UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC, Petitioner

v.

ALCON RESEARCH, LTD, Patent Owner

> Case IPR2017-01053 Patent 8,268,299

ALCON RESEARCH, LTD.'S MOTION FOR OBSERVATIONS ON THE DEPOSITION OF PETITIONER'S EXPERT JOHN C. STAINES, JR.



Pursuant to 77 Fed. Reg. 48,767-68, Paper 7 at 6, and Paper 34 at 2, Patent Owner Alcon Research, Ltd. ("Alcon") submits this motion for observations regarding cross-examination of Petitioner's reply declarant John C. Staines, Jr., following his deposition on May 8, 2018 (Exhibit 2168).

Observation 1. Mr. Staines testified:

Q. I think you make the point in your report that that's ultimately what the commercial success inquiry is about in your understanding, whether or not a competitor has an incentive to enter the market; is that right?

A. Yes. That would have been developed. If it had been obvious, somebody else would have already developed it and made that money. So we wouldn't have made the money here; Alcon wouldn't have.

Ex. 2168 at 13:7-15.

Q. So your understanding is that the invention is a preservative system in a formulation that also contains Travoprost as an API? Is that --

A. Right. It's a reformulation of Travatan that incorporates an alternative preservative. . . .

Q. Did you consider whether the '299 patent does not require Travoprost as an active pharmaceutical ingredient?

A. No.

Ex. 2168 at 47:19-48:5 (Argentum's objection omitted).

Q. Weren't Lumigan and Xalatan competitive products to Travatan and Travatan Z at the time that Travatan Z was brought to market?



A. They were, I think, competitive alternative products, yes.

Ex. 2168 at 55:6-10.

Q. . . . Pfizer could have looked at its prostaglandin analog product [Xalatan] and had the same incentive that Alcon had with Travoprost because it too could have benefited from accommodative marketing, pricing and ultimately the removal of the original Pfizer product from the market; right?

A. I'm unaware of the – that the '299 patent can be used for other products. It may well. I didn't consider that. And so for that reason I can't really – I'd have to go back and think about the implications of that, but I haven't considered that.

Ex. 2168 at 85:18-87:6 (Argentum's objection omitted). This testimony is relevant to Petitioner's argument that "the comparisons of sales and prescriptions between TRAVATAN® and TRAVATANZ® reported by Dr. Grabowski fail to account for the advantages that successor product status gave to TRAVATANZ®," Paper 35 at 27, and Mr. Staines' statement that "[a]n alternative developer of a product based on the '299 patent technology would not have benefited from this accommodative marketing, pricing, and ultimately Travatan® removal strategy . . . ," Ex. 1094 ¶ 34. The testimony is relevant because it undermines Petitioner's argument, demonstrates that Mr. Staines' opinion is based on a misunderstanding of the '299 patent technology, and contradicts Mr. Staines' statement in Paragraph 34 of Exhibit 1094.



Observation 2. Mr. Staines testified:

Q. Is it possible to predict ex-ante when – let's assume a commercially successful pharmaceutical product [--] is going to hit its saturation or mature phase?

A. It's impossible to predict that accurately. People can make estimates and maybe forecast, basically. So you can forecast it, and you're either right or wrong. You might be close or you might be way off.

Ex. 2168 at 26:22-27:6 (Argentum's objection omitted).

Q. You concede in your expert declaration that extrapolations like you've made on Exhibit C are subject to uncertainty, right?

A. Yes.

Ex. 2168 at 91:4-7.

Q. Is linear growth typical during the first 10 years after a pharmaceutical product's launch?

A. I don't know what is really typical. I don't know that it's atypical or typical. I think there's a lot of different growth patterns. You would see increasing growth for a number of years and could see increasing growth for 10 years, but it's linear. Sometimes it's accelerating and it can be for 10 years, but it just – every product is different depending on what market forces are working on it.

Q. Is logarithmic growth, as you depicted in the dashed blue line, typical during the first 10 years after a pharmaceutical product's launch?

A. Again, I wouldn't say it's typical or atypical. It's plausible.



Ex. 2168 at 103:13-104:4. 8:23-109:3 (Argentum's objection omitted). This testimony is relevant to Petitioner's argument that "Dr. Grabowski fail[s] to account for the advantages that successor product status gave to TRAVATANZ®." Paper 35 at 27. This testimony is also relevant to evaluating the reliability of Mr. Staines' statement that "the linear regression extrapolation of Travatan®'s 2001 to 2006 sales forward to 2007 to 2010 in Exhibit C indicates that Travatan® sales were on track to slightly exceed the combined Travatan®/Travatan Z® franchise sales actually generated in those years." Ex. 1094 ¶ 40 and Ex. C. The testimony is relevant because it is undermines the reliability of Mr. Staines' analysis, and Petitioner's arguments based on that analysis.

Observation 3. Mr. Staines testified:

Q. So, so far as Dr. Grabowski uses numbers to do his own calculations in his expert declaration, there's none of those that you think he did wrong, that he calculated incorrectly; is that right?

A. Right. Again, I haven't done a thorough examination of them, but the ones that I did and in general just looking at the reasonableness, I'm unaware of any calculation errors.

Q. And if you had found any calculation errors, you would have pointed it out in your expert declaration?

A. I would have been all over it.

Ex. 2168 at 44:13-24. This testimony is relevant to Petitioner's argument that "the actual net revenue levels and growth are lower than reported by the Grabowski



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