

Transcript of Conference Call

Date: June 18, 2018

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

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Celltrion, Inc. v. Genentech IPR2017-01374 Genentech Exhibit 2065



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	UNITED STATES PATENT AND TRADEMARK OFFICE	1 PROCEEDINGS
-		2 JUDGE POLLOCK: Good afternoon. This
	BEFORE THE PATENT TRIAL AND APPEAL BOARD	3 conference call is for IPR2017-01373 and
-		4 IPR2017-01374. I am Judge Pollock. On the line
	CELLTRION, INC.,	5 with me is Judge Yang. I expect Judge Spence to be
	Petitioner,	6 joining us as we continue.
	v.	Who do we have on the line for Patent
	GENENTECH, INC.,	8 Owner Genentech?
	Patent Owner.	9 MR. DANFORD: Good afternoon, Your Honor.
0 _		10 For Patent Owner Genentech, you have Andrew Danford.
1	Case IPR2017-01373	11 And I'm joined by Bob Gunther and Dave Cavanaugh.
2	IPR2017-01374	
3	U.S. Patent No. 6,407,213	JUDGE POLLOCK: Good afternoon, Mr.
4 _ -		13 Danford.
5 s	Conference Call	Who do we have on the line for Petitioner
6 7	Conference Call	15 Celltrion?
8	June 18, 2018	MS. CIPRIANO: Hi. This is Linnea
	ob No.: 194710	17 Cipriano. And on the line with me I have Cynthia
	lages: 1 - 20	18 Hardman.
	eported by: Keith G. Shreckengast, RPR	JUDGE POLLOCK: Good afternoon, Ms.
2	eported by. Referr C. Sin cerengase, N. R.	20 Cipriano.
-		Are there any other parties on the line?
		22 THE COURT REPORTER: The court reporter
		2 4
	APPEARANCES	1 is here. My name is Keith.
		2 JUDGE POLLOCK: Who retained the court
0	N BEHALF OF PATENT OWNER, GENENTECH:	3 reporter?
	ANDREW J. DANFORD, ESQUIRE	4 MR. DANFORD: Your Honor, this is Andre
	ROBERT J. GUNTHER, JR., ESQUIRE	5 Danford. Patent Owner, Genentech, did.
	DAVID L. CAVANAUGH, ESQUIRE	6 JUDGE POLLOCK: Mr. Danford, would yo
	WILMER CUTLER PICKERING HALE & DORR, LLP	7 please submit a copy of the transcript as an exhibit
	1875 Pennsylvania Avenue, NW	8 as soon as it's available?
	Washington, DC 20006	9 MR. DANFORD: We will.
0	(202) 663-6000	10 JUDGE POLLOCK: That will serve as a
1		11 record of this call.
	N BEHALF OF PETITIONER CELLTRION, INC.:	12 MR. DANFORD: We will do that.
3	LINNEA P. CIPRIANO, ESQUIRE	
4	CYNTHIA HARDMAN, ESQUIRE	JUDGE POLLOCK: I understand that the
5	GOODWIN PROCTER The New York Times Ruilding	14 Patent Owner seeks authorization to file a motion to
6 7	The New York Times Building	15 strike relating to certain arguments and evidence in
8	620 Eighth Avenue New York, New York 10018	16 Petitioner's May 25th Reply Brief.
9	(212) 813-8800	Mr. Danford, would you explain the issue
0	(2.2) 013 0000	18 as you see it?
1		19 MR. DANFORD: Sure. And maybe I can ju
2		20 remind you of where we are in these proceedings. I
•		21 think that'll help set this up just a little bit.
		There are two proceedings brought by



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1 Celltrion challenging the same patent. The two

2 petitions are actually copies of petitions that were

3 previously filed by Mylan. Basically what Celltrion

4 did was they, after the Mylan proceedings settled,

5 took the same petitions, put in the same grounds,

6 the same arguments, and expert declarations that are

7 copies of the declarations that were filed in the

8 prior proceeding.

9 We received the Reply from Celltrion on 10 May 25th. When we reviewed the Reply, we believe 11 that there was new argument presented with respect

12 to a claim limitation. This is a claim limitation

13 on the consensus sequence.

In the original petition, the argument
15 and evidence that Celltrion had presented with
16 respect to the consensus sequence limitation was
17 based on the Queen 1990 reference, in one of the
18 petitions, and it was based on a Queen 1989, in
19 combination with Kavat, 1987. That's K-A-V-A-T.
20 And those were the references that Celltrion
21 included and based its arguments with respect to the

6

For the first time in the Reply, and in
the supporting expert declaration that was submitted

3 with it, Celltrion relied on a new exhibit. This is

4 Exhibit 1193. And in their Reply, they for the

22 consensus sequence limitation on in the petition.

5 first time argued that that exhibit, which is not

6 part of the instituted grounds, also discloses a

7 consensus sequence.

We think that that's improper at this

9 stage. They had their opportunity to submit

10 evidence on where they believe the consensus

11 sequence is disclosed. We responded to those

12 arguments. And the first time that the Exhibit 1193

13 came into this proceeding was when they filed the

14 Reply Brief first introducing it.

15 So I think that basically just frames the 16 issue for you. I think that there's really no 17 reason why this exhibit could not have been 18 presented by Celltrion earlier, for at least two 19 reasons.

The first is if you read what Celltrion's 21 expert says about the exhibit, he mentions that this 22 Exhibit 1193 describes research where he actually

1 took part of the research and used it in his own

2 research. But, you know, when he submitted his

3 original declaration in the proceeding, never

4 mentioned this particular aspect of that work, or

5 mentioned that it included anything that had to do

6 with a consensus sequence. So this is something

that came up the first time in the Reply.

And second, this is a reference, Exhibit

9 1193 was something that was presented and discussed 10 during prosecution. So it's part of the file

11 history that was submitted here. It's something

12 that Celltrion could have identified from reviewing

13 the file history. And so in light of that, we think

14 that there's really no excuse for this coming up now

15 at this late stage.

As the Board knows, we have argument 17 scheduled a month from now. It's -- the oral

18 hearing date is July 16th. We think it's too late

19 for these kind of things to be coming into the

20 proceeding now. And we would ask for leave to file

21 a motion to strike to address this. We think that's

22 the most appropriate relief in this proceeding. We

1 can do it in parallel with the motion to exclude.

2 We already have a deadline of Friday to file that.

3 And our suggestion would be that a motion to strike

4 be submitted in parallel with that, so that all

5 these issues can be addressed together at the same

6 time.

JUDGE POLLOCK: Mr. Danford, is the

8 Exhibit 1193, is there a first author?

9 MR. DANFORD: It's Foote, F-O-O-T-E.

10 JUDGE POLLOCK: Foote. If the Foote 11 reference was raised during the prosecution, what's

12 the harm in coming into play now?

13 MR. DANFORD: It was raised during the 14 prosecution, Your Honor, but -- you know, if we had 15 known that this was going to be part of an argument 16 that was presented here, we could have presented 17 ourselves differently. We could have argued under 18 325 D, for example, that this proceeding should not 19 have gone forward simply for that very reason, 20 because the reference was something that was 21 addressed during prosecution.

Now we've gone down and we've responded



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1 to the art that's been raised. We've addressed

- 2 Queen 1989. We've addressed Queen 1989 in
- 3 combination with Kavat 1987. You know, we think
- 4 it's just unfair to have something new come in at
- 5 this point, where we haven't had the ability to
- 6 respond to it. And honestly, if it had come in
- 7 earlier, we could have presented arguments
- 8 differently, for example under 325 D.
- JUDGE POLLOCK: Counsel for Petitioner, 10 how do you respond to that?
- MS. CIPRIANO: So I'd like to make two
- 12 just general statements to correct the record here.
- 13 I just want to make sure, so Mr. Danford
- 14 characterized our petitions, and the declarations
- 15 supporting them as copies of previous petitions. I
- 16 just want to make sure that it's clear that they are
- 17 not exact copies. There are differences. And those
- 18 difference have been discussed throughout these
- 19 proceedings. And Patent Owner is well aware of
- 20 those differences. So these are Celltrion's
- 21 petitions, and they're not happy that they're prior 22 petitions.

And also, my second point generally is

- 2 that Celltrion is not changing its basis of the
- 3 grounds for invalidity here. We're not saying that
- 4 this, the disputed reference, or the Foote
- 5 reference, is an additional ground or even addition
- 6 to the grounds that are instituted currently.
- 7 There's just additional support of the arguments
- 8 that are being made. So in response to the facts
- 9 that were discussed. So Genentech here is really
- 10 seems to be seeking to strike evidence from
- 11 petitioner's papers in an effort to preserve really
- 12 their mischaracterizations of the prior art.
- Mainly Patent Owner's response highlights
- 14 what they consider to be what distinguishes the 15 invention of the 213 Patent from the prior art. And
- 16 that's, as they contend, because it used this human
- 17 consensus sequence in humanizing these antibodies.
- And, in fact as noted throughout
- 19 Petitioner's papers in this proceeding, and in the
- 20 depositions that have gone forward, the prior art 21 shows that others in the field have successfully
- 22 used the human consensus sequence to humanize

1 antibodies in similar ways that the 213 Patent

So it's our position that Genentech

- 4 should not be permitted to mischaracterize the prior
- art and strike any evidence that doesn't fit its
- 6 narrative.

As noted by Mr. Danford, the information

- 8 here in the Foote paper is not a surprise to
- 9 Genentech in any way. As you noted, it was
- 10 discussed if the prosecution history. So Genentech
- 11 admitted that a consensus sequence was used in the
- 12 prior art, in the prosecution history of the 213
- 13 Patent.
- 14 Dr. Riechmann, Celltrion's expert, has 15 submitted a declaration with the Petition, and also
- 16 with our Reply papers, discussed his antibody
- 17 humanization work and his use of a consensus
- 18 sequence in this work, in his declaration. And his
- 19 use of this prior antibody was also discussed during
- 20 his deposition before Patent Owner put in their
- 21 paper.
- 22 JUDGE POLLOCK: It's Ms. Cipriano,

1 correct?

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- MS. CIPRIANO: Yes.
- 3 JUDGE POLLOCK: Ms. Cipriano, Foote was
- not discussed in the Petition, correct?
- MS. CIPRIANO: This specific reference
- was not discussed in the Petition, correct.
- JUDGE POLLOCK: So what prompted this
- additional discussion of Foote? Why is it now
- popping up in the Reply?
- MS. CIPRIANO: So one of the arguments
- 11 that Genentech made in its Patent Owner's response
- 12 is that it was unexpected, that one of the
- 13 unexpected results in rebuttal to our obviousness
- 14 argument was that it would have been unexpected to
- 15 be able to use a single consensus sequence to
- 16 humanize multiple antibodies. And of course I'm
- 17 simplifying that argument, but that's our
- 18 understanding of Genentech's unexpected -- the
- 19 unexpected results argument.
- And our argument, and the reason that the
- 21 Foote paper comes in is that's exactly what Dr.
- 22 Foote and Dr. Riechmann did in the Winter lab in the



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1 prior art. Dr. Foote developed a consensus sequence 2 for his -- in his work, humanizing an antibody. And 3 Dr. Riechmann used part of that consensus sequence 4 in his work in humanizing the PACT antibody.

JUDGE POLLOCK: Mr. Danford, why is this not a legitimate response to your unexpected results argument?

MR. DANFORD: Your Honor, it's not 9 limited just to unexpected results. They cite this 10 as affirmative support for the consensus sequence 11 limitation. For example, I believe that it's on 12 page 15 of the Reply in the 1373 proceeding, for 13 example. So this is not just rebuttal on unexpected 14 results. And if I could maybe go back to just a 15 point that was raised about Dr. Riechmann. 16 JUDGE POLLOCK: Mr. Danford, you are 17 conceding, then, that this is, at least in part, 18 rebuttal to the unexpected results argument?

MR. DANFORD: They have framed a piece of 20 this. They put a sentence in the section responding 21 on unexpected results that addresses this. We do 22 concede that there is a sentence there that

14

1 addresses that. But they have a whole paragraph of

2 discussion that explains when they're affirmatively

3 addressing the consensus with -- including

4 limitation as part of their prima facie case of

obviousness that points to the Foote reference, and

as well this was known in the art because Foote

discloses it.

JUDGE POLLOCK: If it's legitimately used 9 as rebuttal, why can't they use it for this other 10 purpose?

MR. DANFORD: You know, I don't know that 12 we -- I think that we are trying to -- it is not 13 legitimate rebuttal in our view if it is addressing 14 the affirmative prima facie case of obviousness. 15 And I think part of our concern here is that when it 16 comes in for any purpose, it potentially bleeds over 17 to these other issues. They can very well respond 18 to the unexpected results argument based upon the 19 prior art that they already made of record in their 20 petition. I mean it is Celltrion's position that 21 the consensus sequence was known in the art. What

22 they're basically doing is piling on here with

1 additional references that we haven't had an opportunity to address.

JUDGE POLLOCK: Well, if it comes in as 4 rebuttal to unexpected results argument, what's to say that the Board can't draw our own conclusions with respect to the prima facie case?

MR. DANFORD: And, Your Honor, 8 respectfully, we would like to be sure that we're, 9 as a matter of administrative procedure and due 10 process, you know, they -- it is Petitioner's 11 petition, and they are putting forward what their 12 arguments are. These are the arguments that we 13 addressed in response to, with respect to their 14 prima facie case.

15 And we respectfully submit that the 16 Board's consideration should be limited to that. 17 They have gone over the line here, in our view, for 18 example, by citing this evidence as part of their 19 prima facie case on page 15 of the 1373 Reply. And 20 so this isn't just a matter of the Board would have 21 the evidence in front of it and can do with it as it 22 will. It's something where they've actually gone

16

1 over the line, and we want to be sure that is not considered for that informational purpose.

3 JUDGE POLLOCK: And Miss Cipriano, anything more to add?

MS. CIPRIANO: Well, just to respond to 6 our use of the Foote reference on page 15 of the 7 Reply in the 1373 proceeding, I just want to 8 reiterate that that is -- is directly in response to 9 Genentech's characterization that this use of the 10 consensus sequence is -- is some novel step in the 11 prior art. And I guess I'll direct attention to 12 just even their introduction of the patent owner's 13 response, saying that unlike prior art, humanized 14 antibodies, which required hand picking a sequence 15 from the prior art, and I'm paraphrasing here. The 16 claimed antibodies could be produced from a single

17 human consensus sequence, so they really 18 distinguish -- they take a lot of effort to

19 distinguish the consensus sequence from the prior

20 art throughout the Patent Owner's response. And

21 that is -- that is the basis that we think this

22 proper reply as specifically as permitted by the



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