

EXHIBIT “C”

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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

Docket No.6:06-MD-1769-Orl-22DAB

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IN RE: :
SEROQUEL PRODUCTS LIABILITY :
LITIGATION : Orlando, Florida
MDL DOCKET No. 1769 : November 20, 2006
: 10:00 a.m.
ALL CASES :
:
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TRANSCRIPT OF PRETRIAL CONFERENCE
BEFORE THE HONORABLE DAVID A. BAKER
UNITED STATES MAGISTRATE JUDGE

APPEARANCES:

For the Plaintiffs: Paul Pennock
Larry M. Roth
K. Camp Bailey
Fletch Trammell
Matthew E. Lundy
Keith M. Jensen
John J. Driscoll
Lawrence J. Gornick
Michael E. Pederson

Court Reporter: Sandra K. Tremel, RMR/CRR

1 APPEARANCES CONTINUED:

2 For the Plaintiffs: F. Kenneth Bailey, Jr.

3 W. Todd Harvey

4 Ken Smith

5 Karen Schaeffer

6 Lizy Santiago

7 For the Defendant

8 AstraZeneca: Michael W. Davis

9 James W. Mizgala

10 Tamar B. Kelber

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13 Proceedings recorded by mechanical stenography, transcript
14 produced by computer-aided transcription.
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1 documents clearly are not confidential. I mean they're
2 protected right now because they gave them to us, but we'd
3 like to take them off the list and so forth. These
4 documents are not trade secrets. We want to take them off
5 the list. Thus making things a lot easier in terms of as
6 you say third party depositions and so forth.

7 But to get the ball rolling, I must admit that we
8 probably do need an order of this nature.

9 MR. DAVIS: Your Honor, and I think I said at
10 the outset when we were first before the Court and Judge
11 Conway that a protective order was a sine quanon in
12 connection with the documents. We can't emphasize how
13 important it was. The parties have worked on this. This
14 is not a protective order that differs in any material
15 respect from the protective orders that have been entered
16 in dozens of MDLs. I mean, the model for the protective
17 order was protective orders that Mr. Pennock is very
18 familiar with. It reflects and resembles exactly what has
19 been done in any number of other situations.

20 And again, Your Honor, pursuant to the Court's order
21 of September 21, consistent with the Court's most recent
22 order, we produced the IND and NDA pursuant to the
23 protective order that the parties worked out that we
24 submitted. And in connection with the Court's order,
25 there was one provision as we read the order that raised a

1 difficulty. We have had discussions with plaintiffs'
2 Counsel about that one provision, and that's what's --
3 that's the issue that we're discussing and the issue that
4 separates us in terms of what I understood to be the
5 Court's acceptance of the protective order pursuant to,
6 which again, we have produced the IND and the NDA which as
7 the Court knows contains a wealth of critically important
8 information to the plaintiffs. That's been done. We met
9 that deadline, that obligation that the Court imposed.
10 And it was pursuant to that protective order as the Court
11 treated it as a stipulation that we produced the IND and
12 the NDA.

13 THE COURT: Why is it not sufficient for this to
14 continue a stipulation without a court order?

15 MR. DAVIS: Well, I think, Your Honor, the
16 parties contemplated that it would be a court order, and
17 you know, I think the Court -- the Court's imprimatur on
18 the protective order, one, is critical to our going
19 forward and essential to our going forward. So that we
20 can come to the Court if they have a disagreement with
21 respect to the order and say there's some provision in
22 there that is not being lived up to. And similarly to us,
23 if there's something taking place where there's a dispute.
24 We can come to the Court pursuant to the protective order
25 that the parties have agreed to that they worked out over

1 a long period of time. There is this one narrow --

2 THE COURT: Precisely why is it better to have
3 that in the form of an order rather than trying to do
4 enforce a stipulation?

5 MR. DAVIS: Your Honor, I have -- I agree that a
6 stipulation is fine, and we can move to have it pursuant
7 to the stipulation. But I think it's contemplated by the
8 parties that it would be a protective order entered by the
9 Court, and we have submitted it to the Court.

10 THE COURT: I tell you why I don't like doing
11 those and routinely I do not. This is your language. I
12 don't like your language. And like I say, it's -- to me
13 it is what it is, but to me it's -- but it's your language
14 and you agree to whatever you want to agree to as between
15 yourselves if you think you know what it means. And it
16 may be that at some point I'll be called on to interpret
17 or Judge Conway will be called to interpret it to enforce
18 it. We're used to doing that. We can handle that even if
19 we don't like the language. But if I sign it as my order
20 using your language, then I'm interpreting now what is my
21 order. I'm not comfortable doing that when you're the
22 ones that's drafted it and done it in a way I find
23 confusing. And to the extent it affects third parties,
24 for me to enter an order without having heard them or for
25 them to have an opportunity to have some input on this,

1 I'm not comfortable with that either.

2 MR. DAVIS: Well, again, Your Honor, I think in
3 good faith consistent with the Court's order, we produced
4 the NDA and the IND and Court has entered an order saying
5 that this is a stipulation and that the parties, the
6 plaintiffs and the defendants are bound to the language
7 that's contained in the protective order with the
8 exception of this one provision that's being worked out.
9 We would ask the Court to enter it.

10 I recognize that there may be parts of it that the
11 Court has not previously seen. But I can tell the Court
12 that given the number of plaintiffs' lawyers with whom we
13 have dealt and the amount of effort that we have put into
14 it, it took a long time and it was a long road to travel
15 to get to this language. And each one of these sentences
16 was looked at exceptionally carefully and parsed by us and
17 by plaintiffs' counsel. And with all due respect, Your
18 Honor, the plaintiffs' group is quite experienced in MDL
19 and we have substantial experience ourselves.

20 This sort of order that we have tendered to the
21 Court, which I recognize the Court acknowledges, is a
22 stipulation between us and plaintiffs, has been routinely
23 regularly entered in MDLs that we appear in and that
24 plaintiffs' counsel appear in all of the time.

25 So with all due respect -- if there is a time when

1 there is an issue that arises with respect to the
2 protective order, we can explain each and every one of
3 those provisions and explain how it is that it should
4 impact that particular situation.

5 I myself, Your Honor, don't foresee any difficulties
6 arising with respect to the stipulation and the scope and
7 nature of this protective order.

8 The only issue that could be -- that might arise are
9 some issues with respect to what documents have been
10 designated as confidential and whether they should be
11 confidential. But that is not -- that is not uncommon in
12 these sorts of situations, and the Court deals with it on
13 a rather routine regular basis. We're not going to be
14 designating what we believe is an overly broad number of
15 documents confidential, and most of the time that gets
16 worked out between us and plaintiffs' counsel regarding
17 the proper designation. If they pick up the phone with
18 respect to a document that's been designated as
19 confidential and they say, we don't believe it is. We're
20 not going to spend the Court's time trying to file a
21 motion to secure its protection if indeed it is not.

22 So to the extent that that's a concern, it should not
23 be. I do not believe we're going to be before the Court
24 very often with respect to the scope and meaning of this
25 protective order given, again, that the parties have

1 worked on it and it is, as the Court says, a stipulation
2 between the parties.

3 MR. PENNOCK: Your Honor, I have to say, it is
4 honestly and sincerely very refreshing that we're before a
5 Court that recognizes that a lot of this stuff should not
6 be confidential and that the Court does not want, as the
7 Court said at the first hearing, I think you made a
8 comment, I'm sure you don't want a lot of those documents
9 seeing the light of day. But to make this work, and to do
10 all the things we need to do, I must admit that we do
11 need -- they do need some kind of protection going forward
12 so we can start the ball rolling.

13 THE COURT: All right.

14 I understand there's some issue about the format of
15 the documents produced by the defendant with respect to
16 the IND and the NDA.

17 MR. PENNOCK: That's correct. And Camp is going
18 to address that, if you don't mind.

19 MR. CAMP BAILEY: I know we have had
20 conversations and Jonathan Jaffe who is on the phone from
21 Weitz & Luxenberg in New York who I think has had a
22 conversation with the defendants' computer people. When
23 we first came here on September 7, we talked about the
24 obvious necessity for the IND and the NDA and Seroquel.
25 We never discussed the particular format in which it would

1 be produced. There was a discussion about CDs versus hard
2 drives and all that stuff. But Mr. Pennock said he's not
3 a computer expert, doesn't care how it's produced as long
4 as it's searchable and readable. I think under the new
5 federal rules that go into effect here in 10 days, there's
6 a whole bunch of provisions in Rule 34 that talks
7 specifically about the formatting of electronic documents.

8 To make a long story short, when we got the NDA and
9 IND the other day, they were on DVDs that we immediately
10 had Jonathan and his computer people review them. And
11 what they were, they were in multi-page TIFs with no Bates
12 range on them, no way to identify them from the documents.
13 So basically they were unusable, unreadable. And there
14 are certain documents that are over a gig in size that
15 even the most sophisticated computer can't even open. And
16 so we would just like an opportunity to specify the manner
17 in which they produce documents to us to where they're
18 reasonably usable which I think will greatly enable us to
19 try to meet the goals of moving this thing along in a
20 timely fashion.

21 MR. PENNOCK: Your Honor, if I may, Mr. Jaffe is
22 in charge of the IT department of Weitz & Luxenberg, has
23 been for several years. He's been involved in numerous
24 document disclosures in different litigations. And in
25 fact, has helped craft a proprietary document data server

1 or document server that we have used in litigation. So
2 he's very familiar with all these issues if the Court has
3 any questions for him because, unlike Your Honor, I would
4 not be -- I'm not versed in this information.

5 But he runs a very large IT department at our firm
6 servicing 60 lawyers and 350 support staff and he's very
7 familiar with these issues.

8 MR. DAVIS: If I may, Your Honor, I don't have
9 the head of our IT department with me, but I do have with
10 me the head of our IT team in terms of the work that's
11 been done in connection with the production of documents
12 and the person who is familiar to plaintiffs' counsel, my
13 partner, Tamar Kelber, who has addressed all of these
14 issues with plaintiffs' counsel. And with that, Your
15 Honor, I'll ask that Ms. Kelber be permitted to address
16 the Court.

17 MS. KELBER: We, before producing the IND and
18 the NDA, asked plaintiffs for feedback on the format of
19 the production. I think we have different recollections
20 of what our discussions were. But it is true that there
21 was no information provided from the plaintiffs before our
22 production regarding the format that they were interested
23 in. In the absence of direction and with the deadline
24 looming, we reproduced the IND and the NDA in the same
25 format as it's maintained at AstraZeneca.

1 The reference that Mr. Bailey made with regard to
2 file size follows from the fact there are a lot of files
3 in AstraZeneca's system that are large. So we took the
4 file as it was and reproduced it on a disk.

5 Since receiving the IND and NDA disks, the plaintiffs
6 have raised a number of issues. We, last Friday, had a
7 call with their IT person and some people with more
8 specific IT knowledge from our firm. They gave us a list
9 of questions and we are following up on them.

10 At this time I think we seem to be working the issues
11 out amongst ourselves, and I expect and hope that we will
12 resolve all the issues regarding the specific format of
13 further productions and regarding any supplementation that
14 we need to be done with regard to this production amongst
15 ourselves.

16 MR. JENSEN: Keith Jensen for plaintiffs. I'm
17 speaking today -- I don't think it jumps ahead. There's a
18 lot of overlap of issues, I submit, between the
19 preservation order that we proposed to the defendants.
20 There's also not only a classic preservation order but a
21 production protocol order. And I would be happy to sit
22 down and present that as Your Honor deems fit later. But
23 there is a great deal of overlap of the issues addressed
24 in the Manual for Complex Litigation that we're proposing
25 in our preservation and production of protocol order deal

1 with of course the manner in which things will be
2 electronically produced, the manner in which they'll be
3 stored, and the manner in which the parties will be able
4 to communicate with basically native format, as it's
5 called, data from the defendants.

6 If you would like to hear from me now, I would be
7 happy to go through what we're requesting today in that
8 regard and I think you will see that the harmony of the
9 meeting of the issues, if you will, Your Honor.

10 THE COURT: Well --

11 MR. CAMP BAILEY: Let's try to resolve the
12 formatting deal first, though.

13 THE COURT: Are these files actually kept by
14 AstraZeneca in TIF format?

15 MS. KELBER: They're kept PDF and scanned PDF
16 format. They have been converted to TIF to be Bates
17 numbered. So it's a TIF --

18 THE COURT: I don't think that's true.

19 MS. KELBER: Well, that's -- that's what -- when
20 we try to Bates number, then that's what we have been told
21 by the IT people.

22 THE COURT: I think Adobe's got tools that will
23 let you do that without converting to a TIF.

24 MS. KELBER: I'm happy to look into whether or
25 not if it will be possible to do the Bates numbering in

1 PDF, but that issue would not resolve the issue of whether
2 they would like the pages to be broken down as single
3 pages or as multiple pages.

4 The issue with regard to the file format is it has
5 been presented to us is that they would like each document
6 separated out into individual files for each document.
7 And that may well be -- individual files for each page of
8 the documents. So if you had a 50 page document, it was
9 produced as a 50 page file. What they would like is 50
10 separate files and we're looking into whether we can do
11 that and how we can get that done. And I would expect
12 that we will be able to do that. It's just that we
13 weren't asked to do that before we had to produce our
14 documents.

15 THE COURT: Well, I'm assuming that there is a
16 host of different kinds of documents. Some are probably
17 things that were originally written in Word and then other
18 things that were lab reports and other things that were
19 protocols and other things that were things that were
20 submitted to the FDA and attachments, a lot of duplicates
21 and things started one way and then I suspect you stored
22 them in many different ways on various serves, whatever it
23 is AstraZeneca calls it's NDA or the IND, is that -- do
24 they take all those things and then put them into a single
25 place on the computer and everything that was something

1 else is transformed into a PDF?

2 MS. KELBER: Exactly. It's maintained by
3 AstraZeneca in one space as PDFs and that's what we
4 replicated for our production.

5 THE COURT: And is that created by scanning or
6 by an electronic conversion?

7 MS. KELBER: Scanning.

8 MR. CAMP BAILEY: After the first hearing we had
9 on September 7, we got together and kind of had multiple
10 tracks going here. We have the MDL here. We also have
11 some state court litigation going up in Delaware and the
12 Delaware CMO that was proposed on, I think, November --
13 September 20th, we specified kind of a specific format
14 that we'd like them in which is kind of the standard in
15 the industry. And what it is is TIF, single page TIF
16 which has an OCR page that goes with it. It has a load
17 file that tells everything, kind of where it's going. I'm
18 botching this all up because I'm not a computer expert. I
19 think that's how most databases today are run.

20 And what I think the Court's talking about
21 specifically is we had a provision that says after initial
22 production and image file format is complete, a party may,
23 if we have an issue with the particular file or something,
24 upon specific request, seek production of electronic
25 documents in their native format, which means we can ask

1 for the Excel spread sheet with all the attached metadata
2 and revision history and all the other stuff like that.
3 But I think in the Zyprexa litigation, in the Resterol
4 litigation, in all these litigations, I think you will
5 find that for a company to even be able to use their own
6 data, it has to be some way searchable. If the FDA asks
7 AstraZeneca, hey, what did you all send us two years ago?
8 I don't find it believable that there's no searching
9 capabilities in there. And that's all we're asking is
10 that when they produce it to us, we have to be able to
11 look through it in a reasonable manner as contemplated by
12 the new federal rules and old federal rules.

13 THE COURT: In terms of the documents already
14 produced and the need for a preservation and protocol
15 directive for the -- going forward for other things that
16 are produced, I want a specific proposal either agreed to
17 or with the disagreements highlighted. We'll take that up
18 at the next conference which will be in a couple weeks.
19 So we'll get all that resolved shortly. But we need to
20 formalize it.

21 And let me just tell you what my predilections are,
22 which I think are consistent with the new rules. And that
23 is that if we're talking about existing files, and I see
24 this phrase "native formatting" and smile a little bit
25 because there's, in some sense there is no such thing

1 because as soon as you look at it you have changed the
2 document electronically, more than just leaving
3 fingerprints on it.

4 And as I say, I'm sure these documents, these items,
5 whatever they are, are different kinds that were created
6 one way and they have been stored and submitted several
7 other ways and then compiled in yet another way and then
8 recompiled in yet another way. All of those things have
9 potential interest.

10 But in any event, what needs to be produced is the
11 most useful version with other versions available, and
12 there shouldn't be any -- I'm not suggesting there has
13 been, but there should not be any attempt to make it
14 difficult or hide the ball or if defendant actually has
15 already an index, electronic index of the files, that
16 ought to be produced along with the documents.

17 And if there's some -- if there's particularly
18 crucial documents that are already word searchable, they
19 ought to be produced. I don't know how well the scanning
20 ones that were scanned and created in PDFs, how well the
21 OCR works on that or how accurate that is making them
22 searchable. But that's an issue that works fairly well.
23 It solves some of your problems, although it's hard to do
24 that on a large volume.

25 But in any event, I want you to continue discussing

1 among yourselves how you're going to solve those problems
2 and, again, if you can't solve them, we'll get them all
3 solved at the next hearing.

4 MR. JENSEN: May I ask a question, Your Honor?
5 Keith Jensen.

6 I have been a designee on this issue and I have been
7 waiting to ask for this since, actually since September 7,
8 but haven't been able to achieve an agreement on
9 maintaining the status quo so Your Honor has the complete
10 ability to make any orders you deem appropriate or not
11 regarding preservation and protocol, and that is, of
12 course, that any -- as you well know, the Manual for
13 Complex Litigation contemplates as well the new one -- the
14 federal -- new and old federal rules and their comments
15 that once you start litigation that you -- and I have
16 asked for this specific agreement and representation from
17 the defendants. I've not been able to get this agreement
18 to date, Your Honor. I have asked them to agree on the
19 record that AZ has suspended the ordinary routine or
20 automatic deletion or overwriting of discoverable
21 electronic information including e-mails.

22 And I could read you what I most recently got from
23 them, but it does not do that. It in fact only agrees
24 that if you enter an order in the future they might
25 start -- they might start no longer overwriting in the

1 routine or ordinary course of business backup tapes,
2 including e-mails.

3 So I request, if Your Honor deems it appropriate, of
4 course, that even as of today, that defendants agree to
5 that so we have the complete ability to negotiate.

6 The second thing I'd like to rise with Your Honor is,
7 is I have been trying to get this for a while, that you
8 order us to negotiate exactly as the Manual for Complex
9 Litigation -- it's 40.25 as we put in our agenda --
10 contemplates, which is that we have a conference. And I'd
11 like to have you order the IT people be present. I think
12 there's no problem with that from either side. And if
13 we're unable to reach agreement as of that conference date
14 that both parties outline why they want their particular
15 preservation provisions and/or production protocols
16 hypothetically ordered by Your Honor and advocate why
17 within three days of that so Your Honor before we arrive
18 next time has an order and a competing order and briefs to
19 the extent they're necessary on why the parties support or
20 oppose their various provisions.

21 MS. KELBER: As for the specifics of the
22 discussions amongst the parties, as with the other issues,
23 we have disagreements as to the extent and timing of those
24 discussions.

25 With regard to a specific preservation order, there

1 needs to be a specific showing of the need for a
2 preservation order. There has been no such showing here.
3 There are all sorts of computer issues with regard to
4 processing of information. So at this moment, it would
5 not be appropriate for us to entertain any stipulations.
6 But we're, of course, willing to confer with the
7 plaintiffs. And I understood from your last comment that
8 we would be doing that as part of our discussions on the
9 document production issue. Then we will be prepared to
10 submit something jointly at the next hearing. I don't
11 think there is a need for anything more specific than
12 that.

13 MR. JENSEN: Briefly respond, Your Honor.

14 All they told me they are willing to agree to in
15 writing is the following. The pertinent part is three
16 sentences, but this last sentence says it all. They're
17 willing to agree "subject to further order of the Court
18 the party may continue routine erasures of computerized
19 data pursuant to the existing programs but shall preserve
20 any printouts of any such data related to Seroquel."

21 What that clearly says is AstraZeneca wants to
22 continue doing precisely what might inadvertently or
23 advertently destroy existing discoverable electronic
24 information. I think it's appropriate that they be asked
25 to stop that.

1 THE COURT: Well, they're under existing
2 principles that govern spoliation, and for present
3 purposes I'm going to leave it at that. If it turns out
4 something has been erased, is unrecoverable or is -- over
5 the next couple of weeks, we'll deal with that issue. But
6 I do want you to submit either agreed proposals or
7 competing proposals to cover document preservation,
8 production protocol and resolution of this issue about the
9 formatting of things already produced by December 5th.
10 And if you need to cite authority, you can do that too, if
11 there's disagreement on an issue that has some legal
12 precedent.

13 MR. JENSEN: One more thing. Here's the issue.
14 Having read the cases and understanding their position
15 that they take the position there is no need for any
16 preservation order, I need to therefore establish that
17 there is a need, therefore, before December 5, I request
18 one 30(b)(6) deposition of a knowledgeable IT person so I
19 can under some of the case law establish the need for a
20 preservation order. Obviously common first deposition in
21 this case isn't an IT person. I'd request that I have it
22 before I'm required to submit it to Your Honor on
23 December 5th.

24 MS. KELBER: I'd like to note we're under
25 obligation under the Federal Rules to preserve documents.

1 We're taking those obligations seriously and we're
2 following the rules.

3 I think the suggestion that there needs to be a
4 30(b)(6) deposition at this point puts the cart before the
5 horse. I would like to be able to have the opportunity to
6 work out a mutually acceptable order and submit it to the
7 Court at the next hearing.

8 THE COURT: I don't think you need a 30(b)(6) to
9 make your arguments here. If you have a full discussion
10 as to the nature of the recordkeeping and record retention
11 policy, seems to me you will have sufficient basis to make
12 your arguments.

13 All right. I set the next hearing for December 8,
14 10:00.

15 Let's talk about the preemption issues. Judge Conway
16 has indicated to me that she wants to have oral argument
17 on that issue in May of next year. So my thought would be
18 to have defendant's motion due April 2 with response due
19 April 30. I know parties have varying views about the
20 impossibility of meeting those dates. So I'll hear you on
21 that.

22 MR. DAVIS: Well, Your Honor, the Court will be
23 pleased to know that we're prepared on January 15 to file
24 a motion based on preemption. So this is one of those
25 occasions where I think we can expedite matters.

1 The motion we would file is a 12(b)(6) motion, and it
2 would be based on -- it's an exemplar motion that would be
3 based on the complaints that are before the Court. And we
4 would be in a position, we think, to suggest that we file
5 our motion in brief on January 15; that plaintiffs be
6 given 30 days to respond. And that if the Court would
7 agree, we would have a reply within 15 days.

8 We have every reason to believe that the 12(b)(6)
9 vehicle which we're suggesting is appropriate. It's been
10 sanctioned by the Supreme Court. And the rulings that the
11 courts have been entering with respect to preemption would
12 allow us to give to the Court the arguments we make with
13 respect to the preemptive effect of the labeling in place
14 in some of these exemplar cases.

15 MR. TRAMMELL: Flech Trammell for the
16 plaintiffs.

17 As a practical matter, we agree with the Court,
18 January briefing schedules are impractical given the
19 factual nature of the preemption inquiry. If the Court
20 knows whatever type of motion they file, they won't
21 necessarily be factual discovery by the Court or what the
22 regulatory history was dealing with this product. They
23 will make certain assertions about things they represented
24 to the FDA, things the FDA may have told them, things the
25 FDA may have considered. The FDA will probably also weigh

1 THE COURT: Well, let me say this. If you get
2 your requests out by Wednesday, I would expect Mr. Davis
3 to be able to identify for me on the 8th any issues he
4 contemplates in terms of objections or difficulty in
5 production. If not chapter and verse, at least topically
6 so that we can determine whether -- and again, as we
7 discussed back in September, and as I mentioned it at the
8 outset today, the rules provide 30 days for this and two
9 weeks for that and but not everything needs the 30 days.
10 I really -- I know you have done this, but I want you to
11 continue and really take it to heart. If there's
12 important things like an organization chart or issues like
13 that, I'm just not going to have any patience, either
14 side, making it hard for the other side. Do the easy
15 stuff easily. Because it's going to -- it will be to
16 everybody's benefit both in the short-term and the long
17 term. So I'm not going to require that they file a formal
18 response, but Mr. Davis, be ready to talk about any
19 problems with that on the 8th.

20 MR. DAVIS: As the Court knows, we will do the
21 very best we can. We're talking about addressing issues
22 that are figments right now. I don't have the requests so
23 I'm -- I can't respond other than to say, again, that we
24 don't have a completed plaintiffs' fact sheet and here we
25 are responding to some discovery that hasn't even been or