

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD  
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APOTEX, INC.,  
Petitioner,  
v.  
UCB BIOPHARMA SPRL,  
Patent Owner.

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U. S. Patent No. 8,633,194  
Inter Partes Review No.: IPR2019-00400  
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DEPOSITION OF DR. SARFARAZ NIAZI  
NEW YORK, NEW YORK  
FRIDAY, DECEMBER 6, 2019

REPORTED BY:  
DANIELLE GRANT

Page 2

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2  
3  
4 December 6, 2019  
5 9:35 a.m.  
6  
7  
8  
9  
10 Deposition of DR. SARFARAZ NIAZI, held  
11 at the offices of Fenwick & West LLP, 902  
12 Broadway, New York, New York pursuant to Notice  
13 before DANIELLE GRANT, a Shorthand Reporter and  
14 Notary Public of the State of New York.  
15  
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1 DR. SARFARAZ NIAZI  
2 DR. SARFARAZ NIAZI, called as a witness, having  
3 been first duly sworn by Danielle Grant,  
4 a Notary Public within and for the State  
5 of New York, was examined and testified  
6 as follows:  
7 DIRECT EXAMINATION BY  
8 MR. MALIK:  
9 Q Good morning, Dr. Niazi.  
10 A Good morning.  
11 Q So I've given you four exhibits.  
12 So the record is clear, I've given you your  
13 declaration, first one, correct?  
14 A Yes, I have it here.  
15 Q And you signed it October 14,  
16 2019, as on Page 89, correct?  
17 A Yes.  
18 Q I've also given you the '194  
19 Patent, Exhibit 1001, correct?  
20 A Yes.  
21 Q I assume you've seen this patent  
22 before?  
23 A Yes.  
24 Q And I have also given you WO 094,  
25 Exhibit 1007, correct? At the very bottom

Page 3

1 A P P E A R A N C E S:  
2  
3 KATTEN MUCHIN ROSENMAN, LLP  
4 Attorneys for the Petitioner Apotex  
5 550 South Tryon Street  
6 Suite 2900  
7 Charlotte, North Carolina 28202-4213  
8 BY: JITENDRA MALIK, Ph.D., ESQ., of Counsel  
9 ALISSA M. PACCHIOLI, ESQ., of Counsel  
10  
11  
12 FENWICK & WEST, LLP  
13 Attorneys for the Patent Owner, UCB Biopharma  
14 902 Broadway  
15 Suite 14  
16 New York, New York 10010  
17 BY: ERICA R. SUTTER, ESQ., of Counsel  
18 ROBERT COUNIHAN, ESQ., of Counsel  
19  
20  
21  
22  
23  
24  
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1 DR. SARFARAZ NIAZI  
2 you'll see 1007.  
3 A This one here?  
4 Q Yes.  
5 A Yes.  
6 Q And then the fourth document, if  
7 you look on the -- and the last document, the  
8 fourth document that I've handed you right at  
9 the beginning is, if you look on the bottom  
10 right, Exhibit 1004, which is EP 203, correct?  
11 A This one?  
12 Q Yes.  
13 A Yeah. Four.  
14 MS. SUTTER: Yeah, Jitty, I'm  
15 just going to make that statement on  
16 the record.  
17 MR. MALIK: Oh, yes, of course  
18 sorry. Of course.  
19 MS. SUTTER: Pursuant to our  
20 agreement before the last depositions  
21 going forward, any objections except  
22 for hearsay, relevance, privilege,  
23 foundation, all other objections are  
24 preserved, if I stated that correctly.  
25 MR. MALIK: Correct. That is my

<p style="text-align: right;">Page 6</p> <p>1 DR. SARFARAZ NIAZI</p> <p>2 understanding too.</p> <p>3 Q Dr. Niazi, you understand you're</p> <p>4 under oath to today?</p> <p>5 A Yes.</p> <p>6 Q You understand you're obligated</p> <p>7 to answer my questions?</p> <p>8 A Yes.</p> <p>9 Q Any reason today you cannot tell</p> <p>10 you truth?</p> <p>11 A No.</p> <p>12 Q Okay. If you -- if I ask a</p> <p>13 question and you don't say it's unclear, I</p> <p>14 assume you understood the question, fair enough?</p> <p>15 A Yes.</p> <p>16 Q And I ask that all the answers</p> <p>17 that you give me today are from the perspective</p> <p>18 of a POSA unless you indicate otherwise, fair</p> <p>19 enough?</p> <p>20 MS. SUTTER: Object to form.</p> <p>21 A Yes.</p> <p>22 Q And do you understand that this</p> <p>23 is an IPR deposition?</p> <p>24 A Yes.</p> <p>25 Q And PTAB rules prevent you from</p>	<p style="text-align: right;">Page 8</p> <p>1 DR. SARFARAZ NIAZI</p> <p>2 owner in this proceeding.</p> <p>3 Do you see that?</p> <p>4 A Yes.</p> <p>5 Q In connection with forming your</p> <p>6 opinion, did you look at any other documents</p> <p>7 other than what's mentioned in Paragraph 12?</p> <p>8 MS. SUTTER: Object to form.</p> <p>9 A In forming opinion I looked at</p> <p>10 quite a few documents in my own experience.</p> <p>11 Q Okay. Let me ask you this: Have</p> <p>12 you read the deposition of Mr. Fanara?</p> <p>13 A Yes.</p> <p>14 Q When did you read the deposition</p> <p>15 of Mr. Fanara?</p> <p>16 A I believe yesterday.</p> <p>17 Q Yesterday, okay.</p> <p>18 Have you seen UCB's complete</p> <p>19 response to the PTAB?</p> <p>20 A No, I have not seen that complete</p> <p>21 response.</p> <p>22 Q Is it fair to say that in</p> <p>23 connection with forming your opinions in this</p> <p>24 matter, you relied on all of the documents at</p> <p>25 least referenced in your declaration?</p>
<p style="text-align: right;">Page 7</p> <p>1 DR. SARFARAZ NIAZI</p> <p>2 discussing the substance of your testimony and</p> <p>3 anticipated testimony for the duration of this</p> <p>4 cross?</p> <p>5 Do you understand that?</p> <p>6 A Yes.</p> <p>7 Q That includes during the breaks.</p> <p>8 A Yes.</p> <p>9 MR. MALIK: And, Counsel, to the</p> <p>10 extent Dr. Niazi says anything today</p> <p>11 that will support a motion to strike,</p> <p>12 I will give you the full basis at the</p> <p>13 end of the cross, and that way you</p> <p>14 have the opportunity to redirect him</p> <p>15 however, but I'll give you a notice of</p> <p>16 it.</p> <p>17 Q Paragraph 12, in your</p> <p>18 declaration, those are the documents you</p> <p>19 considered, correct -- well, turn to Paragraph</p> <p>20 12, I'm sorry, of your declaration.</p> <p>21 MS. SUTTER: Object to form.</p> <p>22 Q Let me know when you're there.</p> <p>23 A Yes.</p> <p>24 Q It says in Paragraph 12: I</p> <p>25 considered the materials as submitted by patent</p>	<p style="text-align: right;">Page 9</p> <p>1 DR. SARFARAZ NIAZI</p> <p>2 A That's correct.</p> <p>3 MS. SUTTER: Object to form.</p> <p>4 Just if you can, you know,</p> <p>5 pause so I have time to object.</p> <p>6 THE WITNESS: Okay.</p> <p>7 Q Sitting here today, are you aware</p> <p>8 of any document that's in your declaration that</p> <p>9 you did not rely on in forming your opinions?</p> <p>10 A No.</p> <p>11 Q I assume you read the deposition</p> <p>12 transcript of Dr. Laskar, correct?</p> <p>13 MS. SUTTER: Object to form.</p> <p>14 A Yes.</p> <p>15 Q Now, do you have an understanding</p> <p>16 that the declaration Exhibit 202 -- sorry, 2034</p> <p>17 was exposed to be a complete response to Dr.</p> <p>18 Laskar as of the date you signed the</p> <p>19 declaration?</p> <p>20 MS. SUTTER: Object to form?</p> <p>21 MR. MALIK: The basis of the</p> <p>22 objection, counsel?</p> <p>23 MS. SUTTER: Legal. If he has an</p> <p>24 understanding of how the proceedings</p> <p>25 work and what you're saying a complete</p>

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<p>1 DR. SARFARAZ NIAZI 2 response is supposed to be. 3 MR. MALIK: Fair enough. 4 Q Do you understand that this was 5 supposed to be a response to Dr. Laskar, the 6 declaration? 7 A Yes. 8 Q And so as of the signing of this 9 declaration, which is October 14, 2019, have you 10 formed any additional opinions that are not 11 reflected in Exhibit 2034? 12 A No. 13 Q Have you received any additional 14 information that would make you change the 15 opinions reflected in Exhibit 2034? 16 A No. 17 Q Any corrections I should be aware 18 of in Exhibit 2034 before we get started? 19 A Not that I think I can think of 20 now. 21 Q Do you stand by the opinions in 22 Exhibit 2034? 23 A I do. 24 Q Okay. Let's start at 25 Paragraph 16. There in Paragraph 16 you say: I</p>	<p>1 DR. SARFARAZ NIAZI 2 Q And in Paragraph 22 you say: The 3 POSA would extensive experience formulating 4 multiple types of liquid pharmaceutical 5 formulations, including oral solutions, nasal 6 drops, eye drops, and ear drops. 7 Do you see that? 8 A Yes. 9 Q Can you expand on what you mean 10 by "extensive experience"? 11 MS. SUTTER: Object to form. 12 A I think extensive is a broad 13 experience dealing with many types of dosage 14 forms. 15 Q Can you expand on what you mean 16 by "expansive experience formulating multiple 17 types of liquid pharmaceutical formulations"? 18 MS. SUTTER: Objection to form. 19 Q As stated in Paragraph 22 of your 20 declaration? 21 A What I mean here is that they 22 would have formulated product, many different 23 active ingredients many active different 24 properties of solutions like pH, dielectric 25 constant, solubility, presence or need for</p>
Page 11	Page 13
<p>1 DR. SARFARAZ NIAZI 2 understand the earliest priority date to which 3 the '194 Patent is entitled is July 4, 2004. 4 Do you see that? 5 A Yes. 6 Q And in Paragraph 17 you state: I 7 understand that an obviousness analysis is 8 viewed from the perspective of a person of 9 ordinary skill in the art, POSA. 10 Do you see that? 11 A Yes. 12 Q Is it your understanding that a 13 person of ordinary skill in the art is a 14 hypothetical person that is assumed to be aware 15 of all pertinent art? 16 A Yes. 17 Q Paragraph 21, you provide the 18 definition of a POSA, correct? 19 A Yes. 20 Q And there you say that a POSA has 21 certain educational requirements and certain 22 years of relevant experience in developing and 23 formulating aqueous pharmaceutical formulations, 24 correct? 25 A Yes.</p>	<p>1 DR. SARFARAZ NIAZI 2 preservatives, the need for delivering a dosage 3 form which is suitable for the purpose, meaning 4 is it an adult dosage form or children's dosage 5 form. All of those very large number 6 considerations that go into formulating any 7 dosage form. 8 Q So the POSA would also have 9 experience with preservatives, correct? 10 A If the formulation requires a 11 preservative, that would be one of the many 12 things that he or she would have knowledge of. 13 Q Have you ever worked with 14 Levocetirizine? 15 A No, I've not. 16 Q Have you are worked with 17 Getirizine? 18 A No, I've not. 19 Q Let's turn to Exhibit 20 1007 -- strike that. 21 Yeah, 1007, which is W0094. 22 Let me know when you have that. Turn to Page 23 4, Lines 24, start there. Let me know when 24 you are a ready to proceed? 25 A Okay.</p>

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1 DR. SARFARAZ NIAZI  
 2 Q Okay. You see where it says:  
 3 Best results have been obtained with an oral  
 4 dosage form, in particular liquid formulations  
 5 such as syrup for children and film-coated  
 6 tablets for adults.  
 7 Do you see that? Line 24.  
 8 A On which page is that?  
 9 Q Page 4.  
 10 A Oh, yes.  
 11 Q You see where it says -- just so  
 12 the record is clear line, on W0094, Line 24:  
 13 Best results have been obtained with oral dosage  
 14 form, in particular liquid formulations such as  
 15 a syrup for children and film-coated tablets.  
 16 Do you see that?  
 17 A Yes.  
 18 Q Paragraph 22 you say that: The  
 19 POSA would have extensive experience with  
 20 multiple types of liquid pharmaceutical  
 21 formulations including oral solutions, nasal  
 22 drops, eye drops, and ear drops, correct?  
 23 A Yes.  
 24 Q Show me in that declaration where  
 25 the POSA has any experience with tablet

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1 DR. SARFARAZ NIAZI  
 2 formulations? Sorry, Paragraph 22.  
 3 A Yeah. Well, if to this form is  
 4 supposed to be a tablet, then that's a delivery  
 5 system, then a POSA would have that experience.  
 6 Q I'm simply asking in Paragraph  
 7 22, show me any -- or Paragraph 21, where you  
 8 state that the POSA has any experience in tablet  
 9 formulations.  
 10 A I'm referring to a POSA who will  
 11 be formulating this product, I'm not generically  
 12 talking about POSA.  
 13 Q Do you understand that you were  
 14 supposed to give your opinions on the definition  
 15 of a POSA?  
 16 A Yes.  
 17 Q Do you understand the definition  
 18 of a personal of ordinary skill in the art that  
 19 you provided is reflected in Section 4 of your  
 20 declaration?  
 21 A Yeah. A POSA would have  
 22 extensive experience in pharmaceutical liquid  
 23 formulations which is where the '194 is all  
 24 about.  
 25 Q Okay. I'm asking in, Paragraphs

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1 DR. SARFARAZ NIAZI  
 2 20, 21, 22, or 23 under the section Person of  
 3 Ordinary Skill in the Art in your declaration,  
 4 show me where it says that the POSA would have  
 5 any experience in tablet formulations?  
 6 A Again, I will provide the same  
 7 answer is that, if a POSA is required to make a  
 8 tablet, then a POSA will know all about tablets.  
 9 In this statement I'm specifically referring to  
 10 designing and making a formulation which is a  
 11 liquid formulation.  
 12 Q My question, though, now  
 13 remember, at the beginning of the declaration --  
 14 I mean deposition -- one of the rules I said was  
 15 you were obligated to answer my questions?  
 16 Do you remember that?  
 17 A Yes.  
 18 Q And you said under oath that you  
 19 would agree to that, correct?  
 20 A Yes.  
 21 Q In Paragraph 20 through 23, the  
 22 word "tablet" do not appear, correct?  
 23 A Yes, for reason.  
 24 Q The words "solid dosage form" do  
 25 not appear in Paragraphs 20 through 23, correct?

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1 DR. SARFARAZ NIAZI  
 2 A Yes, for reason.  
 3 Q What reason?  
 4 A Because this opinion is specific  
 5 to a formulation, and it's not a general opinion  
 6 for any POSA.  
 7 Q Are you giving the opinions in  
 8 this declaration from the definition of POSA  
 9 that you have provided in Paragraphs 20 through  
 10 23, or is it some other POSA?  
 11 A No, this is a POSA capable of  
 12 formulating the product in question.  
 13 Q And that POSA has extensive  
 14 experience in liquid formulations, but I can see  
 15 no experience in tablet formulations, correct,  
 16 based on Paragraphs 20 through 23?  
 17 A If he's making a solution, then  
 18 it has to have liquid formulations, all types,  
 19 to do a liquid formulation.  
 20 Q Let me ask you this: Would you  
 21 agree that if the POSA had no experience in  
 22 tablet formulations but extensive experience  
 23 with multiple types of liquid formulations, in  
 24 W0094 what we discussed on paragraph -- on Page  
 25 4, Line 24, they would focus on the liquid

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