

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 Patent Owner'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 Phillipps,² and Segal,³ and on the ground of obviousness over Hettche, Phillipps, 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. Patent Owner now files a Request for Rehearing of both obviousness grounds. Paper 15 (“Rehearing Request” or “Reh’g Req.”). For the following reasons, we deny Patent Owner’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 the party 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

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

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

the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of 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

Patent Owner requests rehearing on the ground of obviousness over Hettche, Phillipps, and Segal, and on the ground of obviousness over Hettche, Phillipps, Segal, and the Flonase Label. Patent Owner contends that the Board’s Institution Decision “misapprehended or overlooked key evidence and arguments” Patent Owner presented in its Preliminary Response. Reh’g Req. 2.

In the Institution Decision, the Board determined that “no claim term requires express interpretation for purposes of this Decision.” Instit. Dec. 7. In its Rehearing Request, Patent Owner argues that the Board “misapprehended or overlooked the importance of construing the terms ‘nasal spray’ and ‘suitable for nasal administration’” found in all the challenged claims. Reh’g Req. 2. In particular, Patent Owner asserts that those terms mean “pharmaceutical formulations that are tolerable to patients, homogeneous, and can be suitably deposited onto the nasal mucosa.” *Id.* (citing Paper 7, Preliminary Response (“Prelim. Resp.”), 9). Patent Owner alleges that, had the Board construed “nasal spray” and “suitable for nasal administration,” then the Board would have denied the obviousness grounds because “none of the combinations of cited art teach a person of ordinary skill in the art how to make the claimed fixed-dose combination ‘nasal

spray’ or formulation ‘suitable for nasal administration’ with a reasonable expectation of success.” *Id.* at 2–3 (citing Prelim. Resp. 9).

We are not persuaded that the Board abused its discretion by declining to expressly interpret “nasal spray” and “suitable for nasal administration” in the Institution Decision. As the Board explained in the Institution Decision, Petitioner showed sufficiently for the purpose of institution that the prior art teaches pharmaceutical compositions in the form of nasal sprays. Instit. Dec. 14. Specifically, the Board found that the prior-art references explicitly teach nasal sprays that are administered nasally. *See id.* (citing Ex. 1007 (Hettche), 1:28–30, 2:12–17, 41–43), 15 (citing Ex. 1009 (Phillips), 32:57–60, 33:12–14). Patent Owner does not allege its proposed construction of “nasal spray” and “suitable for nasal administration” is different from the plain and ordinary meaning of those terms to an ordinarily skilled artisan. *Id.* at 4–6; *see also* Prelim. Resp. 9–11. As a consequence, we are not persuaded that the Board overlooked or misapprehended this matter or that the Board would have declined institution on the obviousness grounds had it explicitly adopted Patent Owner’s proposed interpretation.

Patent Owner also argues that the Board’s findings about the prior art are insufficient because the prior-art reference Cramer⁵ (and by extension, Segal) “does not teach a [person of ordinary skill in the art] how to make a ‘nasal spray’ that is ‘suitable for nasal administration.’” Reh’g Req. 7–8 (citing Prelim. Resp. 12–16, 40, 41–42). We understand Patent Owner’s contentions about known formulation difficulties and the “unacceptably high

⁵ Ronald Dean Cramer, European Patent (EP) Application No. 0,780,127 A1 (published June 25, 1997) (“Cramer”). Ex. 1011.

osmolality, poor spray quality, and unacceptable settling and caking” resulting from the attempted formulation of Cramer’s Example III. *Id.* at 8–10; *see also* Prelim. Resp. 25. The Board, however, addressed those issues in the Institution Decision and determined that “Patent Owner’s arguments and expert testimony highlight disputed issues of fact about whether the skilled artisan would have been motivated to combine the teachings of Hettche, Phillipps, and Segal to arrive at the claimed subject matter, and would have had a reasonable expectation of success.” Instit. Dec. at 20 (citing Ex. 1002, 268–87; Ex. 2007 ¶¶ 40–47; Ex. 2111, 1; Ex. 2044, 1–2). The Board concluded that those “issues are best resolved following trial with the benefit of a full record.” *Id.* We are still of that view. Accordingly, we are not persuaded that the Board misapprehended or overlooked the issue of reasonable expectation of success.

IV. ORDER

Accordingly, it is

ORDERED that Patent Owner’s Rehearing Request is denied.

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FOR PETITIONER:

Michael R. Houston
Joseph P. Meara
James P. McParland
FOLEY & LARDNER LLP
mhouston@foley.com
jmeara-pgp@foley.com
jmcparland@foley.com

Tyler C. Liu
ARGENTUM PHARMACEUTICALS LLC
tliu@agpharm.com

FOR PATENT OWNER:

Dennies Varughese
Deborah A. Sterling
Adam C. LaRock
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
dvarughe-PTAB@skgf.com
dsterlin-PTAB@skgf.com
alarock-PTAB@skgf.com