

1 UNITED STATES PATENT AND TRADEMARK OFFICE

2  
3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4  
5 MYLAN PHARMACEUTICALS INC., CELLTRION, INC., and  
6 APOTEX, INC.,

7  
8 Petitioners,

9  
10 - vs. -

11  
12 REGENERON PHARMACEUTICALS, INC.,

13  
14 Patent Owner.

15  
16 Case IPR2021-00881  
17 Patent No. 9,254,338 B2

18  
19  
20 Wednesday, May 4, 2022

21 The videotaped Deposition of RICHARD  
22 MANNING, PH.D., taken at the Law Offices of  
23 Arnold & Porter Kaye Scholer LLP, 601  
24 Massachusetts Avenue NW, Washington, DC,  
25 beginning at 9:46 a.m., Eastern Standard Time,  
before Ryan K. Black, a Registered Professional  
Reporter, Certified Livenote Reporter and Notary  
Public in and for the District of Columbia.

PORTIONS OF TRANSCRIPT DESIGNATED CONFIDENTIAL

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36 Eileen Wu - Regeneron - Via Zoom

37 Vinny Lee - Mylan

38 Solomon Francis - Legal Videographer

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1 THE VIDEOGRAPHER: Good morning. We're  
2 going on the record at 9:46 a.m. on May 4th,  
3 2022.

4 Please note that the microphones are  
5 sensitive and may pick up whispering, private  
6 conversations and cellular interference. Please  
7 mute all phones at this time. Audio and video  
8 recording will continue to take place unless all  
9 parties agree to go off the record. This is  
10 Media Unit Number 1 of the video-recorded  
11 deposition of Dr. Richard Manning, taken in  
12 the matter of Mylan Pharmaceuticals, Inc.,  
13 petitioners, and Regeneron Pharmaceuticals, Inc.,  
14 patent owner, filed in the United States Patent  
15 and Trademark Office before the Patent and Trial  
16 Appeal Board. Case Number IPR2021-00880 and  
17 IPR2021-00881.

18 This deposition is being held at Arnold  
19 & Porter Kaye Scholer, as well as remotely. My  
20 name is Solomon Francis, with Veritext Legal  
21 Solutions, and I'm the videographer. Our court  
22 reporter today is Ryan Black, with Veritext Legal  
23 Solutions.

24 At this time will counsel please state  
25 their appearances and affiliations for the

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1 record.

2 MS. MAZZOCHI: Good morning. My name is  
3 Deanne Mazzochi, from the law firm Rakoczy Molino  
4 Mazzochi Siwik LLP. Also with me is Jeff Marx.  
5 And I will be questioning the witness today on  
6 behalf of the petitioners.

7 MR. CAINE: Good morning. David Caine,  
8 with Arnold & Porter, on behalf of the patent  
9 owner. With me today are Matthew Wilk, with  
10 Arnold & Porter, and James Evans and Eileen Wu,  
11 who's on the video conference from Regeneron.

12 Let me just note for the record I  
13 believe that Dr. Manning has submitted a  
14 declaration only in the '881 IPR proceeding.

15 MR. MARX: Oh, Ms. Mazzochi already  
16 introduced myself. I'm Jeff Marx, on behalf of  
17 the petitioners, from Rakoczy Molino Mazzochi  
18 Siwik.

19 THE VIDEOGRAPHER: At this time will the  
20 court reporter please swear in the witness and we  
21 can proceed.

22 \* \* \*

23 Whereupon --

24 RICHARD L. MANNING, PH.D.,  
25 called to testify, having been first duly sworn

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1 or affirmed, was examined and testified  
2 as follows:

3 \* \* \*

4 THE REPORTER: Thank you.

5 THE VIDEOGRAPHER: Please proceed,  
6 Counsel.

7 EXAMINATION

8 BY MS. MAZZOCHI:

9 Q. Thank you, Dr. Manning. Could you  
10 please state your full name and address for the  
11 record?

12 A. Richard L. Manning, 1007 Cottage Street  
13 Southwest, in Vienna, Virginia 22180.

14 Q. And, Dr. Manning, you've been deposed  
15 several times before. Yes?

16 A. Yes.

17 Q. Dr. Manning, let's get straight to it,  
18 and I'd like you to take a look at a document  
19 that's been marked in this case as Exhibit 2052.  
20 And I'd like you to confirm that this is your  
21 declaration submitted in this case.

22 (Previously marked Exhibit No. 2052 was  
23 introduced.)

24 MS. MAZZOCHI: And so while Mr. Manning  
25 -- or Dr. Manning is reviewing, I'll just note

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1 for the record we plan on marking any new  
2 exhibits to the deposition as Manning Exhibit  
3 with the exhibit number. Any previously marked  
4 exhibits that have already been submitted in this  
5 proceeding will use their existing exhibit  
6 numbers.

7 Thank you.

8 BY MS. MAZZOCHI:

9 Q. All right. So, Dr. Manning, can you  
10 confirm that Exhibit 2052 is your expert  
11 declaration for this proceeding?

12 A. It does appear to be, yes.

13 Q. All right. If we could take a little  
14 look at some of your background information. If  
15 you could turn to Page 1 of your report, which is  
16 at Page 007 of 289, and I believe it's Paragraph  
17 3. Let me know when you're there.

18 THE REPORTER: Can we turn the volume up  
19 on this?

20 THE WITNESS: I'm sorry. Paragraph 3?

21 MS. MAZZOCHI: Yep.

22 THE WITNESS: Okay. I'm there.

23 BY MS. MAZZOCHI:

24 Q. All right. It states that your career  
25 included serving as -- at multinational

3 (Pages 6 - 9)

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1 pharmaceutical companies including Merck and  
2 Pfizer. Yes?  
3 A. That's correct.  
4 Q. All right. Did either of those years of  
5 your career involve ophthalmic drugs or devices?  
6 A. Not specifically, no. I mean --  
7 Q. Okay. When you were at --  
8 A. -- I didn't work --  
9 Q. When you were --  
10 A. Sorry.  
11 Q. Sorry.  
12 When you were at Merck or Pfizer, did  
13 you work on any drugs targeting the retina?  
14 A. Not that I recall, no.  
15 Q. And let's talk about your time at Pfizer  
16 that concluded in 2009. Where did you start at  
17 Pfizer? Was it within Pfizer proper or a company  
18 that was acquired into Pfizer?  
19 A. I was hired into Pfizer from academics,  
20 so I came into Pfizer directly from the outside.  
21 Q. And when you were at Pfizer, what drug  
22 compounds did you do work on?  
23 A. Well, my role at Pfizer was not  
24 typically product-specific. I mean, I would get  
25 involved in questions that touched on specific

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1 drugs from time to time, but I was not on a  
2 product team. I was a -- an economist at the  
3 corporate -- in the corporate center, so my  
4 responsibilities weren't very often or weren't  
5 typically tied to a specific product issue.  
6 Q. Then what exactly were you doing at  
7 Pfizer?  
8 A. I was, as I said, an economist in the  
9 corporate center. I worked on a variety of  
10 issues where, as it describes in my report, I led  
11 economic analysis to shape the practices relating  
12 to emerging business concerns. I would provide  
13 input to senior executives on a variety of  
14 business or -- or other external challenges that  
15 were facing the company. I would interface with  
16 outside academic economists and others who were  
17 evaluating the economic situation that the  
18 company and the industry faced; things associated  
19 with intellectual property challenges, for  
20 example, threats to intellectual property, in --  
21 in the U.S. and abroad; questions about price  
22 controls or questions about, both internationally  
23 and domestically, the prospect of them; questions  
24 about how marketing might be affected by either  
25 regulatory or legislative actions that might

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1 have been contemplated; questions about payment  
2 policies; questions about financing for  
3 healthcare.  
4 I could go on. I think I've summarized  
5 those in my report, though, and I guess I  
6 would --  
7 Q. So was your role -- yeah. So just so I  
8 have a sense, was your role more of a public  
9 policy-type role where you were trying to drive  
10 and influence policy or were -- well, I'll just  
11 stop with that.  
12 A. My -- I was in the corporate strategic  
13 planning and policy department or division.  
14 That was a small division at the corporate center  
15 where we would not directly affect policy, but  
16 analyze the environment, which included the  
17 policy environment, but also included the payor  
18 environment or the business environment as it was  
19 evolving. So I was not a lobbyist. Although I  
20 would work on occasion with the Washington  
21 office, that was not my primary responsibility.  
22 Q. Okay. Were -- did you ever do any con  
23 -- any analyses in connection with off-label use  
24 promotions of any Pfizer drugs, or off-label  
25 promotions, in general?

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1 A. Well, I guess I'm hanging up on the  
2 question of "analysis." I mean, certainly,  
3 off-label utilization was something that we  
4 talked about or I -- I had work about. But I  
5 wouldn't -- unless you were more specific about  
6 the question, I don't know that I could really  
7 give you an answer.  
8 Q. Okay. Well, during your time at Pfizer,  
9 was that at around the time when there was a huge  
10 criminal complaint filed with Pfizer, as well as  
11 a large civil settlement, in connection with  
12 off-label promotions?  
13 A. There was a -- I don't remember the  
14 exact timing of it, and I was not directly  
15 involved in it -- that, but I do remember there  
16 being a large settlement in a case like that,  
17 yes. I don't remember the exact timing of it.  
18 Q. Did you do any economic analyses  
19 in connection with what was ultimately the  
20 settlement that Pfizer did with the federal  
21 government?  
22 A. No.  
23 Q. Were you involved in any efforts to try  
24 to improve Pfizer's corporate compliance plans in  
25 connection with that criminal and civil charge?

4 (Pages 10 - 13)

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1 A. No.  
2 THE WITNESS: Sorry. But I -- I'd like  
3 to tell the videographer that there's something  
4 on the screen that --  
5 MR. CAINE: Yeah. Maybe we could just  
6 dismiss that.  
7 BY MS. MAZZOCHI:  
8 Q. Let's go ahead and go to Page 3 of your  
9 Expert Declaration, Exhibit 2052. Paragraph 8.  
10 THE REPORTER: You're cutting out.  
11 MS. MAZZOCHI: Sorry. Let me try that  
12 again.  
13 BY MS. MAZZOCHI:  
14 Q. Turn to Page 3 of Exhibit 2052, your  
15 expert declaration, Page 009 of 289, specifically  
16 Paragraph 8.  
17 A. Okay.  
18 Q. It states you're being compensated at  
19 your standard hourly rate. What is that rate?  
20 A. \$950 per hour.  
21 Q. Okay.  
22 A. To be --  
23 Q. And how many --  
24 A. To be clear, Intensity, the firm, is  
25 being compensated at that rate.

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1 Q. Right. And how many others worked on  
2 this -- at the firm worked on this project with  
3 you?  
4 A. Two staff members, primarily. There are  
5 two others that I know worked a fair amount, and  
6 then probably a couple of others in some of the,  
7 you know, document preparation.  
8 Q. Okay. And who are the two staff members  
9 you primarily worked with?  
10 A. Ryan Marsh, who's a Ph.D from  
11 Northwestern University, was the man -- project  
12 manager. Max Urman, and I'm actually not sure  
13 how to spell his last name, but he was one of the  
14 lead consultants. The two others I have in mind  
15 at this moment -- and I may not remember  
16 everybody, I'm sorry -- were Elizabeth Parker and  
17 Arvin Mohapatra.  
18 Q. And what -- what did you ask Mr. Urman  
19 to do in connection with the preparation of this  
20 declaration?  
21 A. Well, there were a variety of things  
22 that were done to prepare for and execute the  
23 declaration. We looked at data, we looked at  
24 large number of data sets or -- or presentations  
25 that were provided to organize the work, to think

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1 about what the key questions were and to bring  
2 the analyses into a form so the -- I don't know  
3 exactly who did this, but, as you see, the attach  
4 -- the attachments to the declaration had to be  
5 processed and put into that, things like that, to  
6 generate the -- the information that is included  
7 in those attachments.  
8 Q. Okay. And what did Ryan Marsh do in  
9 connection with the preparation of your  
10 declaration?  
11 A. Ryan was the project manager. As I  
12 mentioned, he's also a Ph.D economist, so he and  
13 I -- he and I talked very frequently about my  
14 view of what the questions -- key questions were,  
15 what I wanted him to evaluate, what I wanted the  
16 team to explore, and then we talked about what  
17 the findings implied and what -- what -- what --  
18 how they fit into what I can -- ultimately came  
19 to as my opinion on the matter.  
20 Q. In connection with preparing what -- you  
21 know, some of these documents that are cited in  
22 your expert report, did you prepare any Excel  
23 spreadsheets?  
24 A. Yes. I'm sure there -- in fact, I think  
25 all of the attachments that were here are in some

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1 form in an Excel spreadsheet.  
2 Q. Okay. Did you produce the native  
3 forms of those or just paper copies with your  
4 declaration?  
5 A. To tell you the truth, I'm not sure.  
6 Q. Do you still have the original Excel  
7 spreadsheets in native form?  
8 A. Not on me today, no. I -- but if -- but  
9 if we did, they would be on my firm's network.  
10 Q. Okay. Well, we'll ask that those be  
11 looked for and produced.  
12 Do you know approximately how much your  
13 firm has billed Regeneron to date?  
14 A. Approximately?  
15 Q. Yeah.  
16 A. \$500,000, more or less. I'm not sure.  
17 (Previously marked Exhibit No. 2051 was  
18 introduced.)  
19 BY MS. MAZZOCHI:  
20 Q. If you take a look at Page 4 of your  
21 declaration, Paragraph 11, which is Exhibit 2051  
22 [sic] Page 10 of 289, it states that interviews  
23 were conducted with some Regeneron people. Why  
24 did -- did you ask to conduct these interviews or  
25 were they simply offered to you?

5 (Pages 14 - 17)

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