Filed on behalf of: Mallinckrodt Hosp. Prods. IP Ltd.

Entered: February 10, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRAXAIR DISTRIBUTION, INC.
Petitioner

v.

MALLINCKRODT HOSPITAL PRODUCTS IP LTD.,
Patent Owner

Case IPR2015-00529
U.S. Patent No. 8,846,112 B2

Before LORA M. GREEN, TINA E. HULSE, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

PATENT OWNER'S SUR-REPLY TO PRAXAIR DISTRIBUTION, INC.'S PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,846,112

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I. INTRODUCTION[1]

Petitioner's arguments assume that claims 1-11 of the '112 Patent are directed only to the provision of prior art nitric oxide gas. They are not; the claimed methods require providing pharmaceutically acceptable nitric oxide gas, along with critical information to effectuate new *methods of using* the drug—a safer treatment that helps avoid serious adverse events in at-risk patient populations. As set forth in the specification, these new methods would not exist without the claimed information. The providing information claim element is entitled to patentable weight because it is inextricably intertwined with the implementation—and function—of the claimed methods. The Board should affirm the claims' validity.

II. THE CONSTRUCTION OF "PHARMACEUTICALLY ACCEPTABLE NITRIC OXIDE GAS" IS UNDISPUTED

Petitioner neither disputes Patent Owner's construction of "pharmaceutically acceptable nitric oxide gas" nor proposes an alternative. The *only* expert testimony comes from Patent Owner's expert. (*See* Ex. 2020 at 30-31; Ex. 1057 at 64:4-21.) The Board should adopt Patent Owner's uncontested construction: "suitably safe

[1] Patent Owner sought, and was granted, leave to file a 10 page sur-reply to respond to arguments first raised in Petitioner's Reply.

for pharmaceutical use." (*See* Resp. at 21-23.)[2,3]

III. THE "PROVIDING . . . INFORMATION" ELEMENTS OF CLAIMS 1-11 ARE ENTITLED TO PATENTABLE WEIGHT

Petitioner contends that the "providing . . . information" elements cannot be functionally related to the claimed methods for two reasons: (1) per *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042 (Fed. Cir. 2010), "instructions for use do not create a new or unobvious *drug* or change the *drug's ability* to treat [a disease]"; and (2) per *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267 (Fed. Cir. 2010), "[i]nformation regarding how to *administer* [a pharmaceutically acceptable drug] does not change the *method of obtaining and supplying that* [*drug*]." (Reply at 8,

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[2] Petitioner's suggestion that the "preamble is not limiting," (Reply at 6 n.3), is wrong; Patent Owner relied on the preamble to overcome prior art and it is therefore limiting as a matter of law. (*See* Resp. at 19-20.)

[3] Petitioner's suggestion that this construction may be impermissible because it could "var[y] over time" (Reply at 6-7 n.4) is incorrect. *See Mass. Inst. of Tech. & Elecs. for Imaging, Inc. v. Abacus Software*, 462 F.3d 1344, 1353 (Fed. Cir. 2006) (meaning of claim terms set at time of filing). Such terms are common. *See, e.g.*, *Apotex Inc. v. Alcon Pharm., Ltd.*, No. IPR2013-00012, 2013 WL 5970130, at *4 (P.T.A.B. Mar. 19, 2013) (defining "pharmaceutically acceptable vehicle" to include composition that can be "safely" used).

10.)[4] Neither point has merit.

A. *AstraZeneca* Is Inapposite

Petitioner's reliance on *AstraZeneca* is misplaced. There, the Federal Circuit found instructions contained in an FDA-required label to be functionally unrelated to a *claimed drug product*, 633 F.3d at 1048, 1063, reasoning that "[t]he instructions in no way function with the drug to create a new, unobvious *product*," because "[r]emoving the instructions from the claimed kit does not change the *ability of the drug* to treat respiratory diseases." *Id*. at 1065. Petitioner's argument parrots this language, but ignores the claims at issue here: "Patent Owner's revised instructions for use do not create a new or unobvious *drug* or change the *drug's ability to treat* hypoxic respiratory failure." (Reply at 8.)[5]

[4] All emphases are added unless indicated otherwise.

[5] *AstraZeneca* did not hold printed instruction for a drug to be *per se* unpatentable; it merely found that the required functional relationship was absent. All limitations of a claim, including printed matter, must be considered—"the board cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable." *In re Gulack*, 703 F.2d 1381, 1385 & n.8 (Fed. Cir. 1983) (explaining that its predecessor court grew "notably weary of reiterating th[e] point . . . that printed matter may well constitute structural limitations upon which patentability can be predicated.").

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