Case IPR 2017-01053 Patent 8,268,299

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 SECOND DEPOSITION OF PETITIONER'S EXPERT ERNING XIA, PH.D.

DOCKET

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 Erning Xia, Ph.D.,

following his deposition on May 11, 2018 (Exhibit 2166).

Observation 1. Dr. Xia testified:

Q. Can you point me toward any data that would have led the POSA to a zinc-sorbitol-borate-propylene glycol ionic buffering system as of September 2006?

A. At this point, I left – I used to collect all dry eye products. I have this product [Systane® Free] in my office. So in United States, when you want to introduce a product like this, you have to put all ingredients on the box. I can clearly remember that propylene glycol is in this product. It is in this product, propylene glycol.

Q.... Are those the data in your opinion the POSA would rely upon to be led to the zinc-propylene glycol-sorbitol-borate combination that's claimed in the '299 patent?

A. They may. They may. Some POSA will move forward with that. But if there's not patent – blocking patent there. If you have blocking patent, you cannot do anything.

Q. You said that the POSA may get there. Is that the only place the POSA may have ended up or could the POSA have ended up at -

A. Different formulation?

Q. – different formulation?

A. Oh, yeah, yes.

Ex. 2166 at 106:10-107:12. This testimony is relevant to Petitioner's argument

that "[b]y 2006, a POSA was well-motivated to improve a host of ophthalmic

products to avoid BAK, including the well-known travoprost formulation of

Travatan®, via inclusion of zinc and borate-polyol complexes to achieve PE, and

would have arrived at the claims of the '299 Patent via routine optimization"

Paper 35 at 1 (emphasis added). The testimony is relevant because it is contradicts

Petitioner's argument.

Observation 2. Dr. Xia testified:

Q. What is a micronutrient?

A. Micronutrient, I'm not expert of microbiologist, ...

Ex. 2166 at 12:20-22 (emphasis added).

Q. So, the complete lack of zinc in a solution causes microorganisms in that solution to die because they don't have the zinc they need to survive; is that fair?

A. Again, I'm not a microbiologist. . . .

Ex. 2166 at 14:7-11 (emphasis added).

Q. Would the person of ordinary skill in the art have considered whether zinc was a micronutrient when using zinc as an antimicrobial agent?

A. Using zinc as a preservative at the same time you believe zinc is food source of bacteria, that's what you say, right? That's your question? Same time you think this is food source for bacteria also can kill bacteria because they go both or different ways.

Q. Well, at particular concentrations, they might only go one way, right?

A. Because in order to have bacteria grow, I don't know what kind of nutrients they need for bacteria to grow. That's why I cannot answer that question. <u>I'm not a microbiologist.</u>

Ex. 2166 at 41:14-42:7 (emphasis added; Argentum's objections omitted).

Q. Just to be clear, your opinions in this case are all based on the premise that zinc is not a micronutrient, is not a source of food for bacteria?

A. I told you that before. I say <u>I don't know the answer</u> <u>for that</u>....

Ex. 2166 at 49:16-20. This testimony is relevant to Alcon's argument that "the POSA would affirmatively be concerned that zinc compositions with less zinc than the 0.48 mM in Xia's Example 18 would fail PET," Paper 22 at 19, and to Petitioner's argument that the "POSA would not have relied on any of the references [cited by Alcon's microbiology expert Dr. Zhanel] to assess the potential of zinc to pass PET in an ophthalmic composition," Paper 35 at 5. The testimony is relevant because it demonstrates that Dr. Xia cannot provide credible testimony in response to the testimony of Alcon's Dr. Zhanel (a microbiologist) regarding (i) zinc's properties as a micronutrient and (ii) the POSA's associated concern about using concentrations of zinc lower than the 0.48 mM in Xia's Example 18.

Observation 3. Dr. Xia testified:

Q. When you are referring to high zinc concentrations in that sentence, you are not talking about the concentrations of zinc, the range of which is referred to in Xia, is that fair?

A. It should not.

Ex. 2166 at 53:21-25. This testimony is relevant to Petitioner's argument that the "POSA would have been concerned with using too high a level of zinc, and would therefore have engaged in optimization to find the lowest suitable zinc concentration," Paper 35 at 5, and Dr. Xia's statements regarding the same, Ex. 1093 ¶ 24. This testimony is also relevant to Alcon's argument that "[n]o reference Argentum cites suggests, for example, that the levels of zinc in Xia's examples would cause ocular irritation" and that "the POSA would have known that zinc salts have been used as ophthalmic astringents at concentrations of around 0.25% w/v; that is, concentrations many times higher than the highest concentration of zinc chloride used in any of Xia's examples." Paper 22 at 15. The testimony is relevant because it is consistent with Alcon's argument and contradicts Petitioner's argument.

Observation 4. Dr. Xia testified:

Q. I want you to focus on the words "are useful" in Paragraph 11 of your declaration. By using those words, you are not stating an opinion that Xia teaches that zinc ions alone without a primary preservative agent as

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