

Paper No. _____
Filed: _____

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATORIES LIMITED,
Petitioner,

v.

AVENTIS PHARMA SA,
Patent Owner.

IPR2016-00712

Patent No. 8,927,592

**PETITIONER'S OPPOSITION TO PATENT OWNER'S
MOTION TO AMEND UNDER 37 C.F.R. § 42.121**

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I. OVERVIEW OF WHY AVENTIS'S MOTION SHOULD BE DENIED

Petitioner opposes Aventis Pharma S.A.'s ("Aventis") Contingent Motion to Amend (Paper 22 ("Mot.")). Aventis fails to meet its burden to show it is entitled to amended claims. 37 C.F.R. § 42.20(e)); *Synopsys, Inc. v. Mentor Graphics Corp.*, 814 F.3d 1309, 1323 (Fed. Cir. 2016). Neither the proposed amendment of the preamble nor the prior art pretreatment regimen render the proposed amended claims patentable. Accordingly, Aventis's Motion should be *denied*.

II. AVENTIS'S VARYING CLAIM CONSTRUCTIONS

Aventis may propose only one substitute claim for each canceled claim unless Aventis demonstrates good cause for multiplicative substitutions. 37 C.F.R. §42.121(a)(3), (c); *Idle Free Sys., Inc. v. Bergstrom, Inc.*, Case IPR2012-00027, Paper 26 at 11 ("Idle Free"). Aventis acknowledges this limit (Mot., 1), but functionally ignores it by providing at least four different preamble meanings:

Reflecting a purpose of the treatment:

- "A method *of* increasing survival...." [Appendix 1]
- "a method *for* increasing the survival of a patient in need thereof" [3]
- "[T]he preamble is a statement of intentional purpose" [7]

Requiring a particular result in an individual patient:

- "method that prolongs the life of a *patient* as compared to no treatment...." [8].
- "prior art must teach...method increases the survival of a *patient*." [10-11].

Requiring knowledge of statistical population data:

- "No Prior Art Disclosed...Cabazitaxel...Would Increase *Overall Survival*." [10]
- "*clinical study with sufficient [statistical] power* was necessary...." [13].

- Drug must “increase overall survival in a *phase III*...study.” [14-15].

Requiring FDA approval:

- Drug must “succeed[] in phase III...study *and receiv[e] approval*. [15].

This strategy attempts to draft ambiguity into the claims to further Aventis’s strategy of asserting that present-day performance of the Winquist/TROPIC Listing regimen infringes the claims while arguing that prior art disclosure of the same regimen fails to invalidate the claims. The Board should hold Aventis to proving the proposed claims, as drafted and under their broadest reasonable interpretation, are patentable.

III. CLAIM CONSTRUCTION

In a motion to amend, a Patent Owner must ensure that the metes and bounds of the proposed claims are clearly set forth. *Idle Free* at 7. The Board interprets unexpired claims using the “broadest reasonable construction in light of the specification of the patent in which [they] appear[.]” 37 C.F.R. § 42.100(b); *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131, 2134-35 (2016).

A. Claim 31: “administering to a patient in need thereof”

The Board already construed “a method of increasing the survival of a patient” as “a non-limiting statement of the purpose of the claimed method.” Paper 9 at 10. This same construction should be applied to the language “a method of increasing survival.” EX1043, ¶40. The Board should adopt the plain meaning: “thereof” refers to the elements of the “administering” step that surround it as opposed to the preamble that is more distant. Thus, the plain meaning of the phrase “administering to a patient in need thereof (i) [A], (ii) [B], (iii) [C], and [D]”

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