

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

Case No. PGR2023-0051

U.S. Patent No. 11,617,795

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KINDERFARMS LLC,

Petitioner,

- against -

GENEXA INC.,

Patent Owner.

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August 14, 2024

10:04 a.m.

Remote video-teleconference

deposition via Zoom of DR. CORY BERKLAND,  
pursuant to notice, before Jineen Pavesi,  
a Registered Professional Reporter,  
Registered Merit Reporter, Certified  
Realtime Reporter and Notary Public of the  
State of New York.

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| <p style="text-align: right;">Page 2</p> <p>1<br/>2 A P P E A R A N C E S :<br/>3<br/>4 MAYER BROWN LLP<br/>5 1221 Avenue of the Americas, 14th Floor<br/>6 New York, New York 10020<br/>7 Attorneys for Petitioner KinderFarms<br/>8 LLC<br/>9 BY: BRIAN W. NOLAN, ESQ.<br/>10 bnolan@mayerbrown.com<br/>11 SHANTELE L. LaFAYETTE, MSC, PhD<br/>12 slafayette@mayerbrown.com<br/>13<br/>14<br/>15 COOLEY LLP<br/>16 3175 Hanover Street<br/>17 Palo Alto, California 94304<br/>18 Attorneys for Patent Owner<br/>19 BY: ADAM PIVOVAR, ESQ.<br/>20 apivovar@cooley.com<br/>21<br/>22<br/>23<br/>24<br/>25</p>                                                                                                                                                                                                                                                                                                     | <p style="text-align: right;">Page 4</p> <p>1 BERKLAND<br/>2 I'm going to assume that you understood my<br/>3 question.<br/>4 Do you understand that?<br/>5 A. Yes.<br/>6 Q. If there is a question that I<br/>7 ask you that you do not understand, I<br/>8 would ask you to identify what is causing<br/>9 a problem with the question for you not to<br/>10 be able to understand that.<br/>11 Do you understand that?<br/>12 A. I do.<br/>13 Q. If at some point today that you<br/>14 need a break, please give me some warning<br/>15 and I will do my best to accommodate that<br/>16 request; I just would ask you, I might<br/>17 have to finish a line of questioning<br/>18 and/or a pending question, do you<br/>19 understand that?<br/>20 A. Yes.<br/>21 Q. Is there any reason today why<br/>22 you cannot give full and complete<br/>23 testimony?<br/>24 A. No, no reasons.<br/>25 Q. Have you taken any substances</p>       |
| <p style="text-align: right;">Page 3</p> <p>1<br/>2 C O R Y B E R K L A N D,<br/>3 having first been duly sworn by a Notary<br/>4 Public of the State of New York, was<br/>5 examined and testified as follows:<br/>6 EXAMINATION BY<br/>7 MR. NOLAN:<br/>8 Q. Good morning, Dr. Berkland.<br/>9 A. Good morning.<br/>10 Q. My name is Brian Nolan, I am an<br/>11 attorney at Mayer Brown in New York, my<br/>12 colleague, Shantelle LaFayette, is along<br/>13 with me, and we represent KinderFarms in<br/>14 this matter.<br/>15 Have you been deposed before?<br/>16 A. Yes.<br/>17 Q. How many times?<br/>18 A. Probably about 20 times.<br/>19 Q. So you understand today I'm<br/>20 going to ask you a series of questions and<br/>21 I would ask that you respond to them<br/>22 verbally?<br/>23 A. I do.<br/>24 Q. And to the extent that I ask<br/>25 you a question and you provide a response,</p> | <p style="text-align: right;">Page 5</p> <p>1 BERKLAND<br/>2 that alter your ability to testify?<br/>3 A. No.<br/>4 Q. And you understand that your<br/>5 testimony is under oath today?<br/>6 A. Yes, I do.<br/>7 Q. And this testimony is the same<br/>8 as if you were providing testimony<br/>9 directly in front of the Patent Trial and<br/>10 Appeal Board at the U.S. Patent and<br/>11 Trademark Office?<br/>12 A. I understand.<br/>13 Q. What did you do to prepare for<br/>14 your testimony today?<br/>15 A. Over the past few days I<br/>16 reviewed the various declarations and<br/>17 reports in this matter as well as the<br/>18 cited art from those reports.<br/>19 I also spent time with counsel<br/>20 yesterday preparing.<br/>21 Q. About how long did you spend<br/>22 time preparing?<br/>23 A. Probably somewhere between ten<br/>24 and 15 hours, maybe a little more.<br/>25 Q. How long did you spend with</p> |

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| <p style="text-align: right;">Page 6</p> <p>1 BERKLAND</p> <p>2 counsel yesterday?</p> <p>3 A. Around seven hours.</p> <p>4 Q. As part of your preparation,</p> <p>5 you stated you reviewed the various</p> <p>6 declarations that have been submitted in</p> <p>7 this proceeding, correct?</p> <p>8 A. Correct.</p> <p>9 Q. And was one of those</p> <p>10 declarations your own declaration?</p> <p>11 A. That's correct.</p> <p>12 Q. In reviewing your declaration,</p> <p>13 did you identify any errors in the</p> <p>14 declaration?</p> <p>15 A. Actually I did find one.</p> <p>16 Q. What error was that?</p> <p>17 A. I have a copy of my declaration</p> <p>18 and the cited exhibits in a folder</p> <p>19 provided by counsel.</p> <p>20 Q. Do those documents have any</p> <p>21 annotations on them, sir?</p> <p>22 A. They do not.</p> <p>23 Q. So why don't we introduce as</p> <p>24 Exhibit 1 to this declaration -- excuse</p> <p>25 me -- Exhibit 1 to this deposition, the</p>                                                                               | <p style="text-align: right;">Page 8</p> <p>1 BERKLAND</p> <p>2 to a deposition in a PTAB proceeding from</p> <p>3 a formality perspective.</p> <p>4 MR. NOLAN: We can certainly</p> <p>5 just refer to it as Exhibit 2009, we can</p> <p>6 change the designation on it.</p> <p>7 MR. PIVOVAR: Yes.</p> <p>8 And all exhibits that are</p> <p>9 introduced by a party need to be in</p> <p>10 sequential order if they're going to be</p> <p>11 attached to anything in the PTAB; you have</p> <p>12 to continue with the numbering from the</p> <p>13 last exhibit if you're going to try to</p> <p>14 introduce anything new.</p> <p>15 That is the last number you</p> <p>16 used up-front and it should be 1000 and</p> <p>17 whatever the next number is from the last</p> <p>18 exhibit that was submitted in the Patent</p> <p>19 Office.</p> <p>20 These are all standard PTAB</p> <p>21 proceedings.</p> <p>22 MR. NOLAN: I understand, sir,</p> <p>23 I was trying to -- we'll keep the</p> <p>24 exhibits in line; when we introduce them</p> <p>25 obviously they will be numbered in</p> |
| <p style="text-align: right;">Page 7</p> <p>1 BERKLAND</p> <p>2 declaration of Dr. Cory Berkland in</p> <p>3 support of patent owner's response to</p> <p>4 petition.</p> <p>5 Q. If it is easier for you to</p> <p>6 review the paper copy, sir, as long as</p> <p>7 there is no annotations on it, that's</p> <p>8 acceptable to me, but we're going to make</p> <p>9 the exhibit available on Exhibit Share for</p> <p>10 everyone else that is participating.</p> <p>11 A. Okay.</p> <p>12 Q. It should be in your exhibit</p> <p>13 folder, but, again, if you already have</p> <p>14 the paper copy in front of you and it's</p> <p>15 easier for you to flip through that,</p> <p>16 please feel free to do that, sir.</p> <p>17 A. Okay.</p> <p>18 MR. PIVOVAR: Counsel, is this</p> <p>19 Exhibit 2009?</p> <p>20 MR. NOLAN: Yes, this is</p> <p>21 Exhibit 2009, sir.</p> <p>22 MR. PIVOVAR: Yes, we don't</p> <p>23 need to reintroduce it, we can just rely</p> <p>24 on that, it will be part of the record, it</p> <p>25 is not common to introduce as new exhibits</p> | <p style="text-align: right;">Page 9</p> <p>1 BERKLAND</p> <p>2 accordance with the Patent Office's</p> <p>3 proceedings, but for this deposition, if</p> <p>4 your preference is to do it, we can</p> <p>5 certainly just start with the next one</p> <p>6 that we have.</p> <p>7 Q. But, anyway, Dr. Berkland,</p> <p>8 you're looking at Exhibit 2009, sir?</p> <p>9 A. That's correct, and as a</p> <p>10 clarification, my binder contains Exhibit</p> <p>11 2001 through 2023.</p> <p>12 Q. And so, sir, if you can, I</p> <p>13 believe you indicated that there was a</p> <p>14 revision that you had identified for</p> <p>15 Exhibit 2009, is that accurate?</p> <p>16 A. Yes, sir.</p> <p>17 Q. What is that revision, sir?</p> <p>18 A. In paragraph 137.</p> <p>19 Q. Okay, sir.</p> <p>20 A. The last line at the bottom of</p> <p>21 the page, it says, "A POSA would have been</p> <p>22 motivated," and it should say "A POSA</p> <p>23 would not have been motivated to combine</p> <p>24 nonoverlapping and disparate viscosity</p> <p>25 ranges with each other."</p>              |

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| <p style="text-align: right;">Page 10</p> <p>1           BERKLAND</p> <p>2    Q.    You're looking at 137, the last</p> <p>3 line on page 53?</p> <p>4    A.    Correct.</p> <p>5    Q.    Is there any other edits to</p> <p>6 your report, sir, that you would like to</p> <p>7 make?</p> <p>8    A.    Not at this time.</p> <p>9    Q.    Did you identify that error in</p> <p>10 your report, sir?</p> <p>11   A.    I can't recall; it occurred</p> <p>12 during discussion with counsel yesterday,</p> <p>13 but I don't recall which one of us noticed</p> <p>14 it.</p> <p>15   Q.    You also reviewed the</p> <p>16 declaration of Dr. Crowley, correct, sir?</p> <p>17   A.    That is correct.</p> <p>18   Q.    Do you know Dr. Crowley?</p> <p>19   A.    Yes.</p> <p>20   Q.    How do you know Dr. Crowley?</p> <p>21   A.    I met him in Texas, I believe,</p> <p>22 probably 12, 15 years ago, something like</p> <p>23 that.</p> <p>24   Q.    And do you recall the</p> <p>25 circumstances upon which you were meeting</p>                                 | <p style="text-align: right;">Page 12</p> <p>1           BERKLAND</p> <p>2 business?</p> <p>3    A.    2008, might have been the end</p> <p>4 of 2007, but I think it was 2008.</p> <p>5    Q.    What was the technology in</p> <p>6 general, I don't need any details about</p> <p>7 it, but just the general nature of it.</p> <p>8    A.    Our lab had invented an</p> <p>9 approach to take drug particles and</p> <p>10 improve their aerosol properties.</p> <p>11   Q.    And so at some point you or</p> <p>12 Savara began to consult with Dr. Crowley?</p> <p>13   A.    I remember chatting with him, I</p> <p>14 don't remember if he was retained as a</p> <p>15 consultant, I'm unaware.</p> <p>16   Q.    What did you mean when you said</p> <p>17 he gave a talk about aerosol technology</p> <p>18 then, sir?</p> <p>19   A.    Like I said, we had a talk or a</p> <p>20 discussion about the technology.</p> <p>21        I remember first meeting him</p> <p>22 and just having a discussion about the</p> <p>23 technology we used at first in my lab and</p> <p>24 then at Savara Pharmaceuticals.</p> <p>25   Q.    Where did the meeting occur?</p> |
| <p style="text-align: right;">Page 11</p> <p>1           BERKLAND</p> <p>2 him?</p> <p>3    A.    Yes.</p> <p>4    Q.    What were those circumstances?</p> <p>5    A.    Dr. Crowley was providing some</p> <p>6 advice or discussion around aerosol</p> <p>7 technology that I was maturing in a small</p> <p>8 business.</p> <p>9    Q.    When you say providing advice,</p> <p>10 was he acting as a consultant?</p> <p>11   A.    I don't recall; at this point I</p> <p>12 was kind of arm's length with the company</p> <p>13 and any engagements would have been</p> <p>14 through the company.</p> <p>15   Q.    What company were you working</p> <p>16 with?</p> <p>17   A.    It was called Savara,</p> <p>18 S-A-V-A-R-A, Pharmaceuticals.</p> <p>19   Q.    What was your role with Savara</p> <p>20 Pharmaceuticals?</p> <p>21   A.    The original technology for</p> <p>22 founding the company came out of my</p> <p>23 laboratory at the University of Kansas, so</p> <p>24 I was a co-founder for the business.</p> <p>25   Q.    When did you found that</p> | <p style="text-align: right;">Page 13</p> <p>1           BERKLAND</p> <p>2    A.    I believe it was in Austin,</p> <p>3 Texas.</p> <p>4    Q.    Did you travel to Austin, sir?</p> <p>5    A.    I had traveled to Austin to</p> <p>6 visit the CEO of our company who was also</p> <p>7 in Austin.</p> <p>8    Q.    Did the meeting occur at the</p> <p>9 Savara facilities?</p> <p>10   A.    I don't recall.</p> <p>11   Q.    How long was the meeting?</p> <p>12   A.    I don't know, I'm sure less</p> <p>13 than part of a day, maybe a couple of</p> <p>14 hours, but I actually don't recall.</p> <p>15   Q.    Did you have any other meetings</p> <p>16 with Dr. Crowley related to Savara?</p> <p>17   A.    I don't recall.</p> <p>18   Q.    Did Dr. Crowley provide you any</p> <p>19 information related to the aerosol</p> <p>20 technology that he discussed?</p> <p>21   A.    He might have, but it's been a</p> <p>22 long time ago and I don't remember.</p> <p>23   Q.    Other than that interaction</p> <p>24 with Dr. Crowley, have you had any other</p> <p>25 interactions with him?</p>                                                       |

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| <p style="text-align: right;">Page 14</p> <p>1 BERKLAND</p> <p>2 A. I don't recall, I don't believe</p> <p>3 so.</p> <p>4 Q. Do you still have a</p> <p>5 relationship with Savara Pharmaceuticals?</p> <p>6 A. I am still a shareholder, but I</p> <p>7 haven't done anything on behalf of the</p> <p>8 company since 2014, I believe.</p> <p>9 Q. Other than your interactions</p> <p>10 related to Savara, have you had any other</p> <p>11 interactions with Dr. Crowley?</p> <p>12 A. Not that I recall.</p> <p>13 Q. If you have Exhibit 2009 up, I</p> <p>14 would like you to turn to your discussion</p> <p>15 of a person of ordinary skill in the art,</p> <p>16 sir.</p> <p>17 A. Okay.</p> <p>18 (Witness complying.)</p> <p>19 Q. Do you see in paragraph 21 of</p> <p>20 that you lay out your definition of a</p> <p>21 person of ordinary skill in the art?</p> <p>22 A. Just a moment.</p> <p>23 (Witness perusing document.)</p> <p>24 A. Yes.</p> <p>25 Q. Can you see that you indicated</p> | <p style="text-align: right;">Page 16</p> <p>1 BERKLAND</p> <p>2 time, my apologies.</p> <p>3 Do you mind asking the question</p> <p>4 again.</p> <p>5 Q. Sure.</p> <p>6 Are you holding yourself out as</p> <p>7 an expert in pharmaceutical regulatory</p> <p>8 approvals?</p> <p>9 A. I am not; I have exposure to</p> <p>10 the approval pathways, but I wouldn't call</p> <p>11 myself an expert.</p> <p>12 Q. And so in this definition of a</p> <p>13 POSA, can you explain to me how the</p> <p>14 description that you've provided here of</p> <p>15 access to a pharmaceutical regulatory</p> <p>16 approval personnel impacts your opinions</p> <p>17 in this matter?</p> <p>18 MR. PIVOVAR: Objection to</p> <p>19 form.</p> <p>20 A. The POSA would have access to</p> <p>21 these one or more team members, according</p> <p>22 to this definition, and would take into</p> <p>23 consideration regulatory hurdles, this</p> <p>24 would commonly be called chemistry</p> <p>25 manufacturing and controls, that could</p>                                                          |
| <p style="text-align: right;">Page 15</p> <p>1 BERKLAND</p> <p>2 that the person would have access to one</p> <p>3 or more team members having experience in</p> <p>4 pharmaceutical formulation and</p> <p>5 pharmaceutical regulatory approvals, do</p> <p>6 you see that, sir?</p> <p>7 (Witness perusing document.)</p> <p>8 A. I do see that, it's in the</p> <p>9 context of the larger definition with</p> <p>10 qualifiers, but I see that phrase.</p> <p>11 Q. Would you hold yourself out as</p> <p>12 an expert in pharmaceutical regulatory</p> <p>13 approvals?</p> <p>14 MR. PIVOVAR: Objection to</p> <p>15 form.</p> <p>16 A. I'm sorry, just so I'm clear,</p> <p>17 are you able to hear the objections?</p> <p>18 Q. I heard the objection; it was</p> <p>19 taken down.</p> <p>20 You can answer.</p> <p>21 A. Okay.</p> <p>22 Q. Thank you.</p> <p>23 A. Normally there is a bit of</p> <p>24 feedback and I can't tell when counsel is</p> <p>25 speaking and I didn't hear it at that</p>  | <p style="text-align: right;">Page 17</p> <p>1 BERKLAND</p> <p>2 impact their work.</p> <p>3 Q. Sir, in providing your</p> <p>4 opinions, have you relied upon in any way</p> <p>5 issues related to pharmaceutical</p> <p>6 regulatory approval to develop your</p> <p>7 opinions presented?</p> <p>8 MR. PIVOVAR: Objection to</p> <p>9 form.</p> <p>10 A. Well, certainly to the extent</p> <p>11 that the regulatory pathway is a</p> <p>12 consideration when developing an approved</p> <p>13 pharmaceutical product, I have considered</p> <p>14 that aspect.</p> <p>15 If you're referring to my</p> <p>16 opinions about the prior art cited by</p> <p>17 Crowley and whether I think the patent is</p> <p>18 obvious, maybe we should just specify what</p> <p>19 you mean when you say opinions, are you</p> <p>20 talking about my opinions regarding</p> <p>21 obviousness or the opinions throughout the</p> <p>22 declaration?</p> <p>23 Q. Well, if there is any opinions</p> <p>24 in your declaration that you think are</p> <p>25 impacted by your definition, that a POSA</p> |

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| <p style="text-align: right;">Page 18</p> <p>1           BERKLAND</p> <p>2 would have access to a regulatory person</p> <p>3 with pharmaceutical regulatory approval</p> <p>4 experience, I'd want you to identify</p> <p>5 those.</p> <p>6           If there's some that don't,</p> <p>7 then you can identify those as well.</p> <p>8           MR. PIVOVAR: Objection, form.</p> <p>9           (Witness perusing document.)</p> <p>10 A.    I think the answer I've given</p> <p>11 is sufficient.</p> <p>12 Q.    Okay.</p> <p>13        So tell me which opinions in</p> <p>14 your report are affected by your view that</p> <p>15 the person of skill in the art would have</p> <p>16 access to one or more team members having</p> <p>17 experience in pharmaceutical regulatory</p> <p>18 approvals.</p> <p>19        MR. PIVOVAR: Objection, form.</p> <p>20 A.    My opinions are simply in</p> <p>21 response to Dr. Crowley and are from the</p> <p>22 perspective of a POSA, who is a</p> <p>23 formulator, with the qualifications I laid</p> <p>24 out.</p> <p>25        It would be helpful to have an</p>                                                                                                                     | <p style="text-align: right;">Page 20</p> <p>1           BERKLAND</p> <p>2 Q.    With respect to your opinions</p> <p>3 on the formulations in the '795 patent,</p> <p>4 have any of those opinions been influenced</p> <p>5 by your requirement that a POSA have</p> <p>6 access to one or more team members having</p> <p>7 experience in pharmaceutical regulatory</p> <p>8 approval?</p> <p>9        MR. PIVOVAR: Objection to</p> <p>10 form.</p> <p>11 A.    I have a lot of opinions in</p> <p>12 this declaration.</p> <p>13        We can probably try to pick</p> <p>14 them up one-by-one as we go through the</p> <p>15 opinions.</p> <p>16 Q.    But, sir, can you answer my</p> <p>17 question; can you tell me right now are</p> <p>18 any of the opinions that you've presented</p> <p>19 impacted by your requirement that the POSA</p> <p>20 have access to one or more team members</p> <p>21 having experience in pharmaceutical</p> <p>22 regulatory approvals?</p> <p>23        MR. PIVOVAR: Objection to</p> <p>24 form.</p> <p>25 A.    That's my answer; I mean, we</p> |
| <p style="text-align: right;">Page 19</p> <p>1           BERKLAND</p> <p>2 understanding of the regulatory pathway,</p> <p>3 which I believe I do to the extent it</p> <p>4 applies to, say, chemistry manufacturing</p> <p>5 and control aspects of pharmaceutical</p> <p>6 products that need to be addressed in</p> <p>7 order to be approved or on the shelf.</p> <p>8 Q.    When I initially asked you if</p> <p>9 you're holding yourself out as a</p> <p>10 regulatory expert, I thought you stated</p> <p>11 you were not, but you do think you have</p> <p>12 sufficient regulatory experience to fit</p> <p>13 into this one or more team members having</p> <p>14 experience in pharmaceutical formulation</p> <p>15 and pharmaceutical regulatory approvals?</p> <p>16 A.    To the extent that the</p> <p>17 regulatory piece shapes or provides</p> <p>18 information to the formulator, I have</p> <p>19 experienced that many times.</p> <p>20        I'm not an expert in regulatory</p> <p>21 approval pathways, like the documentation</p> <p>22 for 505b2 pathways or generic pathways</p> <p>23 from a paperwork perspective.</p> <p>24        But to the extent it relates to</p> <p>25 formulation, I have experience.</p> | <p style="text-align: right;">Page 21</p> <p>1           BERKLAND</p> <p>2 haven't -- I don't know if you're calling</p> <p>3 opinions just cabinining them to the</p> <p>4 obviousness opinions or all the opinions I</p> <p>5 provided in the declaration.</p> <p>6        I'm happy to go through them</p> <p>7 and --</p> <p>8 Q.    You can use your own definition</p> <p>9 of opinion, sir.</p> <p>10        I am just asking you to</p> <p>11 identify anything you consider an opinion</p> <p>12 in this report that is affected by the way</p> <p>13 you've defined the POSA to include access</p> <p>14 to pharmaceutical regulatory approval</p> <p>15 knowledge.</p> <p>16        MR. PIVOVAR: Objection to</p> <p>17 form.</p> <p>18 A.    I would say the bulk of my</p> <p>19 criticisms of Dr. Crowley's report and</p> <p>20 analysis don't require that knowledge.</p> <p>21 Q.    Thank you, sir.</p> <p>22        Is there any criticisms that</p> <p>23 you think do require that knowledge?</p> <p>24 A.    That's --</p> <p>25        MR. PIVOVAR: Objection to</p>      |

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| <p style="text-align: right;">Page 22</p> <p>1           BERKLAND</p> <p>2 form.</p> <p>3     A.    That's a tougher one to answer;</p> <p>4 I think we'd have to try to pin down a</p> <p>5 particular opinion and then maybe I can do</p> <p>6 the analysis at that time.</p> <p>7     Q.    Thank you, sir.</p> <p>8           You mentioned criticisms of</p> <p>9 Dr. Crowley's declaration, right, sir?</p> <p>10          MR. PIVOVAR: Objection, form.</p> <p>11          MR. NOLAN: I will fix that.</p> <p>12     Q.    You mentioned that you have</p> <p>13 criticisms of Dr. Crowley's declaration,</p> <p>14 correct, sir?</p> <p>15     A.    Yes.</p> <p>16     Q.    One of those -- strike that.</p> <p>17           Is one of those criticisms a</p> <p>18 mis-citation to a viscosity for agave</p> <p>19 syrup?</p> <p>20     A.    I can't tell if it is a</p> <p>21 mis-citation or a misunderstanding or how</p> <p>22 the error arises.</p> <p>23     Q.    Did you review the declaration</p> <p>24 exhibits, sir?</p> <p>25     A.    For my report or Dr. Crowley's?</p> | <p style="text-align: right;">Page 24</p> <p>1           BERKLAND</p> <p>2           Objection to form.</p> <p>3     A.    There were a lot of documents,</p> <p>4 I'm sure I didn't read every page of every</p> <p>5 document, but I did search them.</p> <p>6     Q.    What do you mean by you</p> <p>7 searched them?</p> <p>8     A.    I recall trying to understand</p> <p>9 this error in viscosity and looking</p> <p>10 through exhibits from Dr. Crowley that</p> <p>11 disclosed viscosity and not being able to</p> <p>12 reconcile the mistake -- well, not being</p> <p>13 able to reconcile where this number came</p> <p>14 from, I actually don't know if it's a</p> <p>15 mistake or a misunderstanding or if that's</p> <p>16 what Dr. Crowley believes to be the</p> <p>17 viscosity.</p> <p>18     Q.    Well, do you understand that</p> <p>19 agave syrup has a range of viscosities,</p> <p>20 sir?</p> <p>21          MR. PIVOVAR: Objection, form.</p> <p>22     A.    I talk about this in my report.</p> <p>23           (Witness perusing document.)</p> <p>24     A.    I believe I use similar</p> <p>25 language to that.</p>                         |
| <p style="text-align: right;">Page 23</p> <p>1           BERKLAND</p> <p>2     Q.    I will clear it up for you.</p> <p>3           Why don't we go to paragraph 17</p> <p>4 of Exhibit 2009, sir.</p> <p>5           (Witness complying.)</p> <p>6     Q.    Are you at that paragraph, sir?</p> <p>7     A.    Yes.</p> <p>8     Q.    It indicates that you reviewed</p> <p>9 United States Patent 11,617,795, correct?</p> <p>10     A.    Yes.</p> <p>11     Q.    You reviewed its prosecution</p> <p>12 history, correct?</p> <p>13     A.    I don't know that I read every</p> <p>14 page of the prosecution history, but, yes,</p> <p>15 I am familiar with the prosecution</p> <p>16 history.</p> <p>17     Q.    And you say "I have also</p> <p>18 reviewed the documents described in the</p> <p>19 index of exhibits," correct?</p> <p>20     A.    Correct.</p> <p>21     Q.    When you said you reviewed</p> <p>22 those documents, did you read the</p> <p>23 documents, sir?</p> <p>24     A.    There were a lot --</p> <p>25          MR. PIVOVAR: Hold on.</p>                | <p style="text-align: right;">Page 25</p> <p>1           BERKLAND</p> <p>2     Q.    And so where are you</p> <p>3 referencing, sir?</p> <p>4     A.    At least one location is</p> <p>5 paragraph 49 of my report, in the opening</p> <p>6 line I talk about petitioner acknowledging</p> <p>7 the variability of agave syrup's</p> <p>8 properties, including viscosity,</p> <p>9 describing agave syrup as capable of</p> <p>10 having a thinner or thicker viscosity.</p> <p>11     Q.    Is it your understanding that,</p> <p>12 as you defined it, a person of ordinary</p> <p>13 skill in the art would understand that</p> <p>14 different types of agave syrup can have</p> <p>15 different viscosities, correct, sir?</p> <p>16     A.    My understanding is that agave</p> <p>17 syrups can have different viscosities; it</p> <p>18 also occurs in the patent.</p> <p>19     Q.    It occurs in the patent, you</p> <p>20 say that agave syrups can have different</p> <p>21 types of viscosity?</p> <p>22     A.    In the patent I believe it says</p> <p>23 syrups.</p> <p>24     Q.    And so you're telling me that</p> <p>25 the patent discusses the types of</p> |

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| <p style="text-align: right;">Page 26</p> <p>1           BERKLAND</p> <p>2 viscosity that agave syrup can have?</p> <p>3    A.    It would be helpful just to</p> <p>4 look at the patent.</p> <p>5    Q.    From your memory, are you</p> <p>6 saying, is it your testimony that the</p> <p>7 patent discloses that agave syrup has</p> <p>8 different ranges of viscosity?</p> <p>9    A.    I don't want to try to recall</p> <p>10 that from memory.</p> <p>11   Q.    So then what was your basis of</p> <p>12 the testimony you just gave, sir?</p> <p>13   A.    Just a moment.</p> <p>14   Q.    Sir, can you tell me what</p> <p>15 you're reviewing right now.</p> <p>16   A.    I am trying to find the patent</p> <p>17 so I can go to that language.</p> <p>18   Q.    But what I was asking you was</p> <p>19 what was the basis for your testimony that</p> <p>20 you gave without reviewing the patent,</p> <p>21 sir.</p> <p>22   A.    I recall the patent disclosing</p> <p>23 a range of viscosities.</p> <p>24   Q.    Is it your testimony that you</p> <p>25 recall it disclosing a range of</p>           | <p style="text-align: right;">Page 28</p> <p>1           BERKLAND</p> <p>2 5 of Exhibit 1001.</p> <p>3    A.    I have it.</p> <p>4    Q.    And you see the first claim, it</p> <p>5 says "a pharmaceutical syrup formulation,"</p> <p>6 sir?</p> <p>7    A.    I see that.</p> <p>8    Q.    Here it is using the term syrup</p> <p>9 separate and apart from agave syrup,</p> <p>10 correct?</p> <p>11       MR. PIVOVAR: Objection to</p> <p>12 form.</p> <p>13    A.    That's correct, but it's the</p> <p>14 only syrup in the pharmaceutical syrup</p> <p>15 formulation.</p> <p>16    Q.    But the pharmaceutical syrup</p> <p>17 formulation here is not just agave syrup,</p> <p>18 correct, sir?</p> <p>19    A.    It's the only syrup in the</p> <p>20 formulation, but it includes other things,</p> <p>21 yes.</p> <p>22    Q.    And so the pharmaceutical syrup</p> <p>23 described in claim 1 is not just agave</p> <p>24 syrup, correct?</p> <p>25       MR. PIVOVAR: Objection, form.</p>                                                                                    |
| <p style="text-align: right;">Page 27</p> <p>1           BERKLAND</p> <p>2 viscosities for agave syrup?</p> <p>3    A.    That's what I am trying to</p> <p>4 resolve; if helpful, you can point me to</p> <p>5 the exhibit for the patent.</p> <p>6    Q.    Sure.</p> <p>7       Why don't we go to what was</p> <p>8 previously marked as I think it was 1001.</p> <p>9       Do you have that, sir, it's in</p> <p>10 your Exhibit Share?</p> <p>11    A.    I have it, I'm looking at the</p> <p>12 paper copy from the Crowley binder, and</p> <p>13 just for your information, it covers</p> <p>14 Exhibit 1001 to 1043.</p> <p>15    Q.    Sir, I would like to direct you</p> <p>16 to maybe column 2 of that Exhibit 1001.</p> <p>17    A.    Okay.</p> <p>18    Q.    You see around line 7 it has</p> <p>19 the term agave syrup in quotes, sir?</p> <p>20    A.    I see that.</p> <p>21    Q.    And so it provides a definition</p> <p>22 for the term agave syrup, correct, sir?</p> <p>23    A.    Yes.</p> <p>24    Q.    I would like you to turn to,</p> <p>25 before we continue, can you turn to column</p> | <p style="text-align: right;">Page 29</p> <p>1           BERKLAND</p> <p>2    A.    The predominant ingredient is</p> <p>3 agave syrup, but there are other</p> <p>4 ingredients.</p> <p>5    Q.    Was the answer to my question</p> <p>6 correct, that the pharmaceutical syrup</p> <p>7 formulation of claim 1 is not just agave</p> <p>8 syrup, correct?</p> <p>9    A.    I think I answered that, the</p> <p>10 predominant ingredient is agave syrup,</p> <p>11 that is the syrup in the pharmaceutical</p> <p>12 formulation.</p> <p>13       But, yes, there are other</p> <p>14 ingredients present.</p> <p>15    Q.    And those other ingredients,</p> <p>16 will they affect the characteristics of</p> <p>17 the pharmaceutical syrup, sir?</p> <p>18       MR. PIVOVAR: Objection to</p> <p>19 form.</p> <p>20    A.    They will have an effect on the</p> <p>21 pharmaceutical syrup.</p> <p>22    Q.    For example, those ingredients</p> <p>23 will have effect on the viscosity of the</p> <p>24 pharmaceutical syrup, correct?</p> <p>25       MR. PIVOVAR: Objection to</p> |

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| <p style="text-align: right;">Page 30</p> <p>1           BERKLAND</p> <p>2 form.</p> <p>3     A.     They could.</p> <p>4     Q.     Would you expect them to have</p> <p>5 an effect on the viscosity of the</p> <p>6 pharmaceutical formulation?</p> <p>7           MR. PIVOVAR: Objection to</p> <p>8 form.</p> <p>9     Q.     Would you expect them to have</p> <p>10 an effect on the pharmaceutical syrup of</p> <p>11 claim 1?</p> <p>12          MR. PIVOVAR: Objection to</p> <p>13 form.</p> <p>14     A.     I haven't conducted that</p> <p>15 analysis.</p> <p>16          What comes to mind is that they</p> <p>17 may or may not.</p> <p>18     Q.     Would you expect a diluent to</p> <p>19 affect the viscosity of the pharmaceutical</p> <p>20 syrup of claim 1?</p> <p>21          MR. PIVOVAR: Objection to</p> <p>22 form.</p> <p>23     A.     I would expect that to have an</p> <p>24 effect if it was added enough to create a</p> <p>25 change in the viscosity, for example.</p>                                                                                               | <p style="text-align: right;">Page 32</p> <p>1           BERKLAND</p> <p>2 the syrup formulation," would you agree</p> <p>3 that the term the syrup formulation is</p> <p>4 referencing back to a pharmaceutical syrup</p> <p>5 formulation listed in the preamble of this</p> <p>6 claim?</p> <p>7     A.     I see the term pharmaceutical</p> <p>8 syrup formulation in claim 1 and I see the</p> <p>9 term in column 2.</p> <p>10    Q.     Sir, what I am asking you is,</p> <p>11 looking at claim 1, and we see that on</p> <p>12 column 5, around line 38, it says --</p> <p>13 maybe 39 -- it says "the pharmaceutical</p> <p>14 formulation," do you see that, sir?</p> <p>15          (Witness perusing document.)</p> <p>16     A.     I don't see "pharmaceutical</p> <p>17 formulation," "pharmaceutical syrup</p> <p>18 formulation"?</p> <p>19     Q.     Let me clear up my question, my</p> <p>20 apologies, sir.</p> <p>21     A.     Okay.</p> <p>22     Q.     If we go back to Exhibit 1001,</p> <p>23 column 5, looking at claim 1, do you see</p> <p>24 around line 38 there's the term "wherein</p> <p>25 the syrup formulation," do you see that,</p> |
| <p style="text-align: right;">Page 31</p> <p>1           BERKLAND</p> <p>2     Q.     So the pharmaceutical syrup</p> <p>3 will have different characteristics than</p> <p>4 the agave syrup that is a constituent of</p> <p>5 that pharmaceutical syrup, correct, sir?</p> <p>6          MR. PIVOVAR: Objection to</p> <p>7 form.</p> <p>8     A.     I mean, the agave syrup is the</p> <p>9 syrup component of the pharmaceutical</p> <p>10 syrup.</p> <p>11          I'm not sure if that's what you</p> <p>12 mean.</p> <p>13     Q.     Well, would you expect the</p> <p>14 agave syrup that's the constituent to have</p> <p>15 the same characteristics as the</p> <p>16 pharmaceutical formulation, for example,</p> <p>17 with respect to viscosity?</p> <p>18          MR. PIVOVAR: Objection to</p> <p>19 form.</p> <p>20     A.     I mean, I really haven't</p> <p>21 conducted that analysis, it may or may not</p> <p>22 be the same, it depends on a number of</p> <p>23 factors.</p> <p>24     Q.     And if you look at this claim,</p> <p>25 sir, you see that it says that "wherein</p> | <p style="text-align: right;">Page 33</p> <p>1           BERKLAND</p> <p>2 sir?</p> <p>3     A.     I do.</p> <p>4     Q.     And do you understand "wherein</p> <p>5 the syrup formulation" is referencing back</p> <p>6 to the language in line 34 of column 5</p> <p>7 that says "a pharmaceutical syrup</p> <p>8 formulation"?</p> <p>9          (Witness perusing document.)</p> <p>10    A.     I really haven't conducted that</p> <p>11 analysis.</p> <p>12          I mean, contextually -- I</p> <p>13 don't know.</p> <p>14     Q.     You're providing opinions on</p> <p>15 whether or not this claim is obvious and</p> <p>16 you don't understand what the language of</p> <p>17 the claim references, sir, is that your</p> <p>18 testimony here?</p> <p>19          MR. PIVOVAR: Objection to</p> <p>20 form.</p> <p>21     A.     I do understand.</p> <p>22     Q.     Okay.</p> <p>23          So does the language "wherein</p> <p>24 the syrup formulation" of line 38, in your</p> <p>25 understanding, reference back to the</p>                                                                                                                        |

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| <p style="text-align: right;">Page 34</p> <p>1           BERKLAND</p> <p>2 language "a pharmaceutical syrup</p> <p>3 formulation" in line 34 of column 5?</p> <p>4           MR. PIVOVAR: Objection, form.</p> <p>5           (Witness perusing document.)</p> <p>6       A.    It would make sense that the</p> <p>7 syrup formulation is referring to the</p> <p>8 combined ingredients.</p> <p>9       Q.    And so by that you mean his</p> <p>10 referencing back to the preamble, that</p> <p>11 includes all of the combined ingredients</p> <p>12 of this claim, correct, sir?</p> <p>13       MR. PIVOVAR: Objection to</p> <p>14 form.</p> <p>15       A.    Well, at least in the scope of</p> <p>16 the claim it would include the active</p> <p>17 acetaminophen, the agave and the diluent.</p> <p>18       Q.    And so that pharmaceutical</p> <p>19 syrup formulation of claim 1, which at a</p> <p>20 minimum includes acetaminophen, agave</p> <p>21 syrup and a diluent, if we look forward in</p> <p>22 this claim, that formulation has to have a</p> <p>23 viscosity less than 1500 centipoise at</p> <p>24 about 22 degrees, correct, sir?</p> <p>25       A.    It seems you've read that</p> | <p style="text-align: right;">Page 36</p> <p>1           BERKLAND</p> <p>2       A.    To me it doesn't make sense if</p> <p>3 you don't understand the syrup as the</p> <p>4 driving ingredient of the viscosity.</p> <p>5       Q.    Sir, what I am asking you, are</p> <p>6 you putting any limitation on this claim</p> <p>7 as to the type of agave that can be used</p> <p>8 based on the viscosity of that agave</p> <p>9 syrup?</p> <p>10       MR. PIVOVAR: Objection to</p> <p>11 form.</p> <p>12       A.    No, I'm giving you the POSA's</p> <p>13 perspective, I'm giving you how this would</p> <p>14 be understood as a formulation.</p> <p>15       Q.    But I'm asking you as a POSA</p> <p>16 and I'm asking your interpretation of this</p> <p>17 claim.</p> <p>18           Is it your interpretation that</p> <p>19 the agave syrup as recited in this</p> <p>20 limitation has some sort of viscosity</p> <p>21 limitation associated with it?</p> <p>22       MR. PIVOVAR: Objection, form.</p> <p>23       A.    I might have misunderstood the</p> <p>24 question now.</p> <p>25           Maybe you can rephrase it for</p> |
| <p style="text-align: right;">Page 35</p> <p>1           BERKLAND</p> <p>2 correctly.</p> <p>3       Q.    Well, do you agree, sir, that</p> <p>4 what is being requested there is the</p> <p>5 viscosity of the pharmaceutical syrup</p> <p>6 formulation of the claim?</p> <p>7       A.    That makes sense, yes.</p> <p>8       Q.    And so this viscosity</p> <p>9 limitation that's recited in claim 1 is</p> <p>10 not referencing to a requirement for the</p> <p>11 viscosity of the agave syrup of claim 1,</p> <p>12 is that fair, sir?</p> <p>13       MR. PIVOVAR: Objection to</p> <p>14 form.</p> <p>15       A.    There's no explicit indication</p> <p>16 of a requirement for the agave syrup</p> <p>17 viscosity.</p> <p>18           However, agave is the only</p> <p>19 syrup in the formulation.</p> <p>20       Q.    But you agree, sir, that from</p> <p>21 an analysis perspective, there's not a</p> <p>22 limitation in this claim that limits the</p> <p>23 viscosity of the agave syrup, correct,</p> <p>24 sir?</p> <p>25       MR. PIVOVAR: Object to form.</p>                                                                                                                     | <p style="text-align: right;">Page 37</p> <p>1           BERKLAND</p> <p>2 we.</p> <p>3       Q.    Certainly.</p> <p>4           You agree that claim 1 of the</p> <p>5 '795 patent requires agave syrup, correct,</p> <p>6 sir?</p> <p>7       A.    Correct.</p> <p>8       Q.    Does that claim, in your</p> <p>9 opinion, limit the type of agave syrup</p> <p>10 that can be used based on the viscosity of</p> <p>11 that agave syrup?</p> <p>12       MR. PIVOVAR: Objection to</p> <p>13 form.</p> <p>14       A.    A POSA would understand that</p> <p>15 syrup is the contributing factor to the</p> <p>16 viscosity in the formulation.</p> <p>17       Q.    Sir, is there a reason why you</p> <p>18 don't want to answer my question?</p> <p>19       MR. PIVOVAR: Objection, that's</p> <p>20 not a question --</p> <p>21       MR. NOLAN: I am going to ask</p> <p>22 the court reporter to read my last</p> <p>23 question back.</p> <p>24       Q.    And I would like you to answer</p> <p>25 that question; if you can't answer that</p>                                                                                          |

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| <p style="text-align: right;">Page 38</p> <p>1           BERKLAND</p> <p>2 question, you can put on the record "I</p> <p>3 cannot answer that question because."</p> <p>4           (Record read.)</p> <p>5           MR. PIVOVAR: Objection to</p> <p>6 form.</p> <p>7     A.    And I believe my answer was</p> <p>8 something to the effect that the agave</p> <p>9 syrup is the only syrup in the</p> <p>10 pharmaceutical syrup formulation, so it</p> <p>11 would be contributing to the viscosity in</p> <p>12 part to that formulation.</p> <p>13     Q.    And so what I'm asking you is,</p> <p>14 is there in agave syrup, in your opinion</p> <p>15 -- strike that.</p> <p>16           Is there a range of viscosities</p> <p>17 for agave syrup that in your view could</p> <p>18 not be used in this patent claim?</p> <p>19           MR. PIVOVAR: Objection to</p> <p>20 form.</p> <p>21     A.    That's a different question; I</p> <p>22 haven't conducted that analysis.</p> <p>23     Q.    And so if you have agave syrup,</p> <p>24 irrespective of its viscosity of that</p> <p>25 syrup, and the overall pharmaceutical</p>                                                                                                                    | <p style="text-align: right;">Page 40</p> <p>1           BERKLAND</p> <p>2 correct, sir?</p> <p>3           MR. PIVOVAR: Objection to</p> <p>4 form.</p> <p>5     A.    I mean, they're linked, because</p> <p>6 the pharmaceutical syrup properties are at</p> <p>7 least in part determined by or driven by</p> <p>8 the agave syrup properties, the</p> <p>9 pharmaceuticals -- sorry, go ahead.</p> <p>10     Q.    It's also driven by the</p> <p>11 diluent, correct, sir?</p> <p>12     A.    The diluent would contribute as</p> <p>13 well.</p> <p>14     Q.    And so even if you had a high</p> <p>15 viscosity of agave syrup, but you had</p> <p>16 added a low viscosity diluent, the overall</p> <p>17 viscosity of the pharmaceutical syrup</p> <p>18 formulation very well may be within the</p> <p>19 viscosity limitation of this claim,</p> <p>20 correct, sir?</p> <p>21           MR. PIVOVAR: Objection, form.</p> <p>22     A.    That seems reasonable.</p> <p>23     Q.    And so it is not just the</p> <p>24 viscosity of the agave syrup that dictates</p> <p>25 the viscosity of the pharmaceutical syrup</p>         |
| <p style="text-align: right;">Page 39</p> <p>1           BERKLAND</p> <p>2 formulation has the viscosity of less than</p> <p>3 1500 centipoise, do you understand that to</p> <p>4 be within the scope of this claim, sir?</p> <p>5           MR. PIVOVAR: Object to form.</p> <p>6     A.    I didn't conduct that analysis,</p> <p>7 but that seems to make sense.</p> <p>8     Q.    So as long as you have the 1500</p> <p>9 centipoise or lower for the entire</p> <p>10 pharmaceutical formulation, the claim is</p> <p>11 not limiting you to the viscosity range</p> <p>12 for the agave syrup, correct?</p> <p>13     A.    You keep trying to separate the</p> <p>14 two and, I mean, a POSA would see this and</p> <p>15 understand that the agave syrup is the</p> <p>16 driving factor for the viscosity.</p> <p>17     Q.    But the driving claim language</p> <p>18 is the syrup formulation has a certain</p> <p>19 viscosity, sir, and I am just trying to</p> <p>20 understand whether you appreciate that the</p> <p>21 viscosity limitation is only to the syrup</p> <p>22 formulation, correct, sir?</p> <p>23     A.    I understand that.</p> <p>24     Q.    And the viscosity limitation is</p> <p>25 not to viscosity of the agave syrup,</p> | <p style="text-align: right;">Page 41</p> <p>1           BERKLAND</p> <p>2 formulation of claim 1, right, sir?</p> <p>3     A.    But it is the only syrup in the</p> <p>4 formulation, so what I'm trying to</p> <p>5 communicate is that the POSA would</p> <p>6 understand agave syrup has to be the syrup</p> <p>7 in a pharmaceutical syrup formulation.</p> <p>8     Q.    Sir, your view is that agave</p> <p>9 syrup needs to be part of the formulation,</p> <p>10 right, sir?</p> <p>11     A.    Yes.</p> <p>12     Q.    But when we're looking at the</p> <p>13 viscosity, we're looking at the viscosity</p> <p>14 of the formulation as opposed to the</p> <p>15 viscosity of the agave syrup, correct,</p> <p>16 sir?</p> <p>17     A.    Yes, I understand that.</p> <p>18     Q.    And so if you could go to</p> <p>19 column 2, and you see around line 9 it</p> <p>20 says, "The term 'syrup' means a</p> <p>21 formulation that has a flow without</p> <p>22 applied pressures and is sticky or tacky</p> <p>23 to the touch," do you see that, sir?</p> <p>24     A.    Yes.</p> <p>25     Q.    And you understand that</p> |

11 (Pages 38 - 41)

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| <p style="text-align: right;">Page 42</p> <p>1           BERKLAND</p> <p>2 definition is separate from the definition</p> <p>3 of the agave syrup that's above, correct,</p> <p>4 sir?</p> <p>5           MR. PIVOVAR: Objection, form.</p> <p>6     A.     I do, but agave syrup is the</p> <p>7 only syrup in that formulation that would</p> <p>8 be contributing this sticky or tackiness</p> <p>9 to the touch.</p> <p>10    Q.    But just so we're clear, the</p> <p>11 patent is using the term agave syrup and</p> <p>12 it's also using the term syrup separate</p> <p>13 and independent, correct, sir?</p> <p>14       MR. PIVOVAR: Objection, form.</p> <p>15    A.    Yeah, well, I see the term</p> <p>16 agave syrup and pharmaceutical syrup,</p> <p>17 formulation and syrup formulation.</p> <p>18       Syrup is used in a couple of</p> <p>19 different contexts there.</p> <p>20    Q.    And then if you go on in column</p> <p>21 2, it says, "The syrup can have a</p> <p>22 viscosity of the type used with</p> <p>23 pharmaceutical suspensions or syrup</p> <p>24 formulations," do you see that, sir?</p> <p>25    A.    I do.</p>                                     | <p style="text-align: right;">Page 44</p> <p>1           BERKLAND</p> <p>2 form.</p> <p>3     A.     I don't disagree with the</p> <p>4 language in the patent.</p> <p>5     Q.     So you agree that the patent is</p> <p>6 instructing the POSITA that the ranges</p> <p>7 that follow for viscosity are those that</p> <p>8 are used in pharmaceutical suspensions and</p> <p>9 formulations, correct, sir?</p> <p>10    A.    They can be, yeah, it says the</p> <p>11 syrup can have viscosity in those ranges.</p> <p>12    Q.    And do you agree from your</p> <p>13 experience in the pharmaceutical</p> <p>14 formulation that the ranges listed below</p> <p>15 in column 2, lines, say, 13 through 27,</p> <p>16 are viscosity ranges that, as of the time</p> <p>17 of this patent, were used with</p> <p>18 pharmaceutical suspensions and syrup</p> <p>19 formulations?</p> <p>20       MR. PIVOVAR: Objection, form.</p> <p>21    A.    I can agree that the viscosity</p> <p>22 of pharmaceutical suspension products are</p> <p>23 within those ranges often; I cite a couple</p> <p>24 of examples in my report.</p> <p>25    Q.    So the patent at this time, at</p>             |
| <p style="text-align: right;">Page 43</p> <p>1           BERKLAND</p> <p>2     Q.     And then it lists a whole host</p> <p>3 of viscosities, correct, sir?</p> <p>4     A.     I see those, yes, the ranges</p> <p>5 and sort of book-ends.</p> <p>6     Q.     And so the patent is telling a</p> <p>7 POSA that the syrup can have the</p> <p>8 viscosities of the type used in the</p> <p>9 pharmaceutical suspensions and syrup</p> <p>10 formulations and then defines a whole host</p> <p>11 of viscosity ranges, correct?</p> <p>12       MR. PIVOVAR: Objection, form.</p> <p>13    A.    I see that.</p> <p>14    Q.    Do you agree that's how a POSA</p> <p>15 would understand this, sir?</p> <p>16       MR. PIVOVAR: Objection, form.</p> <p>17    A.    I think you just read it, so, I</p> <p>18 mean, I agree that's what it says.</p> <p>19    Q.    What I am asking you, sir, is</p> <p>20 would a POSA reading this understand that</p> <p>21 the viscosity ranges that are listed after</p> <p>22 the first sentence are viscosities of the</p> <p>23 type used in pharmaceutical suspensions or</p> <p>24 syrup formulations?</p> <p>25       MR. PIVOVAR: Objection to</p> | <p style="text-align: right;">Page 45</p> <p>1           BERKLAND</p> <p>2 least with respect to the viscosity</p> <p>3 requirements, was pointing to viscosity</p> <p>4 requirements that were known to be used in</p> <p>5 pharmaceutical suspensions in syrup</p> <p>6 formulations, is that what the patent</p> <p>7 states, sir?</p> <p>8       MR. PIVOVAR: Object to form.</p> <p>9     A.     I don't think it explicitly</p> <p>10 says that or gives citations, but in my</p> <p>11 report, for example, I point to a couple</p> <p>12 that are around 2000 centipoise.</p> <p>13    Q.    And did you see any viscosity</p> <p>14 formulations -- strike that --</p> <p>15 pharmaceutical suspensions and syrup</p> <p>16 formulations that were below 2000, sir?</p> <p>17    A.    Are you asking if I saw those</p> <p>18 in my analysis or in my report or in the</p> <p>19 text here in front of us?</p> <p>20    Q.    Well, in your analysis, are you</p> <p>21 aware of any pharmaceutical formulations</p> <p>22 that existed as of the date of the '795</p> <p>23 patent that would have been below 1500</p> <p>24 centipoise?</p> <p>25       MR. PIVOVAR: Objection, form.</p> |

12 (Pages 42 - 45)

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| <p style="text-align: right;">Page 46</p> <p>1           BERKLAND</p> <p>2    A.    I didn't look, I didn't conduct</p> <p>3    that analysis, but I suspect there were.</p> <p>4    Q.    I think we got a little</p> <p>5    side-tracked initially on this, because I</p> <p>6    had asked you about whether you had done</p> <p>7    an analysis related to Dr. Crowley's --</p> <p>8    strike that -- an analysis of the</p> <p>9    criticism that you had for Dr. Crowley's</p> <p>10   report, do you recall that, sir?</p> <p>11   A.    I recall that discussion.</p> <p>12   Q.    And I believe one of the</p> <p>13   criticisms was related to the citation of</p> <p>14   the viscosity of agave syrup, correct?</p> <p>15   A.    Yes, and I clarified that I</p> <p>16   don't know if it was the citation or</p> <p>17   mistake or if that was his understanding</p> <p>18   of the viscosity or where that came from.</p> <p>19           THE COURT REPORTER: The</p> <p>20   witness all of a sudden sounds echoey; am</p> <p>21   I the only one hearing it?</p> <p>22           MR. NOLAN: I'm hearing it as</p> <p>23   well.</p> <p>24           THE WITNESS: Counsel muted</p> <p>25   now, so we're good.</p> | <p style="text-align: right;">Page 48</p> <p>1           BERKLAND</p> <p>2    you want a little bit and try to come up</p> <p>3    with a list, but I don't recall.</p> <p>4    Q.    Do you recall if you looked at</p> <p>5    Exhibit 1030, and we can add that to the</p> <p>6    Exhibit Share.</p> <p>7    A.    I have that one, just a moment.</p> <p>8           (Witness perusing document.)</p> <p>9    A.    1030 is by Soto?</p> <p>10   Q.    Correct, sir.</p> <p>11   A.    Give me a second, please.</p> <p>12           (Witness perusing document.)</p> <p>13   A.    Yes, I believe I did look at</p> <p>14   this one, at least superficially.</p> <p>15   Q.    And so this report right in its</p> <p>16   abstract talks about the viscosity of</p> <p>17   agave syrup, correct, sir?</p> <p>18   A.    Correct.</p> <p>19   Q.    And so when you were trying to</p> <p>20   review the exhibits to identify the origin</p> <p>21   of the 212 viscosity that Dr. Crowley</p> <p>22   cited for agave syrup, did you look at</p> <p>23   this exhibit, sir?</p> <p>24   A.    I suspect I did, there were so</p> <p>25   many that I don't recall specifically the</p> |
| <p style="text-align: right;">Page 47</p> <p>1           BERKLAND</p> <p>2    Q.    Are you in the same room with</p> <p>3    counsel, sir?</p> <p>4    A.    Yeah, we're across the table.</p> <p>5    Q.    Okay.</p> <p>6           And you stated that you had</p> <p>7    conducted a review of the exhibits</p> <p>8    provided with the petition to try to</p> <p>9    understand the origin of I believe it was</p> <p>10   the 212 centipoise viscosity for agave</p> <p>11   syrup referenced in Dr. Crowley's report?</p> <p>12   A.    Correct.</p> <p>13   Q.    Please describe for me how you</p> <p>14   went about conducting the review of the</p> <p>15   exhibits to Dr. Crowley's report.</p> <p>16   A.    I focused my review on exhibits</p> <p>17   where I knew of a viscosity disclosure and</p> <p>18   then I searched those particular exhibits</p> <p>19   for information on the viscosity of agave.</p> <p>20   Q.    Do you recall which exhibits</p> <p>21   you reviewed?</p> <p>22   A.    There was quite a few, I don't</p> <p>23   recall which ones.</p> <p>24           I'm looking at the 40 plus</p> <p>25   exhibits here, I can pick through them if</p>                                    | <p style="text-align: right;">Page 49</p> <p>1           BERKLAND</p> <p>2    ones that I searched.</p> <p>3    Q.    Do you think you read this</p> <p>4    exhibit, sir?</p> <p>5           MR. PIVOVAR: Objection, form.</p> <p>6    A.    I'm familiar with this exhibit.</p> <p>7    Q.    Did you look at the tables of</p> <p>8    this exhibit, sir?</p> <p>9    A.    I recall reviewing the figures</p> <p>10   and the tables, at least to the extent of</p> <p>11   trying to resolve viscosities.</p> <p>12   Q.    And were you able to resolve</p> <p>13   the issue with Dr. Crowley's citation of</p> <p>14   212 for centipoise for the viscosity of</p> <p>15   agave syrup?</p> <p>16           MR. PIVOVAR: Objection, form.</p> <p>17   A.    At the time I was not able to</p> <p>18   resolve it.</p> <p>19   Q.    Are you able to resolve it now,</p> <p>20   sir?</p> <p>21   A.    Can you point me to a</p> <p>22   particular table you're referencing?</p> <p>23   Q.    Why don't we look at the one</p> <p>24   that talks about physical characteristics</p> <p>25   of syrups, Table 4.</p>                                                                   |

13 (Pages 46 - 49)

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| <p style="text-align: right;">Page 50</p> <p>1           BERKLAND</p> <p>2           (Witness perusing document.)</p> <p>3     A.    Yes, I see it.</p> <p>4     Q.    Does that help you resolve part</p> <p>5 of your criticism to Dr. Crowley's report?</p> <p>6           MR. PIVOVAR: Objection, form.</p> <p>7     A.    I see the 212 for viscosity in</p> <p>8 Table 4, that's the same number that</p> <p>9 Dr. Crowley used.</p> <p>10          I wouldn't be able to tell you</p> <p>11 if he pulled it from this citation or</p> <p>12 others.</p> <p>13    Q.    But you would agree that agave</p> <p>14 syrup has been reported to have a</p> <p>15 viscosity of 212 centipoise, right, sir?</p> <p>16          MR. PIVOVAR: Objection, form.</p> <p>17    A.    As I say in my report, agave</p> <p>18 syrup comes in a variety of grades and</p> <p>19 from a number of resources and they can</p> <p>20 have a range of viscosities.</p> <p>21          But I do see in this particular</p> <p>22 exhibit the agave syrup they used is</p> <p>23 reported to have a viscosity of 212</p> <p>24 centipoise.</p> <p>25    Q.    Do you agree that the viscosity</p> | <p style="text-align: right;">Page 52</p> <p>1           BERKLAND</p> <p>2 on that exhibit number, sir.</p> <p>3     A.    I'm there.</p> <p>4     Q.    You see it talks about the</p> <p>5 physical characterization of the syrups?</p> <p>6     A.    Yes.</p> <p>7     Q.    You see the first full</p> <p>8 paragraph, it says, "Both surface tension</p> <p>9 and viscosity of the syrup depend on the</p> <p>10 fructose and glucose content and as a</p> <p>11 result of the higher content of glucose,</p> <p>12 both properties were higher in corn</p> <p>13 syrup," do you see that?</p> <p>14    A.    I see it.</p> <p>15    Q.    If you go further down on that</p> <p>16 paragraph, it talks about the impact of</p> <p>17 fructose and glucose and fructose</p> <p>18 combinations and sucrose on viscosity,</p> <p>19 sir.</p> <p>20          MR. PIVOVAR: Objection to</p> <p>21 form.</p> <p>22    A.    I see that.</p> <p>23    Q.    Just so we're clear, I'm</p> <p>24 talking about the sentence that starts</p> <p>25 "these results are consistent with those</p>                                                                                                                                                                  |
| <p style="text-align: right;">Page 51</p> <p>1           BERKLAND</p> <p>2 of the agave syrup will be affected by the</p> <p>3 types of sugar that are in that agave</p> <p>4 syrup?</p> <p>5          MR. PIVOVAR: Objection to</p> <p>6 form.</p> <p>7     A.    It can be.</p> <p>8     Q.    And how can it be affected by</p> <p>9 the type of sugar that's in the agave</p> <p>10 syrup?</p> <p>11    A.    Just a moment.</p> <p>12          (Witness perusing document.)</p> <p>13    A.    Factors like the types of</p> <p>14 sugars and the ratios of those sugars and</p> <p>15 the concentration of those sugars, for</p> <p>16 example, can contribute to viscosity.</p> <p>17    Q.    So, for example, higher</p> <p>18 fructose content may result in a lower</p> <p>19 viscosity for the agave syrup, correct?</p> <p>20          MR. PIVOVAR: Objection to</p> <p>21 form.</p> <p>22    A.    You would have to point me to</p> <p>23 that.</p> <p>24    Q.    Why don't we stay with Exhibit</p> <p>25 1030 and I can direct you to page 5 of 7</p>                                                                                                             | <p style="text-align: right;">Page 53</p> <p>1           BERKLAND</p> <p>2 reported," and this is on Exhibit 1030,</p> <p>3 page 5 of 7 on the bottom right; are you</p> <p>4 looking at the same text, sir?</p> <p>5     A.    I am.</p> <p>6     Q.    And do you agree that the</p> <p>7 percentage of fructose in agave syrup will</p> <p>8 affect the viscosity?</p> <p>9          MR. PIVOVAR: Objection, form.</p> <p>10          (Witness perusing document.)</p> <p>11    A.    I don't think it's quite that</p> <p>12 simple since there's a variety of factors</p> <p>13 that contribute to viscosity, we can't say</p> <p>14 that just increasing the fructose content</p> <p>15 will result in an increase in viscosity,</p> <p>16 especially if the comparison is between</p> <p>17 agave and corn syrup or frudex.</p> <p>18    Q.    Do you agree with the statement</p> <p>19 that "The viscosity of the syrup depends</p> <p>20 on the type of sugar, this viscosity being</p> <p>21 lower in fructose syrup, followed in</p> <p>22 ascending order by the invert sugar syrup</p> <p>23 (50 glucose and 50 percent fructose) and</p> <p>24 then by sucrose syrups and finally glucose</p> <p>25 syrups, whose viscosity was much higher</p> |

14 (Pages 50 - 53)

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| <p style="text-align: right;">Page 54</p> <p>1           BERKLAND</p> <p>2 than everyone else," do you see that, sir?</p> <p>3           MR. PIVOVAR: Objection to</p> <p>4 form.</p> <p>5     A.    I do see that.</p> <p>6     Q.    Do you agree with that</p> <p>7 statement, sir?</p> <p>8           MR. PIVOVAR: Objection to</p> <p>9 form.</p> <p>10    A.    The authors do state fructose</p> <p>11 is a contributor, the fructose content,</p> <p>12 but then in the remainder of that</p> <p>13 paragraph they talk about other</p> <p>14 differences, the way the extraction is</p> <p>15 done, there could be maillard differences.</p> <p>16           Anyway, the extraction process,</p> <p>17 the preparation of the syrup, led to</p> <p>18 differences in colors, differences in</p> <p>19 other things that are present in the</p> <p>20 syrup.</p> <p>21           In this section they're</p> <p>22 comparing the fructan content, but other</p> <p>23 things are changing.</p> <p>24    Q.    I am asking you, sir, whether</p> <p>25 you agree or disagree with the statement</p>                                                      | <p style="text-align: right;">Page 56</p> <p>1           BERKLAND</p> <p>2 was fructose and in another all the sugar</p> <p>3 was glucose, would you expect those to</p> <p>4 have the same viscosity?</p> <p>5           MR. PIVOVAR: Objection to</p> <p>6 form.</p> <p>7     A.    The concentrations of the</p> <p>8 sugars are the same and so forth?</p> <p>9     Q.    Everything is the same.</p> <p>10    A.    I don't recall.</p> <p>11           I know some of the sugars are</p> <p>12 very close to the same and some have</p> <p>13 differences, but I don't recall sitting</p> <p>14 here which one of them is more viscous as</p> <p>15 a pure solution versus the other.</p> <p>16    Q.    Have you ever heard the term</p> <p>17 brix, B-R-I-X?</p> <p>18    A.    You might have to give me some</p> <p>19 context, I'm not sure.</p> <p>20    Q.    Well, if you look Exhibit 1030,</p> <p>21 and we can stay on page 5 of 7 at the top,</p> <p>22 maybe that will give you some context when</p> <p>23 we talk about the chemical</p> <p>24 characterizations of the syrups, you can</p> <p>25 also look at Table 4, sir, of the same</p> |
| <p style="text-align: right;">Page 55</p> <p>1           BERKLAND</p> <p>2 that the article makes.</p> <p>3           MR. PIVOVAR: Objection to</p> <p>4 form.</p> <p>5     A.    And my answer is I believe in</p> <p>6 that comparison the authors are sort of</p> <p>7 setting aside the other differences in</p> <p>8 making the observation that the fructose</p> <p>9 content does have an effect on viscosity.</p> <p>10    Q.    And do you agree that the</p> <p>11 fructose content's effect would tend to</p> <p>12 lower viscosity relative to glucose and</p> <p>13 sucrose?</p> <p>14           MR. PIVOVAR: Objection, form.</p> <p>15    A.    It's really hard to tell from</p> <p>16 this one cite and the reason is because</p> <p>17 natural products like these tend to have a</p> <p>18 lot of variability.</p> <p>19           There are many other</p> <p>20 differences besides just the fructose</p> <p>21 contribution.</p> <p>22    Q.    I'm asking you from your</p> <p>23 experience; if you had two pharmaceutical</p> <p>24 formulations that were identical, with the</p> <p>25 exception of in one you had all the sugar</p> | <p style="text-align: right;">Page 57</p> <p>1           BERKLAND</p> <p>2 exhibit.</p> <p>3           (Witness perusing document.)</p> <p>4     A.    I don't see brix in Table 4 --</p> <p>5 oh, are you referring to the soluble</p> <p>6 solids and then there is a unit?</p> <p>7     Q.    Yes, sir.</p> <p>8     A.    I see it.</p> <p>9     Q.    Have you ever heard of that</p> <p>10 unit beforehand, sir?</p> <p>11    A.    Maybe a long time ago, it</p> <p>12 sounds familiar, but I'm having trouble</p> <p>13 placing it in time.</p> <p>14    Q.    In reading the various exhibits</p> <p>15 for your declaration, did you come across</p> <p>16 discussions of brix at any time?</p> <p>17    A.    I think I have, but it didn't</p> <p>18 use that term.</p> <p>19    Q.    Do you have an understanding of</p> <p>20 whether or not the brix content of agave</p> <p>21 syrup will affect viscosity of the agave</p> <p>22 syrup?</p> <p>23           MR. PIVOVAR: Objection to</p> <p>24 form.</p> <p>25    A.    At least in this study it looks</p>                                                                                    |

15 (Pages 54 - 57)

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| <p style="text-align: right;">Page 58</p> <p>1           BERKLAND</p> <p>2 like they've controlled for it, so the</p> <p>3 soluble solids --</p> <p>4           THE WITNESS: You might have to</p> <p>5 mute, counsel.</p> <p>6           Thank you.</p> <p>7     A.     -- so the soluble solids in</p> <p>8 the top line of Table 4 are both showing a</p> <p>9 brix value of 70.</p> <p>10    Q.    And I'm just trying to</p> <p>11 understand from your expert perspective,</p> <p>12 does the brix content of an agave syrup</p> <p>13 affect the viscosity of the agave syrup?</p> <p>14       MR. PIVOVAR: Objection to</p> <p>15 form.</p> <p>16    A.    It should, because the brix is</p> <p>17 the soluble solids content and the counter</p> <p>18 to that is akin to the moisture content,</p> <p>19 and so it's almost -- the analog in my</p> <p>20 mind is concentration and concentration</p> <p>21 can affect viscosity of course.</p> <p>22    Q.    Would you expect a higher brix</p> <p>23 content to result in a higher viscosity?</p> <p>24       MR. PIVOVAR: Objection to</p> <p>25 form.</p> | <p style="text-align: right;">Page 60</p> <p>1           BERKLAND</p> <p>2     Q.    And would you expect that it</p> <p>3 could end up in a lower viscosity --</p> <p>4 strike that.</p> <p>5       Can you provide an instance</p> <p>6 where you think it would end up in a lower</p> <p>7 viscosity if you increase the brix level.</p> <p>8       MR. PIVOVAR: Objection to</p> <p>9 form.</p> <p>10    A.    This is obviously an incomplete</p> <p>11 hypothetical, but if you remove moisture</p> <p>12 to the extent that you just have a lot of</p> <p>13 solids, I suppose there's a possibility</p> <p>14 viscosity could go down.</p> <p>15       It's almost like viscosity</p> <p>16 isn't as relevant as you go more towards a</p> <p>17 solid and remove moisture.</p> <p>18       So I'm having a dilemma here in</p> <p>19 terms of answering your question.</p> <p>20    Q.    But when you remove moisture,</p> <p>21 wouldn't you be increasing the brix</p> <p>22 content, sir, because isn't -- the brix</p> <p>23 content is a soluble and then there is a</p> <p>24 moisture content, correct, sir?</p> <p>25       MR. PIVOVAR: Object to form.</p> |
| <p style="text-align: right;">Page 59</p> <p>1           BERKLAND</p> <p>2     A.    I can think of in both</p> <p>3 instances the instances where it would and</p> <p>4 instances where it wouldn't.</p> <p>5     Q.    Give me an instance where it</p> <p>6 would impact viscosity by resulting in a</p> <p>7 higher viscosity.</p> <p>8     A.    That feels like a difficult</p> <p>9 hypothetical; maybe you can help me narrow</p> <p>10 it down.</p> <p>11    Q.    Let's talk about it in the</p> <p>12 context of agave syrup.</p> <p>13       So if we're using the same</p> <p>14 percentage of sugar content in that agave</p> <p>15 syrup, would you expect the -- by</p> <p>16 percentage of sugar, I mean percentage</p> <p>17 between fructose and sucrose and glucose</p> <p>18 -- would you expect a higher brix content</p> <p>19 to result in a higher viscosity of the</p> <p>20 agave syrup?</p> <p>21       MR. PIVOVAR: Objection to</p> <p>22 form.</p> <p>23    A.    It could very well, it depends</p> <p>24 if those solids are dissolving or</p> <p>25 interacting in some way.</p>        | <p style="text-align: right;">Page 61</p> <p>1           BERKLAND</p> <p>2     A.    That's reasonably right, yes.</p> <p>3     Q.    And so if you remove moisture,</p> <p>4 you wouldn't be decreasing the brix</p> <p>5 content in your response, correct, sir?</p> <p>6     A.    I thought we were talking about</p> <p>7 viscosity.</p> <p>8     Q.    No, but what I am asking you</p> <p>9 is, I've asked you for an instance in</p> <p>10 which you think if you lowered the brix</p> <p>11 content that would result in an increased</p> <p>12 viscosity and your response was if you</p> <p>13 change the moisture content.</p> <p>14       I am just trying to understand</p> <p>15 your response to that, sir.</p> <p>16       MR. PIVOVAR: Objection to</p> <p>17 form.</p> <p>18    A.    In this hypothetical, I</p> <p>19 properly or improperly, I'm kind of</p> <p>20 anchoring on Table 3 and in that</p> <p>21 application --</p> <p>22       THE WITNESS: I'm getting</p> <p>23 feedback again, Adam, sorry.</p> <p>24    A.    -- looking at that table,</p> <p>25 they're adjusting the moisture and it</p>                                            |

16 (Pages 58 - 61)

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| <p style="text-align: right;">Page 62</p> <p>1           BERKLAND</p> <p>2 doesn't sound like you are in your</p> <p>3 hypothetical, is that correct?</p> <p>4     Q.    No, I think if we look at, for</p> <p>5 completeness, Exhibit 1030, page 5 of 7,</p> <p>6 it says, "Since the content of soluble</p> <p>7 solids in syrups was previously adjusted</p> <p>8 to 70 percent brix, in this way the</p> <p>9 moisture content of 30 was also adjusted,"</p> <p>10 so it's coming up to a hundred percent,</p> <p>11 right, sir?</p> <p>12    A.    I think that's correct, it says</p> <p>13 Table 3 in parenthesis and that's why I</p> <p>14 was trying to resolve this with Table 3.</p> <p>15    Q.    Do you see the humidity</p> <p>16 percentage of 30 percent is the same for</p> <p>17 both, sir?</p> <p>18    A.    Yes.</p> <p>19    Q.    And you see on Table 4 the</p> <p>20 solid percent of 70 percent is the same</p> <p>21 for both, sir?</p> <p>22    A.    I see that.</p> <p>23    Q.    And I am just asking you, would</p> <p>24 you expect the viscosity of either of</p> <p>25 these components, the frudex of 55 or the</p>                 | <p style="text-align: right;">Page 64</p> <p>1           BERKLAND</p> <p>2 the only thing changing in this particular</p> <p>3 example from Exhibit 1030.</p> <p>4           To extrapolate that to other</p> <p>5 situations would require a new framework</p> <p>6 of variables or assumptions.</p> <p>7     Q.    Are you agreeing or disagreeing</p> <p>8 with my statement, sir?</p> <p>9     A.    Maybe you can --</p> <p>10          MR. PIVOVAR: Objection -- go</p> <p>11 ahead.</p> <p>12    A.    Can you offer the statement</p> <p>13 again, please.</p> <p>14    Q.    In general, if you increase the</p> <p>15 solid component of a syrup and decrease</p> <p>16 the moisture component, would you expect</p> <p>17 the viscosity to increase?</p> <p>18          MR. PIVOVAR: Objection, form.</p> <p>19    A.    And I believe my answer was</p> <p>20 that you might expect the viscosity to</p> <p>21 increase as moisture content goes down.</p> <p>22          However, I provided a couple of</p> <p>23 my assumptions that are baked into that,</p> <p>24 one of which is that something doesn't</p> <p>25 happen with the solids, for example, you</p> |
| <p style="text-align: right;">Page 63</p> <p>1           BERKLAND</p> <p>2 agave syrup, to decrease if you change the</p> <p>3 soluble solids to 75 percent and the</p> <p>4 humidity to 25 percent?</p> <p>5          MR. PIVOVAR: Objection to</p> <p>6 form.</p> <p>7     A.    Less water or less moisture</p> <p>8 would seemingly increase the viscosity,</p> <p>9 but that assumes that the soluble solids</p> <p>10 are still soluble and we don't know that.</p> <p>11          In other words, as you decrease</p> <p>12 the water, the moisture content by 5</p> <p>13 percent, you might be having more of a</p> <p>14 portion of it be a powder-like consistency</p> <p>15 or particulate.</p> <p>16          It can do weird things when</p> <p>17 you're making viscometry measurements.</p> <p>18    Q.    But you would agree in general</p> <p>19 as you reduce the water content, the</p> <p>20 viscosity -- strike that.</p> <p>21          Would you agree in general if</p> <p>22 you increase the solid content and reduce</p> <p>23 the water content, the viscosity will</p> <p>24 increase?</p> <p>25    A.    You're cabining this to being</p> | <p style="text-align: right;">Page 65</p> <p>1           BERKLAND</p> <p>2 have more powder-like properties and less</p> <p>3 fluid-like properties because you've</p> <p>4 removed enough water or moisture to change</p> <p>5 the system and then you can get straight</p> <p>6 rheological effects.</p> <p>7     Q.    I think we have been going for</p> <p>8 a little under 90 minutes, why don't we</p> <p>9 take a break if that works for you, sir.</p> <p>10    A.    That would be fine.</p> <p>11          (Recess taken.)</p> <p>12 BY MR. NOLAN:</p> <p>13    Q.    Dr. Berkland, you had mentioned</p> <p>14 that you had looked at certain parts of</p> <p>15 the prosecution history, is that fair to</p> <p>16 state?</p> <p>17    A.    Yes.</p> <p>18    Q.    I'd like to direct your</p> <p>19 attention to Exhibit 1001, sir, do you</p> <p>20 have that?</p> <p>21    A.    I do.</p> <p>22    Q.    The '795 patent.</p> <p>23    A.    Please give me just a moment to</p> <p>24 flip all the way back to it.</p> <p>25          (Pause.)</p>                                                                                                           |

17 (Pages 62 - 65)

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| <p style="text-align: right;">Page 66</p> <p>1 BERKLAND</p> <p>2 Q. You can tell me when you're</p> <p>3 ready.</p> <p>4 A. I'm ready.</p> <p>5 Q. If you look at the first page</p> <p>6 it talks about related U.S. application</p> <p>7 data?</p> <p>8 A. Can you point me to that.</p> <p>9 Q. On the first page, on the left,</p> <p>10 there should be a heading that says</p> <p>11 "Related U.S. Application Data."</p> <p>12 A. I see it now.</p> <p>13 Q. It states, "Continuation of</p> <p>14 Application No. 17/342,414, filed on June</p> <p>15 8, 2021, which is a continuation-in-part</p> <p>16 of Application No. 16/827,529, filed on</p> <p>17 March 23, 2020."</p> <p>18 Do you see that, sir?</p> <p>19 A. I do.</p> <p>20 Q. Do you have an understanding of</p> <p>21 the terminology continuation-in-part?</p> <p>22 A. Yes.</p> <p>23 Q. What is your understanding?</p> <p>24 A. You can correct me if I get</p> <p>25 this wrong, but this would be continuing</p>                                                                                                                                                                            | <p style="text-align: right;">Page 68</p> <p>1 BERKLAND</p> <p>2 A. Just a moment.</p> <p>3 (Witness perusing document.)</p> <p>4 A. I don't recall seeing that in</p> <p>5 the petition nor any of the documents I</p> <p>6 reviewed, I was focused on the technical</p> <p>7 subject matter.</p> <p>8 Q. Dr. Berkland, do you understand</p> <p>9 that the original application that's</p> <p>10 listed on Exhibit 1001, that's at the</p> <p>11 bottom of related U.S. application,</p> <p>12 specifically Application No. 15/912,785,</p> <p>13 did not include a discussion of any</p> <p>14 viscosity parameters for the formulation,</p> <p>15 sir?</p> <p>16 MR. PIVOVAR: Objection, form.</p> <p>17 A. I don't recall having reviewed</p> <p>18 that.</p> <p>19 Q. And do you know if that</p> <p>20 application included any information about</p> <p>21 using acetaminophen in a formulation, sir?</p> <p>22 MR. PIVOVAR: Objection, form.</p> <p>23 A. It's been a while since I</p> <p>24 looked, I don't recall.</p> <p>25 Q. If you look at your report,</p> |
| <p style="text-align: right;">Page 67</p> <p>1 BERKLAND</p> <p>2 the same original filing typically with</p> <p>3 largely the same specification, if not</p> <p>4 completely the same specification, and</p> <p>5 pursuing different or additional claims.</p> <p>6 Q. So that's your understanding of</p> <p>7 the terminology continuation-in-part, sir?</p> <p>8 A. That's at least part of my</p> <p>9 understanding.</p> <p>10 Q. Do you understand that there is</p> <p>11 a difference between an application that's</p> <p>12 called a continuation and an application</p> <p>13 that's called a continuation-in-part?</p> <p>14 A. I am not aware of the legal</p> <p>15 distinction for that.</p> <p>16 Q. Do you understand that a</p> <p>17 continuation-in-part is an application in</p> <p>18 which an applicant has added additional</p> <p>19 materials to the specification, sir?</p> <p>20 MR. PIVOVAR: Objection, form.</p> <p>21 A. If that's what you're</p> <p>22 representing, I can accept that.</p> <p>23 Q. Have you conducted an analysis</p> <p>24 of what the earliest priority date that</p> <p>25 the '795 application is entitled to?</p> | <p style="text-align: right;">Page 69</p> <p>1 BERKLAND</p> <p>2 Exhibit 2009, paragraph 56, sir, can you</p> <p>3 turn to that.</p> <p>4 (Witness complying.)</p> <p>5 A. Okay.</p> <p>6 Q. You see that you discuss the</p> <p>7 various related U.S. applications, at</p> <p>8 least list them here, sir, correct?</p> <p>9 MR. PIVOVAR: Objection, form.</p> <p>10 (Witness perusing document.)</p> <p>11 A. Yes, I at least list them</p> <p>12 there.</p> <p>13 Q. As part of your analysis to</p> <p>14 understand the earliest filing date</p> <p>15 associated with the '795, did you compare</p> <p>16 the content of Application No. 16/827,529,</p> <p>17 with the content of the application that's</p> <p>18 No. 15,912,785?</p> <p>19 MR. PIVOVAR: Objection to</p> <p>20 form.</p> <p>21 A. I didn't conduct that analysis.</p> <p>22 Q. Did you look back to the</p> <p>23 exhibits cited associated with the</p> <p>24 petition, sir?</p> <p>25 A. I recall at least seeing them.</p>                                                                     |

18 (Pages 66 - 69)

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| <p style="text-align: right;">Page 70</p> <p>1 BERKLAND</p> <p>2 Q. Did you look at Exhibit 1011,</p> <p>3 sir?</p> <p>4 MR. PIVOVAR: Objection, form.</p> <p>5 A. It's in my binder, if you give</p> <p>6 me a moment.</p> <p>7 (Pause.)</p> <p>8 A. I have it.</p> <p>9 Q. Do you know what that document</p> <p>10 is?</p> <p>11 MR. PIVOVAR: Objection, form.</p> <p>12 (Witness perusing document.)</p> <p>13 MR. PIVOVAR: Brian, what</p> <p>14 exhibit are we on?</p> <p>15 MR. NOLAN: This is Exhibit</p> <p>16 1011, sir.</p> <p>17 MR. PIVOVAR: Thank you.</p> <p>18 (Witness perusing document.)</p> <p>19 A. I might have to go to the</p> <p>20 citation of this exhibit to better</p> <p>21 understand what it is, it looks like a</p> <p>22 portion of the filing history.</p> <p>23 Q. Sir, why don't you look at</p> <p>24 Exhibit 1010, sir.</p> <p>25 A. Okay.</p>                                                                                             | <p style="text-align: right;">Page 72</p> <p>1 BERKLAND</p> <p>2 A. Down at the bottom, yes.</p> <p>3 Q. If you just read that</p> <p>4 paragraph, sir, do you understand that it</p> <p>5 is disclosing a viscosity of less than</p> <p>6 1500 centipoise at 22 degrees?</p> <p>7 (Witness perusing document.)</p> <p>8 A. I see that disclosure.</p> <p>9 Q. Do you know if that disclosure</p> <p>10 was in any of the earlier applications,</p> <p>11 sir?</p> <p>12 MR. PIVOVAR: Objection to</p> <p>13 form.</p> <p>14 A. I can't recall from memory</p> <p>15 sitting here.</p> <p>16 Q. Just quickly, it says 22</p> <p>17 degrees; do you know if that's Celsius or</p> <p>18 Fahrenheit?</p> <p>19 MR. PIVOVAR: Objection to</p> <p>20 form.</p> <p>21 A. It would be understood to be</p> <p>22 Celsius.</p> <p>23 Q. Why would it be understood to</p> <p>24 be Celsius?</p> <p>25 A. It is an approximation of room</p>                                            |
| <p style="text-align: right;">Page 71</p> <p>1 BERKLAND</p> <p>2 Q. Do you understand that this is</p> <p>3 from application 17/342,414, that</p> <p>4 application, sir?</p> <p>5 A. I see that application number</p> <p>6 in the upper left-hand corner.</p> <p>7 Q. And you see that if you go to</p> <p>8 page 3 of 38 of this, sir.</p> <p>9 A. Sorry, which page?</p> <p>10 Q. Exhibit 1010, page 3 of 38.</p> <p>11 A. Yes.</p> <p>12 Q. And you see that it says</p> <p>13 "domestic priority date" -- excuse me,</p> <p>14 "domestic priority data as claimed by</p> <p>15 applicant"?</p> <p>16 A. I see it.</p> <p>17 Q. It says, "This application is a</p> <p>18 CIP of 16/827,529 from March 23, 2022," do</p> <p>19 you see that, sir?</p> <p>20 A. Yes.</p> <p>21 Q. And then if you can turn to</p> <p>22 page 18 of 38 of Exhibit 1010.</p> <p>23 A. Okay.</p> <p>24 Q. Do you see in the summary there</p> <p>25 is a paragraph that's identified as 0005?</p> | <p style="text-align: right;">Page 73</p> <p>1 BERKLAND</p> <p>2 temperature.</p> <p>3 Q. But you agree that oftentimes</p> <p>4 it's appropriate to write the measurement</p> <p>5 that you're using here, right, sir?</p> <p>6 MR. PIVOVAR: Objection to</p> <p>7 form.</p> <p>8 A. That would be a little clearer.</p> <p>9 Q. When you draft things, do you</p> <p>10 normally leave out the Celsius or</p> <p>11 Fahrenheit?</p> <p>12 MR. PIVOVAR: Objection to</p> <p>13 form.</p> <p>14 A. I would normally include the</p> <p>15 units, but I understand here what 22</p> <p>16 degrees means and I believe a POSA would</p> <p>17 as well.</p> <p>18 Q. If you go down on page 19 of</p> <p>19 Exhibit 1010, you see the paragraph that's</p> <p>20 identified as 0009, sir?</p> <p>21 A. I see it.</p> <p>22 Q. Do you see that this paragraph</p> <p>23 discusses potential active ingredients?</p> <p>24 (Witness perusing document.)</p> <p>25 A. I see that.</p> |

19 (Pages 70 - 73)

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| <p style="text-align: right;">Page 74</p> <p>1 BERKLAND</p> <p>2 Q. Do those active ingredients</p> <p>3 include acetaminophen?</p> <p>4 A. I see acetaminophen on the</p> <p>5 list.</p> <p>6 Q. What I'm asking you, sir, the</p> <p>7 applications that were filed before this</p> <p>8 application, do they include any</p> <p>9 disclosure of the viscosity range that we</p> <p>10 just discussed for active ingredients</p> <p>11 including acetaminophen as being part of</p> <p>12 the pharmaceutical formulation?</p> <p>13 MR. PIVOVAR: Objection to</p> <p>14 form.</p> <p>15 A. I haven't reviewed that, I</p> <p>16 assume it is a factual matter, but I</p> <p>17 haven't reviewed it.</p> <p>18 Q. Do you --</p> <p>19 A. At least, sorry, let me</p> <p>20 clarify, I can't recall.</p> <p>21 Q. If you go back to your Exhibit</p> <p>22 2009, paragraph 56, do you see that, sir?</p> <p>23 A. Just a moment.</p> <p>24 (Pause.)</p> <p>25 A. Okay.</p>                                                                                                                                          | <p style="text-align: right;">Page 76</p> <p>1 BERKLAND</p> <p>2 but at least as it stands today, that's</p> <p>3 the date of my assumption.</p> <p>4 Q. But I am asking you, did you</p> <p>5 review the file history to determine if</p> <p>6 there would be any basis to allege that</p> <p>7 the accused claims are entitled to a</p> <p>8 priority date earlier than June 8, 2021?</p> <p>9 MR. PIVOVAR: Objection, form.</p> <p>10 A. I didn't conduct that analysis.</p> <p>11 Q. Was there anything preventing</p> <p>12 you from conducting that analysis and</p> <p>13 including it in your opening report?</p> <p>14 MR. PIVOVAR: Objection to</p> <p>15 form.</p> <p>16 A. I am not sure what you mean if</p> <p>17 there is anything preventing.</p> <p>18 Q. I said was there anything</p> <p>19 preventing you from doing that in your</p> <p>20 opening report?</p> <p>21 MR. PIVOVAR: Objection to</p> <p>22 form.</p> <p>23 A. I didn't see a reason to do so.</p> <p>24 Q. Do you have Dr. Crowley's</p> <p>25 expert report, Exhibit 1003, sir?</p> |
| <p style="text-align: right;">Page 75</p> <p>1 BERKLAND</p> <p>2 Q. Do you see the last line you</p> <p>3 say "I understand Genexa contents that</p> <p>4 each accused claim has a priority date at</p> <p>5 least as early as June 8, 2021," do you</p> <p>6 see that, sir?</p> <p>7 A. That should probably be</p> <p>8 "contends," but, yes, I see that line.</p> <p>9 Q. You used the term "at least as</p> <p>10 early as," do you see that, sir?</p> <p>11 MR. PIVOVAR: Object to form.</p> <p>12 A. I see that.</p> <p>13 Q. Do you intend to give any</p> <p>14 testimony that the asserted accused claims</p> <p>15 of the '795 patent are entitled to a</p> <p>16 priority date that is earlier than June 8,</p> <p>17 2021?</p> <p>18 MR. PIVOVAR: Objection to</p> <p>19 form, beyond scope.</p> <p>20 A. I state back in paragraph 19</p> <p>21 when defining a person of ordinary skill</p> <p>22 in the art that I used June 8th, 2021, as</p> <p>23 the date, and it is an assumption; if</p> <p>24 something else comes up that I need to</p> <p>25 evaluate, perhaps I would change the date,</p> | <p style="text-align: right;">Page 77</p> <p>1 BERKLAND</p> <p>2 A. I do.</p> <p>3 Would you like me to go to it?</p> <p>4 Q. Yes, can you, sir.</p> <p>5 (Witness complying.)</p> <p>6 A. I have it.</p> <p>7 Q. Can you turn to page 21 of that</p> <p>8 report, sir.</p> <p>9 A. I'm there.</p> <p>10 Q. You see there is a section in</p> <p>11 this report that says "the priority date</p> <p>12 to which the '795 patent is entitled"?</p> <p>13 A. I see that title.</p> <p>14 Q. Did you review this when you</p> <p>15 reviewed Dr. Crowley's declaration?</p> <p>16 A. I recall reading this.</p> <p>17 Q. And you did not provide any</p> <p>18 testimony in your expert report to address</p> <p>19 Dr. Crowley's opinion here, correct, sir?</p> <p>20 MR. PIVOVAR: Objection.</p> <p>21 A. I mean, ultimately we both</p> <p>22 state June 8, 2021, so I'm not sure what I</p> <p>23 would contend.</p> <p>24 Q. You used some language that</p> <p>25 said at least as early as.</p>                                                                    |

20 (Pages 74 - 77)

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| <p style="text-align: right;">Page 78</p> <p>1           BERKLAND</p> <p>2           So to the extent that you</p> <p>3 intend to provide testimony that it is</p> <p>4 entitled to a date before June 8, 2021,</p> <p>5 what is your basis for that position?</p> <p>6           MR. PIVOVAR: Objection to</p> <p>7 form.</p> <p>8           And, counsel, just to help you</p> <p>9 out here, at what point in this proceeding</p> <p>10 are you worried about Dr. Berkland giving</p> <p>11 additional testimony, I'm confused?</p> <p>12           MR. NOLAN: I just want to make</p> <p>13 sure that at some point we're not going to</p> <p>14 get an opposition that says it's not</p> <p>15 entitled to the earlier priority date,</p> <p>16 sir.</p> <p>17           He used the term "at least as,"</p> <p>18 which gives him room to change his</p> <p>19 testimony and so I want to explore that.</p> <p>20           MR. PIVOVAR: It is not in</p> <p>21 dispute, this is a waste of time.</p> <p>22           But, look, you have been doing</p> <p>23 it, it is fine, but this isn't an issue</p> <p>24 that's in dispute in this proceeding --</p> <p>25           MR. NOLAN: That's fine, if</p> | <p style="text-align: right;">Page 80</p> <p>1           BERKLAND</p> <p>2           Q.   Dr. Crowley, I would like to</p> <p>3 direct you to your Exhibit 2020, sir.</p> <p>4           A.   You said Dr. Crowley, so I got</p> <p>5 confused.</p> <p>6           Q.   Dr. Berkland, my apologies,</p> <p>7 Dr. Berkland, I would like to direct you</p> <p>8 to your Exhibit 2020.</p> <p>9           A.   Okay, give me just a moment to</p> <p>10 flip to it, please.</p> <p>11           Q.   Take your time.</p> <p>12           (Witness complying.)</p> <p>13           A.   Okay.</p> <p>14           Q.   I believe you cited this</p> <p>15 document to point to certain viscosities</p> <p>16 of existing pharmaceutical formulation, is</p> <p>17 that fair?</p> <p>18           A.   I would have to go back to my</p> <p>19 report to see how I rely on this document,</p> <p>20 I can't recall all the citations from my</p> <p>21 report.</p> <p>22           Q.   If you look at the abstract of</p> <p>23 Exhibit 2020, you see that it discusses</p> <p>24 the viscosity range of various of the</p> <p>25 pediatric liquid medicines in this</p> |
| <p style="text-align: right;">Page 79</p> <p>1           BERKLAND</p> <p>2 you're going to represent that you're not</p> <p>3 going to challenge the earliest priority</p> <p>4 date for this application is the June 8th,</p> <p>5 2021, date, I can move on, but that's not</p> <p>6 how you drafted his declaration.</p> <p>7           MR. PIVOVAR: We haven't</p> <p>8 challenged that at all, but that's fine, I</p> <p>9 understand where you're trying to go with</p> <p>10 this.</p> <p>11           It just seems like everybody</p> <p>12 agrees the operative date is June 8, 2021,</p> <p>13 for this proceeding.</p> <p>14           MR. NOLAN: That's fine and we</p> <p>15 can move on.</p> <p>16           I just didn't want to have</p> <p>17 something pop up later with that.</p> <p>18           So with your representation,</p> <p>19 that June 8th, 2021, is the priority date</p> <p>20 for the claims of the '795 patent, we can</p> <p>21 proceed.</p> <p>22           MR. PIVOVAR: Yes, and I'm</p> <p>23 saying we're not challenging that issue</p> <p>24 here now because we don't have to, not</p> <p>25 that we are forever agreeing on that.</p>                               | <p style="text-align: right;">Page 81</p> <p>1           BERKLAND</p> <p>2 article?</p> <p>3           A.   Yes.</p> <p>4           Q.   What viscosity range does it</p> <p>5 discuss for the pediatric medicines in</p> <p>6 this article?</p> <p>7           (Witness perusing document.)</p> <p>8           A.   In this particular article,</p> <p>9 they evaluate a handful of pediatric</p> <p>10 liquid medicaments and they list the range</p> <p>11 of 307.33 centipoise to 2408.33</p> <p>12 centipoise.</p> <p>13           THE WITNESS: We're getting a</p> <p>14 little feedback again, Adam.</p> <p>15           Q.   Earlier when we discussed the</p> <p>16 disclosure of the '795 patent, that</p> <p>17 mentioned the types of viscosity used with</p> <p>18 pharmaceutical suspensions and syrup</p> <p>19 formulations -- strike that.</p> <p>20           Do you recall earlier we</p> <p>21 discussed in the '795 patent, column 2,</p> <p>22 its disclosure about the types of</p> <p>23 viscosity used with pharmaceutical</p> <p>24 suspensions in syrup formulations, do you</p> <p>25 recall that, sir?</p>                               |

21 (Pages 78 - 81)

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| <p style="text-align: right;">Page 82</p> <p>1 BERKLAND</p> <p>2 A. Yes.</p> <p>3 Q. Are those ranges disclosed in</p> <p>4 the patent consistent with what we see in</p> <p>5 your Exhibit 2020, that states ranges of</p> <p>6 307.33 centipoise to 2408.33 centipoise?</p> <p>7 A. I am not sure what you mean.</p> <p>8 Q. Well, you agree that Exhibit</p> <p>9 2020 shows pediatric liquid formulations</p> <p>10 that existed as of the date of this</p> <p>11 article, which I believe is from 2012,</p> <p>12 right, sir?</p> <p>13 A. Correct.</p> <p>14 Q. And those formulations had</p> <p>15 viscosity ranges between about 307 to 2408</p> <p>16 centipoise, correct, sir?</p> <p>17 MR. PIVOVAR: Objection to</p> <p>18 form.</p> <p>19 A. That's the range that they give</p> <p>20 for a handful of pediatric liquid</p> <p>21 medicaments that they review.</p> <p>22 I don't even believe they're</p> <p>23 all syrups, but that is the range they</p> <p>24 give for viscosities.</p> <p>25 Q. And those ranges are consistent</p> | <p style="text-align: right;">Page 84</p> <p>1 BERKLAND</p> <p>2 Are you referring to the range</p> <p>3 that's disclosed and how it relates to</p> <p>4 this published article?</p> <p>5 Q. I am asking do you think the</p> <p>6 viscosity ranges are consistent with what</p> <p>7 was in the public in 2012, in the patent</p> <p>8 statement, that it is using the</p> <p>9 viscosities of the type used with</p> <p>10 pharmaceutical suspensions in syrup</p> <p>11 formulations?</p> <p>12 MR. PIVOVAR: Objection, form.</p> <p>13 A. The disclosure in column 2</p> <p>14 starts with viscosity of between about 200</p> <p>15 and 3500 centipoise.</p> <p>16 Q. So does the disclosure in 2020</p> <p>17 fall within that range, sir?</p> <p>18 MR. PIVOVAR: Objection to</p> <p>19 form.</p> <p>20 A. It does; the ongoing viscosity</p> <p>21 disclosure in column 2 further limits it</p> <p>22 below 1500 centipoise and so forth, about</p> <p>23 half of the medicaments in Table 1 of</p> <p>24 Exhibit 2020 are above 1500 centipoise and</p> <p>25 about half are below.</p>  |
| <p style="text-align: right;">Page 83</p> <p>1 BERKLAND</p> <p>2 with the '795 patent's description that it</p> <p>3 is using viscosities of the type used with</p> <p>4 pharmaceutical suspensions in syrup</p> <p>5 formulations, correct, sir?</p> <p>6 MR. PIVOVAR: Objection, form.</p> <p>7 A. You haven't specified any</p> <p>8 viscosity in your statement.</p> <p>9 Q. Well, I am looking at column 2,</p> <p>10 sir, the patent's disclosure.</p> <p>11 A. Yes.</p> <p>12 Q. Exhibit 1001, column 2, line 12</p> <p>13 through 27.</p> <p>14 A. Okay.</p> <p>15 (Witness perusing document.)</p> <p>16 Q. Sir, do you understand Exhibit</p> <p>17 2020, which existed in 2012, is consistent</p> <p>18 with what the patent is saying it is using</p> <p>19 viscosity ranges for the formulations that</p> <p>20 are used for pharmaceutical suspensions in</p> <p>21 syrup formulations?</p> <p>22 MR. PIVOVAR: Objection to</p> <p>23 form.</p> <p>24 A. There's lots of viscosity</p> <p>25 disclosure in that column.</p>               | <p style="text-align: right;">Page 85</p> <p>1 BERKLAND</p> <p>2 Q. So 2020 is teaching that about</p> <p>3 half of its formulations have a viscosity</p> <p>4 below 1500 centipoise, correct, sir?</p> <p>5 A. I said half are above and half</p> <p>6 are below and it is a sampling of ten in</p> <p>7 the field at the time.</p> <p>8 Q. So it was known that there are</p> <p>9 pharmaceutical formulations before the</p> <p>10 '795 patent -- strike that.</p> <p>11 It was known that there were</p> <p>12 pharmaceutical suspensions in syrup</p> <p>13 formulations in the prior art before the</p> <p>14 '795 patent that had viscosities below</p> <p>15 1500 centipoise, correct, sir?</p> <p>16 A. I'll agree that it's</p> <p>17 pharmaceutical pediatric liquid</p> <p>18 medicaments.</p> <p>19 I don't know which of these are</p> <p>20 syrups.</p> <p>21 Q. So you agree that there were</p> <p>22 pharmaceutical pediatric liquid</p> <p>23 medicaments that existed before the '795</p> <p>24 patent that had viscosity below 1500</p> <p>25 centipoise, correct, sir?</p> |

22 (Pages 82 - 85)

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| <p style="text-align: right;">Page 86</p> <p>1           BERKLAND</p> <p>2    A.    There were.</p> <p>3    Q.    And that would be known to a</p> <p>4 person of ordinary skill in the art,</p> <p>5 right?</p> <p>6    A.    They would be aware.</p> <p>7           THE WITNESS: You might have to</p> <p>8 mute, counsel, because it is looping back</p> <p>9 to me.</p> <p>10 Q.   You cited Exhibit 2020 in your</p> <p>11 declaration, right, sir, and I can point</p> <p>12 you to Exhibit 52 -- excuse me, paragraph</p> <p>13 52 of your exhibit.</p> <p>14 A.   Okay.</p> <p>15 Q.   In this section, though, you</p> <p>16 only chose viscosities that were above</p> <p>17 1500 centipoise, correct, sir?</p> <p>18       MR. PIVOVAR: Object to the</p> <p>19 form.</p> <p>20 A.   Just to be clear, I was looking</p> <p>21 for analgesics, for pain relievers, and</p> <p>22 the pain reliever formulations have the</p> <p>23 viscosities that I record there.</p> <p>24 Q.   Were you only selecting pain</p> <p>25 reliever formulations?</p> | <p style="text-align: right;">Page 88</p> <p>1           BERKLAND</p> <p>2 persons of skill in the art knew that a</p> <p>3 viscosity of 307 centipoise could be used</p> <p>4 with antitussive medicaments for pediatric</p> <p>5 liquids?</p> <p>6       MR. PIVOVAR: Objection to</p> <p>7 form.</p> <p>8    A.    With pediatric liquids, yes.</p> <p>9       Again, I don't know which of</p> <p>10 these is syrups and which are solutions or</p> <p>11 suspensions, I didn't parse that.</p> <p>12 Q.   Do you know what the purpose of</p> <p>13 the study that's in Exhibit 2020 was?</p> <p>14 A.   I'm sorry, the preference?</p> <p>15 Q.   The purpose of the study that</p> <p>16 was discussed in 2020.</p> <p>17       MR. PIVOVAR: Objection to</p> <p>18 form.</p> <p>19 A.   At least one of their concerns</p> <p>20 is the contribution of sugar containing</p> <p>21 pediatric liquid medicaments leading to</p> <p>22 tooth decay or cavities.</p> <p>23 Q.   And does this study assess</p> <p>24 viscosity of the formulation's impact on</p> <p>25 leading to cavities or tooth decay?</p> |
| <p style="text-align: right;">Page 87</p> <p>1           BERKLAND</p> <p>2    A.    I also selected an antitussive</p> <p>3 which appears right below -- sorry --</p> <p>4 right above paragraph 53.</p> <p>5       One of the prior art references</p> <p>6 that Dr. Crowley relies on uses an</p> <p>7 antitussive formulation.</p> <p>8 Q.   And if you could go to Exhibit</p> <p>9 2020, sir, do you see Table 1?</p> <p>10 A.   Yes.</p> <p>11 Q.   You see there is another</p> <p>12 antitussive right above the one that you</p> <p>13 highlighted?</p> <p>14 A.   I see that.</p> <p>15 Q.   And you didn't highlight that</p> <p>16 one in your report, correct, sir?</p> <p>17 A.   It does not appear in my</p> <p>18 report.</p> <p>19 Q.   What is the viscosity of that</p> <p>20 antitussive?</p> <p>21 A.   The viscosity of that</p> <p>22 antitussive is 307.33 centipoise, but it</p> <p>23 doesn't include an active that overlaps</p> <p>24 with prior art reference from Crowley.</p> <p>25 Q.   But you agree, sir, that</p>            | <p style="text-align: right;">Page 89</p> <p>1           BERKLAND</p> <p>2       MR. PIVOVAR: Object to form.</p> <p>3    A.    I don't recall.</p> <p>4 Q.   You see the discussion on page</p> <p>5 2 of Exhibit 2020, and I should say it's</p> <p>6 also Page No. 358 on that, sir?</p> <p>7 A.   Okay.</p> <p>8 Q.   Do you see that it talks about,</p> <p>9 "However, the cariogenic potential of</p> <p>10 these medications depends on factors such</p> <p>11 as pH and viscosity"?</p> <p>12 A.   I don't see that.</p> <p>13 Q.   Do you see that the title of</p> <p>14 discussion?</p> <p>15 A.   Yes.</p> <p>16 Q.   Can you read what appears to be</p> <p>17 the third full sentence.</p> <p>18       (Witness perusing document.)</p> <p>19 A.   "However, the cariogenic</p> <p>20 potential of these medications depends on</p> <p>21 factors such as pH, viscosity, sugar</p> <p>22 content, high frequency of ingestion,</p> <p>23 bedtime consumption and reduced salivary</p> <p>24 flow caused by the use of some drugs."</p> <p>25 Q.   And do you know what impact the</p>                 |

23 (Pages 86 - 89)

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| <p style="text-align: right;">Page 90</p> <p>1           BERKLAND</p> <p>2 viscosity has on the potential for tooth</p> <p>3 decay or cavities?</p> <p>4           MR. PIVOVAR: Objection to</p> <p>5 form.</p> <p>6     A.    At least one consideration is</p> <p>7 the viscosity can prolong the resident</p> <p>8 time in the mouth.</p> <p>9           I'm not saying it happens or</p> <p>10 not, I'm just saying that's a</p> <p>11 consideration that a person reading this</p> <p>12 would have in mind.</p> <p>13     Q.    When you say would prolong the</p> <p>14 resident time of the syrup in the mouth,</p> <p>15 is that associated with higher or lower</p> <p>16 viscosity of the formulation?</p> <p>17           MR. PIVOVAR: Objection to</p> <p>18 form.</p> <p>19     A.    It really depends what's</p> <p>20 causing the viscosity.</p> <p>21     Q.    You think what's causing the</p> <p>22 viscosity will affect the amount of time</p> <p>23 the liquid stays in the mouth and in</p> <p>24 contact with a child's teeth?</p> <p>25           MR. PIVOVAR: Objection to</p> | <p style="text-align: right;">Page 92</p> <p>1           BERKLAND</p> <p>2 varied from 307 cP to 2408 cP. Neves, et</p> <p>3 al, reported that viscosity of PLM in</p> <p>4 their study ranged from 4.7 to 412.3 cP."</p> <p>5           Do you see that, sir?</p> <p>6     A.    I do.</p> <p>7     Q.    Did you look at the study since</p> <p>8 it was reporting viscosity ranges for</p> <p>9 pediatric liquid medicaments?</p> <p>10    A.    I am not even able to resolve</p> <p>11 that cite, because it says Neves, et al.,</p> <p>12 and then No. 9 and the references that are</p> <p>13 cited in Lima --</p> <p>14     Q.    Why don't you look at Reference</p> <p>15 No. 14 in the pediatric liquid</p> <p>16 medicaments.</p> <p>17           Do you see that there is a</p> <p>18 Neves reference there, sir?</p> <p>19     A.    Yes, there is also one that's</p> <p>20 No. 6, it starts with Neves, I don't know</p> <p>21 how to resolve that citation.</p> <p>22     Q.    Did you look at either of</p> <p>23 those, sir?</p> <p>24     A.    One is Pediatrician's</p> <p>25 Perception of the Use of Sweetened</p> |
| <p style="text-align: right;">Page 91</p> <p>1           BERKLAND</p> <p>2 form.</p> <p>3     A.    I can think of a number of ways</p> <p>4 that viscosity can occur and I don't fully</p> <p>5 understand how those relate to residence</p> <p>6 time in the mouth.</p> <p>7     Q.    I would like to point you to</p> <p>8 Exhibit 2020, page 360, sir.</p> <p>9     A.    Okay.</p> <p>10    Q.    It's the second full paragraph</p> <p>11 on the left column that I'm looking at.</p> <p>12           (Witness perusing document.)</p> <p>13    A.    I have it.</p> <p>14    Q.    Do you see that this paragraph</p> <p>15 discusses other studies that reported</p> <p>16 various viscosities of oral formulations?</p> <p>17           MR. PIVOVAR: Objection to</p> <p>18 form.</p> <p>19    A.    Maybe you can point me to the</p> <p>20 sentence.</p> <p>21    Q.    Sure.</p> <p>22           Either the last or the</p> <p>23 second-to-the-last sentence on the second</p> <p>24 full paragraph of page 360 of Exhibit</p> <p>25 2020, it states, "In our study, viscosity</p>           | <p style="text-align: right;">Page 93</p> <p>1           BERKLAND</p> <p>2 Medications Related to Oral Health and the</p> <p>3 other one is Are Pediatric Medicines Risk</p> <p>4 Factors For Dental Caries and Dental</p> <p>5 Erosion?</p> <p>6           I didn't look at either.</p> <p>7     Q.    I am going to introduce as</p> <p>8 Exhibit 1046 a document that is entitled</p> <p>9 "Are Pediatric Medicines Risk Factors For</p> <p>10 Dental Caries and Dental Erosion?".</p> <p>11           (Berkland Exhibit 1046,</p> <p>12 document entitled "Are Pediatric Medicines</p> <p>13 Risk Factors For Dental Caries and Dental</p> <p>14 Erosion?", was marked for identification,</p> <p>15 as of this date.)</p> <p>16           (Pause.)</p> <p>17    A.    Okay.</p> <p>18    Q.    Do you see the title of that,</p> <p>19 sir?</p> <p>20    A.    Yes.</p> <p>21    Q.    Does that title match with</p> <p>22 either of the titles referenced in what</p> <p>23 you cited as Exhibit 2020 in the list of</p> <p>24 references?</p> <p>25    A.    Yes.</p>                                                               |

24 (Pages 90 - 93)

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| <p style="text-align: right;">Page 94</p> <p>1 BERKLAND</p> <p>2 Q. Which one does it match with?</p> <p>3 A. The title matches reference 14.</p> <p>4 Q. If you go to Table 4 of what we</p> <p>5 marked as 1046, does that include a range</p> <p>6 of viscosities for these liquid pediatric</p> <p>7 medicines?</p> <p>8 MR. PIVOVAR: Objection, form.</p> <p>9 A. There is a table listed there,</p> <p>10 I was just looking at the abstracts since</p> <p>11 it is my first preview into this article</p> <p>12 and it says the objective to assess the in</p> <p>13 vitro, the cariogenic and erosive</p> <p>14 potentials of Brazilian liquid oral</p> <p>15 pediatric medications.</p> <p>16 Q. Does Table 4 of this reference</p> <p>17 list the viscosities of the medications?</p> <p>18 A. I don't see it on Table 1 --</p> <p>19 Q. I said Table 4, sir.</p> <p>20 A. I'm sorry.</p> <p>21 (Witness perusing document.)</p> <p>22 A. Viscosities are listed on Table</p> <p>23 4.</p> <p>24 Q. What's the highest viscosity</p> <p>25 for these liquid pediatric medicines?</p> | <p style="text-align: right;">Page 96</p> <p>1 BERKLAND</p> <p>2 viscosity?</p> <p>3 MR. PIVOVAR: Objection, form.</p> <p>4 A. The article says, "Other</p> <p>5 factors related to pediatric medicines</p> <p>6 might also contribute to the risk of</p> <p>7 dental caries and erosion, for example,</p> <p>8 high frequency of ingestion, bedtime</p> <p>9 consumption, reduced salivary flow caused</p> <p>10 by the use of some drugs and high</p> <p>11 viscosity (implying longer contact time</p> <p>12 with tooth surface)."</p> <p>13 Q. Would you understand that high</p> <p>14 viscosities has the potential to</p> <p>15 contribute to the risk of dental caries</p> <p>16 and erosion, sir?</p> <p>17 A. It may, there is a number of</p> <p>18 factors listed there.</p> <p>19 Q. But high viscosity is one of</p> <p>20 the factors that's being called out</p> <p>21 because that will imply longer contact</p> <p>22 time with the tooth surface, correct, sir?</p> <p>23 MR. PIVOVAR: Objection to</p> <p>24 form.</p> <p>25 A. It may.</p>                                                       |
| <p style="text-align: right;">Page 95</p> <p>1 BERKLAND</p> <p>2 (Witness perusing document.)</p> <p>3 A. Highest viscosity listed is</p> <p>4 412.3 centipoise.</p> <p>5 However, we don't know if these</p> <p>6 are syrups or solutions, at least I can't</p> <p>7 find it.</p> <p>8 Q. I'd like to take you back to</p> <p>9 the first page of Exhibit 1046, sir.</p> <p>10 If you can look into the</p> <p>11 introduction, I would like you to look at</p> <p>12 the carry-over paragraph on the first page</p> <p>13 in the introduction, starting with "other</p> <p>14 factors."</p> <p>15 A. I see it.</p> <p>16 Q. Does this discussion mention</p> <p>17 what effect viscosity may have on --</p> <p>18 strike that.</p> <p>19 Does this discussion list</p> <p>20 viscosity as a factor that can contribute</p> <p>21 to the risk of dental caries and erosion?</p> <p>22 (Witness perusing document.)</p> <p>23 A. Viscosity is a consideration on</p> <p>24 a list given there.</p> <p>25 Q. What does it say about</p>                                                         | <p style="text-align: right;">Page 97</p> <p>1 BERKLAND</p> <p>2 Q. And a person of skill in the</p> <p>3 art would have this article available to</p> <p>4 them when they were making a</p> <p>5 pharmaceutical syrup formulation, correct,</p> <p>6 sir?</p> <p>7 MR. PIVOVAR: Objection to</p> <p>8 form.</p> <p>9 A. This article was published.</p> <p>10 Q. And in fact it's cited by an</p> <p>11 article that you included in your analysis</p> <p>12 of the '795 patent, correct, sir?</p> <p>13 A. That's accurate.</p> <p>14 Q. And the article that you cited</p> <p>15 also discussed viscosity as an impact on</p> <p>16 potential cariogenic issues resulting from</p> <p>17 medicines, correct, sir?</p> <p>18 MR. PIVOVAR: Objection, form.</p> <p>19 A. Well, that article specifically</p> <p>20 states, I'm in the middle of page 360 of</p> <p>21 Exhibit 2020, "These viscous syrup</p> <p>22 medicines with prolonged oral clearance</p> <p>23 can constitute a risk to dental health.</p> <p>24 Information about the relation between</p> <p>25 viscosity and dissolution of dental hard</p> |

25 (Pages 94 - 97)

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| <p style="text-align: right;">Page 98</p> <p>1           BERKLAND</p> <p>2 tissues is rare in literature."</p> <p>3     Q.    But you agree, sir, we have it</p> <p>4 here and we have it in the article we just</p> <p>5 looked at, sir, right?</p> <p>6           MR. PIVOVAR: Objection to</p> <p>7 form.</p> <p>8     A.    It is in the list of</p> <p>9 considerations.</p> <p>10    Q.    And so the viscosity of the</p> <p>11 syrup prolonged oral clearance was known</p> <p>12 as potentially affecting tooth decay,</p> <p>13 correct, sir?</p> <p>14           MR. PIVOVAR: Objection to</p> <p>15 form.</p> <p>16    A.    It was a factor that was</p> <p>17 considered among multiple factors.</p> <p>18    Q.    And is tooth decay a particular</p> <p>19 concern with pediatric populations?</p> <p>20           MR. PIVOVAR: Objection, form.</p> <p>21    A.    I suppose it would be a</p> <p>22 trade-off.</p> <p>23           You're trying to give a</p> <p>24 medication for better health, I guess if</p> <p>25 your overall health has improved compared</p>                                                                      | <p style="text-align: right;">Page 100</p> <p>1           BERKLAND</p> <p>2 suggests are rare in the literature</p> <p>3 relating to viscosity.</p> <p>4     Q.    But you selected this article</p> <p>5 to cite in support of the '795 patent,</p> <p>6 correct, sir?</p> <p>7     A.    I can't remember if it is in</p> <p>8 the background section --</p> <p>9           THE WITNESS: Sorry if I</p> <p>10 interrupted, counsel.</p> <p>11    A.    This is in a section called</p> <p>12 Section C starting at paragraph 50,</p> <p>13 viscosity of liquid pharmaceutical</p> <p>14 formulations.</p> <p>15    Q.    Direct me to what exactly</p> <p>16 you're looking at, you said Section C, but</p> <p>17 I wasn't sure.</p> <p>18    A.    Section C, paragraph 50,</p> <p>19 starting at paragraph 50 on page 17 of my</p> <p>20 report, it's background on liquid</p> <p>21 pharmaceutical formulations.</p> <p>22    Q.    But you selected to cite this</p> <p>23 article in this section, correct, sir?</p> <p>24    A.    That is true.</p> <p>25    Q.    And Section 2 of this article</p> |
| <p style="text-align: right;">Page 99</p> <p>1           BERKLAND</p> <p>2 to getting a cavity or having some tooth</p> <p>3 decay in a baby tooth, I don't know,</p> <p>4 maybe.</p> <p>5     Q.    Would it be something you think</p> <p>6 a person skilled in the art would consider</p> <p>7 when coming up with the viscosity of a</p> <p>8 formulation for a pediatric patient?</p> <p>9           MR. PIVOVAR: Objection to</p> <p>10 form.</p> <p>11    A.    I haven't really considered</p> <p>12 that; perhaps.</p> <p>13    Q.    But you cited an article about</p> <p>14 pediatric liquid medicaments and the</p> <p>15 cariogenic potential of those medicaments,</p> <p>16 but you haven't considered that?</p> <p>17           MR. PIVOVAR: Objection to</p> <p>18 form.</p> <p>19    A.    I guess in my mind I'm putting</p> <p>20 it in the bucket of a very minor concern,</p> <p>21 because if somebody is taking a medication</p> <p>22 four times a day, then to me it seems like</p> <p>23 that is going to have a larger effect</p> <p>24 compared to unknown changes in the</p> <p>25 residence time that the article I cited</p> | <p style="text-align: right;">Page 101</p> <p>1           BERKLAND</p> <p>2 is called "acceptable viscosities of</p> <p>3 liquid pharmaceutical formulations,"</p> <p>4 correct, sir?</p> <p>5     A.    That's a correct reading.</p> <p>6     Q.    And the article that you cite</p> <p>7 in here has viscosities that range from</p> <p>8 307 centipoise to 2040 centipoise,</p> <p>9 correct, sir?</p> <p>10           MR. PIVOVAR: Objection, form.</p> <p>11    A.    I lost your question, I</p> <p>12 apologies.</p> <p>13    Q.    Sure.</p> <p>14           The title of your section is</p> <p>15 "Acceptable Viscosities of Liquid</p> <p>16 Pharmaceutical Formulations," correct?</p> <p>17    A.    Correct.</p> <p>18    Q.    And in that section you cite</p> <p>19 Exhibit 2020, correct?</p> <p>20    A.    They're talking generally about</p> <p>21 viscosity.</p> <p>22    Q.    And the viscosity reported for</p> <p>23 the formulations in Exhibit 2020 range</p> <p>24 from 307 centipoise to about 2040</p> <p>25 centipoise, correct?</p>                                       |

26 (Pages 98 - 101)

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| <p style="text-align: right;">Page 102</p> <p>1 BERKLAND</p> <p>2 A. They do, but I specify we don't</p> <p>3 know which ones of those are syrups and I</p> <p>4 was particularly interested in actives</p> <p>5 related to the prior art.</p> <p>6 Q. The actives that you selected,</p> <p>7 are they syrups?</p> <p>8 A. The actives would be the drugs.</p> <p>9 Q. The drugs that you selected,</p> <p>10 the pediatric liquid medicaments that you</p> <p>11 selected, are they syrups?</p> <p>12 A. The viscosities would suggest</p> <p>13 that they are; however, I don't see</p> <p>14 explicit disclosure in a cursory review of</p> <p>15 Exhibit 2020.</p> <p>16 Q. Do you know whether the active</p> <p>17 ingredient would be suspended in those</p> <p>18 systems?</p> <p>19 MR. PIVOVAR: Objection to</p> <p>20 form.</p> <p>21 A. When you say those systems, are</p> <p>22 you referring to the three that I cite?</p> <p>23 Q. The three that you cite, sir.</p> <p>24 (Witness perusing document.)</p> <p>25 A. I suspect that the analgesics</p> | <p style="text-align: right;">Page 104</p> <p>1 BERKLAND</p> <p>2 Dr. Crowley's report there, right, sir?</p> <p>3 A. Paragraph 52 you mean?</p> <p>4 Q. Yes.</p> <p>5 (Witness perusing document.)</p> <p>6 Q. Can you look at paragraph 52 of</p> <p>7 Dr. Crowley's report and tell me what</p> <p>8 you're referencing.</p> <p>9 (Witness complying.)</p> <p>10 A. It looks like I'm citing the</p> <p>11 wrong paragraph for that quote.</p> <p>12 Q. What paragraph should you be</p> <p>13 citing?</p> <p>14 (Witness perusing document.)</p> <p>15 A. 59.</p> <p>16 Q. Do you agree that generally</p> <p>17 suspensions having viscosity in a range of</p> <p>18 20 to 150 cP are considered readily</p> <p>19 pourable?</p> <p>20 A. I don't entirely appreciate</p> <p>21 what he means by readily.</p> <p>22 I mean, maybe -- is there an</p> <p>23 exhibit cite that he uses here.</p> <p>24 Q. Well, didn't you review his</p> <p>25 report, sir, when you went through it?</p>               |
| <p style="text-align: right;">Page 103</p> <p>1 BERKLAND</p> <p>2 are suspensions simply because those are</p> <p>3 the drug that particularly puts it above</p> <p>4 the solubility limit, the liquid</p> <p>5 medicament.</p> <p>6 The antitussive listed below</p> <p>7 that, that's maybe a solution, I would</p> <p>8 have to dig a layer deeper.</p> <p>9 Q. Sir, would I like to point you</p> <p>10 to your report at 150.</p> <p>11 (Witness complying.)</p> <p>12 A. Okay.</p> <p>13 Q. You see you discuss a section</p> <p>14 of Dr. Crowley's report in section 150?</p> <p>15 A. Yes.</p> <p>16 Q. You say, "Such formulations</p> <p>17 would be a formulation that Dr. Crowley</p> <p>18 has recognized as being readily pourable."</p> <p>19 A. I'm sorry, are you asking if I</p> <p>20 see that?</p> <p>21 Q. Yes, do you see that language,</p> <p>22 sir?</p> <p>23 A. Yes.</p> <p>24 Q. I would like to direct you to a</p> <p>25 little -- you cite paragraph 52 of</p>                                                                          | <p style="text-align: right;">Page 105</p> <p>1 BERKLAND</p> <p>2 A. I did.</p> <p>3 Q. Didn't you review the citations</p> <p>4 that were used when you specifically</p> <p>5 quoted readily pourable, sir?</p> <p>6 A. That's just quoted from his</p> <p>7 report.</p> <p>8 Q. Well, did you look at Exhibit</p> <p>9 1014 that's cited right where you took</p> <p>10 that quote from?</p> <p>11 A. I'm sure I did.</p> <p>12 Q. And did you have an</p> <p>13 understanding of what was meant when you</p> <p>14 reviewed that, sir?</p> <p>15 A. That's what I'm trying to</p> <p>16 resolve.</p> <p>17 A. He takes that from Santos</p> <p>18 Exhibit 1014.</p> <p>19 Q. You decided in your declaration</p> <p>20 to cite Dr. Crowley here and I'm asking</p> <p>21 you, when you cited it, did you consider</p> <p>22 viscosity in the range of 20 to 150 cP to</p> <p>23 be readily pourable?</p> <p>24 A. I just don't fully understand</p> <p>25 if that's distinguishing it from 200 cP or</p> |

27 (Pages 102 - 105)

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| <p style="text-align: right;">Page 106</p> <p>1 BERKLAND</p> <p>2 something lower, viscosity of water is 1,</p> <p>3 that's pourable, readily pourable.</p> <p>4 I appreciate what he said, I'm</p> <p>5 just telling you about my wrestling match</p> <p>6 with it.</p> <p>7 Q. As an expert opining on</p> <p>8 viscosity of oral syrup formulations,</p> <p>9 would you consider something that has a</p> <p>10 viscosity of 20 to 150 cP to be readily</p> <p>11 pourable?</p> <p>12 MR. PIVOVAR: Objection to</p> <p>13 form.</p> <p>14 A. My hang-up here is we just</p> <p>15 walked through ten other products in</p> <p>16 Exhibit 2020 and however many products</p> <p>17 made in Brazil that are liquid medicaments</p> <p>18 ranging in viscosity up to 2400 centipoise</p> <p>19 and I believe those are all readily</p> <p>20 pourable, you can dose them into a cup and</p> <p>21 give them to a child or a geriatric</p> <p>22 patient.</p> <p>23 Q. But, sir, you would agree</p> <p>24 pourability is not the only thing that you</p> <p>25 consider with viscosity, correct, sir?</p> | <p style="text-align: right;">Page 108</p> <p>1 BERKLAND</p> <p>2 form.</p> <p>3 A. Probably so, but then you may</p> <p>4 be exchanging like accuracy of dosing or</p> <p>5 risk of aspiration for something that's</p> <p>6 really low viscosity.</p> <p>7 You may put formulation</p> <p>8 parameters at risk, like this section in</p> <p>9 768 of 1012.</p> <p>10 Q. The lower the viscosity may</p> <p>11 make it more difficult to keep the active</p> <p>12 ingredient in suspension, correct?</p> <p>13 A. Possible.</p> <p>14 Q. In fact that's exactly what is</p> <p>15 stated in 768, sir, right?</p> <p>16 MR. PIVOVAR: Objection to</p> <p>17 form.</p> <p>18 A. That's one thing that's stated,</p> <p>19 and it actually starts on 767, but a</p> <p>20 variety of challenges and trade-offs are</p> <p>21 stated there.</p> <p>22 Q. And so a higher viscosity</p> <p>23 compared to a lower viscosity generally</p> <p>24 has the potential to keep the active in</p> <p>25 suspension better, correct, sir?</p>                                                                                                            |
| <p style="text-align: right;">Page 107</p> <p>1 BERKLAND</p> <p>2 MR. PIVOVAR: Objection to</p> <p>3 form.</p> <p>4 A. I don't fully understand the</p> <p>5 question.</p> <p>6 Q. Do you see right before Exhibit</p> <p>7 1014, in the same paragraph Dr. Crowley</p> <p>8 cites Exhibit 1012?</p> <p>9 A. Yes.</p> <p>10 Q. Did you review 1012?</p> <p>11 A. Yes.</p> <p>12 Q. And did you review page 768 of</p> <p>13 that, sir?</p> <p>14 A. I did.</p> <p>15 Q. And does that section explain</p> <p>16 what may be the benefits and/or detriments</p> <p>17 associated with the viscosity of</p> <p>18 suspensions, sir?</p> <p>19 MR. PIVOVAR: Objection, form.</p> <p>20 A. I think I concur, I believe</p> <p>21 there's both benefits and detriments to,</p> <p>22 say, for example, higher viscosity.</p> <p>23 Q. So the lower the viscosity, the</p> <p>24 easier it is going to be to pour, correct?</p> <p>25 MR. PIVOVAR: Objection to</p>                                                                                                                                             | <p style="text-align: right;">Page 109</p> <p>1 BERKLAND</p> <p>2 MR. PIVOVAR: Object to form.</p> <p>3 A. It may.</p> <p>4 I've also experienced times</p> <p>5 where it's conducive to coagulation or</p> <p>6 agglomeration, so if the viscosity</p> <p>7 increased, it causes other issues with</p> <p>8 particle stability, not just settling like</p> <p>9 in the Stokes' Einstein equation.</p> <p>10 But stability issues, then you</p> <p>11 have a separation phenomena.</p> <p>12 Q. Would you agree that higher</p> <p>13 viscosity may make it harder to disperse</p> <p>14 the suspension in the formulation?</p> <p>15 MR. PIVOVAR: Object to form.</p> <p>16 A. I mean, it's a trade-off again,</p> <p>17 so it may, I've seen instances where you</p> <p>18 get a better dispersion and less settling</p> <p>19 and I've seen instances where at higher</p> <p>20 viscosities you got a poorer dispersion</p> <p>21 and flocculation.</p> <p>22 Q. I would like you to look at</p> <p>23 Exhibit 1012, sir, page 768, and the</p> <p>24 paragraph that starts off "the</p> <p>25 sedimentation rate is indirectly related</p> |

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| <p style="text-align: right;">Page 110</p> <p>1           BERKLAND</p> <p>2 to," do you see that, sir?</p> <p>3    A.    Yes.</p> <p>4    Q.    Can you read that paragraph,</p> <p>5 sir.</p> <p>6    A.    The whole thing?</p> <p>7    Q.    Yes, to yourself, not out loud.</p> <p>8    A.    Oh, okay.</p> <p>9           (Witness perusing document.)</p> <p>10   A.    Okay.</p> <p>11   Q.    You've defined person of</p> <p>12 ordinary skill in the art as a person with</p> <p>13 a bachelor's degree and I believe two</p> <p>14 years of laboratory experience, something</p> <p>15 along that line?</p> <p>16           MR. PIVOVAR: Objection to</p> <p>17 form.</p> <p>18   A.    That seems reasonable, I don't</p> <p>19 have it in front of me, but I'm with you.</p> <p>20   Q.    And so after reading what is</p> <p>21 written on the paragraph on 768 of Exhibit</p> <p>22 1012, starting with "the sedimentation</p> <p>23 rate is indirectly related to the medium</p> <p>24 viscosity," do you think the person</p> <p>25 skilled in the art as you've defined them</p>      | <p style="text-align: right;">Page 112</p> <p>1           BERKLAND</p> <p>2           And there are a number of</p> <p>3 trade-offs for viscosity adjustments, your</p> <p>4 active ingredient, how much active</p> <p>5 ingredient, nature of the colloid and so</p> <p>6 forth.</p> <p>7    Q.    Are any of those trade-offs</p> <p>8 that you mentioned discussed in the '795</p> <p>9 patent?</p> <p>10           MR. PIVOVAR: Objection to</p> <p>11 form.</p> <p>12   A.    We know the nature of the API</p> <p>13 and were given guidance on the viscosity</p> <p>14 of the works for that specific API, these</p> <p>15 are syrups.</p> <p>16           This chapter is talking about</p> <p>17 solutions, emulsions, suspensions and</p> <p>18 extracts, so we do have a context, a good</p> <p>19 context, in the patent.</p> <p>20   Q.    Sir, the section that we're</p> <p>21 talking about here is talking about</p> <p>22 suspensions, correct, sir?</p> <p>23   A.    That's correct, it is a</p> <p>24 subsection.</p> <p>25   Q.    And so this is specific to</p>     |
| <p style="text-align: right;">Page 111</p> <p>1           BERKLAND</p> <p>2 would disagree with what's written in that</p> <p>3 paragraph?</p> <p>4           MR. PIVOVAR: Objection, form.</p> <p>5           (Witness perusing document.)</p> <p>6    A.    I think that paragraph is</p> <p>7 reasonable, but it is only one small</p> <p>8 section of all the considerations of the</p> <p>9 physical characteristics of suspensions,</p> <p>10 that's the title of this section.</p> <p>11   Q.    And this is from Remington: The</p> <p>12 Science and Practice of Pharmacy, Edition</p> <p>13 21, correct?</p> <p>14   A.    Correct.</p> <p>15   Q.    Have you heard of Remington</p> <p>16 before?</p> <p>17   A.    I have.</p> <p>18   Q.    Is this something that's often</p> <p>19 used by pharmaceutical formulators?</p> <p>20   A.    It is.</p> <p>21           What I'm saying is you can't</p> <p>22 pick one paragraph in isolation, you have</p> <p>23 to consider the entire context of what's</p> <p>24 said in this section as well as the rest</p> <p>25 of the chapter.</p> | <p style="text-align: right;">Page 113</p> <p>1           BERKLAND</p> <p>2 suspensions, what we just discussed,</p> <p>3 correct?</p> <p>4    A.    That's correct.</p> <p>5    Q.    And you said that the patent</p> <p>6 discusses the specific active ingredient;</p> <p>7 was that your testimony, sir?</p> <p>8           MR. PIVOVAR: Objection to</p> <p>9 form.</p> <p>10   A.    Well, the claim at least as to</p> <p>11 acetaminophen, as an example to</p> <p>12 acetaminophen, has disclosure in the</p> <p>13 specification of that active.</p> <p>14           I didn't mean to limit it to</p> <p>15 that active, but it has disclosure.</p> <p>16   Q.    So you agree that the '795</p> <p>17 patent has a general disclosure of a</p> <p>18 viscosity range and a list of a whole host</p> <p>19 of potential active ingredients, right,</p> <p>20 sir?</p> <p>21           MR. PIVOVAR: Objection to</p> <p>22 form.</p> <p>23   A.    I was talking about the claim,</p> <p>24 which is focused on acetaminophen.</p> <p>25           But if I recall correctly,</p> |

29 (Pages 110 - 113)

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| <p style="text-align: right;">Page 114</p> <p>1           BERKLAND</p> <p>2 there is disclosure of analgesics</p> <p>3 generally.</p> <p>4     Q.   Is there anything more than</p> <p>5 analgesics disclosed, sir?</p> <p>6           MR. PIVOVAR: Objection to</p> <p>7 form.</p> <p>8     A.   Yes, in column 3 I see more</p> <p>9 disclosure.</p> <p>10    Q.   Does the patent specifically</p> <p>11 discuss the appropriate viscosity range</p> <p>12 relative to each of the various active</p> <p>13 ingredients that are listed on column 3,</p> <p>14 around lines 25 through, say, 34?</p> <p>15           MR. PIVOVAR: Objection to</p> <p>16 form.</p> <p>17    A.   I don't see the specific</p> <p>18 disclosure to each active that you're</p> <p>19 suggesting, but I do see like a working</p> <p>20 example for acetaminophen suspension and</p> <p>21 general disclosure as to the viscosity of</p> <p>22 a pharmaceutical syrup formulation using</p> <p>23 agave syrup.</p> <p>24    Q.   Can you tell me what the</p> <p>25 viscosity is of Example 1 of the '795</p>                                                                                  | <p style="text-align: right;">Page 116</p> <p>1           BERKLAND</p> <p>2           I was thinking more of the</p> <p>3 claims.</p> <p>4     Q.   But I am asking you what's</p> <p>5 disclosed, sir, what's actually taught in</p> <p>6 the specification, sir.</p> <p>7           (Witness perusing document.)</p> <p>8           MR. PIVOVAR: Objection, is</p> <p>9 there a pending question.</p> <p>10    MR. NOLAN: Yes.</p> <p>11           I am asking him whether he can</p> <p>12 tell me what the viscosity is of Example 1</p> <p>13 of the '795 patent.</p> <p>14           MR. PIVOVAR: Objection, asked</p> <p>15 and answered.</p> <p>16    A.   I gave the answer; I haven't</p> <p>17 conducted that analysis, but I gave you my</p> <p>18 perspective.</p> <p>19    Q.   But I am asking you, sir, can</p> <p>20 you conduct that analysis without knowing</p> <p>21 the type of agave syrup that is being used</p> <p>22 in Example 1?</p> <p>23    A.   Could I?</p> <p>24           MR. PIVOVAR: Objection to</p> <p>25 form.</p>                                                                       |
| <p style="text-align: right;">Page 115</p> <p>1           BERKLAND</p> <p>2 patent, Exhibit 1001, column 5.</p> <p>3           MR. PIVOVAR: Object to form.</p> <p>4     A.   I didn't conduct that analysis,</p> <p>5 I don't see it explicitly stated there,</p> <p>6 but I didn't conduct that analysis.</p> <p>7     Q.   In fact you couldn't conduct</p> <p>8 that analysis because there's not</p> <p>9 sufficient information, right, sir?</p> <p>10    MR. PIVOVAR: Objection to</p> <p>11 form.</p> <p>12    A.   I don't know.</p> <p>13    Q.   Without knowing the type of</p> <p>14 agave used, you cannot determine the</p> <p>15 viscosity of Example 1, correct, sir?</p> <p>16    A.   Based on my review of the</p> <p>17 literature, I would know that a high-grade</p> <p>18 agave syrup started with a high viscosity,</p> <p>19 and my opinion is that the '795 gives us a</p> <p>20 resulting range of viscosities that are</p> <p>21 suitable for the invention.</p> <p>22    Q.   And that resulting range is 200</p> <p>23 to 3500 cP, right, sir?</p> <p>24           MR. PIVOVAR: Object to form.</p> <p>25    A.   That's not what's claimed.</p> | <p style="text-align: right;">Page 117</p> <p>1           BERKLAND</p> <p>2     A.   I'm sure I could do that</p> <p>3 analysis; I have not.</p> <p>4     Q.   How would you do it, sir, if</p> <p>5 you didn't know the type of agave that was</p> <p>6 selected?</p> <p>7     A.   At least as a general matter --</p> <p>8 again, I haven't conducted a thorough</p> <p>9 analysis of this, so I can only go so far</p> <p>10 -- but at least as a general matter, the</p> <p>11 agave syrup is the syrup in the</p> <p>12 pharmaceutical syrup formulation and the</p> <p>13 claim is to this pharmaceutical syrup</p> <p>14 formulation having a resulting viscosity</p> <p>15 of less than 1500.</p> <p>16           So as a POSA, it tells me that</p> <p>17 I need to be using agave grade, agave</p> <p>18 syrup, that can get me to that claimed</p> <p>19 result.</p> <p>20    Q.   A POSA would know how to do</p> <p>21 that, right, sir?</p> <p>22    A.   A POSA would have some</p> <p>23 perspective.</p> <p>24    Q.   A POSA would have known how to</p> <p>25 do that before the '795 patent was filed,</p> |

30 (Pages 114 - 117)

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| <p style="text-align: right;">Page 118</p> <p>1           BERKLAND</p> <p>2 right, sir?</p> <p>3           MR. PIVOVAR: Objection, form.</p> <p>4           A. I have not seen any evidence</p> <p>5 that would lead me to believe that.</p> <p>6           Q. So a POSA would not know how to</p> <p>7 get an agave syrup formulation down to</p> <p>8 below 1500 centipoise before the '795</p> <p>9 patent was filed, is that your testimony?</p> <p>10          MR. PIVOVAR: Objection to</p> <p>11 form.</p> <p>12          A. No.</p> <p>13          Q. Then what's your testimony, sir</p> <p>14 -- let's step this back.</p> <p>15          Would you agree that before the</p> <p>16 '795 patent was filed a person of ordinary</p> <p>17 skill in the art would understand how to</p> <p>18 make an agave formulation that had a</p> <p>19 viscosity below 1500 centipoise?</p> <p>20          MR. PIVOVAR: Objection to</p> <p>21 form.</p> <p>22          A. I have restricted my analysis</p> <p>23 to respond to Dr. Crowley and all I've</p> <p>24 seen in the art relating to agave syrups</p> <p>25 is what he has provided.</p> | <p style="text-align: right;">Page 120</p> <p>1           BERKLAND</p> <p>2           A. I was replying to Dr. Crowley's</p> <p>3 assertions of obviousness.</p> <p>4           I can tell you that --</p> <p>5           THE WITNESS: You might have to</p> <p>6 mute your end.</p> <p>7           Q. -- I can tell you that just</p> <p>8 looking at his exhibits and knowing that</p> <p>9 agave syrups can come in viscosities of at</p> <p>10 least 2560 centipoise, that then in</p> <p>11 hindsight the '795 patent is achievable,</p> <p>12 it teaches you that those viscosities</p> <p>13 would work for the pharmaceutical syrup</p> <p>14 formulation.</p> <p>15          Q. Is it your testimony that the</p> <p>16 '795 patent is achievable because --</p> <p>17 strike that.</p> <p>18          What I'm asking you is, the</p> <p>19 '795 patent doesn't tell you the type of</p> <p>20 agave syrup to use, do you agree with me,</p> <p>21 sir?</p> <p>22          A. I didn't look carefully, I</p> <p>23 didn't conduct that analysis.</p> <p>24          Q. You opined on a patent that is</p> <p>25 a total of four columns -- excuse me --</p> |
| <p style="text-align: right;">Page 119</p> <p>1           BERKLAND</p> <p>2           Q. But you've analyzed the '795</p> <p>3 patent, correct, sir?</p> <p>4           A. Correct.</p> <p>5           Q. And you've analyzed Example 1,</p> <p>6 correct, sir?</p> <p>7           A. That's right.</p> <p>8           Q. And you acknowledge that the</p> <p>9 '795 patent doesn't tell you the type of</p> <p>10 agave syrup to use, correct?</p> <p>11          A. My analysis was restricted to</p> <p>12 responding to Professor Crowley or</p> <p>13 Dr. Crowley, excuse me.</p> <p>14          I didn't look for the grade or</p> <p>15 type of agave syrup; I could look, but I</p> <p>16 haven't conducted that analysis.</p> <p>17          Q. So you read the '795 patent,</p> <p>18 you're opining about whether or not it was</p> <p>19 known in the art that an agave formulation</p> <p>20 with acetaminophen was obvious, but you</p> <p>21 didn't look at the '795 patent to see</p> <p>22 whether or not it discussed the type of</p> <p>23 agave to use?</p> <p>24          MR. PIVOVAR: Objection to</p> <p>25 form.</p>      | <p style="text-align: right;">Page 121</p> <p>1           BERKLAND</p> <p>2 five columns, excluding the claims, and</p> <p>3 you didn't conduct the analysis on whether</p> <p>4 or not it disclosed the type of agave to</p> <p>5 use?</p> <p>6           MR. PIVOVAR: Object to form.</p> <p>7           A. I know from my background that</p> <p>8 natural products like agave syrup can come</p> <p>9 in a variety of grades and I know from my</p> <p>10 analysis of Dr. Crowley's declaration and</p> <p>11 his exhibits that there are agave syrups</p> <p>12 available that are very high-grade, high</p> <p>13 viscosity, at least 2500 centipoise.</p> <p>14          And the resulting claims makes</p> <p>15 sense to me in the '795 patent.</p> <p>16          Q. Sir, can you just answer my</p> <p>17 question.</p> <p>18          Does the '795 patent disclose</p> <p>19 the type of agave to use, yes or no</p> <p>20 question?</p> <p>21          MR. PIVOVAR: Objection to</p> <p>22 form.</p> <p>23          Q. And if it does, point to me</p> <p>24 exactly where you're reading to where it</p> <p>25 discloses the type of agave to use.</p> |

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| <p style="text-align: right;">Page 122</p> <p>1           BERKLAND</p> <p>2           MR. PIVOVAR: Objection to</p> <p>3 form.</p> <p>4       A.    I believe I have already</p> <p>5 answered that question.</p> <p>6       Q.    Point to me precisely where in</p> <p>7 the '795 patent it tells you what kind of</p> <p>8 agave to use, sir.</p> <p>9           MR. PIVOVAR: Object to form.</p> <p>10       Q.    I know it is not there and you</p> <p>11 don't want to admit that, but let's be</p> <p>12 honest; point to me right in the '795</p> <p>13 patent where it tells you the type of</p> <p>14 agave to use.</p> <p>15           MR. PIVOVAR: Objection, form.</p> <p>16       A.    I don't think you're accurately</p> <p>17 restating my position.</p> <p>18       Q.    I am going to ask you a</p> <p>19 question --</p> <p>20       A.    I wasn't finished.</p> <p>21           A formulator would understand</p> <p>22 that many excipients come in different</p> <p>23 grades, different molecular weights,</p> <p>24 different viscosities.</p> <p>25           For example, thickening agents</p>                                         | <p style="text-align: right;">Page 124</p> <p>1           BERKLAND</p> <p>2 patent does tell you the specific agave to</p> <p>3 use, sir?</p> <p>4           MR. PIVOVAR: Objection to</p> <p>5 form.</p> <p>6       A.    As I said, the POSA would</p> <p>7 understand it's a natural product, there</p> <p>8 is some variability in it and I can find</p> <p>9 the ones that are useful for achieving the</p> <p>10 result.</p> <p>11           Not sure what else to tell you.</p> <p>12       Q.    By achieving the result, you</p> <p>13 mean the POSA could select the type of</p> <p>14 agave and then manipulate that agave to</p> <p>15 get it down to a viscosity of the final</p> <p>16 formulation that is within the claimed</p> <p>17 range?</p> <p>18           MR. PIVOVAR: Object to form.</p> <p>19       A.    I don't know if manipulate is</p> <p>20 the right word; formulate.</p> <p>21           I am not aware of approved</p> <p>22 products that used agave syrups and there</p> <p>23 is precious little art, background art.</p> <p>24       Q.    Is it your testimony that a</p> <p>25 person of skill in the art would not know</p> |
| <p style="text-align: right;">Page 123</p> <p>1           BERKLAND</p> <p>2 like carboxymethylcellulose, it's the same</p> <p>3 chemical backbone but it comes in</p> <p>4 different grades, it comes in different</p> <p>5 molecular weights, comes in different</p> <p>6 viscosities.</p> <p>7           Agave syrup is a natural</p> <p>8 product, there would be a variety of</p> <p>9 sources, I talk about that in my</p> <p>10 declaration, there would be a variety of</p> <p>11 processing approaches, I talk about that</p> <p>12 in my declaration.</p> <p>13           We have in the patent a target</p> <p>14 viscosity for the final formulation and a</p> <p>15 POSA would know there were agave syrups</p> <p>16 available to achieve that result.</p> <p>17       Q.    What I just want to make clear,</p> <p>18 though, you agree that this patent does</p> <p>19 not direct you to use a specific type of</p> <p>20 agave syrup, correct, sir?</p> <p>21           MR. PIVOVAR: Objection to</p> <p>22 form.</p> <p>23       A.    I've given you the POSA's</p> <p>24 position on this.</p> <p>25       Q.    So the POSA's position is this</p> | <p style="text-align: right;">Page 125</p> <p>1           BERKLAND</p> <p>2 how to take an agave of a certain</p> <p>3 viscosity and then formulate it in a way</p> <p>4 that achieved the viscosity range for the</p> <p>5 final pharmaceutical formulation as</p> <p>6 claimed?</p> <p>7           MR. PIVOVAR: Objection to</p> <p>8 form.</p> <p>9       A.    I think I'm clear in my report</p> <p>10 that I don't see the motivation or</p> <p>11 expectation of results based on</p> <p>12 Dr. Crowley's report.</p> <p>13       Q.    I appreciate that you want to</p> <p>14 keep going back to you're talking points,</p> <p>15 but I would really like you to answer my</p> <p>16 question.</p> <p>17           I'm trying to understand, do</p> <p>18 you think a person of ordinary skill in</p> <p>19 the art at the time of filing the '795</p> <p>20 patent would have the capability to select</p> <p>21 an agave syrup and then formulate an</p> <p>22 acetaminophen formulation in which the</p> <p>23 viscosity of the entire formulation was</p> <p>24 below 1500 centipoise?</p> <p>25           MR. PIVOVAR: Objection to</p>                 |

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| <p style="text-align: right;">Page 126</p> <p>1           BERKLAND</p> <p>2 form.</p> <p>3     A.    I've answered that question</p> <p>4 multiple times.</p> <p>5           If they had the guidance of the</p> <p>6 patent, absolutely.</p> <p>7     Q.    The guidance of the patent</p> <p>8 would simply be to point you to a range of</p> <p>9 viscosity for the final formulation,</p> <p>10 right, sir?</p> <p>11          MR. PIVOVAR: Objection to</p> <p>12 form.</p> <p>13     A.    That was one aspect I</p> <p>14 mentioned.</p> <p>15     Q.    With respect to the range of</p> <p>16 the viscosity used in the patent, the</p> <p>17 patent describes that as the viscosities</p> <p>18 of the type used in pharmaceutical</p> <p>19 suspensions in syrup formulations,</p> <p>20 correct, sir?</p> <p>21          MR. PIVOVAR: Objection to</p> <p>22 form.</p> <p>23           When you say that, what are you</p> <p>24 referring to?</p> <p>25          MR. NOLAN: I'm referring to</p>                                                                                                                                                   | <p style="text-align: right;">Page 128</p> <p>1           BERKLAND</p> <p>2 form.</p> <p>3           I think you're misreading that.</p> <p>4          MR. NOLAN: Counsel, I am here</p> <p>5 to get Dr. Berkland's testimony and not</p> <p>6 yours.</p> <p>7          MR. PIVOVAR: Objection to</p> <p>8 form.</p> <p>9     A.    I haven't analyzed that for an</p> <p>10 error, I don't have reason to believe it's</p> <p>11 an error.</p> <p>12          MR. NOLAN: I think this may be</p> <p>13 a good time to take a break.</p> <p>14          (Recess taken.)</p> <p>15 BY MR. NOLAN:</p> <p>16     Q.    Dr. Berkland, before you were</p> <p>17 mentioning a POSA would know how to select</p> <p>18 an agave syrup to be used with the '795</p> <p>19 patent, do you recall that testimony?</p> <p>20     A.    Roughly speaking, yes.</p> <p>21     Q.    And I thought you said</p> <p>22 something about the quality of the agave</p> <p>23 syrup, did I mishear you?</p> <p>24     A.    I mentioned both grade and</p> <p>25 quality in my report at paragraph 121, it</p>                                                                                        |
| <p style="text-align: right;">Page 127</p> <p>1           BERKLAND</p> <p>2 column 2, Exhibit 1001, line 11 to 12,</p> <p>3 quoting from the patent, sir.</p> <p>4          MR. PIVOVAR: Thanks.</p> <p>5     A.    That range is disclosed there.</p> <p>6     Q.    And that range is described as</p> <p>7 being the ranges that are typically used</p> <p>8 -- strike that -- are the types used</p> <p>9 with pharmaceutical suspensions in syrup</p> <p>10 formulations, correct, sir?</p> <p>11          MR. PIVOVAR: Object to form.</p> <p>12     A.    The patent says what it says.</p> <p>13     Q.    Do you disagree with what the</p> <p>14 patent is saying there, sir?</p> <p>15          MR. PIVOVAR: Objection to</p> <p>16 form.</p> <p>17     A.    I'm not sure what you're</p> <p>18 implying, but I don't disagree with what's</p> <p>19 written.</p> <p>20     Q.    Do you think that's an error in</p> <p>21 the patent, that what is listed after that</p> <p>22 are the viscosities of the type used with</p> <p>23 pharmaceutical suspensions of shared</p> <p>24 formulations?</p> <p>25          MR. PIVOVAR: Object to the</p> | <p style="text-align: right;">Page 129</p> <p>1           BERKLAND</p> <p>2 talks about high quality agave syrup.</p> <p>3     Q.    What is high quality agave</p> <p>4 syrup?</p> <p>5     A.    In this paragraph I discuss --</p> <p>6 do you have it?</p> <p>7     Q.    I'm getting to 121.</p> <p>8     A.    Okay.</p> <p>9           Here I'm just contrasting the</p> <p>10 121 centipoise viscosity and the viscosity</p> <p>11 of 2560 centipoise, I'm referring to the</p> <p>12 higher viscosity agave as higher quality</p> <p>13 or higher grade viscosity.</p> <p>14     Q.    What is your basis for saying</p> <p>15 higher viscosity is equal to higher grade</p> <p>16 or higher quality?</p> <p>17     A.    I also talk about the processes</p> <p>18 employed to purify agave and at least as</p> <p>19 one example, if you have a higher water</p> <p>20 content or a higher content of other</p> <p>21 things, residuals, other diluents, that</p> <p>22 would probably be lower grade, lower</p> <p>23 quality agave, compared to a more viscous,</p> <p>24 more concentrated, higher quality agave.</p> <p>25     Q.    I guess what I am trying to</p> |

33 (Pages 126 - 129)

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| <p style="text-align: right;">Page 130</p> <p>1           BERKLAND</p> <p>2 understand, though is, did you cite</p> <p>3 anything to support your statement that</p> <p>4 higher viscosity agave is equivalent to</p> <p>5 higher grade or higher quality agave here?</p> <p>6     A.    I don't see a citation there.</p> <p>7     Q.    And so what is your basis again</p> <p>8 to state that the viscosity of the agave</p> <p>9 syrup tells you the quality or the grade</p> <p>10 of the agave syrup?</p> <p>11           (Witness perusing document.)</p> <p>12     A.    In Exhibit 1031 cited by</p> <p>13 Crowley, I don't know if you want to get</p> <p>14 that or just have me read from it.</p> <p>15     Q.    I have it, sir, you can provide</p> <p>16 your testimony.</p> <p>17     A.    I will just read the first</p> <p>18 couple of sentences, it says, "Agave</p> <p>19 syrup, a natural product with high</p> <p>20 sweetener capacity, is obtained from</p> <p>21 cooking and concentrating the juice of</p> <p>22 agave plants. Viscosity is one of the</p> <p>23 most significant physical chemical</p> <p>24 properties in determining the quality and</p> <p>25 acceptability of syrup."</p> | <p style="text-align: right;">Page 132</p> <p>1           BERKLAND</p> <p>2 say that the higher viscosity syrup would</p> <p>3 often be an indicator of higher quality,</p> <p>4 higher concentration, of the syrup</p> <p>5 component and less of, say, a diluent or</p> <p>6 other things.</p> <p>7     Q.    What I'm asking you, sir, you</p> <p>8 cited this exhibit for the proposition</p> <p>9 that a higher viscosity agave syrup is of</p> <p>10 higher quality.</p> <p>11           That's not stated in this</p> <p>12 exhibit in comparison to other agave</p> <p>13 syrups, correct, sir?</p> <p>14           MR. PIVOVAR: Objection to</p> <p>15 form.</p> <p>16     A.    To me it seems like it's</p> <p>17 linking viscosity and using rheology to</p> <p>18 measure viscosity as an indicator of</p> <p>19 quality and acceptability.</p> <p>20     Q.    What it compares on viscosity</p> <p>21 is the viscosity of the agave syrup to the</p> <p>22 viscosity of sugar cane and honey bee,</p> <p>23 correct, sir?</p> <p>24           MR. PIVOVAR: Objection to</p> <p>25 form.</p>    |
| <p style="text-align: right;">Page 131</p> <p>1           BERKLAND</p> <p>2     Q.    And this section is comparing</p> <p>3 viscosity of agave -- strike that.</p> <p>4           This section is comparing agave</p> <p>5 syrup to sugar cane, right, sir?</p> <p>6           MR. PIVOVAR: Objection to</p> <p>7 form.</p> <p>8     Q.    And honey bee, right, sir?</p> <p>9           MR. PIVOVAR: Objection, form.</p> <p>10           (Witness perusing document.)</p> <p>11     A.    I mean, it says explicitly</p> <p>12 viscosity is one of the most significant</p> <p>13 physical chemical properties in</p> <p>14 determining the quality and acceptability</p> <p>15 of syrup.</p> <p>16           It doesn't limit that to</p> <p>17 particular types of syrup.</p> <p>18           Both the sentence before talks</p> <p>19 about agave and the sentence after talk</p> <p>20 about agave.</p> <p>21     Q.    Does this section say that high</p> <p>22 viscosity agave syrup has higher quality</p> <p>23 than lower viscosity agave syrup?</p> <p>24     A.    I can poke through other</p> <p>25 citations, but I think it's reasonable to</p>                                                         | <p style="text-align: right;">Page 133</p> <p>1           BERKLAND</p> <p>2     A.    Later on in that paragraph</p> <p>3 that's the comparisons that are being</p> <p>4 made, yes.</p> <p>5     Q.    That's the only viscosity</p> <p>6 comparison that's being made in this</p> <p>7 reference, correct, sir?</p> <p>8           MR. PIVOVAR: Objection to</p> <p>9 form.</p> <p>10     A.    The back-drop for conducting</p> <p>11 the viscosity studies is that viscosity is</p> <p>12 a significant physical chemical property</p> <p>13 in determining the quality and</p> <p>14 acceptability of syrup.</p> <p>15     Q.    And the syrups that are being</p> <p>16 compared are agave syrup, sugar cane syrup</p> <p>17 and honey bee syrup, correct, sir?</p> <p>18           MR. PIVOVAR: Objection to</p> <p>19 form.</p> <p>20     A.    The comparison that's made</p> <p>21 doesn't negate that statement.</p> <p>22     Q.    But the statement just made</p> <p>23 about syrups in general is correct, sir?</p> <p>24           MR. PIVOVAR: Object to form.</p> <p>25     A.    It is.</p> |

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| <p style="text-align: right;">Page 134</p> <p>1           BERKLAND</p> <p>2     Q.    And the statement doesn't say</p> <p>3 low viscosity syrup is of low quality and</p> <p>4 high viscosity syrup is of high quality,</p> <p>5 correct, sir?</p> <p>6           MR. PIVOVAR: Object to form.</p> <p>7           (Witness perusing document.)</p> <p>8     A.    I mean, I'm not going to go</p> <p>9 through other literature and process this</p> <p>10 to make agave, but I think that statement</p> <p>11 is consistent with grading the agave.</p> <p>12     Q.    I am just asking you, sir, does</p> <p>13 this article state that low viscosity</p> <p>14 agave is low quality?</p> <p>15           MR. PIVOVAR: Objection, form.</p> <p>16     A.    Those specific words aren't</p> <p>17 there, but the meaning of the statement is</p> <p>18 understood that applied to viscosity being</p> <p>19 a quality property of agave.</p> <p>20     Q.    And it's a quality property for</p> <p>21 comparing syrups, correct, sir?</p> <p>22           MR. PIVOVAR: Objection, form.</p> <p>23     A.    It doesn't say that.</p> <p>24     Q.    What's the only comparison</p> <p>25 that's done here, sir, is it between the</p> | <p style="text-align: right;">Page 136</p> <p>1           BERKLAND</p> <p>2 question, I'm sorry.</p> <p>3     Q.    You see it says "The mean</p> <p>4 viscosity values of agave syrup, sugar</p> <p>5 cane and honey bee were 2.5 pascal per</p> <p>6 second, 6.06 pascal per second and 10.47</p> <p>7 pascal per second."</p> <p>8           Would the measurement of</p> <p>9 viscosity of a syrup allow you to</p> <p>10 categorize what type of syrup you may have</p> <p>11 had?</p> <p>12           MR. PIVOVAR: Objection to</p> <p>13 form.</p> <p>14     A.    Not based on viscosity alone.</p> <p>15     Q.    In your paragraph 121, what do</p> <p>16 you mean by watered-down low quality agave</p> <p>17 syrup?</p> <p>18     A.    Here I'm just commenting on</p> <p>19 Dr. Crowley's viscosities from what he</p> <p>20 says in his report, which is 212, which is</p> <p>21 what the exhibit he cited says, which is</p> <p>22 2560 centipoise.</p> <p>23     Q.    But you agree that there is an</p> <p>24 exhibit that he included that shows 212</p> <p>25 centipoise, correct, sir?</p> |
| <p style="text-align: right;">Page 135</p> <p>1           BERKLAND</p> <p>2 different types of syrups here being agave</p> <p>3 syrup, sugar cane syrup and honey bee?</p> <p>4           MR. PIVOVAR: Objection, form.</p> <p>5     A.    Those are the test samples, but</p> <p>6 I don't see that somehow excluding</p> <p>7 comparisons within a syrup type.</p> <p>8     Q.    And it does list a viscosity of</p> <p>9 agave syrup at 1.16 PA per second,</p> <p>10 correct?</p> <p>11     A.    0.16?</p> <p>12     Q.    0.16, yes.</p> <p>13     A.    That would be a really high</p> <p>14 temperature, so it goes on to say that's</p> <p>15 the book-end of a range and that</p> <p>16 temperature range is 10 to 80 degrees</p> <p>17 Celsius.</p> <p>18     Q.    Understood.</p> <p>19           Would the viscosity of the</p> <p>20 syrup be a manner in which you could</p> <p>21 distinguish between, say, sugar cane syrup</p> <p>22 and honey bee syrup and agave syrup?</p> <p>23           MR. PIVOVAR: Objection to</p> <p>24 form.</p> <p>25     A.    I don't understand the</p>                                                                                                                                 | <p style="text-align: right;">Page 137</p> <p>1           BERKLAND</p> <p>2           MR. PIVOVAR: Objection to</p> <p>3 form.</p> <p>4     A.    You did point that out to me</p> <p>5 earlier, yes.</p> <p>6     Q.    And so as you had miscited</p> <p>7 paragraph 52 as opposed to 59, and</p> <p>8 Dr. Crowley miscited Exhibit 1030 to 1031,</p> <p>9 do you think your error affects your</p> <p>10 ability to provide testimony here, sir?</p> <p>11           MR. PIVOVAR: Objection to</p> <p>12 form.</p> <p>13     A.    Viscosity number seems pretty</p> <p>14 pivotal, but it doesn't affect my ability</p> <p>15 to provide testimony.</p> <p>16     Q.    So you acknowledge that the</p> <p>17 agave syrup cited in Exhibit 10030 is an</p> <p>18 agave syrup that can be used with the '795</p> <p>19 patent, correct?</p> <p>20     A.    Sorry, 10030?</p> <p>21     Q.    Yes, Exhibit 10030, that's the</p> <p>22 exhibit that has agave at 212 centipoise.</p> <p>23           MR. PIVOVAR: I think you meant</p> <p>24 1030.</p> <p>25           MR. NOLAN: Exhibit 1030.</p>           |

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| <p style="text-align: right;">Page 138</p> <p>1           BERKLAND</p> <p>2     Q.    Why don't we go to Exhibit 1030</p> <p>3 so the record is clear, do you have that,</p> <p>4 sir?</p> <p>5     A.    We clarified this earlier, I</p> <p>6 understand.</p> <p>7     Q.    And so earlier you were talking</p> <p>8 about a person of skill in the art reading</p> <p>9 the '795 patent would appreciate that they</p> <p>10 should select an agave syrup that allows</p> <p>11 them to get into the target viscosity</p> <p>12 range, correct?</p> <p>13       MR. PIVOVAR: Objection to</p> <p>14 form.</p> <p>15     A.    No, what I said earlier is that</p> <p>16 a POSA would know a range of viscosities</p> <p>17 of agave is available and they would know</p> <p>18 from the patent the properties for the</p> <p>19 pharmaceutical syrup formulation and they</p> <p>20 would be able to make the decisions to</p> <p>21 create the claimed formulation.</p> <p>22     Q.    And the property we're talking</p> <p>23 about is viscosity of the final</p> <p>24 formulation, correct, sir?</p> <p>25       MR. PIVOVAR: Objection to</p> | <p style="text-align: right;">Page 140</p> <p>1           BERKLAND</p> <p>2           (Witness perusing document.)</p> <p>3     A.    Once a person understood from</p> <p>4 the patent that that was achievable, they</p> <p>5 could do so.</p> <p>6     Q.    What do you mean by a person</p> <p>7 understood from the patent that was</p> <p>8 achievable; does the patent actually give</p> <p>9 you an example that actually was made in</p> <p>10 which it achieved a formulation with the</p> <p>11 viscosity less than 1500 centipoise?</p> <p>12       MR. PIVOVAR: Objection, form.</p> <p>13     A.    I think the hypothetical we</p> <p>14 just walked through would do so.</p> <p>15     Q.    So if the POSA selected the</p> <p>16 agave of Exhibit 1030, that would result</p> <p>17 in a pharmaceutical syrup formulation with</p> <p>18 a viscosity of less than 1500 centipoise,</p> <p>19 is that your testimony?</p> <p>20       MR. PIVOVAR: Objection.</p> <p>21     A.    I think they would be able to</p> <p>22 take the teachings of the patent and</p> <p>23 select an agave that's appropriate to</p> <p>24 achieve the claim limited viscosity of the</p> <p>25 pharmaceutical syrup formulation.</p> |
| <p style="text-align: right;">Page 139</p> <p>1           BERKLAND</p> <p>2 form.</p> <p>3     A.    That's what's in the claim.</p> <p>4     Q.    And the agave that's shown in</p> <p>5 1030, which has a viscosity of 212</p> <p>6 centipoise would be one that would be</p> <p>7 available for a POSA to select, correct?</p> <p>8     A.    I presume so.</p> <p>9     Q.    And if that was selected, would</p> <p>10 a POSA understand that that would fall</p> <p>11 within the desired viscosity range of the</p> <p>12 final formulation?</p> <p>13       MR. PIVOVAR: Objection to</p> <p>14 form.</p> <p>15     A.    That seems pretty loosely</p> <p>16 specified, but with the patent in hand it</p> <p>17 sounds reasonable.</p> <p>18     Q.    And so if you had selected</p> <p>19 agave syrup with the 212 viscosity range</p> <p>20 of Exhibit 1030 and put that into Example</p> <p>21 1 of the '795 patent, would you expect</p> <p>22 that to have a formulation viscosity of</p> <p>23 below 1500 centipoise?</p> <p>24       MR. PIVOVAR: Objection to</p> <p>25 form.</p>                                                    | <p style="text-align: right;">Page 141</p> <p>1           BERKLAND</p> <p>2     Q.    Direct me to the specific</p> <p>3 teachings of the patent that you are</p> <p>4 referencing in your last answer.</p> <p>5       MR. PIVOVAR: Object to the</p> <p>6 form.</p> <p>7     A.    I've already been through this</p> <p>8 a couple of times.</p> <p>9     Q.    Well, direct me to the specific</p> <p>10 teachings that you're discussing, sir.</p> <p>11       MR. PIVOVAR: Objection, form.</p> <p>12     Q.    I want it by column and line</p> <p>13 number.</p> <p>14       MR. PIVOVAR: Same objection.</p> <p>15           (Witness perusing document.)</p> <p>16     A.    I am just going to use Example</p> <p>17 1 as an anchor point.</p> <p>18     Q.    Any other teachings besides</p> <p>19 Example 1?</p> <p>20     A.    Example 1 tells us what the</p> <p>21 active is, tells us the amount of the</p> <p>22 active, tells us put in citric acid in a</p> <p>23 specified amount, we can add flavoring,</p> <p>24 blueberry, in a specified amount, and then</p> <p>25 the ingredient that is the syrup is agave</p>                                                                                           |

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| <p style="text-align: right;">Page 142</p> <p>1           BERKLAND</p> <p>2 syrup and we're trying to make a</p> <p>3 pharmaceutical syrup formulation.</p> <p>4           When I read agave syrup, I</p> <p>5 understand as a POSA the agave syrup comes</p> <p>6 in various grades, we walked through that,</p> <p>7 and I can select an appropriate grade of</p> <p>8 agave syrup using this formulation and</p> <p>9 guidance in the specification to achieve</p> <p>10 the pharmaceutical syrup formulation</p> <p>11 viscosity claim limitation.</p> <p>12    Q.   And so you would be able to</p> <p>13 achieve the viscosity -- strike that.</p> <p>14           The teaching with respect to</p> <p>15 the viscosity is simply that you want to</p> <p>16 be in the range cited in the</p> <p>17 specification, correct, sir?</p> <p>18           MR. PIVOVAR: Objection to</p> <p>19 form.</p> <p>20    A.   I don't know, there is lots of</p> <p>21 ranges in the specification, I don't know</p> <p>22 which one you're referring to.</p> <p>23    Q.   Does it tell you how to get to</p> <p>24 a viscosity of less than 500 centipoise in</p> <p>25 this patent?</p> | <p style="text-align: right;">Page 144</p> <p>1           BERKLAND</p> <p>2 well-specified question, sorry.</p> <p>3    Q.   Before the '795 patent was</p> <p>4 published, would a person of ordinary</p> <p>5 skill in the art understand that they</p> <p>6 could affect viscosity of a pharmaceutical</p> <p>7 formulation by adding water?</p> <p>8           MR. PIVOVAR: Objection to</p> <p>9 form.</p> <p>10   A.   Again, it's under-specified,</p> <p>11 but for certain formulations they could be</p> <p>12 diluted with water and the viscosity could</p> <p>13 be adjusted.</p> <p>14   Q.   Do you think that a POSITA</p> <p>15 would understand adding water to an</p> <p>16 acetaminophen formulation would affect the</p> <p>17 viscosity?</p> <p>18           MR. PIVOVAR: Object to form.</p> <p>19   A.   If it is just acetaminophen and</p> <p>20 water, it's going to have the viscosity of</p> <p>21 water.</p> <p>22   Q.   Of a pharmaceutical formulation</p> <p>23 that includes acetaminophen, sir.</p> <p>24           MR. PIVOVAR: Objection to</p> <p>25 form.</p>                                                      |
| <p style="text-align: right;">Page 143</p> <p>1           BERKLAND</p> <p>2           MR. PIVOVAR: Object to form.</p> <p>3    A.   In example 2 it tells us we can</p> <p>4 take a hundred milligrams of the active, a</p> <p>5 hundred milliliters of agave, warm it up</p> <p>6 and then stir in water to achieve the</p> <p>7 desired consistency.</p> <p>8           So that's at least one way to</p> <p>9 hit the target viscosity.</p> <p>10   Q.   Is this the first time that</p> <p>11 somebody has taught using water to obtain</p> <p>12 a specific viscosity?</p> <p>13           MR. PIVOVAR: Objection to</p> <p>14 form.</p> <p>15   A.   I mean, what are you referring</p> <p>16 to?</p> <p>17   Q.   I'm just referring to, do you</p> <p>18 think this is a novel disclosure, that the</p> <p>19 inventors here are telling everyone you</p> <p>20 can achieve a desired consistency by</p> <p>21 controlling the amount of water that you</p> <p>22 add to a formulation?</p> <p>23           MR. PIVOVAR: Object to the</p> <p>24 form.</p> <p>25   A.   That still is not a</p>                                                                             | <p style="text-align: right;">Page 145</p> <p>1           BERKLAND</p> <p>2   A.   I'm sorry, the question is</p> <p>3 under-specified.</p> <p>4   Q.   Would the acetaminophen in that</p> <p>5 solution contribute to the viscosity of</p> <p>6 the formulation?</p> <p>7           MR. PIVOVAR: Objection to</p> <p>8 form.</p> <p>9   A.   I think we know as a general</p> <p>10 matter, and Dr. Crowley would agree, that</p> <p>11 the nature and amount of solids in a</p> <p>12 suspension can contribute to the</p> <p>13 viscosity, it's discussed in the</p> <p>14 suspension section of the chapter he wrote</p> <p>15 in Remington's.</p> <p>16   Q.   And so how would the nature of</p> <p>17 the acetaminophen affect the viscosity of</p> <p>18 the formulation?</p> <p>19           MR. PIVOVAR: Objection, form.</p> <p>20   A.   Well, you can imagine like two</p> <p>21 extreme book-ends where one particle of</p> <p>22 acetaminophen wouldn't have any effect,</p> <p>23 but a high concentration of acetaminophen</p> <p>24 particles would create more of a cake, you</p> <p>25 know, something that was very hard to flow</p> |

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| <p style="text-align: right;">Page 146</p> <p>1           BERKLAND</p> <p>2 or displace.</p> <p>3    Q.    Would the acetaminophen in</p> <p>4 Example 1 of the '795 patent affect the</p> <p>5 viscosity of the formulation?</p> <p>6           MR. PIVOVAR: Objection to</p> <p>7 form.</p> <p>8    A.    I haven't conducted that</p> <p>9 analysis.</p> <p>10   Q.    Would the citric acid extract</p> <p>11 affect the viscosity of the final</p> <p>12 formulation of Example 1?</p> <p>13       MR. PIVOVAR: Object to form.</p> <p>14   A.    I'm sorry, those are two</p> <p>15 different things, did you put them</p> <p>16 together?</p> <p>17   Q.    I asked would the citric acid</p> <p>18 extract of Example 1 affect the viscosity</p> <p>19 of the final formulation?</p> <p>20       MR. PIVOVAR: Objection to</p> <p>21 form.</p> <p>22       (Witness perusing document.)</p> <p>23   A.    I would say the risk there is</p> <p>24 low because it's used in a small</p> <p>25 percentage.</p>                                                                                                                  | <p style="text-align: right;">Page 148</p> <p>1           BERKLAND</p> <p>2 it, yes.</p> <p>3    Q.    And so the total amount of</p> <p>4 water in Example 1 of the '795 patent</p> <p>5 would be dependent on the water added as</p> <p>6 the diluent and the water that was</p> <p>7 included with the agave syrup, correct?</p> <p>8           MR. PIVOVAR: Objection to</p> <p>9 form.</p> <p>10   A.    Once you know that the</p> <p>11 formulation works, then a formulator can</p> <p>12 take that into consideration.</p> <p>13   Q.    But are you agreeing that the</p> <p>14 total amount of water in that formulation</p> <p>15 would have contribution from the water</p> <p>16 added as the diluent and the water that</p> <p>17 was part of the agave syrup?</p> <p>18       MR. PIVOVAR: Objection, form.</p> <p>19   A.    It could, water could be</p> <p>20 present in the agave syrup.</p> <p>21   Q.    Would you expect water to be</p> <p>22 present in the agave syrup?</p> <p>23   A.    Most of the extraction</p> <p>24 techniques would present residual water.</p> <p>25   Q.    Are you aware of any agave</p>                       |
| <p style="text-align: right;">Page 147</p> <p>1           BERKLAND</p> <p>2    Q.    Would the masking agent affect</p> <p>3 the viscosity of the final formulation?</p> <p>4       MR. PIVOVAR: Objection to</p> <p>5 form.</p> <p>6    A.    Usually those are applied in</p> <p>7 low quantities, there may have to be an</p> <p>8 adjustment in the viscosity, so that</p> <p>9 parameter could affect other parameters.</p> <p>10       But in Example 1 it's unlikely</p> <p>11 or the risk would be low.</p> <p>12   Q.    Would the water referenced in</p> <p>13 example 1 affect the viscosity of the</p> <p>14 final formulation?</p> <p>15   A.    The water content will.</p> <p>16   Q.    The agave syrup that is listed</p> <p>17 in Example 1, would you expect that to</p> <p>18 have some water associated with it?</p> <p>19       MR. PIVOVAR: Objection to</p> <p>20 form.</p> <p>21   A.    There would be some water.</p> <p>22   Q.    And would the water be</p> <p>23 associated with the percent moisture of</p> <p>24 the agave syrup that was used?</p> <p>25   A.    That's one way of quantifying</p> | <p style="text-align: right;">Page 149</p> <p>1           BERKLAND</p> <p>2 syrup that doesn't have water in it?</p> <p>3    A.    You might not call it --</p> <p>4 sorry, counsel, did I interrupt.</p> <p>5    Q.    You didn't interrupt me, no.</p> <p>6    A.    You can lyophilize or purify</p> <p>7 agave syrup to remove water and I think I</p> <p>8 talk about that a little bit in one of the</p> <p>9 background paragraphs.</p> <p>10       But if there were a flowing</p> <p>11 syrup, you would expect it to have either</p> <p>12 some water content or some other</p> <p>13 extraction fluid that was used to prepare</p> <p>14 the agave.</p> <p>15   Q.    If you use a lyophilized</p> <p>16 powdered agave in Example 1, would you</p> <p>17 expect the amount of water you had to add</p> <p>18 would be greater than using an agave that</p> <p>19 was in the form of a liquid syrup?</p> <p>20       MR. PIVOVAR: Objection to</p> <p>21 form.</p> <p>22   A.    Probably so, yes, that would be</p> <p>23 in the purview of the POSA.</p> <p>24   Q.    So a person skill in the art</p> <p>25 would understand that it could use an</p> |

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| <p style="text-align: right;">Page 150</p> <p>1           BERKLAND</p> <p>2 agave syrup that had less water content</p> <p>3 and add more water as a diluent in order</p> <p>4 to practice Example 1 of the '795 patent,</p> <p>5 correct?</p> <p>6           MR. PIVOVAR: Objection to</p> <p>7 form.</p> <p>8     A.    They would certainly have</p> <p>9 formulation expertise like that.</p> <p>10    Q.    So they'd have that</p> <p>11 understanding, correct, sir?</p> <p>12           MR. PIVOVAR: Objection to</p> <p>13 form.</p> <p>14    A.    Maybe you could restate the</p> <p>15 understanding that you're implying.</p> <p>16    Q.    That a person of ordinary skill</p> <p>17 in the art would understand that if it</p> <p>18 used an agave syrup form that had a lower</p> <p>19 water content, then it may need to use a</p> <p>20 larger amount of the water as a diluent.</p> <p>21           MR. PIVOVAR: Objection, form.</p> <p>22    A.    They may need to do so and I</p> <p>23 believe they would understand.</p> <p>24    Q.    And if they used an agave syrup</p> <p>25 that had a higher water content, they</p> | <p style="text-align: right;">Page 152</p> <p>1</p> <p>2       AFTERNOON SESSION</p> <p>3           2:29 p.m.</p> <p>4 CORY BERKLAND, resumed.</p> <p>5 EXAMINATION CONTINUED</p> <p>6 BY MR. NOLAN:</p> <p>7     Q.    Dr. Berkland, can you pull out</p> <p>8 Exhibit 1001.</p> <p>9     A.    Yes.</p> <p>10           (Witness complying.)</p> <p>11    Q.    This is a copy of the patent,</p> <p>12 correct?</p> <p>13    A.    The '795, yes.</p> <p>14    Q.    Yes.</p> <p>15           And do you recall that one of</p> <p>16 the reasons that the patent is discussing</p> <p>17 making a pharmaceutical formulation is for</p> <p>18 the benefit of having an oral</p> <p>19 pharmaceutical formulation for pediatric</p> <p>20 patients and elderly patients?</p> <p>21    A.    Did you read that from</p> <p>22 somewhere, I am just trying to find that</p> <p>23 section.</p> <p>24    Q.    I was just asking you in</p> <p>25 general if you recall that?</p>                                                                                                      |
| <p style="text-align: right;">Page 151</p> <p>1           BERKLAND</p> <p>2 would also understand that they may need</p> <p>3 to add less water as a diluent with</p> <p>4 respect to Example 1 of the '795 patent,</p> <p>5 correct?</p> <p>6     A.    I think that sounds logical.</p> <p>7           I didn't conduct this analysis</p> <p>8 in detail, but these are certainly skills</p> <p>9 that a POSA would possess.</p> <p>10    Q.    You and your counsel asked we</p> <p>11 only go half an hour more before we have</p> <p>12 lunch, so I think we're right about that</p> <p>13 point?</p> <p>14           MR. NOLAN: Why don't we break</p> <p>15 for lunch.</p> <p>16           (Discussion off the record.)</p> <p>17           (Lunch recess: 1:00 p.m.)</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>                                                                                                                                                                                                                                                                                       | <p style="text-align: right;">Page 153</p> <p>1           BERKLAND</p> <p>2     A.    I don't recall it off the top</p> <p>3 of my head, but that is a typical</p> <p>4 application for syrups.</p> <p>5     Q.    Let me see if I can help you</p> <p>6 out with that.</p> <p>7     A.    First line of background says</p> <p>8 children and older persons, I found it.</p> <p>9     Q.    So you agree that the patent</p> <p>10 acknowledges that children and older</p> <p>11 persons have trouble with tablets and</p> <p>12 capsules, correct?</p> <p>13    A.    They can.</p> <p>14    Q.    It also acknowledges another</p> <p>15 problem -- strike that.</p> <p>16           And so for that reason it is</p> <p>17 desirable to have something that could be</p> <p>18 in an oral formulation such as a syrup,</p> <p>19 correct?</p> <p>20    A.    A liquid like a syrup could be</p> <p>21 helpful.</p> <p>22    Q.    But that was known before the</p> <p>23 '795 patent was filed, correct, sir?</p> <p>24           MR. PIVOVAR: Object to the</p> <p>25 form.</p> |

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| <p style="text-align: right;">Page 154</p> <p>1 BERKLAND</p> <p>2 A. Yes.</p> <p>3 Q. And in fact FR458 provides the</p> <p>4 same disclosure, correct, FR458 can be</p> <p>5 found as Exhibit 1004?</p> <p>6 MR. PIVOVAR: Objection to</p> <p>7 form.</p> <p>8 (Witness perusing document.)</p> <p>9 Q. Maybe I can help you; in</p> <p>10 Exhibit 1004, and I'm using the corrected</p> <p>11 version of that exhibit, on page 19 of 33</p> <p>12 I can direct you to that.</p> <p>13 A. I'm there.</p> <p>14 Q. And you see around line 39,</p> <p>15 this is on page 2 here, it says solid</p> <p>16 dosage forms are not suitable for children</p> <p>17 or for the elderly. This is why they are</p> <p>18 formulating liquid dosage forms."</p> <p>19 Do you see that, sir?</p> <p>20 A. I see that.</p> <p>21 Q. And so this is the same issue</p> <p>22 that we just discussed with respect to the</p> <p>23 '795 patent at column 1, lines about 12</p> <p>24 through 15?</p> <p>25 (Witness perusing document.)</p> | <p style="text-align: right;">Page 156</p> <p>1 BERKLAND</p> <p>2 A. Yes.</p> <p>3 Q. Why would you taste mask a</p> <p>4 pharmaceutical formulation?</p> <p>5 A. You could potentially improve</p> <p>6 compliance taking medication.</p> <p>7 Q. And that's because compliance</p> <p>8 may be low if it has an unpleasant taste,</p> <p>9 correct?</p> <p>10 A. That's a possibility.</p> <p>11 Q. And if we look at Exhibit 1004,</p> <p>12 FR '458 at page 2, and on the exhibit it's</p> <p>13 19 of 33, it also talks about the concept</p> <p>14 of taste masking to address unpleasant</p> <p>15 taste, correct?</p> <p>16 A. Yes.</p> <p>17 Q. So both FR458 and the '795 seem</p> <p>18 to be addressing some of the same issues,</p> <p>19 correct?</p> <p>20 A. At least in the background and</p> <p>21 state-of-the-art sections they refer to</p> <p>22 those two issues together, yes.</p> <p>23 Q. I would like you to turn to</p> <p>24 Exhibit 1006, which is what we've referred</p> <p>25 to as WO 133, sir.</p> |
| <p style="text-align: right;">Page 155</p> <p>1 BERKLAND</p> <p>2 Q. Do you agree, sir, that they're</p> <p>3 discussing the same issue?</p> <p>4 A. I'm sorry, I was speaking over</p> <p>5 you, please go ahead.</p> <p>6 Q. Do you agree they're both</p> <p>7 discussing the same issue, that the '795</p> <p>8 patent in column 1 and what we just looked</p> <p>9 at in Exhibit 1004 on page 2?</p> <p>10 MR. PIVOVAR: Objection to the</p> <p>11 form.</p> <p>12 A. Yes.</p> <p>13 Q. And if you look at Exhibit</p> <p>14 1001, column 1, it talks about -- strike</p> <p>15 that.</p> <p>16 If you look at Exhibit 1001,</p> <p>17 column 1, it also talks about unpleasant</p> <p>18 taste, correct?</p> <p>19 (Witness perusing document.)</p> <p>20 A. Can you point me to that,</p> <p>21 please.</p> <p>22 Q. If you look at column 1, lines</p> <p>23 20 through 26, for clarity, it talks about</p> <p>24 the concept of taste masking</p> <p>25 pharmaceutical formulations, correct?</p>                     | <p style="text-align: right;">Page 157</p> <p>1 BERKLAND</p> <p>2 A. Okay.</p> <p>3 Q. If you look for this Exhibit 3</p> <p>4 of 24.</p> <p>5 A. I'm there.</p> <p>6 Q. Does this also identify the</p> <p>7 concern with solid dosage forms for</p> <p>8 elderly and young patients?</p> <p>9 A. Could you point that to me,</p> <p>10 please.</p> <p>11 Q. Sure.</p> <p>12 You can look around lines 14 or</p> <p>13 a little above that, downwards to 17</p> <p>14 maybe.</p> <p>15 (Witness perusing document.)</p> <p>16 A. I see it.</p> <p>17 Q. And so the WO133, Exhibit 1006,</p> <p>18 is also identifying the same concern that</p> <p>19 the '795 patent identified a few years</p> <p>20 later, correct?</p> <p>21 A. I don't know about the timing,</p> <p>22 but I see it identified there.</p> <p>23 Q. Do you understand that WO133,</p> <p>24 Exhibit 1006, published before the</p> <p>25 priority date for the '795 patent?</p>                                                                                  |

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| <p style="text-align: right;">Page 158</p> <p>1 BERKLAND</p> <p>2 A. I do.</p> <p>3 Q. So that means they would have</p> <p>4 identified this before the '795 patent was</p> <p>5 filed, correct, they being what's</p> <p>6 disclosed in Exhibit 1006?</p> <p>7 A. It is before, yes.</p> <p>8 Q. If you look at 1006, it also</p> <p>9 discusses the unpalatable taste of</p> <p>10 acetaminophen and the need to taste mask,</p> <p>11 correct?</p> <p>12 A. I see that.</p> <p>13 Q. And so that's the same issue</p> <p>14 that the '795 patent subsequently is</p> <p>15 talking about as compared to Exhibit 1006,</p> <p>16 right?</p> <p>17 A. Taste masking is present in</p> <p>18 both.</p> <p>19 Q. And WO 133, Exhibit 1006,</p> <p>20 disclosed addressing this problem before</p> <p>21 the '795 patent, correct?</p> <p>22 MR. PIVOVAR: Objection to</p> <p>23 form.</p> <p>24 A. It is prior art.</p> <p>25 Q. In paragraph 65 of your expert</p>                                              | <p style="text-align: right;">Page 160</p> <p>1 BERKLAND</p> <p>2 form.</p> <p>3 A. I am just giving that as a</p> <p>4 background generally.</p> <p>5 Q. Are there any excipients that</p> <p>6 you understand are excluded from the</p> <p>7 claims of the '795 patent?</p> <p>8 MR. PIVOVAR: Object to form.</p> <p>9 A. I haven't really considered</p> <p>10 that.</p> <p>11 Q. Does the patent describe any</p> <p>12 excipients that would materially affect</p> <p>13 the basic and novel properties of the</p> <p>14 claims that are in the '795 patent?</p> <p>15 MR. PIVOVAR: Object to form.</p> <p>16 A. I haven't considered that.</p> <p>17 Q. Do you agree that the patent</p> <p>18 disclosed in the specification the use of</p> <p>19 artificial flavoring?</p> <p>20 MR. PIVOVAR: Objection to</p> <p>21 form.</p> <p>22 (Witness perusing document.)</p> <p>23 A. I see at the bottom of column 3</p> <p>24 both natural and artificial flavors</p> <p>25 stated.</p>        |
| <p style="text-align: right;">Page 159</p> <p>1 BERKLAND</p> <p>2 report, Exhibit 2009, you discussed the</p> <p>3 '795 patent and taste masking.</p> <p>4 Can you look at that, sir.</p> <p>5 A. 65?</p> <p>6 Q. Yes, sir.</p> <p>7 (Witness complying.)</p> <p>8 A. Okay.</p> <p>9 Q. So in this section you talk</p> <p>10 about the types of inactive ingredients</p> <p>11 that the '795 patent mentions using.</p> <p>12 MR. PIVOVAR: Objection to the</p> <p>13 form.</p> <p>14 A. I'm sorry, is there a question?</p> <p>15 Q. Yes.</p> <p>16 Do you see where you talk about</p> <p>17 "It discloses that this can be done with</p> <p>18 clean and active ingredients that are</p> <p>19 gluten-free, non-GMO and certified vegan</p> <p>20 or unnatural ingredients, such as</p> <p>21 Aspartame," so is it your understanding</p> <p>22 that the '795 patent is suggesting to use</p> <p>23 both natural and artificial ingredients to</p> <p>24 taste-mask?</p> <p>25 MR. PIVOVAR: Objection to</p> | <p style="text-align: right;">Page 161</p> <p>1 BERKLAND</p> <p>2 Q. So as a person of skill in the</p> <p>3 art reading this patent specification,</p> <p>4 they would understand that you could use</p> <p>5 both natural and artificial ingredients in</p> <p>6 the claims, correct?</p> <p>7 MR. PIVOVAR: Object to form.</p> <p>8 A. I haven't formed an opinion</p> <p>9 there.</p> <p>10 Q. Well, did you read the patent,</p> <p>11 sir?</p> <p>12 A. Yes.</p> <p>13 Q. Did you understand the claims</p> <p>14 that you're opining on, sir?</p> <p>15 A. I did.</p> <p>16 Q. Do those claims exclude</p> <p>17 artificial ingredients?</p> <p>18 MR. PIVOVAR: Objection, form.</p> <p>19 A. I don't see that in the claims.</p> <p>20 Q. Having read the patent and</p> <p>21 seeing that it mentions the potential to</p> <p>22 use artificial flavoring, do you</p> <p>23 understand the claims as excluding</p> <p>24 artificial ingredients?</p> <p>25 MR. PIVOVAR: Objection to</p> |

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| <p style="text-align: right;">Page 162</p> <p>1           BERKLAND</p> <p>2 form.</p> <p>3     A.    I haven't considered that</p> <p>4 possibility.</p> <p>5     Q.    So when you looked at the</p> <p>6 claims to understand their scope, you</p> <p>7 didn't look at what the scope may be?</p> <p>8           MR. PIVOVAR: Objection to</p> <p>9 form.</p> <p>10    A.    I hadn't evaluated the question</p> <p>11 you posed, which is around artificial</p> <p>12 flavors.</p> <p>13    Q.    Well, I asked you about</p> <p>14 artificial ingredients, sir.</p> <p>15    A.    That wasn't part of my</p> <p>16 analysis.</p> <p>17    Q.    For the '795 patent, what</p> <p>18 function does the agave syrup form in that</p> <p>19 formulation?</p> <p>20           MR. PIVOVAR: Objection.</p> <p>21    A.    It's listed in Example 1 in the</p> <p>22 table as providing the function of a base,</p> <p>23 it's the major ingredient.</p> <p>24           We also know that it's a syrup,</p> <p>25 so therefore it contributes to at least</p> | <p style="text-align: right;">Page 164</p> <p>1           BERKLAND</p> <p>2 formulation?</p> <p>3           MR. PIVOVAR: Object to the</p> <p>4 form.</p> <p>5     A.    I am not sure what you mean by</p> <p>6 syrup aspect.</p> <p>7     Q.    Well, you had stated before</p> <p>8 that the agave syrup in Example 1 provided</p> <p>9 the syrup aspect I thought of the</p> <p>10 formulation.</p> <p>11           I am just trying to understand</p> <p>12 if that's the same with respect to Example</p> <p>13 1 of the FR458, and let me clear that up.</p> <p>14           I believe with respect to</p> <p>15 Example 1 of the '795 patent you described</p> <p>16 the agave as providing the syrup aspect of</p> <p>17 that formulation and I am just trying to</p> <p>18 understand is the same true for the agave</p> <p>19 syrup in Example 1 of FR458.</p> <p>20           MR. PIVOVAR: Objection to</p> <p>21 form.</p> <p>22    A.    And I think my answer was syrup</p> <p>23 is a major component in that example.</p> <p>24    Q.    By that example, you mean</p> <p>25 Example 1, correct?</p>              |
| <p style="text-align: right;">Page 163</p> <p>1           BERKLAND</p> <p>2 viscosity of the pharmaceutical syrup</p> <p>3 formulation.</p> <p>4     Q.    What do you mean by it's the</p> <p>5 base, what would your understanding of</p> <p>6 that be?</p> <p>7           MR. PIVOVAR: Objection.</p> <p>8     A.    The major component.</p> <p>9     Q.    I would like you to turn to</p> <p>10 Example 1 of FR458 and this is Exhibit</p> <p>11 1004.</p> <p>12    A.    Okay.</p> <p>13    Q.    That has agave syrup in it,</p> <p>14 right, sir?</p> <p>15    A.    Yes.</p> <p>16    Q.    Is agave syrup the major</p> <p>17 component of that formulation?</p> <p>18           MR. PIVOVAR: Objection, form.</p> <p>19    A.    It is a major component,</p> <p>20 although I think they had quite a bit of</p> <p>21 water; I did an analysis on this and I</p> <p>22 think in the end they had 50 percent or</p> <p>23 more water.</p> <p>24    Q.    Would you understand the agave</p> <p>25 syrup to provide the syrup aspect of this</p>   | <p style="text-align: right;">Page 165</p> <p>1           BERKLAND</p> <p>2     A.    Correct.</p> <p>3     Q.    '795?</p> <p>4     A.    I was talking about the '458.</p> <p>5     Q.    So syrup, agave syrup, is a</p> <p>6 major component of Example 1 of the '458</p> <p>7 and it's a major component of Example 1 of</p> <p>8 the '795, correct?</p> <p>9           MR. PIVOVAR: Objection to</p> <p>10 form.</p> <p>11    A.    We know in Example 1 of the</p> <p>12 '458 there is a lot of water added, so it</p> <p>13 is a major component, but it's exceeded by</p> <p>14 water in the end.</p> <p>15    Q.    Would you expect Example 1 of</p> <p>16 the '458 to be with acetaminophen</p> <p>17 suspended in it?</p> <p>18           MR. PIVOVAR: Objection, form.</p> <p>19    A.    I don't recall the solubility</p> <p>20 of paracetamol, which is acetaminophen,</p> <p>21 off the top of my head.</p> <p>22    Q.    Maybe we can clear this up.</p> <p>23           In your opinion, sir, you have</p> <p>24 not provided an opinion where you stated</p> <p>25 the prior art by Dr. Crowley does not</p> |

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| <p style="text-align: right;">Page 166</p> <p>1 BERKLAND</p> <p>2 disclose every limitation of the claims of</p> <p>3 the '795 patent, correct?</p> <p>4 MR. PIVOVAR: Objection to</p> <p>5 form.</p> <p>6 A. I don't understand.</p> <p>7 Q. You limited your opinion as to</p> <p>8 why the '795 patent is unobvious to the</p> <p>9 fact that you believe a person skilled in</p> <p>10 the art would not combine, for example,</p> <p>11 FR458 and the other references that</p> <p>12 disclose appropriate viscosity ranges,</p> <p>13 correct?</p> <p>14 MR. PIVOVAR: Object to form.</p> <p>15 A. I believe that's a correct</p> <p>16 rendering of one of my opinions.</p> <p>17 Q. When you say one of your</p> <p>18 opinions, are there other opinions you</p> <p>19 have where you think that the prior art</p> <p>20 fails to disclose each limitation of any</p> <p>21 claim of the '795 patent?</p> <p>22 MR. PIVOVAR: Object to form.</p> <p>23 A. I'm getting a little lost in</p> <p>24 the jargon, but on grounds 2 of my opinion</p> <p>25 I don't compare the '458 patent.</p> | <p style="text-align: right;">Page 168</p> <p>1 BERKLAND</p> <p>2 pharmaceutical formulation there is agave</p> <p>3 syrup, is that correct?</p> <p>4 A. Agave syrup is present in</p> <p>5 Example 1.</p> <p>6 Q. And Example 1 of 1004 also</p> <p>7 includes a diluent in the form of purified</p> <p>8 water, correct?</p> <p>9 A. I don't know if they call it a</p> <p>10 diluent or not, but, yeah, it's purified</p> <p>11 water and they use it in the formulation.</p> <p>12 Q. Would you consider that to be a</p> <p>13 diluent in that formulation?</p> <p>14 A. It is a reasonable conclusion.</p> <p>15 Q. And depending on the agave</p> <p>16 syrup that is used, would you expect that</p> <p>17 the formulation of Example 1 of 1004 may</p> <p>18 have formulation viscosity below 1500</p> <p>19 centipoise?</p> <p>20 MR. PIVOVAR: Objection to</p> <p>21 form.</p> <p>22 A. We don't know without making</p> <p>23 assumptions.</p> <p>24 Q. What assumptions would you have</p> <p>25 to make?</p>                                                                                                                        |
| <p style="text-align: right;">Page 167</p> <p>1 BERKLAND</p> <p>2 Q. But in ground 2 your rationale</p> <p>3 is still you wouldn't have combined those</p> <p>4 references, not that those references fail</p> <p>5 to teach a specific claim limitation, is</p> <p>6 that correct?</p> <p>7 MR. PIVOVAR: Objection to</p> <p>8 form.</p> <p>9 A. I am a little lost in the legal</p> <p>10 jargon, but I think you've rendered that</p> <p>11 properly.</p> <p>12 Q. If we consider claim 1 of the</p> <p>13 '795 patent in comparison to Example 1 of</p> <p>14 Exhibit 1004, so Example 1 of Exhibit 1004</p> <p>15 is discussing a pharmaceutical syrup</p> <p>16 formulation for oral administration,</p> <p>17 correct, sir?</p> <p>18 A. That's correct.</p> <p>19 Q. And Example 1 of Exhibit 1004</p> <p>20 discloses that that formulation includes</p> <p>21 acetaminophen, but here called</p> <p>22 paracetamol?</p> <p>23 A. Those are the same thing,</p> <p>24 correct.</p> <p>25 Q. And Example 1 of 1004, in that</p>                                                             | <p style="text-align: right;">Page 169</p> <p>1 BERKLAND</p> <p>2 A. There would have to be</p> <p>3 disclosure of the agave syrup, I see other</p> <p>4 ingredients included here, gums and agar,</p> <p>5 A-G-A-R, and I'm just not entirely sure</p> <p>6 how these in combination contribute to the</p> <p>7 viscosity, there's no disclosure.</p> <p>8 Q. What do you mean by you would</p> <p>9 need the disclosure of the agave syrup?</p> <p>10 A. I discuss that analysis in my</p> <p>11 report --</p> <p>12 Q. I am just trying to understand,</p> <p>13 you said there would need to be disclosure</p> <p>14 of the agave syrup and if you say you</p> <p>15 discuss it in your report, point to me</p> <p>16 where you're talking about it in your</p> <p>17 report.</p> <p>18 MR. PIVOVAR: Objection, form.</p> <p>19 A. Finally we don't know the</p> <p>20 viscosity of the formulation in Example 1</p> <p>21 because it's not measured.</p> <p>22 I walked through the analysis</p> <p>23 of rebutting Dr. Crowley's assertion of a</p> <p>24 212 centipoise viscosity of agave syrup.</p> <p>25 Q. Can you point me to the</p> |

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| <p style="text-align: right;">Page 170</p> <p>1 BERKLAND</p> <p>2 paragraph you're talking about here.</p> <p>3 MR. PIVOVAR: Object to the</p> <p>4 form.</p> <p>5 A. It starts at the bottom of page</p> <p>6 61, paragraph 154 -- actually, since we're</p> <p>7 talking about claim 1, we should back up.</p> <p>8 (Witness perusing document.)</p> <p>9 A. That analysis starts around</p> <p>10 paragraph 139.</p> <p>11 (Witness perusing document.)</p> <p>12 Q. Sir, I believe my questions</p> <p>13 asking you about Example 1 of FR458.</p> <p>14 You had said, you talked about</p> <p>15 what was needed to be known in order to</p> <p>16 understand the viscosity of that.</p> <p>17 Is that what you're pointing me</p> <p>18 to right now?</p> <p>19 MR. PIVOVAR: Objection to</p> <p>20 form.</p> <p>21 I am a little lost, counsel, so</p> <p>22 if you want to recalibrate where we're at,</p> <p>23 that would be helpful.</p> <p>24 MR. NOLAN: I am asking, what I</p> <p>25 was asking about, Example 1, is, depending</p>                                                            | <p style="text-align: right;">Page 172</p> <p>1 BERKLAND</p> <p>2 specific, do you agree that the patent</p> <p>3 does not disclose for the example that's</p> <p>4 listed what the viscosity is of that</p> <p>5 example?</p> <p>6 A. A measured value of the</p> <p>7 viscosity in Example 1 is not reported.</p> <p>8 Q. And it also doesn't tell you</p> <p>9 the specific agave syrup that was used in</p> <p>10 Example 1, correct, of the '795 patent?</p> <p>11 MR. PIVOVAR: Objection, form.</p> <p>12 A. That is also correct, but the</p> <p>13 specification in the claims give you</p> <p>14 guidance for viscosity.</p> <p>15 Q. Do you agree that FR458</p> <p>16 discloses using agave syrup as a main</p> <p>17 constituent of a pharmaceutical</p> <p>18 formulation with acetaminophen before that</p> <p>19 was disclosed in the '795 patent?</p> <p>20 MR. PIVOVAR: Objection to</p> <p>21 form.</p> <p>22 A. With the small clarification</p> <p>23 that water ends up being the major</p> <p>24 ingredient, that is true.</p> <p>25 Q. Water ends up being the major</p> |
| <p style="text-align: right;">Page 171</p> <p>1 BERKLAND</p> <p>2 on the agave selected, would that have a</p> <p>3 formulation viscosity of less than 1500</p> <p>4 centipoise, and I believe that</p> <p>5 Dr. Berkland stated he did not know for</p> <p>6 two reasons; one, the viscosity was not</p> <p>7 measured in this example, and the example</p> <p>8 does not disclose the agave syrup that is</p> <p>9 used.</p> <p>10 MR. PIVOVAR: I am just going</p> <p>11 to object to any question that's there, if</p> <p>12 there is one.</p> <p>13 And you can proceed.</p> <p>14 Q. Did I accurately reflect your</p> <p>15 response, Dr. Berkland?</p> <p>16 A. I think roughly, yes, since</p> <p>17 there is no viscosity reported we don't</p> <p>18 have disclosure of the viscosity.</p> <p>19 Q. By viscosity reported, do you</p> <p>20 mean there is no viscosity shown for the</p> <p>21 formulation in Example 1?</p> <p>22 A. I don't see any viscosity</p> <p>23 anywhere in this filing.</p> <p>24 Q. When we asked about Example 1</p> <p>25 of the '795 patent, I want to be very</p> | <p style="text-align: right;">Page 173</p> <p>1 BERKLAND</p> <p>2 ingredient in your view in Example 1, but</p> <p>3 there is a general disclosure in the '458</p> <p>4 patent, correct, about using agave syrup</p> <p>5 and acetaminophen, right, sir?</p> <p>6 MR. PIVOVAR: Objection, form.</p> <p>7 A. I don't know.</p> <p>8 Q. Did you read FR458?</p> <p>9 A. I did; I don't remember</p> <p>10 everything in the patent application.</p> <p>11 Q. Did you understand it suggested</p> <p>12 using agave syrup for its low glycemic</p> <p>13 index?</p> <p>14 A. That may be in there, I don't</p> <p>15 recall.</p> <p>16 Q. Well, if you look at Exhibit</p> <p>17 1004, page 20 of 33, lines 70 through 74,</p> <p>18 do you understand that that's one of the</p> <p>19 reasons for using agave syrup?</p> <p>20 MR. PIVOVAR: Objection to</p> <p>21 form.</p> <p>22 (Witness perusing document.)</p> <p>23 A. Yes, I see that.</p> <p>24 Q. And you agree that paracetamol</p> <p>25 is one of the active ingredients it</p>                                                      |

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| <p style="text-align: right;">Page 174</p> <p>1           BERKLAND</p> <p>2 discloses using, right?</p> <p>3    A.    It does.</p> <p>4    Q.    The '795 patent wasn't the</p> <p>5 first patent to come up and suggest using</p> <p>6 acetaminophen and agave syrup together in</p> <p>7 an oral pharmaceutical formulation,</p> <p>8 correct?</p> <p>9    A.    Well, certainly those two items</p> <p>10 are paired here.</p> <p>11   Q.    And in your report you stated</p> <p>12 that the '458 patent only provides a</p> <p>13 single example of acetaminophen and agave</p> <p>14 syrup in a pharmaceutical formulation, do</p> <p>15 you recall stating that?</p> <p>16   A.    I don't recall.</p> <p>17   Q.    Do you know if the FR458</p> <p>18 provides other examples of using</p> <p>19 acetaminophen and agave syrup in a</p> <p>20 pharmaceutical formulation?</p> <p>21   A.    Example 4 has those two</p> <p>22 ingredients together.</p> <p>23   Q.    And so if in your report you</p> <p>24 stated that the only example was Example</p> <p>25 1, would that be an error?</p>                                                                       | <p style="text-align: right;">Page 176</p> <p>1           BERKLAND</p> <p>2    A.    Yes, it does; it just adds</p> <p>3 another active ingredient to it.</p> <p>4    Q.    Is the '795 patent claims</p> <p>5 limited to only a single active</p> <p>6 ingredient, sir?</p> <p>7           MR. PIVOVAR: Object to the</p> <p>8 form.</p> <p>9    A.    I didn't have an opinion on</p> <p>10 that in terms of what comprising means as</p> <p>11 part of that claim, I don't see a</p> <p>12 limitation, but I didn't have an opinion.</p> <p>13   Q.    You will agree, though, that</p> <p>14 the '458 provides more than just one</p> <p>15 example of a pharmaceutical syrup</p> <p>16 formulation that includes agave and</p> <p>17 paracetamol, right, sir?</p> <p>18   A.    That is true and I've addressed</p> <p>19 what I was contemplating when making the</p> <p>20 statement at paragraph 81.</p> <p>21   Q.    And in addition to the FR458,</p> <p>22 you looked at Exhibit 1007, too, correct,</p> <p>23 sir?</p> <p>24   A.    Yes.</p> <p>25   Q.    And this also discloses using</p>             |
| <p style="text-align: right;">Page 175</p> <p>1           BERKLAND</p> <p>2           MR. PIVOVAR: Objection, form.</p> <p>3    A.    It probably just means that it</p> <p>4 is the formulation where acetaminophen is</p> <p>5 the active ingredient; Example 4 has two</p> <p>6 active ingredients.</p> <p>7           But I don't know where that is</p> <p>8 in my report to address it.</p> <p>9    Q.    If you can look at paragraph 81</p> <p>10 of your report --</p> <p>11   A.    Actually, I found it, it's in</p> <p>12 paragraph 81, the only example containing</p> <p>13 paracetamol, also known as acetaminophen,</p> <p>14 is Example 1, the formulation of which has</p> <p>15 been reproduced below.</p> <p>16           I was referring when that was a</p> <p>17 singular active ingredient, just for</p> <p>18 clarity.</p> <p>19   Q.    The only example containing</p> <p>20 paracetamol is Example 1, and you meant</p> <p>21 the only example that only includes</p> <p>22 paracetamol is Example 1, right?</p> <p>23   A.    That's accurate.</p> <p>24   Q.    But you would agree Example 4</p> <p>25 includes paracetamol, correct, sir?</p> | <p style="text-align: right;">Page 177</p> <p>1           BERKLAND</p> <p>2 agave syrup in a formulation with</p> <p>3 acetaminophen, correct?</p> <p>4    A.    Just a moment.</p> <p>5           (Witness perusing document.)</p> <p>6           MR. PIVOVAR: Object to the</p> <p>7 form.</p> <p>8    A.    Yes.</p> <p>9    Q.    And so again, before the '795</p> <p>10 patent, others had disclosed using agave</p> <p>11 syrup and acetaminophen in a</p> <p>12 pharmaceutical syrup formulation, correct?</p> <p>13   A.    Just one clarification; Example</p> <p>14 9 in the one we're calling the WO742,</p> <p>15 Exhibit 1007, it has acetaminophen and</p> <p>16 agave, that's correct, I was just going to</p> <p>17 add that it also includes other actives.</p> <p>18   Q.    Are you suggesting that because</p> <p>19 it includes other actives, somehow it</p> <p>20 doesn't show using agave syrup and</p> <p>21 acetaminophen in a pharmaceutical</p> <p>22 formulation before the filing of the '795</p> <p>23 patent?</p> <p>24   A.    No, I'm just adding that</p> <p>25 clarification.</p> |

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| <p style="text-align: right;">Page 178</p> <p>1           BERKLAND</p> <p>2     Q.    And WO742 discusses the</p> <p>3 viscosity of agave here, correct?</p> <p>4           MR. PIVOVAR: Object to the</p> <p>5 form.</p> <p>6     A.    You could shortcut this if you</p> <p>7 want to point me to it; otherwise I'll try</p> <p>8 to find it.</p> <p>9     Q.    Sure.</p> <p>10          If we go to Exhibit 1007, page</p> <p>11 9 of 31, it says around line 9, "Agave</p> <p>12 syrup is similar to honey in color and</p> <p>13 texture, but it is not as viscous and</p> <p>14 flows more easily," correct, sir?</p> <p>15    A.    That's a qualitative disclosure</p> <p>16 of viscosity.</p> <p>17    Q.    This is actually a disclosure</p> <p>18 of the viscosity relative to agave syrup,</p> <p>19 correct?</p> <p>20    A.    I'm sorry --</p> <p>21          MR. PIVOVAR: Objection to</p> <p>22 form.</p> <p>23          Go ahead.</p> <p>24    Q.    Do you agree what is written</p> <p>25 here is discussing the viscosity of the</p>                                                                               | <p style="text-align: right;">Page 180</p> <p>1           BERKLAND</p> <p>2 of the formulation.</p> <p>3     Q.    So it is viscosity limitation</p> <p>4 of the formulation, is that correct, sir?</p> <p>5     A.    That's correct.</p> <p>6     Q.    It is not a viscosity</p> <p>7 limitation of the agave syrup, correct?</p> <p>8     A.    Yeah, I don't recall seeing a</p> <p>9 limitation for that.</p> <p>10    Q.    Okay.</p> <p>11          If you go further down in</p> <p>12 Exhibit 1007, WO472, page 9 of 31, around</p> <p>13 lines 21 through 22, it also says, talking</p> <p>14 about agave syrup, "It can be light to</p> <p>15 dark in color, thicker or thinner in</p> <p>16 consistency (viscosity)," do you see that?</p> <p>17    A.    Yes, I even quote that in my</p> <p>18 report at paragraph 99.</p> <p>19    Q.    Before the filing of the '795</p> <p>20 patent, prior art is discussing agave</p> <p>21 syrup and acetaminophen in formulations</p> <p>22 and understanding that the agave</p> <p>23 constituent of those formulations may have</p> <p>24 varying viscosities, correct?</p> <p>25    A.    That's a fair understanding.</p> |
| <p style="text-align: right;">Page 179</p> <p>1           BERKLAND</p> <p>2 agave syrup as opposed to the viscosity of</p> <p>3 the formulation?</p> <p>4          (Witness perusing document.)</p> <p>5     A.    No, it doesn't talk about the</p> <p>6 viscosity of the agave syrup specifically,</p> <p>7 it just offers like a comparison.</p> <p>8          We don't know what the</p> <p>9 viscosity or type of honey this is, it's</p> <p>10 just kind of giving you a qualitative</p> <p>11 understanding.</p> <p>12    Q.    What qualitative understanding</p> <p>13 does the '795 patent give about the</p> <p>14 viscosity of the agave disclosed in that</p> <p>15 specification?</p> <p>16          MR. PIVOVAR: Objection, form.</p> <p>17    A.    I am not really sure what you</p> <p>18 mean.</p> <p>19          My answer to this line of</p> <p>20 questioning previously is that the</p> <p>21 specification in the claims provide</p> <p>22 viscosity limitations.</p> <p>23    Q.    It's viscosity limitations for</p> <p>24 the formulation, right, sir?</p> <p>25    A.    To reach the desired properties</p> | <p style="text-align: right;">Page 181</p> <p>1           BERKLAND</p> <p>2     Q.    If you look at the Exhibit</p> <p>3 1007, page 15 of 31, it's talking about</p> <p>4 selecting a high fructose syrup such as</p> <p>5 agave nectar, do you see that, sir?</p> <p>6     A.    I don't see that, could you</p> <p>7 point me to the line, please.</p> <p>8     Q.    Sure.</p> <p>9          Are you on page 15 of 31 of</p> <p>10 Exhibit 1007?</p> <p>11    A.    Yes.</p> <p>12    Q.    If you look around line 5.</p> <p>13    A.    I see it, thank you.</p> <p>14    Q.    And so do you understand</p> <p>15 whether fructose syrup would have a higher</p> <p>16 or lower glycemic index?</p> <p>17          MR. PIVOVAR: Objection to</p> <p>18 form.</p> <p>19    A.    Compared to what?</p> <p>20    Q.    Compared to other sugars like</p> <p>21 glucose or sucrose.</p> <p>22    A.    It could.</p> <p>23    Q.    In what instance could it have</p> <p>24 a higher glycemic index?</p> <p>25    A.    We haven't specified the</p>                                                                                                                            |

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| <p style="text-align: right;">Page 182</p> <p>1           BERKLAND</p> <p>2 amounts of those other sugars.</p> <p>3    Q.    If they were in the same</p> <p>4 amounts, everything in the same amounts,</p> <p>5 except one was fructose, one was glucose</p> <p>6 and one was sucrose, which would you</p> <p>7 expect to have the lowest glycemic index?</p> <p>8           MR. PIVOVAR: Object to form.</p> <p>9    A.    Probably as you stated.</p> <p>10   Q.    Is a lower glycemic index</p> <p>11 beneficial for, say, diabetic patients?</p> <p>12           MR. PIVOVAR: Objection, form.</p> <p>13   A.    I don't know how much taking</p> <p>14 this medication as a diabetic patient</p> <p>15 would even move the needle, so I don't</p> <p>16 know that I can opine on that.</p> <p>17   Q.    You mentioned Example 9 of</p> <p>18 Exhibit 1007 before.</p> <p>19           Can you turn to that example.</p> <p>20           (Witness complying.)</p> <p>21   A.    Okay.</p> <p>22   Q.    Would you consider the agave</p> <p>23 syrup to be a major constituent of that</p> <p>24 pharmaceutical formulation?</p> <p>25           MR. PIVOVAR: Objection to</p> | <p style="text-align: right;">Page 184</p> <p>1           BERKLAND</p> <p>2    Q.    How would you expect it to</p> <p>3 compare to the 11 milliliters in this</p> <p>4 formulation?</p> <p>5           MR. PIVOVAR: Objection, form.</p> <p>6    A.    This one is difficult to</p> <p>7 resolve, because it's unclear if the</p> <p>8 specified amounts are for the 15</p> <p>9 milliliter dose or a formulation that's</p> <p>10 ultimately given as a 15 milliliter dose.</p> <p>11           One of the reasons it's</p> <p>12 confusing is when you add up ingredients,</p> <p>13 it doesn't jive with a 15 milliliter dose.</p> <p>14           So I can't really opine as to</p> <p>15 how much water is present.</p> <p>16   Q.    What do you mean that it</p> <p>17 doesn't jive with a 15 milliliter dose?</p> <p>18   A.    I just mean I was unable to</p> <p>19 resolve the total mass or total volume of</p> <p>20 those ingredients with the assumption that</p> <p>21 it's a 15 milliliter dose.</p> <p>22   Q.    Did the total mass or total</p> <p>23 volume come to something greater than 15</p> <p>24 milliliters when you added it up?</p> <p>25   A.    I didn't complete that analysis</p> |
| <p style="text-align: right;">Page 183</p> <p>1           BERKLAND</p> <p>2 form.</p> <p>3    A.    Here we have a lot more</p> <p>4 ingredients, but agave is at a high amount</p> <p>5 comparatively.</p> <p>6    Q.    And so would that be forming a</p> <p>7 base of that ingredient?</p> <p>8    A.    Sorry, I wasn't quite finished.</p> <p>9    Q.    My apologies.</p> <p>10   A.    I'm not entirely sure how much</p> <p>11 water is added here, I don't think I</p> <p>12 figured it out, but -- yeah.</p> <p>13   Q.    And so would you describe agave</p> <p>14 nectar as being a base of this</p> <p>15 formulation?</p> <p>16           MR. PIVOVAR: Objection, form.</p> <p>17   A.    I don't know if I would import</p> <p>18 that word or not, I just don't know enough</p> <p>19 about how the inventors were contemplating</p> <p>20 this formulation.</p> <p>21   Q.    Would you expect the amount of</p> <p>22 water in this formulation to be higher</p> <p>23 than 11 milliliters?</p> <p>24           MR. PIVOVAR: Objection, form.</p> <p>25   A.    Probably not.</p>                                                                                 | <p style="text-align: right;">Page 185</p> <p>1           BERKLAND</p> <p>2 because -- that is approximately true,</p> <p>3 but I didn't have like the full densities</p> <p>4 on everything, so it's unclear to me what</p> <p>5 exactly the dose is and if this</p> <p>6 formulation represents the 15 milliliter</p> <p>7 dose.</p> <p>8    Q.    But if you add all these up and</p> <p>9 they come close to the 15 milliliters,</p> <p>10 would that mean that the amount of water</p> <p>11 that you had to add to get up to the 15</p> <p>12 milliliters would be very limited?</p> <p>13           MR. PIVOVAR: Object to form.</p> <p>14   A.    That would be a reasonable</p> <p>15 conclusion, it doesn't change my opinions</p> <p>16 at all, but it's a reasonable conclusion.</p> <p>17   Q.    If you look at Exhibit 1007,</p> <p>18 Exhibit 10 of 31 --</p> <p>19   A.    You mean page 10 of 31?</p> <p>20   Q.    Yes, page 10 of 31, sorry, sir.</p> <p>21           You see the reference to U.S.</p> <p>22 Patent 2009/0148580?</p> <p>23   A.    Yes.</p> <p>24   Q.    Did you look at that patent,</p> <p>25 sir, that patent publication, I should</p>                                     |

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| <p style="text-align: right;">Page 186</p> <p>1           BERKLAND</p> <p>2 say?</p> <p>3   A.    I don't recall.</p> <p>4   Q.    Can you turn to Exhibit 1008,</p> <p>5 sir, of the petitioner exhibits.</p> <p>6           (Witness complying.)</p> <p>7   A.    Yes, I have it.</p> <p>8   Q.    Have you reviewed that, sir?</p> <p>9   A.    I have.</p> <p>10 Q.    And so just for clarity, if we</p> <p>11 can go back to page 10 of 31 of Exhibit</p> <p>12 1007, it is describing U.S. 2009/0148580</p> <p>13 as disclosing using natural agave extract</p> <p>14 as sweeteners in medicines, correct?</p> <p>15       MR. PIVOVAR: Object to form.</p> <p>16   A.    Yes.</p> <p>17   Q.    And the benefit of that is</p> <p>18 described in page 10 of 31 of Exhibit</p> <p>19 1007, is the reduction in calorie and</p> <p>20 elimination of artificial sweeteners, is</p> <p>21 that correct?</p> <p>22       (Witness perusing document.)</p> <p>23       MR. PIVOVAR: Objection to</p> <p>24 form.</p> <p>25   A.    I see that statement.</p>                                                                                        | <p style="text-align: right;">Page 188</p> <p>1           BERKLAND</p> <p>2 disclosure, I'm just coloring in what it</p> <p>3 specifically discloses later in the patent</p> <p>4 filing.</p> <p>5   Q.    Can you read into the record</p> <p>6 what is disclosed in paragraph 36 on page</p> <p>7 3 of 3 of Exhibit 1008.</p> <p>8   A.    Paragraph 36?</p> <p>9   Q.    0036, sir.</p> <p>10 A.    No. 10 in list of 12 items,</p> <p>11 medicine, pharmaceutical, and medicines as</p> <p>12 well as other health food products.</p> <p>13   Q.    So this reference is</p> <p>14 specifically teaching the use of agave</p> <p>15 syrup in medicines, correct, sir?</p> <p>16       MR. PIVOVAR: Objection, form.</p> <p>17   A.    I don't even know what they</p> <p>18 mean by medicine, because I don't see a</p> <p>19 single example of an active pharmaceutical</p> <p>20 ingredient or list of them anywhere.</p> <p>21       Maybe they think food has</p> <p>22 medicinal properties, I don't know, but</p> <p>23 all I'm saying is I don't see active</p> <p>24 pharmaceutical ingredients in here</p> <p>25 anywhere.</p> |
| <p style="text-align: right;">Page 187</p> <p>1           BERKLAND</p> <p>2   Q.    Do you agree that Exhibit 1008</p> <p>3 explains using agave syrup in medicines?</p> <p>4       MR. PIVOVAR: Object to form.</p> <p>5   A.    It says foods and medicines.</p> <p>6   Q.    If we look at paragraph 3 on</p> <p>7 page 2 of 3 of Exhibit 1008, it</p> <p>8 specifically says the invention is about</p> <p>9 using natural agave extract as natural</p> <p>10 sweeteners, and it specifically teaches</p> <p>11 placing it in medicines, correct, sir?</p> <p>12       MR. PIVOVAR: Objection, form.</p> <p>13   A.    They also state foods and</p> <p>14 medicines.</p> <p>15   Q.    You agree this is a teaching to</p> <p>16 use agave syrup in medicines, correct,</p> <p>17 sir?</p> <p>18       MR. PIVOVAR: Objection, form.</p> <p>19   A.    I'm looking at the examples now</p> <p>20 and they all talk about pancake syrup, ice</p> <p>21 cream, low calorie soft drinks.</p> <p>22   Q.    Are you limiting this</p> <p>23 disclosure, sir?</p> <p>24       MR. PIVOVAR: Objection, form.</p> <p>25   A.    I am not limiting the</p> | <p style="text-align: right;">Page 189</p> <p>1           BERKLAND</p> <p>2   Q.    But I am asking you what would</p> <p>3 a POSITA understand the word medicine to</p> <p>4 mean?</p> <p>5       MR. PIVOVAR: Objection to</p> <p>6 form.</p> <p>7   A.    Our POSITA is a pharmaceutical</p> <p>8 formulator, so they would understand it to</p> <p>9 mean pharmaceuticals.</p> <p>10       But I don't know for this; to</p> <p>11 me this is not talking about</p> <p>12 pharmaceutical formulations or active</p> <p>13 pharmaceutical ingredient.</p> <p>14   Q.    What about the term</p> <p>15 pharmaceutical, sir, is this disclosing</p> <p>16 use of agave syrup in a pharmaceutical?</p> <p>17   A.    The word is in there.</p> <p>18   Q.    Would a person of ordinary</p> <p>19 skill in the art understand what the term</p> <p>20 pharmaceutical means?</p> <p>21   A.    They would have a hard time</p> <p>22 reconciling that word in the context of</p> <p>23 this patent application.</p> <p>24   Q.    Would they know what a</p> <p>25 pharmaceutical is?</p>                                                    |

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| <p style="text-align: right;">Page 190</p> <p>1 BERKLAND</p> <p>2 A. It's related to the art in</p> <p>3 their field, so, yes.</p> <p>4 Q. Would they know what a</p> <p>5 sweetener in a pharmaceutical is?</p> <p>6 A. They would.</p> <p>7 Q. Would they understand that this</p> <p>8 patent is stating you can use agave nectar</p> <p>9 as a sweetener in a pharmaceutical?</p> <p>10 A. The only working examples they</p> <p>11 have are related to food, so, I mean, you</p> <p>12 wouldn't know if it is an enema or</p> <p>13 mouthwash or suspension.</p> <p>14 I mean, there is no additional</p> <p>15 disclosure.</p> <p>16 Q. So does an enema have a</p> <p>17 sweetener in it, sir?</p> <p>18 A. Well, some of them have</p> <p>19 osmotically active agents like polyols and</p> <p>20 a sweetener is a polyol.</p> <p>21 All I'm saying is this is</p> <p>22 unspecified.</p> <p>23 Q. But you would agree that an</p> <p>24 oral pharmaceutical formulation is a</p> <p>25 pharmaceutical, correct?</p>        | <p style="text-align: right;">Page 192</p> <p>1 BERKLAND</p> <p>2 challenges of oral liquids and the need</p> <p>3 for artificial sweeteners in the context</p> <p>4 of pharmaceuticals.</p> <p>5 Q. Does the '795 patent talk about</p> <p>6 the challenges of oral liquids in the</p> <p>7 pharmaceutical context?</p> <p>8 A. Yeah, we went through them</p> <p>9 together, taste masking, palatability,</p> <p>10 pourability, whatever, viscosity.</p> <p>11 Q. Is a sweetener added to a</p> <p>12 product to address palatability?</p> <p>13 A. It can be.</p> <p>14 Q. In understanding that a</p> <p>15 sweetener can be added to a product to</p> <p>16 address palatability and the disclosure</p> <p>17 that the sweetener can be added to</p> <p>18 pharmaceuticals, would a POSITA understand</p> <p>19 that the agave syrup teaching here could</p> <p>20 be used to address palatability issues in</p> <p>21 a pharmaceutical?</p> <p>22 MR. PIVOVAR: Objection to</p> <p>23 form.</p> <p>24 A. It is talking about calorie</p> <p>25 reduction in the abstract and background.</p> |
| <p style="text-align: right;">Page 191</p> <p>1 BERKLAND</p> <p>2 A. Yes.</p> <p>3 Q. And you would agree that an</p> <p>4 oral pharmaceutical can certainly have a</p> <p>5 sweetener in it, correct?</p> <p>6 A. It can.</p> <p>7 Q. And they often do have</p> <p>8 sweeteners in them, correct?</p> <p>9 A. Tablets usually don't and</p> <p>10 capsules usually don't, but in many of the</p> <p>11 liquids, they do.</p> <p>12 Q. This patent is stating that you</p> <p>13 can replace sweeteners in pharmaceuticals</p> <p>14 with agave nectar, correct?</p> <p>15 A. And all I'm saying is it is</p> <p>16 making a generalization, I don't see any</p> <p>17 sort of enabling subtext or description or</p> <p>18 examples, that's the only point I'm</p> <p>19 making.</p> <p>20 Q. What do you mean by enabling</p> <p>21 subtext?</p> <p>22 A. They don't have such</p> <p>23 definitions that we just walked through,</p> <p>24 they don't talk anywhere about oral</p> <p>25 liquids, they don't talk about the</p> | <p style="text-align: right;">Page 193</p> <p>1 BERKLAND</p> <p>2 Q. Is your answer that a person of</p> <p>3 skill in the art in reading this wouldn't</p> <p>4 understand that agave syrup using a</p> <p>5 sweetener in a pharmaceutical may address</p> <p>6 a palatability issue?</p> <p>7 A. I don't see that explicitly in</p> <p>8 this prior art reference.</p> <p>9 Q. So in order for it to teach it</p> <p>10 you would say it has to explicitly show</p> <p>11 it?</p> <p>12 MR. PIVOVAR: Objection to</p> <p>13 form.</p> <p>14 A. No.</p> <p>15 Q. And so would a POSITA knowing</p> <p>16 that sweeteners are put in pharmaceutical</p> <p>17 formulations to potentially address</p> <p>18 palatability issues and the disclosure</p> <p>19 here to use agave in place of sweeteners</p> <p>20 in pharmaceuticals show that it could be</p> <p>21 used to address palatability issues?</p> <p>22 A. I think my earlier answer was</p> <p>23 it could, a POSITA would have that</p> <p>24 background, that sweeteners could be used</p> <p>25 to mask the taste of drugs.</p>       |

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| <p style="text-align: right;">Page 194</p> <p>1 BERKLAND</p> <p>2 Q. Including agave syrups, right?</p> <p>3 A. There is no evidence of that</p> <p>4 here.</p> <p>5 Q. But a POSITA would have the</p> <p>6 knowledge that a sweetener could mask the</p> <p>7 taste of drugs and agave syrup is a</p> <p>8 sweetener, correct, sir?</p> <p>9 A. Perhaps, we don't have -- I</p> <p>10 don't have the context and timing and what</p> <p>11 not for this filing.</p> <p>12 Q. Well, this was filed, published</p> <p>13 in 2009, sir, right, so that would have</p> <p>14 been before the '795 patent, correct?</p> <p>15 A. You can't ask me to import our</p> <p>16 definition of a POSITA into this filing,</p> <p>17 though, and I haven't reviewed the date</p> <p>18 and the state-of-the-art at this time.</p> <p>19 Q. But a POSITA would have Exhibit</p> <p>20 1008 available to him or her at the time</p> <p>21 of the filing of the '795 patent, correct,</p> <p>22 sir?</p> <p>23 A. Yes.</p> <p>24 Q. So we don't have to consider</p> <p>25 the knowledge and skill of the art in</p>                  | <p style="text-align: right;">Page 196</p> <p>1 BERKLAND</p> <p>2 for the POSITA to review?</p> <p>3 A. Of course.</p> <p>4 Q. And that POSITA would have all</p> <p>5 the information that was available,</p> <p>6 including the other references that we</p> <p>7 looked at that talked about using agave in</p> <p>8 pharmaceutical formulations, correct?</p> <p>9 A. Absolutely.</p> <p>10 Q. And so when they read this</p> <p>11 reference, and it says to use agave syrup</p> <p>12 as a sweetener in a pharmaceutical</p> <p>13 product, they would understand that this</p> <p>14 could be used in an oral formulation,</p> <p>15 correct, sir?</p> <p>16 MR. PIVOVAR: Objection, form.</p> <p>17 A. I think we're kind of back</p> <p>18 where we started and I don't -- I just</p> <p>19 don't see support in this filing to</p> <p>20 conclude that by itself from this filing.</p> <p>21 Q. The word pharmaceutical is not</p> <p>22 support for using agave syrup in a</p> <p>23 pharmaceutical?</p> <p>24 MR. PIVOVAR: Objection, form.</p> <p>25 Q. If that's what you want to tell</p> |
| <p style="text-align: right;">Page 195</p> <p>1 BERKLAND</p> <p>2 2009, we're asking about the knowledge in</p> <p>3 2021, sir, right?</p> <p>4 A. Okay.</p> <p>5 Q. And so in 2021, that POSITA</p> <p>6 would understand from this disclosure that</p> <p>7 agave could be used as a sweetener in</p> <p>8 pharmaceutical formulations, correct, sir?</p> <p>9 MR. PIVOVAR: Objection, form.</p> <p>10 A. All I'm saying is you're</p> <p>11 reading back our definition of the POSITA</p> <p>12 for the priority date of this patent onto</p> <p>13 this 2009 patent application that was</p> <p>14 originally filed in 2007.</p> <p>15 So maybe, I don't know.</p> <p>16 Q. But, sir, don't you understand</p> <p>17 that your analysis needs to always be at</p> <p>18 the filing date of the '795 patent, so</p> <p>19 this is in 2021, sir, correct?</p> <p>20 MR. PIVOVAR: Objection, form.</p> <p>21 A. For the '795, that's correct.</p> <p>22 Q. Yes.</p> <p>23 And so the day before the '795</p> <p>24 patent is filed, you would agree that this</p> <p>25 would be, Exhibit 1008, would be available</p> | <p style="text-align: right;">Page 197</p> <p>1 BERKLAND</p> <p>2 the Patent Office, go ahead, you can tell</p> <p>3 them that.</p> <p>4 A. I feel like you're badgering me</p> <p>5 here a little bit.</p> <p>6 But to be clear, the word</p> <p>7 pharmaceutical is disclosed and a person</p> <p>8 of skill would understand what the word</p> <p>9 pharmaceutical means.</p> <p>10 The disclosure does not have</p> <p>11 pharmaceutical formulations, it doesn't</p> <p>12 contemplate an active pharmaceutical</p> <p>13 ingredient, so what I'm telling you is</p> <p>14 it's thin in regards to having support for</p> <p>15 pharmaceuticals.</p> <p>16 Q. But it discloses that, sir,</p> <p>17 correct?</p> <p>18 MR. PIVOVAR: Objection to</p> <p>19 form.</p> <p>20 A. It says the word</p> <p>21 pharmaceutical.</p> <p>22 Q. And a POSITA would understand</p> <p>23 what a pharmaceutical is, correct, sir?</p> <p>24 A. They would understand the word</p> <p>25 pharmaceutical.</p>                                                                                                     |

50 (Pages 194 - 197)

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| <p style="text-align: right;">Page 198</p> <p>1 BERKLAND</p> <p>2 Q. Is one type of pharmaceutical</p> <p>3 an oral liquid formulation, sir?</p> <p>4 A. That is a type of</p> <p>5 pharmaceutical.</p> <p>6 Q. Do most oral liquid</p> <p>7 formulations have sweeteners in them, sir?</p> <p>8 MR. PIVOVAR: Objection to</p> <p>9 form.</p> <p>10 A. I don't know if most do.</p> <p>11 Q. Do many pharmaceutical oral</p> <p>12 formulations have sweeteners in them?</p> <p>13 MR. PIVOVAR: Objection, form.</p> <p>14 A. Some of them do.</p> <p>15 Q. The publication is stating that</p> <p>16 you can use agave syrup as a replacement</p> <p>17 for sweeteners in pharmaceuticals,</p> <p>18 correct?</p> <p>19 (Witness perusing document.)</p> <p>20 A. It lists agave as a</p> <p>21 replacement; again, there is little</p> <p>22 support.</p> <p>23 Q. Have you ever heard of the term</p> <p>24 unique ingredient identifier?</p> <p>25 A. Yes.</p>                       | <p style="text-align: right;">Page 200</p> <p>1 BERKLAND</p> <p>2 because there's many chemicals that have</p> <p>3 unique ingredient identifiers that then</p> <p>4 come in various grades.</p> <p>5 MR. NOLAN: I am going to mark</p> <p>6 as Exhibit 1047 a document from the FDA</p> <p>7 Precision Database on UNII-GVG8G02070.</p> <p>8 (Berkland Exhibit 1047,</p> <p>9 document from the FDA Precision Database</p> <p>10 on UNII-GVG8G02070, was marked for</p> <p>11 identification, as of this date.)</p> <p>12 Q. Do you see that?</p> <p>13 A. Yes, it's populated now, thank</p> <p>14 you.</p> <p>15 Q. Have you ever conducted a</p> <p>16 search of the FDA for different unique</p> <p>17 ingredient identifiers?</p> <p>18 A. Yes.</p> <p>19 Q. Do you see this printout, do</p> <p>20 you see this is identifying a unique</p> <p>21 ingredient identifier for, the synonym</p> <p>22 shown, agave nectar and agave syrup?</p> <p>23 MR. PIVOVAR: Objection, form.</p> <p>24 A. Are you on page 2?</p> <p>25 Q. Yes.</p> |
| <p style="text-align: right;">Page 199</p> <p>1 BERKLAND</p> <p>2 Q. What does a unique ingredient</p> <p>3 identifier mean?</p> <p>4 MR. PIVOVAR: Objection to</p> <p>5 form.</p> <p>6 A. It's sort of like a serial</p> <p>7 number for a specific chemical or compound</p> <p>8 or ingredient.</p> <p>9 Q. Does the FDA use unique</p> <p>10 ingredient identifiers?</p> <p>11 A. They often do.</p> <p>12 Q. Why does the FDA use unique</p> <p>13 ingredient identifiers?</p> <p>14 MR. PIVOVAR: Objection, form.</p> <p>15 A. It's a way of verifying that</p> <p>16 you're talking about the same thing.</p> <p>17 Q. Did you search the United</p> <p>18 States Food and Drug Administration to see</p> <p>19 if it had a unique ingredient identifier</p> <p>20 for agave syrup?</p> <p>21 A. I don't recall.</p> <p>22 Q. Would you be surprised if the</p> <p>23 FDA had a unique ingredient identifier for</p> <p>24 agave syrup?</p> <p>25 A. I would not be surprised,</p> | <p style="text-align: right;">Page 201</p> <p>1 BERKLAND</p> <p>2 (Witness perusing document.)</p> <p>3 A. Is there more to this document?</p> <p>4 Q. I want to understand whether</p> <p>5 you know this would be a unique ingredient</p> <p>6 identifier number for agave syrup and</p> <p>7 agave nectar, does this look familiar to</p> <p>8 what you've seen in the past?</p> <p>9 MR. PIVOVAR: Objection, form.</p> <p>10 A. Normally there would be more</p> <p>11 detail.</p> <p>12 I see the list of synonyms.</p> <p>13 Q. Do you know why the FDA would</p> <p>14 have assigned a unique ingredient</p> <p>15 identifier for agave syrup?</p> <p>16 MR. PIVOVAR: Object to form.</p> <p>17 A. I am not aware of why or when</p> <p>18 that would have occurred.</p> <p>19 Q. What would the purpose of doing</p> <p>20 it be, though?</p> <p>21 MR. PIVOVAR: Objection to</p> <p>22 form.</p> <p>23 A. I can't tell from this limited</p> <p>24 disclosure.</p> <p>25 MR. NOLAN: I am going to ask</p>                           |

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| <p style="text-align: right;">Page 202</p> <p>1 BERKLAND</p> <p>2 my colleague to mark as Exhibit 1048 a</p> <p>3 document related to Little Remedies infant</p> <p>4 Essential Kit.</p> <p>5 (Berkland Exhibit 1048,</p> <p>6 document related to Little Remedies infant</p> <p>7 Essential Kit, was marked for</p> <p>8 identification, as of this date.)</p> <p>9 MR. NOLAN: We have to change</p> <p>10 the exhibit number, it got in as 1036, it</p> <p>11 should be 1048.</p> <p>12 (Pause.)</p> <p>13 MR. NOLAN: We can ignore the</p> <p>14 one that is in as 1036, because we don't</p> <p>15 want it to overlap with the other ones.</p> <p>16 Q. This is 1048, do you see that,</p> <p>17 sir?</p> <p>18 A. Understood.</p> <p>19 Q. Have you ever heard the term</p> <p>20 gripe water?</p> <p>21 A. I believe so, yes.</p> <p>22 Q. What is gripe water?</p> <p>23 A. I don't recall.</p> <p>24 Q. If I represent that it may be a</p> <p>25 formulation you would give to children for</p>                             | <p style="text-align: right;">Page 204</p> <p>1 BERKLAND</p> <p>2 patent, right?</p> <p>3 A. Those are prior to the '795</p> <p>4 date.</p> <p>5 Q. That is a formulation for</p> <p>6 administration to a human patient that</p> <p>7 uses agave syrup, correct, sir?</p> <p>8 MR. PIVOVAR: Objection.</p> <p>9 A. Agave is in there, but we can't</p> <p>10 tell how much, and agave is often used as</p> <p>11 a sweetener, according to some of the</p> <p>12 documents we've reviewed.</p> <p>13 Q. The claims of the '795 patent</p> <p>14 require agave to be used for a specific</p> <p>15 purpose?</p> <p>16 A. A POSA would understand it</p> <p>17 contributes to the viscosity.</p> <p>18 Q. What I am asking you, sir, is</p> <p>19 do the claims require agave be in there</p> <p>20 for a specific purpose?</p> <p>21 A. The claims don't have a</p> <p>22 limitation for the purpose, but claims are</p> <p>23 read in light of the specification.</p> <p>24 Q. If agave was put in a</p> <p>25 formulation for a sweetener, you would</p> |
| <p style="text-align: right;">Page 203</p> <p>1 BERKLAND</p> <p>2 maybe ingestion or colic issues, does that</p> <p>3 help you place your memory?</p> <p>4 A. That helps.</p> <p>5 Q. If you can look at 1048, sir, I</p> <p>6 am going to be looking at the page that</p> <p>7 should say 4/5, 5/5, the two pages.</p> <p>8 A. Okay.</p> <p>9 Q. Do you see what it describes is</p> <p>10 the ingredients for the gripe water?</p> <p>11 A. I do.</p> <p>12 Q. Is agave syrup used as an</p> <p>13 inactive ingredient in this?</p> <p>14 A. I see the agave juice on the</p> <p>15 list, which I believe is a synonym.</p> <p>16 Q. And so this formulation, if you</p> <p>17 look at the bottom, when was this</p> <p>18 formulation available for use?</p> <p>19 A. Strange it says dietary</p> <p>20 supplement, 2/15 of 2017.</p> <p>21 Q. What is the next one,</p> <p>22 2/15/2019?</p> <p>23 A. Unapproved drug, 2/15/2019.</p> <p>24 Q. Both of these would have been</p> <p>25 before the priority date for the '795</p> | <p style="text-align: right;">Page 205</p> <p>1 BERKLAND</p> <p>2 understand that as falling within the '795</p> <p>3 patent claims that would have the</p> <p>4 appropriate viscosity, is that correct,</p> <p>5 sir?</p> <p>6 MR. PIVOVAR: Objection to</p> <p>7 form.</p> <p>8 A. That's a pretty broad</p> <p>9 statement.</p> <p>10 Q. I am asking your understanding</p> <p>11 of the claims, you're an expert that's</p> <p>12 opining on it.</p> <p>13 A. I have to disagree with your</p> <p>14 assertion.</p> <p>15 Q. So tell me what you disagree</p> <p>16 with.</p> <p>17 MR. PIVOVAR: Objection, form.</p> <p>18 A. I disagree with your statement.</p> <p>19 Q. If agave is present in an</p> <p>20 acetaminophen formulation with a diluent</p> <p>21 and a flavoring component and meets the</p> <p>22 viscosity limitation, does the purpose of</p> <p>23 agave syrup in that formulation matter</p> <p>24 when you consider the claims of the '795</p> <p>25 patent?</p>                                                               |

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| <p style="text-align: right;">Page 206</p> <p>1 BERKLAND</p> <p>2 MR. PIVOVAR: Object to form.</p> <p>3 A. I think I answered that</p> <p>4 question already.</p> <p>5 Q. What's your answer, sir.</p> <p>6 A. That there wasn't a limitation</p> <p>7 for the purpose of the agave, the claims</p> <p>8 are read in light of the specification,</p> <p>9 the POSA knows it's used as part of this</p> <p>10 viscosity property of the syrup.</p> <p>11 Q. So the POSA knows it's used as</p> <p>12 part of the viscosity property of the</p> <p>13 syrup; would that POSA understand if the</p> <p>14 agave was being used for a purpose other</p> <p>15 than the viscosity property of the syrup,</p> <p>16 that would fall outside the scope of the</p> <p>17 '795 patent, is that your testimony?</p> <p>18 MR. PIVOVAR: Objection to</p> <p>19 form.</p> <p>20 A. I mean, the new art that you</p> <p>21 put in front of me is emulsion.</p> <p>22 I don't see the word syrup</p> <p>23 anywhere, we don't know the amounts of</p> <p>24 these ingredients, so I'm just having</p> <p>25 trouble seeing how it's related to the</p> | <p style="text-align: right;">Page 208</p> <p>1 BERKLAND</p> <p>2 Q. Well, if you know the scope of</p> <p>3 the claims, you can resolve my question.</p> <p>4 MR. PIVOVAR: There is no</p> <p>5 question pending.</p> <p>6 MR. NOLAN: Why don't we take a</p> <p>7 break.</p> <p>8 MR. PIVOVAR: Ten minutes,</p> <p>9 five?</p> <p>10 MR. NOLAN: Ten minutes is</p> <p>11 fine, thank you.</p> <p>12 (Recess taken.)</p> <p>13 BY MR. NOLAN:</p> <p>14 Q. Dr. Berkland, at any time</p> <p>15 during the breaks during your testimony or</p> <p>16 during lunch did you have any discussions</p> <p>17 with counsel about the substance of your</p> <p>18 report or the questions that have been</p> <p>19 raised today?</p> <p>20 A. No.</p> <p>21 Q. I would like to direct you to</p> <p>22 your report at Exhibit 2009, specifically</p> <p>23 paragraph 147.</p> <p>24 Are you there?</p> <p>25 A. Okay.</p>                                                                                                                                                                 |
| <p style="text-align: right;">Page 207</p> <p>1 BERKLAND</p> <p>2 patent.</p> <p>3 Q. I am just asking you about the</p> <p>4 patents irrespective of this art, sir.</p> <p>5 I am trying to get your</p> <p>6 understanding of the scope of the claims</p> <p>7 and you continually say that, although</p> <p>8 agave is not limited by purpose in the</p> <p>9 claim specifically, a POSA would read the</p> <p>10 claims in the context of the patent and</p> <p>11 understand the agave must contribute to</p> <p>12 the viscosity, that's what you testified</p> <p>13 to.</p> <p>14 I am trying to understand what</p> <p>15 you mean by that.</p> <p>16 MR. PIVOVAR: Objection to</p> <p>17 form, mischaracterizes his testimony.</p> <p>18 A. I didn't opine on this either.</p> <p>19 Q. You didn't opine on the scope</p> <p>20 of the claim, sir?</p> <p>21 MR. PIVOVAR: Objecting to the</p> <p>22 form.</p> <p>23 A. I opined on the scope of the</p> <p>24 claims, I just can't resolve your</p> <p>25 question.</p>                                                                                                       | <p style="text-align: right;">Page 209</p> <p>1 BERKLAND</p> <p>2 Q. You're providing your opinion</p> <p>3 concerning the motivation to combine the</p> <p>4 teachings that Dr. Crowley has presented,</p> <p>5 correct?</p> <p>6 A. Correct.</p> <p>7 Q. Can you describe for me the</p> <p>8 combinations that Dr. Crowley has</p> <p>9 presented.</p> <p>10 A. It would include combinations</p> <p>11 of what I call FR458 with the '4666 patent</p> <p>12 and/or WO133 and then the WO742 in</p> <p>13 combination with what I call the '4666</p> <p>14 and/or the WO133.</p> <p>15 Q. You understand that Dr. Crowley</p> <p>16 has presented arguments that FR458</p> <p>17 combined with the disclosure of the '4666</p> <p>18 patent renders the claims obvious,</p> <p>19 correct?</p> <p>20 A. I disagree with that claim, but</p> <p>21 I think that's his opinion.</p> <p>22 Q. You agree that Dr. Crowley</p> <p>23 opines that the combination of FR458 and</p> <p>24 the disclosure in WO133 renders the claim</p> <p>25 to the '795 patent obvious, correct?</p> |

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| <p style="text-align: right;">Page 210</p> <p>1           BERKLAND</p> <p>2    A.    I believe he makes that, I</p> <p>3 would have to go back and look at his</p> <p>4 report.</p> <p>5    Q.    Just for clarity, if you'd</p> <p>6 like, you can look at Exhibit 1003,</p> <p>7 paragraph 129, that's Dr. Crowley's</p> <p>8 report.</p> <p>9           (Witness perusing document.)</p> <p>10 A.    Okay.</p> <p>11 Q.    Does that clarify for you that</p> <p>12 first he is stating the FR458 combined</p> <p>13 with the '4666 patent discloses all of the</p> <p>14 limitations of claim 1 of the '795 patent</p> <p>15 along with his motivation to combine and</p> <p>16 that's a basis for obviousness?</p> <p>17       MR. PIVOVAR: Objection, form.</p> <p>18       (Witness perusing document.)</p> <p>19 A.    Yes.</p> <p>20 Q.    If you would look at the next</p> <p>21 sentence, he also states, based upon the</p> <p>22 discussion above, which shows FR458</p> <p>23 combined with WO133, discloses all the</p> <p>24 limitations of claim 1 along with his</p> <p>25 explanation for the reasons to combine and</p> | <p style="text-align: right;">Page 212</p> <p>1           BERKLAND</p> <p>2    Q.    You agree when you were</p> <p>3 drafting your report, you understood those</p> <p>4 and that's what you were responding to,</p> <p>5 correct?</p> <p>6    A.    Correct.</p> <p>7    Q.    I'd like to go back to your</p> <p>8 report, Exhibit 2009, paragraph 147.</p> <p>9    A.    I have it.</p> <p>10 Q.    First you provide a few reasons</p> <p>11 for why you disagree with Dr. Crowley,</p> <p>12 correct, do you see that, sir?</p> <p>13       MR. PIVOVAR: Are we on 147?</p> <p>14       MR. NOLAN: 147, yes, of</p> <p>15 Exhibit 2009.</p> <p>16       MR. PIVOVAR: Can you repeat</p> <p>17 the question again, please.</p> <p>18 Q.    I am just asking you identify</p> <p>19 several criticisms of Dr. Crowley's</p> <p>20 opinion in that.</p> <p>21 A.    Yes.</p> <p>22 Q.    And so the first one is the</p> <p>23 erroneous assertion that agave syrup has a</p> <p>24 viscosity of 212 cP, do you see that, sir?</p> <p>25 A.    I see it.</p>                                                                                       |
| <p style="text-align: right;">Page 211</p> <p>1           BERKLAND</p> <p>2 that would render claim 1 obvious, that's</p> <p>3 another one of his opinions, correct?</p> <p>4    A.    Where are you?</p> <p>5    Q.    Same paragraph, 129, next</p> <p>6 sentence, sir.</p> <p>7           (Witness perusing document.)</p> <p>8    A.    Okay.</p> <p>9    Q.    Do you agree with that, sir?</p> <p>10 A.    I don't agree with his opinions</p> <p>11 of course, but I see what you're pointing</p> <p>12 to.</p> <p>13 Q.    You understood that was the</p> <p>14 opinions that were being presented when</p> <p>15 you drafted your report, correct, sir?</p> <p>16       MR. PIVOVAR: Objection, form.</p> <p>17 A.    I understand that's at least</p> <p>18 part of his opinions, yes.</p> <p>19 Q.    Another one of his opinions is</p> <p>20 a third one in that same paragraph, which</p> <p>21 is the teachings of FR458 combined with</p> <p>22 the teachings of the '4666 and the WO133</p> <p>23 render the claims, claim 1 in the '795</p> <p>24 patent, obvious, correct?</p> <p>25 A.    I see that, yes.</p>          | <p style="text-align: right;">Page 213</p> <p>1           BERKLAND</p> <p>2    Q.    Do you think that's an</p> <p>3 erroneous assertion in his report?</p> <p>4    A.    We've resolved the location,</p> <p>5 his citation, for 212 centipoise, but it's</p> <p>6 still the case that agave syrup has a</p> <p>7 range of grades or viscosities.</p> <p>8    Q.    But are you suggesting that 212</p> <p>9 centipoise is not within that range?</p> <p>10       MR. PIVOVAR: Objection, form.</p> <p>11 A.    I didn't say that.</p> <p>12 Q.    And Dr. Crowley also</p> <p>13 acknowledges that agave can be of thicker</p> <p>14 and thinner consistency, correct, sir?</p> <p>15       MR. PIVOVAR: Objection, form.</p> <p>16 A.    If I recall correctly, he</p> <p>17 states that in his report.</p> <p>18       I don't know if he acknowledges</p> <p>19 it, I think he is quoting it from</p> <p>20 somewhere.</p> <p>21 Q.    But you would understand that</p> <p>22 to mean that he is quoting that agave</p> <p>23 syrup can have different viscosities,</p> <p>24 correct, sir?</p> <p>25 A.    I don't know, his analysis uses</p> |

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| <p style="text-align: right;">Page 214</p> <p>1           BERKLAND</p> <p>2 212 centipoise.</p> <p>3    Q.   His analysis doesn't rely on</p> <p>4 the 212 centipoise, correct, sir?</p> <p>5           MR. PIVOVAR: Objection, form.</p> <p>6    A.   Can you clarify.</p> <p>7    Q.   Sure.</p> <p>8           When he cites 212 centipoise,</p> <p>9 he says in fact he doesn't need to rely</p> <p>10 upon that because the viscosity ranges are</p> <p>11 specifically disclosed in, for example,</p> <p>12 WO133.</p> <p>13           MR. PIVOVAR: Objection, form.</p> <p>14    A.   I can't resolve what you're</p> <p>15 saying.</p> <p>16    Q.   Let me point you to the</p> <p>17 paragraph, give me a second.</p> <p>18           First go to paragraph 93 of</p> <p>19 Dr. Crowley's report?</p> <p>20    A.   I am there.</p> <p>21    Q.   You see this talks about the</p> <p>22 term agave syrup?</p> <p>23           (Witness perusing document.)</p> <p>24    A.   Yes.</p> <p>25    Q.   And he talks about the</p>                                                                                        | <p style="text-align: right;">Page 216</p> <p>1           BERKLAND</p> <p>2 to viscosity, do you recall that, sir?</p> <p>3    A.   If you add the term thinner or</p> <p>4 thicker it makes more sense, but I don't</p> <p>5 see that.</p> <p>6    Q.   So you don't think consistency</p> <p>7 here is referencing viscosity?</p> <p>8           (Witness perusing document.)</p> <p>9    A.   I am not sure what he means</p> <p>10 there.</p> <p>11    Q.   And if you go to paragraph 119</p> <p>12 of his report, sir, do you see he says a</p> <p>13 POSITA would know 212 centipoise was the</p> <p>14 viscosity of the agave syrup?</p> <p>15    A.   Two lines up from the bottom of</p> <p>16 the page of 119?</p> <p>17    Q.   Yes.</p> <p>18    A.   I see that.</p> <p>19    Q.   But he doesn't rely upon that</p> <p>20 to teach this limitation, is that correct,</p> <p>21 sir, instead he points to the teachings of</p> <p>22 WO133 or the teachings of the '4666</p> <p>23 patent, correct?</p> <p>24           MR. PIVOVAR: Object to the</p> <p>25 form.</p>                                    |
| <p style="text-align: right;">Page 215</p> <p>1           BERKLAND</p> <p>2 consistency of the agave syrup, correct,</p> <p>3 in that section?</p> <p>4           MR. PIVOVAR: Objection, form.</p> <p>5    A.   You mean where he says it's</p> <p>6 sticky or tacky.</p> <p>7    Q.   He also says "consistency can</p> <p>8 be obtained from agave plants depending on</p> <p>9 the means or degree of processing of the</p> <p>10 plants," correct?</p> <p>11    A.   I see that statement.</p> <p>12    Q.   He says "a POSITA would</p> <p>13 understand you can get different</p> <p>14 consistencies with agave syrup," right,</p> <p>15 sir?</p> <p>16           (Witness perusing document.)</p> <p>17    A.   In this section he appears to</p> <p>18 be just recapitulating what this '795</p> <p>19 patent says.</p> <p>20    Q.   Would you understand</p> <p>21 consistency there to refer to viscosity?</p> <p>22    A.   I don't know what he means.</p> <p>23    Q.   When we've used consistency</p> <p>24 during this deposition, thinner or thicker</p> <p>25 consistency, we've used that with respect</p> | <p style="text-align: right;">Page 217</p> <p>1           BERKLAND</p> <p>2    A.   I don't know what you mean by</p> <p>3 he doesn't rely on that.</p> <p>4    Q.   Well, in fact, sir, he just</p> <p>5 says with that viscosity, the examples 1</p> <p>6 through 4 of the FR458 may have a</p> <p>7 viscosity less than 1500 centipoise, but</p> <p>8 he doesn't rely upon that because he then</p> <p>9 goes and talks about the specific</p> <p>10 viscosity teachings in WO133 and a</p> <p>11 teaching in '4666 that shows specifically</p> <p>12 directed toward the viscosity range of</p> <p>13 these claims?</p> <p>14           MR. PIVOVAR: Objection to</p> <p>15 form.</p> <p>16           Is there a question pending?</p> <p>17    Q.   Do you understand that, sir?</p> <p>18           MR. PIVOVAR: Objection to</p> <p>19 form.</p> <p>20    A.   That's not my understanding; it</p> <p>21 says what it says.</p> <p>22    Q.   Do you agree that the WO133</p> <p>23 patent discloses a preferred viscosity for</p> <p>24 an acetaminophen solution between 200 and</p> <p>25 900 centipoise?</p> |

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| <p style="text-align: right;">Page 218</p> <p>1 BERKLAND</p> <p>2 A. You're jumping around on me</p> <p>3 here, so maybe we can go to that.</p> <p>4 Q. Why don't we go back and walk</p> <p>5 through 147 of your report, Exhibit 2009.</p> <p>6 A. Okay.</p> <p>7 Q. You started off with the</p> <p>8 statement "the erroneous assertion that</p> <p>9 agave syrup has a viscosity of 212 cP."</p> <p>10 Is your critique here that he's</p> <p>11 identifying a specific viscosity of agave</p> <p>12 syrup as opposed to a range?</p> <p>13 MR. PIVOVAR: Objection to</p> <p>14 form.</p> <p>15 A. That's part of it, yes.</p> <p>16 Q. You're not taking the position</p> <p>17 that agave syrup cannot have a viscosity</p> <p>18 of 212 cP, right?</p> <p>19 A. It's variable.</p> <p>20 Q. But any agave that you use in</p> <p>21 any formulation is going to have a</p> <p>22 specific agave -- strike that.</p> <p>23 Any agave syrup you select for</p> <p>24 a specific formulation is going to have a</p> <p>25 specific velocity, correct?</p> | <p style="text-align: right;">Page 220</p> <p>1 BERKLAND</p> <p>2 So the actual agave syrup</p> <p>3 that's put in the formulation is not going</p> <p>4 to have a range of viscosities, correct,</p> <p>5 sir?</p> <p>6 A. You can select any of the</p> <p>7 range, I'm having trouble following.</p> <p>8 Q. What I am asking you is what</p> <p>9 they put in there is not going to be a</p> <p>10 range, right, sir?</p> <p>11 A. Are you talking about just as a</p> <p>12 general matter, not related to any patent?</p> <p>13 Q. Just as a general matter; if I</p> <p>14 selected agave syrup, for example, to use</p> <p>15 with FR458 formulation, that agave syrup</p> <p>16 when I put it in there is going to have a</p> <p>17 specific viscosity, correct, sir?</p> <p>18 A. It will have a specific</p> <p>19 physical property like viscosity, but it</p> <p>20 can be selected from a range of grades and</p> <p>21 types of agaves.</p> <p>22 Q. And when you go on here in 147,</p> <p>23 before this you had a critique of</p> <p>24 combining viscosity range of the '4666</p> <p>25 patent with the WO133 patent, do you</p> |
| <p style="text-align: right;">Page 219</p> <p>1 BERKLAND</p> <p>2 MR. PIVOVAR: Objection.</p> <p>3 MR. NOLAN: Let me start that</p> <p>4 again.</p> <p>5 Q. Any agave syrup that you use in</p> <p>6 an oral pharmaceutical formulation will</p> <p>7 have a specific viscosity, is that fair to</p> <p>8 say?</p> <p>9 A. I don't think I fully</p> <p>10 appreciate the question.</p> <p>11 Q. We've been talking about agave</p> <p>12 syrup potentially having a range of</p> <p>13 viscosities, do you recall that?</p> <p>14 A. Yes.</p> <p>15 Q. If I select an agave syrup and</p> <p>16 I use that, would you expect the agave</p> <p>17 syrup that I select out of one batch will</p> <p>18 have a range of viscosities or will have a</p> <p>19 single viscosity measurement associated</p> <p>20 with that specific agave syrup?</p> <p>21 A. I think I'm confused.</p> <p>22 If it's like an ingredient for</p> <p>23 a formulation, the properties are whatever</p> <p>24 that ingredient is you've selected.</p> <p>25 Q. Exactly.</p>          | <p style="text-align: right;">Page 221</p> <p>1 BERKLAND</p> <p>2 recall that, sir?</p> <p>3 A. During our deposition today?</p> <p>4 Q. No, during your report here</p> <p>5 where you're opining on this section.</p> <p>6 A. Yeah, I'm just saying they</p> <p>7 disclose different viscosity ranges.</p> <p>8 Q. And do you agree that the</p> <p>9 viscosity range disclosed in the '4666</p> <p>10 patent includes a range that is below 1500</p> <p>11 centipoise, right?</p> <p>12 MR. PIVOVAR: Objection, form.</p> <p>13 A. I say in my report specifically</p> <p>14 it discloses a range of 1000 and 3000</p> <p>15 centipoise.</p> <p>16 Q. And so that would encompass</p> <p>17 part of the range in several of the claims</p> <p>18 of the '795 patent, correct?</p> <p>19 A. Are you referring to the</p> <p>20 limitation?</p> <p>21 Q. Yes, sir, the limitation of the</p> <p>22 claim; claim 1 that requires a viscosity</p> <p>23 below 1500, does the '4666 patent include</p> <p>24 ranges of viscosity below 1500 centipoise?</p> <p>25 A. There's some overlap, but it</p>                                                 |

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| <p style="text-align: right;">Page 222</p> <p>1           BERKLAND</p> <p>2 really doesn't -- you don't have a</p> <p>3 motivation to combine to reach that range,</p> <p>4 is that what you're talking about?</p> <p>5     Q.   No, I am just asking does it</p> <p>6 disclose that range, disclose below 1500</p> <p>7 centipoise, right, sir?</p> <p>8           MR. PIVOVAR: Objection, form.</p> <p>9     A.   There is information in the</p> <p>10 claim 1 about below 1500 centipoise.</p> <p>11     Q.   Now, in your critique of 147,</p> <p>12 No. 3, you talk about you wouldn't have a</p> <p>13 motivation to combine the viscosity range</p> <p>14 of the '4666 patent and WO133, do you see</p> <p>15 that, sir?</p> <p>16     A.   Yes.</p> <p>17     Q.   I'd like you to focus on, say,</p> <p>18 the opinion that Dr. Crowley gave with</p> <p>19 respect to combining the FR458 with the</p> <p>20 range, viscosity range, in WO133.</p> <p>21           Did you analyze that</p> <p>22 combination, sir?</p> <p>23     A.   One more time.</p> <p>24     Q.   The combination of the</p> <p>25 disclosure at FR458 with the disclosure of</p>                 | <p style="text-align: right;">Page 224</p> <p>1           BERKLAND</p> <p>2 also cited sections that talked about the</p> <p>3 need to have balanced viscosity to keep</p> <p>4 things in suspension, do you recall that,</p> <p>5 sir?</p> <p>6           MR. PIVOVAR: Objection to</p> <p>7 form.</p> <p>8     A.   I recall the conversation of</p> <p>9 viscosity as it relates to suspensions and</p> <p>10 various factors.</p> <p>11     Q.   And so are you relying upon the</p> <p>12 fact that he said 20 to 150 is readily</p> <p>13 pourable as a reason why a person of skill</p> <p>14 in the art would not think that the</p> <p>15 viscosity range disclosed in WO133 would</p> <p>16 be an appropriate range for an oral</p> <p>17 pharmaceutical formulation with</p> <p>18 acetaminophen?</p> <p>19           MR. PIVOVAR: Object,</p> <p>20 objection, form.</p> <p>21     Q.   Explain that at that me, sir,</p> <p>22 why would a person of ordinary skill in</p> <p>23 the art conclude that you wouldn't combine</p> <p>24 the '495 disclosure -- excuse me.</p> <p>25           Explain for me why a person of</p>                                                          |
| <p style="text-align: right;">Page 223</p> <p>1           BERKLAND</p> <p>2 a preferred viscosity range for an oral</p> <p>3 pharmaceutical formulation shown in WO133.</p> <p>4     A.   Okay.</p> <p>5     Q.   Did you focus on that</p> <p>6 combination at any time in your report?</p> <p>7     A.   I'm sorry, I am getting a</p> <p>8 little lost in your question again,</p> <p>9 apologies.</p> <p>10     Q.   I want to understand your</p> <p>11 opinions with respect to the specific</p> <p>12 combination of FR458, disclosure in that,</p> <p>13 with the disclosed viscosity ranges for</p> <p>14 the formulation as you report here of 200</p> <p>15 to 900 centipoise, I'm trying to</p> <p>16 understand your opinions with respect to</p> <p>17 that combination specifically, sir.</p> <p>18     A.   I talk about that in 148 and</p> <p>19 139 and 150.</p> <p>20     Q.   And so you rely upon in 148,</p> <p>21 you rely upon the fact that Dr. Crowley</p> <p>22 noted that suspensions between 20 to 150</p> <p>23 are readily pourable, right, sir?</p> <p>24     A.   That's part of my analysis.</p> <p>25     Q.   We discussed earlier that he</p> | <p style="text-align: right;">Page 225</p> <p>1           BERKLAND</p> <p>2 ordinary skill in the art wouldn't combine</p> <p>3 FR458 disclosure with the teaching of 2 to</p> <p>4 900 in WO133 because of the fact that a</p> <p>5 viscosity of 2 to 150 is considered</p> <p>6 readily pourable.</p> <p>7           MR. PIVOVAR: Objection to</p> <p>8 form.</p> <p>9     A.   I give several reasons.</p> <p>10           Dr. Crowley puts forth this</p> <p>11 concept of viscosity range of 20 to 150</p> <p>12 centipoise as being readily pourable and</p> <p>13 he's talking about in the context of</p> <p>14 suspensions, this is a desirable range and</p> <p>15 property to be readily pourable.</p> <p>16           The WO133 patent discloses a</p> <p>17 higher range, so its own statements are</p> <p>18 teaching away from that patent.</p> <p>19     Q.   So a statement that --</p> <p>20     A.   I wasn't finished.</p> <p>21           He also says that higher</p> <p>22 viscosity is generally not desirable and</p> <p>23 the WO133 teaches a higher viscosity.</p> <p>24           And then the third piece of the</p> <p>25 analysis is if we rely on his value for</p> |

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| <p style="text-align: right;">Page 226</p> <p>1           BERKLAND</p> <p>2 viscosity of agave syrup, you end up below</p> <p>3 the 200 centipoise lower limit taught in</p> <p>4 the WO133 patent.</p> <p>5     Q.   How did you come to the</p> <p>6 conclusion that you would end up below the</p> <p>7 200 centipoise of the WO133 if you use an</p> <p>8 agave syrup of 212, sir?</p> <p>9     A.   It's reasonable based on the</p> <p>10 other ingredients, I talk about that</p> <p>11 actually in paragraph 150.</p> <p>12     Q.   You're just talking about the</p> <p>13 example specifically, right, sir?</p> <p>14     A.   Yeah, example --</p> <p>15     Q.   You're not talking about the</p> <p>16 general disclosure in FR458 which tells</p> <p>17 you to use agave syrup as a base with</p> <p>18 acetaminophen formulation, correct?</p> <p>19           MR. PIVOVAR: Objection to the</p> <p>20 form, beyond scope.</p> <p>21     A.   Yeah, I'm referring to the</p> <p>22 example in the instructions there.</p> <p>23     Q.   So you're not considering the</p> <p>24 general teaching, sir, correct?</p> <p>25           MR. PIVOVAR: Objection, form.</p> | <p style="text-align: right;">Page 228</p> <p>1           BERKLAND</p> <p>2     A.   This is Dr. Crowley's</p> <p>3 assertion; he gave the top end of 150</p> <p>4 centipoise; I'm merely responding to that.</p> <p>5     Q.   Sir, he cited a reference that</p> <p>6 stated 20 to 150 is readily pourable and</p> <p>7 then he explained there are other aspects</p> <p>8 that were involved and cited references</p> <p>9 that showed those other aspects.</p> <p>10           So you agree that he's just</p> <p>11 citing what's in the art, right, sir?</p> <p>12           MR. PIVOVAR: Objection to</p> <p>13 form.</p> <p>14     A.   It's his art and he's relying</p> <p>15 on it; I'm just countering.</p> <p>16     Q.   Do you think 200 centipoise is</p> <p>17 readily pourable?</p> <p>18           MR. PIVOVAR: Objection, form.</p> <p>19     A.   Earlier I expressed some, like,</p> <p>20 what would be the word I would use; when</p> <p>21 we talked about his use of this term</p> <p>22 earlier and walked through his analysis,</p> <p>23 I'm just relying on the conclusion he came</p> <p>24 to.</p> <p>25           So that's the metes and bounds</p>                          |
| <p style="text-align: right;">Page 227</p> <p>1           BERKLAND</p> <p>2     A.   I don't think that's true,</p> <p>3 because the general teachings inform how</p> <p>4 to conduct the formulation of the example.</p> <p>5           But I am countering</p> <p>6 Dr. Crowley's position.</p> <p>7     Q.   The difference between readily</p> <p>8 pourable, he gives an example, 150 cP as</p> <p>9 readily pourable, correct, sir?</p> <p>10           MR. PIVOVAR: Objection to</p> <p>11 form.</p> <p>12     A.   20 to 150 cP, yes.</p> <p>13     Q.   And so the lower limit of WO133</p> <p>14 is 200, correct, sir?</p> <p>15     A.   That's correct, it's 200 to 900</p> <p>16 cP.</p> <p>17     Q.   And so when seeing 150 listed</p> <p>18 as something that's readily pourable, it</p> <p>19 is your view that a person of ordinary</p> <p>20 skill in the art would then conclude that</p> <p>21 a range that starts at 200 would be</p> <p>22 teaching away from a readily pourable</p> <p>23 solution, is that what you're proposing?</p> <p>24           MR. PIVOVAR: Objection to</p> <p>25 form.</p>                                                          | <p style="text-align: right;">Page 229</p> <p>1           BERKLAND</p> <p>2 of my opinion.</p> <p>3     Q.   I am asking you, sir, as an</p> <p>4 expert, would you consider 2 to 900 cP</p> <p>5 readily pourable?</p> <p>6           MR. PIVOVAR: Objection, form.</p> <p>7     A.   I hadn't considered that.</p> <p>8     Q.   So as an expert opining on</p> <p>9 viscosity in oral formulations, as you sit</p> <p>10 here today, can you give me an answer as</p> <p>11 to whether 2 to 900, a POSITA would consider</p> <p>12 2 to 900 cP readily pourable?</p> <p>13           MR. PIVOVAR: Object to form.</p> <p>14     A.   I'm countering Dr. Crowley's</p> <p>15 declaration.</p> <p>16     Q.   And part of it you're saying is</p> <p>17 because he identified 20 to 150 as readily</p> <p>18 pourable, that would exclude 2 to 900.</p> <p>19           So I am asking you, sir, do you</p> <p>20 consider 2 to 900 cP from a POSITA's</p> <p>21 perspective as readily pourable?</p> <p>22           MR. PIVOVAR: Object to form.</p> <p>23     A.   I consider Dr. Crowley to be an</p> <p>24 expert and this is what he set forth, so</p> <p>25 I'm merely responding to his position.</p> |

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| <p style="text-align: right;">Page 230</p> <p>1           BERKLAND</p> <p>2    Q.    But I am asking you, sir,</p> <p>3    you're holding yourself out as an expert,</p> <p>4    do you consider 2 to 900 cP of an</p> <p>5    acetaminophen formulation to be readily</p> <p>6    pourable?</p> <p>7           MR. PIVOVAR: Objection, form.</p> <p>8    A.    I have given you my answer.</p> <p>9    Q.    Your answer is you cannot tell</p> <p>10   me whether or not you consider that</p> <p>11   readily pourable?</p> <p>12          MR. PIVOVAR: Objection, form.</p> <p>13   A.    I don't see a reason to</p> <p>14   disagree with Dr. Crowley's position, it's</p> <p>15   his position.</p> <p>16          I'm merely countering it.</p> <p>17   Q.    Did Dr. Crowley say anywhere in</p> <p>18   his report that something above 150 cP is</p> <p>19   not readily pourable, you keep on telling</p> <p>20   me he limited himself to this range, did</p> <p>21   he say anywhere else that 150 is the upper</p> <p>22   limit of readily pourable?</p> <p>23          MR. PIVOVAR: Objection to</p> <p>24   form.</p> <p>25   A.    It is not really my job to</p> | <p style="text-align: right;">Page 232</p> <p>1           BERKLAND</p> <p>2    himself to 150 here, sir, is he?</p> <p>3           MR. PIVOVAR: Objection to</p> <p>4    form.</p> <p>5    A.    I mean, it says what it says in</p> <p>6    his report.</p> <p>7    Q.    Would you consider these</p> <p>8    pediatric liquid oral antibiotic</p> <p>9    formulations to be readily pourable?</p> <p>10          MR. PIVOVAR: Objection to</p> <p>11   form.</p> <p>12   A.    I didn't form an opinion on</p> <p>13   that, I'm relying on his assertion and</p> <p>14   responding.</p> <p>15   Q.    Would you consider them to be</p> <p>16   -- strike that.</p> <p>17          To be a pediatric liquid oral</p> <p>18   antibiotic formulation, would you have to</p> <p>19   be pourable?</p> <p>20          MR. PIVOVAR: Object to form.</p> <p>21   A.    You would have to be pourable?</p> <p>22   Q.    Yes.</p> <p>23   A.    You would have to be able to</p> <p>24   pour a liquid formulation.</p> <p>25   Q.    And so would you consider 20 to</p>                                                                                                                |
| <p style="text-align: right;">Page 231</p> <p>1           BERKLAND</p> <p>2    understand what Dr. Crowley was thinking</p> <p>3    when providing this range, he does provide</p> <p>4    a top end of 150 cP, I'm responding to</p> <p>5    that.</p> <p>6    Q.    He cites a document that's 150</p> <p>7    cP.</p> <p>8           But I am asking you, are you</p> <p>9    saying that he's limiting himself to 150</p> <p>10   cP and I'm just asking you what is your</p> <p>11   basis for that.</p> <p>12   A.    It is his citation and his</p> <p>13   logic.</p> <p>14   Q.    Can you go to paragraph 58 of</p> <p>15   Dr. Crowley's report, sir.</p> <p>16          (Witness complying.)</p> <p>17   A.    58?</p> <p>18   Q.    Yes, sir.</p> <p>19   A.    I have it.</p> <p>20   Q.    Do you see that he talks about</p> <p>21   viscosity ranges of 20 to 1780 cP, sir?</p> <p>22          MR. PIVOVAR: Objection to</p> <p>23   form.</p> <p>24   A.    I see that.</p> <p>25   Q.    And so he's not limiting</p>                                                                                                                                             | <p style="text-align: right;">Page 233</p> <p>1           BERKLAND</p> <p>2    1780 cP pourable?</p> <p>3    A.    I assume that you can poor</p> <p>4    them; I didn't really conduct this</p> <p>5    analysis.</p> <p>6    Q.    Then you see he talks about</p> <p>7    children's Tylenol having a viscosity of a</p> <p>8    thousand centipoise, do you see that, or</p> <p>9    less than a thousand centipoise.</p> <p>10          Would you consider that to be</p> <p>11   pourable?</p> <p>12   A.    I think you're missing the</p> <p>13   point, because, I mean, he puts forth a</p> <p>14   certain range that's particularly</p> <p>15   desireable and readily pourable; I'm just</p> <p>16   relying on what he says.</p> <p>17   Q.    He doesn't put forward.</p> <p>18          He says generally suspension</p> <p>19   time viscosity in the range of 20 to 150</p> <p>20   cP are considered readily pourable and he</p> <p>21   cites a document, that's what he says, do</p> <p>22   you agree with me, sir?</p> <p>23   A.    Yeah, that's what he says.</p> <p>24   Q.    Does he say that is the</p> <p>25   limitation for viscosity ranges of oral</p> |

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| <p style="text-align: right;">Page 234</p> <p>1           BERKLAND</p> <p>2 formulations, that's how you read this?</p> <p>3           MR. PIVOVAR: Objection to</p> <p>4 form.</p> <p>5     A.     It says what it says.</p> <p>6     Q.     Exactly, it says suspensions</p> <p>7 having viscosity in the range of 20 to 150</p> <p>8 cP are considered readily pourable.</p> <p>9           So why are you capping that at</p> <p>10 150 as that is what the viscosity range of</p> <p>11 a suspension would be?</p> <p>12     A.     It says readily pourable.</p> <p>13     Q.     Does he say and those are the</p> <p>14 only ones that would be pourable, sir?</p> <p>15           MR. PIVOVAR: Objection, form.</p> <p>16     A.     I assume if he says readily</p> <p>17 pourable, that that's a desirable</p> <p>18 property and he relies on a citation for</p> <p>19 that; I'm responding.</p> <p>20     Q.     Okay.</p> <p>21           And do you agree that WO133</p> <p>22 discloses a viscosity range that is</p> <p>23 pourable?</p> <p>24           MR. PIVOVAR: Objection, form.</p> <p>25     A.     You would have to be able to</p> | <p style="text-align: right;">Page 236</p> <p>1           BERKLAND</p> <p>2 really sure what you're getting at.</p> <p>3     Q.     Have you ever used children's</p> <p>4 Tylenol, sir, oral formulation of</p> <p>5 children's Tylenol?</p> <p>6     A.     I believe so.</p> <p>7     Q.     And did that take a long time</p> <p>8 for it to pour out of the bottle, sir?</p> <p>9           MR. PIVOVAR: Objection, form.</p> <p>10     A.     I don't know what you mean by a</p> <p>11 long time.</p> <p>12     Q.     Did it take minutes to pour out</p> <p>13 of the bottle?</p> <p>14           MR. PIVOVAR: Objection, form.</p> <p>15     A.     I don't recall.</p> <p>16     Q.     Do you think it took more than</p> <p>17 a minute for it to pour out a dose of</p> <p>18 children's Tylenol, an oral formulation of</p> <p>19 that, sir?</p> <p>20           MR. PIVOVAR: Objection to</p> <p>21 form.</p> <p>22     A.     I don't recall.</p> <p>23     Q.     I am asking you as an expert,</p> <p>24 do you think it would take more than a</p> <p>25 minute to pour out a dose of children's</p> |
| <p style="text-align: right;">Page 235</p> <p>1           BERKLAND</p> <p>2 pour an oral pharmaceutical formulation</p> <p>3 that's a liquid.</p> <p>4     Q.     When you say you would have to</p> <p>5 be able to pour it, do you expect it would</p> <p>6 take you minutes with the bottle turned</p> <p>7 over before it would come out?</p> <p>8     A.     I haven't conducted that type</p> <p>9 of analysis.</p> <p>10     Q.     Have you ever poured an oral</p> <p>11 formulation, sir, out of a bottle?</p> <p>12     A.     Yes.</p> <p>13     Q.     Do you expect it to take</p> <p>14 minutes to come out?</p> <p>15     A.     I'm not entirely sure what you</p> <p>16 mean.</p> <p>17     Q.     Have you ever used children's</p> <p>18 Tylenol?</p> <p>19     A.     Probably, yes.</p> <p>20     Q.     When you poured out the oral</p> <p>21 formulation of children's Tylenol, did you</p> <p>22 expect it would take minutes for it to</p> <p>23 come out?</p> <p>24     A.     Some of these are pretty thick</p> <p>25 and some of them use a syringe, so I'm not</p>                                                            | <p style="text-align: right;">Page 237</p> <p>1           BERKLAND</p> <p>2 Tylenol in oral formulation.</p> <p>3           MR. PIVOVAR: Objection to</p> <p>4 form.</p> <p>5     A.     You want me to guess?</p> <p>6     Q.     No, I am asking, you're an</p> <p>7 expert.</p> <p>8           You're saying I am an expert on</p> <p>9 oral formulations of viscosity and I can't</p> <p>10 tell you what my expectation would be for</p> <p>11 how long it would take to pour out</p> <p>12 children's Tylenol oral formulation; you</p> <p>13 can tell us that.</p> <p>14           MR. PIVOVAR: Objection to form</p> <p>15 and please stop badgering the witness.</p> <p>16     A.     I don't recall it taking more</p> <p>17 than a minute.</p> <p>18     Q.     Do you think it took --</p> <p>19     A.     But I don't know.</p> <p>20     Q.     Do you think it took more than</p> <p>21 30 seconds?</p> <p>22     A.     I don't know.</p> <p>23     Q.     As an expert, do you think it</p> <p>24 would take more than 30 seconds to pour</p> <p>25 out, sir?</p>                                      |

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| <p style="text-align: right;">Page 238</p> <p>1           BERKLAND</p> <p>2    A.    I recall typically using a</p> <p>3    syringe for this.</p> <p>4    Q.    You've never used children's</p> <p>5    Tylenol that you pour into a cup, sir?</p> <p>6    A.    I think I always used a</p> <p>7    syringe, but I'm not sure.</p> <p>8    Q.    As an expert, a person holding</p> <p>9    himself out as an expert in oral</p> <p>10   formulations and viscosity, would you</p> <p>11   expect a children's Tylenol oral</p> <p>12   formulation to take more than a few</p> <p>13   seconds to pour into a cup?</p> <p>14           MR. PIVOVAR: Objection, form.</p> <p>15   A.    I tend to concur with</p> <p>16   Dr. Crowley on this matter, that readily</p> <p>17   pourable is a desired property.</p> <p>18   Q.    Is that the only property that</p> <p>19   a POSITA looks at when coming up with a</p> <p>20   formulation?</p> <p>21           MR. PIVOVAR: Objection to</p> <p>22   form.</p> <p>23   A.    We have had this discussion</p> <p>24   before; no.</p> <p>25   Q.    And so they would look at</p>                                                                                           | <p style="text-align: right;">Page 240</p> <p>1           BERKLAND</p> <p>2    Dr. Crowley's assertion of the readily</p> <p>3    pourable viscosity range as being teaching</p> <p>4    away.</p> <p>5    Q.    It teaches away because that's</p> <p>6    150 and the other one starts at 200 cP,</p> <p>7    correct, sir?</p> <p>8    A.    Only in that particular</p> <p>9    comparison.</p> <p>10   Q.    But those are the comparisons</p> <p>11   of the ranges, right, one ends at 150 and</p> <p>12   the other one starts at 200, correct, sir?</p> <p>13   A.    That's one of the ranges I</p> <p>14   compare.</p> <p>15   Q.    In that range, you're saying it</p> <p>16   is teaching away because there is a 50</p> <p>17   centipoise difference, is that fair to</p> <p>18   say?</p> <p>19           MR. PIVOVAR: Objection, form.</p> <p>20   A.    You can call it 50 centipoise</p> <p>21   or you can call it a 33 percent increase</p> <p>22   over 150, which is the top limit provided</p> <p>23   by Dr. Crowley.</p> <p>24   Q.    You asserted there is an error</p> <p>25   in the '4666 patent, correct, sir.</p> |
| <p style="text-align: right;">Page 239</p> <p>1           BERKLAND</p> <p>2    properties that may balance between the</p> <p>3    pourability and the ability to keep things</p> <p>4    in suspension, correct, sir?</p> <p>5           MR. PIVOVAR: Objection, form.</p> <p>6    A.    They could.</p> <p>7    Q.    And in that instance, then you</p> <p>8    would have a viscosity that is likely</p> <p>9    higher than the 150 because you'd want to</p> <p>10   be -- to have a higher viscosity to keep</p> <p>11   things in suspension, correct, sir?</p> <p>12           MR. PIVOVAR: Object to the</p> <p>13   form.</p> <p>14   A.    I don't know what that</p> <p>15   threshold is in this hypothetical and I</p> <p>16   have no reason to disagree with</p> <p>17   Dr. Crowley's range for readily pourable.</p> <p>18   Q.    So you're limiting it, the only</p> <p>19   consideration on whether it's readily</p> <p>20   pourable, despite the fact that a POSA</p> <p>21   would know there would be other reasons to</p> <p>22   select a viscosity in final formulation,</p> <p>23   right, sir?</p> <p>24           MR. PIVOVAR: Objection, form.</p> <p>25   A.    I am simply pointing to</p> | <p style="text-align: right;">Page 241</p> <p>1           BERKLAND</p> <p>2    A.    That's correct.</p> <p>3    Q.    Do you limit the teaching in</p> <p>4    the '4666 patent to 100 to 3000, sir?</p> <p>5    A.    Sorry, can I limit it?</p> <p>6    Q.    Do you limit the teaching on</p> <p>7    the viscosity range of the '4666 patent to</p> <p>8    1000 to 3000?</p> <p>9    A.    I stated there is an error in</p> <p>10   the claim limitation.</p> <p>11   Q.    But I am asking you, do you</p> <p>12   conclude that the '4666 patent only</p> <p>13   teaches viscosity ranges of a thousand to</p> <p>14   3000?</p> <p>15           MR. PIVOVAR: Objection to</p> <p>16   form.</p> <p>17   Q.    And just for clarity, the</p> <p>18   exhibit number we're talking about is</p> <p>19   1005.</p> <p>20           (Witness perusing document.)</p> <p>21   Q.    And to maybe make it easier, if</p> <p>22   you look at your paragraph 147, when you</p> <p>23   talk about the '4666 patent, you state the</p> <p>24   range is a thousand to 3000 cP.</p> <p>25   A.    I see that.</p>                                  |

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| <p style="text-align: right;">Page 242</p> <p>1           BERKLAND</p> <p>2     Q.    So are you limiting the</p> <p>3 disclosure of the '4666 patent to a</p> <p>4 viscosity range of a thousand to 3000</p> <p>5 centipoise?</p> <p>6           MR. PIVOVAR: Objection, form.</p> <p>7     A.    That's the range I saw repeated</p> <p>8 throughout the patent.</p> <p>9     Q.    But are you limiting the patent</p> <p>10 to that range, sir, disclosure to that</p> <p>11 range?</p> <p>12           MR. PIVOVAR: Objection, form.</p> <p>13     A.    That's the teaching of the</p> <p>14 opinion, in my opinion.</p> <p>15           It does use the word about.</p> <p>16     Q.    Where does it use the word</p> <p>17 about?</p> <p>18     A.    Go ahead, counsel.</p> <p>19     Q.    I was asking you to direct me</p> <p>20 to where you were talking about the word</p> <p>21 about.</p> <p>22     A.    In the claims, 9, 10, 11.</p> <p>23     Q.    Do you understand it to be</p> <p>24 teaching a viscosity below a thousand</p> <p>25 centipoise?</p> | <p style="text-align: right;">Page 244</p> <p>1           BERKLAND</p> <p>2           (Witness complying.)</p> <p>3     A.    I have it.</p> <p>4     Q.    You cited the language of heavy</p> <p>5 and uniform viscosity in a thousand to</p> <p>6 3000 centipoise, correct, we just looked</p> <p>7 at that?</p> <p>8     A.    Those are separately cited,</p> <p>9 but, yes, I'm with you.</p> <p>10    Q.    Is there a reason why you</p> <p>11 didn't cite -- I'd like to actually</p> <p>12 strike that.</p> <p>13           If you can go to -- I would</p> <p>14 like you to look at column 2 of Exhibit</p> <p>15 1005.</p> <p>16           (Witness complying.)</p> <p>17     A.    I'm with you.</p> <p>18     Q.    In the same section that you're</p> <p>19 talking about rather heavy and uniform</p> <p>20 viscosities, it is a little below that</p> <p>21 that I'm directing you to.</p> <p>22           (Witness perusing document.)</p> <p>23     A.    Okay.</p> <p>24     Q.    You see it talks about</p> <p>25 polyhydric alcohols?</p> |
| <p style="text-align: right;">Page 243</p> <p>1           BERKLAND</p> <p>2           MR. PIVOVAR: Objection, form.</p> <p>3     A.    Not substantially.</p> <p>4     Q.    If you could go to your</p> <p>5 paragraph 86 of Exhibit 2009.</p> <p>6     A.    Okay.</p> <p>7     Q.    You cite the statement</p> <p>8 "materials that contribute to a rather</p> <p>9 heavy and uniform viscosity in the final</p> <p>10 composition," do you see that, sir?</p> <p>11    A.    I see that.</p> <p>12    Q.    Do you consider about a</p> <p>13 thousand to 3000 centipoise to be a rather</p> <p>14 heavy and uniform viscosity?</p> <p>15    A.    Here I'm going from the patent.</p> <p>16    Q.    What I am asking you, though,</p> <p>17 is what's your consideration of what is a</p> <p>18 heavy viscosity?</p> <p>19           MR. PIVOVAR: Objection to</p> <p>20 form.</p> <p>21    A.    I have no reason to disagree</p> <p>22 with this statement in the context of the</p> <p>23 patent.</p> <p>24    Q.    Can you go to Exhibit 1005,</p> <p>25 sir.</p>  | <p style="text-align: right;">Page 245</p> <p>1           BERKLAND</p> <p>2     A.    Can you point me to the line,</p> <p>3 please.</p> <p>4     Q.    Around 47.</p> <p>5           (Witness perusing document.)</p> <p>6     A.    Okay.</p> <p>7     Q.    It describes as one of those</p> <p>8 acceptable alcohols propylene glycol?</p> <p>9     A.    I see it.</p> <p>10    Q.    You agree that the patent is</p> <p>11 teaching that the formulation could have</p> <p>12 propylene glycol?</p> <p>13    A.    It could.</p> <p>14    Q.    If you go down further, it</p> <p>15 talks about other permissible materials</p> <p>16 includes sucrose, right?</p> <p>17           (Witness perusing document.)</p> <p>18           MR. PIVOVAR: Objection, form.</p> <p>19    A.    Can you point me to the line?</p> <p>20    Q.    Sure.</p> <p>21           Line 59.</p> <p>22    A.    Okay.</p> <p>23    Q.    And so sucrose, would that be a</p> <p>24 sweetening agent?</p> <p>25    A.    Calls it a bodying agent here.</p>                     |

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| <p style="text-align: right;">Page 246</p> <p>1           BERKLAND</p> <p>2   Q.   It says it is an incidental</p> <p>3 part of the bodying agent, correct, sir?</p> <p>4   A.   It says what it says, yes.</p> <p>5   Q.   Would you expect sucrose to be</p> <p>6 a sweetening agent and I can maybe direct</p> <p>7 you to clarify; look at lines 15 through</p> <p>8 16.</p> <p>9           (Witness perusing document.)</p> <p>10  Q.   Of column 2.</p> <p>11           (Witness perusing document.)</p> <p>12  A.   Okay.</p> <p>13  Q.   You see that it's talking about</p> <p>14 sucrose sweetened?</p> <p>15  A.   Yes.</p> <p>16  Q.   Would you agree that this</p> <p>17 patent is showing that a sweetening agent</p> <p>18 can be sucrose?</p> <p>19  A.   There is disclosure of sucrose</p> <p>20 and the word sweetened.</p> <p>21  Q.   If you look at line 35, it</p> <p>22 talks about sweetening agents.</p> <p>23           Would you consider sucrose to</p> <p>24 be a nutritive or non-nutritive sweetener</p> <p>25 that is pharmaceutically acceptable and</p>                                                         | <p style="text-align: right;">Page 248</p> <p>1           BERKLAND</p> <p>2 agents," that's really pointing us in the</p> <p>3 direction of polyhydric alcohols.</p> <p>4   Q.   As the bodying agent, correct,</p> <p>5 sir?</p> <p>6   A.   Yes.</p> <p>7   Q.   One of those bodying agents for</p> <p>8 the polyhydric alcohol is propylene</p> <p>9 glycol, correct, sir?</p> <p>10  A.   I see propylene glycol as an</p> <p>11 option.</p> <p>12  Q.   I would like you to turn to</p> <p>13 claim 7, sir, of the '4666, Exhibit 105.</p> <p>14           (Witness complying.)</p> <p>15  Q.   Do you see that claim, sir?</p> <p>16  A.   I do.</p> <p>17  Q.   This claim would include a</p> <p>18 composition that had ibuprofen suspended</p> <p>19 in a bodying agent that was more than 50</p> <p>20 percent and had a sweetening agent in it,</p> <p>21 right, sir?</p> <p>22  A.   It says "a stabilized liquid</p> <p>23 ibuprofen syrup suitable for oral</p> <p>24 administration comprising from 50 to 400</p> <p>25 milligrams of ibuprofen per 5 mls of</p>                                                                                                                |
| <p style="text-align: right;">Page 247</p> <p>1           BERKLAND</p> <p>2 stable in aqueous solution?</p> <p>3   A.   I'm not sure where you're going</p> <p>4 with this.</p> <p>5           Sucrose could be a sweetener,</p> <p>6 but it says at line 41 "an important</p> <p>7 aspect of this invention is the inclusion</p> <p>8 of a major portion of water compatible</p> <p>9 material or materials that contribute to a</p> <p>10 rather heavy and uniform viscosity in the</p> <p>11 final composition."</p> <p>12  Q.   Would you understand that to be</p> <p>13 part of the disclosure as to a bodying</p> <p>14 agent, and maybe I can direct you to</p> <p>15 column 2, line 22, that talks about</p> <p>16 water-compatible bodying agents.</p> <p>17           (Witness perusing document.)</p> <p>18  A.   I see that.</p> <p>19  Q.   So bodying agent is a solution</p> <p>20 that can provide increased viscosity,</p> <p>21 correct?</p> <p>22  A.   It says what it says there.</p> <p>23           It goes on to say</p> <p>24 "pharmaceutically acceptable polyhydric</p> <p>25 alcohols are highly useful as bodying</p> | <p style="text-align: right;">Page 249</p> <p>1           BERKLAND</p> <p>2 syrup, said ibuprofen suspended in an</p> <p>3 aqueous liquid, having more than 50</p> <p>4 percent by weight of a pharmaceutically</p> <p>5 acceptable polyhydric alcohol bodying</p> <p>6 agent, a sweetening agent, and a pH from 7</p> <p>7 to 7.7."</p> <p>8   Q.   And so you agree that propylene</p> <p>9 glycol is a polyhydric alcohol bodying</p> <p>10 agent, correct?</p> <p>11           MR. PIVOVAR: Object to form.</p> <p>12  A.   It's listed in that disclosure</p> <p>13 back in column 2.</p> <p>14  Q.   And so this claim could cover a</p> <p>15 formulation that had ibuprofen and 51</p> <p>16 percent propylene glycol in addition to a</p> <p>17 sweetening agent, correct, sir?</p> <p>18  A.   I mean, there's more than just</p> <p>19 that in the whole disclosure of the claim.</p> <p>20  Q.   What else is there, sir?</p> <p>21  A.   It has to have the right amount</p> <p>22 of ibuprofen, per 5 mls of syrup, it has</p> <p>23 to have the right pH, it has to have a</p> <p>24 sweetening agent and it has to be a</p> <p>25 stabilized liquid suspension of ibuprofen.</p> |

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| <p style="text-align: right;">Page 250</p> <p>1 BERKLAND</p> <p>2 Q. Do you know what the pH would</p> <p>3 be of about 50 percent solution of</p> <p>4 propylene glycol?</p> <p>5 MR. PIVOVAR: Objection to</p> <p>6 form.</p> <p>7 A. You'll have to specify more</p> <p>8 than just 50 percent propylene glycol.</p> <p>9 Q. Why don't I pull up an exhibit</p> <p>10 discussing propylene glycol.</p> <p>11 (Pause.)</p> <p>12 (Berkland Exhibit 1049, article</p> <p>13 with the citation J. Chem Eng. Data 2004,</p> <p>14 49, 1311 to 1317, was marked for</p> <p>15 identification, as of this date.)</p> <p>16 MR. NOLAN: 1049 is going to be</p> <p>17 an article with the citation J. Chem Eng.</p> <p>18 Data 2004, 49, 1311 to 1317.</p> <p>19 The article is titled "Density,</p> <p>20 Viscosity and Thermal Conductivity of</p> <p>21 Aqueous Solutions of Propylene Glycol,</p> <p>22 Dipropylene Glycol, and Tripropylene</p> <p>23 Glycol between 290 K and 460 K."</p> <p>24 Q. Do you see the article, sir?</p> <p>25 A. I have it.</p> | <p style="text-align: right;">Page 252</p> <p>1 BERKLAND</p> <p>2 experimental densities, viscosities and</p> <p>3 thermal conductivities of glycol plus</p> <p>4 water mixtures containing 25, 50, and 75</p> <p>5 mol percent glycol."</p> <p>6 Does that help you, sir?</p> <p>7 A. It helps with that point.</p> <p>8 Q. And so when we go up back to</p> <p>9 Table 2, and I would like you to focus on</p> <p>10 the X1 equals 50, one column lists</p> <p>11 temperatures in kelvin, correct, do you</p> <p>12 see that, sir?</p> <p>13 A. I see that.</p> <p>14 Q. Do you understand that 297.5 is</p> <p>15 about room temperature?</p> <p>16 MR. PIVOVAR: Objection, form.</p> <p>17 A. I think it's slightly above</p> <p>18 room temperature, like 25 Celsius.</p> <p>19 Q. What do you consider room</p> <p>20 temperature?</p> <p>21 A. Usually around 22 to 23</p> <p>22 Celsius.</p> <p>23 Q. If I represent to you the 295</p> <p>24 kelvin is equal to 21.85 Celsius, would</p> <p>25 you consider that to be about room</p> |
| <p style="text-align: right;">Page 251</p> <p>1 BERKLAND</p> <p>2 Q. I would like to direct you to</p> <p>3 Table 2, viscosities of glycol plus water</p> <p>4 mixtures.</p> <p>5 Do you see that table has three</p> <p>6 columns, one for 25 percent solution, one</p> <p>7 for 50 percent solution and one for 75</p> <p>8 percent solution of glycols and water</p> <p>9 mixtures?</p> <p>10 MR. PIVOVAR: Objection to</p> <p>11 form.</p> <p>12 A. You call those percentages, but</p> <p>13 I'm just seeing this article for the first</p> <p>14 time.</p> <p>15 On mine it says .25, .5 and</p> <p>16 .75.</p> <p>17 Q. Do you understand that to be</p> <p>18 the amount of the glycol in the water</p> <p>19 mixture?</p> <p>20 MR. PIVOVAR: Objection, form.</p> <p>21 A. I don't know, I'm looking at</p> <p>22 this in isolation.</p> <p>23 Q. Why don't you look at the</p> <p>24 results and discussion at the bottom, it</p> <p>25 says, "Tables 1 through 3 list the</p>                                                                     | <p style="text-align: right;">Page 253</p> <p>1 BERKLAND</p> <p>2 temperature?</p> <p>3 MR. PIVOVAR: Objection, form.</p> <p>4 A. Sure, I'm with you.</p> <p>5 Q. And so what is the viscosity of</p> <p>6 the 50 percent glycol water solution at</p> <p>7 room temperature listed here?</p> <p>8 MR. PIVOVAR: Objection to</p> <p>9 form.</p> <p>10 A. I'll sorry, you're in table?</p> <p>11 Q. Table 2, I guess it would be</p> <p>12 the fourth column in the first row.</p> <p>13 (Witness perusing document.)</p> <p>14 MR. PIVOVAR: Can you repeat</p> <p>15 the question, please, counsel.</p> <p>16 Q. This is showing that the</p> <p>17 viscosity would be, of a propylene glycol</p> <p>18 50, percent glycol water solution at room</p> <p>19 temperature?</p> <p>20 MR. PIVOVAR: Object to form.</p> <p>21 A. It looks like it says 17.5</p> <p>22 milipascal seconds.</p> <p>23 Q. Would that be 17.5 centipoise?</p> <p>24 A. It would.</p> <p>25 Q. I would like to direct your</p>                                          |

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| <p style="text-align: right;">Page 254</p> <p>1 BERKLAND</p> <p>2 attention to your Exhibit 2022.</p> <p>3 A. Okay.</p> <p>4 Q. On page 5 you identify --</p> <p>5 strike that.</p> <p>6 On page 5 of that exhibit, it</p> <p>7 identifies the viscosity of various</p> <p>8 sucrose solutions, correct?</p> <p>9 A. It does.</p> <p>10 Q. What's the viscosity of a 10</p> <p>11 percent sucrose solution?</p> <p>12 A. You will have to specify more</p> <p>13 than just the 10 percent.</p> <p>14 Q. I'm looking, do you see Table</p> <p>15 131, sir?</p> <p>16 A. Yes.</p> <p>17 Q. It lists percentages of</p> <p>18 sucrose, right?</p> <p>19 A. It does.</p> <p>20 Q. Does it list the viscosities</p> <p>21 for those?</p> <p>22 A. Yes.</p> <p>23 Q. What is the viscosity for 10</p> <p>24 percent listed?</p> <p>25 A. 1.333.</p>                                                                                    | <p style="text-align: right;">Page 256</p> <p>1 BERKLAND</p> <p>2 correct?</p> <p>3 A. Correct.</p> <p>4 Q. What's the viscosity for the 20</p> <p>5 percent solution at 20 degrees Celsius?</p> <p>6 A. 1.945.</p> <p>7 Q. I would like you to turn back</p> <p>8 to Table 131.</p> <p>9 Do you see that this is listing</p> <p>10 the viscosities for the 23 degree Celsius</p> <p>11 measurement?</p> <p>12 A. Yes.</p> <p>13 Q. How does the sucrose number</p> <p>14 listed next to 20 percent on this table</p> <p>15 compare to the number that we just looked</p> <p>16 at?</p> <p>17 A. For which concentration?</p> <p>18 Q. 20 percent at 20 degrees?</p> <p>19 A. 1.941.</p> <p>20 Q. Would that suggest to you that</p> <p>21 Table 131 is also in centipoise?</p> <p>22 A. Yes.</p> <p>23 Q. What does Table 131 list as the</p> <p>24 viscosity of 10 percent sucrose solution?</p> <p>25 A. 1.333.</p>                                                                                                                  |
| <p style="text-align: right;">Page 255</p> <p>1 BERKLAND</p> <p>2 Q. Is that centipoise?</p> <p>3 A. I don't see it.</p> <p>4 Q. Do you see the next table, sir,</p> <p>5 in this chart?</p> <p>6 A. Table 132?</p> <p>7 Q. Yes.</p> <p>8 A. I do.</p> <p>9 Q. And what does it show the</p> <p>10 viscosity measurement is in that table?</p> <p>11 A. You're going to have to specify</p> <p>12 --</p> <p>13 MR. PIVOVAR: Objection to</p> <p>14 form.</p> <p>15 Q. Look at the table title, sir,</p> <p>16 what does it say it's being measured in?</p> <p>17 A. Viscosity in centipoises of</p> <p>18 sucrose solutions from zero to 40 degrees</p> <p>19 Celsius in 5 degree intervals.</p> <p>20 Q. If you look at the first entry,</p> <p>21 it is 20 percent sucrose solution, do you</p> <p>22 see that?</p> <p>23 A. Yes.</p> <p>24 Q. It then provides different</p> <p>25 viscosities at different temperatures,</p> | <p style="text-align: right;">Page 257</p> <p>1 BERKLAND</p> <p>2 Q. Centipoise that is, right, sir?</p> <p>3 A. That's our presumption.</p> <p>4 Q. That presumption is consistent</p> <p>5 with the information we just looked at for</p> <p>6 the next table, right, sir?</p> <p>7 A. That's correct.</p> <p>8 Q. What would be the viscosity of</p> <p>9 a solution that was 40 percent sucrose?</p> <p>10 A. You'll have to specify.</p> <p>11 Q. I'm looking at table 131, 40</p> <p>12 percent sucrose for the 20 degrees</p> <p>13 Celsius.</p> <p>14 A. 6.15.</p> <p>15 Q. I'd like you to keep the 17.5</p> <p>16 cP for propylene glycol in mind as well as</p> <p>17 the viscosity for sucrose that we just</p> <p>18 discussed in mind and I would like you to</p> <p>19 look back at claim 7 of '4666 patent, sir.</p> <p>20 (Witness complying.)</p> <p>21 Q. Are you back at that claim,</p> <p>22 sir?</p> <p>23 A. Yes.</p> <p>24 Q. You would agree we discussed</p> <p>25 earlier that propylene glycol in that</p> |

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| <p style="text-align: right;">Page 258</p> <p>1           BERKLAND</p> <p>2 claim could be 51 percent?</p> <p>3     A.   Well, I'll just remind you that</p> <p>4 it has to meet all the other limitations</p> <p>5 in that claim.</p> <p>6     Q.   But 51 percent would be within</p> <p>7 the limitation for the bodying agent of</p> <p>8 propylene -- of the polyhydric alcohol</p> <p>9 bodying agent, correct, sir?</p> <p>10    A.   Yes, 51 percent is more than 50</p> <p>11 percent.</p> <p>12    Q.   Yes.</p> <p>13           And that would have, from what</p> <p>14 we just looked at, that would have a</p> <p>15 viscosity of around 17.5 centipoise, that</p> <p>16 ingredient?</p> <p>17           MR. PIVOVAR: Objection, form.</p> <p>18    A.   You can't consider it in</p> <p>19 isolation; you have to consider the</p> <p>20 viscosity of the totality of the claim and</p> <p>21 that's a formulated ibuprofen suspension.</p> <p>22    Q.   Would you expect the ibuprofen</p> <p>23 constituent of this to substantially</p> <p>24 contribute to the viscosity of that</p> <p>25 formulation?</p>                                           | <p style="text-align: right;">Page 260</p> <p>1           BERKLAND</p> <p>2 form.</p> <p>3     A.   Did you say polypropylene</p> <p>4 glycol?</p> <p>5     Q.   I meant propylene glycol, my</p> <p>6 apologies.</p> <p>7     A.   I don't know, I would have to</p> <p>8 sit down and conduct a thorough analysis</p> <p>9 of that.</p> <p>10    Q.   Would you expect that to be</p> <p>11 more than a thousand?</p> <p>12           MR. PIVOVAR: Objection to</p> <p>13 form.</p> <p>14    A.   Sitting here I don't know.</p> <p>15    Q.   You agree that what we've</p> <p>16 looked at is ten -- a sucrose solution of</p> <p>17 10 percent to 40 percent, ranges in</p> <p>18 viscosity values of 1.3 centipoise to 6.15</p> <p>19 centipoise, based on the exhibit that</p> <p>20 you've submitted in this proceeding?</p> <p>21    A.   I don't think we came to that</p> <p>22 conclusion.</p> <p>23    Q.   Are you disagreeing with what's</p> <p>24 reported in your Exhibit 2022?</p> <p>25    A.   No.</p>                                                                                             |
| <p style="text-align: right;">Page 259</p> <p>1           BERKLAND</p> <p>2           MR. PIVOVAR: Objection, form.</p> <p>3     A.   I don't think you can consider</p> <p>4 that, those viscosities in isolation.</p> <p>5           The teachings of the patent are</p> <p>6 towards the entire formulation and we know</p> <p>7 that the solids content can contribute to</p> <p>8 the overall viscosity.</p> <p>9     Q.   And the solids content here can</p> <p>10 be, it says, 50 milligrams per 5</p> <p>11 millimeters, so that would be 10 mgs per</p> <p>12 ml of ibuprofen, correct, sir?</p> <p>13    A.   You're using the low end?</p> <p>14    Q.   Yes.</p> <p>15    A.   Yes.</p> <p>16    Q.   And then we know that -- would</p> <p>17 you expect a ten mgs per ml of</p> <p>18 ibuprofen -- strike that.</p> <p>19           What contribution to the</p> <p>20 viscosity of a formulation that includes</p> <p>21 ten mgs per ml ibuprofen, 51 percent</p> <p>22 polypropylene glycol and 10 percent</p> <p>23 sucrose, what would you expect the</p> <p>24 contribution of the ibuprofen to be?</p> <p>25           MR. PIVOVAR: Objection to</p> | <p style="text-align: right;">Page 261</p> <p>1           BERKLAND</p> <p>2     Q.   That shows that a 10 percent</p> <p>3 solution of sucrose at 20 degrees would</p> <p>4 have a viscosity of around 1.33</p> <p>5 centipoise, correct?</p> <p>6     A.   Yes.</p> <p>7     Q.   And you would agree that it</p> <p>8 also shows that a 40 percent solution at</p> <p>9 20 degrees Celsius would have a viscosity</p> <p>10 of around 6.15 centipoise, correct?</p> <p>11    A.   I am assuming you're reading</p> <p>12 the numbers directly from the art and that</p> <p>13 sounds correct.</p> <p>14    Q.   Yes, I am, sir.</p> <p>15           And then we looked at a</p> <p>16 reference that talked about what the</p> <p>17 viscosity of propylene glycol in a 50</p> <p>18 percent solution would be and that was</p> <p>19 around 17.5 centipoise, correct?</p> <p>20    A.   That's correct.</p> <p>21           MR. NOLAN: Can we just take a</p> <p>22 quick break, I don't think this is going</p> <p>23 to be much longer, but if we have a</p> <p>24 moment.</p> <p>25           (Recess taken.)</p> |

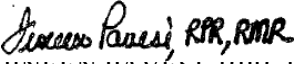
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| <p style="text-align: right;">Page 262</p> <p>1           BERKLAND</p> <p>2 BY MR. NOLAN:</p> <p>3     Q.    Just quickly, so we can move</p> <p>4 through this, we've uploaded another</p> <p>5 exhibit, Exhibit 1050, it's Journal of</p> <p>6 Pharmaceutical Science, Volume 97, No. 1,</p> <p>7 January 2008, starting at page 185.</p> <p>8           (Berkland Exhibit 1050, Journal</p> <p>9 of Pharmaceutical Science, Volume 97, No.</p> <p>10 1, January 2008, starting at page 185, was</p> <p>11 marked for identification, as of this</p> <p>12 date.)</p> <p>13     A.    I have it.</p> <p>14     Q.    I just want to make sure I'm</p> <p>15 understanding something quickly.</p> <p>16           You can look at anything you</p> <p>17 want in here, but if I could just take you</p> <p>18 to Figure 8.</p> <p>19           Do you have an understanding of</p> <p>20 what is meant by dynamic viscosity?</p> <p>21     A.    I do.</p> <p>22     Q.    What is dynamic viscosity?</p> <p>23     A.    Looking back at their</p> <p>24 measurement methods in the methods</p> <p>25 section, so they define it in the last</p>                                                   | <p style="text-align: right;">Page 264</p> <p>1           BERKLAND</p> <p>2 form.</p> <p>3     A.    It does not, but you would want</p> <p>4 something reflective of the features, like</p> <p>5 the portability or actual viscosity of the</p> <p>6 solution, not a different viscosity</p> <p>7 measurement.</p> <p>8           So what I'm telling you is I</p> <p>9 don't know if this falling ball viscometer</p> <p>10 is an analog to the typical way that it's</p> <p>11 measured.</p> <p>12     Q.    Just the term dynamic</p> <p>13 viscosity, the viscosity is measured in</p> <p>14 the '795 -- strike.</p> <p>15           Is the viscosity recited in the</p> <p>16 '795 patent a dynamic viscosity?</p> <p>17           MR. PIVOVAR: Objection to</p> <p>18 form.</p> <p>19     A.    I don't know, I'd have to</p> <p>20 compare, I'd have to go back and look at</p> <p>21 the different ways viscosity is measured.</p> <p>22     Q.    Have you heard the term</p> <p>23 absolute viscosity?</p> <p>24     A.    I have.</p> <p>25     Q.    What is absolute viscosity?</p>                                                         |
| <p style="text-align: right;">Page 263</p> <p>1           BERKLAND</p> <p>2 section of their methods, it's on 189,</p> <p>3 right before the results and discussion</p> <p>4 heading.</p> <p>5     Q.    Looking at that definition, do</p> <p>6 you understand that dynamic viscosity to</p> <p>7 be the same type of viscosity that is the</p> <p>8 subject of the claims of the '795 patent?</p> <p>9           MR. PIVOVAR: Objection, form.</p> <p>10     A.    It's a pretty different method,</p> <p>11 this falling ball viscometer is atypical.</p> <p>12     Q.    Do you understand that this is</p> <p>13 not measuring the viscosity of the</p> <p>14 formulation?</p> <p>15           MR. PIVOVAR: Object to form.</p> <p>16     A.    It's measuring a viscosity; I</p> <p>17 just need more time to go back and look at</p> <p>18 the literature comparing viscosity</p> <p>19 measurement types.</p> <p>20     Q.    Does the claim of the '795</p> <p>21 patent define a specific type of viscosity</p> <p>22 measurement procedure you must use to</p> <p>23 attain the viscosity of the formulation</p> <p>24 recited in that?</p> <p>25           MR. PIVOVAR: Objection to</p> | <p style="text-align: right;">Page 265</p> <p>1           BERKLAND</p> <p>2           MR. PIVOVAR: Objection to</p> <p>3 form.</p> <p>4     A.    I don't want to get it wrong,</p> <p>5 so I'd want to go back to the literature</p> <p>6 and remind myself of the definition.</p> <p>7     Q.    Is the viscosity that's being</p> <p>8 discussed in the '795 patent a measurement</p> <p>9 of a fluid's resistance to flow?</p> <p>10     A.    Well, that's a general</p> <p>11 understanding of viscosity.</p> <p>12     Q.    Would that be the understanding</p> <p>13 that a POSITA would bring when reading the</p> <p>14 claim limitation of the '795 patent of</p> <p>15 less than 1500 centipoise?</p> <p>16           MR. PIVOVAR: Objection to</p> <p>17 form.</p> <p>18     A.    Yes.</p> <p>19     Q.    And would, when somebody reads</p> <p>20 the term dynamic viscosity here in Exhibit</p> <p>21 1050, looking at Figure 8, would they</p> <p>22 understand the reference to dynamic</p> <p>23 viscosity to be a reference to the fluid's</p> <p>24 internal resistance to flow?</p> <p>25           MR. PIVOVAR: Objection to</p> |

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| <p style="text-align: right;">Page 266</p> <p>1           BERKLAND</p> <p>2 form.</p> <p>3     A.    It is a viscosity measurement,</p> <p>4 I would have to go and look to compare</p> <p>5 this viscosity measurement, which I view</p> <p>6 as rare to others.</p> <p>7     Q.    Now, when you look at Figure 8,</p> <p>8 what's the dynamic viscosity measured in?</p> <p>9     A.    Milipascal seconds.</p> <p>10    Q.    Is that centipoise?</p> <p>11    A.    Yes.</p> <p>12    Q.    And at what temperature is it</p> <p>13 measured?</p> <p>14    A.    It's 20 degrees Celsius.</p> <p>15    Q.    The bottom of this chart shows</p> <p>16 the percent of propylene glycol, correct?</p> <p>17           MR. PIVOVAR: Objection to</p> <p>18 form.</p> <p>19    A.    I don't know what PG stands</p> <p>20 for, give me a moment.</p> <p>21           (Witness perusing document.)</p> <p>22    A.    I assume it is propylene</p> <p>23 glycol.</p> <p>24    Q.    You can just look at the</p> <p>25 abstract, that may help.</p>                                                                                                                                                                               | <p style="text-align: right;">Page 268</p> <p>1           BERKLAND</p> <p>2     A.    I mean, it says what it says,</p> <p>3 it's a factual matter.</p> <p>4           I don't know how to deal with</p> <p>5 it off the cuff.</p> <p>6     Q.    Thank you for your time today,</p> <p>7 Dr. Berkland, I have no further questions.</p> <p>8           MR. PIVOVAR: I have no</p> <p>9 questions for Dr. Berkland at this time</p> <p>10 either and we consider the deposition</p> <p>11 closed.</p> <p>12           (Time noted: 5:39 p.m.)</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> <p>23</p> <p>24</p> <p>25</p>                                                                                                                                                                                                 |
| <p style="text-align: right;">Page 267</p> <p>1           BERKLAND</p> <p>2           (Witness perusing document.)</p> <p>3     Q.    Do you see that PG reference is</p> <p>4 propylene glycol in the abstract, sir?</p> <p>5     A.    I do; I don't know what to do</p> <p>6 with this data though, because I have not</p> <p>7 evaluated a falling ball viscometry data</p> <p>8 for a long time.</p> <p>9     Q.    But this chart is providing the</p> <p>10 centipoise viscosity measurement of</p> <p>11 various percent solutions of propylene</p> <p>12 glycol with ibuprofen in those solutions,</p> <p>13 correct, sir?</p> <p>14           MR. PIVOVAR: Object to form.</p> <p>15    A.    I don't know the amount of</p> <p>16 ibuprofen, and even if we figured that</p> <p>17 out, I can't draw conclusions from this</p> <p>18 without digging into the method and</p> <p>19 comparing it to other viscometer methods.</p> <p>20    Q.    But you agree with me it is</p> <p>21 reporting a viscosity for certain</p> <p>22 percentages of propylene glycol at room</p> <p>23 temperature for formulation saturated with</p> <p>24 ibuprofen, correct, sir?</p> <p>25           MR. PIVOVAR: Objection, form.</p> | <p style="text-align: right;">Page 269</p> <p>1 KINDERFARMS LLC vs. GENEXA INC.</p> <p>2 8/14/2024 - CORY BERKLAND</p> <p>3           ACKNOWLEDGEMENT OF DEPONENT</p> <p>4     I, CORY BERKLAND, do hereby declare</p> <p>5 that I have read the foregoing transcript,</p> <p>6 I have made any corrections, additions, or</p> <p>7 changes I deemed necessary as noted on the</p> <p>8 Errata to be appended hereto, and that the</p> <p>9 same is a true, correct and complete</p> <p>10 transcript of the testimony given by me.</p> <p>11</p> <p>12 _____</p> <p>13 CORY BERKLAND                      Date</p> <p>14 *If notary is required</p> <p>15</p> <p>16           SUBSCRIBED AND SWORN TO BEFORE ME THIS</p> <p>17        ____ DAY OF _____, 20____.</p> <p>18</p> <p>19</p> <p>20 _____</p> <p>21           NOTARY PUBLIC</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> |

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| <p style="text-align: right;">Page 270</p> <p>1<br/>2 CERTIFICATION<br/>3<br/>4<br/>5<br/>6 I, Jineen Pavesi, a Registered<br/>7 Professional Reporter, Registered Merit<br/>8 Reporter, Certified Realtime Reporter and<br/>9 a Notary Public, do hereby certify that<br/>10 the foregoing witness, CORY BERKLAND, was<br/>11 duly sworn on the date indicated, and that<br/>12 the foregoing is a true and accurate<br/>13 transcription of my stenographic notes.<br/>14 I further certify that I am not employed<br/>15 by nor related to any party to this<br/>16 action.<br/>17<br/>18<br/>19<br/>20 <br/>21 JINEEN PAVESI, RPR, RMR, CRR<br/>22<br/>23<br/>24<br/>25</p> | <p style="text-align: right;">Page 272</p> <p>1<br/>2 Exhibit 1050 Journal of 262<br/>3 Pharmaceutical<br/>4 Science, Volume 97,<br/>5 No. 1, January<br/>6 2008, starting at<br/>7 page 185<br/>8<br/>9<br/>10<br/>11<br/>12<br/>13<br/>14<br/>15<br/>16<br/>17<br/>18<br/>19<br/>20<br/>21<br/>22<br/>23<br/>24<br/>25</p>                                                                                                                                                                                                                                                                                              |
| <p style="text-align: right;">Page 271</p> <p>1<br/>2 EXHIBITS<br/>3<br/>4 Berkland<br/>5 EXHIBIT DESCRIPTION PAGE<br/>6<br/>7 Exhibit 1046 document entitled 93<br/>8 "Are Pediatric<br/>9 Medicines Risk<br/>10 Factors For Dental<br/>11 Caries and Dental<br/>12 Erosion?"<br/>13 Exhibit 1047 document from the 200<br/>14 FDA Precision<br/>15 Database on<br/>16 UNII-GVG8G02070<br/>17 Exhibit 1048 document related to 202<br/>18 Little Remedies<br/>19 infant Essential<br/>20 Kit<br/>21 Exhibit 1049 article with the 250<br/>22 citation J. Chem<br/>23 Eng. Data 2004, 49,<br/>24 1311 to 1317<br/>25</p>                                                                                                                                         | <p style="text-align: right;">Page 273</p> <p>1 KINDERFARMS LLC vs. GENEXA INC.<br/>2 8/14/2024 - CORY BERKLAND<br/>3 ERRATA SHEET<br/>4 PAGE____ LINE____ CHANGE_____<br/>5 _____<br/>6 REASON_____<br/>7 PAGE____ LINE____ CHANGE_____<br/>8 _____<br/>9 REASON_____<br/>10 PAGE____ LINE____ CHANGE_____<br/>11 _____<br/>12 REASON_____<br/>13 PAGE____ LINE____ CHANGE_____<br/>14 _____<br/>15 REASON_____<br/>16 PAGE____ LINE____ CHANGE_____<br/>17 _____<br/>18 REASON_____<br/>19 PAGE____ LINE____ CHANGE_____<br/>20 _____<br/>21 REASON_____<br/>22 _____<br/>23 _____<br/>24 CORY BERKLAND Date<br/>25</p> |

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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