

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner,

v.

CIPLA LTD.,
Patent Owner.

Case IPR2017-00807
Patent 8,168,620 B2

Before JAMES T. MOORE, ZHENYU YANG, and
KRISTI L. R. SAWERT, *Administrative Patent Judges*.

SAWERT, *Administrative Patent Judge*.

DECISION
Denying Petitioner's Request for Rehearing
37 C.F.R. § 42.71(d)

I. INTRODUCTION

Argentum Pharmaceuticals LLC (“Petitioner”) filed a Petition for an *inter partes* review of claims 1, 4–6, 24–26, 29, and 42–44 of U.S. Patent No. 8,168,620 B2 (“the ’620 patent,” Ex. 1001). Paper 2 (“Pet.”). The Board instituted an *inter partes* review of claims 1, 4–6, 24–26, 29, and 42–44 on the ground of obviousness over Hettche,¹ Phillips,² and Segal,³ and on the ground of obviousness over Hettche, Phillips, Segal, and the Flonase Label.⁴ Paper 11 (“Instit. Dec.”), 27. The Board declined to institute an *inter partes* review of claims 1 and 25 on Petitioner’s proposed ground of anticipation by Segal. *Id.* at 14. Petitioner now files a Request for Rehearing on that ground. Paper 13 (“Rehearing Request” or “Reh’g Req.”). For the following reasons, we deny Petitioner’s Rehearing Request.

II. STANDARD OF REVIEW

A party requesting rehearing bears the burden of showing that a decision should be modified. 37 C.F.R. § 42.71(d). The party must identify all matters it believes the Board misapprehended or overlooked, and the place where each matter was addressed previously in a motion, an opposition, or a reply. *Id.* When rehearing a decision on petition, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of

¹ Helmut Hettche, U.S. Patent No. 5,164,194 (Nov. 17, 1992) (“Hettche”). Ex. 1007.

² Gordon H. Philipps, et al., U.S. Patent No. 4,335,121 (Jun. 15, 1982) (“Philipps”). Ex. 1009.

³ Catherine A. Segal, Int’l Publication No. WO 98/48839 (Nov. 5, 1998) (“Segal”). Ex. 1012.

⁴ FLONASE® (fluticasone propionate) Nasal Spray, 50 mcg Product Information (Dec. 1998) (“Flonase Label”). Ex. 1010.

discretion occurs when a “decision was based on an erroneous conclusion of law or clearly erroneous factual findings, or . . . a clear error of judgment.” *PPG Indus. Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988) (citations omitted).

III. DISCUSSION

Petitioner requests rehearing the decision declining to institute review on the ground of anticipation by Segal. Petitioner contends that the Board misapplied the applicable law and misapprehended the prior art in finding that Segal “literally discloses more than 800 million combinations within its broad genus,” rather than the 54 combinations cited in the Petition. Reh’g Req. 1 (quoting Instit. Dec. 13). In particular, Petitioner asserts that the Board’s finding “disregard[s] the express preferences set forth in Segal’s specification” and ignores the “preferred embodiments” identified in Segal’s claims. *Id.* at 1–2. Petitioner also asserts that this finding led the Board to incorrectly determine that Segal does not anticipate the challenged claims. *Id.* at 2.

A. The Scope of Segal’s Disclosure

In declining institution of an *inter partes* review of claims 1 and 25 over Segal, the Board found that Petitioner had not shown sufficiently, for the purpose of institution, that an ordinarily skilled artisan would immediately envision from Segal’s disclosure the combination of fluticasone propionate and azelastine, as recited in the challenged claims. Instit. Dec. 11. Specifically, the Board was not persuaded by Petitioner’s assertion that Segal discloses the combination of fluticasone propionate and azelastine as one of “at most 54 discrete compositions.” *Id.* at 11–13 (citing Pet. 19).

The Board explained that Petitioner arrived at the “54 discrete components” number by improperly multiplying the number of anti-inflammatory agents recited in claim 2 by the number of antihistamines recited in claim 4 (i.e., $6 \times 9 = 54$). *Id.* at 13. The Board was not persuaded by this analysis, in part, because claim 4 of Segal depends from claim 1, instead of claim 2. *Id.*

In its Request for Rehearing, Petitioner asserts that Segal does, in fact, disclose a “small[] genus of 54 compositions.” Reh’g Req. 7. Petitioner points out that Segal discloses 6 preferred topical anti-inflammatory agents, of which fluticasone propionate is one. *Id.* at 8 (citing Ex. 1012, 2:23–26, 5 (claim 2)). Petitioner also points out that Segal identifies azelastine as one of 9 preferred antihistamines. *Id.* (citing Ex. 1012, 3:19–20, 5 (claim 4)). Petitioner contends that the Board “erred by not finding that Segal discloses merely 54 readily envisioned compositions.” *Id.* at 7.

We remain unpersuaded that Segal discloses a limited genus of “at most 54” compositions, Pet. 19, such that the claimed composition would be immediately envisioned by an ordinarily skilled artisan. Although Segal discloses 6 topical anti-inflammatory agents and 9 antihistamines, Segal also discloses 4 vasoconstrictors, 3 antiallergic agents, 1 anticholinergic agent, 3 anesthetics, 3 mucolytic agents, 3 leukotriene inhibitors, and 1 neuraminidase inhibitor. *See* Instit. Dec. 11–12 (citing Ex. 1012, 2:23–26, 3:3–9, 5 (claims 1 and 2)). Petitioner fails to explain persuasively how Segal expresses a preference for the particular combination of a topical anti-inflammatory agent and an antihistamine over the other possible combinations encompassed in Segal’s broad disclosure. *See In re Petering*, 301 F.2d 676, 681 (CCPA 1962) (affirming finding of anticipation where

prior art set forth a “pattern of . . . specific preferences in connection with [a] generic formula” so as to “constitute[] a description of a definite and limited class of compounds”). Thus, we are not persuaded that Segal discloses “merely 54 readily envisioned compositions,” as Petitioner contends. Reh’g Req. 7.

Also in its Request for Rehearing, Petitioner alleges that the Board erred by failing to consider Segal’s disclosure of 6 preferred anti-inflammatory agents and 9 antihistamines as a “*starting point* for an anticipation analysis under § 102.” Reh’g Req. 10 (emphasis added). We are not persuaded that the Board erred, because that “starting point” is in our view likely the product of hindsight. *See In re Ruschig*, 343 F.2d 965, 974 (CCPA 1965) (criticizing “the mechanistic dissection and recombination of the components of the specific illustrative compounds in every chemical reference containing them, to create hindsight anticipations with the guidance of an applicant’s disclosures”).

Specifically, the Petition highlighted claims 2 and 4 of Segal to create a genus of “at most 54” compositions encompassing the combination of fluticasone propionate and azelastine, Pet. 18–19, but did not address all other compositions recited in Segal’s other claims, i.e., claim 3 (four vasoconstrictors), claim 5 (three antiallergic agents), claim 6 (one anticholinergic agent), claim 7 (three anesthetics), claim 8 (three mucolytic agents), claim 9 (three leukotriene inhibitors), and claim 10 (one neuraminidase inhibitor). Ex. 1012, 5–6. Petitioner did not adequately explain in the Petition why those compositions should be disregarded.

Finally, we are unpersuaded that the Board “incorrectly credited Patent Owner’s argument that Segal discloses more than 800 million compositions,” Reh’g Req. 7, because this argument fails to take into consideration Segal’s description of the therapeutic agents. As explained in the Institution Decision, Segal consistently describes the disclosed nasal compositions as comprising an anti-inflammatory agent and “at least one” additional therapeutic agent. Instit. Dec. 13 (citing Ex. 1012, 2:12, 2:19, 3:3, 3:5, 3:30, 4:16, 5 (claim 1)). Given that description, the Board agreed with Patent Owner that the potential combinations in Segal could result in more than 800 million possible compositions. *Id.* (citing Prelim. Resp. 21 & n.4). Regardless, Petitioner does not show persuasively that that the genus of compositions is “at most 54,” as set forth in the Petition. Pet. 19. We therefore are unpersuaded the Board overlooked or misapprehended any fact or argument in the Institution Decision.

B. The Case Law Does Not Compel a Different Outcome

We now turn to Petitioner’s argument that the Board misapplied the applicable law of *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356 (Fed. Cir. 2012), *In re Schaumann*, 572 F.2d 312 (CCPA 1978), and *In re Petering*, 301 F.2d 676 (CCPA 1962), in the Institution Decision. Reh’g Req. 1–6. Petitioner asserts that these cases require the Board to use Segal’s disclosure of 6 preferred anti-inflammatory agents and 9 antihistamines as a “starting point for conducting” an anticipation analysis, and that the Board erred in not doing so. *Id.* at 2. In particular, Petitioner first cites to *Petering* and *Schaumann* 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.” Reh’g Req. 2–3. Petitioner then cites to *Wrigley* for the proposition that “a reference’s disclosure of other optional ingredients is immaterial to the § 102 analysis . . . where such optional ingredients are not implicated or precluded by the claim being analyzed.” *Id.* at 6. We disagree that these cases compel a different outcome for the fact pattern presented here.

In *Petering* and *Schaumann*, the Court of Customs and Patent Appeals found that the prior art disclosed a pattern of preferences that narrowed the scope of a broadly disclosed generic formula to a limited class of compounds, thus anticipating claims covering specific chemical compounds. In *Schaumann*, the prior-art reference disclosed a class of B-(meta-hydroxyphenyl)-isopropylamines having a general formula with a single variable substituent “R” in its specification. 572 F.2d at 314. The prior-art reference narrowed that broad class of compounds by expressly setting forth in claim 1 a limited genus of isopropylamine compounds having “lower alkyl radicals” as the “R” substituent. *Id.* The specification listed, in the definition of “alkyl radical,” an ethyl group. *Id.* The CCPA thus found that claim 1 “expresses a preference for lower alkyl secondary amines.” *Id.*

Because claim 1 “embraces a very limited number of compounds closely related to one another in structure,” the court explained, “we are led inevitably to the conclusion that the reference provides a description of those compounds just as surely as if they were identified in the reference by name.” *Id.* at 316–17. The court in *Petering* found a similar disclosure of “specific preferences” that limited the prior-art reference’s “broad generic

disclosure” to a “definite and limited class” of approximately 20 compounds. 301 F.2d at 681–82.

Here, however, Petitioner has failed to show persuasively a similar “pattern of preferences” that inevitably leads the ordinarily skilled artisan to a limited class of compositions encompassing the specific combination of fluticasone propionate and azelastine. Claim 1 here—unlike claim 1 in *Schaumann*—encompasses a large number of drug combinations, and Petitioner has not alleged that these drug combinations share closely related chemical structures. Instit. Dec. 13. Petitioner’s assertions otherwise notwithstanding⁵, claim 4 does not in our view narrow that broad genus into “at most 54” compositions. Although claim 4 lists certain antihistamines, it does not limit the “at least one” therapeutic agent recited in claim 1 to an antihistamine, nor does it express a “preference” for antihistamines over other therapeutic agents suitable for topical nasal administration. *See* Ex. 1012, 5 (claims 1 and 4).

Moreover, the “pattern of preferences” in *Petering* and *Schaumann* instructed the skilled artisan to narrow a large, generically described genus of compounds to a limited, specific set of preferred compounds. *See Petering*, 301 F.2d at 681 (stating that the prior art “discloses certain specific preferences . . . through [its] preferred R groups and [its] eight specific isoalloxazines”); *Schaumann*, 572 F.2d at 316–17. Petitioner does not direct us to similar disclosure in Segal that—through the expression of preferences—specifically narrows the broad genus of a topical anti-

⁵ Reh’g Req. 4.

inflammatory agent in combination with at least one therapeutic agent to a preferred class of compositions encompassing fluticasone and azelastine.

Finally, Petitioner alleges that, in *Wrigley*, the Court of Appeals for the Federal Circuit found that the prior art anticipated a chewing gum composition comprising the combination of menthol and WS-23, even though the prior art disclosed an untold “number of combinations that the other disclosed optional ingredients could hypothetically be used to create.” *Id.* at 5–6 (citing *Wrigley*, 683 F.3d at 1360, 1362). Thus, Petitioner alleges, “the [Institution] Decision’s reliance on Patent Owner’s argument that Segal discloses more than 800 million combinations does not comport with *Wrigley*—because the claims here do not exclude any of the other optional ingredients identified in Segal.” Reh’g Req. 6 (citation omitted).

Even if we read claim 1 as limited to an anti-inflammatory agent and only one therapeutic agent suitable for topical nasal administration, Petitioner’s calculation of “at most 54 discrete compositions” still underrepresents the total number of compositions encompassed by Segal’s disclosure. Accordingly, we are unpersuaded that the Board misapprehended or overlooked any fact or argument made in the Petition.

C. Summary

In summary, we are unpersuaded that Petitioner’s arguments, as set forth in the Petition, satisfied Petitioner’s burden to show that an ordinarily skilled artisan would readily envision the combination of fluticasone propionate and azelastine from Segal’s disclosure. None of the arguments Petitioner presents in the Request for Rehearing persuade us that the Board misapplied the applicable law or misapprehended the prior art.

IV. ORDER

Accordingly, it is
ORDERED that Petitioner's Rehearing Request is denied.

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