

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC AND AMNEAL
PHARMACEUTICALS OF NEW YORK LLC

Petitioner

v.

ALMIRALL, S.A.

Patent owner

Case No. IPR2019-00207

U.S. Patent 9,517,219

DEPOSITION OF ELAINE S. GILMORE, M.D., Ph.D.

Washington, D.C.

July 25, 2019 at 9:01 a.m.

Reported by: Michele E. Eddy, RPR, CRR, CLR

DIGITAL EVIDENCE GROUP

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2

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1 EXAMINATION INDEX

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3 EXAMINATION BY MR. TRAINOR 5

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5 EXHIBITS

6 DEPOSITION EXHIBIT PAGE

7 Exhibit 1 Declaration of Elaine S. Gilmore, M.D., Ph.D., in the Case IPR2019-00207; AMN1018 5

8 Exhibit 2 Curriculum Vitae of Elaine S. Gilmore, M.D., Ph.D.; AMN1019 5

9 Exhibit 3 U.S. Patent No. 9,517,219, AMN1001 5

10 Exhibit 4 PDR excerpt, 2011 Edition; AMN1010 42

11 Exhibit 5 Article titled "Innovative Use of Dapsone" by V.E. Gottfried Wozel, M.D.; AMN1022 55

12 Exhibit 6 WO 2009/061298; AMN1004 62

13 Exhibit 7 Article titled "Treatment of acne vulgaris" by Rebecca Nguyen and John Su; AMN1024 98

14 Exhibit 8 Article titled "Pharmacokinetics of Dapsone Gel, 5% for the Treatment of Acne Vulgaris" by Diane M. Thiboutot, etc.; AMN1023 123

15 Exhibit 9 (Not used)

16 Exhibit 10 WO2009/108147; Admirall, LLC Exhibit 2001 141

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1 Deposition of ELAINE S. GILMORE, M.D.,

2 Ph.D., held at the offices of:

3 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

4 1100 New York Avenue, Northwest

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8

9 Pursuant to Notice, before Michele E.

10 Eddy, Registered Professional Reporter, Certified

11 Realtime Reporter, and Notary public in and for

12 the District of Columbia.

13

14

15 PROCEEDINGS

16 Washington, D.C.

17 July 25, 2019

18 - - -

19 ELAINE S. GILMORE, M.D., PH.D.,

20 having been duly sworn, testified as follows:

21 EXAMINATION BY COUNSEL FOR THE PATENT OWNER

22 BY MR. TRAINOR:

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1 Q Good morning, Dr. Gilmore. Thanks very

2 much for being here today. I know there are other

3 places you would rather be. I'll do my best to

4 get through this today.

5 Before we get on the record, I asked the

6 court reporter just to mark for your own

7 identification, for identification of the record,

8 three documents, which are exhibits in this

9 petition which brings us here today, which is a

10 petition for inter partes review of U.S. Patent

11 Number 9,517,219. This is IPR2019-00207.

12 (Exhibit 1, Exhibit 2, and Exhibit 3 were

13 marked for identification and attached to the

14 deposition transcript.)

15 BY MR. TRAINOR:

16 Q Dr. Gilmore, the first document I would

17 like you to just take a look at is marked Exhibit

18 -- what's been designated as Exhibit No. 1018 in

19 this proceeding, which appears to be your

20 declaration submitted in this case; is that right?

21 Do you see that?

22 A I see it.

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1 Q Okay. Also in front of you is Exhibit
 2 1019, which is an exhibit to your declaration. It
 3 appears to be your CV. Do you see that?
 4 A I see it.
 5 Q Okay. And the third document I asked to
 6 be marked is Exhibit 1001 of record in this
 7 proceeding, and that is United States Patent
 8 9,517,219.
 9 Do you see that?
 10 A I see it.
 11 Q Okay. And you understand that what I
 12 will refer to as the '219 patent, Exhibit 1001, is
 13 the patent in dispute in these proceedings?
 14 A I understand.
 15 Q Okay. And the declaration, Exhibit
 16 1018, is a declaration you submitted in support of
 17 the petitioner's petition for IPR in this case,
 18 correct?
 19 A Correct.
 20 Q I only put these three documents in
 21 front of you preliminarily in case -- you know,
 22 we'll probably refer to your declaration a bit. I

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1 wanted you to be able to have that in front of you
 2 and refer to it whenever you feel the need to.
 3 The same thing with the patent. I'm going to
 4 begin by just asking you a few questions about
 5 your CV so that's why I put that in front of you
 6 as well.
 7 So, Dr. Gilmore, in another U.S. patent
 8 office proceeding related to a different patent
 9 but between these same parties, you gave a
 10 deposition, I believe, in the last year or so. Do
 11 you recall?
 12 A Yes.
 13 Q Have you had a chance to review the
 14 transcript of that deposition?
 15 A Not completely.
 16 Q Is there anything that you can think of
 17 that you provided testimony about at that time
 18 that you realize you want to clarify or anything
 19 like that?
 20 A I haven't reviewed the whole document.
 21 Nothing comes to mind.
 22 Q Okay. You understand that we're here

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1 today in conjunction with a separate dispute
 2 concerning a separate patent. Is that right?
 3 A Yes.
 4 Q Now, if we could just turn to Exhibit
 5 1019, which is your CV, you were asked about this
 6 at your past deposition. I just have a few
 7 questions.
 8 I just want to be clear, your -- the
 9 time when you would have begun treating patients
 10 for dermatologic conditions would have been during
 11 your residency at Yale; is that correct?
 12 A I also treated patients during my
 13 internship in California.
 14 Q Okay.
 15 A And as a medical student.
 16 Q As a medical student.
 17 So as part of seeing patients for
 18 general internal medicine, you would have treated
 19 patients for dermatological conditions; is that
 20 right?
 21 A Yes.
 22 Q And would that have been -- what

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1 percentage of the patients before your residency
 2 would have been patients seeing you for
 3 dermatological conditions?
 4 A I don't remember exactly, but primary
 5 care physicians treat a lot of skin disease,
 6 including acne.
 7 Q And a lot of other conditions, correct?
 8 A Yes.
 9 Q So I'm just trying to establish if there
 10 was a focus on dermatology in the time prior to
 11 your residency, or no.
 12 A Prior to my dermatology residency?
 13 Q Correct.
 14 A No, but it's quite frequently seen by
 15 internal medicine doctors.
 16 Q So would -- if we just begin with your
 17 residency in 2004, that would put us at about 15
 18 years you've been treating patients; is that
 19 right?
 20 A If we want to talk about the start of
 21 dermatology residency, yes.
 22 Q With respect to the publications listed

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<p>1 on the second page and across to the third page of 2 your CV, could you identify which, if any, report 3 in any way on the treatment of the condition of 4 acne.</p> <p>5 A None specifically. I don't recall the 6 first content of the immunocompromised patients. 7 There we discussed a lot of different conditions 8 so I'm not sure if there's anything within that.</p> <p>9 Q Which number is that?</p> <p>10 A No. 15.</p> <p>11 Q I'll ask a similar question. To your 12 recollection, do any of these publications that 13 you authored or coauthored concern the treatment 14 of rosacea?</p> <p>15 A I don't believe they do.</p> <p>16 Q To your recollection, do any of these 17 publications concern or otherwise report about the 18 use of dapsons?</p> <p>19 A No, they do not.</p> <p>20 Q And do any of these publications, to 21 your recollection, concern or otherwise report on 22 the use of adapalene?</p> <p style="text-align: right;">Page 10</p>	<p>1 Q Travel Award. 2 So what was the award there?</p> <p>3 A That they funded my travel to the 4 meeting.</p> <p>5 Q I see.</p> <p>6 A It was something given by the meeting 7 you had to apply for.</p> <p>8 Q And you received a Dermatology 9 Foundation Fellowship Grant at Yale Medicine, Yale 10 Medical School.</p> <p>11 Did you need to apply for that grant?</p> <p>12 A Yes, that is very competitive.</p> <p>13 Q And was it part of the application 14 process related to dermatology specifically? How 15 is it that the Dermatology Foundation provided 16 that grant to you?</p> <p>17 A It was dermatology research.</p> <p>18 Q That you had done before applying for 19 the grant?</p> <p>20 A The grant covered the research to be 21 done.</p> <p>22 Q I see. I see.</p> <p style="text-align: right;">Page 12</p>
<p>1 A No, they do not.</p> <p>2 Q Just turning back to the front page of 3 your CV, you've listed a number of honors and 4 awards. I see the second entry is an 5 "International Investigative Dermatology Meeting, 6 'Poster Walk.'"</p> <p>7 Do you see that?</p> <p>8 A Yes.</p> <p>9 Q What kind of an award is that?</p> <p>10 A This was an international meeting where 11 the organizers choose some of the best research to 12 highlight on a kind of tour of the research on 13 display.</p> <p>14 Q So that be more an honor than an actual 15 award, correct?</p> <p>16 A Yes. The title is "Honors and Awards."</p> <p>17 Q Would you similarly characterize the 18 next entry directed to the "7th World of Congress 19 on Itch" as an honor rather than an award?</p> <p>20 A That was called a Travel Award.</p> <p>21 Q Travel grant?</p> <p>22 A It was called the Travel Award.</p> <p style="text-align: right;">Page 11</p>	<p>1 So aside from any of the three events or 2 grants -- three awards -- sorry -- any of the two 3 honors in the fellowship grant, are any of the 4 honors or awards listed on your CV specific to 5 dermatology or do they relate to medicine or more 6 generally?</p> <p>7 A I'm not sure I understand your question.</p> <p>8 Q I'm just trying to find out which of the 9 honors or awards here are anchored to your 10 practice of dermatology as opposed to, for 11 example, being a mentor or the best teacher or 12 generally a good doctor.</p> <p>13 A I see.</p> <p>14 So everything from 2007 to present is 15 related to dermatology.</p> <p>16 Q Okay.</p> <p>17 A Including a teaching award where I'm 18 teaching dermatology residents dermatology.</p> <p>19 Q Okay. So does lymphoma connect with 20 dermatological conditions?</p> <p>21 A Lymphoma is a broad disease, and one of 22 the manifestations is a rare type called cutaneous</p> <p style="text-align: right;">Page 13</p>

1 T-cell lymphoma.
 2 Q Okay.
 3 A Often these patients present with itch,
 4 and so dermatologists frequently are those who
 5 diagnose it.
 6 Q Okay. You can put the CV aside, but,
 7 again, if you feel the need to refer back to it at
 8 any point, it's there for you.
 9 I would like to take a look at the
 10 patent that's in dispute here. I'll probably
 11 refer to it more often than not as the '219 patent
 12 rather than Exhibit 1001, but those are the same
 13 thing.
 14 Have you had the occasion to review the
 15 '219 patent recently?
 16 A Yes.
 17 Q Okay. Did you review the '219 patent --
 18 well, when was the last time you reviewed it?
 19 A I reviewed the parts relevant to me
 20 yesterday.
 21 Q Okay. I want to ask you to turn to the
 22 claims at the back of the '219 patent, which begin

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1 at column 15 and/or in column 16. Do you see
 2 column -- do you see claim 6?
 3 A I see it.
 4 Q Okay.
 5 Now, do you understand what a dependent
 6 claim is?
 7 A No.
 8 Q Okay. You see in the next claim, claim
 9 7, it says, "The method of claim 6, wherein the
 10 topical pharmaceutical composition further
 11 comprises methyl paraben."
 12 A I see where it says that.
 13 Q So if I represent to you that that means
 14 claim 7 is everything that claim 6 is, plus the
 15 additional element of claim 7, you -- you
 16 understand sort of the concept?
 17 A Yes.
 18 Q If I ask you the same question about
 19 claim 8 where it says, "The method of claim 6,
 20 wherein the dermatological condition is acne
 21 vulgaris," you have the same understanding,
 22 correct? That is just claim 6 but specific to

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1 acne vulgaris.
 2 A Okay.
 3 Q All right. So thinking about what claim
 4 8 entails, which is everything in claim 6, plus
 5 further limited to the condition being acne
 6 vulgaris, is it your understanding that what is
 7 set forth there, claim 6 combined with claim 8, is
 8 the Aczone 7.5 percent formulation that I believe
 9 you use in your practice?
 10 DR. VARUGHESE: Objection to the extent
 11 it calls for a legal conclusion and it's outside
 12 the scope of Dr. Gilmore's declaration.
 13 Q Let me ask you a question this way. Are
 14 you familiar with the composition of the Aczone
 15 7.5 percent formulation?
 16 A What do you mean by "composition"?
 17 Q Anything about the composition beyond
 18 the fact that the concentration of the active
 19 ingredient is 7.5 percent.
 20 DR. VARUGHESE: Objection. Vague and
 21 ambiguous.
 22 A I know that the 7.5 percent product

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1 exists because I use it in my clinic. I didn't
 2 look any further into it, though, as far as
 3 composition.
 4 Q Whether it's for the deposition or not,
 5 I'm just trying to understand, what is your
 6 familiarity or understanding of the commercial
 7 dapsone 7.5 percent formulation besides the fact
 8 that the active ingredient concentration is 7.5
 9 percent?
 10 DR. VARUGHESE: Objection. Asked and
 11 answered.
 12 A I know that the product exists and I use
 13 it for the treatment of acne.
 14 Q So you're not really familiar with the
 15 excipients beyond the active ingredient or how
 16 they make up the composition relative to the
 17 active ingredient?
 18 A That's probably better answered by a
 19 formulator and a clinician.
 20 Q That's fine. That's what I'm trying to
 21 understand.
 22 If I were to ask you can you describe to

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