

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

Mylan Technologies, Inc.,)
)
 Petitioner,) Case No.
) IPR2017-00200
vs.)
)
MonoSol RX, LLC,)
)
 Patent Owner.)
_____)

VIDEOTAPED DEPOSITION OF GRAHAM BUCKTON, Ph.D.

San Diego, California

July 17, 2017

9:09 a.m.

Reported by:
Tricia Rosate, RDR, RMR, CRR, CCRR
Job No. 51121

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3	<p>1 VIDEOTAPED DEPOSITION OF GRAHAM BUCKTON, PhD,</p> <p>2 taken at 11682 El Camino Real, San Diego, California,</p> <p>3 commencing at 9:09 a.m. and concluding at 2:42 p.m.,</p> <p>4 Monday, July 17, 2017, before Tricia Rosate, RDR, RMR,</p> <p>5 CRR, CCRR, CSR 10891, a Certified Shorthand Reporter.</p> <p>6</p> <p>7</p> <p>8 I N D E X</p> <p>9 WITNESS: Graham Buckton, PhD</p> <p>10 EXAMINATION PAGE</p> <p>11 By Mr. Brahma 6, 151</p> <p>12 By Mr. Mills 177</p> <p>13</p> <p>14</p> <p>15 E X H I B I T S</p> <p>16 EXHIBIT DESCRIPTION PAGE</p> <p>17 Exhibit 1 Declaration of Graham Buckton, PhD 8</p> <p>18 Exhibit 2 Research paper "In-Vitro studies 14</p> <p>19 on Buccal strips of Glibenclamide</p> <p>20 using Chitosan"</p> <p>21 Exhibit 3 International Application Publication 14</p> <p>22 Under The Patent Cooperation Treaty</p> <p>23 (PCT), International Publication</p> <p>24 Number: WO 00/42992</p> <p>25 Exhibit 4 United States Patent No. 174</p> <p>US 8,603,514 B2</p>	5
3	<p>1 A P P E A R A N C E S (Continued):</p> <p>2 For the Patent Owner and Real Party In Interest</p> <p>3 MONOSOL RX, LLC:</p> <p>4 TROUTMAN SANDERS, LLP</p> <p>5 875 Third Avenue</p> <p>6 New York, New York 10022</p> <p>7 212/704-6000</p> <p>8 BY: DANIEL A. LADOW, ESQ.</p> <p>9 daniel.ladow@troutmansanders.com</p> <p>10</p> <p>11 For MONOSOL RX, LLC:</p> <p>12 STEPTOE & JOHNSON, LLP</p> <p>13 115 South LaSalle Street</p> <p>14 Suite 3100</p> <p>15 Chicago, Illinois 60603</p> <p>16 312/577-1300</p> <p>17 BY: JOHN L. ABRAMIC, ESQ.</p> <p>18 jabramic@steptoe.com</p> <p>19</p> <p>20 For INDIVIOR INC. & INDIVIOR UK LIMITED:</p> <p>21 COVINGTON & BURLING, LLP</p> <p>22 One City Center</p> <p>23 850 Tenth Street, NW</p> <p>24 Washington, D.C. 20001-4956</p> <p>25 202/662-6000</p> <p>BY: JEFFREY B. ELIKAN, ESQ.</p> <p>jelikan@cov.com</p> <p>Also Present:</p> <p>DAVID WRIGHT, The Videographer</p>	5

<p style="text-align: right;">6</p> <p>1 MR. ABRAMIC: John Abramic from Steptoe & 2 Johnson on behalf of MonoSol. 3 MR. MILLS: Jad Mills here on behalf of 4 Mylan Technologies, Inc., and with the witness. And 5 also with me are my colleagues Elham Steiner and 6 David Hanna, each of us for Wilson Sonsini Goodrich & 7 Rosati. 8 Before we be- -- begin the questioning, I 9 just want to make a record. The parties have not 10 reached an agreement about the videotaping of the 11 deposition or the use of the videotape in the IPR 12 proceeding. 13 THE VIDEOGRAPHER: Will the court reporter 14 please swear in the witness. 15 GRAHAM BUCKTON, PhD, 16 having been first duly sworn, testified as follows: 17 EXAMINATION 18 BY MR. BRAHMA: 19 Q Good morning, Dr. Buckton. 20 A Good morning. 21 Q You understand that this inter partes review 22 is about the '514 patent; correct? 23 A I do. 24 Q Okay. And you've also discussed that 25 separately in a separate District Court litigation;</p>	<p style="text-align: right;">8</p> <p>1 A It is. 2 Q Okay. Would you mind if I looked at that? 3 A Very well. I haven't yet, but you can. 4 Q I -- I was just trying to -- 5 A I didn't bring it with me. It's not mine. 6 Q Oh, okay. Oh, okay. 7 A But you are very welcome to it. 8 Q Is this a -- is this just a clean copy, as 9 far as you know? 10 A I believe so. 11 Q Okay. I was -- to the extent that there are 12 any notations on it or anything -- 13 A No. No. No. No. It's not mine. 14 Q Okay. 15 A But it is now. 16 Q There you go. 17 All right. Why don't we actually go ahead 18 and mark that as our first exhibit. 19 MR. MILLS: And for the record, the exhibit 20 is already marked as Mylan Exhibit 1001. 21 MR. BRAHMA: 1002; right? 22 MR. MILLS: Sorry. Yes. 1002. 23 (Exhibit 1 was marked for identification.) 24 BY MR. BRAHMA: 25 Q And, actually, since you have your own copy,</p>
<p style="text-align: right;">7</p> <p>1 right? 2 A That's correct. 3 Q Okay. And in that District Court 4 litigation, there's also an expert report you've 5 recently received from a Dr. Langer about the 6 validity of the '514 patent; right? 7 A That's correct. 8 Q You've had a chance to review that; is that 9 right? 10 A I've begun reviewing it, but I will be 11 reviewing it in the coming weeks or days or -- well, 12 not weeks. Days. 13 Q Okay. So I'm going to try and limit my 14 questioning today to the scope of the inter partes 15 review as opposed to the District Court litigation. 16 A Understood. 17 Q Do you understand that? 18 A Sorry. I interrupted you. Sorry. 19 Understood. Yes. 20 Q And with respect to your work in this 21 inter partes review, you prepared a declaration; 22 right? 23 A That's correct. 24 Q And I see you have a document in front of 25 you. Is that your declaration?</p>	<p style="text-align: right;">9</p> <p>1 I will just hang on to this one. 2 A Is that -- 3 Q And can you just -- 4 Well, can you confirm that it is the same? 5 I'll give you what I have, and if there's any 6 difference -- 7 A These look different sizes. Maybe they're 8 not. Maybe it's just different quality of paper. 9 That might be the -- might be the -- 10 Q Why don't you go ahead and check really 11 quickly and -- 12 A Sure. 13 Q -- let me know if there's any difference. 14 A I would say they're the same. 15 Q Okay. 16 A They just look different. 17 Q Okay. 18 MR. MILLS: It appears that one of them is 19 printed one-sided. 20 THE WITNESS: Ah. Double-sided and -- 21 double-sided and single-sided. That would be the 22 difference. 23 BY MR. BRAHMA: 24 Q Yes. So someone was very environmentally 25 conscious.</p>

10	<p>1 A Yeah.</p> <p>2 Q So Deposition Exhibit 1, Mylan -- which has</p> <p>3 previously been marked as Mylan Exhibit 1002 in the</p> <p>4 IPR, is that a true and correct copy of the</p> <p>5 declaration that you submitted in the inter partes</p> <p>6 review proceeding?</p> <p>7 A I think it is. Yes.</p> <p>8 Q Okay. Do you understand that this</p> <p>9 declaration was submitted to the Patent Trial and</p> <p>10 Appeal Board along with a petition for inter partes</p> <p>11 review?</p> <p>12 A I think that's right. Yes.</p> <p>13 Q Did you ever see that petition?</p> <p>14 A I think I probably did. I don't remember</p> <p>15 when, but I think I probably did.</p> <p>16 Q Did you see it after you had submitted your</p> <p>17 declaration?</p> <p>18 A I don't remember when, to be honest. So --</p> <p>19 but I -- I -- I have a -- a recollection I may have</p> <p>20 seen it at some stage, but I really can't help you</p> <p>21 with when I saw it.</p> <p>22 Q Okay. And do you understand that there was</p> <p>23 a decision issued by the Patent Trial and Appeal</p> <p>24 Board instituting the inter partes review?</p> <p>25 A Yes.</p>	12	<p>1 think that's true.</p> <p>2 Q Okay.</p> <p>3 A If it's not true, it's not a deliberate</p> <p>4 attempt to --</p> <p>5 But I -- as far as I remember sitting here</p> <p>6 today, I think that's true.</p> <p>7 Q Okay. Understood.</p> <p>8 In your declaration, you have a list of</p> <p>9 exhibits starting on page 64 and going to page 65.</p> <p>10 A Yes.</p> <p>11 Q Is that a complete list of the materials</p> <p>12 that you considered as part of preparing your</p> <p>13 declaration in the inter partes review proceeding?</p> <p>14 A I think so, but I'm not sure. I don't know</p> <p>15 if there was anything else I considered, but I -- I</p> <p>16 think these are the ones that I've talked about and</p> <p>17 relied upon.</p> <p>18 Q Okay.</p> <p>19 A I don't remember if there was anything else</p> <p>20 or not. I can't think of anything just at the moment</p> <p>21 as to what it would have been.</p> <p>22 Q Okay. Is there anyplace you recorded what</p> <p>23 else you may have considered other than these</p> <p>24 exhibits that were specifically cited in your</p> <p>25 declaration?</p>
11	<p>1 Q Which is why we're here today.</p> <p>2 A Yes.</p> <p>3 Q Have you seen that decision?</p> <p>4 A I have.</p> <p>5 Q Okay. Have you also seen materials from the</p> <p>6 prior District Court litigations relating to the '514</p> <p>7 patent?</p> <p>8 A Not as far as I'm aware.</p> <p>9 Q Okay.</p> <p>10 A But maybe if you can point me to anything</p> <p>11 that's from that. Maybe I -- I have without knowing,</p> <p>12 but I -- I -- as far as I'm aware, no.</p> <p>13 Q So let me back up a step.</p> <p>14 Are you aware that there have been other</p> <p>15 District Court litigations involving the '514 patent</p> <p>16 and its validity?</p> <p>17 A Yes. I've been told there have been, and</p> <p>18 I -- I think --</p> <p>19 Various people have made reference to it, so</p> <p>20 I think there have been. Yes.</p> <p>21 Q Okay. So am I understanding correctly that,</p> <p>22 as far as you know, you haven't seen any expert</p> <p>23 reports or trial testimony from those prior</p> <p>24 District Court litigations?</p> <p>25 A Sitting here today, as best I remember, I</p>	13	<p>1 A No. I don't have any recollection of there</p> <p>2 being any, but I -- I --</p> <p>3 So "I don't know" is the answer, but I have</p> <p>4 no record of any others. No.</p> <p>5 Q Okay. And one other question about</p> <p>6 materials you've considered. You understand that,</p> <p>7 before the Patent Trial and Appeal Board issued its</p> <p>8 decision to institute this inter partes review</p> <p>9 proceeding, MonoSol filed a preliminary patent owner</p> <p>10 response?</p> <p>11 A It's not ringing a bell, I'm afraid.</p> <p>12 Q Okay.</p> <p>13 A But it doesn't -- it doesn't mean anything</p> <p>14 to me as that. If you were to show me a document, I</p> <p>15 could let you know if I've seen such a thing, but</p> <p>16 I -- I -- it doesn't ring a bell as you -- you</p> <p>17 mention the word.</p> <p>18 Q Okay. So as far as you know right now, you</p> <p>19 didn't review patent owner's preliminary response; is</p> <p>20 that right?</p> <p>21 A If you show it to me, maybe I -- I could</p> <p>22 tell you, "Yes, I recognize having seen that."</p> <p>23 Q Okay.</p> <p>24 A But sitting here just now, I don't remember</p> <p>25 if I've seen such a thing. It doesn't mean I</p>

<p style="text-align: right;">14</p> <p>1 haven't, I'm sorry to say, but I have no recollection 2 of it. But -- 3 Q Okay. Fair enough. 4 MR. BRAHMA: I'm going to mark this as 5 Deposition Exhibit 2. It's previously been submitted 6 as Mylan Exhibit 1005. 7 (Exhibit 2 was marked for identification.) 8 THE WITNESS: Thank you. 9 MR. BRAHMA: And I'm also going to have 10 marked Deposition Exhibit 3, which was previously 11 submitted as Mylan Exhibit 1006. 12 (Exhibit 3 was marked for identification.) 13 THE WITNESS: Thank you. Thank you. 14 BY MR. BRAHMA: 15 Q And as we previously discussed, in the 16 inter partes review proceeding, you argue that the 17 claims of the '514 patent that are at issue are 18 invalid as obvious in light of the combination of the 19 Ilango reference, which is Deposition Exhibit 2, 20 Mylan Exhibit 1005, and the Chen reference, which is 21 Deposition Exhibit 3, previously marked as 22 Mylan Exhibit 1006; right? 23 A Yes. The combination of those two you said. 24 Yes. 25 Q Okay.</p>	<p style="text-align: right;">16</p> <p>1 A Drug release is part of it. Yes. 2 Q Yeah. Why don't I point you to something 3 more specific. 4 So if you look at the -- the paragraph right 5 at the top of the cover page. 6 A The "As glibenclamide"? That one? 7 Q Yes. That paragraph right at the top. 8 A Yes. 9 Q So it says, "The objective of this work is 10 to investigate the possibility of obtaining a slow 11 release, relatively constant effective levels of 12 glibenclamide from buccal strips using chitosan"; 13 right? 14 A Yes. 15 Q Okay. This article, the focus of it isn't 16 about maintaining drug content uniformity in 17 pharmaceutical films; right? 18 MR. MILLS: Objection to form. 19 THE WITNESS: Well, it goes on to say that 20 attempts were made to develop suitable chitosan-based 21 buccal strips and to characterize it using different 22 in vitro methods and look at their suitability. 23 So was your question that it was just about 24 release or -- 25 ///</p>
<p style="text-align: right;">15</p> <p>1 A Yes. 2 Q Had you -- 3 First, can you confirm, is 4 Deposition Exhibit 2 a true and correct copy of the 5 Ilango reference that you relied upon? 6 A Yes. 7 Q And is Deposition Exhibit 3 a true and 8 correct copy of the Chen reference that you relied 9 on? 10 A It looks like it is. Yes. 11 Q Okay. 12 A Yes. 13 Q Prior to your work on the inter partes 14 review proceeding or the District Court litigation 15 relating to the '514 patent, had you ever seen either 16 of these two references before? 17 A Not as far as I remember. No. 18 Q Okay. So let's start with the Ilango 19 reference, Deposition Exhibit 2. 20 The Ilango reference discusses an 21 investigation of films made to compare drug release 22 characteristics; is that right? 23 A That is part of it. There are drug 24 release -- 25 Q I apologize. Why don't I --</p>	<p style="text-align: right;">17</p> <p>1 BY MR. BRAHMA: 2 Q Well, my question was: The focus of this 3 Ilango reference wasn't about maintaining drug 4 content uniformity in pharmaceutical films; right? 5 A It depends what you mean by "focus." I 6 mean, that's obviously a precursor to the -- the 7 testing of the product. So you make a product with 8 suitable properties, and then you test the product, 9 so there will be different aspects to it. 10 Q Okay. And the Ilango reference doesn't talk 11 about the -- the factors that may possibly cause a 12 loss of drug content uniformity during the casting 13 and drying of pharmaceutical films; right? 14 MR. MILLS: Objection. Form. 15 THE WITNESS: It talks about a method, and 16 the method describes properties, which obviously are 17 the properties that are related to making the 18 product. 19 What was your question? Does -- does it 20 talk about those? It does talk about those by virtue 21 of them being there, but was there a more detailed 22 part of the question? 23 BY MR. BRAHMA: 24 Q Well, the question I was asking was that 25 this Ilango reference -- it doesn't talk about the</p>

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