

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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 a more limited genus, 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’ is determinative in an analysis of anticipation under 35 USC 102.” *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 preferences identified in the claims may also be read in conjunction with the specification 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

“signification” for alkyl radical, describes a very limited number of compounds, one of which anticipates the claimed species).

The analysis in *Wrigley* (cited in the Decision) is consistent with the analyses in *Petering* and *Schaumann*, but has also been overlooked by the Board. In *Wrigley*, the Court found anticipation of a chewing gum claim composition that included a combination of WS-23 (a coolant) and menthol (a flavorant and a coolant). *Wrigley*, 683 F.3d at 1362. In its analysis, the Court relied on a prior art reference that disclosed a variety of oral compositions, including chewing gum, each containing certain required ingredients (*i.e.*, xylitol and copper bis-glycinate) as well as optional ingredients. *Id.* at 1359-60. Among the optional ingredients were cooling agents; WS-23 was disclosed to be one of three preferred cooling agents. A second list provided 23 “most suitable” flavoring agents that could optionally be used, including menthol. *Id.* at 1360.

In finding the prior art anticipated the claimed combination of menthol and WS-23, the Court relied on the prior art’s express disclosure of preferred cooling agents and preferred flavoring agents, which provide a readily envisioned 69 possible combinations. *Id.* at 1360, 1362 (3 x 23 = 69 combinations). Equally significant, the Court did not review the number of combinations that the other disclosed optional ingredients could

hypothetically be used to create, nor was the Court concerned with the number of other flavoring agents used, since such ingredients were not excluded from the claims. *Id.* at n.4. Thus, the Decision’s reliance on Patent Owner’s argument that Segal discloses more than 800 million possible combinations (Dec. 13 (citing Prelim. Resp. 21 & n.4)) does not comport with *Wrigely*—because the claims here do not exclude any of the other optional ingredients identified in Segal, Petitioner’s analysis identifying 54 relevant combination is the correct one.

The case law cited by Petitioner and in the Decision establishes that (1) a prior art reference’s disclosure in the specification of preferred embodiments can and should be used to narrow the reference’s disclosure of a broad genus for purposes of analyzing anticipation under § 102; (2) the claims of a reference should be interpreted as likewise disclosing preferences within a broad genus, which preferences can be read in conjunction with other preferences taught in the specification; and (3) a reference’s disclosure of other optional ingredients is immaterial to the § 102 analysis under *Wrigley* where such optional ingredients are not implicated or precluded by the claim being analyzed. As discussed below, the Decision fails to correctly apply this legal analysis when it considered anticipation by Segal under Ground 1 of the Petition.

II. Under the Proper Legal Analysis Set Forth in the Petition, Segal's Preferences Permit a POSA to Immediately Envision the Combination of Fluticasone and Azelastine

The Board abused its discretion by failing to apply the proper legal analyses found in *Petering*, *Schaumann*, and *Wrigley* and, in so doing, misapprehending the scope of Segal's disclosure. As a result of its erroneous anticipation analysis, the Decision incorrectly credited Patent Owner's argument that Segal discloses more than 800 million compositions, rather than the much smaller genus of 54 compositions identified in the Petition. *Compare* Dec. at 13 *with* Pet. 17-19. As explained above, controlling precedent required consideration of all of the disclosed preferences in Segal, both in the specification and in the claims. In view of the preferences taught by Segal, the Decision erred by not finding that Segal discloses merely 54 readily envisioned compositions (an even smaller genus than the 69 disclosed compositions found to anticipate in *Wrigley*), and therefore finding a reasonable likelihood that Segal anticipates claims 1 and 25.

As described in the Petition, Segal discloses nasal formulations comprising a therapeutically effective amount of a topical anti-inflammatory agent and a therapeutically effective amount of at least one agent suitable for topical nasal administration. Pet. 15, 19-20 (quoting Ex. 1012 at 2:10-15, 3:29-4:5). Thus, Segal's nasal compositions require a topical

anti-inflammatory agent, and (as argued in the Petition at 17) Segal expressly discloses only six preferred topical anti-inflammatory agents in the specification at 2:23-26 (cited at both page 17 and pages 19-20 of the Petition). Petitioner's claim chart expressly quotes this passage in its entirety on pp. 19-20 of the Petition. The same preference is also shown in claim 2 of Segal, which was likewise cited in the Petition. *Id.* at 17, 19-20. The Decision legally erred in not constraining its anticipation analysis to this more limited genus of anti-inflammatory agents. *Merck*, 874 F.2d at 808.

It was further legal error for the Decision to overlook the preference expressed in Segal for nine antihistamines. As described and cited in the Petition at pages 17, 19 and 20, Segal discloses nine anti-histamines as being suitable for the combination with the anti-inflammatory (Segal at 3:19-20). Petitioner's claim charts quote this disclosure in full (Pet. 19), with underlining added to highlight that azelastine is one of the specifically-identified nine anti-histamines. These same anti-histamines, including azelastine, are also taught as preferred embodiments in claim 4, which, per *Schaumann*, should also be considered a teaching of a preferred genus of antihistamines limited to the specifically-enumerated compounds. *Schaumann* at 316-17.

With respect to the alleged more than 800 million combinations of anti-inflammatory and at least one therapeutic agent, the Decision misapprehends Segal's disclosure regarding the vastly more limited numbers of combinations disclosed. As quoted on pages 16, 19, and 20 of the Petition, Segal discloses that the *at least* one agent to be combined with the anti-inflammatory may be selected from eight classes of therapeutic agents. Thus, each combination of anti-inflammatory with a class of therapeutic agent would be understood by a POSA to have been disclosed, just as in *Wrigley* where each combination of the required ingredients with optional ingredients (*e.g.*, flavorants and coolants) was considered disclosed. *Wrigley* at 1360. Hence, Segal expressly discloses the specific combination of an anti-inflammatory agent with an anti-histamine agent. Since this combination is expressly disclosed and thus constitutes a more limited genus, the additional combinations involving the other seven classes of therapeutic agent are not relevant per *Wrigley*. Further, given that both claims 2 and 4 depend from claim 1, which again discloses the combination of an anti-inflammatory agent and an antihistamine, and the teachings of the specification reinforce this linkage, there is no basis in law or logic for why a POSA wouldn't readily envision a subset of 54 distinct combinations when reading claims 1, 2 and 4. *Schaumann* at 316-17 (finding a very limited number of compounds disclosed

when claim 1 of prior art patent was read in conjunction with its specification).

Segal's identification of preferred compounds for the topical anti-inflammatory and therapeutic agents is exactly the type of preference found in *Petering* and *Wrigley* as being sufficient to describe a more limited genus of compounds and compositions to a POSA. *Petering* at 681-82; *Wrigley* at 1361-62. Under a § 102 anticipation analysis, it is these more limited genus groups that must be considered. *Merck*, 874 F.2d at 808. Because the Decision failed to take into account the expressly taught preferences in Segal (from both the specification and the claims), it was an abuse of discretion to not find that Segal discloses a more limited genus of six preferred anti-inflammatory compounds, and a more limited genus of nine preferred antihistamine compounds, resulting in 54 total combinations to be analyzed against the claims at issue.

In sum, given Segal's disclosure of the combination of an anti-inflammatory agent and an anti-histamine agent, and its express identification of a preferred genus of 9 anti-inflammatory agents and 6 anti-histamine agents that encompass the agents at issue in the '620 patent, *Wrigley*, *Petering*, *Schaumann*, and *Merck* all require that these more limited groups form the starting point for an anticipation analysis under § 102, and

strongly suggest that a POSA would view the six preferred anti-inflammatory agents with the nine suitable anti-histamines to define a limited and readily-envisioned class of compositions having 54 members. The combination of fluticasone propionate and azelastine is undeniably one of those 54 compositions. Because Segal also enables such a combination as a nasal composition, for the reasons set forth in the Petition (Pet. 17-18), the Board should find a reasonable likelihood that claims 1 and 25 will be found anticipated by Segal.

For the foregoing reasons, Petitioner asks the Board to reconsider its Decision as to anticipation by Segal, and institute Trial on Ground 1 of the Petition.

Respectfully submitted,

Dated: September 5, 2017

By: /Michael R. Houston/

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Counsel for Petitioner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing
PETITIONER'S REQUEST FOR REHEARING PURSUANT TO 37
C.F.R. § 42.71(d) was served on September 5, 2017, on Counsel for Patent
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