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Transcript of Paul J. Carter, Ph.D.

Date: April 27, 2018

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

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<p style="text-align: right;">Page 1</p> <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 PAUL J. CARTER, Ph.D. 23 San Francisco, California 24 Friday, April 27, 2018 25 9:09 a.m.</p>	<p style="text-align: right;">Page 3</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 11 (Via 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 style="text-align: right;">Page 2</p> <p>1 Job No.: 186256 2 Pages: 1 - 177 3 Reported By: Charlotte Lacey, RPR, CSR No. 14224 4 5 VIDEOTAPED DEPOSITION OF PAUL J. CARTER, Ph.D., 6 held at the offices of DURIE TANGRI, 217 Leidesdorff 7 Street, San Francisco, California 8 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 style="text-align: right;">Page 4</p> <p>1 I N D E X 2 WITNESS PAGE 3 PAUL J. CARTER, Ph.D. 4 Examination by Mr. Lasky 7 5 Examination by Mr. Danford 174 6 Further Examination by Mr. Lasky 175 7 8 9 I N D E X O F E X H I B I T S 10 EXHIBITS DESCRIPTION PAGE 11 (None offered) 12 13 PREVIOUSLY MARKED EXHIBITS 14 EXHIBIT DESCRIPTION PAGE 15 Exhibit 1001 U.S. Patent Number 6,407,213 34 16 Exhibit 1193 Leopoldina-Symposium 19 17 Functional and Regulatory Aspects 18 of Enzyme Action article, 19 "Humanized Antibodies" 20 Exhibit 2003 Copy of laboratory notebook 130 21 number 11268 22 Exhibit 2004 Copy of laboratory notebook 130 23 number 11643 24 Exhibit 2017 Declaration of Dr. Paul J. Carter 8 25 in Case IPR2017-01488</p>

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Transcript of Paul Carter, Ph.D.

Conducted on April 27, 2018

<p>1 Exhibit 2017 Declaration of Dr. Paul J. Carter 2 in Case IPR2017-01489 3 Exhibit 2020 Article, "Humanization of an 4 anti-p185HER2 antibody for human 5 cancer therapy" 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p>Page 5 8 15</p>	<p>Page 7 1 THE VIDEOGRAPHER: Thank you. 2 On the video conference we have: 3 MS. CIPRIANO: Linnea Cipriano of Goodwin 4 Procter representing Celltrion. 5 THE VIDEOGRAPHER: The court reporter today is 6 Charlotte Lacey representing Planet Depos. 7 Would the reporter please administer the oath. 8 PAUL J. CARTER, Ph.D., 9 the witness herein, having been first duly sworn, was 10 examined and testified as follows: 11 EXAMINATION 12 BY MR. LASKY: 13 Q Good morning, Dr. Carter. 14 A Good morning. 15 Q Do you understand today that you're being 16 deposed in proceedings before the Patent Office 17 challenging your patent, the '213 patent? 18 A Yes, I do I understand that. 19 Q Okay. 20 And you've submitted several declarations in 21 the proceedings relating to that patent, correct? 22 A There's at least one declaration that I'm 23 aware of. 24 Q Right. Okay. 25 And that same declaration, are you aware that</p>
<p>1 PROCEEDINGS 2 THE VIDEOGRAPHER: Here begins video number 1 3 in the videotaped deposition of Paul J. Carter, Ph.D., 4 in the matter of Pfizer Incorporated, et al. versus 5 Genentech Incorporated in the United States Patent and 6 Trademark Office before the Patent Trial and Appeal 7 Board, IPR numbers 2017-01488 and 01489 regarding Pfizer 8 versus Genentech and 01373 and 01374 regarding Celltrion 9 versus Genentech. 10 Today's date is April 27th, 2018. The time on 11 the video monitor is 9:10 a.m. The videographer is 12 Joseph Mourgos representing Planet Depos. This video 13 deposition is taking place at 217 Leidesdorff Street, 14 San Francisco, California. 15 Would counsel please voice identify yourselves 16 and state whom you represent, beginning with those in 17 the room. 18 MR. LASKY: My name is Benjamin Lasky. I'm 19 from Kirkland & Ellis, and I represent Pfizer. And with 20 me today is my colleague Sharick Naqi, also from 21 Kirkland & Ellis. 22 MR. DANFORD: And I'm Andrew Danford, 23 WilmerHale. I represent Genentech. And I'm joined 24 today by colleague, Nora Passamaneck of WilmerHale and 25 Traci Ropp of Genentech.</p>	<p>Page 6</p>	<p>Page 8 1 it has been submitted different times in different 2 proceedings? 3 A I am aware of that. 4 Q Okay. 5 Dr. Carter, I've handed you what has been 6 marked as Exhibit 2017 in two different proceedings. 7 And I'm just doing this for the record. The proceedings 8 are IPR2017-01488 and 2017-01489. 9 Are these the declarations that you submitted 10 in these proceedings? 11 A Let me look at them, and then I'll be able to 12 answer your question. 13 Q Sure. 14 A This one looks good. So this is 01488. 15 Let me look at 01489. Is this the same... 16 Q Well, let me ask you this -- 17 A Well, let me look first. 18 Q Sure. You can -- you can look. Take your 19 time. 20 A So this is declaration 01489. This also seems 21 to be in order. 22 Q Okay. Do you know of any differences between 23 the two declarations or are they substantively 24 identical? 25 A To the best of my knowledge, they're the same.</p>

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1 Q Okay.
 2 And I guess for all of these proceedings
 3 regarding the '213 patent, do you remember preparing
 4 more than one declaration with the -- with differences?
 5 That's a bad question. Let me -- strike that.
 6 Are you aware of any differences between the
 7 declarations that I've put before you that were
 8 submitted in the Pfizer proceedings and the declarations
 9 that were submitted in other proceedings involving
 10 Celltrion?
 11 A To the best of my knowledge, there are no
 12 differences.
 13 Q Okay.
 14 Did you review your declarations in
 15 preparation for the deposition today?
 16 A Yes, I did review the declaration.
 17 Q Okay.
 18 In re-reviewing the declaration, have you
 19 found anything that was inaccurate?
 20 A To the best of my knowledge, there -- I'm
 21 unaware of anything that's inaccurate.
 22 Q Okay.
 23 And in reviewing -- re-reviewing your
 24 declarations, did you find anything that you would now
 25 change?

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1 A There's nothing that I would change after
 2 re-reviewing.
 3 Q Okay.
 4 I'd like to ask you some questions about the
 5 background section of your declaration. And we can
 6 focus on the 01488 declaration. You can put the other
 7 one aside. If there's any differences you work out, you
 8 can let me know.
 9 So you obtained your BA in Natural Sciences
 10 from Cambridge in 1982; is that correct?
 11 A Yes, that is correct.
 12 Q And the Ph.D. in Molecular Biology in 1986 was
 13 obtained at the Medical Research Counsel Laboratory; is
 14 that right?
 15 A Laboratory of Molecular Biology --
 16 Q Uh-huh.
 17 A -- correct.
 18 Q And is that -- was that Dr. Winter's lab at
 19 the time?
 20 A It is Dr. Gregory Winter. Actually now,
 21 Sir Gregory Winter.
 22 Q Okay. And when did you begin working in
 23 Dr. Winter's lab, either as a Ph.D., researcher,
 24 postdoctoral fellow, or otherwise?
 25 A So I began in Sir Gregory's lab in 1982.

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1 Q Okay.
 2 And from the time you began in Sir Gregory
 3 Winter's lab, were you working on antibody chemistry at
 4 that time?
 5 A Most of the time, I was working on a -- my
 6 thesis project, which was, Site-directed mutagenesis of
 7 tyrosyl tRNA synthetase from -- from Bacillus --
 8 Bacillus stearothermophilus.
 9 Q Okay.
 10 That work did not involve work with
 11 antibodies; is that right?
 12 A This particular project did not.
 13 Q Okay.
 14 When -- strike that.
 15 Did you do any antibody-related work while you
 16 were in the Winter lab?
 17 A I did a very small amount of antibody work.
 18 Q Okay.
 19 And when would that have started?
 20 A To the best of my recollection, that was
 21 towards the end of my Ph.D., actually after I had
 22 submitted my thesis.
 23 Q Okay.
 24 And would that be, then, around about 1985
 25 onwards?

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1 A That period would have been from late 1985
 2 through early 1986.
 3 Q Okay.
 4 And at that point, is that when you joined
 5 Genentech as a postdoctoral fellow?
 6 A That is correct.
 7 Q Okay.
 8 The work that you did in late 1985 through
 9 early 1986, what was the project?
 10 A It was a project that I initiated trying to
 11 explore a new technology that had just been published
 12 using polymerase chain reaction.
 13 Q And how was -- and polymerase chain reaction
 14 also referred to as PCR?
 15 A Correct. We can call it PCR.
 16 Q Okay.
 17 PCR, how was that being used in the project
 18 that you were doing at the Winter lab in late 1985
 19 through early 1986?
 20 A I was trying to get the PCR technology to --
 21 to work, and I chose a human -- humanized antibody gene
 22 to -- to do that.
 23 Q Which gene did you choose?
 24 A I believe it would have been one of the genes
 25 from the early humanization work from the -- from the

<p style="text-align: right;">Page 13</p> <p>1 Winter laboratory. 2 Q Okay. 3 You don't recall which particular project? 4 A I believe that it was the antibody genes in 5 the -- in the Jones, et al., publication, to the best of 6 my knowledge, something which is more than 30 years 7 later. 8 Q Yes. Understandable. 9 The -- who at the Winter lab was working with 10 you on this project at the time? 11 A It was really nobody else. It was just 12 myself. 13 Q Okay. 14 Were you seeking advice from anyone in the 15 laboratory at that time on this project? 16 MR. DANFORD: Objection to form. 17 A I was -- I don't remember clearly this -- 18 this -- these number of years later. Sorry. 19 Q Okay. 20 Did you ever overlap in time at the Winter lab 21 with Lutz Riechmann? 22 A To the best of my recollection, Lutz Riechmann 23 joined the -- Sir Gregory Winter's laboratory after I 24 joined at Genentech. 25 Q Okay.</p>	<p style="text-align: right;">Page 15</p> <p>1 A I was aware of at least some of that work, 2 including work that had begun prior to my joining 3 Genentech. 4 Q Okay. One of the projects that was undertaken 5 in the Winter lab in the late 1980s was attempts to 6 humanize an anti-lysozyme protein antibody. Is that -- 7 well, strike that. 8 Are you aware of a project that was undertaken 9 in the Winter labs in the 1980s to humanize an 10 anti-lysozyme antibody? 11 MR. DANFORD: Objection; outside the scope. 12 A Yes. I am aware of that antibody humanization 13 project. 14 Q Were you aware of that project while you were 15 at Genentech between 1986 and 1989? 16 A I was aware of that work, in part because it 17 was published. 18 Q Okay. Do you happen do you recall where it 19 was published? 20 A If you can provide me with my PNAS paper, we 21 can -- we can look at the exact reference. 22 Q Okay. Dr. Carter, I've handed you a copy of 23 what's been marked as Genentech Exhibit 2020 in both the 24 1488 and 1499 -- 89 proceedings. And it's a copy of an 25 article titled "Humanization of an anti-p185HER2</p>
<p style="text-align: right;">Page 14</p> <p>1 And did you overlap in the Winter lab at any 2 time with Jeffrey Foote? 3 A To the best of my recollection, Jeff Foote 4 joined Sir Gregory Winter's lab after I left -- 5 actually, my recollection is that Jeff inherited my 6 bench. 7 Q Okay. 8 At the time that you joined Genentech in 1986 9 through -- to the spring of 1989, when you started your 10 own laboratory, did you have any contact with the Winter 11 lab anymore? 12 A I had intermittent contact. 13 Q And did any of that contact involve Jeff 14 Foote? 15 MR. DANFORD: Objection to form. 16 A I don't honestly remember this far -- it was a 17 long time ago. 18 Q Okay. 19 And is the same true with respect to Lutz 20 Riechmann? 21 A I don't remember. It's a very long time ago. 22 Q Okay. At the time that you were in -- at 23 Genentech in the 1986 to 1989 time frame, were you aware 24 of the work that was being done at Winter lab in 25 humanization of antibodies?</p>	<p style="text-align: right;">Page 16</p> <p>1 antibody for human cancer therapy," from the Proceedings 2 of the National Academy of Sciences, U.S.A., in May 2 of 3 1982. Is this the PNA reference that you were referring 4 to? 5 A It's May 1992. 6 Q Sorry. 7 A It is the right -- it is the right reference, 8 yes. 9 Q Apologize. I misspoke. Yes. May 1992. 10 And you were referring to a paper that 11 published the anti-lysozyme work. Is that one of the 12 cited references? 13 A Yes. It is one of cited references. 14 Q And which one is this? 15 A To the best -- best of my recollection, it's 16 the reference on ATN, that's the Verhoeyen, et al., 17 Science, Volume 239, pages 1534 to 1536. 18 Q And for the record, Verhoeyen, 19 V-e-r-h-o-e-y-e-n? 20 A Correct. 21 Q Okay. Other than through the published 22 literature or the Verhoeyen reference, were you aware of 23 the work being done to humanize the anti-lysozyme 24 antibody at the Winter lab? 25 A I have no clear recollection beyond this</p>

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