Trials@uspto.gov
Tel: 571-272-7822

Paper 9
Entered: February 4, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAWAI USA, INC. AND SAWAI PHARMACEUTICAL CO., LTD.,
Petitioners,

v.

NISSAN CHEMICAL INDUSTRIES LTD.,
Patent Owner.

Cases IPR2015-01647
Patent No. 5,856,336 B2

Before JACQUELINE WRIGHT BONILLA, SHERIDAN K. SNEDDEN, and TINA E. HULSE, *Administrative Patent Judges.*

SNEDDEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Sawai USA Inc. and Sawai Pharmaceutical Co., Ltd. ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1 and 2 (Paper 1, "Pet.") of U.S. Patent No. 5,856,336 B2 (Ex. 1001, "the '336 patent"). Nissan Chemical Industries, Ltd. ("Patent Owner") filed a Patent Owner Preliminary Response. Paper 8 ("Prelim. Resp.").

Upon consideration of the Petition and Patent Owner Preliminary Response, we conclude that Petitioner has not established that there is a reasonable likelihood that it will prevail with respect to at least one of the challenged claims. For the reasons that follow, we do not institute an *inter partes* review.

A. Related Proceedings

The parties inform us of no related litigation between them involving the '336 patent. Pet. 5–6; Paper 4. Concurrent with the filing of the present Petition, Petitioner also filed a different Petition requesting *inter partes* review of claims 1–2 of the '336 patent (IPR2015-01648).

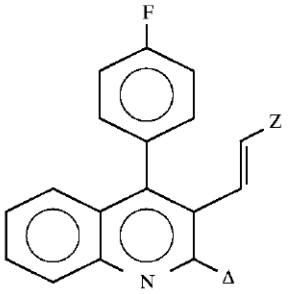
B. The '336 patent (Ex. 1001)

The '336 patent discloses mevalonolactone derivatives having a quinoline ring and their use as a pharmaceutical for reducing hyperlipidemia, hyperlipoproteinemia, or atherosclerosis. Ex. 1001, 1:6–35. The compounds are active against the enzyme HMG-CoA (or 3-hydroxy-3-methylglutaryl-coenzyme A). *Id.* at Abstract.

C. Challenged claims

Challenged claims 1 and 2 are reproduced below:

1. A compound of the formula,



[A]

Z= —CH(OH)—CH_2—CH(OH) —CH_2—COO. ½Ca.

2. A method for reducing hyperlipidemia, hyperlipoproteinemia or atherosclerosis, which comprises administering an effective amount of the compound of formula A as defined in claim 1.

Ex. 1001, 32:20–40.

D. Asserted Grounds of Unpatentability

Petitioner challenges claims 1 and 2 of the '336 patent on the following ground. Pet. 20–57.

References	Basis	Claim[s] challenged
Picard[1] and Kesseler[2]	§ 103(a)	1 and 2

[1] Joseph A. Picard et al., U.S. Patent No. 4,761,419, issued Aug. 2, 1988. Ex. 1009 ("Picard").

[2] Kurt Kesseler et al., U.S. Patent No. 4,925,852, issued May 15, 1990. Ex. 1010 ("Kesseler").

Petitioner relies also on the Declaration of Dr. Milton Brown in support of the proposed ground of unpatentability. Ex. 1012 ("Brown Declaration" or "Brown Decl.").

II. ANALYSIS

A. Claim Interpretation

We interpret claims using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b); *see also* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs., LLC v. Lee*, 84 U.S.L.W. 3218 (U.S. Jan. 15, 2016) (No. 15-446). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). "Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaim[s] the broader definition." *In re Bigio*, 381 F.3d 1320, 1325 (Fed Cir. 2004). "Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We determine that no explicit construction of any specific claim term is necessary to determine whether to institute a trial in this case. *See, e.g., Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011)

("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). At this stage of the proceeding, we have not made a final determination as to the construction of any claim term.

B. Effective Filing Date of Claims 1 and 2 of the '336 Patent

The '336 Patent claims the benefit of Japanese Patent Applications JP 63-193606 ("JP '606," filed August 3, 1988),[3] JP 63-15585 ("JP '585," filed January 26, 1988),[4] and JP 62-207224 ("JP '224," filed August 20, 1987).[5] Petitioner contends that neither JP '585 nor JP '224 provides written description for a ½ calcium salt, as specifically required by claims 1 and 2 of the '336 patent. Pet. 10–15. Thus, Petitioner contends that the earliest effective filing date for the '336 Patent is no earlier than the filing date of JP '606, or August 3, 1988. *Id.*

In its Preliminary Response, Patent Owner does not direct us to any portion of either JP '585 or JP '224 that provides written description for a ½ calcium salt, instead arguing that the Board need not address priority at this time in light of the deficiencies in Petitioner's arguments. Prelim. Resp. 2 n.1. For the purposes of this Decision, we treat Picard and Kesseler as prior art references and consider the patentability challenge set forth in the Petition.

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[3] Certified English translation provided as Ex. 1013.

[4] Certified English translation provided as Ex. 1014.

[5] Certified English translation provided as Ex. 1015.

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