

August 24, 2016 Deposition of Cara Christann Lansden
Patent 8,399,514 B2

1

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

COALITION FOR AFFORDABLE DRUGS V LLC; et al.,

Petitioners,

v.

BIOGEN MA, INC.,

Patent Owner

Case IPR2015-01993

Patent 8,399,514 B2

COMPLETE CAPTION ON PAGE 2

DEPOSITION OF CARA CHRISTANN LANSDEN

Wednesday, August 24th, 2016

9:50 a.m.

Finnegan, Henderson, Farabow,

Garrett & Dunner, LLP

Two Seaport Lane

Boston, Massachusetts 02210

Reporter: Cheryll A. Kerr, RPR, SHR

Registered Professional Reporter

Henderson Legal Services, Inc.

Henderson Legal Services, Inc. Coalition Exhibit 1056

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2 (Pages 2 to 5)

<p style="text-align: center;">2</p> <p>1 UNITED STATES PATENT AND TRADEMARK OFFICE 2 BEFORE THE PATENT TRIAL AND APPEAL BOARD</p> <hr/> <p>3 4 5 COALITION FOR AFFORDABLE DRUGS V LLC; 6 HAYMAN CREDES MASTER FUND, LP; 7 HAYMAN ORANGE FUND SPC - PORTFOLIO A; 8 HAYMAN CAPITAL MASTER FUND, L.P.; 9 HAYMAN CAPITAL MANAGEMENT, L.P.; 10 HAYMAN OFFSHORE MANAGEMENT, INC.; 11 HAYMAN INVESTMENTS, LLC; 12 NXN PARTNERS, LLC; 13 IP NAVIGATION GROUP, LLC; 14 J KYLE BASS, and ERICH SPANGENBERG, 15 Petitioners, 16 v. 17 BIOGEN MA, INC., 18 Patent Owner</p> <hr/> <p>19 20 Case IPR2015-01993 21 Patent 8,399,514 B2 22 23 24 25</p>	<p style="text-align: center;">3</p> <p>1 APPEARANCES: 2 3 Carmichael IP, PLLC 4 BY: CAROL A. SPIEGEL, ESQ. 5 8000 Towers Crescent Drive, 13th Floor 6 Tysons Corner, VA 22182 7 (703) 646-9249 8 carol@carmichaelip.com 9 Counsel for Petitioners; 10 11 Finnegan, Henderson, Farabow, Garrett & 12 Dunner, LLP 13 BY: MICHAEL J. FLIBBERT, ESQ. 14 901 New York Avenue, N.W. 15 Washington, D.C. 20001-4413 16 (202) 408-4000 17 michael.flibbert@finnegan.com 18 19 Counsel for Respondents 20 Also Present: 21 Carol Loeschorn, Biogen 22 23 24 25</p>
<p style="text-align: center;">4</p> <p>1 INDEX 2 EXAMINATION BY PAGE 3 Ms. Spiegel 5 4 5 EXHIBITS 6 BIOGEN FOR ID DESCRIPTION PAGE 7 Exhibit 2079 Declaration of Cara Christann Lansden 7 8 Exhibit 2318 Email Fumapharm Update October 10, 2003 16 9 Exhibit 2309 Email chain CTRB Meeting regarding BG-12/MS dated February 19, 2004 31 10 Exhibit 2316 Email to Cara Christann Lansden dated July 6, 2006 43 11 Exhibit 2310 Redacted Clinical Trial Review Board Meeting Agenda, Item: Meeting Minutes dated February 19th, 2004 54 12 Exhibit 2255 Redacted e-mail, BG-12 IND Hold Response dated May 1st, 2006 79 13 Exhibit 2131 Redacted BG-12 MS Clinical Development Team Minutes dated May 17th, 2006 81 14 Exhibit 2115 Redacted BG 00012 SMT Kickoff Meeting dated May 2006 83 15 Exhibit 2126 Email chain with top email from Gilmore O'Neill 85 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: center;">5</p> <p>1 C A R A C H R I S T A N N L A N S D E N , 2 called as a witness, having been duly 3 sworn, was examined and testified 4 as follows: 5 THE SHORTHAND REPORTER: Please state 6 your full name and your address for the 7 record. 8 THE WITNESS: Cara Christann Lansden. 9 My address is 145 Boardman Avenue, 10 Melrose, Massachusetts 02176. 11 THE SHORTHAND REPORTER: Thank you. 12 Please proceed. 13 14 DIRECT EXAMINATION 15 BY MS. SPIEGEL: 16 17 Q. Okay. I'm with Carmichael IP Law Firm, 18 and I will be asking you a series of questions here 19 today. 20 I want you to answer them to the best of your 21 ability. If there is something about the way I 22 phrase a question that you don't understand, just 23 say so, and I will try and rephrase it or restate 24 it. 25 If you need a break, we can take one at any</p>

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<p style="text-align: right;">6</p> <p>1 time. The only thing I ask is if I have asked you a 2 question, would you please complete the answer 3 before we break? 4 A. (Nodding). 5 Q. Now, the court reporter is transcribing 6 our deposition, so it's important you give verbal 7 answers and we don't talk over each other. 8 Is that okay? 9 A. Yes. 10 Q. Would you please state your full name for 11 the record? 12 A. Cara Christann Lansden. 13 Q. Do you understand your testimony is under 14 oath today? 15 A. I do. 16 Q. I will be referring to the patent at 17 issue here as the '514 patent. 18 Is that okay? 19 A. That is fine. 20 Q. I will also refer to the Patent Office 21 inter partes review proceeding as an IPR. 22 Is that okay? 23 A. Could you explain that, please? 24 Q. The name of the proceeding that we are 25 involved in is called an inter partes IPR.</p>	<p style="text-align: right;">7</p> <p>1 A. Okay. 2 Q. I will just be referring to it by the 3 first three initials of those words. 4 A. (Nodding) that is fine. Thank you. 5 Q. I will probably just say MS instead of 6 multiple sclerosis. 7 Is that okay? 8 A. That is fine. 9 Q. Is there any reason you cannot give a 10 full and truthful testimony today? 11 A. No reason. 12 Q. Are you taking any medications that would 13 impair your ability to testify today? 14 A. No. 15 (Thereupon, a document was presented 16 as Biogen Exhibit 2079 for identification.) 17 BY MS. SPIEGEL: 18 Q. I am handing Ms. Lansden -- 19 A. Yes. 20 Q. -- a copy of a document premarked as 21 Biogen Exhibit 2079. 22 Is this the declaration that you submitted in 23 the IPR proceeding? 24 (Pause) 25 THE WITNESS: It is.</p>
<p style="text-align: right;">8</p> <p>1 BY MS. SPIEGEL: 2 Q. Can you confirm that it is your signature 3 on page 30 of 31, and by "page numbers," I am 4 referring to the numbers in the lower left-hand 5 corner of the document. 6 A. It is my signature. 7 Q. Looking at your declaration, are you 8 aware of any errors or mistakes in your declaration? 9 A. No. 10 Q. Did you review your declaration before 11 signing it? 12 A. I did. 13 Q. Have you provided any declarations in any 14 other patent matters, other than in Biogen's 15 Interference No. 106023, as stated in your 16 declaration of Footnote 2 on page 10 of 31? 17 (Informal discussion held off the 18 record.) 19 THE WITNESS: Could you repeat the 20 question? 21 (Thereupon, the requested portion of 22 the record was read back by the shorthand 23 reporter.) 24 THE WITNESS: No, I have not. Thank 25 you.</p>	<p style="text-align: right;">9</p> <p>1 BY MS. SPIEGEL: 2 Q. Have you -- 3 Have you provided any expert reports in any 4 other patent matters other than this Biogen IPR 5 proceeding and the interference No. 106023? 6 A. I don't -- 7 MR. FLIBBERT: Objection, lack of 8 foundation. 9 THE WITNESS: I don't know. 10 (Informal discussion held off the 11 record.) 12 BY MS. SPIEGEL: 13 Q. Have you ever been deposed before? 14 A. Prior to this? 15 Q. Yes. 16 A. Yes. The 106063. 17 Q. So you were deposed in the Biogen 18 Interference No. 106023, correct? 19 A. Yes. 20 Q. Do you remember about when that was? 21 A. April -- 22 Q. Okay. 23 A. -- of this year. 24 Q. How did you prepare for your deposition 25 today?</p>

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<p style="text-align: right;">10</p> <p>1 A. I reviewed my declaration.</p> <p>2 Q. Was that the extent of it? Did you</p> <p>3 review any documents?</p> <p>4 A. Only documents that were cited in my</p> <p>5 declaration.</p> <p>6 Q. Did you meet with counsel?</p> <p>7 A. I did.</p> <p>8 Q. And who was the counsel you met with?</p> <p>9 A. Lawyers from Finnegan and Biogen.</p> <p>10 Q. Do you recall their names?</p> <p>11 (Pause)</p> <p>12 THE WITNESS: Sorry. I'm trying to</p> <p>13 remember the -- the first Finnegan lawyer.</p> <p>14 Well, Carol Loeschorn and Michael</p> <p>15 Flibbert, here, as well as Wendy Plotkin</p> <p>16 from Biogen, and Erin, I'm not sure what</p> <p>17 her last name is, from Finnegan.</p> <p>18 BY MS. SPIEGEL:</p> <p>19 Q. Was anyone else present that helped you</p> <p>20 prepare for your deposition besides counsel that was</p> <p>21 here today?</p> <p>22 A. No.</p> <p>23 Q. Do you recall reviewing anything --</p> <p>24 anything other than the written documents you cited</p> <p>25 in your declaration in preparation for today's</p>	<p style="text-align: right;">11</p> <p>1 deposition?</p> <p>2 A. Not that I recall.</p> <p>3 Q. How long did you meet with counsel to</p> <p>4 prepare for your deposition?</p> <p>5 A. Three to four hours on two separate days.</p> <p>6 Q. Each day, or total?</p> <p>7 A. Each day.</p> <p>8 Q. Okay.</p> <p>9 Do you have any questions, before we begin?</p> <p>10 A. No.</p> <p>11 Q. Can you describe your higher education</p> <p>12 for me?</p> <p>13 A. I went to Vassar College.</p> <p>14 Q. And did you receive a degree?</p> <p>15 A. I did.</p> <p>16 Q. What was the degree?</p> <p>17 A. Bachelor's in biology.</p> <p>18 Q. Do you have any postgraduate degrees?</p> <p>19 A. I do not.</p> <p>20 Q. You were employed by Biogen from 1999 to</p> <p>21 2013, correct?</p> <p>22 A. That is correct.</p> <p>23 Q. From the time you graduated from college</p> <p>24 until your employment at Biogen, how were you</p> <p>25 employed, generally speaking?</p>
<p style="text-align: right;">12</p> <p>1 A. I have worked at other biotech companies,</p> <p>2 and for a short time, a -- a trading company.</p> <p>3 Q. Do you recall the name of the biotech</p> <p>4 companies?</p> <p>5 A. Biopure and Vertex, and those were the</p> <p>6 only ones prior to Biogen.</p> <p>7 Q. Can you give me a general idea of what</p> <p>8 your responsibilities were at the biotech companies?</p> <p>9 A. I managed clinical trials. At those</p> <p>10 studies, I did --</p> <p>11 At those companies, I did stability studies and</p> <p>12 I managed people.</p> <p>13 Q. Okay. When you started working at Biogen</p> <p>14 in 1999, generally speaking, what were your</p> <p>15 responsibilities?</p> <p>16 A. I managed clinical trials, initially.</p> <p>17 Then I managed clinical programs, and then I became</p> <p>18 a line manager.</p> <p>19 Q. Do you recall the area of clinical -- the</p> <p>20 clinical area you were involved in?</p> <p>21 Was it just clinical studies in general, or</p> <p>22 clinical studies related to a specific area such as</p> <p>23 neurology or immunology?</p> <p>24 A. I managed immunology and neurology</p> <p>25 studies.</p>	<p style="text-align: right;">13</p> <p>1 Q. Were any of the studies that you managed</p> <p>2 involving therapeutic drug products?</p> <p>3 A. Yes.</p> <p>4 Q. If I use the abbreviation "DMF" for</p> <p>5 dimethyl fumarate, would you understand that?</p> <p>6 A. Yes, I would.</p> <p>7 Q. Okay, so were any of these drug products</p> <p>8 DMF?</p> <p>9 A. Not at the study level. At the program</p> <p>10 level.</p> <p>11 Q. This is in the 1999 to 2002 time frame?</p> <p>12 A. Oh, the 1999 to 2002 time frame? No,</p> <p>13 they did not involve DMF.</p> <p>14 Q. Okay.</p> <p>15 When you became a senior clinical project</p> <p>16 manager in 2002, how did your responsibilities</p> <p>17 change?</p> <p>18 A. I was then responsible for clinical</p> <p>19 programs rather than the individual studies within a</p> <p>20 clinical program.</p> <p>21 Q. What do you mean by being "responsible"</p> <p>22 for clinical programs?</p> <p>23 A. I was the clinical operations</p> <p>24 representative and ensured consistency and guidance</p> <p>25 to the clinical operations staff who were involved</p>

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<p style="text-align: right;">14</p> <p>1 in the studies themselves.</p> <p>2 Q. In 2003, you became a clinical program</p> <p>3 lead.</p> <p>4 Do you remember when in 2003 that occurred?</p> <p>5 A. Not precisely.</p> <p>6 Q. Did you become a clinical program leader</p> <p>7 in any particular clinical area?</p> <p>8 A. Yes, neurology.</p> <p>9 BY MS. SPIEGEL:</p> <p>10 Q. When did you start working on Biogen's</p> <p>11 drug development program BG-12?</p> <p>12 A. At the very end of 2003.</p> <p>13 Q. Could you be more specific than "the very</p> <p>14 end"?</p> <p>15 A. December.</p> <p>16 Q. Okay. What is BG-12?</p> <p>17 A. BG-12 is the internal designation of the</p> <p>18 drug that would eventually be known as Tecfidera.</p> <p>19 Q. Was the only active pharmaceutical</p> <p>20 ingredient in BG-12 DMF?</p> <p>21 A. To my knowledge, yes.</p> <p>22 Q. When we are talking about BG-12, we are</p> <p>23 just talking about the drug DMF, and not a specific</p> <p>24 specification -- specific dose or a specific</p> <p>25 indication, are we?</p>	<p style="text-align: right;">15</p> <p>1 A. When I refer to BG-12, I am referring to</p> <p>2 D -- the drug, not a dosage.</p> <p>3 Q. Or a specific indication?</p> <p>4 A. Or a specific indication, correct.</p> <p>5 Q. Now, when we're talking about Tecfidera,</p> <p>6 we are talking about the drug product that was</p> <p>7 approved by the FDA as an oral therapy using 480</p> <p>8 milligram per day of DMF, and one or more</p> <p>9 pharmaceutically acceptable excipients to treat MS;</p> <p>10 is that correct?</p> <p>11 A. Is that a question?</p> <p>12 Q. I am asking you if that is the correct</p> <p>13 definition of Tecfidera as we are using it today?</p> <p>14 A. I cannot speak to how Tecfidera is</p> <p>15 defined in a general -- in a -- in a pharmaceutical</p> <p>16 company manner. If that is how you are defining it</p> <p>17 for today to clarify, then that's different.</p> <p>18 Q. Well, I would like to clarify whether</p> <p>19 BG-12 and Tecfidera are identical in terms of their</p> <p>20 composition?</p> <p>21 A. I'm not sure I understand the question.</p> <p>22 Tecfidera -- the way you defined Tecfidera --</p> <p>23 Q. Is Tecfidera --</p> <p>24 A. -- seemed different than the drug -- just</p> <p>25 the drug product itself.</p>
<p style="text-align: right;">16</p> <p>1 (Pause)</p> <p>2 BY MS. SPIEGEL:</p> <p>3 Q. Could you please refer to paragraph 5 of</p> <p>4 your declaration on page 8 of 31?</p> <p>5 (Pause)</p> <p>6 THE WITNESS: Which paragraph?</p> <p>7 Sorry.</p> <p>8 BY MS. SPIEGEL:</p> <p>9 Q. Five.</p> <p>10 A. Oh, five?</p> <p>11 Q. And I'm talking about the lower left-hand</p> <p>12 corner numbers, page 8 of 31.</p> <p>13 A. Yes, thank you.</p> <p>14 Q. I'm asking you to confirm that when</p> <p>15 you're talking about Tecfidera, we're referring to a</p> <p>16 drug product containing DMF as the sole, active</p> <p>17 ingredient, and one or more pharmaceutically</p> <p>18 acceptable excipients that are used as an oral</p> <p>19 therapy to treat MS using 480 milligrams per day of</p> <p>20 DMF.</p> <p>21 A. Yes, thank you.</p> <p>22 (Thereupon, a document was presented</p> <p>23 as Biogen Exhibit 2318 for identification.)</p> <p>24 BY MS. SPIEGEL:</p> <p>25 Q. I am handing you a copy of a document</p>	<p style="text-align: right;">17</p> <p>1 premarked as Biogen Exhibit 2318.</p> <p>2 It's an email with redactions sent to you,</p> <p>3 among others, with a subject line that reads</p> <p>4 "Fumapharm Update," and is dated October 10th, 2003.</p> <p>5 Do you see that?</p> <p>6 A. I do.</p> <p>7 Q. Did Biogen obtain a drug product, which</p> <p>8 Biogen referred to as BG-12, from Fumapharm by at</p> <p>9 least October 10th, 2003?</p> <p>10 A. From this announcement, yes.</p> <p>11 Q. Was BG-12 to be developed for psoriasis</p> <p>12 and MS?</p> <p>13 A. According to this email, that is what it</p> <p>14 says.</p> <p>15 Q. So in 2003, there was already a drug</p> <p>16 product containing BG-12; is that correct?</p> <p>17 A. I don't think that's accurate.</p> <p>18 The product was BG-12. It wasn't containing</p> <p>19 BG-12.</p> <p>20 Q. Well, according to Exhibit 2318, it says,</p> <p>21 "We have brought a new product into our pipeline.</p> <p>22 The product, BG00012, will be developed in psoriasis</p> <p>23 and MS"; is that correct?</p> <p>24 A. Yes.</p> <p>25 Q. So did Biogen obtain that drug product</p>

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