UNITED STATES PATENT AND TRADEMARK OFFICE
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BEFORE THE PATENT TRIAL AND APPEAL BOARD
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ARGENTUM PHARMACEUTICALS LLC
Petitioner

v.

CIPLA LTD.
Patent Owner

Patent No. 8,168,620
Issue Date: May 1, 2012
Title: COMBINATION OF AZELASTINE AND STEROIDS
_____

Inter Partes Review No. IPR2017-00807

PETITIONER'S REQUEST FOR REHEARING UNDER 37 C.F.R. §42.71(d)

Pursuant to 37 C.F.R. § 42.71(d), Argentum ("Petitioner") hereby requests rehearing of the Board's Decision (Paper 11, entered August 21, 2017;"Dec."). The Board reviews a request for rehearing for abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion may be determined if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if the decision represents an unreasonable judgment in weighing relevant factors. *Star Fruits S.N.C. v. U.S.*, 393 F.3d 1277, 1281 (Fed. Cir. 2005). As set forth below, this standard is met.

Petitioner requests rehearing as to Ground 1 on the basis that the Decision misapplied the applicable law and misapprehended the prior art record evidence in relying on a finding that Segal (Ex. 1012) "literally discloses more than 800 million combinations within its broad genus" (Dec. 13), rather than the 54 combinations cited in the Petition (Pet. 18-19). Specifically, the Decision erred in disregarding the express preferences set forth in Segal's specification, as expressly quoted in Petitioner's claim chart (*id*. 19-20). The Decision also erred in faulting Petitioner for "improperly reading claim 4 as dependent upon claim 2, when, in fact, claim 4 depends from claim 1" (Dec. 13), because claims are properly interpreted as identifying preferred embodiments in general, irrespective of their

dependency. While Petitioner did not have an opportunity to respond to Patent Owner's erroneous assertion that Segal disclosed more than 800 million combinations of compounds (Paper 7 at 21-22, n.4), case law cited in the Petition as well as by the Board itself shows why this calculation and the analysis that followed from it are legally incorrect.

I.   **Controlling Law, Cited in both the Petition and the Decision, Requires that a Prior Art Reference Be Found To Define a Limited Class of Species Based on Preferences Expressed in the Specification and/or the Claims.**

The Decision quotes *WM. Wrigley Jr. Co. v. Cadbury Adams USA LLC* (683 F.3d 1356 (Fed. Cir. 2012)) for the analysis of anticipation where the anticipating disclosure is found in separate lists, *i.e.*, "whether the number of categories and components in [the single prior-art reference is] so large that the combination of [one item from each list] would not be immediately apparent to one of ordinary skill in the art." Dec. 11. However, the Decision overlooks the additional guidance provided by *Wrigley*, as well the cases cited by Petitioner, regarding the starting point for conducting such a legal analysis.

Petitioner cited *In re Petering* (301 F.2d 676, 681 (CCPA 1962)) and *In re Schaumann* (572 F.2d 312, 315-16 (CCPA 1978)) for the proposition that if a person of ordinary skill in the art can envision each and every species of a "limited" genus taught by the prior art, the reference will anticipate each of those species if later claimed. Pet. 16, 19. Importantly, both of these

decisions relied on expressed preferences within a genus as disclosing <u>a more limited genus</u>, from which the species at issue were readily apparent, which was the argument presented by Petitioner here (*see* Pet. 19). Indeed, as noted by Petitioner (Pet. 16), the required use of such preferences in this way was expressly affirmed by the Federal Circuit in *Merck v. Biocraft* (874 F.2d 804, 808 (Fed. Cir. 1989)), which quoted *Petering* in stating that "description of 'specific preferences in connection with a generic formula' <u>is determinative in an analysis of anticipation under 35 USC 102</u>." *Id.* (underline added).

Applications of this rule are found in both cases cited in the Petition. For example, in *Petering*, the Court found that a prior art reference anticipated the claimed isoallooxazine compounds even though the broadest genus described by the reference "perhaps contained an infinite number of compounds." *Petering*, 301 F.2d at 681. Despite this large overall genus, the Court credited the prior art reference's disclosure (in the specification) of "specific preferences [of R groups] in connection with [its] generic formula" and found that such disclosure "constitutes a description of a definite and limited class of compounds." *Id.* Thus, as argued by Petitioner here, *Petering* clearly established that the disclosure of a limited number of preferred groups selected from different lists describes each possible combination derived therefrom to the POSA. *Id.* at 681-82 (finding that the prior art reference

"described to those with ordinary skill in this art each of the various permutations here involved as fully as if he had drawn each structural formula or had written each name").

Similarly, the Board also overlooked the import of *Schaumann*, which Petitioner cited (Pet. 16) along with *Petering*, in support of the anticipation of species by a genus based on preferences described in the reference. In *Schaumann*, Appellant's claimed compound was found to be anticipated by a reference disclosing a genus of compounds, where some preferences within that genus were disclosed in a claim, and another limitation on that preference was disclosed in the specification. *Schaumann*, 572 F.2d at 317. The Court specifically rejected the reasoning relied upon in the Decision here (Dec. at 12-13) that claims cannot act as independent teachings of preferences and that a POSA cannot rely on the combined teachings of the claims and specification for preferences. *Id.* Instead, not only did the Court rule that claims may be relied upon to indicate preferences for particular groups, but that <u>preferences identified in the claims may also be read in conjunction with the specification</u> to describe a more limited genus, which can then be analyzed under the rubric of *Wrigley* to find anticipation of a claimed species. *Id.* at 316-17 (finding that claim 1 of the prior art reference, read in conjunction with the specification's

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