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

COALITION FOR AFFORDABLE DRUGS VII LLC,

Petitioner,

vs.

Case No. IPR2015-01718
Patent No. 8,945,621

POZEN, INC.,

Patent Owner.

DEPOSITION OF ROBERT W. MAKUCH, PH.D.

Monday, September 19, 2016

9:00 a.m.

Reported by:

Joan Ferrara, RMR, CRR

Job No. 181513

<p style="text-align: right;">Page 2</p> <p>1 2 3 September 19, 2016 4 9:00 a.m. 5 New York, New York 6 7 8 9 Deposition of Robert W. Makuch, 10 Ph.D., held at the offices of Cooley, LLP, 11 1114 Avenue of the Americas, New York, 12 New York, Pursuant to Notice, before Joan 13 Ferrara, a Registered Merit Reporter and 14 Notary Public of the State of New York. 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 4</p> <p>1 2 A P P E A R A N C E S : (Continued) 3 4 5 COOLEY, LLP 6 Attorneys for Horizon Pharma and The Witness 7 3175 Hanover Street 8 Palo Alto, California 94304-1130 9 BY: RICARDO RODRIGUEZ, ESQ. 10 rr@cooley.com 11 12 13 14 FINNEGAN HENDERSON FARABOW GARRETT & DUNNER 15 Attorneys for Horizon Pharma 16 901 New York Avenue, N.W. 17 Washington, D.C. 20001-4413 18 BY: DANIELLE C. PFIFFERLING, ESQ. 19 danielle.pfifferling@finnegan.com 20 21 22 23 ALSO PRESENT: 24 Laura Stevens, Horizon Pharma 25</p>
<p style="text-align: right;">Page 3</p> <p>1 2 A P P E A R A N C E S : 3 4 5 WICK PHILLIPS 6 Attorneys for Petitioner - Coalition for 7 Affordable Drugs VII LLC 8 3131 McKinney Avenue, Suite 100 9 Dallas, Texas 75204 10 BY: AMY E. LaVALLE, ESQ. 11 amy.lavalle@wickphillips.com 12 13 14 15 BAKER BOTTS, LLP 16 Attorneys for Patent Owner - Pozen 17 98 San Jacinto Boulevard 18 Suite 1500 19 Austin, Texas 78701-4078 20 BY: JEFF GRITTON, ESQ. 21 jeff.gritton@bakerbotts.com 22 23 24 25</p>	<p style="text-align: right;">Page 5</p> <p>1 2 R O B E R T M A K U C H , 3 called as a witness, having been 4 duly sworn by a Notary Public, was 5 examined and testified as follows: 6 EXAMINATION BY 7 MS. LaVALLE: 8 Q Hi, Dr. Makuch. Is that right? 9 A Yes. 10 Q Sorry. 11 I'm Amy LaValle. I represent 12 the petitioner Coalition for Affordable 13 Drugs. 14 Could you please state your full 15 name for the record. 16 A My name is Robert W. Makuch, 17 M-A-K-U-C-H. 18 Q Could you please state your 19 current home address? 20 A My current home address is 8 21 Greenbrier Road in Westport, Connecticut. 22 Q Do you have any medical issues 23 that might affect your testimony today? 24 A I do not. 25 Q Are you taking any medication?</p>

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1 R. Makuch
2 A I take no medications.
3 Q Have you ever been deposed?
4 A Yes, I have.
5 Q When was that?
6 A It's been quite a while ago, so
7 I don't recall the exact date, but it might
8 be 4 years ago in one particular case.
9 Q Were you deposed just one time
10 before?
11 A No. I've been deposed in the
12 more distant past as well.
13 Q Just one other time?
14 A No, other times, plural. And
15 again, I can't recall. It's not something
16 that I tend to do. I really don't recall
17 the dates.
18 Q When you were deposed
19 previously, were you working as an expert
20 witness in a legal proceeding?
21 A I can't even tell you whether I
22 was an expert witness or I was a fact
23 witness. I really don't recall.
24 Q Have you ever testified in a
25 patent case before?

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1 R. Makuch
2 A Yes, I have.
3 Q Was that the case 4 years ago,
4 approximately?
5 A That is the case roughly 4 years
6 ago. Again, I could be off by as much as a
7 year or two on either side.
8 Q What type of case was that?
9 A I tend to recall it was involved
10 in a drug-related issue for HIV.
11 Q And did you represent the patent
12 owner?
13 A I tend to recall that I did.
14 Q Do you recall if you testified
15 on any issues of patent validity?
16 A I don't recall.
17 Q Other than that representation
18 that you did and that was related to your
19 deposition, have you ever served as an
20 expert witness or consultant in a legal
21 proceeding?
22 A Yes, I have.
23 Q How many times before?
24 A I really couldn't say. Again,
25 it's not something that I do consistently

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1 R. Makuch
2 and I could not even give you a rough
3 estimate, actually.
4 Q Do you recall ever having done
5 an expert declaration or a written expert
6 report?
7 A I know that I have done expert
8 reports in the past.
9 Q Do you recall ever in the past
10 doing an expert report on the issue of
11 patent validity?
12 A I don't believe so, but I can't
13 really state for sure. I simply just don't
14 recall.
15 Q And you did provide an expert
16 declaration for this proceeding, correct?
17 A That I did, yes.
18 Q So other than the declaration
19 that you provided for this proceeding, you
20 do not recall whether you've provided any
21 expert written reports or declarations in
22 other prior legal proceedings?
23 A Not really. I just, I think,
24 again, the last one was 4 years ago or
25 more, and so I just don't recall.

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1 R. Makuch
2 Q Do you have any patents of your
3 own?
4 A Not that I'm aware of.
5 Q So to your knowledge, you are
6 not a named inventor on any patents?
7 A To my knowledge, I am not a
8 named inventor on any patent.
9 Q Any pending patent applications?
10 A Not that I'm aware of.
11 Q Do you have any experience with
12 the patent process?
13 A I don't have any direct
14 experience with the Patent Office or
15 individuals who work there.
16 Q I didn't really mean to ask
17 about the Patent Office.
18 Do you have any experience
19 dealing with applicants for patents or
20 patents after they issue through your work
21 or anything like that?
22 A I just simply do not do those
23 kinds of activities. Whether someone spoke
24 to me about something that they then used,
25 I have no idea.

<p style="text-align: right;">Page 10</p> <p>1 R. Makuch</p> <p>2 Q Prior to your preparation for</p> <p>3 this legal proceeding, have you done any</p> <p>4 consulting or other type of work for the</p> <p>5 patent owners in this case?</p> <p>6 A I know I shouldn't ask a</p> <p>7 question, but to be clear, who is the</p> <p>8 patent owner?</p> <p>9 Q No problem. When I say patent</p> <p>10 owners, I mean it plural, Pozen and Horizon</p> <p>11 Pharma.</p> <p>12 A Okay. So please ask your</p> <p>13 question again.</p> <p>14 Q Prior to this engagement for</p> <p>15 this legal proceeding, have you ever done</p> <p>16 any consulting or other type of work for</p> <p>17 either Pozen or Horizon Pharma?</p> <p>18 A Yes, I have.</p> <p>19 Q Was it for Pozen or Horizon</p> <p>20 Pharma?</p> <p>21 A It was for Horizon Pharma, that</p> <p>22 I recall.</p> <p>23 Q What type of work did you do for</p> <p>24 Horizon Pharma?</p> <p>25 A A long time ago, I recall that I</p>	<p style="text-align: right;">Page 12</p> <p>1 R. Makuch</p> <p>2 A As part of my work, I</p> <p>3 occasionally am invited by sponsors to</p> <p>4 either work with them on what are called</p> <p>5 mock advisory committees or going with them</p> <p>6 on actual advisory committees to the FDA.</p> <p>7 Q Are you formally paid for that</p> <p>8 type of work?</p> <p>9 A I am paid for that kind of work.</p> <p>10 Q And so that one project that you</p> <p>11 did with Horizon Pharma, were you paid for</p> <p>12 that?</p> <p>13 A I would assume so.</p> <p>14 Q Are you normally paid by the</p> <p>15 hour?</p> <p>16 A I am generally paid by the hour.</p> <p>17 Q Would you have been paid by the</p> <p>18 hour for that project?</p> <p>19 A I don't recall.</p> <p>20 Q Have you ever done any</p> <p>21 consulting or other type of work for</p> <p>22 Astrazeneca?</p> <p>23 A I tend to recall that, again, in</p> <p>24 the fairly distant past, I did work with</p> <p>25 them on one project.</p>
<p style="text-align: right;">Page 11</p> <p>1 R. Makuch</p> <p>2 was contacted to provide input into some</p> <p>3 advisory committee activities that Horizon</p> <p>4 was invited by the FDA to attend.</p> <p>5 Q What type of advisory committee</p> <p>6 was it?</p> <p>7 A I actually don't recall the</p> <p>8 title, nor the intent. I just remember</p> <p>9 going with the Horizon people to the</p> <p>10 meeting and working with them beforehand in</p> <p>11 preparation for it.</p> <p>12 Q Was this related to a certain</p> <p>13 type of drug product?</p> <p>14 A I tend to recall it was more of</p> <p>15 a general discussion by the FDA about ways</p> <p>16 to examine products, more generally,</p> <p>17 because I tend to recall there were several</p> <p>18 other companies invited by the FDA.</p> <p>19 Q What would your role have been</p> <p>20 in providing input for an advisory</p> <p>21 committee?</p> <p>22 A I can't recall. It was a long</p> <p>23 time ago.</p> <p>24 Q Is that something that you would</p> <p>25 normally do as part of your work?</p>	<p style="text-align: right;">Page 13</p> <p>1 R. Makuch</p> <p>2 Q Do you remember what the subject</p> <p>3 matter of that project was?</p> <p>4 A I believe I served on a data</p> <p>5 monitoring committee for a trial that I</p> <p>6 don't even remember.</p> <p>7 Q The trial would have been for a</p> <p>8 drug product?</p> <p>9 A I recall that the trial was for</p> <p>10 a drug product. I can't even tell you what</p> <p>11 disease it was for.</p> <p>12 Q Okay.</p> <p>13 So you do not recall the name of</p> <p>14 the drug?</p> <p>15 A No.</p> <p>16 (Whereupon, Exhibit 1 was marked</p> <p>17 for Identification.)</p> <p>18 BY MS. LaVALLE:</p> <p>19 Q I'm going to hand you a document</p> <p>20 that is Patent No. 8,945,621. This is the</p> <p>21 patent that is at issue in this proceeding.</p> <p>22 Can you confirm that this is a</p> <p>23 copy of the patent that's at issue in this</p> <p>24 proceeding?</p> <p>25 A I do see the signees and I</p>

<p style="text-align: right;">Page 14</p> <p>1 R. Makuch 2 imagine this is referred to as the '621 3 Patent? 4 Q Correct, yes. If I do refer to 5 this document as the '621 Patent, I'm 6 talking about this. 7 A Okay. Then I'm comfortable to 8 indicate that this is the '621 Patent that 9 I have been involved with. 10 Q And you have reviewed this 11 document before, is that correct? 12 A Yes, I have. 13 Q On the first page, if you look 14 in the upper left-hand column, there is a 15 listing of the inventors. 16 Do you see that? 17 A Yes, I do. 18 Q Do you recognize any of those 19 names? 20 A I recognize none of those names. 21 Q You do not personally know any 22 of the named inventors on this patent? 23 A I do not recognize the names of 24 any of these individuals. 25 Q To your knowledge, you haven't</p>	<p style="text-align: right;">Page 16</p> <p>1 R. Makuch 2 A I do not. 3 (Whereupon, Exhibit 2 was marked 4 for Identification.) 5 BY MS. LaVALLE: 6 Q I'm going to hand you another 7 document that we've marked as Exhibit 2. 8 The title of this document is 9 Declaration of Robert W. Makuch, Ph.D, in 10 Support of Patent Owner's Response. 11 Can you confirm that this is the 12 declaration that you prepared for this 13 proceeding? 14 A Yes, this appears to be the 15 declaration I did prepare for this group 16 and for this activity. 17 Q And it appears that there are 18 two sets of page numbering, but if you 19 could turn to page 21 of 52, if you look in 20 the lower left-hand corner. 21 A Sure, yes. 22 Q Can you confirm there on that 23 page that that is your signature? 24 A Yes, I confirm that's my 25 signature.</p>
<p style="text-align: right;">Page 15</p> <p>1 R. Makuch 2 ever met these individuals? 3 A To my knowledge, I have not 4 approached or met these individuals. 5 Q Have you ever communicated with 6 anyone who is an employee of Pozen? 7 A I do not recall such discussion. 8 It could have happened, but I don't recall. 9 Q Since you've been hired to work 10 on this proceeding, do you recall ever 11 communicating with an employee of Horizon 12 Pharma? 13 A Since the time of this 14 proceeding and my involvement, I've spoken 15 to no one at Horizon Pharma. 16 Q And before you were engaged to 17 work on this proceeding, had you 18 communicated with the anyone from Horizon 19 other than the one project you told me 20 about? 21 A In the distant past, I did work 22 with Horizon on other issues, but that 23 would be a long time ago, again. 24 Q Do you recall what other issues 25 you worked on?</p>	<p style="text-align: right;">Page 17</p> <p>1 R. Makuch 2 Q Going back to the title page, 3 the title states that this declaration is 4 in support of patent owner's response. 5 My question is, have you 6 reviewed patent owner's response brief? 7 A I recall looking at some of 8 those documents, but again, that was not my 9 primary response in this report. 10 Q Do you recall reviewing the 11 portions of the response brief that cite to 12 your declaration? 13 A I'm sorry, what part of the 14 report? 15 Q Part of the patent owner's 16 response brief that cites to your 17 declaration, do you recall reviewing those 18 portions? 19 A I'd have to see what portions 20 those are, but I'd be glad to look at them. 21 Q Is that not something that you 22 did as part of your job when you were hired 23 to prepare this declaration? 24 A Yes, and it was a while ago and 25 I just don't know which items you're</p>

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