

Filed On Behalf Of:

Novartis AG and LTS Lohmann Therapie-Systeme AG

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

NOVARTIS AG AND LTS LOHMANN THERAPIE-SYSTEME AG,
Patent Owners

Inter Partes Review No. 2015-00268

U.S. Patent 6,335,031

PRELIMINARY RESPONSE BY
PATENT OWNERS PURSUANT TO 37 C.F.R. § 42.107

TABLE OF CONTENTS

I.	The Board Should Deny Institution Of Grounds 1 And 2 Because Mylan Does Not Seek Institution Of Those Grounds	1
II.	The Board Should Deny Institution Of Ground 1 Because Elmalem Does Not Anticipate Claim 15.....	2

TABLE OF AUTHORITIES

Cases

<i>In re Roth</i> , No. 92-2941, 1993 WL 13725366 (B.P.A.I. Mar. 16, 1993)	3
<i>In re Williams</i> , 171 F.2d 319 (C.C.P.A. 1948).....	3
<i>Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.</i> , 267 F. Supp. 2d 533 (N.D. W. Va. 2003).....	3
<i>Power Mosfet Techs., L.L.C. v. Siemens AG</i> , 378 F.3d 1396 (Fed. Cir. 2004)	4
<i>Sanofi-Synthelabo v. Apotex, Inc.</i> , 550 F.3d 1075 (Fed. Cir 2008)	3
<i>Spectrum Int’l, Inc. v. Sterlite Corp.</i> , 164 F.3d 1372 (Fed. Cir. 1998)	4
<i>Teva Neuroscience, Inc. v. Watson Labs., Inc.</i> , No. 10-cv-5078, 2013 WL 1595585 (D.N.J. Apr. 12, 2013).....	4
<i>Texas Instruments Inc. v. U.S. Int’l Trade Comm’n</i> , 988 F.2d 1165 (Fed. Cir 1993)	4

Statutes

35 U.S.C. 315(c)	2
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Patent Owners Novartis AG and LTS Lohmann Therapie-Systeme AG respectfully submit this Preliminary Response to the Petition of Mylan Pharmaceuticals Inc. seeking *inter partes* review of U.S. Patent No. 6,335,031 (“’031 patent”).

I. The Board Should Deny Institution Of Grounds 1 And 2 Because Mylan Does Not Seek Institution Of Those Grounds

Mylan’s IPR petition asserts the following five grounds, which are identical to the five grounds asserted by Noven Pharmaceuticals Inc. in the petition for IPR2014-00550 (“Noven IPR”):

1. Claim 15 is anticipated by Elmalem;
2. Claims 16 and 18 are obvious over Elmalem and the Handbook;
3. Claims 1, 2, 7, 15 and 18 are obvious over Enz and the Handbook, optionally in view of Rosin and/or Elmalem and/or Ebert;
4. Claims 3 and 16 are obvious over Enz and the Handbook and/or Rosin and/or Ebert; and
5. Claims 1, 2, 3, 7, 15, 16 and 18 are obvious over Enz and Sasaki.

On October 14, 2014, the Board in the Noven IPR instituted grounds 3-5 (IPR2014-00550, Paper 10 at 10-26), but denied grounds 1 and 2 in view of the fact that grounds 3-5 provided sufficient alternatives for the petitioner to challenge the patentability of claims 15, 16 and 18. (*Id.* at 26-27.)

On November 13, 2014, Mylan moved under 35 U.S.C. 315(c) (Paper 3) to join this IPR with the Noven IPR. Mylan in its joinder motion admits that its IPR petition is identical to the Noven IPR petition. (Paper 3 at 1, 6). Mylan also admits that “[a]lthough Mylan has submitted a verbatim copy of the Noven petition, including the grounds not instituted by the Board [*i.e.*, grounds 1 and 2], *Mylan seeks institution only as to the three grounds of invalidity already instituted by the Board in the Noven IPR* [*i.e.*, grounds 3-5].” (*Id.* at 6, emphasis added; *see also* Paper 12 at 5.)

In view of (i) Mylan’s express representation that it does not seek institution of grounds 1 and 2, (ii) the Board’s mandate to ensure the efficient resolution of these IPR proceedings, and (iii) the Board’s previous October 14, 2014 decision in the Noven IPR denying grounds 1 and 2, Patent Owners respectfully request that the Board deny grounds 1 and 2 in this IPR.

II. The Board Should Deny Institution Of Ground 1 Because Elmalem Does Not Anticipate Claim 15

Independent of Mylan’s express representation that it does not seek institution of ground 1, Patent Owners respectfully request that the Board deny ground 1 because Elmalem does not anticipate claim 15.

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