

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.

Case IPR2015-01648
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 6. Concurrent with the filing of the present Petition, Petitioner also filed a different petition requesting *inter partes* review of claims 1 and 2 of the ’336 patent (IPR2015-01647).

B. *The ’336 patent (Ex. 1001)*

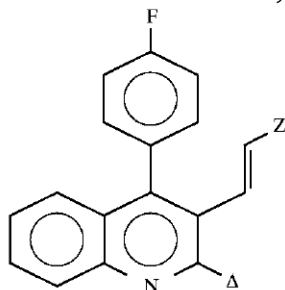
The ’336 patent discloses mevalonolactone derivatives having a quinoline ring and their use as a pharmaceutical for reducing hyperlipidemia, hyperlipoproteinemia, or atherosclerosis. Ex. 1001, 1:6–35.

C. Challenged claims

Challenged claims 1 and 2 are reproduced below:

1. A compound of the formula,

[A]



$Z = \text{—CH(OH)—CH}_2\text{—CH(OH)—CH}_2\text{—COO. } \frac{1}{2}\text{Ca.}$

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. 25–35.

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

¹ Kurt Kessler et al., U.S. Patent No. 4,925,852, issued May 15, 1990. Ex. 1010 (“Kessler”).

² Joseph A. Picard et al., U.S. Patent No. 4,761,419, issued Aug. 2, 1988. Ex. 1009 (“Picard”).

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 Kessler as prior art references and consider the patentability challenge set forth in the

³ Certified English translation provided as Ex. 1013.

⁴ Certified English translation provided as Ex. 1014.

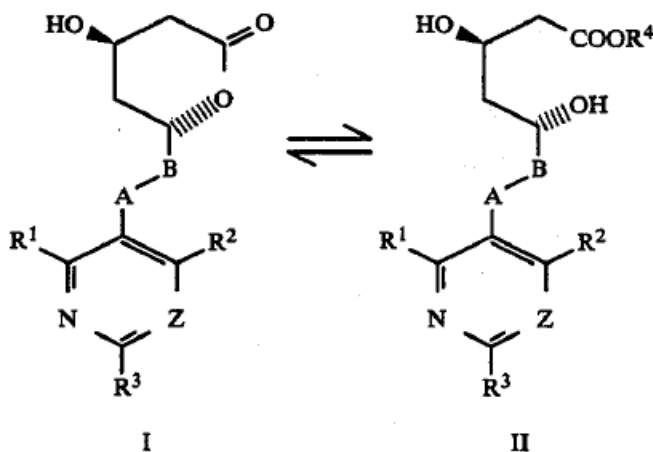
⁵ Certified English translation provided as Ex. 1015.

Petition.

C. Petitioner's Asserted Obviousness Ground

1. Petitioner's Contentions

Petitioner contends that claims 1 and 2 of the '336 patent are obvious over the combination of Kessler and Picard. Pet. 25–35. Kessler discloses a genus of compounds having the general structures I and II, as depicted below:

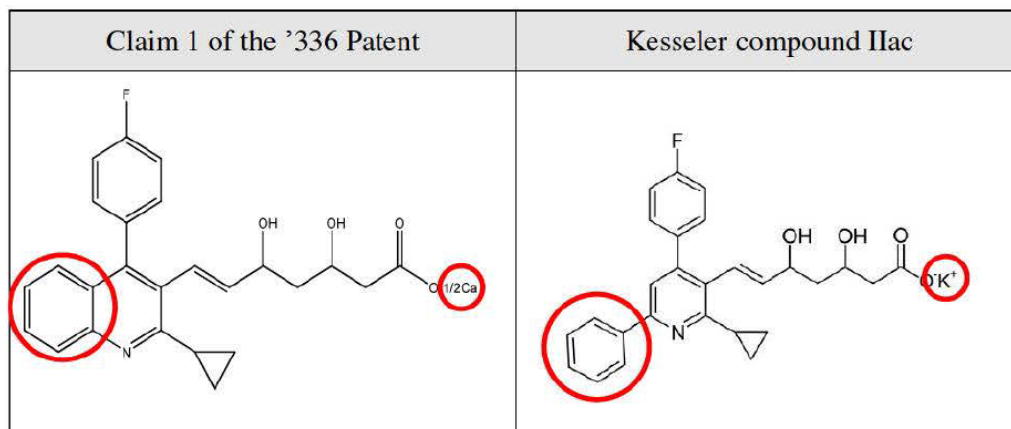


Ex. 1010, Abstract, 1:35–49. The A–B is either –CH=CH– or –CH₂–CH₂– and Z is either –CH or a nitrogen atom. *Id.* at 1:50–54. The structures may further be modified at any one of R₁, R₂, and R₃. *Id.* at 1:55–2:3.

Petitioner contends that “Kessler specifically names about 80 compounds in the specification (Ex. 1010 at 10:4–13:62), and actually prepares approximately 20 compounds, both in dihydroxy acid derivative (e.g., Table 14) and δ-lactone forms (e.g., Table 1),” suggesting that “a POSA would consider the most biologically active compounds as potential candidates for further research.” Pet. 25 (citing Brown Decl. ¶ 32).

Petitioner contends that “[m]any of the compounds reported on Tables 1 and 14 have isopropyl groups at the R₁ position (including compound IIw), but only compound IIac contains a cyclopropyl group at that position,” suggesting that “[a] POSA would have been interested in further exploring the only exemplified compound having a cyclopropyl group at the R₁ position, and which also had remarkable activity.” *Id.* at 27 (citing Brown Decl. ¶ 35).

With reference to the table reproduced below, Petitioner directs our attention to compound IIac disclosed by Kessler, and contends that “it is immediately apparent that Compound IIac is structurally similar to the compound of formula A of claims 1 and 2 of the ’336 Patent, and the table below provides a side-by-side comparison of these two compounds, with the only differences between them circled.” *Id.* at 27–28 (citing Brown Decl. ¶ 30).



Petitioner acknowledges the lack of a fused ring structure in compound IIac, but contends that the fusion of rings would have been obvious to a person of ordinary skill in the art. *Id.* at 28–29 (citing Brown Decl. ¶ 38). In particular, Petitioner contends that “ring-fused compounds

(compound B in the figure) were generally accepted as being analogs of their ring-cracked counterparts (compound A in the figure), and vice-versa.” *Id.* at 29 (citing Brown Decl. ¶ 39 (“Given a split-ring compound . . . , a person having ordinary skill in the art would have naturally attempted to create a compound containing fused rings in order to further develop the compound . . . because ring-fused compounds (compound B in the figure) were generally accepted being analogs of their ring-cracked counterparts (compound A in the figure), and vice-versa.”)).

2. Patent Owner’s Contentions

Patent Owner contends Petitioner concedes that there are many potentially beneficial compounds disclosed in the prior art, and that “Kessler alone discloses hundreds of different possible compounds.” Prelim. Resp. 15–17 (citing Pet. 15, 17–18; Brown Decl. ¶ 25 n.1; Ex. 1010, 1:35–54).

Patent Owner contends that Petitioner fails to establish that Kessler Compound IIac is structurally similar to the compound of the challenged claims. *Id.* at 25–28. Rather, Patent Owner argues that the “core” of the Kessler compounds is a single-ring structure, which is distinct from the double-ring structure of the compound claimed in the ‘336 patent. *Id.* at 27–28. Patent Owner contends that the fusion of the rings in the Kessler compounds—the change proposed by Petitioner (Pet. 29)—changes the core of the compound structure disclosed in Kessler and is not a “small, conservative” change of a lead compound that can support a chemical obviousness challenge. *Id.* (citing *Bristol-Myers Squibb Co. v. Teva Pharm.*

USA, Inc., 752 F.3d 967, 975 (Fed. Cir. 2014)).

Patent Owner further contends that Petitioner fails to identify a reason to modify the Kessler compounds “to go from the single-ring pyridine and pyrimidine cores of Kessler to the double-ring quinoline core of the ‘336 Patent,” and that “[a] POSA would not have had a reasonable expectation of success that making such a change would improve the properties of the Kessler ‘lead’ compound.” *Id.* at 28–30.

With regard to Picard, Patent Owner notes that Kessler discloses an entire class of monocyclic compounds (referred to as pyridines and pyrimidines) with better activity against HMG-CoA reductase than any of the bicyclic compounds (referred to as quinoline compounds) disclosed in Picard, thereby suggesting that a person of ordinary skill in the art would not have been motivated to fuse the rings of Kessler’s general structure. *Id.* at 29–30 (citing Ex. 1010, 14:24–45 (Table 1); Ex. 1009, 1:25–40). According to Patent Owner, Kessler discloses at least 14 compounds having IC₅₀ values against HMG-CoA reductase between 0.9–5.0 nanomolar, whereas the IC₅₀ values disclosed in Picard were between 32 and 350 nanomolar. *Id.* (citing Ex. 1010, 14:24–45; Ex. 1009, 11 (Table 1)).

3. Analysis

We generally follow a two-part inquiry to determine whether a new chemical compound would have been obvious over particular prior art compounds. *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1291–93 (Fed. Cir. 2012). First, we determine “whether a chemist of ordinary skill would have selected the asserted prior art compounds as lead compounds, or

starting points, for further development efforts.” *Id.* at 1291. Second, we analyze whether there was a reason to modify a lead compound to make the claimed compound with a reasonable expectation of success. *Id.* at 1292.

A lead compound is defined as “‘a compound in the prior art that would be most promising to modify in order to improve upon its . . . activity and obtain a compound with better activity.’” *Id.* at 1291 (citing *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007)). Stated another way, “a lead compound is ‘a natural choice for further development efforts.’” *Id.* (citing *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1008 (Fed. Cir. 2009)). The analysis of whether a chemist of ordinary skill would have chosen the prior art compound as a lead compound “is guided by evidence of the compound’s pertinent properties” including “positive attributes such as activity and potency,” “adverse effects such as toxicity,” “and other relevant characteristics in evidence.” *Id.* at 1292.

Importantly, “[a]bsent a reason or motivation based on such prior art evidence, mere structural similarity between a prior art compound and the claimed compound does not inform the lead compound selection.” *Id.*; see also *Daiichi Sankyo Co., Ltd. v. Matrix Laboratories, Ltd.*, 619 F.3d 1346, 1354 (Fed. Cir. 2010) (“[P]roving a reason to select a compound as a lead compound depends on more than just structural similarity, but also knowledge in the art of the functional properties and limitations of the prior art compounds”). Establishing that a chemical compound would have been obvious over a structurally similar compound requires “a showing that the prior art would have suggested making the specific molecular modifications

necessary to achieve the claimed invention.” *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356 (Fed. Cir. 2007) (internal quotations omitted).

In the present case, Petitioner identifies compound IIac disclosed in Kessler as a “lead compound” and then proceeds to walk us through the steps a person of ordinary skill in the art would have had to perform in order to arrive at the compound of the claims. Pet. 25–34. These steps involve fusing the ring structures shown in Kessler’s general structure in a process Petitioner refers to as “benzofusion.” *Id.* at 29. Based on the record before us, however, we are not convinced that the steps needed to go from Kessler’s monocyclic compounds to a bicyclic compound—such as the compounds disclosed in Picard—would be considered routine optimization such that a person of ordinary skill in the art would have had a reasonable expectation of success in improving the activity of Kessler’s monocyclic compounds. Fusion of the monocyclic ring structure of the Kessler compounds would have altered significantly the core structure of the Kessler compounds and expanded greatly the number of variant compounds resulting from the proposed modification. We therefore agree with Patent Owner that use of the benzofusion process as proposed by Petitioner to achieve the compound of the challenged claims is a product of hindsight. Prelim. Resp. 18–24.

Moreover, we determine, based on the current record, that Petitioner has failed to establish that a person of ordinary skill in the art would have been motivated to make the precise modifications necessary to transform Kessler’s compound IIac to the compound of the challenged claims based

on the combination of Kessler and Picard. As noted by Patent Owner, Kessler's monocyclic compounds generally exhibited better activity against HMG-CoA reductase as compared to any of the bicyclic compounds tested in Picard. Prelim. Resp. at 29–30 (compare Ex. 1010, 14:24–45 (Table 1); Ex. 1009, 1:25–40). As such, even if Petitioner's proposed benzofusion process was considered a routine optimization process, we are not persuaded that a person of ordinary skill in the art would have had a reasonable expectation of success in performing the process to achieve compounds having improved properties based on the combination of Kessler and Picard.

In view of the above, we are not persuaded that there is a reasonable likelihood that Petitioner would prevail at trial with respect to at least one claim of the '336 patent on its obviousness challenges

D. Interference Estoppel

Petitioner contends that “[t]he grandparent application of the '336 patent was involved in two interferences,” both of which the Patent Owner lost. Pet. 41 (citing Ex. 1005; Ex. 1006). Petitioner attempts to use arguments made in those interferences to support arguments that the Patent Owner disclaimed or otherwise lost the right to claim the compound of claims 1 and 2 of the '336 patent. *Id.* at 41–60. It thus appears that Petitioner is attempting to rely on estoppel based on prior judgments in the above-mentioned interferences (Ex. 1005 and Ex. 1006), not on asserted unpatentability under 35 U.S.C. §§ 102, 103 based on prior art.

Under 35 U.S.C. § 311(b), a petitioner in an *inter partes* review “may request to cancel as unpatentable 1 or more claims of a patent only on a

ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.” Petitioner has not directed us to any authority that allows this Board to cancel claims in an *inter partes* review based on arguments by a Petitioner that the Patent Owner may have disclaimed the subject matter of challenged claims in a related grandparent application, which is the relief requested by Petitioner (see Pet. 41–60).

The ’336 patent itself was not involved in the two interference cases cited by Petitioner. Pet. 41–42. Nonetheless, Petitioner relies on alleged “estoppel” based on judgments in those interferences, and specifically Petitioner’s assertion that certain claims at issue in those cases recite subject matter that “is not patentably distinct” from the subject matter recited in the challenged claims. Pet. 46, 48. Thus, Petitioner does not assert unpatentability under 35 U.S.C. §§ 102, 103 based on prior art. *See also W. L. Gore & Associates, Inc. v. LifePort Sciences LLC*, Case IPR2014-01319, Paper 7, slip op. at 14–15 (PTAB Feb. 23, 2015) (addressing a similar type of argument regarding asserted “interference estoppel”). Accordingly, we do not institute an *inter partes* review based on the alleged interference estoppel asserted by Petitioner.

III. CONCLUSION

Petitioner does not persuade us that there is a reasonable likelihood that at least one of the challenged claims is unpatentable based on the asserted ground. We deny the petition for *inter partes* review and decline to institute trial on the asserted ground as to any of the challenged claims.

IV. ORDER

In consideration of the foregoing, it is hereby ORDERED that the petition is *denied* as to all challenged claims and no trial is instituted.

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