Page 1

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

3 4 SANDOZ, INC., APOTEX, INC., AND APOTEX CORP., EMCURE 5 PHARMACEUTICALS, LTD., HERITAGE PHARMA LABS., INC., HERITAGE 6 PHARMACEUTICALS, INC., GLENMARK PHARMACEUTICALS, INC., USA, GLENMARK 7 HOLDINGS, SA, GLENMARK PHARMACEUTICALS, LTD., MYLAN 8 LABORATORIES LIMITED, TEVA PHARMACEUTICALS, FRESENIUS KABI USA, 9 LLC AND WOCKHARDT BIO AG, 10 Petitioners, 11 vs. 12 ELI LILLY & COMPANY, 13 Patent Owner. 14 Case No. IPR2016-00318 15 Patent No. 7,772,209 16 17 18 19 VIDEOTAPED DEPOSITION OF 20 RON D. SCHIFF, M.D., PH.D. 21 Tampa, Florida 22 Friday, January 27, 2017 23 Reported by: RHONDA HALL-BREUWET, RDR, CRR, LCR, CCR, FPR, 24 CLR, NCRA Realtime Systems Administrator 25 JOB NO. 118353

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2	January 27, 2017	2	DDINING CH CON & LIONE
3	8:05 a.m.	4	BRINKS GILSON & LIONE
4	Videotaped Deposition of RON D.	5	Attorneys for Petitioner Sandoz, Inc.
5	SCHIFF, M.D., PH.D., held at the	6	455 North Cityfront Plaza Drive Chicago, Illinois 60611
6	Sheraton Tampa Riverwalk Hotel, 200 N.	7	BY: LAURA LYDIGSEN, ESQUIRE
7	Ashley Drive, Tampa, Florida 33602, before	8	- and $-$
8	Rhonda Hall-Breuwet, Registered Diplomate	9	4721 Emperor Boulevard
9	Reporter, Certified Realtime Reporter,	10	Durham, North Carolina 27703
10	Licensed Court Reporter (TN), Certified Court	11	BY: BRYAN RICHARDSON, ESQUIRE
11	Reporter (GA), Florida Professional Reporter,	12	(Via Telephone)
12 13	Certified Livenote Reporter, NCRA Realtime	13	
13	Systems Administrator, and Notary Public of the State of Florida.	14	
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1 2	A P P E A R A N C E S:	1 2	A P P E A R A N C E S:
3	RAKOCZY MOLINO MAZZOCHI SIWIK	3	ALSTON & BIRD
4	Attorneys for Petitioner Apotex, Inc.,	4	Attorneys for Mylan
5	and Apotex Corp.	5	90 Park Avenue
6	6 West Hubbard Street	6	New York, New York 10016
7	Chicago, Illinois 60654	7	BY: THOMAS PARKER, ESQUIRE
8	BY: PATRICK KILGORE, ESQUIRE	8	
9		9	
10		10	
11		11	
12		12	
13		13	WILLIAMS & CONNOLLY
14	SKIERMONT DERBY	14	Attorneys for Patent Owner
15	Attorneys for Petitioner Neptune	15	725 Twelfth Street, N.W.
16	2200 Ross Avenue	16	Washington, DC 20005
17	Dallas, Texas 75201	17	BY: ADAM PERLMAN, ESQUIRE
18	BY: SARAH SPIRES, ESQUIRE	18 19	— and —
19 20	(VIA TELEPHONE)	20	BY: DAVID KRINSKY, ESQUIRE
20 21		20	
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22		23	
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1 A P P E A R A N C E S: 1		Page 6		Page 7
2 MITNESS: EXAMINATION PAGE 3 ALSO PRESENT: PAMES P. LEEDS, ESQUIRE PAMES P. LEEDS, ESQUIRE PAMES P. LEEDS, ESQUIRE 4 JAMES P. LEEDS, ESQUIRE PAMES P. LEEDS, ESQUIRE PAMES P. LEEDS, ESQUIRE PAMES P. LEEDS, ESQUIRE 7 VIDEOGRAPHER: DONALD J. BREUWET PAME PERLMAN 428 10 10 (None marked.) 11 11 (None marked.) 12 12 13 13 13 14 14 14 14 15 15 15 16 16 16 17 17 17 18 19 10 19 10 10 10 11 10 11 11 11 12 12 12 13 13 14 14 14 14 15 15 15 16 16 16 17 17 17 18 17 18 18	1		1	
3 ALSO PRESENT: 8 RON D. SCHIFF, MD., Ph.D. WR. PRELMAN 9 4 JAMES P. LEEDS, ESQUIRE 5 BY MS. LYDIGSEN 426 5 ELi Lily and Company 5 BY MS. LYDIGSEN 426 6 Assistant General Patent Counsel 7 7 VIDEOGRAPHER: 7 9 DONALD J. BREUWET 7 10 In the second se		AFFEAKANCES.		
4 JAMES P. LEEDS, ESQUIRE 4 BY MR. LYDRGSTN 426 5 Eli Lilly and Company 5 BY MR. PERLMAN 428 7 VIDEOGRAPHER: 7 9 DONALD J. BREUWET 7 10 10 10 11 11 10 12 12 13 13 13 13 14 14 14 15 15 15 16 16 16 17 17 18 18 19 19 20 20 21 21 22 22 22 22 22 23 24 24 24 25 25 Page 8 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 5 5 Schiff in the matter of Sandoz, Inc. et 9 4 United States Patent and Trademark 7 7 This deposition is being held at 200 9 9 North Ashley Drive, Tamap, Florida, on 18 19 Acanswedegde having been duly s		ALSO PRESENT:	3	
5 Eli Lilly and Company 5 BY MR. PERLMAN 428 6 Assistant General Patent Counsel 7 7 VIDEOGRAPHER: 7 9 DONALD J. BREUWET 7 10 10 10 11 10 10 12 10 10 13 13 13 14 14 15 16 16 17 17 10 18 10 19 10 20 20 21 22 22 23 23 24 25 25 Page 8 Page 9 RON D. SCHIFF, M.D., Ph.D. 17 10 2 10 2 10 2 11 3 11 4 12 5 11 7 11 14 12 7 11 15 11 16 11 17 11 18 10 19 11 10 11 111<			4	
6 Assistant General Patent Counsel 6 7 VIDEOGRAPHER: 7 9 DONALD J. BREUWET 7 10 11 12 11 12 13 12 13 13 14 14 15 16 16 16 17 17 18 18 19 19 20 20 21 22 23 24 24 25 25 24 26 7 7 THE VIDEOGRAPHER: This is the start of Media Label Number 1 in the deposition of Dr. Ron Schiff in the matter of Sandoz, Inc., et al., v. Eli Lilly & Company, in the flip deposition of Dr. Ron Schiff in the matter of Sandoz, Inc., et al., v. Eli Lilly & Company, in the flip deposition of Dr. Ron Schiff in the matter of Sandoz, Inc., et al., v. Eli Lilly & Company, in the flip deposition of Dr. Ron Schiff in the matter of Sandoz, Inc., et al., v. Eli Lilly & Company, in the flip deposition of Dr. Ron Schiff in the matter of Sandoz, Inc., et al., v. Eli Lilly & Company, in the flip deposition of Dr. Ron Schiff in the matter of Sandoz, Inc., et al., v. Eli Lilly & Company, in the flip deposition of Dr. Ron Schiff in the matter of Sandoz, Inc., et al., v. Eli Lilly & Company, in the flip deposition of Dr. Ron Schiff in the matter of Sandoz, Inc., et al., v. Eli Lilly & Company, in the flip deposition of Dr. Ron Schiff in the witness. 19 Reporting, Incorporated, headquartr			5	
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18 14 19 20 21 20 22 21 23 21 24 24 25 26 Page 8 1 RON D. SCHIFF, M.D., Ph.D. 2 21 23 23 24 24 25 25 Page 8 1 RON D. SCHIFF, M.D., Ph.D. 2 THE VIDEOGRAPHER: This is the start 3 of Media Label Number 1 in the 4 video-recorded deposition of Dr. Ron 5 Schiff in the matter of Sandoz, Inc., et 6 al., v. Eli Lilly & Company, in the 7 United States Patent and Trademark 8 Office, Case Number IPR2016-00318. 9 This deposition is being held at 200 9 This deposition is being held at 200 10 North Ashley Drive, Tampa, Florida, on 11 January 27th Orito Avenue, New York, New York. 12 My name is Don Breuwet. I'm the 13 astocation with TSG Reporting. 14	16		16	
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1	RON D. SCHIFF, M.D., Ph.D.	1	RON D. SCHIFF, M.D., Ph.D.
2	Do you see that?	2	Q. Okay. I'd like to direct before
3	A. I do.	3	I direct you to something, am I correct that
4	Q. And when's the last time you had the	4	this reply declaration is intended by you to
5	opportunity to review your reply declaration?	5	be your response to the opinions Dr. Chabner
6	A. Yesterday.	6	and Zeisel put forward on behalf of Eli
7	Q. Okay. Did you review the whole	7	Lilly?
8	thing?	8	A. And also Lilly's reply declaration
9	A. No, just selected portions.	9	following my prior deposition in late August.
10	Q. Okay. When's the last time you	10	Q. Lilly's reply declaration? You
11	reviewed the entirety of it?	11	mean Lilly's brief, you mean? Lilly's
12	A. That would have been approximately	12	A. It wasn't labeled a brief.
13	Sunday and Monday, but I may be off by a day	13	Q. Lilly's response?
14	or so.	14	A. Perhaps.
15	Q. Okay. Do you feel comfortable that	15	Q. Let me tell you, we filed three
16	you recall the contents of your declaration?	16	things: We filed a patent owner response; we
17	A. I do, but I would like to reserve	17	
18		18	filed Dr. Chabner's declaration; we filed
19	the right to refer to it as needed.	19	Dr. Schiff's declaration. Is it responding to all three of those?
20	Q. Certainly. And all I would ask is	20	
20	if you are going to be reading from your	20	A. Zeisel, you mean.
22	declaration, that you identify the paragraph	22	Q. Zeisel. That's
22	and page number for us	22	A. It was yeah, all three what you
23	A. I certainly will.	23	described as patent owner's response is what
24	Q so that we can all follow along.	24	I refer to as a reply declaration by Lilly.
25	A. Correct.	23	So that's the same thing.
	Page 12		Page 13
1	RON D. SCHIFF, M.D., Ph.D.	1	RON D. SCHIFF, M.D., Ph.D.
2	Q. Okay. So this is this	2	A. Most of the time, yes. I mean, I
3	declaration by you is intended, to summarize,	3	did certain other activities, but most of
4	to be responsive to the arguments and	4	what I did on the creative side was working
5	evidence that Lilly put forward a few months	5	on this. That was last fall.
6	ago in response to what Sandoz had initially	6	Q. And as you sat down to work on your
7	put forward?	7	declaration and you were discussing
8	A. Exactly.	8	particular references, did you have the
9	Q. And can you estimate for us how much	9	references with you at that time so that you
10	time you spent considering your opinions and	10	could sort of consult the reference as you
11	response prior to drafting your reply	11	prepared the relevant paragraph about the
12	declaration?	12	reference?
13	A. I did not give that prior thought or	13	A. Yes, I did that.
14	calculate it. I would have to say perhaps 10	14	Q. And so if you have testimony in your
15	to 20 hours before I started working on it.	15	reply declaration about the teaching of a
16	Q. And then from that point forward, in	16	reference, you weren't doing that from
17	terms of preparing the declaration, how many	17	memory; you were doing that from
18	additional hours do you think it took?	18	contemporaneously reviewing the reference as
19	A. I worked on that for pretty close to	19	you were writing your opinion?
	three weeks, just about every day and didn't	20	A. I'm more meticulous than to rely on
20		21	memory for that, so, yes, I looked at the
20 21	do a whole lot else on those days. So I		THETHER Y TOT THAT, SO, YES, I TOUNED AT THE
	do a whole lot else on those days. So I can't really tell you hours, but that was	22	
21	can't really tell you hours, but that was		actual references as I worked on my reply.
21 22	•	22 23 24	

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Page 14		Page 15
RON D. SCHIFF, M.D., Ph.D.	1	RON D. SCHIFF, M.D., Ph.D.
	2	a whole rather than looking at select bits of
as a whole?	3	it potentially out of context?
A. I would say yes. I mean, I tried	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?
and to see where that fit into the scientific	8	A. It is.
or clinical issue that I was dealing with.	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
to a conclusion about what it teaches as a	15	white and the replacement pages were put
whole?	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.)
same way you did, looking at the reference as	25	THE VIDEOGRAPHER: Going on the
Page 16		Page 17
RON D SCHIFF M D Ph D	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
		tested were not being tested with folic acid?
Q. And if that ministerial problem	20	A. I cannot speak to the assessment
	21	whether it was a majority or some other
causes you difficulty later just let me		
causes you difficulty later, just let me know, and we'll resolve it. We're looking at	22	
know, and we'll resolve it. We're looking at		proportion of studies. I know there were
	22	
	 RON D. SCHIFF, M.D., Ph.D. it important to you to consider the reference as a whole? A. I would say yes. I mean, I tried not to just fish out individual statements but to look at everything in context to understand what a particular report was about and to see where that fit into the scientific or clinical issue that I was dealing with. Q. And do you think that's the approach that the person of ordinary skill in the art would take when reviewing the literature and references in this case; that is, they would review the entirety of the reference and come to a conclusion about what it teaches as a whole? A. Well, that's the proper way to do it. And I think a person of ordinary skill in the art would know better than to seek out statements out of context. Q. Okay. And just to get a direct any way you did, looking at the references are way you did, looking at the reference and come to a conclusion about what's happened here. Certain of the pages have color highlighting on them. And when the exhibit was originally printed, it was printed in black and white. I requested that that page be replaced with the color page, which, in fact, happened, but the original page was left in the exhibit with a line through it. So that appears to be the only alteration that was done. I'm hopeful that won't cause any confusion, but that's what's happened here. BY MR. PERLMAN: Q. There you go, Doctor. A. Thank you. 	RON D. SCHIFF, M.D., Ph.D.1it important to you to consider the reference as a whole?3A. I would say yes. I mean, I tried not to just fish out individual statements but to look at everything in context to

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