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CONFIDENTIAL - UNDER PROTECTIVE ORDER

Transcript of Leonard George Presta, Ph.D.

Date: May 1, 2018

Case: Pfizer, Inc. -v- Genentech, Inc. (PTAB)

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1 (1 to 4)

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<p>1 UNITED STATES PATENT AND TRADEMARK OFFICE 2 ----- 3 BEFORE THE PATENT TRIAL AND APPEAL BOARD 4 ----- 5 PFIZER, INC. and SAMSUNG BIOEPIS CO., LTD., 6 Petitioner, 7 v. 8 GENENTECH, INC., 9 Patent Owner. 10 ----- 11 Case Nos. IPR2017-01488, IPR2017-01489 12 ----- 13 CELLTRION, INC., 14 Petitioner, 15 v. 16 GENENTECH, INC., 17 Patent Owner. 18 ----- 19 Case Nos. IPR2017-01373, IPR2017-01374 20 21 ** CONFIDENTIAL - UNDER PROTECTIVE ORDER ** 22 VIDEOTAPED DEPOSITION OF LEONARD GEORGE PRESTA, Ph.D. 23 San Francisco, California 24 Tuesday, May 1, 2018 25 8:58 a.m.</p>	<p>1 A P P E A R A N C E S 2 ON BEHALF OF PETITIONER PFIZER, INC.: 3 BENJAMIN LASKY, ESQUIRE 4 SHARICK NAQI, ESQUIRE 5 KIRKLAND & ELLIS, LLP 6 601 Lexington Avenue 7 New York, New York 10022 8 (212) 446-6415 9 ON BEHALF OF PETITIONER CELLTRION: 10 LINNEA P. CIPRIANO, ESQUIRE (videoconference) 11 ROBERT CERWINSKI, ESQUIRE (videoconference) 12 GOODWIN PROCTER LLP 13 620 Eighth Avenue 14 New York, New York 10019 15 (212) 813-8800 16 ON BEHALF OF PATENT OWNER GENENTECH, INC.: 17 ANDREW J. DANFORD, ESQUIRE 18 NORA Q.E. PASSAMANECK, ESQUIRE 19 WILMER CUTLER PICKERING HALE AND DORR, LLP 20 60 State Street 21 Boston, Massachusetts 02109 22 (617) 526-6022 23 ALSO PRESENT: 24 Joseph A. Mourgos, Videographer 25 Traci Ropp, Genentech</p>
<p>1 Job No.: 186258 2 Pages: 1 - 185 3 Reported By: Charlotte Lacey, RPR, CSR No. 14224 4 5 6 VIDEOTAPED DEPOSITION OF LEONARD GEORGE 7 PRESTA, Ph.D., held at the offices of DURIE TANGRI, 8 217 Leidesdorff Street, San Francisco, California 9 10 11 12 Pursuant to notice, before Charlotte Lacey, 13 Certified Shorthand Reporter, in and for the State of 14 California. 15 16 17 18 19 20 21 22 23 24 25</p>	<p>1 I N D E X 2 WITNESS PAGE 3 LEONARD GEORGE PRESTA, Ph.D. 4 Examination by Mr. Lasky 7 5 Examination by Mr. Danford 170 6 Further Examination by Mr. Lasky 174 7 Further Examination by Mr. Danford 178 8 Further Examination by Mr. Lasky 179 9 Further Examination by Mr. Danford 183 10 11 12 I N D E X O F E X H I B I T S 13 EXHIBITS DESCRIPTION PAGE 14 Exhibit 1196 Annual Reports in Medicinal 131 15 Chemistry, Volume 29, Chapter 32, 16 "Humanized Monoclonal Antibodies" 17 18 19 P R E V I O U S L Y M A R K E D E X H I B I T S 20 EXHIBIT DESCRIPTION PAGE 21 Exhibit 1001 U.S. Patent Number 6,407,213 81 22 Exhibit 1193 Leopoldina-Symposium 53 23 Functional and Regulatory Aspects 24 of Enzyme Action article, 25 "Humanized Antibodies"</p>

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2 (5 to 8)

Conducted on May 1, 2018

<p>1 Exhibit 1194 Article, "Humanization of a mouse 2 anti-human IgE antibody: A 3 potential therapeutic for 4 IgE-mediated allergies" 5 Exhibit 2001 Copy of laboratory notebook 6 number 10098 7 Exhibit 2002 Copy of laboratory notebook 8 number 10823 9 Exhibit 2003 Copy of laboratory notebook 10 number 11268 11 Exhibit 2016 Declaration of Dr. Leonard G. 12 Presta in Case IPR2017-01488 13 Exhibit 2016 Declaration of Dr. Leonard G. 14 Presta in Case IPR2017-01489 15 Exhibit 2020 Article, "Humanization of an 16 anti-p185HER2 antibody for human 17 cancer therapy." 18 19 20 21 22 23 24 25</p>	<p>5 138 59 59 160 12 12 21 6</p>	<p>1 MS. CIPRIANO: Linnea Cipriano of Goodwin 2 Procter representing Celltrion. 3 THE VIDEOGRAPHER: Thank you. The court 4 reporter is Charlotte Lacey representing Planet Depos. 5 Would the reporter please administer the oath. 6 7 LEONARD GEORGE PRESTA, Ph.D., 8 the witness herein, having been first duly sworn, was 9 examined and testified as follows: 10 11 EXAMINATION 12 BY MR. LASKY: 13 Q Good morning, Dr. Presta. 14 A Good morning. 15 Q Can you please state your name for the record. 16 A Leonard George Presta. 17 Q And have you had your deposition taken before? 18 A Yes. 19 Q How many times? 20 A Three times. 21 Q Okay. 22 When was the first time you had your 23 deposition taken? 24 A That was in the mid-'90s. 25 Q And what was the subject matter of that</p>	<p>7</p>
<p>1 PROCEEDINGS 2 THE VIDEOGRAPHER: Here begins video number 1 3 in the videotaped deposition of Dr. Leonard G. Presta in 4 the matter of Pfizer Incorporated, et al., versus 5 Genentech Incorporated, IPR number 2017-01488 and 01489, 6 and Celltrion versus Genentech, IPR number 2017-01373 7 and 01374. In the United States Patent and Trademark 8 Office before the Patent Trial and Appeal Board. 9 Today's date is May 1st, 2018, and the time on 10 the video monitor is 8:59 a.m. The videographer today 11 is Joseph Mourgos representing Planet Depos. This video 12 deposition is taking place at 217 Leidesdorff Street, 13 San Francisco, California. 14 Would counsel please voice identify yourselves 15 and state whom you represent. 16 MR. LASKY: Good morning. My name is Ben 17 Lasky. I'm from Kirkland & Ellis. I represent Pfizer. 18 With me today is my colleague, Sharick Naqui, also from 19 Kirkland & Ellis. 20 MR. DANFORD: My name is Andrew Danford of 21 WilmerHale. I'm here today representing Genentech and 22 the witness. And I'm joined today by my colleague Nora 23 Passamaneck and Traci Ropp of Genentech. 24 THE VIDEOGRAPHER: And on the telephone, we 25 have...</p>	<p>6</p>	<p>1 deposition? 2 A It was for a European Union Patent Office 3 action, Genentech, et al. versus Protein Design Labs. 4 Q And what was that patent dispute about, to the 5 extent that you recall? 6 A It was the -- the humanization patent of Cary 7 Queen. 8 Q And was Genentech challenging that 9 humanization patent of Cary Queen to the best of your 10 recollection? 11 A I think Genentech and I think the total there 12 were 18 companies at the... 13 Q And were you representing Genentech as an 14 expert witness in that case? 15 A No, I was an employee. 16 Q Okay. 17 And what was the subject matter of your 18 testimony in that case? 19 A I never actually gave testimony, just did the 20 declaration. 21 Q Okay. 22 The declaration -- sorry. Strike that. 23 So just to be clear, did you actually have a 24 deposition taken in that case? 25 A Yes.</p>	<p>8</p>

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<p style="text-align: right;">9</p> <p>1 Q Okay.</p> <p>2 So what, in general, was the subject matter of</p> <p>3 the declaration you submitted in that case?</p> <p>4 A The -- it was so long ago. It was primarily</p> <p>5 just countering the -- the Cary Queen PDL humanization</p> <p>6 patent.</p> <p>7 Q Okay.</p> <p>8 The second deposition that you had taken, out</p> <p>9 of the three that you mentioned, what -- what case was</p> <p>10 that for?</p> <p>11 A These were not Genentech cases. These were</p> <p>12 for consulting clients.</p> <p>13 Q Okay.</p> <p>14 And you were representing them as a -- an</p> <p>15 expert witness in those cases?</p> <p>16 A Expert witness, yes.</p> <p>17 Q Okay.</p> <p>18 Which -- starting with the first deposition,</p> <p>19 which company were you retained consultant for in that</p> <p>20 case?</p> <p>21 A I don't think they want me divulging that.</p> <p>22 Q Is this -- well, let me -- let me start with</p> <p>23 when was this?</p> <p>24 A The first -- this was 2013 to 2014.</p> <p>25 Q Okay.</p>	<p style="text-align: right;">11</p> <p>1 Q Okay.</p> <p>2 A So it never went to court.</p> <p>3 Q Okay.</p> <p>4 Do you know if the dispute was filed in a</p> <p>5 court?</p> <p>6 A No, I do not.</p> <p>7 Q Okay. The third deposition you had taken,</p> <p>8 that was also as a retained expert?</p> <p>9 A Yes.</p> <p>10 Q Was any -- were any of your opinions in that</p> <p>11 case made publicly available through submission to a</p> <p>12 court or otherwise.</p> <p>13 A I do not know.</p> <p>14 Q Okay.</p> <p>15 When -- when was this?</p> <p>16 A This was soon after that same company.</p> <p>17 Q Okay.</p> <p>18 So it's also for Alder Pharmaceuticals?</p> <p>19 A Right.</p> <p>20 Q Okay.</p> <p>21 The only time you have had your deposition</p> <p>22 taken, when an employee of Genentech, related to that</p> <p>23 action challenging PDL's patent; is that right?</p> <p>24 A Correct.</p> <p>25 Q Okay.</p>
<p style="text-align: right;">10</p> <p>1 And were any of your opinions made public at</p> <p>2 that time through -- through either, you know, being</p> <p>3 included in a submission to a court or otherwise?</p> <p>4 A Submission to the court.</p> <p>5 Q Okay.</p> <p>6 So just focusing on what was made public as a</p> <p>7 submission to the court, what was your -- what was the</p> <p>8 company that you were retained by?</p> <p>9 A Alder Pharmaceuticals.</p> <p>10 Q Okay.</p> <p>11 And what was the subject matter of your</p> <p>12 testimony that was made public?</p> <p>13 A They were challenge --</p> <p>14 Q Just -- I apologize -- that was made public</p> <p>15 through submission to the court.</p> <p>16 A They were challenging the patent of another</p> <p>17 company.</p> <p>18 Q Okay.</p> <p>19 And do you recall what company that was?</p> <p>20 A No, I don't. It was a very small company. I</p> <p>21 don't remember the name.</p> <p>22 Q Okay. Do you remember what jurisdiction it</p> <p>23 was in in the sense of was it in the patent office or in</p> <p>24 a court?</p> <p>25 A It -- it -- I think they settled.</p>	<p style="text-align: right;">12</p> <p>1 Have you submitted any declarations in any</p> <p>2 proceedings other -- for Genentech other than the inter</p> <p>3 partes review proceedings that we are here for today?</p> <p>4 A Other than the PDL case, I cannot remember</p> <p>5 any.</p> <p>6 Q Okay. What is your current position?</p> <p>7 A I'm retired. And I do -- but I do do</p> <p>8 consulting for various companies.</p> <p>9 Q Okay.</p> <p>10 When did you retire?</p> <p>11 A December 2012.</p> <p>12 Q Okay.</p> <p>13 In December 2012 when you retired or before</p> <p>14 you retired, what was your position at that point?</p> <p>15 A I was a scientist at Merck & Company in Palo</p> <p>16 Alto, California.</p> <p>17 Q Okay.</p> <p>18 Dr. Presta, I've handed you copies of two</p> <p>19 documents. For the record, the first document I've</p> <p>20 handed you has been marked as Genentech Exhibit 2016 in</p> <p>21 IPR2017-01488, and the second document that I handed you</p> <p>22 has been marked Genentech Exhibit 2016 in IPR2017-01489.</p> <p>23 Do you recognize these documents?</p> <p>24 A Yes.</p> <p>25 Q Are these the declarations that you prepared</p>

<p style="text-align: right;">13</p> <p>1 that have been submitted in the inter partes reviews</p> <p>2 brought by Pfizer relating to U.S. patent</p> <p>3 number 6,407,213?</p> <p>4 A Yes.</p> <p>5 Q And if I refer to that patent as the</p> <p>6 '213 patent in this deposition, will you understand what</p> <p>7 I'm saying?</p> <p>8 A Yes.</p> <p>9 Q Okay.</p> <p>10 There are also declarations -- well, strike</p> <p>11 that.</p> <p>12 Are you aware of any differences between the</p> <p>13 two declarations that I've handed you?</p> <p>14 A No.</p> <p>15 Q Okay.</p> <p>16 Are you aware that declarations in your name</p> <p>17 have also been submitted in proceedings brought by</p> <p>18 Celltrion relating to the '213 patent?</p> <p>19 A Yes.</p> <p>20 Q And are those declarations substantively</p> <p>21 identical to the declarations that you provided in the</p> <p>22 Pfizer case?</p> <p>23 A As far as I know, yes.</p> <p>24 Q Okay.</p> <p>25 And so if I focus on one of the declarations</p>	<p style="text-align: right;">15</p> <p>1 Now, prior to joining -- well, strike that.</p> <p>2 Your position at Genentech was your first</p> <p>3 position in industry; is that right?</p> <p>4 A Correct.</p> <p>5 Q And prior to that, had you had any experience</p> <p>6 working on antibody humanization projects?</p> <p>7 A No.</p> <p>8 Q Okay.</p> <p>9 As a postdoctoral -- well, strike that.</p> <p>10 In paragraph 3, you mention that after</p> <p>11 obtaining your Ph.D., you took a postdoctoral position</p> <p>12 in the group of Dr. George Rose at Hershey Medical</p> <p>13 Center, Penn State University.</p> <p>14 Do you see that?</p> <p>15 A Yes.</p> <p>16 Q And you worked on molecular modeling in that</p> <p>17 position, right?</p> <p>18 A Correct.</p> <p>19 Q What was the purpose of the molecular modeling</p> <p>20 you did while in postdoctoral position at the Hershey</p> <p>21 Medical Center?</p> <p>22 A I came up with a hypothesis governing how</p> <p>23 alpha helices, the protein sequence in a protein, starts</p> <p>24 and stops alpha helices.</p> <p>25 Q And did you consider at the time that that</p>
<p style="text-align: right;">14</p> <p>1 today, will your testimony generally apply to all of the</p> <p>2 declarations in your name that have been submitted in</p> <p>3 this IPR proceeding?</p> <p>4 A Yes.</p> <p>5 Q Okay. So let's focus on the Exhibit 2016 in</p> <p>6 IPR2017-01488. Are you aware of any errors in that</p> <p>7 declaration?</p> <p>8 A No.</p> <p>9 Q Is there anything in the declaration you would</p> <p>10 change if you had the opportunity today?</p> <p>11 A No.</p> <p>12 Q Okay.</p> <p>13 If you can open up to the background section</p> <p>14 of your declaration, which starts in paragraph 1 and it</p> <p>15 goes through to paragraph 8, I want to focus on that</p> <p>16 section first.</p> <p>17 As you mention in paragraph 4, you joined</p> <p>18 Genentech as a molecular modeler in the protein</p> <p>19 engineering department in 1988.</p> <p>20 Do you see that?</p> <p>21 A Yes.</p> <p>22 Q Do you recall when in 1988 you joined</p> <p>23 Genentech?</p> <p>24 A September 1st.</p> <p>25 Q Okay.</p>	<p style="text-align: right;">16</p> <p>1 work might have any further applications beyond the</p> <p>2 study itself?</p> <p>3 MR. DANFORD: Objection to form.</p> <p>4 Q I'm -- I'm asking for you --</p> <p>5 A Yeah.</p> <p>6 Q -- what you were thinking at the time.</p> <p>7 A This was purely scientific.</p> <p>8 Q Okay.</p> <p>9 A Protein folding.</p> <p>10 Q Uh-huh. Okay.</p> <p>11 And was any of that protein folding</p> <p>12 investigation specific to antibodies?</p> <p>13 A No.</p> <p>14 Q Now, during your Ph.D. work at the Texas A&M</p> <p>15 University, you also did work on molecular modeling and</p> <p>16 X-ray crystallography, right?</p> <p>17 A Correct.</p> <p>18 Q And what was the focus of that research?</p> <p>19 A A class of proteins called serine proteases.</p> <p>20 Q And what was known about the function of</p> <p>21 serine proteases at that time?</p> <p>22 A They are enzymes that clip specific sequences</p> <p>23 and other proteins.</p> <p>24 Q And what were you modeling the serine</p> <p>25 proteases for?</p>

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