UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and AMNEAL PHARMACEUTICALS LLC,
Petitioner

v.

YEDA RESEARCH & DEVELOPMENT CO. LTD.,
Patent Owner

Case No. IPR2015-00644
Patent 8,399,413

PATENT OWNER'S REQUEST FOR REHEARING

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I. SUMMARY OF ISSUES FOR REHEARING

Patent Owner Yeda Research and Development Co. Ltd. ("Yeda" or "Patent Owner") requests rehearing under 37 C.F.R. § 42.71(d) of the Board's Final Written Decision ("FWD") holding that claims 1-20 of U.S. Patent No. 8,399,413 ("the '413 patent") are unpatentable. Rehearing is appropriate in this case because the Board misapprehended or overlooked evidence in the prior art teaching that less frequent dosing of 40 mg of glatiramer acetate ("GA") would lead to more injection related adverse events. Thus, the Board's rulings on patentability should be revisited.

In its decision, the Board found that the treatment regimens claimed in the '413 patent are obvious over the prior art. The claims of the '413 patent are directed to: (a) methods of reducing the frequency of relapses in a patient with multiple sclerosis with a regimen comprising three subcutaneous injections of a 40 mg dose of glatiramer acetate ("GA") over a period of seven days with at least one day between every subcutaneous injection (*see, e.g.* Claim 1); and (b) methods of reducing the frequency of relapses in a patient with multiple sclerosis with the above regimen, wherein the frequency of an immediate post injection reaction or the frequency of an injection site reaction is reduced relative to these reactions caused by 20 mg daily treatment of GA (*see* Claim 7). In rendering its decision, the Board found that a person of ordinary skill in the art would have been

motivated to develop a regimen of GA treatment to reduce side effects and thereby increase tolerability over the prior art GA regimens. (FWD at 12, 13, 15.) The Board also found that a person of skill at the time of the invention would have expected a 40 mg, three times per week dosing regimen to improve the tolerability of GA treatment through a reduction in the number of injection related adverse events such as injection site reactions and immediate post injection reactions. (FWD at 24.) The teaching of the prior art as a whole, however, does not support either of these findings.

Contrary to the Board's findings and Petitioner's "common sense" arguments that reducing frequency of injections would increase tolerability of treatment, the prior art as a whole taught that a less frequent dosing schedule with 40 mg of GA would decrease the tolerability of GA treatment. For example, the Board explicitly erred in its analysis of the Flechter prior art reference and the adverse event data therein. Data in the Flechter reference reflects that more frequent adverse events were observed in patients being administered a 20 mg every other day regimen compared to daily treatment. The Board rejected Patent Owner's evidence on this issue by pointing to the wrong data in Flechter, citing efficacy data on relapse rate rather than the data cited by Patent Owner's experts concerning the incidence of injection related adverse events. (FWD at 26.) The Board thus conflated the data regarding tolerability and efficacy. Analyzing this

data correctly makes clear that the teaching of the prior art as a whole did not identify a tolerability advantage with less frequent dosing of GA.

Moreover, the Board overlooked other important data in the prior art that suggested a 40 mg, three times per week regimen would result in worse tolerability than the 20 mg daily regimen. For instance, the Board's decision did not address tolerability data from the prior art Cohen reference, which reported that "features of injection site reactions and immediate postinjection reactions were more common and severe with the higher [40 mg] dose [of GA]." (emphasis added) (Ex. 1006 at Abstract.) Nor did the Board's decision address the finding from the FORTE study – the only statistically significant finding from that large Phase III study reported in the prior art – that a 40 mg dose of GA resulted in nearly double the rate of early treatment discontinuation due primarily to injection site reactions. (Ex. 2028 at 5.)

This data and the adverse event data from Flechter, when properly analyzed, make clear that the prior art as a whole would not have motivated a person of skill to pursue a 40 mg, three times per week regimen. Nor would the prior art have supported a reasonable expectation that such a regimen would result in improved tolerability. The Board's errors and omissions are particularly acute with respect to claim 7 that includes a limitation explicitly requiring an increase in tolerability as compared with the older GA regimen of daily subcutaneous injections of 20 mg.

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