

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

PHARMACYCLICS LLC,
Patent Owner.

Case IPR2019-00865
Patent 9,795,604 B2

Before SUSAN L. C. MITCHELL, JENNIFER MEYER CHAGNON, and
DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

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

Institution of an *inter partes* review is authorized by statute only when “the information presented in the petition . . . and any response . . . shows that 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; *see* 37 C.F.R. §§ 42.4, 42.108. Upon considering the Petition, the Preliminary Response, and the cited evidence, we conclude that Petitioner has satisfied the burden under 35 U.S.C. § 314(a) to show that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims.

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

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.

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.

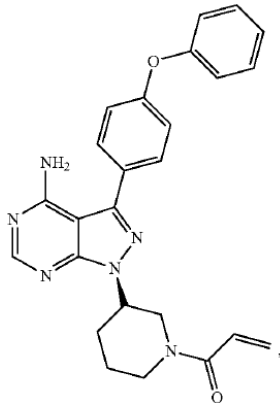
Id. at 1:29–36. The '604 patent discloses “methods for treating and preventing graft versus host disease using . . . an ACK inhibitor such as ibrutinib.” *Id.* at Abstract.

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, 77:41–68.

D. Prior Art and Asserted Grounds

Petitioner asserts that claims 1, 4, 6-10, 13, 15, 24, 28-31, 35, 39, 43-46, 50-53, and 55 of the '604 would have been unpatentable on the following grounds:

Claims Challenged	Statutory Basis	Reference(s)
1, 4, 6–10, 13, 15, 24, 28–31, 35, 39, 43–46, 50–53, and 55	§ 102(a)(2)	The '085 publication ³
1, 4, 6–10, 13, 15, 24, 28–31, 35, 39, 43–46, 50–53, and 55	§ 103(a)	The '085 publication

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

Claims Challenged	Statutory Basis	Reference(s)
1, 4, 6–10, 13, 15, 24, 28–31, 35, 39, 43–46, 50–53, and 55	§ 103(a)	The '085 publication, Shimabukuro-Vornhagen, ⁴ and Herman ⁵
1, 4, 6–10, 13, 15, 24, 28–31, 35, 39, 43–46, 50–53, and 55	§ 103(a)	The '085 publication, Shimabukuro-Vornhagen, and Uckun ⁶

Petitioner submits the Declaration of Dr. James L. Ferrara (Ex. 1006) in support of institution of *inter partes* review.

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 the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field.” *Jacobson Bros., Inc. v. U.S.*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co., v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*).

Petitioner contends that the person of ordinary skill “would have had an advanced degree in the field of medicine with additional, specialized

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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