

Transcript of Joel M. Cohen

Date: May 19, 2022

Case: Regeneron -v- Novartis (PTAB)

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WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY



Transcript of Joel M. Cohen Conducted on May 19, 2022

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UNITED STATES PATENT AND TRADEMARK OFFICE
                                                                     1 APPEARANCES (cont'd):
        BEFORE THE PATENT TRIAL AND APPEAL BOARD
                                                                        ON BEHALF OF PATENT OWNERS:
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                                                                             DANIEL MARGOLIS, ESQUIRE
  REGENERON PHARMACEUTICALS, INC., :
                                                                             ALLEN & OVERY LLP
                Petitioner
                               : Case No.
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                                                                             New York, NY 10020
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   PHARMACEUTICALS CORPORATION,
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10
               Patent Owners
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                                                                             HAROLD RODRIGUEZ, A/V Technician
12
                                                                              JAMES EVAN, ESQUIRE, Regeneron
13
                  Oral deposition of
                                                                    13
                                                                              ANDREW GEISOR, ESQUIRE, Regeneron
14
                     JOEL M. COHEN
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                VIA VIDEO/TELECONFERENCE
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                THURSDAY, MAY 19, 2022
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20 Job No.: 448286
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21 Pages: 1 - 128
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22 Reported by: Lisa V. Feissner, RDR, CRR, CLR
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        CHRISTOPHER M. PEPE, ESQUIRE
                                                                             By Mr. Margolis
        NATALIE C. KENNEDY, ESQUIRE (NY office)
        MATTHEW D. SIEGER, ESQUIRE
        ISHA AGARWAL, ESQUIRE
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1		May 19, 2022
JOEL M. COHEN, having been first duly sworn, was examined and testified as follows: EXAMINATION BY MR. MARGOLIS: OG of morning. How are you? A I'm good this morning. Q Good morning. How are you? B A I'm good this morning. Q Is it Dr. Cohen? Cohen? Cohen? Cohen? Cohen. Co	PROCEEDINGS	7 1 prefilled syringes?
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4 Q Okay. Did any of those cases involve 5 EXAMINATION 5 Parylene C? 6 A No, none of the cases I supported 7 Gradient expert witnesses involved Parylene C. 8 A I'm good this morning. 8 Q Did any of those cases involved Silicone 9 Q Is it Dr. Cohen? 9 oil? 10 A Either is fine, Dr., Mr., no preference. 11 Q Okay. And would you just mind please 12 stating your name for the record. 13 A Joel Cohen. 14 Q And Dr. Cohen, have you ever been deposed 15 before? 16 A I've never been deposed, but I've been 17 retained as an expert witness and submitted expert 15 witness work at Gradient did not involve Parylene C, 16 prefilled syringes, silicone oil, in other contexts, 17 my professional activities have involved prefilled 19 syringes, and the materials and various components 18 witness work at Gradient did not involve Parylene C, 16 prefilled syringes, and the materials and various components 19 witness on those syringes. 19 witness on those syringes or prefilled syringes. 19 witness on the expert witness or in support of an expert witness in a case involved prefilled 19 syringes, and the materials and various components 10 witness on the expert testimony and expert reports. 19 witness on the expert witness or in support of an expert witness in a case involving syringes or prefilled syringes. 20 of it, okay. 20 Okay. So what do you mean by that? 21 A A number of times. Over the past eight 15 years at my career at Gradient, on the order of 20 16 to 30 different projects. 10 witness on those matters. However, in other 11 contexts, have conducted toxicological risk 12 assessments on prefilled syringes. 13 was expert witness or supported an expert 10 witness on those matters. However, in other 11 contexts, have conducted toxicological risk 12 assessments on prefilled syringes. 13 was expert witness or supported an expert 10 witness on those matters. However, in other 11 contexts, have conducted	· ·	_
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- 1 was a complaint that a consumer product had caused a
- 2 skin irritation hazard, and I was evaluating the
- 3 likelihood that the consumer product could have
- posed that risk to the consumer.
- Q And what was the product?
- A I'm not at liberty to say.
- Q Okay. Can you tell me who you were
- representing?
- A I was not -- I was representing the

10 defendant in that instance.

- 11 Okay.
- A So that would have been --12
- 13 Q Go ahead.
- A Oh, so the retailer that was selling the
- 15 consumer product to the consumer. That was who I 16 was representing.
- Q Okay. And can you tell me who that 17
- 18 retailer was?
- 19 A No, I'm not at liberty to say.
- Q Okay. Was it any of the parties involved
- 21 in this case? And by that I mean either Regeneron
- 22 or Novartis.

- No. It was none of the parties involved
- in this case today.
- Okay. Was it a pharmaceutical company?
- No, it was not a pharmaceutical company.
 - Q Okay. And is that case still ongoing?
- 6 A No. That case resolved.
- Q Okay. So this is -- sorry.
- Did you end up testifying in any capacity
- 9 in that case, either at trial or by deposition?
- No, I was not deposed in that case. It 11 was - the expert report was enough to resolve the 12 matter.
- O Okay. And in this case, you've submitted 14 a declaration on behalf of Regeneron, correct?
- A Yes, that is correct.
- Q And prior to this case, had you ever done 16 17 any work with Regeneron?
- A No, I've not worked with Regeneron prior 19 to this case.
- Okay. Had Gradient worked with Regeneron 21 prior to this case?
- Yes, I believe so, but I was not involved 22

1 and don't have a lot of understanding of -- or

- really any understanding of what that project
- involved.
 - Q Okay. Did it involve syringes?
 - Not that I'm aware.
- I think I asked this, but I'll ask it
- again just to make sure.
- Have you ever worked with Novartis
- before?
- 10 A No, I've never worked with Novartis.
- 11 Q Okay. And to your knowledge, has
- 12 Gradient ever worked with Novartis before?
- 13 To my knowledge, I don't believe so, no.
- 14 Q And so you submitted a declaration in 15 this case, and is that Exhibit 1108? And if you
- 16 like, I can pull that up for you.
- Yes, that's Exhibit 1108 is my 17 A 18 declaration.
- Q And when were you first contacted to work 20 on this case?
- I was first contacted about this case 22 maybe winter 2022.
- - Q Winter of 2022. So earlier this year? 1
 - 2 A That's correct.
 - Like January, around?
 - Around then, yes.
 - Q Okay. And who contacted you?
 - A Chris Pepe. 6
 - Q And were you provided any materials?
 - 8 At that time --
 - MR. PEPE: I'll just object and caution
 - 10 you not to divulge the substance of any of our 11 communications.
 - 12 But you can answer that question yes or 13 no.
 - At that time, I was more asked about my 15 experience in expert testimony and extractables and 16 leachables, things of that nature, as more about my 17 qualifications.
 - Okay. And at what point in time -- well, 19 at some point in time, you were asked to provide a 20 declaration by Regeneron, right?
 - 21 Yes, that's correct. A
 - 22 Q Okay. And when was that?

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A Late winter 2022. So February, March, around that time.

Q Okay. And what did you understand the subject matter of your declaration would be?

MR. PEPE: I'm going to object and just caution you not to divulge the substance of any communications we had. But to the extent you can answer the question without doing that, you can answer.

10 A As indicated in paragraph 2 of my 11 declaration that defines the scope of my analysis 12 and opinions, that's been my understanding of my 13 role in this case.

14 Q Okay. And what did you do in order to 15 prepare your declaration? Well, let me take that in 16 pieces. I'll strike that question.

Did you review materials in order to 18 prepare your declaration?

19 A The materials I reviewed for preparing my 20 declaration are all cited within the declaration, 21 included as exhibits.

22 Q You didn't review anything other than the

1 exhibits cited in your declaration in order to 2 prepare your declaration?

A That is correct. I didn't review anything that was not cited in my declaration in preparing the declaration.

Okay. Did you talk to anyone other than counsel in preparing your declaration?

8 A No.

9 Q You didn't have anybody helping you out 10 like you would have helped out somebody else in one 11 of those cases you were mentioning before?

12 A No. No one helped me write the 13 declaration.

14 Q Okay. And you didn't do any independent 15 searching for additional documents beyond the 16 exhibits cited in your declaration; is that correct?

17 A That's correct, I did not.

18 Q And the documents that you do cite in 19 your declaration, they were all provided to you by 20 counsel; is that right?

21 A Yes, that is correct.

22 Q Okay. Prior to your involvement in this

1 case, had you -- were you familiar with any of the

2 documents that you rely on in your declaration?

A So Exhibits 2042 and 2181 are the ISO 4 10993-1 standard. That, I'm familiar with and have

5 been familiar with this prior to this project.

Q Were you familiar with any of the other exhibits cited in your declaration prior to your involvement in this case?

9 A No, I was not familiar with the other 10 exhibits provided or cited in my declaration.

11 Q Okay. So you weren't familiar, prior to 12 your involvement with this case, with the Chang 13 article that's Exhibit 2030?

14 A No, I had not seen that article prior to 15 this case.

16 Q Okay. And you had not seen the Kaminska 17 article, Exhibit 2031, prior to this case?

18 A Correct, I had not seen that article 19 either.

20 (Reporter interruption.)

21 Q Dr. Cohen, prior to your involvement in 22 this case, you had not seen either of these SCS

22 this ease, you had not seen either of these see

1 documents, Exhibits 1074, 1075, about Parylene C; is

2 that correct?

3 A That's correct.

Q You currently work at Gradient; is that

5 right?

4

14

6 A Yes, I currently work at Gradient.

7 Q And could you just describe what Gradient

8 is, what field they operate in.

9 A So Gradient is a scientific consulting
10 firm with a number of practice areas. My practice
11 area is what's described as the product stewardship
12 area supporting toxicological risk assessment,
13 consulting services for a variety of products.

14 And my practice area focuses on medical 15 device toxicological risk assessment and 16 pharmaceutical toxicological risk assessment, among 17 others things. But that's one of the practice areas 18 that the consulting firm at large focuses on.

19 Q Okay. Is one of the areas Gradient is 20 involved in providing expert witness support in 21 litigations?

22 A Gradient principals do offer expert

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