

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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TARO PHARMACEUTICALS U.S.A., INC.,

Petitioner,

v.

APOTEX TECHNOLOGIES, INC.,

Patent Owner

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Case IPR2017-01446  
U.S Patent No. 7,049,328

Title: USE FOR DEFERIPRONE

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Washington, D.C.

Wednesday, June 6, 2018

VIDEOTAPED CROSS-EXAMINATION

DUDLEY J. PENNELL, M.D.

Henderson Legal Services, Inc.

2	<p>1 Videotaped Cross-Examination of DUDLEY</p> <p>2 J. PENNELL, M.D., a witness herein, called for</p> <p>3 examination by counsel for Petitioner in the</p> <p>4 above-entitled matter, pursuant to notice, the</p> <p>5 witness being duly sworn by SUSAN L. CIMINELLI, CRR,</p> <p>6 RPR, a Notary Public in and for the District of</p> <p>7 Columbia, taken at the offices of Goodwin Procter,</p> <p>8 901 New York Avenue, N.W., Washington, D.C.</p> <p>9 commencing at 8:11 a.m.</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>	4	<p>1 C O N T E N T S</p> <p>2 DUDLEY J. PENNELL, M.D. EXAMINATION</p> <p>3 By Ms. Wu 7</p> <p>4 By Mr. Lukas 196</p> <p>5 By Ms. Wu 214</p> <p>6</p> <p>7 Afternoon Session - Page 146</p> <p>8</p> <p>9 E X H I B I T S</p> <p>10 EXHIBIT NO. PAGE NO.</p> <p>11 Exhibit 1055 Myocardial iron deposition in</p> <p>12 Thalassaemia studies by magnetic</p> <p>13 resonance imaging - Mavrogeni 163</p> <p>14 Exhibit 1056 Non-invasive Myocardial Iron</p> <p>15 Assessment in Thalassaemic</p> <p>16 Patients - Papanikolaou 165</p> <p>17 Exhibit 1057 Blood Journal - Pennell Group</p> <p>18 Article May 1, 2006 184</p> <p>19</p> <p>20 PREVIOUSLY MARKED EXHIBITS PAGE NO.</p> <p>21 Exhibit 2016 14</p> <p>22 Exhibit 2004 34</p>
3	<p>1 APPEARANCES:</p> <p>2 On behalf of the Patent Owner:</p> <p>3 BARRY GOLOB, ESQUIRE</p> <p>4 W. BLAKE COBLENTZ, ESQUIRE</p> <p>5 AARON LUKAS, Ph.D., ESQUIRE</p> <p>6 Cozen O'Connor</p> <p>7 1200 Nineteenth Street, N.W.</p> <p>8 Washington, D.C. 20036</p> <p>9 (202) 912-4837</p> <p>10 bgolob@cozen.com</p> <p>11 wcoblentz@cozen.com</p> <p>12 alukas@cozen.com</p> <p>13</p> <p>14 On behalf of the Petitioner:</p> <p>15 HUIYA WU, ESQUIRE</p> <p>16 TIFFANY MAHMOOD, ESQUIRE</p> <p>17 Goodwin Procter, LLP</p> <p>18 The New York Times Building</p> <p>19 620 Eighth Avenue</p> <p>20 New York, New York 10018</p> <p>21 (212) 459-7270</p> <p>22 hwu@goodwinlaw.com</p> <p>tmahmood@goodwinlaw.com</p> <p>ALSO PRESENT:</p> <p>Daniel Holmstock, Videographer</p>	5	<p>1 PREVIOUSLY MARKED EXHIBITS PAGE NO.</p> <p>2 Exhibit 2003 69</p> <p>3 Exhibit 1001 75</p> <p>4 Exhibit 2026 79</p> <p>5 Exhibit 1037 99</p> <p>6 Exhibit 1010 146</p> <p>7 Exhibit 1012 148</p> <p>8 Exhibit 2033 164</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>

6	<p style="text-align: center;">PROCEEDINGS</p> <p>THE VIDEOGRAPHER: We are now on the record. This is video number 1 in the video recorded deposition of Dr. Dudley Pennell, taken in the matter of Taro Pharmaceuticals USA, Inc., Petitioners versus Apotex Technologies, Inc., Patent Owner, pending before the United States Patent and Trademark Office, before the Patent Trial and Appeal Board, IPR Number 2018-01446, for Patent Number 7,049,328. This testimony -- deposition is being held at the office of Goodwin Procter, LLP, at 901 New York Avenue, Northwest, in Washington, D.C., on June 6th, 2018. The time on the video screen is 8:11 a.m.</p> <p>My name is Daniel Holmstock, and with me is Sue Ciminelli. We are in association with Henderson Legal Services, located at 1560 Wilson Boulevard, Suite 750, in Arlington, Virginia. For the record, will counsel please introduce themselves and whom they represent.</p> <p>MS. WU: Huiya Wu and Tiffany Mahmood, Goodwin Procter, on behalf of the Taro Petitioners.</p>	8
7	<p>MR. GOLOB: Barry Golob and Blake Coblentz from Cozen O'Connor, on behalf of Apotex. Whereupon,</p> <p>DUDLEY J. PENNELL, M.D., was called as a witness by counsel for Petitioner, and having been duly sworn, was examined and testified as follows:</p> <p>EXAMINATION BY COUNSEL FOR PETITIONER BY MS. WU:</p> <p>Q. Good morning, Dr. Pennell.</p> <p>A. Good morning.</p> <p>Q. Have you been deposed before?</p> <p>A. No.</p> <p>Q. So because you haven't, I'll go through some ground rules, if that's okay.</p> <p>A. Sure. Sure.</p> <p>Q. I'll be asking questions, and you'll be answering questions today. I will try to ask clear questions, but if they are not, please let me know, okay?</p> <p>A. Sure.</p> <p>Q. If you answer a question, I will assume</p>	9
	<p>you have understood it, all right?</p> <p>A. Yes. You're asking me to say yes. That's a nod, yes.</p> <p>Q. Next rule, which is please answer verbally, so the court reporter can take down your answers.</p> <p>A. Yes. I'm with you.</p> <p>Q. Another rule, try to wait until I finish my question before you answer, and I'll try to wait for you to finish your question -- your answer before I question, so that the court reporter can take down our questions and answers in order, all right?</p> <p>A. Yes. Yes.</p> <p>Q. Now, is there any reason why you can't give complete and accurate testimony today?</p> <p>A. No.</p> <p>Q. Are you taking any medication or anything like that, that might impact your testimony?</p> <p>A. No.</p> <p>Q. Now, you live overseas?</p> <p>A. Yes.</p> <p>Q. How many days have you been in the U.S.?</p> <p>A. I arrived not yesterday, the day before. Monday. Monday evening.</p> <p>Q. Did you spend time preparing for your depositions today?</p> <p>A. Yes.</p> <p>Q. If you can, about how much time did you spend getting ready for this deposition, which is for the IPR proceeding?</p> <p>A. Several days, over the last few weeks.</p> <p>Q. Did you review your declarations that you submitted in the IPR proceeding in preparation for your depositions?</p> <p>A. Yes.</p> <p>Q. Did you notice any errors, or did you want to make any corrections to your opinions?</p> <p>A. No.</p> <p>Q. So let's briefly go through your education. You are a trained medical doctor?</p> <p>A. I am.</p> <p>Q. A cardiologist?</p> <p>A. Yes.</p>	

10	<p>1 Q. You're not a hematologist, is that right?</p> <p>2 <b>A. Absolutely not, no.</b></p> <p>3 Q. What experience, if any, do you have in</p> <p>4 hematology?</p> <p>5 <b>A. My experience in hematology is limited</b></p> <p>6 <b>only to the patients that I've seen and scanned and</b></p> <p>7 <b>worked with through the development of the T2*</b></p> <p>8 <b>technology, which I'm sure we'll deal with today.</b></p> <p>9 Q. When did that work begin?</p> <p>10 <b>A. Approximately 1998. Actually, I could</b></p> <p>11 <b>make one correction, I think. When I was in</b></p> <p>12 <b>training, prior to that, I did handle the cardiac</b></p> <p>13 <b>management of patients with thalassemia as a</b></p> <p>14 <b>trainee.</b></p> <p>15 Q. Before you were licensed?</p> <p>16 <b>A. No, no. Oh, it depends on what you mean</b></p> <p>17 <b>by licensed. I'm sorry, that might be an American</b></p> <p>18 <b>term. I was already a doctor, qualified. But I</b></p> <p>19 <b>think perhaps -- I don't know what licensed means in</b></p> <p>20 <b>the U.S. I wasn't yet a consultant, independent</b></p> <p>21 <b>practitioner. I don't know what "licensed" means</b></p> <p>22 <b>here. Sorry.</b></p>	12	<p>1 <b>A. Correct.</b></p> <p>2 Q. What iron chelators, if any, were those</p> <p>3 thalassemia patients taking?</p> <p>4 <b>A. In 1998, deferoxamine.</b></p> <p>5 Q. Did there come a time when you started</p> <p>6 working with thalassemia patients who were taking</p> <p>7 deferiprone?</p> <p>8 <b>A. Yes.</b></p> <p>9 Q. When was that?</p> <p>10 <b>A. Well, it's difficult to be accurate.</b></p> <p>11 <b>It's not a question I've considered before, but it</b></p> <p>12 <b>would have been within -- probably quite soon after</b></p> <p>13 <b>we developed the technology. I'm sorry, I can't be</b></p> <p>14 <b>more specific than that.</b></p> <p>15 Q. All right. So after 2000?</p> <p>16 <b>A. Well, probably before that. I mean,</b></p> <p>17 <b>because we got the technology up and running with a</b></p> <p>18 <b>research grant. And we would have been looking at a</b></p> <p>19 <b>range of patients. It's difficult for me to put a</b></p> <p>20 <b>year on the detail you're asking.</b></p> <p>21 Q. Would you have seen thalassemia patients</p> <p>22 taking deferiprone after deferiprone had been</p>
11	<p>1 Q. Thanks for clarifying. What type of</p> <p>2 patients did you manage during your training period?</p> <p>3 <b>A. So when I was in training, in my</b></p> <p>4 <b>cardiology training, we would have handled every</b></p> <p>5 <b>type of patient with every kind of condition, right</b></p> <p>6 <b>up to being qualified as an independent</b></p> <p>7 <b>practitioner.</b></p> <p>8 Q. Some of those patients were thalassemia</p> <p>9 patients?</p> <p>10 <b>A. They were in my case, yes. That's how I</b></p> <p>11 <b>got my interest in the area.</b></p> <p>12 Q. Do you know what chelating agents were</p> <p>13 being used by those thalassemia patients who you</p> <p>14 were seeing during your training period?</p> <p>15 <b>A. Yes, way back in the '90s, it was</b></p> <p>16 <b>deferoxamine. Should I say that word again?</b></p> <p>17 <b>Deferoxamine. There are three iron chelators, they</b></p> <p>18 <b>all start with D-E-F-E-R. Very difficult, they are</b></p> <p>19 <b>to pronounce.</b></p> <p>20 Q. I agree. So in 1998, that was when you</p> <p>21 first started scanning thalassemia patients after</p> <p>22 the training period?</p>	13	<p>1 approved in Europe?</p> <p>2 <b>A. When was that? Remind me.</b></p> <p>3 Q. I believe it was around 1999.</p> <p>4 <b>A. Well, after '99, I think it's quite</b></p> <p>5 <b>likely we were scanning patients on deferiprone,</b></p> <p>6 <b>yes.</b></p> <p>7 Q. Do you understand what compassionate use</p> <p>8 is?</p> <p>9 <b>A. I do.</b></p> <p>10 Q. Were you scanning any thalassemia</p> <p>11 patients taking deferiprone on a compassionate use</p> <p>12 basis, prior to its approval in Europe?</p> <p>13 <b>A. Right. So I'm not sure if we have</b></p> <p>14 <b>compassionate use in the UK. Let me say that from</b></p> <p>15 <b>the outside -- outset. It might be easiest to</b></p> <p>16 <b>answer this in a slightly different way.</b></p> <p>17 <b>We published a paper on the use of MR in</b></p> <p>18 <b>patients with deferiprone in the Lancet. We could</b></p> <p>19 <b>work back from that, to work out when we first</b></p> <p>20 <b>started analyzing patients on deferiprone.</b></p> <p>21 <b>But I mean, I think the central date was</b></p> <p>22 <b>the development of the technology with a research</b></p>

14	<p>1 grant that we gained in 1998. That's -- the first</p> <p>2 authored paper was Anderson, LJ, in the Lancet.</p> <p>3 Q. Let me hand you what's been previously</p> <p>4 marked as Exhibit 2016.</p> <p>5 (Exhibit No. 2016 was</p> <p>6 previously marked.)</p> <p>7 BY MS. WU:</p> <p>8 Q. Dr. Pennell, is Exhibit 2016 the</p> <p>9 publication that reflects your initial work with</p> <p>10 deferiprone-taking thalassemia patients?</p> <p>11 A. Yes. Yes.</p> <p>12 Q. And that work started in May 1999?</p> <p>13 A. I'm looking at -- under the methods,</p> <p>14 where I think you're referring to that. It says we</p> <p>15 included patients who received chelation with</p> <p>16 deferiprone alone for longer than three years,</p> <p>17 between May 1999 and December 2000.</p> <p>18 So I think that means that we did the</p> <p>19 scans between May 1999 and December 2000. That's my</p> <p>20 interpretation. I must say I haven't looked at this</p> <p>21 paper for a long time, but the patients had received</p> <p>22 chelation for more than three years. And the</p>	16	<p>1 life. Sometimes something comes across your path</p> <p>2 that you don't expect, or don't understand. And as</p> <p>3 you say, it piques your interest. And before you</p> <p>4 know it, you've gone off in that direction rather</p> <p>5 unexpectedly.</p> <p>6 So I was as a registrar, we say in</p> <p>7 England, I'm sorry I don't know what the equivalent</p> <p>8 is here, but I would be around 30 years old,</p> <p>9 something equivalent to whatever you do here. It's</p> <p>10 an internship or something like that.</p> <p>11 And I will be working under a consultant,</p> <p>12 so someone in charge of the service. And this</p> <p>13 particular consultant was Malcolm Walker. And I was</p> <p>14 one of his trainees. And the thalassemia patients</p> <p>15 were referred to Dr. Walker for cardiology</p> <p>16 assessment from the hematologist.</p> <p>17 And I would have seen some of those</p> <p>18 patients in training. So I'm familiar with some of</p> <p>19 the difficulties of handling the cardiovascular</p> <p>20 aspects of thalassemia patients, but I wasn't</p> <p>21 responsible for their treatment of iron chelation.</p> <p>22 Q. What sorts of cardiological assessments</p>
15	<p>1 duration indicated is only 18 months, which would</p> <p>2 indicate to me that we did the scanning between May</p> <p>3 1999 and December 2000. And that's compatible with</p> <p>4 my recollection of the time course of development of</p> <p>5 the technology.</p> <p>6 Q. Do you have any experience with</p> <p>7 diagnosing whether a person has thalassemia?</p> <p>8 A. No.</p> <p>9 Q. Other than scanning thalassemia patients,</p> <p>10 are you involved in any other aspects of their</p> <p>11 treatment?</p> <p>12 A. No.</p> <p>13 Q. What involvement, if any, do you have</p> <p>14 with respect to determining the dosage amounts of a</p> <p>15 chelating agent for thalassemia patients?</p> <p>16 A. I don't determine that at all.</p> <p>17 Q. You've never done that?</p> <p>18 A. No, that's for my hematology colleagues.</p> <p>19 Q. And how was it your work during your</p> <p>20 training period with thalassemia patients piqued</p> <p>21 your interest in this area?</p> <p>22 A. Well, I suppose it's like all things in</p>	17	<p>1 were made by Dr. Walker with respect to thalassemia</p> <p>2 patients during the time that you were training with</p> <p>3 him?</p> <p>4 A. Physical examination. Obviously, taking</p> <p>5 a history, which is critical for all of these</p> <p>6 things. And then cardiovascular assessments. The</p> <p>7 key ones being an electrocardiogram and an</p> <p>8 echocardiogram. There are a large range of other</p> <p>9 cardiovascular assessments that are possible, but</p> <p>10 these are the most important. And in 1995,</p> <p>11 somewhere around there, I'm sorry I don't have the</p> <p>12 exact date, those would have been the assessments</p> <p>13 that we would have been doing.</p> <p>14 Q. What's the difference between</p> <p>15 electrocardiogram and echocardiogram assessment?</p> <p>16 A. So the electrocardiogram, or I think you</p> <p>17 call it EKG here, we say ECG in the United Kingdom,</p> <p>18 is a recording of the electrical activity of the</p> <p>19 heart.</p> <p>20 And typically, we would have -- well,</p> <p>21 typically, we do have 10 electrodes attached, one on</p> <p>22 both arms, one on both legs, six across the chest.</p>

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