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Transcript of Robert Leonard

Date: February 16, 2018

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

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<p>1 UNITED STATES PATENT AND TRADEMARK OFFICE 2 BEFORE FOR THE PATENT TRIAL AND APPEAL BOARD 3 -----x 4 CELLTRION, INC., : 5 Petitioner, : 6 v. : Case IPR 2017-01373 7 GENENTECH, INC., : Case IPR 2017-01374 8 Patent Owner. : U.S. Patent 6,407,213 9 -----x 10 11 Deposition of ROBERT LEONARD 12 New York, New York 13 Friday, February 16, 2018 14 9:03 a.m. 15 16 17 18 19 Job No.: 178016 20 Pages: 1 - 160 21 Reported By: Nancy Mahoney, CCR/RPR 22</p>	<p>1 A P P E A R A N C E S 2 ON BEHALF OF PETITIONER CELLTRION: 3 CYNTHIA LAMBERT HARDMAN, ESQUIRE 4 chardman@goodwinlaw.com 5 GOODWIN PROCTOR LLP 6 The New York Times Building 7 620 Eighth Avenue 8 New York, New York 10018 9 212.459.7240 10 11 12 13 14 15 16 17 18 19 20 21 22</p>
<p>1 Deposition of ROBERT LEONARD, held at the 2 offices of: 3 4 5 Goodwin Procter LLP 6 The New York Times Building 7 620 Eighth Avenue 8 New York, New York 10018 9 212.813.8800 10 11 12 13 14 15 Pursuant to agreement, before Nancy Mahoney, 16 Notary Public in and for the state of New York. 17 18 19 20 21 22</p>	<p>1 A P P E A R A N C E S C O N T I N U E D: 2 3 ON BEHALF OF PATENT OWNER GENENTECH: 4 ROBERT J. GUNTHER, ESQUIRE 5 robert.gunther@wilmerhale.com 6 WILMER CUTLER PICKERING HALE & DORR LLP 7 7 World Trade Center 8 250 Greenwich Street 9 New York, New York 10007 10 212.230.8850 11 - and - 12 ANDREW H. LE, ESQUIRE 13 andrew.le@wilmerhale.com 14 WILMER CUTLER PICKERING HALE & DORR LLP 15 950 Page Mill Road 16 Palo Alto, California 93404 17 18 19 ALSO PRESENT: 20 21 Charlie Bowman, Videographer 22</p>

Transcript of Robert Leonard
Conducted on February 16, 2018

2 (5 to 8)

5		7	
1	C O N T E N T S	1	P R E V I O U S L Y M A R K E D E X H I B I T S
2	EXAMINATION OF ROBERT LEONARD	2	(Attached to transcript)
3	By Mr. Gunther	3	
4		4	ROBERT LEONARD
5	E X H I B I T S	5	PAGE
6	(Attached to transcript)	6	Exhibit 2020 Article entitled
7		7	Humanization of an Anti-p185HER2
8	ROBERT LEONARD	8	antibody for human cancer therapy
9	PAGE	9	Exhibit 1034 Article entitled A
10	Exhibit 2055 Article entitled	10	humanized antibody that binds to the
11	Antibody-Based Therapy, Humanized	11	interleukin 2 receptor
12	Antibodies	12	Exhibit 1021 Article entitled p185HER2
13	Exhibit 2059 Article entitled	13	Monoclonal Antibody has
14	Monoclonal Antibodies in the Detection	14	Antiproliferative Effects In Vitro and
15	and Therapy of Micrometastatic	15	Sensitizes Human Breast Tumor Cells to
16	Epithelial Cancers	16	Tumor Necrosis Factor
17	Exhibit 2060 Article entitled	17	Exhibit 1048 Article entitled
18	Monoclonal Antibodies in Cancer	18	Monoclonal Antibody Therapy of Human
19	Therapy from Current Opinion in	19	Cancer: Taking the HER2 Protooncogene
20	Immunology 1993	20	to the Clinic
21		21	
22		22	
6		8	
1	P R E V I O U S L Y M A R K E D E X H I B I T S	1	P R O C E E D I N G S
2	(Attached to transcript)	2	THE VIDEOGRAPHER: Here begins disk number
3		3	one of the videotaped deposition of Robert Leonard
4	ROBERT LEONARD	4	in the matter of Celltrion, Inc. v. Genentech,
5	PAGE	5	Inc., in the United States Patent and Trademark
6	Exhibit 1004A Curriculum Vitae of	6	Office, before the Patent Trial and Appeal Board,
7	Robert Leonard	7	Case No. IPR 2017-01373 and 01374.
8	Exhibit 1004 Expert Declaration of	8	Today's date is February 16, 2018; the
9	Robert Charles Fredrick Leonard, M.D.	9	time is approximately 9:03 a.m. The videographer
10	In Support of Petition of Inter Partes	10	today is Charlie Bowman representing Planet Depos.
11	Review of Patent No. 6,407,213, Case	11	This video deposition is taking place in New York,
12	IPR 2017-01373	12	New York.
13	Exhibit 1004 Expert Declaration of	13	Would counsel please voice-identify
14	Robert Charles Fredrick Leonard, M.D.	14	yourselves for the record.
15	In Support of Petition of Inter Partes	15	MR. GUNTHER: For the Patent Owner
16	Review of Patent No. 6,407,213, Case	16	Genentech, Bob Gunther and Andrew Le from the
17	IPR 2017-01374	17	WilmerHale firm.
18	Exhibit 1001 U.S. Patent No. 6,407,213	18	MS. HARDMAN: For Petitioner Celltrion,
19		19	Cynthia Hardman, Goodwin Procter.
20		20	THE VIDEOGRAPHER: The court reporter
21		21	today is Nancy Mahoney representing Planet Depos.
22		22	Would the court reporter please swear in the

<p style="text-align: right;">9</p> <p>1 witness.</p> <p>2 ROBERT LEONARD,</p> <p>3 after having been first duly sworn or affirmed to</p> <p>4 testify to the truth, was examined and</p> <p>5 testified as follows:</p> <p>6 EXAMINATION BY COUNSEL FOR THE PATENT OWNER</p> <p>7 GENENTECH BY ROBERT GUNTHER:</p> <p>8 Q Good morning, Dr. Leonard.</p> <p>9 A Good morning, sir.</p> <p>10 Q Dr. Leonard, have you ever had your</p> <p>11 deposition taken before?</p> <p>12 A Deposition, not in this setting, but we</p> <p>13 had a court case relating to a different patent to</p> <p>14 do with Herceptin in the UK about four years ago.</p> <p>15 Q Right. And you mentioned in your CV --</p> <p>16 let me give your CV just so that we both have it</p> <p>17 in front of us.</p> <p>18 MS. HARDMAN: Would you mind if I just get</p> <p>19 a bottle of water for Dr. Leonard?</p> <p>20 MR. GUNTHER: Not at all.</p> <p>21 THE WITNESS: Thanks. Appreciate that.</p> <p>22 Thank you.</p>	<p style="text-align: right;">11</p> <p>1 versus Roche, 2013, 2014.</p> <p>2 A Um-hum.</p> <p>3 Q Do you see that? That's what you were</p> <p>4 referring to just now when I asked you --</p> <p>5 A Yeah.</p> <p>6 Q Okay. And, sir, in those -- in either of</p> <p>7 those proceedings, do you recall which patents</p> <p>8 were involved?</p> <p>9 A I'm afraid I can't remember the patent</p> <p>10 number.</p> <p>11 Q Okay. Did one of the patents involve the</p> <p>12 amount of acidic variance in the antibody. Do you</p> <p>13 recall that?</p> <p>14 A I don't remember, I'm sorry.</p> <p>15 Q Okay. Do you recall whether one of the</p> <p>16 patents might have involved the dosing for</p> <p>17 trastuzumab?</p> <p>18 A Yeah, the second patent was to do with the</p> <p>19 subcutaneous weekly versus three-weekly, et</p> <p>20 cetera.</p> <p>21 Q Okay, fair enough.</p> <p>22 A Yeah, that was '116, I think.</p>
<p style="text-align: right;">10</p> <p>1 BY MR. GUNTHER:</p> <p>2 Q And if you need anything like that, just</p> <p>3 let us know.</p> <p>4 (Exhibit 1004A Curriculum Vitae of Robert</p> <p>5 Leonard previously marked, is attached to the</p> <p>6 transcript.)</p> <p>7 Q Dr. Leonard, I'm going to put in front of</p> <p>8 you what's been marked -- previously marked as</p> <p>9 Celltrion Exhibit 1004A and just ask you to</p> <p>10 confirm for me that this is your CV, your</p> <p>11 curriculum vitae as of November 2016.</p> <p>12 A Yeah.</p> <p>13 Q And, sir, if you look at the second</p> <p>14 page -- it actually says page 1 of 42, but it</p> <p>15 looks like it's the second page of the document.</p> <p>16 There is a heading at the top that says Current</p> <p>17 Activity.</p> <p>18 Do you see that?</p> <p>19 A Yes.</p> <p>20 Q And then a little bit further down you</p> <p>21 reference expert witness on trastuzumab in</p> <p>22 clinical practice for Hospira in two court cases</p>	<p style="text-align: right;">12</p> <p>1 Q And, sir, just to make sure that I've kind</p> <p>2 of covered the waterfront with respect to this,</p> <p>3 can you recall any other litigations or</p> <p>4 proceedings, whether in the U.S. or outside the</p> <p>5 U.S., that involved trastuzumab that you were</p> <p>6 involved in other than those two?</p> <p>7 A I had one what I would call a desultory</p> <p>8 call with someone in Hong Kong about maybe a year</p> <p>9 after that court case. It seemed to go nowhere</p> <p>10 and they never followed it up, so I don't know</p> <p>11 what happened to that.</p> <p>12 Q Fair enough, okay.</p> <p>13 A And he's doing some background on me and</p> <p>14 so drew a line under that.</p> <p>15 Q Sure, sure, sure. And, sir, in terms of</p> <p>16 the two cases -- they were both in the UK?</p> <p>17 A Yes.</p> <p>18 Q Okay. And did you submit declarations in</p> <p>19 those cases?</p> <p>20 A Yes.</p> <p>21 Q Did you testify at the trials?</p> <p>22 A Yes.</p>

<p style="text-align: right;">13</p> <p>1 Q Okay. Now, is it fair to say that those 2 matters did not involve the -- strike that. 3 Is it fair to say that the -- those 4 matters that you've testified about in terms of 5 your work in the UK relating to trastuzumab, they 6 did not relate to a counterpart of the '213 7 patent. Is that correct? 8 A I think that's right, yeah. 9 Q Okay. So is this the first time, as far 10 as you know, that you've given expert testimony 11 relating to the subject matter of the '213 patent? 12 A Yes, this is a much more technical 13 discussion than the last one, yeah. 14 Q Gotcha. And, sir, just coming back, in 15 those proceedings do you recall being asked 16 questions like -- in a setting like this prior to 17 trial? 18 A No. 19 Q Okay. And is it fair to say that this is 20 the first time you've done something like that? 21 A That's correct. 22 Q Okay. Have you worked on any litigations</p>	<p style="text-align: right;">15</p> <p>1 IPR? 2 A It is. Can I just draw your attention to 3 a mistake? 4 Q Absolutely. I'm going to get to that in 5 just a second. 6 A Oh, okay. 7 Q Before we do that, and I'm going to give 8 you a chance to talk about anything you want to 9 correct or change. If you take a look at page 39, 10 I just want to confirm that that's your signature. 11 A Yes. 12 Q Okay. Now you wanted to draw my attention 13 to a -- an error? 14 A Yes. It's either page 19 or 21. It's 15 item 34, Paragraph 34. 16 Q Let me just get there with you; hang on 17 for one second. 18 A Yeah. 19 Q Okay, I'm with you. 20 A Okay. Under 34 you get to the fourth 21 line, "Unfortunately, this chimeric approach was 22 available for OKT3." Should have been not</p>
<p style="text-align: right;">14</p> <p>1 relating to trastuzumab in the United States? 2 A No. 3 Q Okay. Or any other type of proceeding in 4 the United States? 5 A No. 6 Q Other than this, of course? 7 A That's correct. 8 Q Okay. So let me -- what I'd like to do is 9 put the two declarations that you've submitted in 10 this matter in front of you. So the first one 11 that I'll put in front of you is your declaration 12 in the 01373 IPR which is marked in that 13 proceeding as Celltrion Exhibit 1004. 14 (Exhibit 1004 Expert Declaration of Robert 15 Charles Fredrick Leonard, M.D. in Support of 16 Petition of Inter Partes Review of Patent No. 17 6,407,213, Case IPR 2017-01373 previously marked, 18 is attached to the transcript.) 19 A Thank you. 20 Q And if you can take a look at that, sir, 21 and confirm for me that that is, in fact, your 22 declaration relating to the '213 patent in the 373</p>	<p style="text-align: right;">16</p> <p>1 available. 2 Q Not available. Okay. Do you want to 3 actually make that change on the document just so 4 that we have that. 5 A Yeah. 6 Q Could you put your initials just over -- 7 A Yeah. 8 Q -- next to that. 9 A Yeah. 10 Q Thank you. Right. I actually think that 11 makes quite good sense in the context of the 12 sentence. Thank you for pointing that out. 13 A I'm sorry I missed it four times. 14 Q Yes, well ... 15 Let me ask you this: Any other exchanges 16 or corrections or additions that you'd want to 17 make to Exhibit 1004 in the 373 IPR at this time? 18 A I don't think so. 19 Q Okay. So let me hand you what has been 20 previously marked in the 01374 IPR as Celltrion 21 Exhibit 1004, and I'm going to ask you if you can 22 confirm for me that that is your declaration in</p>

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