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Paper 33
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS INC.,
Petitioner,

v.

POZEN INC.,
Patent Owner.

Case IPR2015-01773
Patent 8,858,996 B2

Before TONI R. SCHEINER, LORA M. GREEN, and JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

BONILLA, *Administrative Patent Judge*.

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

I. INTRODUCTION

In our Decision instituting an *inter partes* review in the current case, we determined that Petitioner had established a reasonable likelihood that it would prevail in showing the unpatentability of challenged claims 1 and 3–11, but not claims 2 and 12–19, of U.S. Patent No. 8,858,996 B2 (Ex. 1001, "the '996 patent"). Paper 15 ("Decision" or "Dec."). Thereafter, Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Petitioner") filed a Request for Rehearing (Paper 17, "Reh'g Req." or "Request") in relation to our Decision denying an *inter partes* review of claims 2 and 12–19 of the '996 patent.

We deny Petitioner's Request for Rehearing for the reasons set forth below.

II. STANDARD OF REVIEW

When reconsidering a decision on institution, the Board reviews the decision for an abuse of discretion. *See* 37 C.F.R. § 42.71(c). An abuse of discretion occurs 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. *See Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005); *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004); *In re Gartside*, 203 F.3d 1305, 1315–16 (Fed. Cir. 2000). "The burden of showing that a decision should be modified lies with the party challenging the decision." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,768 (Aug. 14, 2012). In its request for rehearing, the dissatisfied party

must, in relevant part, "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." 37 C.F.R. § 42.71(d); Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,768. We address Petitioner's arguments with these principles in mind.

III. ANALYSIS

The challenged claims are directed to tablet pharmaceutical compositions comprising two drugs, naproxen, a non-steroidal anti-inflammatory drug (NSAID), and esomeprazole, a proton pump inhibitor. In independent claim 1, "at least a portion of said esomeprazole is released regardless of the pH of the medium, and release of *at least a portion of said naproxen is inhibited unless* the pH of said medium is 3.5 or higher." Ex. 1001, 21:24–35 (emphasis added). In independent claim 12, a core layer comprising naproxen "has a coating that *inhibits* release of said naproxen from said core layer *unless* said dosage form is in a medium with a pH of 3.5 or higher," and a layer comprising esomeprazole that "has a non-enteric film coating that, upon ingestion by a patient, releases said esomeprazole into the stomach of said patient." *Id.* at 22:17–26 (emphasis added).

A. Claim Construction of "Inhibit"

In our Decision, we construed the term "inhibit" to mean prevent (stop), hinder, or restrain. Dec. 7–8 (citing Paper 14 ("Prelim. Resp.") 7–8 (citing Ex. 2012, 6; Ex. 2013, 1)). More specifically, we considered the

ordinary and customary meaning of the term in view of the specification and the claims themselves when we stated:

> For example, claim 1 of the '996 patent recites that "*release of at least a portion*" of naproxen "is *inhibited unless* the pH" is 3.5 or higher (emphasis added). Claim 12 recites a "coating that *inhibits release* of said naproxen from said core layer *unless* said dosage form is in a medium with a pH of 3.5 or higher" (emphasis added). Thus, "inhibit" refers to preventing, hindering, or restraining the release of naproxen "unless" the dosage form is exposed to a pH of 3.5 or higher. The use of "unless" in claim 1 and 12 and "at least a portion" in claim 1 indicates that the terms "inhibited" and "inhibits" in the claims do not encompass a "slowing down" of a release when the pH is below 3.5 (which would make "at least a portion" superfluous in claim 1), but rather refers to no release of "at least a portion" (claim 1) or all (claim 12) of the drug "unless" the dosage form is in a medium with a pH of 3.5 or higher.

Dec. 7–8. Thus, "inhibit" refers to preventing, hindering, or restraining the release of naproxen "unless" the dosage form is exposed to a pH of 3.5 or higher.

In its Request for Rehearing, Petitioner contends that we erred in our construction of "inhibit." According to Petitioner, the broadest ordinary and customary meaning of "inhibit" is "slow down," as Petitioner argued in its Petition. Reh'g Req. 4–7 (citing Pet. 11). Petitioner states that the specification of the '996 patent "teaches use of pH-sensitive enteric coatings to 'inhibit' release," and "Patent Owner itself admits such coatings were known to permit release of up to 10% of a coated drug material under low pH conditions." *Id.* at 5 (citing Prelim. Resp. 14). Referring to dictionary

definitions of record, Petitioner also argues that "inhibit" reasonably may be construed to mean "slow down," and not necessarily stop the release of naproxen. *Id.* at 5–6 (citing Ex. 2012, 6; Ex. 2013, 1).

Petitioner's position regarding alternative "ordinary" meanings of the term "inhibit" rehashes an argument it raised in the Petition, which we squarely address in our Decision. Dec. 7–8 (discussing Pet. 11). Although we considered "ordinary" meanings of the term, we also took into account how the term "inhibit" was used in the claims themselves. *Id.* As stated in our Decision, the "use of 'unless' in claim 1 and 12 and 'at least a portion' in claim 1 indicates that the terms 'inhibited' and 'inhibits' in the claims do not encompass a 'slowing down' of a release when the pH is below 3.5 (which would make 'at least a portion' superfluous in claim 1)." *Id.* at 8. Thus, the terms indicate that "inhibited" and "inhibits" refer to no release of "at least a portion" (claim 1) or all (claim 12) of the drug "unless" the dosage form is in a medium with a pH of 3.5 or higher. *Id.* Petitioner does not persuade us that we erred in our claim construction of "inhibit."

B. Ground Based on WO '185 (Ex. 1015)

In our Decision, we did not institute an *inter partes* review of dependent claim 2, independent claim 12, or its dependent claims 13–19 of the '996 patent. Dec. 39. Among other reasons, we were not persuaded that Petitioner had established a reasonable likelihood of prevailing on the ground that those claims would have been obvious over the '225 patent

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