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Transcript of Horst Koller, Volume 2

Date: May 16, 2022

Case: Regeneron -v- Novartis (PTAB)

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Conducted on May 16, 2022

<p style="text-align: right;">231</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,</p> <p>9 NOVARTIS TECHNOLOGY, LLC,</p> <p>10 NOVARTIS PHARMACEUTICALS CORPORATION,</p> <p>11 Patent Owners</p> <p>12 -----</p> <p>13 Patent Number:</p> <p>14 9,220,631</p> <p>15 -----</p> <p>16 CONTINUED DEPOSITION OF HORST KOLLER</p> <p>17 Monday, May 16, 2022</p> <p>18</p> <p>19</p> <p>20 Reported by:</p> <p>21 STEPHANIE A. BATTAGLIA, CSR, RMR, CRR</p> <p>22 Job No.: 448280</p>	<p style="text-align: right;">233</p> <p>1 PRESENT: (All appeared via Zoom Conference)</p> <p>2 WEIL, GOTSHAL & MANGES</p> <p>3 BY: MR. CHRISTOPHER PEPE</p> <p>4 2001 M Street NW</p> <p>5 Washington, D.C. 20005</p> <p>6 (202) 682-7153</p> <p>7 - and -</p> <p>8 WEIL, GOTSHAL & MANGES</p> <p>9 BY: MR. TOM YU</p> <p>10 767 Fifth Avenue</p> <p>11 New York, New York 10153-0119</p> <p>12 (212) 310-8586</p> <p>13 appeared on behalf of the Petitioner;</p> <p>14 ALLEN & OVERY</p> <p>15 BY: MR. WILLIAM JAMES</p> <p>16 1101 New York Avenue, NW</p> <p>17 Washington, D.C. 20005</p> <p>18 (202) 683-3895</p> <p>19 - and -</p> <p>20 ALLEN & OVERY</p> <p>21 BY: MR. MATTHEW MINER</p> <p>22 One Beacon Street</p> <p>23 Boston, Massachusetts 02108</p> <p>24 (857) 353-4509</p> <p>25 appeared on behalf of the Patent</p> <p>26 Owners.</p> <p>27 ALSO PRESENT:</p> <p>28 Ms. Petra Scamborova</p> <p>29 Mr. Andrew Gesior</p> <p>30 Regeneron</p> <p>31 Ms. Rachel Carrick, Technician</p> <p>32 Ms. Stephanie A. Battaglia, CSR, RMR, CRR</p> <p>33 Planet Depos</p>
<p style="text-align: right;">232</p> <p>1</p> <p>2</p> <p>3</p> <p>4</p> <p>5 May 16, 2022</p> <p>6 6:03 a.m., Central Time</p> <p>7</p> <p>8</p> <p>9 Continued Deposition of HORST KOLLER, held</p> <p>10 virtually, before Stephanie A. Battaglia, a</p> <p>11 Registered Merit Reporter, Certified Realtime</p> <p>12 Reporter, and Notary Public of the State of</p> <p>13 Illinois.</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>	<p style="text-align: right;">234</p> <p>1 I N D E X</p> <p>2 WITNESS: PAGE:</p> <p>3 Horst Koller</p> <p>4 EXAMINATION BY:</p> <p>5 Mr. James 237, 393</p> <p>6 Mr. Pepe 390</p> <p>7 E X H I B I T S</p> <p>8 Exhibit 1 Koller IPR Deposition 338</p> <p>9 February 20, 2021</p> <p>10 Koller Exhibit 1</p> <p>11 Exhibit 1001 U.S. Patent No. 9,220,631 320</p> <p>12 Regeneron 1001.001 -</p> <p>13 Regeneron 1001.013</p> <p>14 Exhibit 1003 Declaration of 243</p> <p>15 Horst Koller</p> <p>16 Regeneron 1003.001 -</p> <p>17 Regeneron 1003.198</p> <p>18 Exhibit 1007 WO 2011/006877 340</p> <p>19 Regeneron 1007.001 -</p> <p>20 Regeneron 1007.035</p> <p>21 Exhibit 1008 Patent Application 243</p> <p>22 No. WO 2009/030976</p> <p>Regeneron 1008.001 -</p> <p>Regeneron 1008.32</p> <p>Exhibit 1009 [REDACTED] [REDACTED]</p> <p>Exhibit 1074 [REDACTED] [REDACTED]</p>

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<p style="text-align: right;">235</p> <p>1 (Cont'd.):</p> <p>2 Exhibit 1105 Reply Declaration of Horst Koller 244 3 Regeneron 1105.001 - 4 Regeneron 1105.188</p> <p>5 Exhibit 1106 Reply Declaration of Dr. Szilard Kiss 310 6 Regeneron 1106.001 - 7 Regeneron 1106.035</p> <p>8 Exhibit 1214 Drug Delivery Technology Delivering Therapeutic siRNA 333 9 Regeneron 1214.001 - 10 Regeneron 1214.076</p> <p>11 Exhibit 2030 Cell and Protein Compatibility of Parylene-C Surfaces 277 12 Novartis Exhibit 2030.001 - 13 Novartis Exhibit 2030.008</p> <p>14 Exhibit 2115 Process Review Summary 374 15 GENEITC_1207-0002409 - 16 GENEITC_1207-0002416</p> <p>17 Exhibit 2121 License and Collaboration Agreement 318 18 Novartis 2121.001 - 19 Novartis 2121.0023</p> <p>20</p> <p>21</p> <p>22</p>	<p style="text-align: right;">237</p> <p>1 Overy on the line today.</p> <p>2 KOLLER HORST,</p> <p>3 called as a witness herein, having been first duly</p> <p>4 sworn was examined and testified virtually as</p> <p>5 follows:</p> <p>6 EXAMINATION</p> <p>7 BY MR. JAMES:</p> <p>8 Q Hello, Mr. Koller.</p> <p>9 A Good morning, Mr. James.</p> <p>10 Q Thank you for taking the time to talk to</p> <p>11 us.</p> <p>12 So just, let's see, we took your</p> <p>13 deposition last December, do you recall that?</p> <p>14 A Right, I recall that.</p> <p>15 Q And have you given any other testimony</p> <p>16 since that time?</p> <p>17 A No, I haven't.</p> <p>18 Q Have you picked up any additional</p> <p>19 consulting work on prefilled syringes since that</p> <p>20 time?</p> <p>21 A Yes, I have.</p> <p>22 Q For Regeneron?</p>
<p style="text-align: right;">236</p> <p>1 MS. REPORTER: Here begins the</p> <p>2 videoconference deposition of Koller Horst in the</p> <p>3 matter of Regeneron versus Novartis.</p> <p>4 Today's date is May 16, 2022, and the time</p> <p>5 is 6:03 a.m., Central Time.</p> <p>6 My name is Stephanie Battaglia of Planet</p> <p>7 Depos.</p> <p>8 Beginning with the noticing party, will</p> <p>9 counsel please introduce themselves, state whom</p> <p>10 they represent, and stipulate to the swearing in</p> <p>11 of the witness remotely.</p> <p>12 Mr. James?</p> <p>13 MR. JAMES: My name is William James from</p> <p>14 Allen & Overy on behalf of the Patentee Novartis,</p> <p>15 and I can confirm that I agree to that.</p> <p>16 MR. PEPE: Chris Pepe representing</p> <p>17 Petitioner Regeneron. With me is Tom Yu, also</p> <p>18 with Weil, Gotshal. And we have on the line Petra</p> <p>19 Scamborova and Andrew Gesior with Regeneron, and</p> <p>20 we confirm as well.</p> <p>21 MR. JAMES: If I could -- sorry to</p> <p>22 interrupt, I also have Matthew Miner from Allen &</p>	<p style="text-align: right;">238</p> <p>1 A No.</p> <p>2 Q Does the prefilled syringe -- let me</p> <p>3 strike that.</p> <p>4 Is it a prefilled syringe for intravitreal</p> <p>5 administration?</p> <p>6 A I am not sure yet because I am helping</p> <p>7 this company to build up an overall syringe</p> <p>8 business, so it is not specific product-related,</p> <p>9 it is more from the technical point of view how to</p> <p>10 make a syringe pump basically.</p> <p>11 Q I see.</p> <p>12 Can you tell me what you did to prepare</p> <p>13 for your deposition today?</p> <p>14 A I was reading of course my reply</p> <p>15 declaration with related exhibits.</p> <p>16 Q Anything else?</p> <p>17 A I had a couple of talks with my counsel.</p> <p>18 Q Other than counsel did you speak with</p> <p>19 anybody else about your deposition?</p> <p>20 A No.</p> <p>21 Q When did you speak with counsel?</p> <p>22 A Last week.</p>

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<p style="text-align: right;">239</p> <p>1 Q On how many occasions?</p> <p>2 A It was three occasions.</p> <p>3 Q For approximately how long in total?</p> <p>4 A Between eight and ten hours.</p> <p>5 Q Did you review any documents in</p> <p>6 preparation for your deposition other than the</p> <p>7 documents that are cited in your reply</p> <p>8 declaration?</p> <p>9 MR. PEPE: Objection to the extent it</p> <p>10 calls for privilege.</p> <p>11 Horst, you can answer yes or no if you</p> <p>12 remember.</p> <p>13 THE WITNESS: Yes, I remember.</p> <p>14 BY MR. JAMES:</p> <p>15 Q You recall reviewing documents outside of</p> <p>16 the documents that are cited in your declaration?</p> <p>17 A Yes.</p> <p>18 Q Were those scientific articles?</p> <p>19 A One I was mentioning was an ISO standard.</p> <p>20 Q Which ISO standard is that?</p> <p>21 A It is ISO standard 11135.</p> <p>22 Q And why did you review that ISO standard</p>	<p style="text-align: right;">241</p> <p>1 Q And can you just tell me generally what</p> <p>2 11135 is about?</p> <p>3 A It shows you this is a guideline on</p> <p>4 process development or cycle development, possible</p> <p>5 related validation of EtO cycling, and it gives</p> <p>6 you a couple of options how to do that and how to</p> <p>7 approach that.</p> <p>8 Q Does it talk about the validation of a</p> <p>9 sterility assurance level?</p> <p>10 A It is mentioning sterility assurance level</p> <p>11 in general terms.</p> <p>12 Q Does it provide for a method of achieving</p> <p>13 any particular sterility assurance level?</p> <p>14 A It is giving you a proposal how to achieve</p> <p>15 the -- for the product specific required sterility</p> <p>16 assurance level.</p> <p>17 Q So the process would be able to achieve a</p> <p>18 sterility assurance level of, for example, 10 to</p> <p>19 the minus 3, is that right?</p> <p>20 A It would give you guideline to do that if</p> <p>21 you pre-specify SAL 10 to the minus 3, yes.</p> <p>22 Q And if you elected to you could select a</p>
<p style="text-align: right;">240</p> <p>1 standard?</p> <p>2 MR. PEPE: Objection, calls for privilege.</p> <p>3 Horst, you can answer to the extent you</p> <p>4 can do so without divulging any of the</p> <p>5 communications we had during our meetings.</p> <p>6 THE WITNESS: This standard talks about</p> <p>7 EtO sterilization and process.</p> <p>8 BY MR. JAMES:</p> <p>9 Q Beyond ethylene oxide sterilization and</p> <p>10 processes do you recall any other -- any of the</p> <p>11 other contents of ISO 11135?</p> <p>12 A No.</p> <p>13 Q Was that ISO standard cited by an expert</p> <p>14 in this matter?</p> <p>15 A I would need to go back to my original</p> <p>16 declaration if-- it was not cited, I am not sure</p> <p>17 if I gave that as an answer to you that you might</p> <p>18 follow certain ISO standards which are related to</p> <p>19 ASTM standards, but I am not too familiar from</p> <p>20 European standards with ASTM standards so my focus</p> <p>21 was usually more on the ISO standard, this is</p> <p>22 where the relation comes from.</p>	<p style="text-align: right;">242</p> <p>1 different SAL such as 10 to the minus 6, would</p> <p>2 that be right?</p> <p>3 A Yes. Then you need to follow a certain</p> <p>4 principle, which is pretty much the same. The</p> <p>5 principals there are described in general terms,</p> <p>6 and then depending on the required SAL they just</p> <p>7 you know what you would need to do.</p> <p>8 Q Does it indicate in the ISO 11135 that the</p> <p>9 ethylene oxide can damage some drug products?</p> <p>10 MR. PEPE: Object to form.</p> <p>11 THE WITNESS: I would need to pull it up.</p> <p>12 I mean, it is divided into whether it addresses</p> <p>13 two parts, one is the sterility part and one is</p> <p>14 the functional terms of the device to sterilize.</p> <p>15 BY MR. JAMES:</p> <p>16 Q The actual device that's used?</p> <p>17 A They talk about device in general terms,</p> <p>18 they don't give specifics, give specific -- it</p> <p>19 gives a guidance how to achieve -- what kind of</p> <p>20 approaches you have to achieve certain SAL levels,</p> <p>21 and one is focusing on the microbiology, which is</p> <p>22 the sterility, and then it gives the indication to</p>

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243	<p>1 say, okay, that functional performance needs to be</p> <p>2 checked as part of the overall approach.</p> <p>3 Q Mr. Koller, do you have a copy of</p> <p>4 Boulange?</p> <p>5 A Yes, if you can send me the exhibit</p> <p>6 number, I have a bunch of files here from the list</p> <p>7 with tab numbers and exhibit numbers.</p> <p>8 Q Okay, one moment.</p> <p>9 A I think this is Boulange, it is 1008.</p> <p>10 Q That's right, yes. So if you can open</p> <p>11 Exhibit 1008, please.</p> <p>12 (Document identified as Exhibit 1008 for</p> <p>13 identification.)</p> <p>14 BY MR. JAMES:</p> <p>15 Q Do you have a copy of your declaration --</p> <p>16 sorry, your reply declaration there in front of</p> <p>17 you?</p> <p>18 A It's listed as Exhibit 1003.</p> <p>19 (Document identified as Exhibit 1003 for</p> <p>20 identification.)</p> <p>21 BY MR. JAMES:</p> <p>22 Q I believe Exhibit 1003 was original</p>	245	<p>1 Q And how many hours did you spend putting</p> <p>2 this together, Mr. Koller?</p> <p>3 A In total 50, 50, 60 hours.</p> <p>4 Q And would you say you spent more time on</p> <p>5 it or the lawyers?</p> <p>6 A I spent more --</p> <p>7 MR. PEPE: Object to form, calls for</p> <p>8 speculation.</p> <p>9 THE WITNESS: I mean, I don't know how</p> <p>10 much time the lawyers spent, but it is based on my</p> <p>11 original declaration, which is baseline for my</p> <p>12 reply declaration, so, as I said, I spent</p> <p>13 approximately 50 to 60 hours.</p> <p>14 BY MR. JAMES:</p> <p>15 Q And how did the process work, did you</p> <p>16 actually draft this declaration on the computer or</p> <p>17 did you -- or did the lawyers provide you with the</p> <p>18 drafts?</p> <p>19 MR. PEPE: Object to form.</p> <p>20 THE WITNESS: The lawyers provided me with</p> <p>21 a general draft and then I was going through and</p> <p>22 made my expert comments and then they had me to</p>
244	<p>1 declaration in the IPR.</p> <p>2 Your reply declaration is Exhibit 1105.</p> <p>3 THE TECHNICIAN: Sir, I have that as</p> <p>4 Tab 67.</p> <p>5 MR. JAMES: I apologize.</p> <p>6 THE WITNESS: I just found it.</p> <p>7 MR. JAMES: I will try to call the tabs</p> <p>8 out. I appreciate the help.</p> <p>9 (Document identified as Exhibit 1105 for</p> <p>10 identification.)</p> <p>11 THE WITNESS: I have now my reply</p> <p>12 declaration and Boulange patent in front of me.</p> <p>13 BY MR. JAMES:</p> <p>14 Q Okay, great.</p> <p>15 It is a patent application, right?</p> <p>16 A It is a WO number, yes.</p> <p>17 Q It's a patent application, correct?</p> <p>18 A Patent application.</p> <p>19 Q And then this declaration, 1105, your rely</p> <p>20 declaration, it was signed by you on the 12th of</p> <p>21 April of this year, is that right?</p> <p>22 A That's right.</p>	246	<p>1 put it into the right language. As you might hear</p> <p>2 English is not native language, so they helped me</p> <p>3 also in sort of some of the language issues I had</p> <p>4 here.</p> <p>5 BY MR. JAMES:</p> <p>6 Q So they provided you with a draft and then</p> <p>7 you provided comments and they helped with the</p> <p>8 language, is that right?</p> <p>9 A That's right.</p> <p>10 MR. PEPE: Object to form.</p> <p>11 BY MR. JAMES:</p> <p>12 Q And if you could look at Paragraph 28 -- I</p> <p>13 am going to apologize, I am going to be jumping</p> <p>14 around a little bit today, sorry for that.</p> <p>15 A 28.</p> <p>16 Q 28, yes.</p> <p>17 28 is under a heading where you say that</p> <p>18 the Parylene-C wouldn't need to come into contact</p> <p>19 with the VEGF-Antagonist, right?</p> <p>20 A Right.</p> <p>21 Q And in the middle of the paragraph you say</p> <p>22 that Boulange describes that the Parylene-C</p>

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