UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

ALLERGAN, INC.
Patent Owner

Case IPR2016-01127[1]
Patent 8,685,930

PATENT OWNER'S REPLY TO PETITIONER'S OPPOSITION TO MOTION TO EXCLUDE EVIDENCE

[1] Cases IPR2017-00576 and IPR2017-00594 have been joined with this proceeding.

I. Allergan's Motion Satisfies the Board's Rules

Mylan criticizes Allergan's motion because Allergan failed to identify specific paragraphs in Mylan's three new expert declarations that Allergan seeks to exclude. Allergan seeks to exclude each declaration in its entirety. Allergan's motion, therefore, is compliant.

II. Mylan's Reply Is Really a New Petition

Mylan changed its theory of unpatentability between its petition and its reply. In its petition, Mylan and its sole declarant, Dr. Amiji, argued that Sall demonstrated the superiority of the 0.05% CsA emulsion. Petition, pp. 8, 50; EX. 1002, ¶¶ 107-108. Mylan had to make these arguments in order to support its theory of obviousness based on Ding '979 and Sall—specifically, that a POSA would have selected a 0.05% CsA emulsion based upon Sall.

In its owner's response, Allergan agreed that Sall demonstrated the superiority of the 0.05% CsA emulsion particularly with respect to tear production, as measured by the Schirmer Tear Test ("STT") with anesthesia. As Allergan noted, the real issue was how much castor oil a POSA would have combined with the 0.05% CsA, since Sall is silent as to the amount of castor oil used with the 0.05% CsA. Allergan proved that based upon thermodynamic principles, and confirmed by bioavailability studies, a POSA would not have selected 1.25% castor oil but, in fact, would have chosen far less. Patent Owner Response, pp. 24-

28. Allergan established that a POSA would have expected that increasing the amount of castor oil would have caused less CsA to reach the lacrimal glands relative to an emulsion containing 0.1% CsA and 1.25% castor oil. *Id.* In this context, the fact that an emulsion having 0.05% CsA/1.25% castor oil was better at increasing tear production than an emulsion having 0.1% CsA/1.25% castor oil was surprising and unexpected. As to Mylan's argument that increasing castor oil had beneficial effects, Allergan proved, with the aid of the STT with anesthesia data shown in Sall Fig. 2, that the castor oil vehicle alone ***decreased*** tear production and was worse than either CsA-containing emulsion. *Id.* at 30. Thus, selecting 1.25% castor oil was ***not*** a matter of optimizing castor oil concentration, as the Board suggested in its Institution Decision. Institution Decision, p. 21. Rather, Sall shows that the 0.05% CsA/1.25% castor oil emulsion is critical to increasing tear production and works differently than the 0.1% CsA/1.25% castor oil emulsion (the closest prior art).

With the aid of three new declarants, Mylan now turns its back on Sall and tries to argue that Sall shows no real difference between the 0.05% and 0.1% CsA emulsions. Notably absent is any new testimony from Dr. Amiji. Mylan tries to argue that it criticized Sall's data all along. Opposition, pp. 2-4. However, Mylan's citations to "data" in its Opposition reveal that it criticized the data in Dr.

Schiffman's declaration, and used Sall as a reliable, robust source of data to support its criticism. Mylan did ***not*** criticize ***Sall's*** data.

Allergan's Response did not rely on Dr. Schiffman's data—it relied on Sall. Having seen the Response, Mylan is simply trying to re-write its original petition.

III. Drs. Bloch and Calman's Methodology Is Scientifically Unsound and Unreliable

To perform his "statistical" analysis, Dr. Bloch relied on numbers that he "gleaned" from Sall Fig. 2 using a ruler and magnifying glass. EX. 1040 at ¶¶ 26, 44; EX. 2083 at 40:4-41:4. Dr. Calman attempted to "infer" raw Schirmer scores from the categorized Schirmer scores disclosed in Sall. EX. 1039 at ¶ 68. Neither is scientifically sound, as Dr. Calman admitted. EX. 2082 at 106:23-107:21.

Mylan attempts to justify their unscientific methods by complaining that Allergan withheld the underlying data. But Mylan never requested raw data for the purpose of attacking the Phase 3 clinical data reported in Sall—a peer-reviewed paper that included error bars and p-values. Mylan never established any reason to doubt the data presented in Sall, especially since Mylan's petition and its original expert, Dr. Amiji, ***relied upon*** Sall. Mylan sought the raw data for the purpose of challenging the data Dr. Schiffman presented to the Patent Office. *See* Paper No. 23. When Allergan confirmed that its Response did not rely on Dr. Schiffman's figures but instead relied solely on the data and analysis presented in Sall, the Board denied Mylan's request for the raw data. *See* Paper No. 28.

Based upon the reasons Mylan presented in its motion for additional discovery, Mylan was never entitled to the raw STT data underlying Sall Fig. 2. Moreover, Mylan's real, albeit unstated, objective in seeking the raw data to challenge Sall Fig. 2 underscores that Mylan's statistical challenge is an entirely new argument supported by new evidence presented for the first time in its reply.

IV. Allergan Is Unable to Offer Its Own Rebuttal Declarations

The Board authorized Allergan to file a surreply. It did not authorize Allergan to file supporting declarations. Nevertheless, the positions Mylan continues to advance make clear that without the ability to offer declarations from its own biostatistician and clinician, Allergan lacks a meaningful opportunity to respond to Mylan's new arguments and evidence. Contrary to Mylan's arguments in its Opposition, Allergan's witnesses (Drs. Sheppard and Loftsson) never confirmed Dr. Bloch and Dr. Calman's analyses. How could they have confirmed analyses that Mylan did not present until after Drs. Sheppard and Loftsson had submitted their declarations? As to Mylan's argument that neither of Allergan's witnesses performed a statistical analysis, this is true—because neither Dr. Sheppard nor Dr. Loftsson is a biostatistician and Mylan's Petition embraced, rather than attacked, Sall's data and statistical analysis.

Allergan now specifically requests leave to file declarations from its own biostatistician and clinician in support of its surreply. The biostatistician would

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