Transcript of James Agalloco

Date: May 4, 2022
Case: Regeneron -v- Novartis (PTAB)

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,

Petitioner

v.

NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,

Patent Owners

Case IPR2021-00816

Patent No. 9,220,631

Remote Zoom Deposition of

JAMES AGALLOCO, taken on

May 4, 2022 at 10:02 a.m.

Job No. 447979

Pages 1-139

Reported by: Lisa M. Barrett, RPR, CRR, CRC, CSR

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REMOTE DEPOSITION OF JAMES AGALLOCO held virtually via Zoom Videoconferencing,

Before Lisa M Barrett, Certified Relatime Court Reporter Reporter, and Notary Public of the State of Maryland.

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A P P E A R A N C E S (CONT'D)

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Wednesday, May 4, 2022
--- Commencing at 10:02 a.m.

REMOTE TECHNICIAN: Before we administer the oath, I just have a brief read on script to do for Planet Depos. One second, let me pull that up. Thank you to everyone for attending this proceeding remotely, which we anticipate will run smoothly. Please remember to speak slowly and do your best not to talk over one another.

Please be aware we are recording this proceeding for backup purposes. Any off-the-record discussions should be had away from the computer. Please remember to mute your mic for those conversations.

Please have your video enabled to help the reporter identify who is speaking. If you are unable to connect with video and are connecting via phone, please identify yourself each time before speaking.

I apologize in advance for any technical-related interruptions. Thank you.

(Court reporter read oath stipulation.

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Counsel agreed.)
JAMES AGALLOCO, having been duly sworn testified as follows,
EXAMINATION
BY MS. HOLLAND:
Q Good morning, Mr. Agalloco, nice to see you again.
A Good morning.
Q I'd like to start by looking at exhibit 1016.
(Whereupon, Exhibit 1016 was identified.)
BY MS. HOLLAND:
Q So Matt, can you put that up on the screen please. Can you -- thank you.
Mr. Agalloco, this is an excerpt from a book called "Pharmaceutical Dosage Forms," edited by Nema and Ludwig.
You are familiar with this reference, correct?
A Yes, I am.
Q And you wrote one of the chapters in here, right?
A That's correct.
Q Can we go to page 1016.210. Thank you.
Mr. Agalloco, this is a chapter in the Exhibit 1016, the Nema book, called:
"Industrial Sterilization Techniques: Principles and Overview" by Anne Booth.
Have you seen this before?
A Only in passing. I have not read it in depth.
Q Well, I want to point your -- direct your attention to six lines down. There is a sentence that says:
"Also, the sterilization treatment must not render the medical product, materials or functions unacceptable." [As read.]
Do you see that?
A Yes, I do.
Q Is that something you agree with?
A I think it is one way of stating it. Yes, I do agree with it.
Q What do you mean by "one way of stating it"?
A It can be written differently, but I agree with it in principle.
Q And then I want to look at the next paragraph, the first sentence, which says that:
"Requirements for the validation and routine operation of sterilization methods are given in a series of ISO and AAMI standards and guidelines." [As read.]
Do you see that?
A Yes, I do.
Q And do you agree with that as well?
A That is only correct within the medical device industry.
The ISO standard are, you know, widely accepted in that industry, which is the one that AAMI represents.
The drug industry tends to follow the standards of the Food and Drug Administration.
They look at these, but they do not follow them exactly.
Q Do you -- let me withdraw that.
Are you familiar with the AAMI standards?
A Only to the extent that I work with a device, but when I'm working with drugs, I look more closely at Food and Drug Administration expectations.
Q Okay, is a syringe a device?
A When it is presented with a drug inside of it, it is a drug.
Q Let me turn now to page 1016.256.
There is a chapter in the NEMA book called:
"Gas Vapor and Liquid Chemical Sterilization."
Is that a chapter that you wrote, Mr. Agalloco?
A Yes, I did.
Q All right, I'd like to turn to page -- that has .259 on the bottom.
There is a section in the middle of that page that says:
"Gas, Vapor, and Liquid Sterilization

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Fundamentals: Material Effects." Do you see that?
A Yes.
Q And the first sentence says:
"Sterilization processes are designed to kill microorganisms and as such they utilize conditions that may be destructive of essential material properties." [As read.]
Is that a sentence you agree with?
A I wrote it, so yes, I agree with it.
Q And the sterilization processes that are being referred to in that sentence, would that include the use of ethylene oxide and vaporized hydrogen peroxide?
A Yes, it would.
Q You agree, Mr. Agalloco, that a terminal sterilization process, in addition to achieving the appropriate level of sterilization, has to also avoid degradation of the drug product?
A Yes, I do.
Q Do you also agree that a sterilization process, in addition to achieving an appropriate

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level of sterilization, also has to avoid leaving traces of toxic substances that could make the drug product unsafe?
MS. KENNEDY: Objection, form.
THE WITNESS: Yes.
BY MS. HOLLAND:
Q Is it also true, Mr. Agalloco, that sterilizing gases can absorb onto syringe components during sterilization?
A That's a possibility with some materials and some gases.
Q Which gases?
A There are many gases, and there are many materials. It is infinity combinations. I can't list them all.
Q All right. Is it -- I appreciate that. Let me try again then.
Is it correct that ethylene oxide and vaporized hydrogen peroxide can absorb onto a rubber stopper that's part of a prefilled syringe?
MS. KENNEDY: Objection, form.
THE WITNESS: It's possible, yes.

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BY MS. HOLLAND:
Q If the hydrogen peroxide or ethylene oxide is absorbed onto the rubber stopper, can it then leach into the drug product over time?
MS. KENNEDY: Objection, form.
THE WITNESS: Potentially. That's a possibility.
BY MS. HOLLAND:
Q Is it correct that if a sterilizing gas like hydrogen peroxide or ethylene oxide gets into a drug product, it can be impossible to remove it from the drug product?
MS. KENNEDY: Objection, form.
THE WITNESS: I'd say it would be extremely difficult to remove it. I can't say it's impossible. There may be methods.
BY MS. HOLLAND:
Q In your declaration, you talk about the claimed construction of terminal sterilization; do you recall that?
A Yes, I do.
Q Why don't we put that up on the screen?

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It is exhibit 1100, at paragraph 20.
(Whereupon, Exhibit 1100 was identified.)
BY MS. HOLLAND:
Q All right. At the bottom of page 8, it's in paragraph 20, you say:
"I understand that, as used in the '631 Patent, the parties have agreed that 'terminally sterilized' refers to a process whereby the outside of a prefilled syringe is sterilized, while contact between the sterilizing agent and the drug product within the syringe is minimized." [As read.]
Do you see that?
A Yes, I do.
Q And is it correct that the reason for minimizing the contact is to avoid chemical action of the sterilizing agent on the contents of the syringe, including the active ingredient?
MS. KENNEDY: Objection, form.
THE WITNESS: Yes, that would be the reason for minimization.

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