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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATORIES LIMITED
Petitioner,
v.
AVENTIS PHARMA S.A.
Patent Owner.

Case IPR2016-00712
U.S. Patent No. 8,927,592

PATENT OWNER'S RESPONSIVE BRIEF ON THE EFFECT OF THE CAFC DECISION ON PATENT OWNER'S MOTION TO AMEND

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

I. Introduction

Under the proper claim construction and burden of persuasion, there can be little dispute that the proposed claims were not obvious. Petitioner's expert Dr. Seth admitted that the TROPIC study was performed to determine ultimately whether cabazitaxel and prednisone increased survival over the standard of care and that a person of ordinary skill in the art ("POSA") would have merely "hoped" at the time that the TROPIC study would be successful. The mere fact that the TROPIC study was ongoing would not have provided a reasonable expectation that the cabazitaxel therapy would increase survival in patients with docetaxel-resistant mCRPC ("DRmCRPC"), particularly in light of the minimal data regarding cabazitaxel (none regarding survival) and the numerous failures of other prostate cancer therapies, which despite having anti-cancer activity, did not increase survival in patients with mCRPC. As to proposed Claim 34, Petitioner's expert testified that a POSA at the time would not have even thought of administering a dose of 20 mg/m^2 to a patient with DRmCRPC. Thus a POSA could not have had a reasonable expectation that such a dose would prolong patients' lives.

Petitioner's argument that the premedication limitations of the proposed claims were obvious rests largely on Petitioner's mischaracterizations of expert testimony, unsupported conclusions about the prior art, and incorrect legal theories. Petitioner fails to credibly explain why a POSA would have been motivated to

employ a more complicated premedication regimen for cabazitaxel (three drugs) as compared to docetaxel (dexamethasone alone), and thereby forego the "significant administration and convenience advantages" of avoiding it. In fact, both parties' ***experts*** testified that when it comes to hypersensitivity reactions ("HSRs") they "err on the side of caution," yet would still not have been motivated to use the claimed three-component premedication regimen prior to knowing the results and full protocol of the TROPIC study. Because the evidence shows that the same would be true for a ***POSA***, the proposed method claims would not have been obvious.

II. Petitioner Must Prove That a POSA Would Have Had a Motivation to Practice the Claimed Invention with a Reasonable Expectation of Increased Survival

Contrary to the Federal Circuit's holding that the preamble of Claim 31 is limiting (C.A. No. 18-1203, D.I. 63 ("Slip Op.") at 8), Petitioner continues to assert that it need not establish that a POSA would have reasonably expected increased survival with the claimed methods. In doing so, Petitioner reverts to its strawman argument that the proposed claims "do not require survival data, a successful trial, or FDA approval" (Paper 109 ("Br.") at 18), a standard that Patent Owner has never

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