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Transcript of **Conference Call**

Date: June 17, 2016

Case: AstraZeneca; Mylan; Wockhardt; Sun Pharmaceutical Industries Ltd., In Re (PTAB)

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AstraZeneca Exhibit 2009
Sun v. AstraZeneca

1	1 UNITED STATES PATENT AND TRADEMARK OFFICE 2 ----- 3 BEFORE THE PATENT TRIAL AND APPEAL BOARD 4 ----- 5 IPR2015-0134, IPR2016-01029, IPR2016-01104 6 Administrative Patent Judges Rama Elluru 7 and Michael Tierney 8 ----- 9 Telephonic Conference 10 Friday, June 17, 2016 11 2:02 p.m. 12 13 Job No.: 115100 14 Pages: 1 - 21 15 16 Reported by: 17 Sandra Bunch VanderPol, RMR, CRR, CSR #3032 18 19 20 21 22	3	1 APPEARANCES (Continued) 2 3 On behalf WOCKHARDT BIO AG: 4 DUANE MORRIS LLP 5 PATRICK C. GALLAGHER, ESQUIRE 6 FREDERICK BALL, ESQUIRE 7 8 On behalf of SUN PHARMACEUTICAL INDUSTRIES, LTD.: 9 WINSTON & STRAWN LLP 10 SAMUEL S. PARK, ESQUIRE 11 12 13 14 15 16 17 18 19 20 21 22
2	1 Telephonic Conference with the Honorable 2 RAMA ELLURU and MICHAEL TIERNEY, Administrative Patent 3 Judges, held pursuant to agreement, before Sandra 4 Bunch VanderPol, Certified Shorthand Reporter No. 3032 5 of the State of California. 6 7 A P P E A R A N C E S 8 ON BEHALF OF ASTRAZENECA AB: 9 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP 10 ANTHONY HARTMANN, ESQUIRE 11 DAVID WEINGARTEN, ESQUIRE 12 -and- 13 MCCARTER & ENGLISH LLP 14 ERIC E. GRONDAHL, ESQUIRE 15 16 On behalf of MYLAN PHARMACEUTICALS INC.: 17 WILSON SONSINI GOODRICH & ROSATI 18 RICHARD TORCZON, ESQUIRE 19 20 21 (Appearances continued on next page) 22	4	1 P R O C E E D I N G S 2 JUDGE ELLURU: Good afternoon. This is 3 Judge Elluru. And with me is Judge Tierney. 4 This is a phone conference for 5 IPR2016-01340, Mylan against AstraZeneca; 6 IPR2016-01029, Wockhardt against AstraZeneca; 7 IPR2016-01104, Amneal against AstraZeneca. 8 Could we please start with identification of 9 counsel for the IPR2016-01340. 10 MR. TORCZON: Rick Torczon for Mylan. 11 MR. HARTMANN: Anthony Hartmann for 12 AstraZeneca. I also have David Weingarten and Eric 13 Grondahl. 14 JUDGE ELLURU: Thank you. 15 And for IPR -- Petitioner Wockhardt? 16 MR. GALLAGHER: This is Patrick Gallagher 17 from Duane Morris. Also on the phone is Frederick 18 Ball, also from Duane Morris. 19 JUDGE ELLURU: And for Petitioner Amneal? 20 MR. PARK: This is Sam Park on behalf of 21 Amneal and Sun, Winston & Strawn. 22 JUDGE ELLURU: Thank you.

<p style="text-align: right;">5</p> <p>1 The reason that we wanted to talk to the 2 parties today is about the two joinder motions in 3 IPR2016-01029 and IPR2016-01104. For the purposes of 4 this current teleconference, we will put aside the 5 filing issue in the 1029 case. 6 And we have read the papers, but we wanted 7 to sort of get a brief update by the parties starting 8 with Petitioner Wockhardt. What do you envision as -- 9 how do you envision the joinder, including with 10 respect to arguments, the schedule, evidence, 11 cooperation between the original petitioner Mylan? 12 MR. BALL: Sure. Your Honor, my name is 13 Frederick Ball. And if it's all right -- Patrick 14 Gallagher is attending. But if it's all right, if you 15 don't mind me speaking on behalf of Wockhardt, we 16 would appreciate that. 17 JUDGE ELLURU: That would be fine. 18 MR. BALL: We have reached an agreement with 19 Mylan, which essentially puts the safeguards in place 20 that the patentholder asked for. We were -- we have 21 reached an agreement to share their expert. We've 22 reached an agreement that they will take the lead. We</p>	<p style="text-align: right;">7</p> <p>1 And the second point I wanted to bring up, I 2 wanted to make sure that the panel is aware there are 3 actually some other IPRs that were filed that have 4 motions for joinder pending. 5 JUDGE ELLURU: They haven't been docketed 6 yet, so -- I think one of the e-mails from petitioners 7 indicated that there might be other petitioners. When 8 those petitioners -- when those cases are docketed and 9 we have them on our dockets, we will have another 10 call. 11 MR. HARTMANN: Okay. And with respect to 12 what Mr. Ball said, I guess our lead point is still 13 that joinder is improper. They did not file the 14 petition in a timely manner. 15 JUDGE ELLURU: As I said at the beginning of 16 this conference, we're going to have a discussion on 17 that issue separately. 18 MR. HARTMANN: Oh, okay. I thought you were 19 talking in regards to the timing of the -- okay. 20 Sorry. 21 MR. WEINGARTEN: If I may. This is David 22 Weingarten, of Finnegan.</p>
<p style="text-align: right;">6</p> <p>1 are not envisioning any additional time needed. We 2 are not envisioning any change in the discovery 3 schedule. We are not envisioning any changes in the 4 schedule. For all practical purposes, we are 5 envisioning taking a backseat and letting Mylan drive 6 this -- drive this car. 7 JUDGE ELLURU: I call it a bus, but we can 8 use car. 9 So did you have anything else to add, 10 Mr. Ball? 11 MR. BALL: No. I mean, it's -- it's the 12 same type of agreements that we have had in other, and 13 right along the lines of what the Board has set forth 14 in its various decisions where it's granted joinder. 15 JUDGE ELLURU: Mr. Hartmann, do you have a 16 response to what Petitioner Wockhardt has just stated? 17 MR. HARTMANN: Initially, I want to indicate 18 that we have a court reporter on the line as well. I 19 forgot to mention that as well. 20 JUDGE ELLURU: Thank you. Could you file 21 that transcript in all three cases. 22 MR. HARTMANN: Certainly.</p>	<p style="text-align: right;">8</p> <p>1 Your Honor, I think that what Mr. Hartmann 2 was referring to was not the -- the timely filing 3 based on the filing date that was recorded but based 4 upon the fact that both Sun Amneal and Wockhardt 5 waited almost two years to file the petition when they 6 knew for well over a year that that Amneal had 7 requested IPR and had the opportunity at that time to 8 do so in a timely manner. 9 JUDGE ELLURU: Thank you. 10 Anything else you would like to add? 11 MR. HARTMANN: This is Mr. Hartmann. 12 It's still not clear to us the extent to 13 which the duly-added Petitioner Wockhardt would be 14 involved as far as the depositions and the oral 15 arguments at the hearing, if there would be 16 limitations on their involvement in those aspects as 17 well. 18 MR. BALL: There are limitations in our 19 involvement. 20 MR. WEINGARTEN: Your Honor, this is David 21 Weingarten, from Finnegan. One of the concerns we 22 have is, as Mr. Ball has indicated, they don't</p>

<p style="text-align: right;">9</p> <p>1 envision certain things, and it is essentially the 2 safeguards we asked. 3 I mean, really, what we are asking for are 4 the safeguards to be in place not -- not -- you know, 5 the language of "essentially" and "not envisioning" 6 doesn't give us the comfort and the protection that we 7 think we should have with regards to not complicating 8 the issues. 9 They have, at least so far in their papers, 10 provided themselves an opportunity to -- to come in 11 and make additional arguments and do additional things 12 later. And that we want to make sure doesn't occur. 13 MR. BALL: Your Honor this is Mr. Ball. We 14 don't have a problem with that. We have reached an 15 agreement with Mylan. We originally filed the papers. 16 We do have an agreement on file. 17 JUDGE ELLURU: Is Petitioner Wockhardt 18 willing to file some kind of notice/stipulation as to 19 the safeguards that it envisions with Mylan? 20 And I also want to point out that in our 21 order, we can order the safeguards that we would like 22 to see.</p>	<p style="text-align: right;">11</p> <p>1 is present. 2 We would like to hear from Petitioner Mylan 3 with respect to its position on whether it has any 4 objection to Petitioner Wockhardt being joined to the 5 original case. 6 MR. TORCZON: Thank you, your Honor. This 7 is Rick Torczon. 8 Mr. Ball's representation is accurate. And 9 it's also going to be true for Sun Amneal. We have 10 essentially the same agreement with both parties. And 11 that commits Mylan not to oppose, but it also -- 12 essentially, both parties agree to take a backseat. 13 And what that will -- should practically meet, from 14 the Board's perspective, is that Mylan will be 15 appearing as sort of the sole party. There will be a 16 lot of consultation going on in the background. And 17 Mylan has the option of appointing counsel, for 18 instance, to cover cross-examination. So we may ask 19 Wockhardt or Amneal to take a particular 20 cross-examination. 21 But as far as the Board its concerned, as 22 far as AstraZeneca is concerned, as long as Mylan is</p>
<p style="text-align: right;">10</p> <p>1 MR. HARTMANN: Your Honor, Wockhardt is 2 perfectly -- as long as they are fine with it, we are 3 fine with filing, and we can work out the safeguards 4 with them -- you know, meet and confer with Mylan and 5 AstraZeneca's counsel to come to, you know, the type 6 of safeguards that are appropriate and that the Board 7 has entered in other decisions. 8 JUDGE ELLURU: Thank you. 9 Mr. Hartmann or Mr. Weingartner, do you have 10 anything briefly to respond with? 11 MR. HARTMANN: Mr. Hartmann here. No. 12 MR. WEINGARTEN: This is David Weingarten. 13 I believe that, you know, we laid out what 14 those safeguards need to be in our opposition papers, 15 and I was certainly open to having those discussions 16 with the parties; Wockhardt in this particular case. 17 JUDGE ELLURU: I am going to put the parties 18 on hold for one minute. 19 (Teleconference on hold.) 20 JUDGE ELLURU: The panel is back on line. 21 And instead of going through the roll call to make 22 sure everyone is present, I'm going to assume everyone</p>	<p style="text-align: right;">12</p> <p>1 in the proceeding, it really should just look like 2 they are facing one party. 3 I mean, there will obviously be a lot of 4 complication in coordination on our end, but it should 5 be transparent on your end. 6 JUDGE ELLURU: Thank you. I appreciate 7 that. 8 So that brings us to Petitioner Amneal. 9 Mr. Park, would you like to comment on your motion for 10 joinder? 11 MR. PARK: Your Honor, this is Sam Park, on 12 behalf of Amneal and Sun, from Winston & Strawn. 13 I don't have anything additional to what you 14 heard from Wockhardt and Mylan. That's all accurate. 15 Actually, what we are envisioning is our 16 taking a so-called silent part of the role. Mylan 17 will be taking the lead. Of course there will be 18 consultations going on in the background. 19 But for purposes of this proceeding, it will 20 be as if Mylan was the party in this case. And there 21 will be additional parties, but we are not going to be 22 asking for additional time, additional papers, and so</p>

<p style="text-align: right;">13</p> <p>1 forth.</p> <p>2 So we believe that the joinder is proper in</p> <p>3 this case, and it won't complication the issues in any</p> <p>4 way.</p> <p>5 JUDGE ELLURU: Thank you.</p> <p>6 Mr. Hartmann or Mr. Weingarten, if you would</p> <p>7 like to comment on Amneal's position.</p> <p>8 MR. HARTMANN: My major concern at this</p> <p>9 point with Amneal is, in their brief they indicate</p> <p>10 that the agreement should be bound to what Mylan is</p> <p>11 doing is contingent on maintaining to be a party,</p> <p>12 which would imply that if Mylan were to settle out,</p> <p>13 they may go in different directions on those issues</p> <p>14 and no longer agree to be bound by the testimony that</p> <p>15 is already of record at that time and the arguments</p> <p>16 that are presented as of that time.</p> <p>17 MR. PARK: Your Honor, if I may address</p> <p>18 that.</p> <p>19 JUDGE ELLURU: And this is Mr. Park?</p> <p>20 MR. PARK: Yes, this is Mr. Park.</p> <p>21 So essentially what will happen, if for some</p> <p>22 reason Mylan were to settle out -- and we have an</p>	<p style="text-align: right;">15</p> <p>1 have is the fact that counsel for Amneal/Sun and</p> <p>2 Wockhardt have a different expert that they rely upon</p> <p>3 as the -- as their only position in the litigation.</p> <p>4 And in the absence of Mylan being in the IPR, while</p> <p>5 they may be bound by Dr. Rotella, the sole declarant</p> <p>6 in the IPR, the spin that they decide to take, the</p> <p>7 gloss that they put on it, could be very different</p> <p>8 than the one that -- that Mylan has been putting on it</p> <p>9 and will continue to put on it.</p> <p>10 And so we have -- you know, one of the</p> <p>11 concerns that we have is sort of a bait-and-switch</p> <p>12 approach they could occur if Mylan is not in the case.</p> <p>13 MR. TORCZON: Your Honor, may I address</p> <p>14 that? This is Rick Torczon, for Mylan.</p> <p>15 JUDGE ELLURU: Yes, please.</p> <p>16 MR. TORCZON: The parties have agreed --</p> <p>17 obviously, AstraZeneca has an excellent point. And,</p> <p>18 of course, Mylan would be concerned that the parties</p> <p>19 not do anything that undermines Mylan's position in</p> <p>20 the District Court litigation.</p> <p>21 So the parties have agreed -- at least these</p> <p>22 two parties have agreed -- not to take any position</p>
<p style="text-align: right;">14</p> <p>1 agreement to retain -- we currently retained</p> <p>2 Dr. Rotella, the sole declarant in the case. And if</p> <p>3 Mylan were to ever settle out, we would essentially go</p> <p>4 forward with Dr. Rotella as if nothing has happened</p> <p>5 for purposes of our cases.</p> <p>6 Wockhardt and we have agreed to consult to</p> <p>7 see who would take more of a lead role as opposed to a</p> <p>8 back role. And we believe, because of that reason, we</p> <p>9 don't believe things will be complicated even if Mylan</p> <p>10 does for some reason settle out of this case and</p> <p>11 leaves the others three petitioners.</p> <p>12 JUDGE ELLURU: I have a question for counsel</p> <p>13 from AstraZeneca. Since the parties will have signed</p> <p>14 on to these papers, assuming we grant the motion for</p> <p>15 joinder, once you sign the papers as co-petitioners,</p> <p>16 they will be bound by their positions taken previously</p> <p>17 even if Mylan settles out.</p> <p>18 MR. WEINGARTEN: Your Honor, this is David</p> <p>19 Weingarten, from Finnegan, on behalf AstraZeneca. If</p> <p>20 I can respond to that?</p> <p>21 JUDGE ELLURU: Yes. Please.</p> <p>22 MR. WEINGARTEN: One of the concerns that we</p>	<p style="text-align: right;">16</p> <p>1 that would be inconsistent with what Mylan has done so</p> <p>2 far in the litigation.</p> <p>3 So at least as far as their use of</p> <p>4 Dr. Rotella, they have committed not to make any</p> <p>5 changes.</p> <p>6 JUDGE ELLURU: Thank you.</p> <p>7 And does Petitioner Wockhardt or</p> <p>8 Petitioner Amneal have anything to add lastly and</p> <p>9 briefly?</p> <p>10 MR. BALL: This is Mr. Ball, from Wockhardt.</p> <p>11 We do not.</p> <p>12 MR. PARK: This is Sam Park. We do not as</p> <p>13 well.</p> <p>14 JUDGE ELLURU: And counsel for AstraZeneca?</p> <p>15 MR. HARTMANN: This is Mr. Hartmann. I have</p> <p>16 nothing to add.</p> <p>17 JUDGE ELLURU: Thank you.</p> <p>18 I am going to put the parties on hold while</p> <p>19 I confirm with my panel member.</p> <p>20 (Teleconference On hold.)</p> <p>21 JUDGE ELLURU: I have confirmed with my</p> <p>22 panel member, and this is what we are going to do.</p>

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