

Transcript of Szilard Kiss, M.D.

Date: January 7, 2022

Case: Regeneron -v- Novartis (PTAB)

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Transcript of Szilard Kiss, M.D. Conducted on January 7, 2022

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UNITED STATES PATENT AND TRADEMARK O ICE
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                   SZILÁRD KISS M.D. UNDER C. .R. § 42.53
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      REPORTED BY: AMANDA GORRONO, CLR
     CLR NO. 052005 0
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                                                                                                                                                 APPEARANCES CONT'D
                                                                           9:34 a.m. (EST)
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                                                                                                                                                 ON BEHALF OF PETITIONER REGENERON PHARMACEUTICALS, INC.:
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Conducted on	January 7, 2022
1 APPEARANCES CONT'D	THE TECH: Please stand by for the
2 Via Zoom Videoconferencing :	2 technician read on and backup recording. Zoom will
3 ON BEHALF OF THE PATENT OWNERS:	
4 Shweta Kumar, Esquire Goodwin Procter LLP	
5 1900 N Street, NW washington, D.C. 20036 6 PHONE: +1 202 346 4254	4 meeting for backup purposes.
6 PHONE: +1 202 346 4254 E MAIL: Skumar@goodwinlaw.com	5 AUTOMATED MESSAGE: Recording in
7	6 progress.
8 a	7 MR. DESAI: I'm sorry, we're not,
ALSO PRESENT:	8 we're not video recording this deposition.
Leah Shenfeld, Technician PlanetDepos 11 Jenevieve Nutovits Goodwin Procter LLP	9 THE TECH: Okay. This is a backup
12	10 video recording. It doesn't mean to be it's not
13	11 like, you know, a videotaped deposition.
14	MR. DESAI: Got it. Okay.
15	THE TECH: Is that okay with you?
16 17	MR. DESAI: That's fine with me as
18	15 long as we're not going to order the video or
19	16 anything like that. That's fine.
20	17 THE TECH: No, no, no. There's no
21	18 videographer. It's not, you know
22	19 MS. HOLLAND: I assume it's just to
	20 make sure the transcript is accurate eventually.
	MR. DESAI: That's fine with me.
	22 THE TECH: Okay. Thank you to
6	8
INDEX	1 everyone for attending this proceeding remotely which
2	2 we anticipate will run smoothly.
3 WITNESS EXAMINATION BY PAGE	Please remember to speak slowly and
4 SZILÁRD KISS, M.D. MS. HOLLAND 8	4 do your best to not talk over one another. Please be
5 6	5 aware there will be a recording of this proceeding
7	6 for backup purposes. Any off-the-record discussions
8	7 should be had away from the computer. Please
9 EXHIBITS IDENTI IED	8 remember to mute your mic for those conversations.
0	9 Please have your video enabled to
EXHIBIT DESCRIPTION PAGE	10 help the reporter identify who is speaking. If
2 Exhibit 03 Declaration of Dr. Szilárd Kiss 0	11 you're unable to connect with video and are
3 Exhibit 007 WO 20 /006877 A	12 connecting via phone, please identify yourself each
4 Exhibit 029 WO 20 /077 55 A 64	13 time before speaking.
5	14 We will provide a complimentary
6	15 unedited recording of this deposition with the
7	16 purchase of a transcript. I apologize in advance for
8	17 any technical-related interruptions.
9	18 Thank you.
20	19 SZILÁRD KISS M.D. called as a witness, having been
2	1
22	20 first duly sworn by a Notary Public of the State of
	21 New York, was examined and testified as follows:
	22 EXAMINATION

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BY MS. HOLLAND:

- 2 Q. Good morning, Dr. Kiss.
- 3 A. Good morning.
- Q. I'd like to start if I could by
- asking you to open up whatever box or envelope yougot with the exhibits.
- 7 A. (Indicating.)
 - Q. Thank you, yeah.
- 9 A. Give me one second. I'm just opening 10 it up here.
- 11 Q. Yeah, sure, no problem.
- 12 A. It looks like I received, one, two, 13 three, four, five, six, seven, eight, nine manila 14 envelopes or these envelopes.
- 15 Q. That sounds right. Thank you.
- Okay. So why don't you take out the 17 one that's your Declaration in this IPR which is 18 Exhibit 1031. And we're going to be using the IPR 19 exhibit numbers as the deposition exhibit numbers as 20 well.
- 21 A. Just give me one moment. At 1031, 22 did you say, the one dated --

- 1 open to the first page of the Declaration. It's
- 2 actually No. 1031.003.
- 3 A. Yes, I'm open to that page.
- 4 Q. Okay. And I'm going to direct your
- 5 attention to Paragraph 3.
- 6 A. Yes. Just give me one moment to read 7 that paragraph.
 - Q. Go ahead.
- 9 A. Yes.
- 10 Q. Okay. And you say that there that
- 11 you've assumed that Claim 1 of the '631 patent was
- 12 separately shown to be obvious based on prior art and
- 13 the Declaration of Horst Koller.
- 14 Do you see that?
- 15 A. Yes, I do.
- 16 Q. Did you actually review Mr. Koller's
- 17 Declaration?
- 18 A. I reviewed a portion of Mr. Koller's 19 Declaration that related to the POSITA but not the 20 whole Declaration.
- Q. Okay. Did you read the parts of the 22 Declaration where he talked about the prior art?

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- (Whereupon, Exhibit 1031, Declaration
- 2 of Dr. Szilárd Kiss, was identified.)
- 3 BY MS. HOLLAND:
- Q. I did.
- 5 A. Okay.
- 6 THE TECH: Ms. Holland, this is the 7 tech. Would you like me to pull up that exhibit on 8 my screen as well?
- 9 MS. HOLLAND: I'll ask Mr. Desai and 10 company if they want everything up on the screen.
- 11 THE WITNESS: As long as I have a 12 copy of it, I don't need it up on the screen. I have 13 a copy of the Declaration, so...
- 14 Q. Okay. Just let us know if you need 15 anything up on the screen and we'll do that.
- 16 A. Yeah.
- 17 THE TECH: Thank you.
- 18 A. I have it.
- 19 Q. You have that out, Dr. Kiss? Thank
- 20 you.
- 21 A. I do.
- Q. Okay. And what I'd like you to do is

- 1 A. I did not read any other part of the 2 Declaration.
- Q. Okay. So when you say you have
- 4 assumed, what was that based on?
- 5 MR. DESAI: Objection to form.
 - A. That is based on an assumption, as I
- 7 stated, that I assumed that the Claim 1 has
- 8 separately been shown to be obvious.
- 9 Q. Okay. I just want to be -- I'm 10 sorry. Go ahead.
- 11 A. It's an assumption.
- 12 Q. Okay. And you were asked to make
- 13 that assumption by counsel, correct?
- 14 A. I made the assumption in order to 15 form my Declaration, correct.
- 16 Q. Okay. And counsel asked you to make 17 that assumption; is that right?
- MR. DESAI: Objection; form, asked
- 19 and answered. And if you're asking for the
- 20 communications between counsel and Dr. Kiss, you
- 20 commonwhere convenience and 21, 1225, je
- 21 know, I don't think he has to answer that question.
- 22 He's otherwise answered it.

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Conducted on	January 7, 2022
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1 MS. HOLLAND: I'm asking for the	1 A. No.
2 basis of the assumption.	Q. Okay. Is it fair to say you do not
3 MR. DESAI: An assumption is an	3 have expertise in syringe design?
4 assumption. You don't have to have a basis for an	4 A. I do not have expertise in syringe
5 assumption. So let's move on.	5 design.
6 Q. What was your basis for providing in	6 Q. Okay. And is it, is it also fair to
7 your Declaration that you would assume that Claim 1	7 say that you don't have expertise in techniques for
8 has been shown to be obvious?	8 sterilizing medical devices?
9 MR. DESAI: Objection; form.	9 A. That's correct. I do not have
10 A. It was my assumption that Claim 1 was	10 expertise in sterilization for medical devices.
11 shown to be obvious and my Declaration is based on	11 Q. Okay. Let's go to Page 11 and
12 that assumption.	12 Paragraph 26.
13 Q. Okay. You don't have an opinion one	13 A. Just give me one moment to turn
14 way or the other about whether Claim 1 is obvious,	14 there.
15 correct?	15 Q. Sure.
16 A. Claim 1 is beyond the scope of my	16 A. I'm just going to read that paragraph
17 Declaration.	17 if you don't mind giving me a moment to do so.
18 Q. Okay. So just if you can answer my	18 Q. Of course.
19 question. Do you have an opinion one way or the	19 A. Yes.
20 other on whether Claim 1 is obvious?	Q. Okay. The second sentence there you
21 A. Claim 1 is beyond the scope of my	21 say: "It was known that numerous medical
22 Declaration.	22 complications could occur from incorrect intravitreal
4	6
1 Q. Okay. So does that mean you don't	1 administration."
2 have an opinion?	2 Do you see that?
3 A. I have not formed an opinion, as I	3 A. I do, yes.
3 A. I have not formed an opinion, as I 4 have not had, and not analyzed Claim 1.	3 A. I do, yes. 4 Q. Okay. What did you mean "incorrect
_	
4 have not had, and not analyzed Claim 1.	4 Q. Okay. What did you mean "incorrect
 4 have not had, and not analyzed Claim 1. 5 Q. All right. And is it correct to say 	4 Q. Okay. What did you mean "incorrect 5 intravitreal administration"?
 4 have not had, and not analyzed Claim 1. 5 Q. All right. And is it correct to say 6 you don't have the appropriate expertise to offer an 	 Q. Okay. What did you mean "incorrect intravitreal administration"? A. If the techniques used to administer
 4 have not had, and not analyzed Claim 1. 5 Q. All right. And is it correct to say 6 you don't have the appropriate expertise to offer an 7 opinion about whether Claim 1 is obvious? 	 Q. Okay. What did you mean "incorrect intravitreal administration"? A. If the techniques used to administer medications into the eye were not properly followed,
4 have not had, and not analyzed Claim 1. 5 Q. All right. And is it correct to say 6 you don't have the appropriate expertise to offer an 7 opinion about whether Claim 1 is obvious? 8 MR. DESAI: Objection; form, outside	4 Q. Okay. What did you mean "incorrect 5 intravitreal administration"? 6 A. If the techniques used to administer 7 medications into the eye were not properly followed, 8 then there could be complications.
4 have not had, and not analyzed Claim 1. 5 Q. All right. And is it correct to say 6 you don't have the appropriate expertise to offer an 7 opinion about whether Claim 1 is obvious? 8 MR. DESAI: Objection; form, outside 9 the scope.	Q. Okay. What did you mean "incorrect intravitreal administration"? A. If the techniques used to administer medications into the eye were not properly followed, then there could be complications. Q. What techniques are you referring to? A. So, those techniques include the
 4 have not had, and not analyzed Claim 1. 5 Q. All right. And is it correct to say 6 you don't have the appropriate expertise to offer an 7 opinion about whether Claim 1 is obvious? 8 MR. DESAI: Objection; form, outside 9 the scope. 10 A. So as I have stated, I have not 	Q. Okay. What did you mean "incorrect intravitreal administration"? A. If the techniques used to administer medications into the eye were not properly followed, then there could be complications. Q. What techniques are you referring to? A. So, those techniques include the
 4 have not had, and not analyzed Claim 1. 5 Q. All right. And is it correct to say 6 you don't have the appropriate expertise to offer an 7 opinion about whether Claim 1 is obvious? 8 MR. DESAI: Objection; form, outside 9 the scope. 10 A. So as I have stated, I have not 11 evaluated Claim 1 and I have not evaluated whether I 	Q. Okay. What did you mean "incorrect intravitreal administration"? A. If the techniques used to administer medications into the eye were not properly followed, then there could be complications. Q. What techniques are you referring to? A. So, those techniques include the livolume of fluid that's injected, using aseptic
4 have not had, and not analyzed Claim 1. 5 Q. All right. And is it correct to say 6 you don't have the appropriate expertise to offer an 7 opinion about whether Claim 1 is obvious? 8 MR. DESAI: Objection; form, outside 9 the scope. 10 A. So as I have stated, I have not 11 evaluated Claim 1 and I have not evaluated whether I 12 would have expertise or not.	Q. Okay. What did you mean "incorrect intravitreal administration"? A. If the techniques used to administer medications into the eye were not properly followed, then there could be complications. Q. What techniques are you referring to? A. So, those techniques include the livolume of fluid that's injected, using aseptic conditions while doing the injection itself, among
4 have not had, and not analyzed Claim 1. Q. All right. And is it correct to say you don't have the appropriate expertise to offer an popinion about whether Claim 1 is obvious? MR. DESAI: Objection; form, outside the scope. A. So as I have stated, I have not revaluated Claim 1 and I have not evaluated whether I would have expertise or not. Q. Okay. So are you telling me that	Q. Okay. What did you mean "incorrect intravitreal administration"? A. If the techniques used to administer medications into the eye were not properly followed, then there could be complications. Q. What techniques are you referring to? A. So, those techniques include the 11 volume of fluid that's injected, using aseptic 12 conditions while doing the injection itself, among 13 other things.
4 have not had, and not analyzed Claim 1. Q. All right. And is it correct to say you don't have the appropriate expertise to offer an popinion about whether Claim 1 is obvious? MR. DESAI: Objection; form, outside the scope. A. So as I have stated, I have not revaluated Claim 1 and I have not evaluated whether I would have expertise or not. Q. Okay. So are you telling me that well, let me step back for a second.	4 Q. Okay. What did you mean "incorrect 5 intravitreal administration"? 6 A. If the techniques used to administer 7 medications into the eye were not properly followed, 8 then there could be complications. 9 Q. What techniques are you referring to? 10 A. So, those techniques include the 11 volume of fluid that's injected, using aseptic 12 conditions while doing the injection itself, among 13 other things. 14 Q. You said "aseptic conditions"?
4 have not had, and not analyzed Claim 1. Q. All right. And is it correct to say byou don't have the appropriate expertise to offer an opinion about whether Claim 1 is obvious? MR. DESAI: Objection; form, outside the scope. MR. So as I have stated, I have not tevaluated Claim 1 and I have not evaluated whether I would have expertise or not. Q. Okay. So are you telling me that well, let me step back for a second. Have you looked at Claim 1?	Q. Okay. What did you mean "incorrect intravitreal administration"? A. If the techniques used to administer medications into the eye were not properly followed, then there could be complications. Q. What techniques are you referring to? A. So, those techniques include the livolume of fluid that's injected, using aseptic conditions while doing the injection itself, among other things. Q. You said "aseptic conditions"? A. Yes, I did.
4 have not had, and not analyzed Claim 1. Q. All right. And is it correct to say you don't have the appropriate expertise to offer an popinion about whether Claim 1 is obvious? MR. DESAI: Objection; form, outside the scope. A. So as I have stated, I have not revaluated Claim 1 and I have not evaluated whether I would have expertise or not. Q. Okay. So are you telling me that well, let me step back for a second. Have you looked at Claim 1? A. I have not looked at Claim 1.	4 Q. Okay. What did you mean "incorrect 5 intravitreal administration"? 6 A. If the techniques used to administer 7 medications into the eye were not properly followed, 8 then there could be complications. 9 Q. What techniques are you referring to? 10 A. So, those techniques include the 11 volume of fluid that's injected, using aseptic 12 conditions while doing the injection itself, among 13 other things. 14 Q. You said "aseptic conditions"? 15 A. Yes, I did. 16 Q. I want to make sure I heard you.
4 have not had, and not analyzed Claim 1. Q. All right. And is it correct to say byou don't have the appropriate expertise to offer an opinion about whether Claim 1 is obvious? MR. DESAI: Objection; form, outside the scope. MR. So as I have stated, I have not tevaluated Claim 1 and I have not evaluated whether I would have expertise or not. Q. Okay. So are you telling me that well, let me step back for a second. Have you looked at Claim 1? M. I have not looked at Claim 1. Okay. So you don't know what Claim 1	4 Q. Okay. What did you mean "incorrect 5 intravitreal administration"? 6 A. If the techniques used to administer 7 medications into the eye were not properly followed, 8 then there could be complications. 9 Q. What techniques are you referring to? 10 A. So, those techniques include the 11 volume of fluid that's injected, using aseptic 12 conditions while doing the injection itself, among 13 other things. 14 Q. You said "aseptic conditions"? 15 A. Yes, I did. 16 Q. I want to make sure I heard you. 17 A. Yes.
4 have not had, and not analyzed Claim 1. Q. All right. And is it correct to say 6 you don't have the appropriate expertise to offer an 7 opinion about whether Claim 1 is obvious? 8 MR. DESAI: Objection; form, outside 9 the scope. 10 A. So as I have stated, I have not 11 evaluated Claim 1 and I have not evaluated whether I 12 would have expertise or not. 13 Q. Okay. So are you telling me that 14 well, let me step back for a second. 15 Have you looked at Claim 1? 16 A. I have not looked at Claim 1. 17 Q. Okay. So you don't know what Claim 1 18 says?	4 Q. Okay. What did you mean "incorrect 5 intravitreal administration"? 6 A. If the techniques used to administer 7 medications into the eye were not properly followed, 8 then there could be complications. 9 Q. What techniques are you referring to? 10 A. So, those techniques include the 11 volume of fluid that's injected, using aseptic 12 conditions while doing the injection itself, among 13 other things. 14 Q. You said "aseptic conditions"? 15 A. Yes, I did. 16 Q. I want to make sure I heard you. 17 A. Yes. 18 Q. And by that you mean you need to make
4 have not had, and not analyzed Claim 1. Q. All right. And is it correct to say you don't have the appropriate expertise to offer an popinion about whether Claim 1 is obvious? MR. DESAI: Objection; form, outside the scope. A. So as I have stated, I have not revaluated Claim 1 and I have not evaluated whether I would have expertise or not. Q. Okay. So are you telling me that well, let me step back for a second. Have you looked at Claim 1? A. I have not looked at Claim 1. Q. Okay. So you don't know what Claim 1 says? A. I have not looked at Claim 1.	4 Q. Okay. What did you mean "incorrect 5 intravitreal administration"? 6 A. If the techniques used to administer 7 medications into the eye were not properly followed, 8 then there could be complications. 9 Q. What techniques are you referring to? 10 A. So, those techniques include the 11 volume of fluid that's injected, using aseptic 12 conditions while doing the injection itself, among 13 other things. 14 Q. You said "aseptic conditions"? 15 A. Yes, I did. 16 Q. I want to make sure I heard you. 17 A. Yes. 18 Q. And by that you mean you need to make 19 sure that the procedure is done under sterile

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