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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS,)
LLC AND AMNEAL)
PHARMACEUTICALS OF NEW)
YORK, LLC,)

) Petitioners,)

) CASE: IPR2018-00608

) vs.)

) PATENT: 9,161,926

) ALMIRALL, LLC)

) Patent Owner.)

DEPOSITION OF JULIE C. HARPER, M.D.

BIRMINGHAM, ALABAMA

MONDAY, MARCH 11, 2019

REPORTED BY: TANYA L. VERHOVEN-PAGE

JOB NO: 156069

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March 11, 2019
9:02 a.m.

Deposition of
JULIE C. HARPER, M.D., held at the offices
of Regus - Birmingham, 420 North 20th Street,
Suite 2200, Birmingham, Alabama before
Tanya L. Verhoven-Page, Certified Court
Reporter and Notary Public of the State of
Georgia.

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EXHIBITS:

Almirall		
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Exhibit 2022	Declaration of Julie C. Harper, M.D.	45
Exhibit 2017	Article from American Family Physician	101
Exhibit 2013	Article from Journal of the Pharmacy Society of Wisconsin	101
Exhibit 2016	"Emerging Drugs for Acne" (Article)	101
Exhibit 2040	"Finding a Place for Topical Anti-inflammatory Acne Therapy" (Article)	102
Exhibit 2006	International Publication Number WO 2009/108147 A1	121

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EXHIBITS:

AMN		
Exhibit	Description	Page
Exhibit 1023	"Pharmacokinetics of Dapsone Gel 5% for the Treatment of Acne Vulgaris" (Article)	138
Exhibit 1009	"Diethylene glycol monoethyl ether: An Emerging Solvent in Topical Dermatology Products" (Article)	142
Exhibit 1041	Dollars for Docs July to December 2011	152
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1 J. HARPER
 2 BIRMINGHAM, ALABAMA; MONDAY, MARCH 11, 2019
 3 9:02 A.M.
 4
 5 Thereupon -
 6 JULIE C. HARPER, M.D.,
 7 called as a witness, having been first duly sworn,
 8 was examined and testified as follows:
 9
 10 EXAMINATION
 11 BY MR. LAROCK:
 12 Q Good morning, Dr. Harper.
 13 A Good morning.
 14 Q Have you been deposed before?
 15 A I have.
 16 Q How many times?
 17 A Once.
 18 Q Okay. And when was that deposition?
 19 A December.
 20 Q Of 20 --
 21 A '18.
 22 Q -- 18?
 23 A Uh-huh.
 24 Q And was that a patent case?
 25 A Yes.

1 J. HARPER
 2 Q Okay. You understand you're under oath?
 3 A I do.
 4 Q Right. And I'm going to ask you
 5 questions and you're going to give truthful, honest
 6 answers to the best of your ability, right?
 7 A Yes, I will.
 8 Q We have a court reporter, so I just ask
 9 you not to talk over one another. Is that fair?
 10 A Yes. Challenging, but yes.
 11 Q And if you don't ask -- or if you don't
 12 understand one of my questions, you'll agree to ask
 13 for clarification?
 14 A Absolutely.
 15 Q Okay. And if you don't ask for
 16 clarification to one of my questions, is it fair to
 17 assume that you've understood it?
 18 A Seems fair.
 19 Q Okay. Is there any reason that you can't
 20 testify truthfully today?
 21 A There is not.
 22 (Almirall Exhibit No. 2023 was
 23 identified for the record.)
 24 BY MR. LAROCK:
 25 Q I'm going to hand you what's been marked

1 J. HARPER
 2 Q And what was that patent case about?
 3 A It was a patent, the '219 patent.
 4 Q And what do you mean by the '219 patent?
 5 A The '219 patent -- I honestly don't
 6 remember details about that.
 7 Q Okay.
 8 A That was a while ago.
 9 Q Okay. That's a different than --
 10 A It's a different patent than today, yes.
 11 I'm not prepared to talk about that one again right
 12 now.
 13 Q Okay. And who were you -- were you an
 14 expert in that case?
 15 A Yes, sir, I was.
 16 Q And who were you an expert on behalf of?
 17 A Allergan slash Almirall.
 18 Q Now, if I say Allergan and Almirall,
 19 you'll understand the companies that I'm referring
 20 to?
 21 A Yes, sir.
 22 Q Okay. So I guess you have some
 23 familiarity with the ground rules for a deposition, I
 24 take it?
 25 A I do.

1 J. HARPER
 2 Almirall Exhibit 2023.
 3 A Yes. Before we go over this, I do have a
 4 couple of changes that were typographical errors in
 5 my declaration.
 6 Q Okay.
 7 A Could I make those corrections?
 8 Q We'll get there.
 9 A Okay. I don't want to forget that.
 10 Q And do you recognize this as -- this
 11 exhibit?
 12 A Yes, very well.
 13 Q Okay. And what is this exhibit?
 14 A This is my curriculum vitae.
 15 Q And is it accurate?
 16 A Yes, it is.
 17 Q Okay. And on page three of your CV --
 18 are you there?
 19 A I am.
 20 Q -- several publications and posters are
 21 listed, right?
 22 A Uh-huh.
 23 Q And were these peer reviewed
 24 publications?
 25 A Let me take a minute to look at these,

J. HARPER

1 please.

2 Q Sure.

3 A I believe all of those on the first page
4 were. The majority of these would be peer reviewed
5 journals.

6 Q And is there a difference between a
7 publication and a poster?

8 A Yes, there is.

9 Q Okay. What's that difference?

10 A So the posters are going to be presented
11 at a meeting and they would be there like in abstract
12 form, where people would come by and actually read
13 the poster.

14 Sometimes those posters go on to be
15 publications, but they would be listed separately.

16 Q Is a poster different than a
17 presentation?

18 A Yes, it is.

19 Q Okay. What's that difference?

20 A So you could present a poster and so
21 those could go together, but a publi -- poster,
22 excuse me, is a written document that truly is a
23 poster.

24 Q A poster?

J. HARPER

1 A Yes, that's attached to a place in a
2 meeting, usually, where people can walk by and read
3 them.

4 A presentation is from the podium.

5 Q Okay. So there may not be a poster
6 associated with a presentation?

7 A It could go either way.

8 Q And how does -- I guess, before these
9 publications are actually published, they are first
10 researched and then submitted for publication, right?

11 A Repeat what you said at first there.

12 Q Before these publications are published?

13 A Before the publications, but not posters.

14 Before the publications are published --

15 Q Yeah. They are researched and then
16 submitted for publication?

17 A That would be true.

18 Q How long does that process take?

19 A Well, I have, I think, 40 publications on
20 here, so it would be different for each one of those.

21 Q Okay. About how long would the process
22 take?

23 A Could we pick an article and look at it?
24 For example, the Zaenglein article, which is when I
25

J. HARPER

1 was one of the authors for the guidelines of the
2 management of acne --

3 Q And just so we're clear, it's page three,
4 the third one down?

5 A This is the third one down on page three,
6 right.

7 Q Okay.

8 A So this was a consensus paper that took
9 us probably about a year, and so different authors
10 were writing different portions of this guidelines
11 for the management of acne.

12 Q And by a year, do you mean a year to
13 write?

14 A A year to research, gather the
15 information and write.

16 Q Okay. And then it was submitted?

17 A Correct.

18 Q And then how long between submission and
19 publication?

20 A I don't know the answer to that.

21 Q Okay.

22 A I could guess.

23 Q Yes.

24 A Based on experience, probably six months.
25

J. HARPER

1 Q Okay.

2 A Or longer.

3 Q Is there an average amount of time? It's
4 not instantaneous, right? There's some lag time
5 between publication?

6 A I am comfortable saying it's not
7 instantaneous. I am not comfortable with giving you
8 an average because I did not go back and look at
9 those time periods. I would be guessing.

10 Q Is it like weeks?

11 A I would say not instantaneous.

12 Q Okay. And how do you decide who -- I
13 guess before we go there.

14 A number of these publications have
15 multiple authors, right?

16 A That is correct.

17 Q And how do you decide who you want to
18 collaborate with in terms of drafting a publication?

19 A Well, I appreciate your compliment, that
20 I would be deciding that. On many of these, that is
21 not the way that that happens.

22 Now, I did volunteer through the American
23 Academy of Dermatology for the guidelines. I
24 volunteered on that. For several of these where I'm
25

1 J. HARPER

2 part of a work group -- this was from the American
3 Acne and Rosacea Society, which I've recently served
4 as president, and so people in that area who would
5 volunteer their time to write the paper would be
6 included.

7 On some of these, if it's actually a
8 study that I participated in, then the authors are
9 going to be the people who participated in the study.
10 And so it's not something where I'm on the phone or
11 e-mail trying to --

12 Q Call up a colleague?

13 A Exactly. That is not usually the way
14 that works.

15 Q Okay. So besides situations where there
16 were a group of people involved in a study and then
17 you're writing up a publication about that study
18 or -- I think it was the American Academy of
19 Dermatology?

20 A Uh-huh, yes.

21 Q Besides those two situations, is there a
22 system that you go through where you would figure
23 out, I'm going to be involved in this paper and not
24 some other paper?

25 A There is no system for that.

1 J. HARPER

2 Q Okay.

3 A I think you would be able to see on here
4 that mine are all, for the most part, about acne and
5 rosacea.

6 Q Uh-huh. But I guess are there
7 publications on your CV where they're a publication
8 not about a study you were associated with and not
9 about the American -- and not a result of your
10 participation in the American Academy of Dermatology?

11 A Yes, there are.

12 Q And can you point me to one of those?

13 A Sure. Let's see here. Well, no, that
14 was a study. Hang on. I'm starting at the bottom
15 here.

16 Third from the bottom. And so I did not
17 participate in that study, but because I am
18 interested in gender issues and acne, I was asked to
19 author that paper.

20 Q And this is third from the bottom on page
21 three?

22 A Yes.

23 Q Which is entitled Efficacy and
24 Tolerability of a Fixed Combination of Clindamycin
25 1.2 Percent and Benzoyl Peroxide 3.75 Percent Aqueous

1 J. HARPER

2 Gel in Patients with Facial Acne Vulgaris: Gender as
3 Clinical Relevant Outcome Variable?

4 A Correct.

5 Q And so you took this publication on
6 yourself because you just had an interest in that
7 area?

8 A Right.

9 Q Are any of these publications sponsored
10 by drug companies or other entities?

11 A I would have to know what you meant by
12 sponsored by.

13 Q Where they had asked you -- are there
14 situations on your CV where you published a
15 publication as a result of a drug company asking you
16 to publish an article, for example?

17 A Yes, there are.

18 Q And can you point me to one of those
19 examples?

20 A Well, the one that we just mentioned
21 would be an example of that.

22 Q Okay. Oh, I thought you had said that
23 you were interested in that area?

24 A I was, but I was asked by the company on
25 that drug. And I was not one of their trialists, I

1 J. HARPER

2 did not do the clinical trials, but I was asked
3 because of this subject if I would be willing to
4 write the paper.

5 Q And who was the company that asked you to
6 write this?

7 A At the time they were Valiant, and that
8 company is now Ortho. Same company.

9 Q And how often does that happen where drug
10 companies will ask you to write a publication?

11 A At this point in my career, a fair
12 amount.

13 Q And what do you mean by at this point in
14 your career?

15 A I've practiced now for about 19 years and
16 I've had a special interest in acne through that
17 entire time, starting my career in full-time
18 academics for seven years. So because of that
19 background in academia and my interest over time, I'm
20 an author that gets asked to write papers.

21 Q And besides this example that we just
22 talked about with the fixed dose combination of
23 clindamycin and benzoyl peroxide, any other examples
24 where you were asked by a drug company to author a
25 paper?

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