Paper No. ___
Date Filed: May 10, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., ACTAVIS LABORATORIES FL, INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, INC., TEVA PHARMACEUTICALS USA, INC., WEST-WARD PHARMACEUTICAL CORP., and HIKMA PHARMACEUTICALS, LLC,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-01332[1]

Patent No. 8,822,438 B2

PATENT OWNER'S OPPOSITION TO PETITIONERS' MOTION TO EXCLUDE EVIDENCE UNDER 37 C.F.R. § 42.64(C)

[1] Case IPR2016-00853 has been joined with this proceeding.

Patent Owner, Janssen Oncology, Inc., respectfully submits this opposition to Petitioners' Motion to Exclude (Paper 72 ("Mot.")). For the reasons discussed below, the Motion should be denied in its entirety.[2]

I. Petitioners Waived by Serving Boilerplate Objections

As a threshold matter, Petitioners waived the arguments in their Motion to Exclude because they did not serve objections that "identify the grounds for the objection with sufficient particularity to allow correction in the form of supplemental evidence" as required by 37 C.F.R. § 42.64(b)(1). Petitioners' March 15, 2017 objections to Patent Owner's evidence (Paper 37 ("Pet. Obj.")) reproduced Patent Owner's entire exhibit list in table format, alongside letters coded according to a two-page "Objection Key." Pet. Obj., Paper 37 at 1-14 (table of objections), 15-16 ("Objection Key"). An example is below:

Exhibit	Description	Objection
JSN 2118	Declaration of Johann S. De Bono	A, B, C, E, D, E, F, G, H, I, M, N, O, S, T, U, W, Y

Id. at 12. The result is a morass of over 950 largely generic objections. Petitioners also objected to all paragraphs in Patent Owner's Response and declarations "that

[2] Petitioners' Motion summarizes their 37 C.F.R. § 42.64(b)(1) objections. Patent Owner addresses herein objections Petitioners purport to explain in their Motion. *See* 37 C.F.R. § 42.64(c) (motions to exclude "must explain the objections").

rely on exhibits objected to" by Petitioners. *Id.* at 14. Petitioners' shotgun approach violates the very purpose of § 42.64(b)(1). Accordingly, Petitioners' motion to exclude should be denied for failure to comply with § 42.64(b)(1). *See Legend3d, Inc. v. Prime Focus Creative Servs. Can. Inc.*, IPR2016-00806, Paper 22 at 2 (Oct. 24, 2016) (criticizing objections that "were generic and failed to identify the basis of the objection with particularity").

II. Petitioners' Objections to Patent Owner's Response Are Unfounded

Petitioners' request to exclude Patent Owner's Response is unfounded. "[A] motion to exclude applies to evidence and not a paper, such as Patent Owner's Response." *Maxlinear, Inc. v. Cresta Tech. Corp.*, IPR2015-00594, Paper 90 at 6, n.9 (Aug. 15, 2016). In addition, Petitioners did not particularly identify the challenged portions of Patent Owner's Response in either their § 42.64(b)(1) objections or their Motion. *Id.*; *see* Pet. Obj., Paper 37 at 14 ("Petitioner objects to paragraphs in the Patent Owner's Response . . . that rely on exhibits objected to in this Petitioner's Objection to Evidence."); Mot., Paper 72 at 4 (asking the Board to exclude "material on at least" pages enumerated).

III. Patent Owner's Reliance Upon the Amerigen IPR Is Proper

Petitioners offer no legitimate reason to exclude declarations and deposition transcripts from *Amerigen Pharms. Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286 (the "Amerigen IPR"). Exs. 2010, 2037, 2120, 2122, 2124, 2125, and 2127 ("the

Amerigen testimony"). The Amerigen IPR involves the same attack on the '438 patent as here, by a generic drug maker similarly situated as Petitioners (Amerigen and Petitioners are co-defendants in parallel district court ANDA litigation).

The Amerigen IPR record is inextricably intertwined with this proceeding. When Petitioner Mylan originally brought this IPR, it moved to join the Amerigen IPR, filing a copycat of Amerigen's petition. Paper 3. Mylan stated in its Motion for Joinder that its petition asserted "the same grounds of invalidity" as Amerigen, and that "while the Petitioner in the Mylan IPR and the Petitioner in the Amerigen IPR have relied upon testimony from separate experts in their respective petitions, the conclusions and underlying reasoning of the experts are congruent." *Id.* at 1, 5. Indeed, Mylan's expert, Dr. Garnick, used the declaration of Amerigen's expert, Dr. Serels (Exs. 2010, 2120), as a template for his own declaration. Ex. 2126 (Garnick) at 109:3-110:3. The other Petitioners copied Mylan's submissions to obtain institution and joinder. *See* IPR2017-00853, Paper 9 (Motion for Joinder) at 1 ("the Petition and supporting expert declarations are identical").

The Board's institution decision here noted that Petitioner raised "the same grounds of unpatentability" as in the Amerigen IPR, and that "Mylan supports its assertions in its Petition with substantially the same art and arguments proffered by Amerigen in the Amerigen IPR." Paper 21 at 3. The Board's institution decision also incorporated by reference its analysis from the Amerigen IPR, which relied on

the Serels declaration (Exs. 2010, 2120). *See* Paper 21 at 5 (citing IPR2016-00286, Paper 14 at 4-15; *see id.* at 9-10, 13, 14 (referencing Serels)).

Petitioners now ask the Board to ignore what Amerigen's experts have said, presumably because their testimony is no longer congruent with their positions. For example, Dr. Serels stated that "mineralocorticoid excess would not occur with ketoconazole," that PSA data in Gerber is insufficient to make "a definite conclusion" that patients administered ketoconazole and prednisone experienced a clinical response, that ZYTIGA® therapy is commercially successful, and that it would not be so but for co-administration with prednisone. Ex. 2122 (Serels) ¶10; Ex. 2037 (Serels) at 71:6-12, 176:24-177:7. Petitioners cannot have it both ways. Having leveraged the Amerigen IPR to gain institution of their own IPR, Petitioners cannot now disavow any connection. For this reason alone, Petitioners' request to exclude the undisputedly relevant Amerigen testimony should be denied.

A. The Amerigen Testimony Is Not Impermissible Hearsay

Petitioners' hearsay attack on the Amerigen testimony fails for multiple additional reasons. First, declarations and testimony from another proceeding clearly can be offered into evidence. The proponent is not required to make the witnesses available for cross examination as a matter of routine discovery because that right is limited to "affidavit testimony ***prepared for the proceeding***." 37 C.F.R. § 42.51(b)(1)(ii) (emphasis added); *GEA Process Eng'g v. Steuben Foods,*

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