UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC

Petitioner

v.

CIPLA LIMITED

Patent Owner

Case No. IPR2017-00807

U.S. Patent No. 8,168,620

CIPLA LIMITED'S REQUEST FOR REHEARING PURSUANT TO 37 C.F.R. § 42.71(d)

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I. Introduction

Patent Owner Cipla Limited requests rehearing under 37 C.F.R. § 42.71(d) of the Board's Decision on Institution ("Decision," Paper 11). The Board correctly denied institution of Ground 1, finding the challenged claims novel over Segal. But the Board wrongly instituted trial on the obviousness grounds (Grounds 2 and 3). At least two statements in the Decision evince that, in doing so, the Board misapprehended or overlooked key evidence and arguments in Cipla's Preliminary Response that warranted denial of trial on Grounds 2 and 3. These statements are: (1) the Board's conclusion that "no claim terms require express interpretation for purposes of this Decision;" and (2) the Board's conclusion that "Patent Owner does not identify any particular claim limitation as not disclosed in the prior art." (Paper 11, 7, 16.)

The first statement shows that the Board misapprehended or overlooked the importance of construing the terms "nasal spray" and "suitable for nasal administration." As Cipla explained in its preliminary response, even under the "broadest reasonable interpretation" standard, the terms "nasal spray" and "suitable for nasal administration" must be construed to mean "pharmaceutical formulations that are tolerable to patients, homogeneous, and can be suitably deposited onto the nasal mucosa." (*See* Paper 7, 9.)

This construction is important because the preliminary response then

demonstrates that 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. This is because the Petition fails to show how Segal (even in combination with Hettche, Phillipps, and/or the Flonase® Label) teaches the composition that would provide for the claimed fixed-dose combination "nasal spray" formulation that is "suitable for nasal administration." (Paper 7, 12-16, 24-25, 41-42.) None of Hettche, Phillipps, nor the Flonase® Label describe formulations with *two* active ingredients, and Segal does not teach how to successfully make a combination formulation suitable for nasal administration.

Because the Board misapprehended or overlooked the relevance of Cipla's proposed claim construction to demonstrating this threshold failure in Argentum's Petition, the Board should grant Cipla's motion for rehearing and reverse its decision to institute trial on Grounds 2 and 3.

II. Legal Standard

"A party dissatisfied with a decision may file a request for rehearing, without prior authorization from the Board." 37 C.F.R. § 42.71(d). The "burden of showing a decision should be modified lies with the party challenging the decision," and the request "must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was

previously addressed in a motion, an opposition, or a reply." *Id.* When rehearing a decision on petition, the Board will review the decision for abuse of discretion. 37 C.F.R. § 42.71(c).

Cipla's request satisfies 37 C.F.R. § 42.71(d) and demonstrates that the Board abused its discretion by overlooking Cipla's proposed claim construction and evidence in Cipla's preliminary response that demonstrates how the Petition failed to show that the cited art taught critical claim elements—"nasal spray" and "suitable for nasal administration."

III. Argument

A. The Board misapprehended or overlooked the importance of the proper claim constructions of "nasal spray" and "suitable for nasal administration."

In its Decision, the Board determined that "no claim term requires express interpretation for purposes of this Decision." (Paper 11, 7.) In doing so, the Board misapprehended or overlooked that a key dispute between the parties is whether the combination of cited references in Grounds 2 and 3 disclose a "nasal spray" that is "suitable for nasal administration." This is important because these elements appear in *every* challenged claim, yet they are not found in the art.

As Cipla explained in its preliminary response, the broadest reasonable interpretation of "nasal spray" or a formulation "suitable for nasal administration" is "pharmaceutical formulations that are tolerable to patients, that are

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