Paper No. ___
Filed: July 27, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC. and AKORN INC.,[1]
Petitioners,

v.

ALLERGAN, INC.,
Patent Owner.

Case IPR2016-01127 (US 8,685,930 B2)
Case IPR2016-01128 (US 8,629,111 B2)
Case IPR2016-01129 (US 8,642,556 B2)
Case IPR2016-01130 (US 8,633,162 B2)
Case IPR2016-01131 (US 8,648,048 B2)
Case IPR2016-01132 (US 9,248,191 B2)

PETITIONERS' RESPONSE TO PATENT OWNER'S MOTION FOR OBSERVATIONS ON THE CROSS-EXAMINATION TESTIMONY OF MR. IVAN T. HOFMANN

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[1] Cases IPR2017-00576 and IPR2017-00594, IPR2017-00578 and IPR2017-00596, IPR2017-00579 and IPR2017-00598, IPR2017-00583 and IPR2017-00599, IPR2017-00585 and IPR2017-00600, and IPR2017-00586 and IPR2017-00601, have respectively been joined with the captioned proceedings. The word-for-word identical paper is filed in each proceeding identified in the caption pursuant to the Board's Scheduling Order (Paper 10).

Petitioner submits this Response to Patent Owner Allergan's Motion for Observations on the Cross-Examination Testimony of Ivan T. Hofmann ("Observations") pursuant to the Standing Order (Paper 9) and the Scheduling Order (Paper 10).

Mr. Hofmann's Testimony That Restasis® Sales Do Not Prove Commercial Success of the Claimed Invention

Allergan omits relevant testimony and mischaracterizes the cited testimony. *Observations* at 1. Mr. Hofmann testified that the commercial performance of Restasis does not provide objective indicia of nonobviousness in this case. EX2084 at 7:24-8:3. While the lack of nexus between the novel aspects of the alleged inventions and the commercial success is one reason for this belief, it is one among several. EX2084 at 7:24–8:12. ("Well, I mean, I defer to the entirety of my declaration. I think there are many reasons I [don't believe commercial performance of Restasis® provides objective indicia of nonobviousness of the claims], including, you know, the blocking patents, and I'm sure we'll get into everything, but among them is the lack of nexus."). Importantly, Mr. Hofmann's declaration and deposition testimony make clear his opinion that the blocking patents prevent the performance of Restasis from providing objective indicia of nonobviousness of the claims-at-issue. *Id.* at 82:13–19. ("We're talking about the patents at issue, which have a very specific claimed range that do cyclosporine, that do use a specific formulation. Those are blocked by the '979 and '342 patent.

So we can't learn anything about those patents at issue with the performance of Restasis."); EX1041 ¶¶30, 33–38. Allergan omits this opinion in its observations.

Mr. Hofmann's Critique of Dr. Maness for Failing to Define a Relevant Market

Allergan omits relevant testimony and mischaracterizes the cited testimony. *Observations* at 1–2. While Mr. Hofmann has not done a "definitive definition of what products would comprise the relevant market," he has identified a number of different products that treat dry eye and would be competitors to Restasis. EX2084 at 18:6–17. Mr. Hofmann has not completed the definitive definition because Allergan did not produce a complete data set to analyze. *Id.* at 18:21–22. Mr. Hofmann testified that he rightly criticized Dr. Maness because "He's asserting commercial success. I'm saying he hasn't done so properly with respect to defining the relevant market. I don't have a data set to do an alternative calculation, but that doesn't mean just because he did it for the wrong market, that that should stand." *Id.* at 20:9–14.

Mr. Hofmann's Discussion of Product Marketing and Nexus

Allergan omits relevant testimony and mischaracterizes the cited testimony. *Observations* at 2. Mr. Hofmann testified that "The point here is not whether the marketing itself is excessive. It's the contribution that marketing has made in combination with all the other points that I've made in my declaration. I think that it has clearly been a marketing intensity at a level that is significant. And that's just

not my words. That's the words of Allergan, both internally and externally." *Id.* at 44:19–45:2.

Mr. Hofmann's Discussion of Marketing as a Percentage of Sales

Allergan omits relevant testimony and mischaracterizes the cited testimony. *Observations* at 3. In his testimony, Mr. Hofmann carefully qualified Dr. Maness's calculations of marketing expenses as a percentage of sales as "a little bit of an apples and oranges." *Id.*at 42:17–43:8 ("I don't quantitatively have a dispute with how he's pulled this together. I do think that this is a different data set than is typically used for when one's looking at these ratios based on IMS data because IMS data uses . . . retail value of samples. This is actual cost of samples."). He further cautioned, "So in terms of the math, I don't disagree with it, but I don't know that it truly reflects the economics as a percentage." *Id.* at 44:1–8. Moreover, Mr. Hofmann questions the utility of analyzing marketing as a function of sales:

> I've looked at the role of marketing and I've looked at it considering this as one metric, and I feel like, as I've explained in my report, this percentage of sales metric masks the true intensity. And when one looks at it relative to the Allergan documents and the testimony and the public statements made by Allergan and looks at that in context, when one looks at that in context with the promotion, rebates, discounts, other financial incentives, looks at it in combination with everything else, it definitely supports the opinion that there's no objective evidence of nonobviousness. You can't pick out one metric

from one spreadsheet over a 13-year period and say, does this tell us the answer. You're looking at it in the context of all the different information, evidence, and data sets.

Id. at 45:15–46:13.

Mr. Hofmann's Discussion of Marketing Expenditures of Other Products

Allergan omits relevant testimony and mischaracterizes the cited testimony. *Observations* at 3–4. Mr. Hofmann testified:

> I reject the utility of looking at [whether the percentage of marketing expenses as a function of revenue is within range of products in the pharmaceutical industry]. As I explain, I think it mutes the marketing intensity. I complain of some of the general statements that Mr. Maness makes about how this fits within general averages, but that is kind of broadly looking at various therapeutic classes. I haven't seen a data set that allows me to look at that relative to other products in the class, and a lot of the products in the class are over-the-counter so I'm not even sure -- you would have to get comparable data. So no, I don't think a useful or meaningful data set exists so I haven't done it.

Id. at 38:1–39:5. Instead Mr. Hofmann has looked at the totality of other sources to determine the importance of marketing to Restasis. *Id.* at 41:11–42:2 ("What I've done is I've looked at the absolute data. I've looked at all the statements that Allergan makes in their internal documents, all the statements that Allergan makes in their external documents, some of the testimony. And together they tell the story of the absolute importance of the marketing efforts that have been made.").

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