

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRISM PHARMA CO., LTD.
Petitioner

v.

CHOONGWAE PHARMA CORPORATION
Patent Owner

Case IPR2014-00315
Patent 8,318,738 B2

Before LORA M. GREEN, SHERIDAN K. SNEDDEN, and
ZHENYU YANG, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Pursuant to 35 U.S.C. §§ 311-319, PRISM Pharma Co., Ltd.¹ (“Petitioner”) filed a Petition for an *inter partes* review of claims 1-3 and 5-7 of U.S. Patent No. 8,318,738 (“the ’738 patent”). Paper 1 (“Pet.”). Choongwae Pharma Corporation² (“Patent Owner”) timely filed its Preliminary Response. Paper 11 (“Prelim. Resp.”).

Petitioner contends that because the challenged claims are entitled to a priority date of no earlier than July 29, 2011, they are anticipated by a reference published on December 12, 2009. Patent Owner counters that the challenge is a disguised written-description attack, a ground barred under 35 U.S.C. § 311(b). In addition, Patent Owner asks the Board to deny the Petition under 35 U.S.C. § 325(d) because during prosecution, Petitioner (through one of the co-inventors of the ’738 patent, who is also a cofounder and outside board member of the Petitioner) presented, and the Examiner considered, the same prior art and substantially the same arguments.

We have jurisdiction under 35 U.S.C. § 314. For the reasons provided below, we exercise our discretion under 35 U.S.C. § 325(d), and deny the Petition.

A. *The Parties*

Petitioner is a Japanese company cofounded in 2006 by Dr. Michael Kahn, one of the co-inventors of the ’738 patent. Ex. 2003, Further Declaration of Dr. Michael Kahn ¶ 2; *id.*, Curriculum Vitae. Dr. Kahn has

¹ PRISM Pharma Co., Ltd. was formerly known as PRISM BioLab Corporation. Pet. 1.

² JW Pharmaceutical Corporation, formerly known as Choongwae Pharma Corporation, is the real party in interest in this proceeding. Paper 6, 1.

been an outside board member of Petitioner. *Id.*, Further Declaration of Dr. Michael Kahn ¶ 2. From 1999 to 2005, Dr. Kahn served as a consultant to Patent Owner. *Id.*, Curriculum Vitae. The parties appear to be engaged in numerous lawsuits, which, although not strictly over the '738 patent, relate to the subject matter claimed therein. *See, e.g.*, Pet. 4-5 n.1; Ex. 1011, 3-4.

According to Patent Owner,

Kahn secretly founded [Petitioner] Prism to develop competing compounds. In 2008, Prism filed the U.S. provisional application that served as the priority document for WO 2009/148192 (hereinafter the "Prism PCT"). [Patent Owner] believes that Prism is actively taking steps to commercialize one or more compounds of the Prism PCT, which compounds are encompassed within the scope of the claims [of the '738 patent].

Ex. 1011, 4. As a result, Patent Owner sued Petitioner and Dr. Kahn in the U.S. District Court for the Central District of California, alleging "breach of contract, fraud, breach of confidentiality[,] and trade secret misappropriation." *Id.* at 3.

According to Petitioner,

PRISM and the Patent Owner have filed suits against one another in Japan and the U.S. alleging that the other has misappropriated its confidential information. PRISM, for example, is accusing Patent Owner of misuse of PRISM's confidential information. PRISM's contention is that Patent Owner obtained confidential information from PRISM regarding the structure of its PRI-724 compound, which Patent Owner then used to fashion claims (including the challenged claims in this petition) in an attempt to cover PRISM's compound.

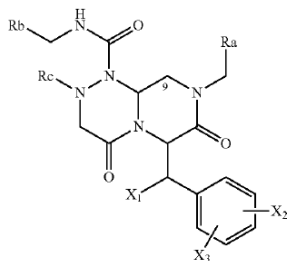
Pet. 4-5 n.1.

B. The '738 Patent

The '738 patent "relates generally to reverse-turn mimetic structures and to a chemical library relating thereto." Ex. 1001, 1:40-41. It discloses conformationally constrained compounds that mimic the secondary structure of reverse-turn regions of biologically active peptides and proteins. *Id.* at Abstract; *see also id.* at 4:38-43. It also relates to the use of such compounds for inhibiting or treating disorders such as cancer. *Id.* at Abstract; *see also id.* at 4:31-37.

Claim 1 is the sole independent challenged claim. It reads:

1. A compound having formula (VI)



wherein,

R_a is a phenyl group; a substituted phenyl group having one or more substituents wherein the one or more substituents are independently selected from one or more of amino, amidino, guanidino, hydrazino, amidazonyl, C₁₋₄alkylamino, C₁₋₄dialkylamino, halogen, perfluoro C₁₋₄alkyl, C₁₋₄alkyl, C₁₋₃alkoxy, nitro, carboxy, cyano, sulfuryl, and hydroxyl groups; or a bicyclic aryl group having 8 to 11 ring members, which may have 1 to 3 heteroatoms selected from nitrogen, oxygen and sulfur;

R_b is a monocyclic aryl group having 5 to 7 ring members, which may have 1 to 2 heteroatoms selected from nitrogen, oxygen or sulfur, and aryl ring in the compound may have one or more substituents selected from a group consisting of halogen, hydroxy, cyano, lower alkyl, and lower alkoxy groups;

R_c is a saturated or unsaturated C_{1-6} alkyl, C_{1-6} alkoxy, perfluoro C_{1-6} alkyl group; and

X_1 , X_2 , and X_3 may be the same or different and independently selected from hydrogen, hydroxyl, and halide;

and wherein the compound of formula [sic] (VI) is substituted with hydrogen or methyl at the 9-position.

C. Asserted Ground of Unpatentability

Petitioner challenges the patentability of claims 1-3 and 5-7 based on a single ground—anticipation under 35 U.S.C. § 102(b) by PCT Publication No. WO 2009/148192 (“the ’192 publication,” Ex. 1004), published on December 12, 2009.

II. BACKGROUND

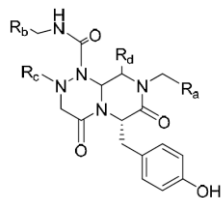
A. Priority Chain

The ’738 patent issued from U.S. Patent Application No. 13/194,428 (“the ’428 application”), filed on July 29, 2011. Ex. 1001. The ’428 application is a continuation of U.S. Patent Application No. 12/553,858 (“the ’858 application”), filed on September 3, 2009. *Id.* at 1:7-8. The ’858 application claims priority, through a series of continuation, divisional, and continuation-in-part applications, to an application filed in 2001. *Id.* at 1:9-19; *see also* Ex. 1012, 1.

B. Prosecution of the ’858 Application

After filing the ’858 application (the parent of the ’428 application, which matured into the patent-at-issue), Patent Owner canceled the original claims, and added new claims 43-66 in a preliminary amendment. Ex. 1013, 5-15. New claims 59-66 were directed to compounds having C_{1-6} alkyl at the 9-position of formula (VI) in claim 1 of the ’738 patent, as well as to compositions comprising such compounds. *Id.* at 12-15. Specifically,

claim 59, added in the preliminary amendment, recites a compound of formula (VII):



(VII)

wherein R_a, R_b, and R_c are as defined in claim 1 of the '738 patent, and R_d is C₁₋₆alkyl. *Id.* at 12-13.

In the First Office Action, the Examiner objected to the abstract, and rejected claims 43-66 on the ground of nonstatutory obviousness-type double patenting. *See* Ex. 2005, 15. In response, Patent Owner revised the abstract and filed a terminal disclaimer.³ *Id.* at 15-16. Patent Owner also informed the Examiner of a related application that was being examined by a different examiner:

USAN 12/541,388 (“the 388 application”) relates to the present application in that it claims prodrugs of compounds that are the same as or similar to the compounds of claims 59-63 of the present application. During prosecution of the ‘388 application, Assignee received an unsolicited Declaration from Dr. Michael Kahn, a co-inventor of the ‘388 application (and the present application), asserting that the claims of the ‘388 application are not patentable for failing to meet the enablement and written description requirements. Assignee submitted the Declaration (including WO2009/148192 referenced therein) to Examiner Venkataraman Balasubramanian in the ‘388 application on September 30, 2010. To ensure compliance with Assignee’s duty of candor and good faith in dealing with the

³ Patent Owner amended certain claims to correct informalities related to chemical structures and amended claim 59 to recite R_d as “C₁₋₇alkyl” (as opposed to “C₁₋₆alkyl”). Ex. 2005, 3-13.

U.S. Patent Office, a copy of this Declaration is submitted herewith in a Supplemental Information Disclosure Statement [Ex. 2002], along with the Amendment filed by the Assignee in the '388 application addressing the same.

Id. at 16-17.

In his Declaration, Dr. Kahn stated that claims directed to prodrugs reciting R_d at the 9-position as hydrogen or C_{1-6} alkyl, or R_d of any type in the context of an adjacent R_a bicyclic aryl group (1) lacked written support in the Specification (Ex. 2001 ¶¶ 5-9), and (2) were anticipated by the '192 publication, the same prior art that Petitioner asserts in the Petition in the instant proceeding (*id.* ¶¶ 11-13).⁴

After the Patent Owner's response, the Examiner allowed all the claims pending in the '858 application. But, on the same day Patent Owner paid the issue fee, the examiner of the '388 application rejected the claims for failing to comply with the written-description requirement. Patent Owner filed an Information Disclosure Statement ("IDS") to bring this rejection to the attention of the Examiner of the '858 application, petitioned to withdraw the '858 application from issuance, and filed a Request for Continued Examination ("RCE"). Ex. 3001.

Acknowledging the IDS, the Examiner of the '858 application rejected claims 59-66 for lack of written description. Ex. 1014, 2-3. According to the Examiner, "[t]he compounds of formula (VII) with new variable R_d (C_{1-7} alkyl) attached to the bicyclic 1,2,4-triazin-5-one ring . . . ha[ve] no written description in this specification" or any

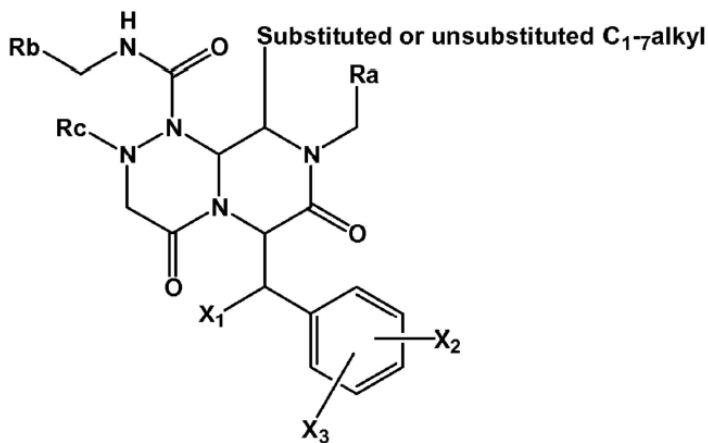
⁴ Dr. Kahn also stated that those claims did not comply with the enablement requirement. Ex. 2001 ¶ 6.

priority document. *Id.* at 3. In addition, even though Table 4 of the '858 application disclosed several species with methyl as R_d , the Examiner concluded that "Applicants are claiming $R_d = C_{1-7}$ alkyl that is broader than the scope of these species." *Id.* at 4. The Examiner allowed claims 43-58 because they have no variable R_d attached to the bicyclic ring. *Id.* at 3, 5.

In response to the rejection, Patent Owner cancelled claims 59-66 (*see* Ex. 3002), pursuing them in a continuation application, the '428 application (Ex. 1002).

C. Prosecution of the '428 Application

Upon filing the '428 application, Patent Owner canceled original claims 1-42 and added new claims 43-61 in a preliminary amendment. Ex. 1005, 2-7. The new claims were directed to compounds having C_{1-7} alkyl at the 9-position of formula (VI). *Id.* Specifically, claim 43 was the same as canceled claim 59 of the '858 application, except that the 9-position shows "substituted or unsubstituted C_{1-7} alkyl" in the formula, instead of the " R_d " substituent:



In the First Office Action, the Examiner rejected all pending claims on the grounds of nonstatutory obviousness-type double patenting, indefiniteness of the term “substituted,” and certain defective chemical structures. *See* Ex. 1006, 3-5. In response, Patent Owner filed a terminal disclaimer, amended claim 43 by replacing “substituted or unsubstituted C₁₋₇alkyl” at the 9-position with “C₁₋₇alkyl,” and cancelled the claims directed to the unsubstituted C₁₋₇alkyl embodiments, including those with defective chemical structures. Ex. 1007, 2-7. The Examiner then allowed all pending claims, and Patent Owner paid the issue fee.

Shortly thereafter, Dr. Kahn sent another Declaration to Patent Owner’s prosecuting attorneys. Ex. 2003. He alleged that claims added in the preliminary amendment, and later amended in Patent Owner’s response to the first office action, lacked written description support.⁵ *Id.* at ¶¶ 6-10. Specifically, according to Dr. Kahn, the Specification provided no support for claims having C₁₋₇alkyl as the R_d group, or C₁₋₇alkyl as R_d in the context of an adjacent bicyclic aryl group as R_a. *Id.* Dr. Kahn contended in his Declaration that the ’192 publication, the same prior art that Petitioner asserts in the Petition in the instant proceeding, anticipated those claims. *Id.* at ¶¶ 15-17. Patent Owner submitted Dr. Kahn’s Second Declaration in an IDS (Ex. 2006), withdrew the ’428 application from issuance, and filed an RCE (Ex. 3003).

Acknowledging the IDS, the Examiner rejected the pending claims for lack of written description. Ex. 1008, 3. Specifically, the Examiner stated:

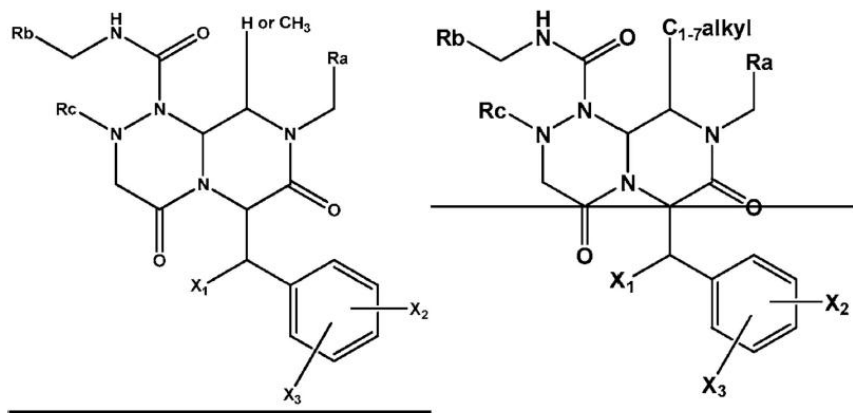
⁵ Dr. Kahn also stated that those claims failed to comply with the enablement requirement. Ex. 2003 ¶ 7.

The scope of Rd at the position 9 attached to the bicyclic ring as (C1-7 alkyl) [is now broader than] the scope disclosed in the specification of this application as well as its related parent and grandparent applications.

In regard to the species 69, 78, 80, 83, 84 and 111 for Rd = methyl disclosed in Table 4, the specification has no written description. Applicants are claiming Rd = C₁₋₇ alkyl that is broader than the scope of these species.

Id. at 4.

In response, Patent Owner amended claim 43 to recite “H or –CH₃” at the 9-position of formula (VI):



Ex. 1009, 2.

Later, in a supplemental amendment, Patent Owner further amended claim 43 by deleting “H or –CH₃” at the 9-position and adding “wherein the compound of formula (VI) is substituted with hydrogen or methyl at the 9-position,” as currently recited in claim 1 of the ’738 patent. Ex. 1010, 3-4. In addition, Patent Owner amended the Specification by inserting language from PCT Publication No. WO 01/00210 (Ex. 1003). According to Patent Owner,

[T]he 2001 PCT was incorporated by reference in its entirety in the specification as filed (*see* page 424, lines 1-6), as well as in all the intervening priority applications going back to the earliest priority document In order to further clarify that the first component piece includes at least hydrogen and methyl as amino acid side chain moieties, Applicants have amended the specification by copying portions of the 2001 PCT into the pending application; namely, the text from pages 16, line 30 through page 17, line 9, and from page 7, lines 26-27 and page 8, lines 7-9.

Ex. 1010, 10.

Patent Owner also submitted an expert declaration in support of its argument that “the specification conveys with a reasonable clarity to those skilled in the art that Applicants were in possession of the invention as now claimed at least by . . . 2004 . . . and as early as . . . 2001.” *Id.* at 11.

After an interview requested by Patent Owner (Ex. 2004), the Examiner allowed all pending claims in the ’428 application, and they issued as the currently challenged claims. Ex. 1011, 1. In the Reasons for Allowance, the Examiner explained that “Applicants [have] overcome the written description problem by incorporating WO 01/00210 A1 by reference as disclosed on pages 3 and 424 of the specification” and that the claims were “free from prior art.” *Id.* at 2.

The Examiner also noted the remarks submitted with the RCE, in which Patent Owner explained the relationship between itself and Dr. Kahn. *Id.* at 3-4. According to Patent Owner, Dr. Kahn, who served as a consultant for Patent Owner, was a co-inventor of the ’428 application. *Id.* at 3. He later founded Petitioner, which filed a patent application that published as the ’192 publication. *Id.* at 4. Patent Owner also alleged that it had sued Petitioner and Dr. Kahn for “breach of contract, fraud, breach of

confidentiality and trade secret misappropriation on the part of Kahn.” *Id.* at

3. In view of these, the Examiner stated:

Due to the nature of the case, the examiner consulted with his SPE for assistance in allowing this case. The examiner and his supervisor (Mr. James Wilson) reviewed [Patent Owner’s expert] declarations and applicant’s argument carefully and decided that the claims are in condition for allowance.

Id. at 4.

III. ANALYSIS

Under 35 U.S.C. § 325(d),

In determining whether to institute or order a proceeding under . . . chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

Here, Petitioner argues that the subject matter recited in the challenged claims do not have written support in the parent ’858 application. Pet. 32-51. Thus, according to Petitioner, those claims are not entitled to a priority date earlier than July 29, 2011, the filing date of the ’428 application that matured into the patent-at-issue. *Id.* Without the benefit of the earlier priority date, Petitioner contends, claims 1-3 and 5-7 are anticipated by the ’192 publication, published on December 12, 2009. *Id.* at 51-59.

The same prior art (i.e., the ’192 publication) and arguments substantially the same as Petitioner’s current contention (i.e., the ’192 publication is an invalidating prior art that anticipates the challenged claims), were presented previously to the Office. Indeed, Dr. Kahn, one of the named co-inventors of the ’738 patent, was a cofounder of Petitioner. Ex. 2003, Further Declaration of Dr. Michael Kahn ¶ 2. Twice during the

prosecution of the '428 application and the parent '858 application, Dr. Kahn brought the '192 publication to the Examiner's attention, asserting that it was anticipatory prior art. *See supra* Sections II.B, II.C. The '192 publication is prior art only if the claims-at-issue lack written description support in the parent '858 application, and therefore, are not entitled to the priority date of September 3, 2009, the filing date of the '858 application. Thus, Dr. Kahn's allegation of lack of written description support in his Declarations must also serve as the basis for challenging the priority claim. Aware of the '192 publication, the Examiner, together with his supervisor, reviewed the materials and determined that the challenged claims were "free from prior art." Ex. 1011, 2.

Based on these facts, we conclude that the same prior art and substantially the same arguments were presented to the Office previously. We exercise our discretion and deny the Petition under 35 U.S.C. § 325(d).

IV. ORDER

Accordingly, it is

ORDERED that Petitioner's request for an *inter partes* review of claims 1-3 and 5-7 of the '738 patent is *denied*.

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Patent 8,318,738 B2

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