

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHARMACOSMOS A/S,
Petitioner,

v.

LUITPOLD PHARMACEUTICALS, INC.,
Patent Owner.

IPR2015-01490; Patent 7,754,702 B2

**PETITIONER'S SUR-REPLY RESPONDING TO PATENT OWNER'S
REPLY TO OPPOSITION TO MOTION TO AMEND**

Petitioner Pharmacosmos A/S (“Petitioner”) hereby submits its sur-reply to Patent Owner’s Reply to Opposition to Motion to Amend (Paper 40) (“Reply”) served on July 19, 2016. Petitioner submits this sur-reply to address an issue that was raised by Patent Owner for the first time in its Reply, rather than in its original Motion to Amend as it should have been.

Patent Owner’s proposed substitute claims contain no limitation that restricts the species of subject being treated, encompassing “mouse to elephant,” so that the Patent Owner is required to demonstrate the support (enablement) and patentability of the proposed substitute claims over veterinary prior art. Opposition (Paper 34) at 6-7. Patent Owner newly argues that the specification of the ‘702 patent “is clear that the ‘subject’ is ‘human’” and that a “POSITA would understand that ‘subject’ only refers to a human.”” Reply (Paper 40) at 3-5. Petitioner disagrees.

Patent Owner’s contention that the use of the term “subject” in the claims necessarily refers to a human is incorrect as a matter of law because it improperly attempts to import a limitation from the specification into the claims. *See Novartis AG v. Mylan Pharms., Inc.*, No. 09-CV-3604 PGS, 2011 WL 3664401, at *7 (D.N.J. Aug. 17, 2011) (“[I]t is important not to import into a claim limitations that are not a part of the claim.” (citation omitted)); *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (“Even when the specification describes only a single embodiment, the claims of the patent will not be read

restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using ‘words or expressions of manifest exclusion or restriction.’” (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002))).

Contrary to the Patent Owner’s contention, the specification of the ‘702 patent does not limit the term “subject” to humans, and discloses: “treating a state, disease, disorder, or condition includes preventing or delaying the appearance of clinical symptoms in a *mammal* that may be afflicted” Ex. 1001 at 6:5-10 (emphasis added).

Therefore, the claim term “subject” is not restricted to humans, should be deemed unenabled, and Patent Owner has not met its burden of proving patentability over the art, which includes veterinary art.

Respectfully submitted,

BAKER BOTTS L.L.P.

July 29, 2016

Date

/s/ Lisa Koie

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**CERTIFICATE OF SERVICE ON PATENT OWNER
UNDER 37 C.F.R. § 42.105(a)**

The undersigned hereby certifies that the foregoing PETITIONER'S SUR-REPLY RESPONDING TO PATENT OWNER'S REPLY TO OPPOSITION TO MOTION TO AMEND is being served on July 29, 2016 by filing through the Patent Review Processing System and delivering a copy via email to the counsel for Patent Owner at the addresses of record:

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Respectfully submitted

Dated: July 29, 2016

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