

1                                    DAVID ROSS, M.D.  
2                    UNITED STATES PATENT AND TRADEMARK OFFICE  
3                    BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

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20                                    Case No. IPR2016-00318  
21                                    Patent No. 7,772,209

22                                    VIDEOTAPED DEPOSITION OF DAVID B. ROSS, M.D.  
23                                    Friday, January 20, 2017  
24                                    Chicago, Illinois

25                    Reported By:  
26                    TRICIA J. FLASKA, CSR, RPR  
27                    JOB NO. 117984

1 DAVID ROSS, M.D.

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3  
4 Friday, January 20, 2017  
5 8:23 a.m.

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7  
8 VIDEOTAPED DEPOSITION OF DAVID B. ROSS,  
9 M.D., held at Brinks, Gilson & Lione, 455 North  
10 Cityfront Plaza Drive, Chicago, Illinois 60611  
11 before Tricia J. Flaska, CSR, RPR.  
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1 DAVID ROSS, M.D.

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17  
18  
19  
20  
21  
22  
23

24 ALSO PRESENT: Jeremy Mangan, Videographer  
25 Jim Leeds

1 DAVID ROSS, M.D.

2 I N D E X

3 W I T N E S S E S

4 All Witnesses: Page

5 DAVID B. ROSS, M.D. for Defendant 6

6 Examination by Mr. Krinsky 130

7 Examination by Mr. James  
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(No exhibits marked.)

1 DAVID ROSS, M.D.

2 THE VIDEOGRAPHER: We are now on the record.  
3 This marks the beginning of media number one in the  
4 deposition of David B. Ross, M.D., in the matter of  
5 Sandoz, Inc., et. al. versus Eli Lilly & Company in  
6 the U.S. Patent and Trademark Office before the  
7 Patent Trial and Appeal Board, Case Number  
8 IPR-201600318.

9 This deposition is being held at 455 North  
10 Cityfront Plaza, Chicago, Illinois on January 20th,  
11 2017, and the time is now 8:23 a.m. All attorneys  
12 present will be noted on the stenographic record.

13 Will the court reporter please swear in the  
14 witness.

15 DAVID ROSS, M.D.

16 called as a witness, having been first duly sworn by  
17 a Notary Public, was examined and testified as  
18 follows:

19 EXAMINATION

20 BY MR. KRINSKY:

21 Q Good morning.

22 A Good morning.

23 Q You're a medical doctor, correct?

24 A Yes.

25 Q So shall I refer to you as Dr. Ross?

1 DAVID ROSS, M.D.

2 A Please.

3 Q Could you briefly describe your -- well,  
4 first of all, have you ever been deposed before?

5 A A few times.

6 Q Okay. So you -- you know how this process  
7 works?

8 A In general. If you can just briefly review  
9 kind of what --

10 Q Well, but the -- your -- I'll let your  
11 counsel, you know, speak to the -- the details, but  
12 I -- I'm here to ask you questions and you're here  
13 to answer those questions and your -- your counsel  
14 has the right to object, but the fact that they  
15 object doesn't mean that you don't still have to  
16 answer the questions, is, I think, the nutshell that  
17 you need to know.

18 A Okay.

19 Q And you understand that you're under oath?  
20 You were just sworn in?

21 A Yes.

22 Q So is there any reason you can't testify  
23 fully and truthfully today?

24 A No.

25 Q Are you on any medication that would

1 DAVID ROSS, M.D.

2 interfere with the ability to testify truthfully?

3 A No.

4 Q Nothing that would impair your cognition?

5 A No.

6 Q Okay. Briefly describe your educational  
7 background.

8 A I received my bachelor of science in  
9 molecular biophysics and biochemistry at Yale  
10 University in 1980. I matriculated at New York  
11 University School of Medicine, as well as the NYU  
12 Graduate School of Arts and Sciences in 1980, and I  
13 was awarded a Master's degree in biochemistry in  
14 1985, an M.D. in 1988, and a Ph.D in biochemistry in  
15 1988.

16 I subsequently completed a categorical  
17 internal medicine residency, again at NYU. I then  
18 went on and did fellowship training in infectious  
19 diseases at Yale University and Yale-New Haven  
20 Hospital, completed that in 1994.

21 And then in terms of other formal  
22 education, I received a Master's in biomedical  
23 informatics at Oregon Health & Sciences University  
24 in, I believe it was 2012.

25 Q And when did you start that master of

1 DAVID ROSS, M.D.

2 biomedical informatics program?

3 A I believe it was around 2004. Although  
4 initially, I think it was a less extensive program  
5 that I enrolled in, and I then decided to proceed  
6 and get a Master's degree after completing that  
7 program.

8 Q So was this something you were doing  
9 part-time while you were working?

10 A Yes.

11 Q And where do you currently work?

12 A I'm -- my full-time job is at the  
13 Department of Veterans Affairs in Washington, DC.

14 Q And -- and what is that full-time job?

15 A I am director of HIV, hepatitis, and  
16 related conditions programs in the Veterans Health  
17 Administration.

18 Q And -- and what is the Veterans Health  
19 Administration?

20 A Veterans Health Administration is a  
21 component of the U.S. Department of Veterans  
22 Affairs, which is a cabinet-level agency. The VHA  
23 is the component of VA that provides healthcare to  
24 enrolled beneficiaries who are primarily veterans  
25 who are eligible for care in VA. And that's

1 DAVID ROSS, M.D.

2 essentially what VHA is.

3 Q And you do -- you do consulting in addition  
4 to your full-time work as a government employee?

5 A I do.

6 Q Have you served as an expert witness before  
7 since your -- beginning your position at the VHA?

8 A Yes.

9 Q In -- in what capacity, to the extent you  
10 can say without breaching any confidentiality  
11 obligations?

12 A When -- I'm sorry -- when you say "in what  
13 capacity" can you --

14 Q Well, what -- what type of cases?

15 A Oh. In general, cases related to my  
16 expertise. Some of these have been related to my  
17 clinical background. Some have been related to my  
18 background and expertise in FDA. So those have  
19 included tort claims, securities fraud litigation.  
20 That's sort of, I think, a summary of the sort of  
21 the cases that I've been involved in.

22 Q Is this your first patent case?

23 A Yes.

24 Q And you say you've done work related to  
25 your clinical background. What do you mean by that?

1 DAVID ROSS, M.D.

2 A So the cases that I've worked on have been,  
3 in general, cases related to clinical infectious  
4 diseases.

5 Q And in what capacity have you testified in  
6 cases related to clinical infectious diseases?

7 A As an expert witness.

8 Q In -- in what types of cases have you  
9 testified as a -- in your capacity as an expert in  
10 infectious disease as opposed to as an expert in  
11 FDA?

12 A Oh. So these have been, in general,  
13 medical malpractice cases. Some of these have been  
14 tort claims that are not necessarily medical  
15 malpractice, but where there's an infectious disease  
16 component in terms of causation or where it's --  
17 that expertise is otherwise relevant.

18 Q Is it fair to say that your -- your area of  
19 medical expertise is in infectious diseases?

20 A Well, clinically I provide both infectious  
21 disease care -- this is in my clinical practice --  
22 but I also practice as a general internist, and so I  
23 provide primary care as well. And in the VA, that  
24 covers quite a lot of ground.

25 Q So you have a job as a director of a

1 DAVID ROSS, M.D.

2 program at the VHA and you also see patients?

3 A Yes.

4 Q And you also do consulting work?

5 A Yes.

6 Q Does the VHA know you do this consulting  
7 work?

8 A Yes.

9 Q Are there rules surrounding the outside  
10 expert witness engagements of employees such as  
11 yourself?

12 A Yes.

13 Q And do you comply with those rules?

14 A Yes.

15 Q What are those rules?

16 A So the most important rule that applies  
17 here -- and I can't give you the exact statutory  
18 language -- is that federal a employee cannot serve  
19 as an expert witness in a federal -- case in federal  
20 court or something under federal jurisdiction  
21 without essentially authorization from the agency if  
22 it's a case in which the United States has a direct  
23 and substantial interest.

24 Q Do you have authorization from the agency  
25 to testify in this case?

1 DAVID ROSS, M.D.

2 A There's not -- it -- it's not really  
3 authorization. If a case does not -- if the U.S. --  
4 United States is not a direct -- does not have a  
5 direct and substantial interest in the case, then no  
6 authorization is -- is needed.

7 On occasions when there have been  
8 questions, I've consulted with the Office of General  
9 Counsel at VHA if I have questions about whether a  
10 particular matter may represent an issue, which  
11 never has.

12 The other issue, I'm sorry, I should  
13 mention is that if there is a case in which it --  
14 there may be a conflict with my official duties,  
15 that -- I either have to not accept the case or  
16 recuse myself from any matters -- official matters  
17 which might be involved in that. And to date, that  
18 has not happened.

19 Q So you don't see this case as bearing on  
20 your role at the VHA?

21 A I do not.

22 Q Is the VHA a consumer of generic drugs?

23 A Is it a consumer of generic drugs?

24 Q Or let me -- let me rephrase. Does the VHA  
25 purchase generic drugs for administration to its

1 DAVID ROSS, M.D.

2 patients?

3 A Yes.

4 Q Does it purchase generic oncology drugs?

5 A I don't know for sure. I'm -- I'm not  
6 involved in the pharmacy aspect of -- of that, of  
7 oncology drugs, so I would presume so, but I don't  
8 have any direct knowledge of what they do.

9 Q Do you ever prescribe generic drugs in your  
10 practice?

11 A I -- what I prescribe are drugs that matter  
12 in which whether they're generic or trade name is  
13 usually not something I'm aware of except on very  
14 rare occasions.

15 Q What are those rare occasions?

16 A There are sometimes patients who have a  
17 need clinically for a particular formulation, and in  
18 those instances, I may make a special request to  
19 make sure that they're prescribed the appropriate  
20 formulation, which if it is the -- excuse me --  
21 innovator drug, if it's a trade name drug, in  
22 essence, I may ask for that, but that -- that's --  
23 off the top of my head, I can only think of one  
24 patient where that's actually happened.

25 Q Do you have an understanding that generic

1 DAVID ROSS, M.D.

2 drugs often are cheaper than brand name  
3 counterparts?

4 A That's my -- not being, you know, involved  
5 directly in this area, that's my -- that is my  
6 understanding.

7 Q Do you have an understanding that the  
8 petitioners in this case are seeking to invalidate  
9 the patent on a drug that's currently sold as a  
10 branded drug?

11 A That's my understanding.

12 Q So if the petitioners prevail, oncology  
13 drugs will get cheaper for the VHA, won't they?

14 MR. JAMES: Objection. Form.

15 A I think it's a very broad statement. I  
16 can't say one way or the other. The only drug that  
17 I've been asked to look at in this case is -- not --  
18 that's at issue here is this particular agent. So  
19 when you say "oncology drugs" --

20 BY MR. KRINSKY:

21 Q That's -- that's fair. Pemetrexed --

22 A Okay.

23 Q -- will get cheaper for the VHA if  
24 petitioners prevail; is that fair?

25 A I actually -- the VA has its own

1 DAVID ROSS, M.D.

2 negotiation and contracting with pharmaceutical  
3 companies, so I don't know that that's true. It --  
4 it could be. Or it could be that the VA is -- VHA,  
5 I should say, is authorized -- has a number of  
6 statutory advantages, if you will, where there's a  
7 statutory discount for drugs.

8 And in addition, because of the -- its  
9 purchasing, the VHA is often able to reach  
10 agreements with pharmaceutical companies over and  
11 above that. So I actually don't know that that's  
12 true.

13 Q I think you mentioned that your post M.D.  
14 fellowship, your first fellowship or residency -- I  
15 apologize if I --

16 A No, that's --

17 Q -- don't get the terminology correct --

18 A Sure.

19 Q -- was in categorical internal medicine?

20 A Yes.

21 Q What is that?

22 A So that is a 36-month training program that  
23 involves -- at the time that I did it, and it's  
24 still this way today -- hospital-based internal  
25 medicine training involving care of patients,

1 DAVID ROSS, M.D.

2 didactic lectures, mentoring by more senior  
3 physicians, as well as maintaining outpatient  
4 continuity clinic generally once a week. And  
5 typically that will involve being -- providing  
6 direct patient care to, in the course of three  
7 years, over a thousand patients.

8 It also comprises receiving both training  
9 not just in general internal medicine, but exposure  
10 to very specialty areas of internal medicine, as  
11 well as consultation on patients outside the general  
12 internal medicine service.

13 Q And then you mentioned after that you  
14 focused more specifically on infectious disease?

15 A Yes.

16 Q And can you just describe -- well, first of  
17 all, your -- your current job with the VHA, I think  
18 you testified earlier, involves both a director role  
19 and patient care?

20 A Just to clarify, I do not receive  
21 compensation for the patient care aspect. That is  
22 -- I am on staff at the Washington, D.C. VA as  
23 what's called a without compensation physician. So  
24 I do not receive any payment or any other kind of  
25 compensation for doing that. That is something that

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