UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC
Petitioner

v.

ALCON RESEARCH, LTD.
Patent Owner

Patent No. 8,268,299
Issue Date: September 18, 2012
Title: SELF PRESERVED AQUEOUS PHARMACEUTICAL COMPOSITIONS

Inter Partes Review No. IPR2017-01053

PETITIONER'S RESPONSE TO ALCON RESEARCH, LTD.'S MOTION FOR OBSERVATIONS ON THE DEPOSITION OF PETITIONER'S EXPERT DR. YVONNE M. BUYS, M.D.

Petitioner Argentum Pharmaceuticals LLC ("Petitioner") hereby responds to Alcon Research Ltd.'s motion for observations on the deposition of Petitioner's expert Dr. Yvonne M. Buys, M.D. (Paper 44, hereafter "Mot."). Office Patent Trial Practice Guide, 77 Fed. Reg. 48756 at 48767-68 (August 14, 2012).

Observation #1: Patent Owner's assertion that Dr. Buy's cited testimony undermines the premise of Petitioner's argument that surgery or laser treatments are suitable or equivalent options to medical therapy overlooks Dr. Buys' other relevant testimony. Dr. Buys pointed out statements in Exhibit 2129 teaching that laser treatments "can be considered as initial therapy in selected patients or an alternative for patients at high risk for nonadherence to medical therapy who cannot or will not use medications reliably due to cost, memory problems, difficulty with installation or intolerance to the medication." *See* EX2167, 11:6-12:9. Dr. Buys further testified that several large trials done prior to 2006 supported using laser treatments as the initial therapy because it can be superior to medical treatment in preserving visual fields and optic nerve status, and also in achieving lower intraocular pressures. *Id*., 13:7-13. Dr. Buys also testified that surgical and laser treatments achieve the dual goals of both lowering IOP and avoiding the exacerbation of OSD symptoms, and that surgical treatment options would not typically be expected to cause or exacerbate OSD symptoms because

successful procedures do not require ongoing medical management. EX1092, ¶11.[1]

Observation #2: Patent Owner's assertion that Dr. Buy's cited testimony undermines the premise of Petitioner's argument that single-use containers are just as desirable as multi-use containers both misapprehends Petitioner's argument and overlooks other relevant testimony. Both Dr. Buys and Patent Owner's expert, Dr. Majumdar, agree that any given PGA drug could easily have been formulated as preservative-free simply by packaging it in single-dose form. EX1092, ¶¶15, 17; EX2023, ¶45; EX1045, 107:12-108:9. Dr. Buys further testified that the only possible advantage of multi-use packaging versus single-use packaging was "ease of use." EX2167, 22:21-23. This testimony supports Petitioner's argument that any alleged "need" identified by Patent Owner was nonexistent or at most, quite modest. Paper 35 at 26.

Observation #3: Patent Owner's assertion that Dr. Buys' cited testimony contradicts Petitioner's argument is false. First, Petitioner pointed out that many of the claims at issue do not require a therapeutic agent at all (compare claims 1 and

[1] Dr. Buys pointed out that a mis-citation occurred in paragraphs 11 and 12 of her reply declaration, such that the cite to "ALCON2011, pp. 24-27" in paragraph 11 should be "Exhibit 2129, P70-P75," and the citation to "ALCON2011, pp. 22-23" should be to "Exhibit 2129, P68-P69." *See* EX2167, 59:5-61:17.

4), let alone an agent for glaucoma (compare claims 1 and 6). Paper 35 at 25. Second, both Dr. Buys and Patent Owner's expert, Dr. Majumdar, agree that any given PGA drug could easily have been formulated as preservative-free simply by packaging it in single-dose form, thereby meeting any need for a drug-treatment option not containing a traditional preservative. EX1092, ¶¶15, 17; EX2023, ¶45; EX1045, 107:12-108:9. Lastly, Dr. Buys testified that because Travatan Z has never been shown to reduce OSD symptoms and may in fact exacerbate such symptoms (*see* EX1092, ¶¶20-39), her current practice is to prescribe Monoprost, which contains the PGA drug latanoprost packaged in single-dose form such that no preservatives are present. EX2167, 35:23-36:14; EX1092, ¶16. This testimony does not contradict but instead supports Petitioner's argument that there was no unmet need for a preservative-free PGA treatment, and to the extent any such need did exist, Travatan Z did not meet it. EX1092, ¶¶18-19, 20-39; Paper 35 at 26-27.

Observation #4: Patent Owner's assertion that Dr. Buys' cited testimony contradicts Petitioner's argument is false. Regarding Exhibit 2132, Dr. Buys testified in her deposition that:

> **Answer:** I am not sure if we mentioned that specific result, but that -- what I was quoting in the declaration was the main purpose of this study was to look at the average OSDI scores for the entire population, and then they did several subanalyses; and I think there's close to 20 comparisons in this paper, of

which only 2 were favorable to show that BAK was -- to show that not using BAK or not having BAK in the medication was associated with a better result, whereas the majority of outcomes studied in this paper did not find any difference between Travatan, travoprost with or without BAK…. This is a swing, like they're kind of swinging the results to try to pull out the ones that had a positive response and ignoring the majority of them that did not show an effect.

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[T]he main outcome measure did not have a significant result; and the numerous other comparisons, for example just looking at mean change in the overall group and those with moderate and severe OSDI symptoms, did not show a significant difference between the groups.

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My point was to find that the paper was misleading as it is because it has so many results that did not show an effect, mind you the abstract conclusions tried to suggest that it was beneficial, where I don't think you can conclude this when you actually critically look at the paper.

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[The Discussion section] highlights those and fails to highlight the nonsignificant results, which is not surprising at all in a paper that was not only funded by a drug company but actually also they funded the writer of the paper, which is written in the

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