

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner

v.

MERCK PATENTGESELLSCHAFT,
Patent Owner

Case IPR2018-00423
Patent 8,673,921 B2

Before SUSAN L.C. MITCHELL, ROBERT A. POLLOCK, and
RICHARD J. SMITH, *Administrative Patent Judges*.

SMITH, *Administrative Patent Judge*.

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

I. INTRODUCTION

Argentum Pharmaceuticals LLC (“Petitioner”) filed a Petition (Paper 2, “Pet.”) to institute an *inter partes* review of claims 1, 11, 12, 14, and 15 of U.S. Patent 8,673,921 (the “’921 patent”). 35 U.S.C. § 311. Merck Patentgesellschaft (“Patent Owner”) filed a Preliminary Response to the Petition (Paper 6). (“Prelim. Resp.”).

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314. Based on the particular circumstances of this case, we exercise our discretion under 35 U.S.C. § 325(d) and do not institute *inter partes* review of the challenged claims.

A. *Related Proceedings*

Petitioner identifies the ’921 patent as being the subject of the following proceedings: *Forest Laboratories, Inc. v. InvaGen Pharm. Inc.*, Civ. Action No. 15-cv-272; *Forest Laboratories, Inc. v. Alembic Pharm. Ltd.*, Civ. Action No. 15-cv-273; *Forest Laboratories, Inc. v. Apotex Inc.*, Civ. Action No. 15-cv-274; *Forest Laboratories, Inc. v. Teva Pharm. USA Inc.*, Civ. Action No. 15-cv-275; *Forest Laboratories, Inc. v. InvaGen Pharm. Inc.*, Civ. Action No. 15-cv-277; and *Forest Laboratories, Inc. v. InvaGen Pharm. Inc.*, Civ. Action No. 15-cv-1078. Pet. 1–2. Patent Owner indicates that the above Civ. Action Nos. 272, 273, 274, 275, 277, and 1078 are now closed, and consolidated into *Forest Laboratories, LLC v. Accord Healthcare, Inc.*, Civ. Action No. 15-cv-272-GMS (consolidated) (D. Del. 2015). Paper 3, 2–3.

B. *The ’921 Patent*

The ’921 patent relates to “new crystalline modifications of the hydrochloride of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine.” Ex. 1001, Abstract; *see also id.* at Title (referencing “Polymorphic

Forms” of same compound). The ’921 patent states that “[m]ethods for preparing pure crystals of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride [vilazodone hydrochloride (VHCl)] have now been found.” *Id.* at 2:25–27. The ’921 patent further states that the morphologic Forms of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride and dihydrochloride (Forms I–XI and XIII–XVI) are referred to as the “products of the invention” and can be used to treat and prevent a number of disorders. *Id.* at 14:58–15:19. The ’921 patent also indicates that “[t]he present invention further provides pharmaceutical compositions or medicaments comprising a Product of the Invention.” *Id.* at 15:22–26.

C. *Illustrative Claims*

Petitioner challenges claims 1, 11, 12, 14, and 15 of the ’921 patent, of which claims 1 and 11 are the only independent claims. Claims 1 and 11 are reproduced below:

1. A compound which is 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride in its crystalline modification, wherein the compound is an anhydrate, hydrate, solvate or dihydrochloride.

Ex. 1001, 27:13–16.

11. A pharmaceutical composition comprising a compound which is 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride anhydrate in its crystalline modification IV, and one or more conventional auxiliary substances and/or carriers.

Id. at 28:5–9.

Claims 12 and 14 generally recite a method of treating certain disorders comprising administering the composition of claim 11 or a compound of claim 1, respectively. Ex. 1001, 28:10–20; 34–44. Claim 15 recites a “pharmaceutical

composition comprising a compound according to claim 1, and one or more conventional auxiliary substances and/or carriers.” *Id.* at 28:45–47.

According to Patent Owner, the challenged claims “relate to crystalline vilazodone hydrochloride including vilazodone hydrochloride Form IV.” Prelim. Resp. 1. Vilazodone hydrochloride is the active ingredient in VIIBRYD[®], which is indicated for the treatment of major depressive disorder. *Id.* at 3–4; Ex. 2019, 1, 21. As set forth in the product labeling, “VIIBRYD tablets for oral administration contain polymorph Form IV vilazodone hydrochloride (HCl), a selective serotonin reuptake inhibitor and a 5HT_{1A} receptor partial agonist.” Ex. 2019, 10.

D. The Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable under 35 U.S.C. §§ 102(b) and 103(a) based on the following grounds. Pet. 3.

Reference[s]	Basis	Claims challenged
'241 patent ¹ as characterized by Patent Owner's Admissions ²	§ 102(b)	1, 14, and 15
'241 patent, as characterized by Patent Owner's Admissions, in view of Bartoszyk ³	§ 103(a)	1, 14, and 15

¹ Böttcher et al., U.S. Patent No. 5,532,241, issued July 2, 1996 (“’241 patent”). Ex. 1004.

² In referring to the term “Patent Owner’s Admissions,” Petitioner states that “[t]he background section of the ‘921 patent makes several admissions” Pet. 4–5. *See* Section II.C.2 *infra*.

³ Bartoszyk et al., WO 00/72832 A2, published Dec. 7, 2000 (“Bartoszyk”). Ex. 1005.

Reference[s]	Basis	Claims challenged
'241 patent, as characterized by Patent Owner's Admissions, in view of Pavia ⁴ and Byrn ⁵	§103(a)	1 and 11
'241 patent, as characterized by Patent Owner's Admissions, in view of Bartoszyk, Pavia, and Byrn	§103(a)	1, 12, 14, and 15

Petitioner also relies on the Declarations of Dr. Robin D. Rogers, Ph.D. (Ex. 1002), Dr. Sanjay J. Mathew, M.D. (Ex. 1003), and Dr. Gabriela Gurau, Ph.D. (Ex. 1039).

II. ANALYSIS

A. *Person of Ordinary Skill in the Art*

Petitioner asserts that a “person of ordinary skill in the art (‘POSA’) at the time of the alleged invention of the ‘921 patent would have at least a bachelor’s degree in chemistry, pharmaceutical sciences, or related discipline, and several years of experience working in pharmaceutical solid product development and/or solid-state chemistry.” Pet. 11. Petitioner further states that “[t]he POSA would have expertise and experience in synthesis, crystallization, and characterization of salts and polymorphic forms. A POSA could have a lower level of formal education if such a person had a higher degree of relevant working experience.” *Id.* at 11–12.

⁴ Donald L. Pavia et al., *Introduction to Organic Laboratory Techniques: A Contemporary Approach*, 3rd ed., 508–540 (1988) (“Pavia”). Ex. 1032.

⁵ Stephen R. Byrn et al., *Solid-State Chemistry of Drugs*, 2nd ed., 1–219 (1999) (“Byrn”). Ex. 1012.

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