

1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD

3
4 MYLAN PHARMACEUTICALS, INC.,) CASE IPR2021-00880
5 CELLTRION, INC., and APOTEX, INC.,) Patent 9,669,069 B2
6 Petitioners,)
7 vs.) CASE IPR2021-00881
8 REGENERON PHARMACEUTICALS, INC.,) Patent 9,254,338 B2
9 Patent Owner)
10 _____) CONFIDENTIAL

11
12 VIDEO DEPOSITION OF ALEXANDER M. KLIBANOV, PH.D.
13 MARCH 24, 2022

14
15 Reported by: Rosalie A. Kramm, CSR No. 5469, CRR
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22
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24
25

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1 APPEARANCES	
2	
3 FOR THE PETITIONER:	
4 RAKOCZY MOLINO MAZZOCHI SIWIK	
5 BY: NEIL B. McLAUGHLIN, PH.D., ESQ.	
6 BY: HEINZ J. SALMEN, ESQ.	
7 BY: THOMAS H. EHRICH, ESQ.	
8 Six West Hubbard Street	
9 Chicago, Illinois 60654	
10 312.222.7241	
11 nmclaughlin@rmmslegal.com	
12 hsalmen@rmmslegal.com	
13 tehlich@rmmslegal.com	
14	
15 FOR THE PATENT OWNER:	
16 ARNOLD & PORTER	
17 BY: JEREMY COBB, ESQ.	
18 601 Massachusetts Avenue, NW	
19 Washington, DC 20001-3743	
20 202.942.6828	
21 jeremy.cobb@arnoldporter.com	
22	
23 ALSO PRESENT: ELAINE WOO	
24 ALSO PRESENT: STEPHEN GAUDET	
25 THE VIDEOGRAPHER: KEVIN MONTGOMERY	

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1 everyone attending remotely will now state their
2 appearances and affiliations for the record.
3 If there are any objections to proceeding,
4 please state them at the time of your appearance,
5 beginning with the noticing attorney.
6 MR. McLAUGHLIN: Neil McLaughlin from the Law
7 Offices of Rakoczy Molino Mazzochi Siwik on behalf of
8 Petitioners, Mylan Pharmaceuticals, Inc.
9 MR. COBB: Jeremy Cobb with Arnold & Porter on
10 behalf of Patent Owner, Regeneron.
11 MS. WOO: Eileen Woo from Regeneron.
12 THE REPORTER: People on the phone, please?
13 MR. GAUDET: Stephen Gaudet from Regeneron.
14 MR. SALMEN: Hi, this is Heinz Salmen of
15 Rakoczy Molino Mazzochi Siwik on behalf of Petitioner,
16 Mylan.
17 MR. EHRICH: Thomas Ehrich of Rakoczy Molino
18 Mazzochi Siwik on behalf of Petitioner Mylan
19 Pharmaceuticals, Incorporated.
20 THE VIDEOTAPE OPERATOR: At this time, the
21 court reporter will now swear in the witness.
22 * * *
23
24
25 //

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1 MARCH 24, 2022 9:47 A M THURSDAY SAN DIEGO, CALIFORNIA
2 THE VIDEOTAPE OPERATOR: Good morning We are
3 now on the record at 9:47 a m on March 24th, 2022
4 Please note that the microphones are sensitive and may
5 pick up whispering, private conversations, and cellular
6 interference Please turn off all cell phones or place
7 them away from the microphones as they can interfere with
8 the deposition audio Audio and video recording will
9 continue to take place unless all parties agree to go off
10 the record
11 This is Media Unit 1 of the Video Recorded
12 Deposition of Alexander Klibanov, Ph D in the matter of
13 Mylan Pharmaceuticals, Incorporated, et al , vs
14 Regeneron Pharmaceuticals, Incorporated, et al, filed in
15 the United States Patent and Trademark Office, before the
16 Patent and Appeal Board, Case Nos IPR02021-00880 and IPR
17 2021-00881
18 This deposition is taking place at Fish &
19 Richardson, located at 122860 El Camino Real, Suite 400,
20 San Diego, California 92130 My name is Kevin Montgomery
21 from the firm Veritext, and I'm the videographer The
22 court reporter is Rosalie Kramm from the firm Veritext
23 I am not related to any party in this action, nor am I
24 financially interested in the outcome
25 Counsel and all present in the room and

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1 ALEXANDER M. KLIBANOV,
2 having been first duly sworn, testified as follows:
3
4 EXAMINATION
5 BY MR. McLAUGHLIN:
6 Q. Dr. Klibanov, how many times have you been
7 deposed?
8 A. Good morning, Mr. McLaughlin.
9 I would say over the last 25, 30 years, maybe
10 three dozen times.
11 Q. And how many of those were patent cases?
12 A. You'll have to slow down, Mr. McLaughlin.
13 Could you repeat your question slower, please?
14 Q. How many of those cases were patent cases?
15 A. The vast majority of them.
16 Q. How many of those were you deposed on behalf of
17 the patentee?
18 A. I don't know. I've been deposed in cases, both
19 on behalf of patent holders and on behalf of patent
20 challengers, but I don't know what the breakdown is.
21 Q. You don't recall sitting here today how many
22 times you've testified on behalf of patentees?
23 A. That's what I said.
24 Once again, you'll have to slow down, sir.
25 Q. How much time did you spend prepping for

Page 10

1 today's deposition?
2 A. Several hours.
3 Q. Approximately how many?
4 A. All together, maybe close to ten.
5 Q. Was that over the course of a single day or
6 multiple days?
7 A. Multiple days.
8 Q. Which days were those?
9 A. Yesterday, the day before yesterday, and also a
10 few hours last week.
11 (Exhibit 1 was marked for identification.)
12 MR. McLAUGHLIN: Dr. Klibanov, I'm going to be
13 handing you what has been marked as Exhibit 1.
14 (Exhibit 2 was marked for identification.)
15 MR. McLAUGHLIN: I'm also going to be handing
16 you what has been marked as Exhibit 2.
17 THE WITNESS: Thank you.
18 BY MR. McLAUGHLIN:
19 Q. So Exhibit 1 is the Expert Declaration of
20 Alexander M. Klibanov Ph.D. Exhibit 2409. And this copy
21 is from IPR 2021-00881.
22 Did you submit identical declarations in both
23 of these matters, Dr. Klibanov?
24 A. I cannot possibly say they are identical, but I
25 did submit an expert declaration, and I did provide a

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1 copy of my curriculum vitae.
2 Q. Okay. And on the cover of your declaration you
3 see there are two case matter numbers there.
4 A. Yes.
5 Q. One ends in 880. The other ends in 881.
6 A. Correct.
7 Q. Now, if you flip to the back, page 52, is that
8 your signature?
9 A. It's a facsimile of my signature, yes.
10 (Exhibit 2 was marked for identification.)
11 BY MR. McLAUGHLIN:
12 Q. Exhibit 2 is the curriculum vitae of Alexander
13 M. Klibanov, IPR Exhibit No. 2082.
14 Do you see that?
15 A. I do see that.
16 Q. Is this CV up-to-date?
17 A. It was up-to-date to the best of my ability at
18 the time when I submitted it.
19 Q. So if you flip to page 24 --
20 A. Okay.
21 Q. -- it appears that the last entry there or the
22 last few entries, I should say, are publications from
23 2017.
24 A. Go ahead, please.
25 Q. Have there been any further publications since

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1 that time?
2 A. Yes, I published another paper that appeared in
3 2091 -- sorry, 2021, another paper.
4 Q. Okay. Then if you flip to page 42, it also
5 appears the last invited presentation is also 2017; is
6 that correct?
7 A. Correct.
8 Q. Have there been any further invited
9 presentations since that time?
10 A. No, I have not given any more presentations.
11 Q. So flipping back to page 24, you said you have
12 some additional publications since 2017.
13 A. I did not say that.
14 Q. I believe you mentioned one or two additional
15 publications.
16 A. I mentioned an additional publication.
17 Q. So there has only been once since 2017?
18 A. As far as I recall, yes. I published in 2021.
19 Q. Do you recall the subject matter of that
20 publication?
21 A. Yes, and I mean I -- it was a use of our -- the
22 technology that was developed in my laboratory at MIT for
23 using antimicrobial materials, and I want to say that it
24 was for the treatment of an eye disease, but I do not
25 recall for sure.

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1 Q. Do you know which eye disease?
2 A. As I just said, I don't recall for sure.
3 Q. Do you know if it would have been an angiogenic
4 eye disorder?
5 A. As I said, I don't recall for sure.
6 Q. If you could flip back to Deposition
7 Exhibit No. 1, this is your declaration from these
8 matters. And if you could flip to paragraph 21, please.
9 A. Okay.
10 Q. Here you set forth Patent Owner's definition of
11 a person of ordinary skill in the art, correct?
12 A. Well, I wouldn't put it quite that way.
13 Q. How would you put it?
14 A. I mean, there is just a single sentence in this
15 paragraph 21, which says, "I understand that Patent Owner
16 contends that the skilled artisan is an ophthalmologist
17 with experience in treating angiogenic eye disorders,
18 including through the use of VEGF antagonists." That's
19 what it says.
20 Q. You're not a person of ordinary skill in the
21 art under the Patent Owner's definition, correct?
22 A. Say it again slowly, please.
23 Q. You are not a person of ordinary skill in the
24 art under the Patent Owner's definition, correct?
25 A. Well, my area of expertise is brought in

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1 chemistry, structure by chemistry. That's what my
2 declaration is about. These are the issues that I
3 testify on in my declaration.
4 I'm not a clinician. I have published a number
5 of papers on treating of eye disease. I have
6 collaborated with -- collaborated with ophthalmologists
7 on a number of occasions as evidenced by my publications.
8 I've reviewed papers, grant proposals in these areas. So
9 that's my experience specifically in the area of
10 ophthalmology.
11 Q. So is that a no? You are not a person of
12 ordinary skill in the art under the Patent Owner's
13 definition?
14 A. I could not answer it with a "yes" or "no,"
15 because I don't think that it's -- it would be
16 appropriate. I can repeat what I just said, if you want
17 me to.
18 Q. No, no need.
19 A. Okay.
20 Q. You are not an ophthalmologist with experience
21 in treating angiogenic eye disorders, correct?
22 A. Yes, I am not -- that is correct. Yes. I -- I
23 probably fall under the person of ordinary skill in the
24 art definition put forth by petitioner. In fact, I
25 definitely do. But I'm not a practicing ophthalmologist,

Page 15

1 nor are the issues that I have opined on in my
2 declaration deal with practicing ophthalmology.
3 Q. So if you could turn to paragraph 41, please.
4 A. Okay.
5 Q. I'm sorry. Page 41 of your declaration.
6 A. Okay. I'm on page 41.
7 Q. There is a heading on that page regarding,
8 "Knowledge of the Amino Acid Sequence of VEGF Trap-Eye
9 Alone Would Not Necessarily Result in Treatment."
10 Do you see that?
11 A. I do see that.
12 Q. And further down in that first paragraph,
13 paragraph 90, underneath that heading, you have a phrase
14 there about treating an angiogenic eye disorder.
15 A. Mr. McLaughlin, I'd like to establish for the
16 routine that when you direct my attention to a particular
17 paragraph, in my declaration, I first would like to read
18 it to myself, and maybe a little more to orient myself.
19 And then I'll be happy to entertain your questions. Is
20 that okay?
21 Q. For right now I'm just asking you about this
22 phrase that's in quotes, "treating the angiogenic eye
23 disorder."
24 A. I still would like to read the paragraph to
25 myself.

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1 Q. Sure. Go ahead. Read that paragraph.
2 A. Thank you, sir.
3 Okay. I read that paragraph to myself.
4 Q. So you're not offering opinions about treatment
5 and treating an angiogenic eye disorder from the
6 perspective of an ophthalmologist experienced in treating
7 angiogenic eye disorders, correct?
8 A. The opinions that I offer are what is found in
9 the four corners of my expert declaration. That's what
10 I'm offering.
11 Q. And that does not include the perspective of an
12 ophthalmologist --
13 MR. COBB: Objection.
14 BY MR. McLAUGHLIN:
15 Q. -- with experience in treating angiogenic eye
16 disorders, correct?
17 MR. COBB: Objection. Asked and answered.
18 THE WITNESS: As I said, the opinions I offered
19 are those that are in my declaration, and I see no reason
20 for me to characterize them.
21 BY MR. McLAUGHLIN:
22 Q. Were you following the development of VEGF
23 Trap-Eye -- VEGF Trap-Eye as it was going through
24 clinical trials in the 2008, 2010 time frame?
25 A. I don't remember. I followed a lot of

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1 scientific developments and have for many years, but I
2 don't specifically recall.
3 Q. Do you have experience working with recombinant
4 VEGF receptor fusion proteins?
5 A. I have a lot of experience in working with
6 recombinant proteins, including antibodies. I'm not
7 specifically sure about VEGF types of proteins.
8 Q. Have you ever been involved in the development
9 of a VEGF fusion protein for use as a therapeutic?
10 A. I don't believe so, but I'm not sure.
11 Q. Have you ever been involved in the design of a
12 purification process for a commercial VEGF receptor
13 fusion protein?
14 A. I have been involved in designing lot of
15 purification schemes for pharmaceutical proteins of
16 different types. But I'm not sure about this particular
17 type of protein.
18 Q. So sitting here today, you don't recall having
19 been involved in the design of a purification process for
20 commercial VEGF receptor fusion proteins?
21 A. Mr. McLaughlin, you will have to slow down.
22 Unless you want me to preface every answer I give you
23 with the request that you slow down, you may want to
24 monitor yourself.
25 Q. Are you having trouble understanding me today,

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