



## P R O C E E D I N G S

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02:06:20

THE COURT: Hello everybody. Y'all can have a seat.  
All right. Who's got this issue for Accord -- the two  
issues for Accord?

MS. CALLSEN: Me.

THE COURT: All right.

MR. LEMMON: Lindsay, are you on the phone?

THE COURT: Is anyone there?

02:06:38

MS. STEVENS: Yes, I'm here. I had my phone on mute  
because I believe Andrew is going to be doing the majority of our  
argument.

THE COURT: All right. So I have a couple of  
questions.

02:06:46

You-all say Accord performs pharmacovigilance functions  
pursuant to regulatory responsibility.

MS. CALLSEN: Correct.

THE COURT: Does it rely in any way on the information  
that's contained in this Lambda database in doing that?

02:06:59

MS. CALLSEN: Not --

THE COURT: I have to believe the answer is "yes."

02:07:15

MS. CALLSEN: Not really. I mean, the thing is, Lambda  
evaluates the adverse events that we, meaning Accord, provides to  
them. They then provide their analysis to Accord in the adverse  
event reports themselves as well as the PADER, which are the

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1 periodic updates as well as the quarterly reports.

2 So that data -- that's what Accord relies upon.

3 THE COURT: That data is what comes back from Lambda?

4 MS. CALLSEN: Correct.

02:07:35 5 I have a PADER, as an example. It is a 222-page  
6 document, and it goes through the analysis of each adverse event  
7 report with respect to docetaxel that Lambda has analyzed and  
8 sent back to us.

9 Then Accord takes that and finalizes it into the report  
02:07:55 10 that's required -- into the format for the report that's required  
11 by the FDA and submits it.

12 THE COURT: And what you-all are looking for is the raw  
13 material in the Lambda analysis?

14 MR. LEMMON: Right. We need to be able to peek at the  
02:08:10 15 data and reach our own conclusions which may be different.

16 And Accord -- you know, the pharmacovigilance  
17 obligation is a non-delegable responsibility, and it is with  
18 Lambda -- I'm sorry, it is with Accord. And Accord seems to be  
19 saying that they're attempting, basically, to delegate it to  
02:08:27 20 Lambda and all they get is a report, and then they turn in the  
21 report and that's that, and we can't then go and find out what  
22 goes on before the report gets prepared. That's what we're  
23 trying to see.

24 MS. CALLSEN: That's not true. Lambda does the actual  
02:08:43 25 medical affairs analysis of the report. We collect the reports.

1 We submit them to this third party who then analyzes the data.  
2 They take a look at whether it's the -- the whole summary that's  
3 in our PADERS. They look at the label; assess whether it is --

02:09:02

4 THE COURT: But they are looking for all the  
5 information that is used to get to the --

6 MS. CALLSEN: Correct. So the raw data Accord never  
7 sees. Accord sees the analysis and they analyzes that data and  
8 they then submit it to the FDA.

02:09:16

9 THE COURT: You told me initially that the raw data is  
10 sent from Accord to Lambda; that's how they get it.

11 MS. CALLSEN: Right. Well, they submit the actual  
12 adverse report.

13 THE COURT: Right.

02:09:28

14 MS. CALLSEN: But in the format that Lambda puts it  
15 into, whatever database they maintain, we never see that.

16 So if Accord gets an adverse event, they submit it to  
17 Lambda to do the analysis and summary.

02:09:47

18 Lambda also, on their own, does literature reviews, and  
19 if there's an adverse event reported in the literature, they then  
20 look at that, they summarize it, and they provide it back to  
21 Accord.

22 THE COURT: There's just no way that that stuff is not  
23 discoverable.

24 MS. CALLSEN: We've already provided --

02:09:56

25 THE COURT: No, you've provided your documents created

1 on the basis of an analysis that you received back from a third  
2 party --

3 MS. CALLSEN: Correct.

4 THE COURT: -- that is, in turn, based on raw data that  
02:10:08 5 you have provided to them, and all you have produced is your  
6 final report.

7 MS. CALLSEN: Anything that we provided to Lambda we  
8 also provided. So if the adverse event comes to us, we've  
9 provided the individual standalone adverse event as it related to  
02:10:21 10 alopecia.

11 THE COURT: So what's missing?

12 MR. LEMMON: Well, what would be, in addition to what  
13 Accord U.S. provided, is the literature that she was just  
14 speaking of.

02:10:31 15 So they did a literature search which goes into their  
16 knowledge, it goes into their pharmacovigilance obligation.  
17 These are the things that go into signal detection to determine  
18 whether or not the label needs to be changed, and so we should be  
19 able to see what the literature says.

02:10:50 20 THE COURT: I agree with that. I think --

21 MS. CALLSEN: The literature -- Your Honor, the  
22 literature is in this PADER that we produced to them. There's  
23 literature analyzed from Japan here --

24 THE COURT: They are entitled to -- they are entitled  
02:11:01 25 to be able to traverse whatever is being shot out at the end of

1 this process by Accord.

2 MS. CALLSEN: That's what's in here (indicating).

3 THE COURT: That's what you say -- I mean, what they  
4 don't know is what you received from Lambda when you put that  
5 together. That's your document, right? That's a document  
6 created by Accord?

7 MS. CALLSEN: Right. Yeah, Lambda prepares the  
8 analysis of the adverse events, but then we just put it into the  
9 format for the FDA.

10 Accord does not employ medical affairs specialists to  
11 review. They just don't have that staff. So the analysis in  
12 here (indicating), Accord doesn't touch that. They just take it  
13 and put it in the format that the FDA requires and submits it.

14 THE COURT: I don't know how you can resist discovery  
15 of this stuff. I just don't.

16 MS. CALLSEN: Well, it's not our stuff, for one thing.  
17 It's a third party --

18 THE COURT: Well, it's not their stuff. I mean,  
19 they're working for Accord. They're your contractor.

20 MS. CALLSEN: Right.

21 THE COURT: They're your -- whatever they are, they are  
22 not doing this on their own. They're doing it because you're  
23 paying them to do it.

24 MS. CALLSEN: Correct.

25 THE COURT: So it is your stuff because you're giving

1 it to them to begin with. They're doing some analysis and then  
2 sending it back to you. And what happens in the interim is  
3 discoverable. It has to be.

02:12:20 4 MS. CALLSEN: There's nothing in addition that they  
5 would get from Lambda that they don't already have in the adverse  
6 event reports.

02:12:34 7 THE COURT: Well, I mean, I don't know if there is or  
8 not, but that sort of goes to the next point, which is the  
9 proportionality argument. If there's nothing in addition, how  
10 can it be disproportionate to the needs of the case for you to go  
11 ask them for it?

12 MS. CALLSEN: Well, again, they're not ours to ask, for  
13 one thing. It's a database. And it's a third party. They can  
14 subpoena the third-party database just as we could.

02:12:48 15 THE COURT: Well, that may be what you have to do.

16 MR. LEMMON: If that's what we have to do --

17 THE COURT: I mean, at the end of the day in any case,  
18 if I'm telling you-all that information is discoverable and you  
19 should be able to obtain it, I would think that the most  
02:13:04 20 foolproof method for obtaining it is to obtain it directly from  
21 that source.

22 MR. LEMMON: That --

02:13:14 23 THE COURT: And they can object, but I don't know on  
24 what grounds they would object because I'm going to issue a  
25 minute entry that says I think the information is discoverable.

02:13:38 1 MR. LEMMON: The foreign database -- you know, the  
2 foreign information -- the information that Accord is obligated  
3 to review, to know about, and is apparently delegating to Lambda,  
4 includes all information, foreign and domestic. And I know that  
5 there are some studies from Japan, but there is also some history  
6 of other adverse event reports from other countries that would be  
7 contained in there as well.

02:13:55 8 THE COURT: I think you need to send them a subpoena.  
9 I don't know -- I mean, I think that -- I think you've raised a  
10 good point. I don't really know --

11 MR. LEMMON: Yeah.

02:14:11 12 THE COURT: -- practically how they would go obtain  
13 this information as a litigant from a non-litigant contractor. I  
14 mean, I think the safest bet would be to try to subpoena the  
15 information from Lambda.

16 MR. LEMMON: I think that that's certainly a way to do  
17 it. And, you know, it's a foreign company. It's not in the U.S.  
18 at all so that creates those problems, but we can navigate  
19 through that.

02:14:24 20 THE COURT: Hopefully.

21 MR. LEMMON: Hopefully, right.

22 But it just struck us that Lambda has a -- I mean,  
23 Accord has this non-delegable responsibility --

02:14:38 24 THE COURT: I get what you're saying and I'm agreeing  
25 with you.

1 MR. LEMMON: And if the FDA said, I want to see the  
2 data and not just the PADER, they would surely go and get it.

3 THE COURT: I think it's all discoverable. On this  
4 topic, on the database, this Lambda database, I think it's  
5 discoverable and I'm going to issue a minute entry that says it's  
6 discoverable. And we have discussed you-all are going to try to  
7 obtain it directly from that company through a subpoena, and if  
8 there is some issue with that, we'll come back and talk about how  
9 to get it.

10 MR. LEMMON: Sure. That sounds fair.

11 THE COURT: Now, on this labeling issue, I have  
12 somewhat of a different view.

13 I'm not sure that you've sufficiently linked the  
14 domestic defendant company to any of these other foreign entities  
15 that either are responsible for foreign labeling or would have  
16 foreign labeling in their possession, because in the letter I got  
17 from Accord, they're telling me -- there's a statement in there  
18 that says they are not in possession of any foreign labeling.

19 MS. CALLSEN: Correct.

20 THE COURT: Which means if I were to order them to  
21 produce it, I would be ordering them to go out and obtain foreign  
22 labeling that they do not have, and I'm not sure that there is a  
23 basis for me to do that, particularly -- this is another issue --  
24 if you can do it without them.

25 MR. LEMMON: I know that Sanofi produced its foreign

1 labels, and I know there was a separate deal that was made in  
2 that regard. And, you know, the interrelationship between the  
3 companies would constitute, back and forth, their full knowledge  
4 of the effects of this drug.

02:16:17 5 THE COURT: I don't know that that's the case.

6 MS. CALLSEN: Yeah. We are structured totally  
7 different than Sanofi and any of these other defendants.

8 THE COURT: That's why I made the initial point which  
9 is I am not satisfied that you-all have sufficiently linked these  
10 companies --

11 MR. LEMMON: Okay.

12 THE COURT: -- to where whatever is happening in  
13 another country label-wise can somehow be imputed to this company  
14 or, you know, that for discovery purposes I should have them  
02:16:41 15 going out and doing that work to gather material they don't  
16 already have.

17 MR. LEMMON: We were limited in some way early on as  
18 far as the discovery of the structures of the organizations and  
19 the other organizations that they are part of, but we'll do that  
02:16:56 20 discovery and --

21 THE COURT: What is EMEA?

22 MS. CALLSEN: EMEA is the European Medical Evaluation  
23 Association.

24 THE COURT: I looked all over and all I found was EMEA.

02:17:14 25 MS. CALLSEN: Yeah.

1 THE COURT: They say you can get this stuff from EMEA;  
2 that it's publicly available.

3 MR. LEMMON: Okay.

4 MS. CALLSEN: That's how I found it.

02:17:20 5 THE COURT: Yeah. I'm not going to order -- I'm not  
6 going to order this defendant to go obtain and produce foreign  
7 labeling.

8 MR. LEMMON: We did do the Google searches and whatnot  
9 to try to find that, and we did find some labels, but we didn't  
02:17:35 10 find all of the periods that we're interested in.

11 THE COURT: Keep trying.

12 MR. LEMMON: It just wasn't available.

13 So maybe it is available. If it is, she's probably a  
14 better Googler than I am.

02:17:48 15 MS. CALLSEN: I just went to EMEA.org, I think.

16 THE COURT: All right. Try that.

17 So the minute entry will reflect that I think that the  
18 database information from Lambda is discoverable, and that you  
19 are going to try to obtain it by subpoena.

02:18:01 20 I'm not going to order Accord to produce any foreign  
21 labeling information.

22 The only other issue is the issue of this discovery  
23 deadline. I'm not ready to make any moves on any deadlines. I'm  
24 not extending any deadlines right now.

02:18:14 25 MR. LEMMON: There is not one set and so that's the --

1 THE COURT: I thought you-all had agreed on one.

2 MR. LEMMON: We did not.

3 MS. CALLSEN: We agreed on December 2019.

4 MR. LEMMON: No, we did not.

02:18:24 5 THE COURT: Hold on. Hold on.

6 MR. LEMMON: We did not.

7 THE COURT: Hold on.

8 MR. LEMMON: So I can give you the whole history.

9 THE COURT: I don't want --

02:18:32 10 MR. LEMMON: The history is not correct in the  
11 submission.

12 THE COURT: Okay. Well, hold on.

13 MS. CALLSEN: Just one thing, Your Honor, I do want to  
14 say. We've been at discovery for almost 20 months. This is the  
02:18:43 15 first time we've had to appear in front of you, so I think we  
16 deserve some accolades because we have worked everything else  
17 out.

18 THE COURT: Absolutely.

19 MR. LEMMON: I don't think any of us is saying that  
02:18:55 20 anything is anybody else's fault. That's not what we're here to  
21 talk about.

22 MS. CALLSEN: That was not my point. It was to say we  
23 have worked together.

24 THE COURT: Just to be clear, so Hospira's letter to me  
02:19:07 25 says that the 16-month CMO 7 discovery window for them began in

1 November 2017 and ended -- or would have ended in March of 2019.  
2 Is that right or wrong?

3 MR. LEMMON: It's correct that when it was -- it  
4 began -- it started on that date and then the trial was  
02:19:26 5 continued. And so that was-- no one -- there was nothing done.  
6 There were no documents offered. There were no depositions  
7 taken. There were some documents that were produced.

8 THE COURT: Was there an agreement to extend the  
9 deadline to July 2019?

02:19:41 10 MR. LEMMON: There was not.

11 MS. CUSKER GONZALEZ: We submitted it to Ms. Menzies.

12 MR. LEMMON: We had a discussion about the deadlines,  
13 what was the deadline going to be, and we agreed that the  
14 earliest that the deadline could be was July, and that we would  
02:19:57 15 report back to the Court in April. That's what we agreed to, and  
16 that's all we agreed to.

17 THE COURT: This says after the Sanofi trial was  
18 continued, Hospira -- am I pronouncing that right?

19 MS. CUSKER GONZALEZ: Yes.

02:20:11 20 THE COURT: -- Hospira was willing to extend the  
21 deadline another five months to December 2019. It does not say  
22 that there's an agreement, but it does say that they offered to  
23 do that.

24 MR. LEMMON: They offered to do that.

02:20:25 25 THE COURT: And y'all --

1 MR. LEMMON: Well, the other way around. We offered  
2 90 days before trial. They offered December 20th. We offered  
3 120 days before trial. That's the end of the discussion.

4 THE COURT: What is 120 days before trial?

02:20:38 5 MR. LEMMON: It would be April. That's the full extent  
6 of the negotiation.

7 MS. CUSKER GONZALEZ: Your Honor, Mara Cusker Gonzalez  
8 for Hospira.

9 The dates are as you laid out. We started discovery in  
02:20:56 10 late 2017. We were producing documents, I think all three  
11 defendants, starting in early 2018. At the same time we were  
12 working up some cases in the trial pool. Eventually a number of  
13 those cases dropped out for various reasons, but we continued  
14 discovery.

02:21:11 15 We've all now been added to another trial pool. We  
16 have been working up cases. We've been doing a lot of work on  
17 our side and we've been continuing productions.

18 The broader schedule did shift out, and that's why we  
19 agreed, yes, of course we'll extend to July. Ms. Menzies  
02:21:24 20 submitted a letter to Your Honor memorializing that agreement.  
21 Everybody reserved their rights, of course, but there was an  
22 agreement out through July.

23 The schedule shifted again. We again agreed to move  
24 it, but we think it really needs to fall before expert reports  
02:21:39 25 are due, and that's really the way it has been working.

1 THE COURT: So before you say anything, I agree with  
2 what was just said. I think that the general discovery deadline  
3 needs to fall before expert reports are due. That's the key  
4 part.

02:21:56 5 MR. CENTOLA: We don't know if there's a Hospira trial.  
6 We don't have a date for a Hospira trial yet.

7 THE COURT: Do you have a date for any expert reports?

8 MS. CUSKER GONZALEZ: Yes, sir.

9 MR. CENTOLA: It is only depending on what defendant is  
02:22:06 10 going to trial in August.

11 THE COURT: So that's going to be decided in October?

12 MR. CENTOLA: Correct. And if it is not Hospira, there  
13 is no reason to have a discovery deadline of December 2019 when  
14 it is so obvious there is a lot of discovery left to do.

02:22:22 15 THE COURT: And I don't disagree with that.

16 My main concern is that we not wind up back in the  
17 situation we were in at the beginning of this case and having  
18 expert reports being written and you-all paying experts a bunch  
19 of money with discovery still going on.

02:22:37 20 MR. CENTOLA: Sure. I understand.

21 THE COURT: I don't want that to happen.

22 MR. CENTOLA: Understood.

23 THE COURT: So I think -- what y'all are telling me is  
24 that there is no current deadline except perhaps for the one that  
02:22:48 25 has already lapsed.

1 MR. LEMMON: That's right.

2 MS. CUSKER GONZALEZ: That's right.

3 MR. CENTOLA: No. Because one fact that they are not  
4 telling you is that there were bellwether cases that were in the  
02:22:58 5 trial pool, and then those were removed, as Ms. Gonzalez said,  
6 and at that point Hospira said, You are not allowed to do  
7 discovery. We are going to shut you off and completely --

8 THE COURT: Here is what we are going to do.

9 MR. CENTOLA: There is no deadline.

02:23:10 10 THE COURT: We're going to get an answer in October as  
11 to what is going to happen, and then you-all are going to sit  
12 down and talk about a discovery plan that makes sense vis-a-vis  
13 expert disclosures. If you still can't come to an agreement,  
14 then you can get on the phone with me or come see me and we'll  
02:23:24 15 work that out.

16 MR. CENTOLA: Yes, sir.

17 THE COURT: Just keep in mind that I don't want to have  
18 this jacked-up situation where y'all are taking expert  
19 depositions and still doing fact discovery, and now we've got an  
02:23:38 20 avalanche of supplemental reports and re-depositions and all of  
21 that. I don't want any of that.

22 MR. LEMMON: None of us want that either.

23 MS. CUSKER GONZALEZ: Your Honor, just to correct the  
24 record, we did say that we think discovery as to us should be  
02:23:51 25 stayed as we don't have a case in this pool. They disagreed. We

1 said fine. We served our responses to interrogatories. We've  
2 continued discovery throughout the last two years.

3 THE COURT: I don't know why you would want to stay  
4 discovery.

02:24:00 5 MS. CUSKER GONZALEZ: And we did not. We agreed to --

6 THE COURT: Sooner or later you're going to do it so  
7 you might as well do it now.

8 MS. CUSKER GONZALEZ: And we agreed.

9 MR. CENTOLA: But they pushed depositions off. We are  
10 not here to cast aspersions. We understand what you are saying.

11 We understand Your Honor's position on this, and it will be  
12 dependent on what cases are selected to move forward.

13 THE COURT: So you-all -- the first thing that happens  
14 after Judge Milazzo makes that decision is you-all get together  
15 and try to come up with a plan that makes sense, and, you know,  
16 you don't have to involve me unless you have to involve me.

17 MR. CENTOLA: Absolutely.

18 MR. LEMMON: Our next status conference I understand is  
19 going to be the --

02:24:35 20 MR. OLINDE: We have one other issue.

21 MR. LEMMON: -- the 18th of October, which is a week  
22 after.

23 THE COURT: A week later.

24 MR. LEMMON: Perhaps if the hearing were set in the  
02:24:49 25 afternoon, maybe that morning we could get together and try and

1 come up with something.

2 THE COURT: Just talk to Blanca about when the hearing  
3 is set. I stopped trying to do that.

4 MR. LEMMON: I didn't mean to interrupt, if there is  
5 something else.

6 MR. OLINDE: You are part of this.

7 THE COURT: Come on.

8 MR. OLINDE: We sent you an e-mail. We sent you an  
9 e-mail, Judge, on Thursday.

10 THE COURT: There is a pretty good chance I didn't see  
11 it.

12 MR. OLINDE: I figured that is what the case was.

13 THE COURT: Well, I don't like people that make those  
14 excuses, but in this case we just changed our entire e-mail  
15 system over the weekend and all kinds of crazy stuff has  
16 happened. So there is an actual reason why I might not have seen  
17 it.

18 MR. OLINDE: You were in a settlement conference. I  
19 know Andrew called. We were on the phone. We said we would like  
20 to have a chance to chat with you about it.

21 This was one specific issue which we have an agreement  
22 on, and we just needed you to bless it, which is that there is  
23 a --

24 THE COURT: I don't need to know what it is.

25 MR. OLINDE: You bless it. Okay.

1 THE COURT: No, go ahead and tell me.

2 MR. OLINDE: I have a loan -- no.

3 Well, the -- this is a case. It is the Dora Sanford  
4 case. It is in the third trial pool. There is -- the Phase I  
02:25:58 5 discovery ends September 20th. The problem is that the doctor,  
6 the treating physician, the prescribing physician, who is  
7 Dr. Judd Patten, is retired, and we're not really sure where he  
8 is. We've tried to locate him. We've jointly sent some letters  
9 to him because both sides want to take his deposition.

02:26:20 10 So we think we might have an address for him in  
11 Baton Rouge, and we want to try to subpoena him in Baton Rouge,  
12 but there is no way we could get that completed by the 20th of  
13 September. So what we suggested in our e-mail was can you, for  
14 the specific purpose of taking this deposition, extend the  
02:26:38 15 September 20th deadline to October 10th?

16 And so I can give you -- well, I've written all over my  
17 e-mail here, but I can send it to you again.

18 THE COURT: Send it to me again and I'll act on it.

19 MR. OLINDE: I gave you the civil action number.

02:26:53 20 But it is just to make -- for that one particular  
21 purpose. And so we're going to go ahead and try to subpoena.  
22 And if we can't get the doctor, we may come back to you and try  
23 to figure out what to do at that point.

02:27:05 24 THE COURT: If you'd resend me the e-mail because I  
25 might not be able to find it.

1 MR. OLINDE: Is it the same e-mail address?

2 THE COURT: Yes. It's just a whole new program.

3 MR. OLINDE: I will do that.

4 THE COURT: How they manage to get almost everything  
5 from one to the other, I don't know.

6 MR. LEMMON: So we're good with that.

7 THE COURT: Okay. Very good. Thank you-all.

8 (Proceedings adjourned.)

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**CERTIFICATE**

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I hereby certify this 18th day of September, 2019, that  
the foregoing is, to the best of my ability and understanding, a  
true and correct transcript of the proceedings in the  
above-entitled matter.

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*/s/ Mary V. Thompson*

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Official Court Reporter

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