

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

3
4 SANDOZ, INC., APOTEX, INC., AND
5 APOTEX CORP., EMCURE
6 PHARMACEUTICALS, LTD., HERITAGE
7 PHARMA LABS., INC., HERITAGE
8 PHARMACEUTICALS, INC., GLENMARK
9 PHARMACEUTICALS, INC., USA, GLENMARK
10 HOLDINGS, SA, GLENMARK
11 PHARMACEUTICALS, LTD., MYLAN
12 LABORATORIES LIMITED, TEVA
13 PHARMACEUTICALS, FRESENIUS KABI USA,
14 LLC AND WOCKHARDT BIO AG,
15 Petitioners,
16 vs.
17 ELI LILLY & COMPANY,
18 Patent Owner.

19 Case No. IPR2016-00318

20 Patent No. 7,772,209

21 VIDEOTAPED DEPOSITION OF
22 RON D. SCHIFF, M.D., PH.D.
23 Tampa, Florida
24 Friday, January 27, 2017

25 Reported by:

26 RHONDA HALL-BREUWET, RDR, CRR, LCR, CCR, FPR,
27 CLR, NCRA Realtime Systems Administrator
28 JOB NO. 118353

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January 27, 2017
8:05 a.m.

Videotaped Deposition of RON D. SCHIFF, M.D., PH.D., held at the Sheraton Tampa Riverwalk Hotel, 200 N. Ashley Drive, Tampa, Florida 33602, before Rhonda Hall-Breuwet, Registered Diplomat Reporter, Certified Realtime Reporter, Licensed Court Reporter (TN), Certified Court Reporter (GA), Florida Professional Reporter, Certified Livenote Reporter, NCRA Realtime Systems Administrator, and Notary Public of the State of Florida.

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Assistant General Patent Counsel

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DONALD J. BREUWET

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----- I N D E X -----

WITNESS:	EXAMINATION	PAGE
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	BY MS. LYDIGSEN	426
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----- E X H I B I T S -----

(None marked.)

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RON D. SCHIFF, M.D., Ph.D.
 THE VIDEOGRAPHER: This is the start of Media Label Number 1 in the video-recorded deposition of Dr. Ron Schiff in the matter of Sandoz, Inc., et al., v. Eli Lilly & Company, in the United States Patent and Trademark Office, Case Number IPR2016-00318.
 This deposition is being held at 200 North Ashley Drive, Tampa, Florida, on January 27th of 2017. The time is 8:05.
 My name is Don Breuwet. I'm the legal video specialist from TSG Reporting, Incorporated, headquartered at 747 Third Avenue, New York, New York. The court reporter is Rhonda Breuwet, in association with TSG Reporting.
 Counsel, please identify yourselves.
 MR. PERLMAN: Adam Perlman, from Williams & Connolly, on behalf of the patent owner, Eli Lilly & Company.
 With me is David Krinsky, also of Williams & Connolly, on behalf of Eli Lilly; and James Leeds of Eli Lilly.
 MS. LYDIGSEN: Laura Lydigsen of

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RON D. SCHIFF, M.D., Ph.D.
 Brinks, Gilson & Lione on behalf of Sandoz, Inc.
 MR. PARKER: Thomas Parker, P-A-R-K-E-R; law firm, Alston & Bird, representing Mylan.
 MR. KILGORE: Patrick Kilgore, from Rakoczy Molino Mazzochi Siwik, on behalf of Apotex Inc. and Apotex Corp.
 THE VIDEOGRAPHER: Will the court reporter please swear in the witness.
 RON D. SCHIFF, M.D., Ph.D.
 acknowledged having been duly sworn to tell the truth and testified upon his oath as follows:
 THE WITNESS: I do.
 DIRECT EXAMINATION
 BY MR. PERLMAN:
 Q. Good morning, Dr. Schiff.
 A. Good morning, Mr. Perlman.
 Q. Good to see you again.
 A. Same. Likewise.
 Q. I put in front of you what has been marked as Exhibit 1075 to these proceedings, your reply declaration.

1 RON D. SCHIFF, M.D., Ph.D.

2 Do you see that?

3 A. I do.

4 Q. And when's the last time you had the
5 opportunity to review your reply declaration?

6 A. Yesterday.

7 Q. Okay. Did you review the whole
8 thing?

9 A. No, just selected portions.

10 Q. Okay. When's the last time you
11 reviewed the entirety of it?

12 A. That would have been approximately
13 Sunday and Monday, but I may be off by a day
14 or so.

15 Q. Okay. Do you feel comfortable that
16 you recall the contents of your declaration?

17 A. I do, but I would like to reserve
18 the right to refer to it as needed.

19 Q. Certainly. And all I would ask is
20 if you are going to be reading from your
21 declaration, that you identify the paragraph
22 and page number for us --

23 A. I certainly will.

24 Q. -- so that we can all follow along.

25 A. Correct.

1 RON D. SCHIFF, M.D., Ph.D.

2 Q. Okay. I'd like to direct -- before
3 I direct you to something, am I correct that
4 this reply declaration is intended by you to
5 be your response to the opinions Dr. Chabner
6 and Zeisel put forward on behalf of Eli
7 Lilly?

8 A. And also Lilly's reply declaration
9 following my prior deposition in late August.

10 Q. Lilly's reply declaration? You
11 mean -- Lilly's brief, you mean? Lilly's --

12 A. It wasn't labeled a brief.

13 Q. Lilly's response?

14 A. Perhaps.

15 Q. Let me tell you, we filed three
16 things: We filed a patent owner response; we
17 filed Dr. Chabner's declaration; we filed
18 Dr. Schiff's declaration. Is it responding
19 to all three of those?

20 A. Zeisel, you mean.

21 Q. Zeisel. That's --

22 A. It was -- yeah, all three what you
23 described as patent owner's response is what
24 I refer to as a reply declaration by Lilly.
25 So that's the same thing.

1 RON D. SCHIFF, M.D., Ph.D.

2 Q. Okay. So this is -- this
3 declaration by you is intended, to summarize,
4 to be responsive to the arguments and
5 evidence that Lilly put forward a few months
6 ago in response to what Sandoz had initially
7 put forward?

8 A. Exactly.

9 Q. And can you estimate for us how much
10 time you spent considering your opinions and
11 response prior to drafting your reply
12 declaration?

13 A. I did not give that prior thought or
14 calculate it. I would have to say perhaps 10
15 to 20 hours before I started working on it.

16 Q. And then from that point forward, in
17 terms of preparing the declaration, how many
18 additional hours do you think it took?

19 A. I worked on that for pretty close to
20 three weeks, just about every day and didn't
21 do a whole lot else on those days. So I
22 can't really tell you hours, but that was
23 labor intensive.

24 Q. Were you doing full days during this
25 time?

1 RON D. SCHIFF, M.D., Ph.D.

2 A. Most of the time, yes. I mean, I
3 did certain other activities, but most of
4 what I did on the creative side was working
5 on this. That was last fall.

6 Q. And as you sat down to work on your
7 declaration and you were discussing
8 particular references, did you have the
9 references with you at that time so that you
10 could sort of consult the reference as you
11 prepared the relevant paragraph about the
12 reference?

13 A. Yes, I did that.

14 Q. And so if you have testimony in your
15 reply declaration about the teaching of a
16 reference, you weren't doing that from
17 memory; you were doing that from
18 contemporaneously reviewing the reference as
19 you were writing your opinion?

20 A. I'm more meticulous than to rely on
21 memory for that, so, yes, I looked at the
22 actual references as I worked on my reply.

23 Q. And as you were considering your
24 opinions about the teachings of the various
25 references you talked about, did you -- was

1 RON D. SCHIFF, M.D., Ph.D.
2 it important to you to consider the reference
3 as a whole?

4 A. I would say yes. I mean, I tried
5 not to just fish out individual statements
6 but to look at everything in context to
7 understand what a particular report was about
8 and to see where that fit into the scientific
9 or clinical issue that I was dealing with.

10 Q. And do you think that's the approach
11 that the person of ordinary skill in the art
12 would take when reviewing the literature and
13 references in this case; that is, they would
14 review the entirety of the reference and come
15 to a conclusion about what it teaches as a
16 whole?

17 A. Well, that's the proper way to do
18 it. And I think a person of ordinary skill
19 in the art would know better than to seek out
20 statements out of context.

21 Q. Okay. And just to get a direct
22 answer to my question, your view is that the
23 person of ordinary skill would have
24 approached the teachings of references the
25 same way you did, looking at the reference as

1 RON D. SCHIFF, M.D., Ph.D.
2 a whole rather than looking at select bits of
3 it potentially out of context?

4 A. I would think so, sure.

5 Q. Okay. Could you turn to
6 paragraph 102, which is on page 70. I'm
7 sorry. Is that a line?

8 A. It is.

9 Q. Can I see that?

10 MS. LYDIGSEN: Yeah. There -- there
11 are lines through pages that were black
12 and white where there was also -- there
13 were color copies, apparently, and it
14 looks like it was printed black and
15 white and the replacement pages were put
16 in. It's 38, 39, and 61 --

17 MR. PERLMAN: Okay.

18 MS. LYDIGSEN: -- in my copy.

19 MR. PERLMAN: Let's go off the
20 record for one second.

21 THE VIDEOGRAPHER: Going off the
22 record. The time is 8:12.

23 (Off the record from 8:12 a.m.
24 to 8:12 a.m.)

25 THE VIDEOGRAPHER: Going on the

1 RON D. SCHIFF, M.D., Ph.D.
2 record. The time is 8:12.

3 MR. PERLMAN: Okay. So I will just
4 state for the record what's happened
5 here. Certain of the pages have color
6 highlighting on them. And when the
7 exhibit was originally printed, it was
8 printed in black and white. I requested
9 that that page be replaced with the
10 color page, which, in fact, happened,
11 but the original page was left in the
12 exhibit with a line through it. So that
13 appears to be the only alteration that
14 was done. I'm hopeful that won't cause
15 any confusion, but that's what's
16 happened here.

17 BY MR. PERLMAN:

18 Q. There you go, Doctor.

19 A. Thank you.

20 Q. And if that ministerial problem
21 causes you difficulty later, just let me
22 know, and we'll resolve it. We're looking at
23 page 70, paragraph 102.

24 And would you read that to yourself,
25 and tell me when you're done.

1 RON D. SCHIFF, M.D., Ph.D.

2 A. (Reviewing document.)
3 I'm finished.

4 Q. Okay. Am I correct that in
5 paragraph 102 you were discussing
6 Dr. Chabner's opinion that he expressed that
7 there were a number of antifolates in
8 clinical trials in the 1990s where folic acid
9 pretreatment was not being used?

10 A. There were some where folic acid
11 were not being used and there were others
12 where folic acid was being used.

13 Q. No, no; correct. What I'm trying to
14 orient you here to, Doctor, is the argument
15 that you're responding to. And is the
16 argument that you're responding to here
17 Dr. Chabner's argument that in the 1990s the
18 majority of antifolates that were being
19 tested were not being tested with folic acid?

20 A. I cannot speak to the assessment
21 whether it was a majority or some other
22 proportion of studies. I know there were
23 some with and some without, some supplemented
24 and some unsupplemented. You know, I'm
25 comfortable with the way I constructed that

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