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**CONFIDENTIAL - UNDER PROTECTIVE ORDER**

# Transcript of Irene Loeffler

**Date:** May 1, 2018

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

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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 IRENE LOEFFLER 23 San Francisco, California 24 Tuesday, May 1, 2018 25 12:59 p.m.</p>	<p>1 A P P E A R A N C E S 2 ON BEHALF OF PETITIONER PFIZER, INC.: 3 SHARICK NAQI, ESQUIRE 4 BENJAMIN LASKY, ESQUIRE 5 KIRKLAND &amp; ELLIS, LLP 6 300 North LaSalle 7 Chicago, Illinois 60654 8 (312) 861-2000 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. Mourgous, Videographer 25 Traci Ropp, Genentech</p>
<p>1 Job No.: 186258 2 Pages: 1 - 52 3 Reported By: Charlotte Lacey, RPR, CSR No. 14224 4 5 6 VIDEOTAPED DEPOSITION OF IRENE LOEFFLER, held at 7 the offices of DURIE TANGRI, 217 Leidesdorff Street, 8 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 IRENE LOEFFLER 4 Examination by Mr. Naqi 10 5 Examination by Mr. Danford 39 6 7 8 I N D E X O F E X H I B I T S 9 EXHIBITS DESCRIPTION PAGE 10 (None offered) 11 12 P R E V I O U S L Y M A R K E D E X H I B I T S 13 EXHIBIT DESCRIPTION PAGE 14 Exhibit 2001 Copy of laboratory notebook 13 15 number 10098 (retained by deponent) 16 Exhibit 2002 Copy of laboratory notebook 13 17 number 10823 (retained by deponent) 18 Exhibit 2003 Copy of laboratory notebook 13 19 number 11268 (retained by deponent) 20 Exhibit 2004 Copy of laboratory notebook 13 21 number 11643 (retained by deponent) 22 Exhibit 2005 Copy of laboratory notebook 13 23 number 10840 (retained by deponent) 24 Exhibit 2006 Copy of laboratory notebook 13 25 number 11162 (retained by deponent)</p>

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Transcript of Irene Loeffler

2 (5 to 8)

Conducted on May 1, 2018

<p>5</p> <p>1 Exhibit 2007 Copy of laboratory notebook 13 2 number 11008 (retained by deponent)</p> <p>3 Exhibit 2008 Copy of laboratory notebook 13 4 number 11297 (retained by deponent)</p> <p>5 Exhibit 2009 Copy of laboratory notebook 13 6 number 11568 (retained by deponent)</p> <p>7 Exhibit 2019 Declaration of Irene Loeffler in 12 8 case number IPR2017-01488 (retained 9 by deponent)</p> <p>10 Exhibit 2019 Declaration of Irene Loeffler in 12 11 case number IPR2017-01489 (retained 12 by deponent)</p> <p>13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p>7</p> <p>1 MS. CIPRIANO: Linnea Cipriano with Goodwin 2 Procter representing Celltrion.</p> <p>3 THE VIDEOGRAPHER: Thank you. 4 The court reporter today is Charlotte Lacey 5 representing Planet Depos. 6 Would the reporter please administer the oath. 7 IRENE LOEFFLER, 8 the witness herein, having been first duly sworn, was 9 examined and testified as follows: 10 MR. LASKY: Before we get started, I'm going 11 to state an objection on the record. During a break in 12 the earlier deposition of Len Presta, we were informed 13 for the first time that counsel had brought today what 14 he said were the microfilmed versions of various 15 documents, notebooks that had been presented as 16 exhibits -- as exhibits by Genentech in this case. 17 At a subsequent break, 12:15, for the first 18 time, counsel put those microfilmed versions in front of 19 us. There are hundreds of pages of documents there. We 20 object to the extent that counsel intends to raise these 21 documents today at the deposition. We have not had the 22 chance to review them. They have not been submitted as 23 exhibits. We were given a very brief time to review 24 them. And despite counsel's representation that the 25 documents are identical to those that were already</p>
<p>6</p> <p>1 P R O C E E D I N G S 2 THE VIDEOGRAPHER: Here begins video number 1 3 in the videotaped deposition of Irene Loeffler in the 4 matter of Pfizer Incorporated versus Genentech 5 Incorporated, IPR number 2017-01488 and 01489, and 6 Celltrion versus Genentech, IPR number 2017-01373 and 7 01374 in the United States Patent and Trademark Office 8 before the Patent Trial and Appeal Board. 9 Today's date is May 1st, 2018, and the time on 10 the video monitor is 12:59 p.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 voice identify yourselves and 15 state whom you represent. 16 MR. NAQI: My name is Sharick Naqi. I'm from 17 Kirkland &amp; Ellis, and I represent Pfizer. And with me 18 today is my colleague, Benjamin Lasky, also from 19 Kirkland &amp; Ellis. 20 MR. DANFORD: My name is Andrew Danford from 21 WilmerHale, and I represent Genentech and the witness. 22 And I'm joined today by my colleague Nora Passamaneck of 23 WilmerHale and Traci Ropp of Genentech. 24 THE VIDEOGRAPHER: And on the telephone, we 25 have...</p>	<p>8</p> <p>1 produced, just in the half an hour we've had a chance to 2 review them today, we've already found at least three 3 differences between the microfilmed versions and the 4 produced -- the versions that were produced to us. 5 And so we object to the use of these documents 6 during the deposition today. We object to their use in 7 these proceedings as a whole. 8 MR. DANFORD: I object to that colloquy. I 9 mean, as I understand it, Mr. Naqi's taking the 10 deposition here today, and you're in the second chair. 11 So -- that's for starters. 12 I also say we gave you sufficient time for 13 this. If you want to ask about the microfilms, you're 14 welcome to do so. We are not pressuring you to go 15 forward with this right now. You could have taken as 16 much time as you wanted to review those. There have 17 been questions raised in these proceedings about the 18 microfilms. There is no difference, from our 19 perspective, from the lab notebooks that have been 20 produced and the microfilms, and so we're making them 21 available to you now in case you had any questions about 22 them. 23 MR. LASKY: Mr. Danford, the issues of 24 microfilms have been -- have been raised since at least 25 Dr. Carter's deposition and possibly even before, and</p>

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9	<p>1 that was days ago. There's no reason why this couldn't</p> <p>2 have been raised earlier. Frankly, there's no reason</p> <p>3 why this couldn't have been produced when the exhibits</p> <p>4 were produced in the first place. I can demonstratively</p> <p>5 prove to you that there are differences between the</p> <p>6 microfilms versions and the versions that were produced</p> <p>7 to us.</p> <p>8 We were not given time to review these today.</p> <p>9 We're here sitting in San Francisco where we've traveled</p> <p>10 for this deposition, and we have not had more than half</p> <p>11 an hour to review this. It was raised -- I don't even</p> <p>12 know why it wasn't raised earlier during Dr. Presta's</p> <p>13 deposition, why you had to wait till the second</p> <p>14 five-minute break that we received.</p> <p>15 And as for the fact that I'm not taking this</p> <p>16 deposition, you raised these documents first during the</p> <p>17 deposition of Dr. Presta, and as you're well aware, my</p> <p>18 colleague and I share in the duties today.</p> <p>19 MR. DANFORD: Well --</p> <p>20 MS. CIPRIANO: And if I can note for the</p> <p>21 record that Celltrion has not been produced -- they have</p> <p>22 not been provided an opportunity to review these</p> <p>23 documents. They were given a hard copy, and I am</p> <p>24 attending the deposition electronically.</p> <p>25 MR. DANFORD: Okay.</p>	11	<p>1 <b>A Verifying lab notebooks at Genentech; previous</b></p> <p>2 <b>jobs, previous documents.</b></p> <p>3 Q And were these patent matters?</p> <p>4 <b>A At Genentech?</b></p> <p>5 Q Yes.</p> <p>6 <b>A I -- I don't really remember the nature of the</b></p> <p>7 <b>case.</b></p> <p>8 Q You are currently employed at Genentech; is</p> <p>9 that right?</p> <p>10 <b>A Yes.</b></p> <p>11 Q What is your current title at Genentech?</p> <p>12 <b>A Associate Director.</b></p> <p>13 Q In general, what is your role in that</p> <p>14 position?</p> <p>15 <b>A Records management.</b></p> <p>16 Q And could you elaborate on that?</p> <p>17 <b>A Specifically for the case, we're talking about</b></p> <p>18 <b>laboratory notebooks, so I oversee the issuing,</b></p> <p>19 <b>tracking, recalling, scanning, indexing, and retrieving</b></p> <p>20 <b>lab notebooks of their images.</b></p> <p>21 Q And what was your title at Genentech in 1989?</p> <p>22 <b>A Whatever it said in my deposition. I don't</b></p> <p>23 <b>remember the exact title at that time.</b></p> <p>24 Q And what was your role in 1989?</p> <p>25 <b>A Records. It's been records my entire career.</b></p>
10	<p>1 MS. CIPRIANO: And we add, for the record, we</p> <p>2 have the same objections as Mr. Lasky.</p> <p>3 MR. DANFORD: All right. Your objections have</p> <p>4 been noted. Let's see where this goes.</p> <p>5 EXAMINATION</p> <p>6 BY MR. NAQI:</p> <p>7 Q Good morning.</p> <p>8 <b>A Good morning.</b></p> <p>9 Q Would you please state your full name for the</p> <p>10 record.</p> <p>11 <b>A Irene Loeffler.</b></p> <p>12 Q Ms. Loeffler, have you had your deposition</p> <p>13 taken before?</p> <p>14 <b>A Yes.</b></p> <p>15 Q How many times?</p> <p>16 <b>A In my life, maybe four or five.</b></p> <p>17 Q And when was the first time you were deposed?</p> <p>18 <b>A Previous employment, back in the -- probably</b></p> <p>19 <b>early '80s.</b></p> <p>20 Q And your subsequent depositions, were they all</p> <p>21 related to your work at Genentech?</p> <p>22 <b>A As I recall, I had perhaps two at my previous</b></p> <p>23 <b>employment and maybe two or three at Genentech.</b></p> <p>24 Q And what was the subject matter of these</p> <p>25 depositions?</p>	12	<p>1 Q So was it similar to your current role?</p> <p>2 <b>A I've been promoted a few times, so I have more</b></p> <p>3 <b>responsibilities as time went on.</b></p> <p>4 Q I've just handed you two documents. The first</p> <p>5 document has been marked as Exhibit 2019 in</p> <p>6 IPR2017-01488 and the other one has been marked as</p> <p>7 Exhibit 2019 in IPR2017-01489.</p> <p>8 Have you seen these documents before?</p> <p>9 <b>A Yes.</b></p> <p>10 Q And are these declarations that you have</p> <p>11 submitted in proceedings regarding U.S. patent</p> <p>12 number 6,407,213?</p> <p>13 <b>A Yes.</b></p> <p>14 Q Is it fair to say that these two declarations</p> <p>15 are substantively identical in terms of their contents?</p> <p>16 <b>A Yes.</b></p> <p>17 Q And to the extent that declarations were</p> <p>18 submitted from you in multiple proceedings involving</p> <p>19 Pfizer and Celltrion, they would be copies of the same</p> <p>20 declaration?</p> <p>21 <b>A Yes.</b></p> <p>22 Q And to the extent I ask you questions about</p> <p>23 one of these, would your answers apply equally to the</p> <p>24 other declarations as well?</p> <p>25 <b>A Yes.</b></p>

<p style="text-align: right;">13</p> <p>1 Q Did you review your declaration in preparation                  2 for this deposition?                  3 A Yes.                  4 Q Was there anything in there that you saw that                  5 was incorrect?                  6 A No.                  7 Q Is there anything in there that you saw that                  8 would change if you could write it again?                  9 A No.                  10 Q Let's turn to page 1 of your declaration. You                  11 can use the one marked for -- 1488. Do you see it --                  12 the proceedings.                  13 So at paragraph 4 on page 1 of your                  14 declaration, do you see the first sentence that says,                  15 "The exhibits listed below are true and authentic copies                  16 of several Genentech laboratory notebooks"?                  17 A Yes.                  18 Q Now, you're referring to the Genentech                  19 Exhibits 2001 through 2009 listed in paragraph 4 of your                  20 declaration; is that correct.                  21 A Yes.                  22 Q Now, do you know how the -- how the copies                  23 that you referred to in paragraph 4, first sentence of                  24 your declaration were made?                  25 MR. DANFORD: Objection to form.</p>	<p style="text-align: right;">15</p> <p>1 Q So Genentech Exhibits 2001 through 2009 are                  2 the high-resolution, color-scanned copies made from the                  3 physical notebooks in 2016; is that correct?                  4 A Right.                  5 Q And separate copies of these notebooks were                  6 also made early earlier in the 1990s using microfilm                  7 technology?                  8 A Right.                  9 Q Now, you have not presented the microfilm                  10 versions of these notebooks made early in '90 -- in                  11 1990s in your declaration.                  12 A The declaration pertained to the scanned ones.                  13 Q So let's turn to page 6 of your declaration                  14 starting at the first sentence. I'm sorry. Paragraph 6                  15 of your declaration starting at the first sentence.                  16 There, you state, "I am familiar with                  17 Genentech's practices regarding the creation,                  18 modification, and keeping of its laboratory notebooks                  19 through my employment at Genentech."                  20 A Right.                  21 Q "Each of the laboratory notebooks listed above                  22 was created by Genentech personnel during the regular                  23 course of business."                  24 A Right.                  25 Q And then you state, "It was the regular</p>
<p style="text-align: right;">14</p> <p>1 A I'm sorry?                  2 MR. DANFORD: I just objected to the form of                  3 the question.                  4 Q You can answer.                  5 MR. DANFORD: If you understand it.                  6 A Yeah. So the copies had been scanned, and                  7 then I believe what you have now are printouts.                  8 Q And when were these copies scanned?                  9 A They were on or around the time of the                  10 declaration.                  11 Q Now, on -- and when was that declaration                  12 prepared?                  13 A August 4th, 2017.                  14 Q So Exhibits 2001 through 2009 are copies that                  15 were scanned from the actual notebooks in August 2017;                  16 is that correct?                  17 A I--                  18 MR. DANFORD: Objection; lacks foundation.                  19 A I don't know exactly when they were scanned,                  20 but, yes, they were scanned from the original lab                  21 notebooks.                  22 Q Maybe I can help you. If you turn to page 3                  23 of your declaration, paragraph 7, last sentence.                  24 Do you see where it says --                  25 A Okay. So around November 2016.</p>	<p style="text-align: right;">16</p> <p>1 practice of Genentech's personnel to create such records                  2 at or near the time the recorded act, event, condition,                  3 or opinion occurred."                  4 A Right.                  5 Q And then you state -- and you state, "It was                  6 the general practice of Genentech's personnel to date                  7 such documents as of the date the record was                  8 modified" -- I'm sorry -- "was created or modified."                  9 A Right.                  10 Q So here in paragraph 6, you're discussing the                  11 regular practice of Genentech's personnel or the general                  12 practice of -- of Genentech's personnel; is that                  13 correct?                  14 A Yes.                  15 Q Do you have any knowledge about the practice                  16 of any particular Genentech employee in terms of making                  17 entries into these notebooks?                  18 MR. DANFORD: Objection to form.                  19 A No.                  20 Q So you don't have any personal knowledge about                  21 how each one of these notebooks was filled in.                  22 A No.                  23 Q And in the last sentence of paragraph 6, you                  24 state, "Such records would only be made by someone with                  25 knowledge or from information transmitted by someone</p>

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