

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

3
4 COALITION FOR AFFORDABLE DRUGS V LLC;
5 HAYMAN CREDES MASTER FUND, L.P. ;
6 HAYMAN ORANGE FUND SPC - PORTFOLIO A ;
7 HAYMAN CAPITAL MASTER FUND, L.P. ;
8 HAYMAN CAPITAL MANAGEMENT, L.P. ;
9 HAYMAN OFFSHORE MANAGEMENT, INC. ;
10 HAYMAN INVESTMENTS, LLC ;
11 NXN PARTNERS, LLC ;
12 IP NAVIGATION GROUP, LLC ;
13 J KYLE BASS, and ERICH SPANGENBERG,

14 Petitioner

15 v.

16 BIOGEN MA INC.,

17 Patent Owner

18
19 Case No. IPR2015-01993
20 U.S. Patent No. 8,399,514

21
22 DEPOSITION OF STEVEN E. LINBERG, Ph.D.

23 Washington, D.C.

24 June 13, 2016

25 Reported by: Mary Ann Payonk, Job No. 107123

June 13, 2016
9:00 a.m.

Deposition of STEVEN E. LINBERG, Ph.D.,
held at the offices of Finnegan, Henderson,
Farabow, Garrett & Dunner, LLP, 901 New York
Avenue, N.W., Washington, D.C., pursuant to
Notice before Mary Ann Payonk, Nationally
Certified Realtime Reporter and Notary Public
of the District of Columbia, Commonwealth of
Virginia, States of Maryland and New York.

APPEARANCES:
ON BEHALF OF PETITIONER:
JAMES CARMICHAEL, ESQUIRE
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Tysons Corner, VA 22182

ON BEHALF OF PATENT OWNER:
MICHAEL FLIBBERT, ESQUIRE
KASSANDRA OFFICER, ESQUIRE
FINNEGAN HENDERSON FARABOW
GARRETT & DUNNER
901 New York Avenue, N.W.
Washington, D.C. 20001

S. Linberg
STEVEN LINBERG,
called as a witness, having been duly
sworn, was examined and testified as
follows:
EXAMINATION
BY MR. FLIBBERT:
Q. Good morning. Mike Flibbert and
Kassie Officer from Finnegan for the patent
owner.

Good morning, Dr. Linberg. Could you
please state your name for the record?

A. Steven Linberg.

Q. As you understand, I'll be asking you
a series of questions today. And all I ask is
that you answer to the best of your ability.
And if you don't understand a question, just
please ask me to repeat it or clarify it. Is
that okay?

A. Yes.

Q. And as you know, the court reporter
is transcribing everything that we say, so it's
important that you give verbal answers such as
yes and no and that we not speak over each
other. Is that okay?

S. Linberg

A. Yes.

Q. And if you need a break at any time,
just let me know; we can take a break. The
only thing that I would ask is that if we're in
the middle of a question, that you finish
answering the question before we take the
break.

A. Yes.

Q. Is that fine?

Is there any reason that you cannot
testify fully and accurately today?

A. No.

Q. Are you taking any medication that
would impair your ability to testify today?

A. No.

Q. And during the day I'll be referring
to the patent at issue here by the last three
numbers, as the '514 patent. Would you
understand that abbreviation?

A. Yes.

Q. And I'll also refer to this
inter partes review Patent Office proceeding as
an IPR. Would you understand that
abbreviation?

1 S. Linberg
 2 A. Yes.
 3 Q. And I'll probably refer to multiple
 4 sclerosis frequently as MS. I assume you'd
 5 understand that.
 6 A. Yes.
 7 Q. Have you been deposed before?
 8 A. Yes.
 9 Q. And in what case or cases?
 10 A. It was a case approximately 15 years
 11 ago, Abbott was a patent holder and I was
 12 involved as a -- someone who had done work on
 13 that drug and was asked questions about the
 14 development of that product.
 15 Q. Can you tell me what the product was?
 16 A. The product was called Curosurf,
 17 C-U-R-O-S-U-R-F.
 18 Q. And is that a pharmaceutical drug?
 19 A. Yes.
 20 Q. What is it indicated to treat?
 21 A. It's indicated for prevention and
 22 treatment of neonatal respiratory distress.
 23 Q. That testimony was essentially as a
 24 fact witness in connection with a litigation?
 25 A. Correct.

1 S. Linberg
 2 Q. Was it a patent litigation?
 3 A. I believe it was.
 4 Q. And Abbott was the patent holder; is
 5 that correct?
 6 A. Yes.
 7 Q. Do you remember who the other side
 8 was in that case?
 9 A. Dey, D-E-Y. Dey LP.
 10 Q. Did you testify at trial in that
 11 matter?
 12 A. No.
 13 Q. Did it settle or get resolved, or go
 14 to trial?
 15 A. I have no idea.
 16 Q. That's fine. So other than the
 17 Abbott case where you testified as a fact
 18 witness, have you testified in any other
 19 matter?
 20 A. I have not.
 21 Q. Have you ever testified in a trial?
 22 A. I have not.
 23 Q. Have you testified as an expert in
 24 any prior case?
 25 A. I have not.

1 S. Linberg
 2 Q. Have you been engaged as an expert in
 3 any other patent matters?
 4 A. I have not.
 5 Q. Have you provided any declarations in
 6 any other patent matters?
 7 A. I have not.
 8 Q. Any expert reports in any patent
 9 matters other than what you've done for the
 10 Biogen IPRs?
 11 A. In patent matters, no.
 12 Q. Have you done expert reports for any
 13 matters other than patent matters?
 14 A. Expert reports in scientific terms,
 15 in reviewing scientific findings.
 16 Q. I understand. And what was the
 17 subject matter of that scientific analysis or
 18 analyses you've done?
 19 A. I couldn't recall exactly what the --
 20 what it was. I've been involved in a number of
 21 scientific reviews over the years.
 22 Q. Okay. Did you prepare for your
 23 deposition today?
 24 A. Yes.
 25 Q. And what did you do to prepare?

1 S. Linberg
 2 A. Reviewed the declaration and reviewed
 3 a number of the exhibits, primarily.
 4 Q. Did you meet with counsel?
 5 A. Yes.
 6 Q. Did you meet with the counsel who are
 7 here today?
 8 A. Yes.
 9 Q. And was there anyone besides counsel
 10 present when you met with them?
 11 A. No.
 12 Q. Okay. And for how long did you meet
 13 with counsel to prepare for the deposition?
 14 A. We met on Thursday and Friday all day
 15 and for a couple hours yesterday.
 16 Q. Now, you indicated you reviewed some
 17 documents in preparing for today's deposition?
 18 A. Yes.
 19 Q. And could you be specific as to what
 20 documents you reviewed?
 21 A. I reviewed my declaration, the '514
 22 patent, the two patents by Joshi, the 2002 and
 23 the 2008.
 24 Q. Okay.
 25 A. The article by Wakkee. The article

1 S. Linberg
2 by Kappos. The ICH Guidance E4. The article
3 by Werdenberg. The ClinicalTrials.gov entry.
4 And the article by Begleiter.

5 Q. Thank you.

6 And other than those documents, do
7 you recall reviewing anything else, any other
8 written documents in preparing?

9 A. I have reviewed some, I guess what is
10 called the file history.

11 Q. And that was for the '514 patent, I
12 assume.

13 A. Yes.

14 Q. Okay. And anything else beside the
15 file history and the documents you've
16 identified?

17 A. Not that I recall at the moment.

18 Q. Have you reviewed the patent owner
19 Biogen's preliminary response that was filed in
20 this case?

21 A. I did, as part of the file history.

22 Q. May not be in the file history. That
23 would be a paper filed in the IPR proceeding
24 apart from the file history of the patent.

25 A. I believe I did, I'm -- I believe I

1 S. Linberg

2 A. I don't recall reading that.

3 Q. And that would be a document stating
4 the grounds of unpatentability that have been
5 instituted by the Patent Office. Do you
6 remember seeing that?

7 A. I -- it -- I don't recall.

8 Q. Do you recall -- you mentioned you
9 reviewed your own declaration in preparing for
10 the deposition. Do you recall approximately
11 how much time you took in reviewing the
12 declaration?

13 A. No, I couldn't put a number on it.
14 Number of hours? No. I certainly didn't
15 memorize it.

16 MR. FLIBBERT: Understood.

17 I'm going to hand you what's been
18 previously marked as the Coalition
19 Exhibit 1005.
20 (Coalition Exhibit No. 1005, previously
21 marked, was referenced and indexed.)

22 BY MR. FLIBBERT:

23 Q. And if you'd take a moment to look at
24 this and confirm that this is a copy of the
25 declaration that you've submitted in this

1 S. Linberg

2 did.

3 Q. Do you remember when you may have
4 looked at it?

5 A. No.

6 Q. Okay. Have you reviewed any of the
7 patent owner Biogen's exhibits that have been
8 filed in this IPR proceeding other than the
9 documents you -- any documents you've already
10 listed?

11 A. There was a -- I guess a declaration
12 by a Dawson and a Riddick that I reviewed.

13 Q. Dr. Rudick?

14 A. Yes, Rudick.

15 Q. And when did you review the Dawson
16 Rudick declarations?

17 A. Within the last week.

18 Q. Do you recall if you have read the
19 petitioner's reply to the patent owner's
20 preliminary response?

21 A. I don't recall offhand. I'd have to
22 see it and I could tell you.

23 Q. Do you recall reading the institution
24 decision that the Patent Office issued to
25 initiate the IPR proceeding?

1 S. Linberg

2 proceeding.

3 A. It has my electronic signature at the
4 back.

5 Q. Thank you. And did you review the
6 declaration before you signed it?

7 A. Yes.

8 Q. Do you recall when you began
9 preparing the declaration?

10 A. This declaration, approximately a
11 year ago.

12 Q. And do you recall approximately how
13 many days or weeks it took you to prepare the
14 declaration? When you started, when you
15 finished?

16 A. I don't recall. I don't recall.

17 Q. Did you write the first draft
18 yourself?

19 A. I was -- it was an interactive
20 process. I approved everything that was in
21 here. These became my own words.

22 Q. Okay. Is there anything in the
23 declaration that, sitting here now, you would
24 like to change?

25 A. There were a couple of typos that I'd

1 S. Linberg
2 like to change. I made a note. One of them is
3 on page 9, paragraph 18.

4 Q. Okay.

5 A. Let me get to that. There is a
6 reference to Exhibit 1001, column 2, lines 12
7 to 14 that should be column 4, lines 65 to 67.

8 Q. Okay, thank you.

9 A. There's another on page 23, paragraph
10 40, four zero. Let's see, the second line from
11 the bottom, Exhibit 19, page 4, columns -- or
12 column 2, lines 6 to 10 should be lines 5
13 through 9.

14 Q. And I think you said Exhibit 19, but
15 you mean Exhibit 1019?

16 A. 1019, yes, I'm sorry. Yes.

17 Q. So other than those two corrections
18 is there anything else that you'd like to
19 correct or change?

20 A. Yes, one on 31 that -- page 31 --

21 Q. Okay.

22 A. -- that corrects a misunderstanding
23 where I talked about at the time concluded that
24 there was a capsule of the 240-milligram dose,
25 a single capsule that contained that dose.

1 S. Linberg
2 additional feel for MS, and in particular for
3 the pharmacokinetics, to see what information
4 was available.

5 Q. So you ran some electronic searches?

6 A. Yes.

7 Q. And what were those searches?

8 A. I don't recall exactly what they
9 were. I'm on PubMed most days and it's sort of
10 a normal part of my life.

11 Q. But the reason you ran those was to
12 get some familiarity with MS for this case?

13 A. To address this case, yes.

14 Q. And do you recall the particular
15 publications that you identified?

16 A. I do not, but I recall that there was
17 one study of pharmacokinetics published prior
18 to 2008 that I believe was the only one that
19 offered me any kind of information to use in
20 this. I could find it again easily.

21 Q. Do you remember the authors?

22 A. I don't recall the author, no.

23 Q. Or the research group?

24 A. I do not.

25 Q. Do you recall the title?

1 S. Linberg

2 I've since learned that it is two capsules that
3 contain that dose.

4 Q. Okay. And so in preparing your first
5 opinion you had an assumption that a
6 240-milligram capsule was available; correct?

7 A. I did.

8 Q. And you now understand that that was
9 incorrect; right?

10 A. I understand that the dose of 240
11 milligrams, instead of being given as one
12 capsule, is given as two capsules.

13 Q. So when you prepared for your
14 deposition did you consult with anyone else
15 besides counsel?

16 A. No.

17 Q. Did you communicate with anyone who
18 had any knowledge about MS?

19 A. No.

20 Q. So after you signed your declaration
21 in September 2015, did you review any documents
22 to increase your knowledge about the topics
23 relevant to this case?

24 A. I at some time would have used PubMed
25 MEDLINE search to get some feel or some

1 S. Linberg

2 A. I do not recall the title.

3 Q. Do you recall the journal?

4 A. No.

5 Q. So how would you find it if you don't
6 know --

7 A. By searching for pharmacokinetics of
8 dimethyl fumarate. And there was a -- one
9 article that popped out of the number of hits
10 that looked most appropriate and most recent to
11 that time.

12 Q. And that was in PubMed?

13 A. I located it in PubMed, that's
14 correct.

15 Q. You did that search after your
16 declaration was completed?

17 A. I did it more recently, but I would
18 have done it at the time to help form an
19 opinion. I just don't recall that first time.

20 Q. Do you cite that in your declaration?

21 A. I do not.

22 Q. And why not?

23 A. No particular reason.

24 Q. I guess I'm trying to understand if
25 you actually relied on it in forming your

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