unpatentable. We deny in part and dismiss in part Patent Owners' Motion to Strike.

A. Related Proceedings

Petitioner and Patent Owner represent that the '604 patent was asserted in *Pharmacyclics LLC v. Zydus Worldwide DMCC*, Civ. No. 1:18-cv-00275-CFC (D. Del.), which has been consolidated with *Pharmacyclics LLC v. Fresenius Kabi USA, LLC*, 1:18-cv-00192-CFC (D. Del). Pet. 2; Paper 4, 1. Petitioner and Patent Owner also represent that U.S. Patent Application No. 15/586,058, filed May 3, 2017, is related to the '604 patent. Pet. 2; Paper 4, 1.

B. The '604 Patent (Ex. 1001)

The '604 patent issued October 24, 2017, identifying John C. Byrd, Jason A. Dubovsky, Natarajan Muthusamy, Amy Jo Johnson, and David Miklos as inventors. Ex. 1001, at codes (45), (72). The patent teaches:

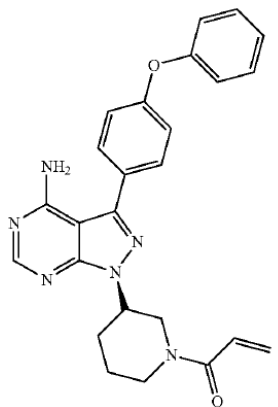
Chronic graft versus host disease (cGVHD) is the most common long-term complication following allogeneic stem cell transplant (SCT), affecting 30-70% of patients who survive beyond the first 100 days. cGVHD and its associated immune deficiency have been identified as a leading cause of non-relapse mortality (NRM) in allogeneic SCT survivors.

Id. at 1:29–36. The '604 patent discloses “methods for treating and preventing graft versus host disease using . . . an ACK inhibitor such as ibrutinib.” *Id.* at Abstract.

C. *Challenged Claims*

Petitioner challenges claims 1, 4, 6–10, 13, 15, 24, 28–31, 35, 39, 43–46, 50–53, and 55 of the '604 patent. Claim 1 is representative and is reproduced below:

1. A method of treating chronic graft versus host disease (GVHD) comprising administering to a patient having chronic GVHD a therapeutically effective amount of a compound of the structure:



thereby treating the chronic GVHD in the patient.

Ex. 1001, 75:41–68.

D. *Prior Art and Asserted Grounds*

We instituted trial based on each challenge to the patentability of the '604 patent presented in the Petition. The Petition challenged the patentability of claims 1, 4, 6–10, 13, 15, 24, 28–31, 35, 39, 43–46, 50–53, and 55 of the '604 patent on the following grounds:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1, 4, 6–10, 13, 15, 24, 28–31, 35, 39, 43–46, 50–53, 55	102	The '085 publication ³
1, 4, 6–10, 13, 15, 24, 28–31, 35, 39, 43–46, 50–53, 55	103	The '085 publication
1, 4, 6–10, 13, 15, 24, 28–31, 35, 39, 43–46, 50–53, 55	103	The '085 publication, Shimabukuro-Vornhagen, ⁴ Herman ⁵
1, 4, 6–10, 13, 15, 24, 28–31, 35, 39, 43–46, 50–53, 55	103	The '085 publication, Shimabukuro-Vornhagen, Uckun ⁶

Pet. 30–31.

Petitioner submits the Declaration of Dr. James L. Ferrara (Ex. 1006) in support of the Petition. Patent Owner submits the Declaration of Dr. John Koreth (Ex. 2055) in support of its Response to the Petition.

E. Person of Ordinary Skill in the Art

Factual indicators of the level of ordinary skill in the art include “the various prior art approaches employed, the types of problems encountered in

³ Goldstein, US Patent Publication No. 2015/0140085 A1, published May 21, 2015 (Ex. 1002, “the '085 publication”).

⁴ Shimabukuro-Vornhagen, et al., *The Role of B Cells in the Pathogenesis of Graft-Versus-Host Disease*, 114(24) BLOOD 4919–4927 (2009) (Ex. 1003, “Shimabukuro-Vornhagen”).

⁵ Herman, et al., *Bruton Tyrosine Kinase Represents a Promising Therapeutic Target for Treatment of Chronic Lymphocytic Leukemia and is Effectively Targeted by PCI-32765*, 117(23) BLOOD 6287–6296 (2011) (Ex. 1004, “Herman”).

⁶ Uckun, et al., *Bruton's Tyrosine Kinase as a Molecular Target in Treatment of Leukemias and Lymphomas as well as Inflammatory Disorders and Autoimmunity*, 20(11) EXPERT OPIN. THER. PATENTS 1457–1470 (2010) (Ex. 1005, “Uckun”).

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