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Transcript of James Agalloco

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

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Conducted on May 4, 2022

<p style="text-align: center;">1</p> <p>1 UNITED STATES PATENT AND TRADEMARK OFFICE</p> <p>2 -----</p> <p>3 BEFORE THE PATENT TRIAL AND APPEAL BOARD</p> <p>4 -----</p> <p>5 REGENERON PHARMACEUTICALS, INC.,</p> <p>6 Petitioner</p> <p>7 v.</p> <p>8 NOVARTIS PHARMA AG, 9 NOVARTIS TECHNOLOGY LLC, 10 NOVARTIS PHARMACEUTICALS CORPORATION, 11 Patent Owners</p> <p>12 -----</p> <p>13 Case IPR2021-00816</p> <p>14 -----</p> <p>15 Patent No. 9,220,631</p> <p>16 -----</p> <p>17 Remote Zoom Deposition of</p> <p>18 JAMES AGALLOCO, taken on</p> <p>19 May 4, 2022 at 10:02 a.m.</p> <p>20 -----</p> <p>21 Job No. 447979</p> <p>22 Pages 1-139</p> <p>23 Reported by: Lisa M. Barrett, RPR, CRR, CRC, CSR</p> <p>24</p>	<p style="text-align: center;">3</p> <p>1 A P P E A R A N C E S:</p> <p>2 ON BEHALF OF PETITIONER REGENERON PHARMACEUTICALS,</p> <p>3 INC.:</p> <p>4 Natalie Kennedy, Esquire 5 Weil, Gotshal & Manges LLP 6 767 Fifth Avenue 7 New York, New York 10153-0119 8 PHONE: +1 (212) 310-8730 9 E-MAIL: Natalie.Kennedy@weil.com 10 -and-</p> <p>11 Andrew Peter Gesior, Esquire 12 Weil, Gotshal & Manges LLP 13 767 Fifth Avenue 14 New York, New York 10153-0119 15 PHONE: +1 (212) 310-8244 16 E-MAIL: andrew.gesior@weil.com 17 -and-</p> <p>18 Christopher Pepe, Esquire 19 Weil, Gotshal & Manges LLP 20 2001 M Street, NW 21 Washington, D.C. 20036 22 PHONE: +1 (202) 682 7153 E-MAIL: Christopher.pepe@weil.com</p>
<p style="text-align: center;">2</p> <p>1 REMOTE DEPOSITION OF JAMES AGALLOCO held</p> <p>2 virtually via Zoom Videoconferencing,</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19 Before Lisa M Barrett, Certified Relatime</p> <p>20 Court Reporter Reporter, and Notary Public of the State of</p> <p>21 Maryland.</p> <p>22</p>	<p style="text-align: center;">4</p> <p>1 A P P E A R A N C E S (CONT'D)</p> <p>2 (Via Zoom Videoconferencing):</p> <p>3 ON BEHALF OF PETITIONER REGENERON PHARMACEUTICALS,</p> <p>4 INC.:</p> <p>5 Petra Scamborova, PhD, JD 6 Regeneron Pharmaceuticals, Inc. 7 777 Old Saw Mill River Road 8 Tarrytown, New York 10591 9 PHONE: +1 (914) 847-7611 10 E-MAIL: Petra.scamborova@regeneron.com</p> <p>11 ON BEHALF OF THE PATENT OWNERS:</p> <p>12 Elizabeth J. Holland, Esquire 13 Allen & Overy LLP 14 1221 Avenue of the Americas 15 New York, New York 10020 16 PHONE: +1 (212) 610 6365 17 E-MAIL: Elizabeth.Holland@allenoverly.com</p> <p>18</p> <p>19 Also present: Matt Weedon, PD Remote Technician</p> <p>20</p> <p>21</p> <p>22</p>

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<p>1 C O N T E N T S</p> <p>2 EXAMINATION OF JAMES AGALLOCO PAGE</p> <p>3 By Ms. Holland 9</p> <p>4 E X H I B I T S PAGE</p> <p>5 (Presented pre-marked exhibits)</p> <p>6 (Attached to the Transcript)</p> <p>7 Exhibit 1016 Excerpt from a book 9</p> <p>8 called "Pharmaceutical Dosage</p> <p>9 Forms," edited by Nema and</p> <p>10 Ludwig</p> <p>11 Exhibit 1100 Expert Declaration by James 16</p> <p>12 Agalloco</p> <p>13 Exhibit 2330 Transcript of James Agalloco 19</p> <p>14 dated February 16, 2021</p> <p>15 Case: Certain Pre-Filled</p> <p>16 Syringes for Intravitreal</p> <p>17 Injection (337-TA-1207)</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>	<p>1 "Sterilization of health</p> <p>2 care products-Requirements</p> <p>3 and for selecting a</p> <p>4 sterility - assurance level</p> <p>5 (SAL) for products labeled</p> <p>6 "sterile" Novartis.</p> <p>7 Exhibit 2206 Document entitled, "Dr. Sigg's 79</p> <p>8 declaration."</p> <p>9 Exhibit 2115 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 Exhibit 2104 Document reflecting 105</p> <p>16 communications between</p> <p>17 [REDACTED]</p> <p>18 Exhibit 1029 Patent Application, Xanthe 115</p> <p>19 Lam</p> <p>20</p> <p>21</p> <p>22</p>
<p>1 E X H I B I T S PAGE</p> <p>2 (Presented pre-marked exhibits)</p> <p>3 (Attached to the Transcript)</p> <p>4 Exhibit 2328 Article co-authored by James 20</p> <p>5 Agalloco with Dr. Aikers,</p> <p>6 published in 2013.</p> <p>7 Exhibit 1007 Document entitled "Sigg 36</p> <p>8 Publication."</p> <p>9 Exhibit 1005 Document from IPR 317. 39</p> <p>10 Exhibit 2148 Technical memorandum from 41</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 Exhibit 2329 Document entitled, 53</p> <p>15 "Pharmaceutical Manufacturing</p> <p>16 Handbook: Production and</p> <p>17 Processes."</p> <p>18</p> <p>19 E X H I B I T S (Continued) PAGE</p> <p>20 (Presented pre-marked exhibits)</p> <p>21 (Attached to the Transcript)</p> <p>22 Exhibit 2187 Document entitled: 67</p>	<p>1 Wednesday, May 4, 2022</p> <p>2 --- Commencing at 10:02 a.m.</p> <p>3 REMOTE TECHNICIAN: Before we</p> <p>4 administer the oath, I just have a brief read on</p> <p>5 script to do for Planet Depos. One second, let me</p> <p>6 pull that up. Thank you to everyone for attending</p> <p>7 this proceeding remotely, which we anticipate will</p> <p>8 run smoothly. Please remember to speak slowly and</p> <p>9 do your best not to talk over one another.</p> <p>10 Please be aware we are recording this</p> <p>11 proceeding for backup purposes. Any</p> <p>12 off-the-record discussions should be had away from</p> <p>13 the computer. Please remember to mute your mic</p> <p>14 for those conversations.</p> <p>15 Please have your video enabled to help</p> <p>16 the reporter identify who is speaking. If you are</p> <p>17 unable to connect with video and are connecting</p> <p>18 via phone, please identify yourself each time</p> <p>19 before speaking.</p> <p>20 I apologize in advance for any</p> <p>21 technical-related interruptions. Thank you.</p> <p>22 (Court reporter read oath stipulation.</p>

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<p style="text-align: right;">9</p> <p>1 Counsel agreed.)</p> <p>2 JAMES AGALLOCO, having been duly</p> <p>3 sworn testified as follows,</p> <p>4 EXAMINATION</p> <p>5 BY MS. HOLLAND:</p> <p>6 Q Good morning, Mr. Agalloco, nice to see</p> <p>7 you again.</p> <p>8 A Good morning.</p> <p>9 Q I'd like to start by looking at exhibit</p> <p>10 1016.</p> <p>11 (Whereupon, Exhibit 1016 was</p> <p>12 identified.)</p> <p>13 BY MS. HOLLAND:</p> <p>14 Q So Matt, can you put that up on the</p> <p>15 screen please. Can you -- thank you.</p> <p>16 Mr. Agalloco, this is an excerpt from a</p> <p>17 book called "Pharmaceutical Dosage Forms," edited</p> <p>18 by Nema and Ludwig.</p> <p>19 You are familiar with this reference,</p> <p>20 correct?</p> <p>21 A Yes, I am.</p> <p>22 Q And you wrote one of the chapters in</p>	<p style="text-align: right;">11</p> <p>1 it"?</p> <p>2 A It can be written differently, but I</p> <p>3 agree with it in principle.</p> <p>4 Q And then I want to look at the next</p> <p>5 paragraph, the first sentence, which says that:</p> <p>6 "Requirements for the validation and routine</p> <p>7 operation of sterilization methods are given in a</p> <p>8 series of ISO and AAMI standards and guidelines."</p> <p>9 [As read.]</p> <p>10 Do you see that?</p> <p>11 A Yes, I do.</p> <p>12 Q And do you agree with that as well?</p> <p>13 A That is only correct within the medical</p> <p>14 device industry.</p> <p>15 The ISO standard are, you know, widely</p> <p>16 accepted in that industry, which is the one that</p> <p>17 AAMI represents.</p> <p>18 The drug industry tends to follow the</p> <p>19 standards of the Food and Drug Administration.</p> <p>20 They look at these, but they do not</p> <p>21 follow them exactly.</p> <p>22 Q Do you -- let me withdraw that.</p>
<p style="text-align: right;">10</p> <p>1 here, right?</p> <p>2 A That's correct.</p> <p>3 Q Can we go to page 1016.210. Thank you.</p> <p>4 Mr. Agalloco, this is a chapter in the</p> <p>5 Exhibit 1016, the Nema book, called:</p> <p>6 "Industrial Sterilization Techniques:</p> <p>7 Principles and Overview" by Anne Booth.</p> <p>8 Have you seen this before?</p> <p>9 A Only in passing. I have not read it in</p> <p>10 depth.</p> <p>11 Q Well, I want to point your -- direct</p> <p>12 your attention to six lines down. There is a</p> <p>13 sentence that says:</p> <p>14 "Also, the sterilization treatment must not</p> <p>15 render the medical product, materials or functions</p> <p>16 unacceptable." [As read.]</p> <p>17 Do you see that?</p> <p>18 A Yes, I do.</p> <p>19 Q Is that something you agree with?</p> <p>20 A I think it is one way of stating it.</p> <p>21 Yes, I do agree with it.</p> <p>22 Q What do you mean by "one way of stating</p>	<p style="text-align: right;">12</p> <p>1 Are you familiar with the AAMI</p> <p>2 standards?</p> <p>3 A Only to the extent that I work with a</p> <p>4 device, but when I'm working with drugs, I look</p> <p>5 more closely at Food and Drug Administration</p> <p>6 expectations.</p> <p>7 Q Okay, is a syringe a device?</p> <p>8 A When it is presented with a drug inside</p> <p>9 of it, it is a drug.</p> <p>10 Q Let me turn now to page 1016.256.</p> <p>11 There is a chapter in the NEMA book</p> <p>12 called:</p> <p>13 "Gas Vapor and Liquid Chemical</p> <p>14 Sterilization."</p> <p>15 Is that a chapter that you wrote,</p> <p>16 Mr. Agalloco?</p> <p>17 A Yes, I did.</p> <p>18 Q All right, I'd like to turn to page --</p> <p>19 that has .259 on the bottom.</p> <p>20 There is a section in the middle of</p> <p>21 that page that says:</p> <p>22 "Gas, Vapor, and Liquid Sterilization</p>

13	<p>1 Fundamentals: Material Effects." Do you see 2 that? 3 A Yes. 4 Q And the first sentence says: 5 "Sterilization processes are designed to 6 kill microorganisms and as such they utilize 7 conditions that may be destructive of essential 8 material properties." [As read.] 9 Is that a sentence you agree with? 10 A I wrote it, so yes, I agree with it. 11 Q And the sterilization processes that 12 are being referred to in that sentence, would that 13 include the use of ethylene oxide and vaporized 14 hydrogen peroxide? 15 A Yes, it would. 16 Q You agree, Mr. Agalloco, that a 17 terminal sterilization process, in addition to 18 achieving the appropriate level of sterilization, 19 has to also avoid degradation of the drug product? 20 A Yes, I do. 21 Q Do you also agree that a sterilization 22 process, in addition to achieving an appropriate</p>	15	<p>1 BY MS. HOLLAND: 2 Q If the hydrogen peroxide or ethylene 3 oxide is absorbed onto the rubber stopper, can it 4 then leach into the drug product over time? 5 MS. KENNEDY: Objection, form. 6 THE WITNESS: Potentially. That's a 7 possibility. 8 BY MS. HOLLAND: 9 Q Is it correct that if a sterilizing gas 10 like hydrogen peroxide or ethylene oxide gets into 11 a drug product, it can be impossible to remove it 12 from the drug product? 13 MS. KENNEDY: Objection, form. 14 THE WITNESS: I'd say it would be 15 extremely difficult to remove it. I can't say 16 it's impossible. There may be methods. 17 BY MS. HOLLAND: 18 Q In your declaration, you talk about the 19 claimed construction of terminal sterilization; do 20 you recall that? 21 A Yes, I do. 22 Q Why don't we put that up on the screen?</p>
14	<p>1 level of sterilization, also has to avoid leaving 2 traces of toxic substances that could make the 3 drug product unsafe? 4 MS. KENNEDY: Objection, form. 5 THE WITNESS: Yes. 6 BY MS. HOLLAND: 7 Q Is it also true, Mr. Agalloco, that 8 sterilizing gases can absorb onto syringe 9 components during sterilization? 10 A That's a possibility with some 11 materials and some gases. 12 Q Which gases? 13 A There are many gases, and there are 14 many materials. It is infinity combinations. I 15 can't list them all. 16 Q All right. Is it -- I appreciate that. 17 Let me try again then. 18 Is it correct that ethylene oxide and 19 vaporized hydrogen peroxide can absorb onto a 20 rubber stopper that's part of a prefilled syringe? 21 MS. KENNEDY: Objection, form. 22 THE WITNESS: It's possible, yes.</p>	16	<p>1 It is exhibit 1100, at paragraph 20. 2 (Whereupon, Exhibit 1100 was 3 identified.) 4 BY MS. HOLLAND: 5 Q All right. At the bottom of page 8, 6 it's in paragraph 20, you say: 7 "I understand that, as used in the '631 8 Patent, the parties have agreed that 'terminally 9 sterilized' refers to a process whereby the 10 outside of a prefilled syringe is sterilized, 11 while contact between the sterilizing agent and 12 the drug product within the syringe is minimized." 13 [As read.] 14 Do you see that? 15 A Yes, I do. 16 Q And is it correct that the reason for 17 minimizing the contact is to avoid chemical action 18 of the sterilizing agent on the contents of the 19 syringe, including the active ingredient? 20 MS. KENNEDY: Objection, form. 21 THE WITNESS: Yes, that would be the 22 reason for minimization.</p>

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