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Paper 24
Entered: October 20, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

NISSAN CHEMICAL INDUSTRIES, LTD.,
Patent Owner.

Case IPR2015-01069
Patent 5,856,336

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

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1 and 2 (Paper 2; "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 7 ("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 the following related litigation between them involving the '336 patent: *Kowa Company, Ltd. v. Mylan, Inc.*, 1:14-cv-02647 (S.D.N.Y. Apr. 14, 2014). Pet. 1; Paper 5.

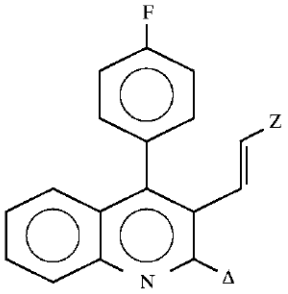
B. The '336 patent (Ex. 1001)

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= —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.

D. Asserted Grounds of Unpatentability

Petitioner challenges claims 1 and 2 of the '336 patent on the following grounds. Pet. 16–60.

Reference[s]	Basis	Claims Challenged
Kathawala,[1] Kathawala Abstract, [2] Hoefle,[3] Roth,[4] Anderson,[5] Wareing,[6] Hansch,[7] Suh,[8] Berge,[9] and Gould[10]	§ 103	1 and 2

[1] U.S. Patent No. 4,739,073, issued Apr. 19, 1988. Ex. 1010.
[2] Faizulla G. Kathawala, et al., *XU 62-320, An HMG-CoA Reductase Inhibitor, More Potent Than Compactin*, Abstract for American Chemical Society library, July 29, 1987 (hereinafter "Kathawala Abstract"). Ex. 1009.
[3] U.S. Patent No. 4,647,576, issued Mar. 3, 1987. Ex. 1016.
[4] U.S. Patent No. 4,681,893, issued July 21, 1987. Ex. 1019.
[5] U.S. Patent No. 4,751,235, issued June 14, 1988. Ex. 1020.
[6] U.S. Patent No. 4,613,610, issued Sept. 23, 1986. Ex. 1018.

Reference[s]	Basis	Claims Challenged
Kathawala, Kathawala Abstract, Hoefle, Roth, Anderson, Wareing, Hansch, Suh, Berge, Gould, Engstrom Abstract,[11] Tobert,[12] Lee,[13] and Picard[14]	§103	1 and 2
Picard	§ 102	1 and 2

Petitioner relies also on the Declaration of Roger Frank Newton, Ph.D. (Ex. 1008) and the Declaration of Dr. David Gortler (Ex. 1015) in support of the proposed grounds of unpatentability.

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[7] Corwin Hansch et al., *"Aromatic" Substituent Constants for Structure-Activity Correlations*, 16 J. MED. CHEM. 1207–1216 (1973) (hereinafter "Hansch"). Ex. 1024.
[8] John T. Suh et al., *Angiotensin-Converting Enzyme Inhibitors New Orally Active Antihypertensive (Mercaptoalkanoyl)- and [(Acylthio)alkanoyl]glycine Derivatives*, 28 J. MED. CHEM. 57–60 (1985) (hereinafter "Suh"). Ex. 1029.
[9] Stephen M. Berge et al., *Pharmaceutical Salts*, 66 J. PHARM. SCI. 1–19 (1977) (hereinafter "Berge"). Ex. 1027.
[10] Philip L. Gould, *Salt Selection for Basic Drugs*, 33 INT. J. PHARM. 201–217 (1986). Ex. 1028.
[11] R. G. Engstrom et al., *Hypolipoproteinemic Effects of a Potent HMG-CoA Reductase Inhibitor*, IX International Symposium on Drugs Affecting Lipid Metabolism, Florence (Italy), Oct. 22-25, 1986 (hereinafter "Engstrom"). Ex. 1011.
[12] Jonathan A. Tobert, *New Developments in Lipid-Lowering Therapy: The Role of Inhibitors of Hydroxymethylglutaryl-Coenzyme A Reductase*, 76 CIRCULATION 534–538 (1987). Ex. 1012.
[13] Ta-Jyh Lee, Synthesis, *SARs and Therapeutic Potential of HMG-CoA Reductase Inhibitors*, 8 TRENDS PHARMACOL. SCI. 442–446 (1987). Ex. 1013.
[14] U.S. Patent No. 4,761,419, issued Aug. 2, 1988. Ex. 1021.

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) ("Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA,"[15] and "the standard was properly adopted by PTO regulation."). 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 explicit construction of any specific claim term is not 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

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[15] The Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) ("AIA").

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