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Paper 80
Entered: June 6, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACRUX DDS PTY LTD., ACRUX LIMITED, and ARGENTUM PHARMACEUTICALS LLC,
Petitioner,

v.

KAKEN PHARMACEUTICAL CO., LTD. and VALEANT PHARMACEUTICALS INTERNATIONAL, INC.,
Patent Owner.

Case IPR2017-00190[1]
Patent 7,214,506 B2

Before ERICA A. FRANKLIN, SUSAN L. C. MITCHELL, and ROBERT A. POLLOCK *Administrative Patent Judges.*

MITCHELL, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
Inter Partes Review
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

[1] Case IPR2017-01429 has been joined with the instant proceeding.

I. INTRODUCTION

This is a final written decision in an *inter partes* review of claims 1 and 2 of U.S. Patent No. 7,214,506 B2 (Ex. 1001, "the '506 patent") entered pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, we determine that Petitioner has shown, by a preponderance of the evidence, that claims 1 and 2 of the '506 patent are unpatentable under 35 U.S.C. § 103(a). *See* 35 U.S.C. § 316(e).

A. Procedural History

Petitioner Acrux DDS Pty Ltd. and Acrux Limited (collectively, "Petitioner")[2] filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1 and 2 (the "challenged claims") of the '506 patent. *See* 35 U.S.C. §§ 311–319. Petitioner relied upon Declarations of Kenneth A. Walters, Ph.D. and Jeff Karr. Exs. 1005, 1044, respectively; *see* Pet. 6–61. Patent Owner Kaken Pharmaceutical Co., Ltd. and Valeant Pharmaceuticals International, Inc. (collectively, "Patent Owner") filed a Preliminary Response. Paper 8 ("Prelim. Resp."). Patent Owner relied upon a Declaration of Yoshiyuki Tatsumi, PhD. Exs. 2003 (English translation).

Pursuant to 35 U.S.C. § 314(a), on May 1, 2017, we instituted an *inter partes* review of challenged claims 1 and 2 to determine if the claims are unpatentable under 35 U.S.C. § 103(a) as obvious over the combinations of Ogura with JP '639, '367 Patent, or Hay, or the Kaken Abstracts with JP '639, '367 Patent, or Hay. Paper 12, 5 ("Dec.").

[2] Argentum Pharmaceuticals LLC is also a petitioner in this case by virtue of joinder with IPR2017-01429.

On May 12, 2017, Argentum Pharmaceuticals LLC ("Argentum") filed a petition asserting the same grounds as the Petition in this case. *See Argentum Pharm. LLC v. Kaken Pharma. Co., Ltd.*, IPR2017-1429, Paper 2, 4. On the same day, Argentum filed a motion to join the instant case. *Id*. at Paper 3, 2. On November 13, 2017, we instituted trial in IPR2017-1429 on the same grounds as in this *inter partes* review and granted Argentum's motion to join. *See id*. at Paper 10, 7; Paper 11, 5.

Patent Owner filed its Patent Owner Response (Paper 27, "PO Resp."), along with Declarations of Dr. Tatsumi, Ph.D. (Exs. 2025), Boni E. Elewski, M.D. (Ex. 2027), and Vincent A. Thomas, CPA, CVA, CFF, ABV (Exhibit 2028) to support its positions. Petitioner filed a Reply (Paper 37, "Reply") to the Patent Owner Response along with Declarations of Dr. Walters (Ex. 1509), Jeffrey M. Weinberg, M.D. (Ex. 1510), and John C. Staines, Jr. (Exhibit 1511).

Petitioner and Patent Owner each filed several motions to seal various papers and exhibits. *See* Papers 25, 36, 50, 59, 62, 72, 77. These motions are decided in a separate order. Patent Owner filed a Motion to Strike (Paper 46), which we authorized (*see* Paper 43), and also filed a Motion to Exclude certain exhibits and portions of Dr. Walter's declarations (Paper 58). Petitioner also filed a Motion to Exclude portions of Mr. Thomas's declaration and associated exhibits. (Paper 51 (public version)). These motions are decided in a separate order.

An oral hearing was held on January 26, 2018. A transcript of the hearing is included in the record. Paper 78 ("Tr.").

B. Related Proceedings

Patent Owner indicated that there is a reissue application pending for the '506 patent. Paper 7. We ordered the examination of Reissue Application No.

15/405,171 involving the ’506 patent stayed pending the termination or completion of this *inter partes* review. *See* Paper 31.

C. The ’506 Patent (Ex. 1001)

The ’506 patent involves a method for accurately evaluating an effect of an antimicrobial agent and a therapeutic agent for onychomycosis that can be obtained using this method. *See* Ex. 1001, Abst., 2:55–62. The ’506 patent states that an object of the invention “is to provide a therapeutic agent for onychomycosis which exhibits the effect on tinea unguium by topical application and which is capable of curing tinea unguium [by a] shorter period than that of the marketed oral preparation due to good permeability, good retention capacity and conservation of high activity in nail plate as well as the potent antifungal activity thereof” and “to provide the effective therapeutic agent for onychomycosis exhibiting no side effect even if therapeutically effective amounts of it are administered sufficiently.” *Id*. at 3:40–51. The ’506 patent lists KP-103 as one of the most preferred antimicrobial agents that can be used to cure “disease such as mycosis completely, and prevent[] a relapse.” *Id*. at 9:10–13, 30–31. KP-103 is also known as efinaconazole. PO Resp. 6; Reply 1.

In describing the disease to be cured, the ’506 patent describes onychomycosis as a superficial mycosis caused by invading and proliferating in the nail of a human by *Trichophyton rubrum* or *Trichophyton mentagrophytes*, and in rare cases, *Microsporum*, *Epidermophyton*, *Candida*, *Aspergillus*, or *Fusarium*. *Id*. at 9:32–39. The ’506 patent includes tinea unguium caused by the *Trichophyton* species in the definition of onychomycosis, the symptoms of which include

"opacity, tylosis, destruction and deformation of [the] nail plate." *Id*. at 2:21–25, 9:40–43.[3]

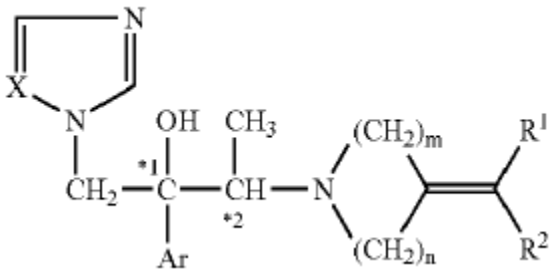
The '506 patent describes the term "nail" as including "nail plate, nail bed, nail matrix, further side nail wall, posterial nail wall, eponychium and hyponychium which make up a tissue around thereof." *Id*. at 4:65–67.

D. Challenged Claims

Claim 1 is independent and claim 2 depends from claim 1. Those claims recite as follows.

1. A method for treating a subject having onychomycosis wherein the method comprises topically administering to a nail of said subject having onychomycosis a therapeutically effective amount of an antifungal compound represented by the following formula:

(II)



wherein, Ar is a non-substituted phenyl group or a phenyl group substituted with 1 to 3 substituents selected from a halogen atom and trifluoromethyl group,

R^1 and R^2 are the same or different and are hydrogen atom, C_{1-6} alkyl group, a non-substituted aryl group, an aryl group substituted with 1 to 3 substituents selected from a halogen atom, trifluoromethyl group, nitro group and C_{1-16} alkyl group, C_{2-8} alkenyl group, C_{2-6} alkynyl group, or C_{7-12} araklyl group,

[3] According to Petitioner's expert, Dr. Walters, "[O]nychomycosis, also referred to as *tinea unguium*, is a fungal infection of the nail usually caused by a group of keratinophilic fungi known as dermatophytes." Ex. 1005 ¶ 41.

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