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6 **IN THE COMPETITION** Case No. : 1746/5/7/25 (T), 1747/5/7/25 (T), 1748/5/7/25 (T)  
7 **APPEAL**  
8 **TRIBUNAL**  
9

10 Salisbury Square House  
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Wednesday 13<sup>th</sup> May

15 Before:  
16 The Honourable Mr Justice Meade  
17 (Sitting as a Tribunal in England and Wales)  
18 **BETWEEN:**

19  
20 The Secretary of State for Health and Social Care & Others

**Claimant**

21 v

22  
23  
24 Servier Laboratories Limited & Others

**Defendant**

25  
26  
27  
28 **A P P E A R A N C E S**

29 Anna Edwards-Stuart KC, Phillip Woolfe KC, David Drake, Julian Gregory and Laura  
30 Elizabeth John (instructed by Peters & Peters LLP, Reynolds Porter Chamberlain LLP,  
31 Geldards LLP) on behalf of The Secretary of State for Health and Social Care & Others  
32

33 Nicholas Saunders KC, Daniel Piccinin KC and Emma Mockford (Instructed by Sidley  
34 Austin LLP) on behalf of Servier Laboratories Limited  
35

36 Sarah Love KC and Robert Steele (Instructed by Simmons & Simmons LLP) on behalf of  
37 Lupin  
38

39 Emily MacKenzie (Instructed by Baker McKenzie LLP) on behalf of Niche Generics and  
40 Unichem Laboratories

41 Jonathan D.C. Turner (Instructed by Penningtons Manches Cooper LLP) on behalf of Krka  
42

43 Sarah Abram KC and Michael Quayle (Instructed by Bristows LLP) on behalf of Teva  
44

45 Tim Johnston (Instructed by Skadden, Arps, Slate, Meagher & Flom (UK) LLP) on behalf of  
46 Mylan Laboratories Limited and Viatris Inc.  
47

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(10.30 am)

(Proceedings delayed)

(10.33 am)

JUDGE MEADE: Some of you are joining us live stream on our website, so I'm going to start there with the customary warning. An official recording is being made and an authorised transcript will be produced, but it's strictly prohibited for anyone else to make an unauthorised recording, audio or visual, of the proceedings and breach of that provision is punishable as a contempt of court.

Yes.

MR WOOLFE: Thank you. If I can just update you on where we are in the RFI: the parties have liaised overnight.

JUDGE MEADE: Okay.

MR WOOLFE: So we made a proposal with -- made another proposal. Servier is taking instructions on that and is going to be able to give an answer somewhat later today. Therefore what I was going to propose, and I think there's no objection to this on the front bench, is if we get on with the point about the concern of the Rule 39 Defendants, so the timing of the next CMC and the question about whether or not (inaudible) their disclosure, we can clear those out the way this morning and then by the time we've done that, it may well be that the RFI point has been effectively agreed. And then in any event, we can go on and deal with the other points relating to Servier, like the PPRS disclosure point, et cetera, and then maybe see how we can possibly leave at that stage.

JUDGE MEADE: Yes, okay.

Submissions by MR WOOLFE

1 MR WOOLFE: Thank you, sir. In which case there are two -- the two inter-related  
2 points on the agenda are the timing of the next CMC and what order is going to be  
3 made in respect of Rule 39 Defendant disclosure. The only point in dispute on that is  
4 about whether they should file EDQ and disclosure reports in advance of that next  
5 CMC. It seems to be common ground that at that next CMC the Claimants will be  
6 bringing forward requests for disclosure of the Rule 39 Defendants, once we've  
7 finished reviewing the Commission file disclosure and taking into account the  
8 disclosure report and EDQs if they are to be filed.

9 I'm in your hands, sir, whether you want to deal with the point about the timing of the  
10 disclosure CMC first or deal with the EDQ.

11 JUDGE MEADE: Will do the EDQ first.

12 MR WOOLFE: Thank you, sir.

13 So on that note, what we are seeking is paragraph 4 of the composite order. So that  
14 is at bundle A, tab 6, paragraph 3.

15 JUDGE MEADE: Yes. Go ahead.

16 MR WOOLFE: So paragraph 4.

17 JUDGE MEADE: Yes. (Pause)

18 MR WOOLFE: Sorry, have you got -- are you looking at a hard copy or -- I'm afraid  
19 that the composite order was updated overnight. I'm not sure it affects this paragraph,  
20 but --

21 JUDGE MEADE: Well, I've written on this one, so I'll just have to manage.

22 MR WOOLFE: Fine, thank you, sir.

23 So as you see by paragraph 4, what we are proposing -- there are two alternative  
24 dates put in there -- but we are asking that the Rule 39 Defendants file a Disclosure  
25 Report and a completed EDQ. Really, this is for -- what I want to do is, first of all,  
26 address you on what disclosure task we think there is to be done that goes beyond

1 the Commission file, and then set out why we think Disclosure Reports and EDQs are  
2 a good way of tackling that specific disclosure task.

3 To begin on what the disclosure task is that requires to be done, so if I take you to the  
4 pleadings and then show you what the issues are, and then show you why we think  
5 the Commission file won't necessarily have captured everything in respect of it.

6 Now, obviously, the key issue in broad terms is whether the pay for delay agreements  
7 in fact delayed generic entry, and if so by how much. But the disclosure issue is really  
8 defined by the nature of the objections that are being advanced. So if we take the  
9 Niche/Unichem defence, which is at bundle B2, tab 1, I take this by way of example.

10 The reason perhaps for focusing on those in particular is because Niche/Unichem/  
11 Matrix, they were the first in time, in terms of the agreements, and therefore perhaps  
12 the most important to the story of loss.

13 So the relevant passage -- I think is in the summary -- starts at page 5, paragraph 10.  
14 And you'll see what they say their problems were that were preventing them from  
15 bringing their perindopril product to market.

16 JUDGE MEADE: B2?

17 MR WOOLFE: B2, tab 1. So bundle B2, tab 1, page 5. Do you have -- paragraph 10.

18 (Pause)

19 So bundle B2, tab 1, page 5. (Pause)

20 JUDGE MEADE: Yes, okay.

21 MR WOOLFE: Perhaps it might be more efficient -- rather than me reading this out to  
22 you, it goes on for a couple of pages -- if you read paragraph 10 -- and then I point out  
23 key features -- you can take some time, otherwise it's quite long. But what they say is  
24 that they faced intractable technical difficulties and also they had -- which they detailed  
25 in this paragraph. Then in paragraph 11, they go on to say they faced financial  
26 difficulties. So ones I would point out in particular amongst these difficulties are -- if

1 you go to subparagraph (e), which is over the page on page 6, they refer to not having  
2 enough stability data. But then at paragraph (f), what becomes apparent is that the  
3 difficulties they are really relying upon are those arising from a change in synthesis  
4 route arising from an attempt to get around -- I think -- the process patents, and they  
5 detail the problems arising from that.

6 So at (h), over the page on page 7, they refer to problems with particle size.

7 At paragraph (l) on page 8, they refer to -- again referring to particle size -- testing,  
8 Unichem's testing in respect of particle size, and the consequences of it are detailed  
9 in little (i) underneath that, which is problems of dissolution profile and problems of  
10 hardness and so forth. They also refer to problems in the proportion of the alpha  
11 polymorph.

12 And then I think at (k) on the same page, they refer to impurity problems.

13 JUDGE MEADE: Right.

14 MR WOOLFE: So that gives you a flavour of what the difficulties they say that they  
15 faced in bringing product to market.

16 Now, with all these difficulties, what we need to do in terms of arguing the case as to  
17 how ready these products were to come to market, is to understand what the difficulty  
18 actually was and what might have been done to solve it. It's not enough there's  
19 a difficulty; it may well be that the problem is readily soluble.

20 JUDGE MEADE: Right.

21 MR WOOLFE: Maybe soluble is the wrong word; these are tablets, there we are. And  
22 so for instance how much of the particle size decreased, was that to an extent that,  
23 really, would pose a problem, what processes were actually being used, given those  
24 processes, were there easy fixes that could be used and so forth.

25 Now we would expect all of these points to have generated documents at the time:  
26 process parameters, test results, analyses of test results, summaries of test results,

1 possibly internal memoranda about these. Again, because these are three companies  
2 involved in this, Niche/Unichem/Matrix, there may well be correspondence regarding  
3 this issue and there were proceedings which were brought by Servier against Niche  
4 and those may have generated further documents.

5 So that gives you an idea of the kinds of documents, in broad terms, that we think  
6 would be relevant to this issue.

7 JUDGE MEADE: Sorry, what would come about in the Servier-Niche proceedings?

8 MR WOOLFE: So there was -- I believe there was -- evidence was actually produced  
9 in those proceedings, which we haven't seen yet, and it doesn't appear to be in the  
10 Commission file.

11 JUDGE MEADE: What were the proceedings for?

12 MR WOOLFE: They were infringement proceedings brought by Servier against --

13 JUDGE MEADE: Okay, all right. Yes.

14 MR WOOLFE: The other point that arises from the (inaudible) is you can see  
15 at -- before I leave this document -- paragraph 13, which is on page 11.

16 JUDGE MEADE: Right.

17 MR WOOLFE: You see a reference to Niche's financial difficulties as well.

18 There's reference in paragraph (d) to approaches to lenders and an unwillingness of  
19 the shareholders to provide a shareholder guarantee, and again we'd expect that kind  
20 of issue to generate a range of documents, such as funding proposals,  
21 correspondence, board documents, et cetera.

22 Okay. Now, you can see it's quite likely these issues would have generated a great  
23 deal of documentation at the time -- obviously it may or may not have survived to the  
24 present day. Now what's clear is it's likely that the EU Commission investigation did  
25 not exhaustively mine this kind of documentation. You can see that first of all from the  
26 documentation, which we have in fact received -- and I'll show you some evidence

1 about that in a moment -- but secondly because the issues that the Commission was  
2 concerned with were such that it didn't have to go into these issues and anything like  
3 the kind of depth which we would want to in this litigation.

4 So in terms of the documentation which we have seen so far in our review of the  
5 Commission file disclosure, this is summarised by Mr Tickner in his 19th statement,  
6 bundle I, tab 15, page 18. (Pause)

7 Perhaps if I ask you to read what he says at paragraph 44.3. It runs just over the  
8 page, it's 44.3, and then two subparagraphs below it, they run over the page, in  
9 technical problems and financial problems. (Pause)

10 So there's a gap between what documentation we think would have been generated  
11 and what we're seeing in the Commission file.

12 The second point: we wouldn't expect the Commission file to be the complete set of  
13 documents, which you would gather in a civil litigation disclosure exercise, because  
14 the issues are not the same. The Commission was concerned with whether or not the  
15 pay for delay agreements removed actual or potential competition that would  
16 otherwise have occurred. But that concept of actual and potential competition is rather  
17 broader than the issue we are looking at, which is when generic entry specifically  
18 would have occurred, and the Commission wasn't -- we understand -- seeking to make  
19 findings about the precise timing of generic entry.

20 You see that from the Commission decision itself. If I take you to bundle E1, tab 1,  
21 which is the entire commission decision, but we're only going to look at three  
22 paragraphs of it. (Pause)

23 Once you have the document, if I ask you to go to page 318. (Pause)

24 Specifically, it's paragraph 1384 at the bottom of the page:

25 "This section will examine the competition that would have existed in the absence of  
26 the restrictive provisions of the Niche/Unichem settlement agreement. The section will

1 focus on the competitive behaviour that Niche/Unichem would have been likely to  
2 engage in, absent the agreement, the other relevant sources of competition." [as read]  
3 So that's the broad rubric. But then at paragraph -- the actual points that they focus  
4 on are really just those set out at 1386 and 1387, which are on the following page.  
5 The first, 1386:  
6 "In the absence of the non-challenge obligation, Niche/Unichem would remain the only  
7 undertaking involved in litigation with Servier before a national court." [as read]  
8 So the actual patent proceedings themselves are in a sense a form of competition.  
9 And then at 1387:  
10 "Niche would have remained in the patent opposition proceedings in the EPO." [as  
11 read]  
12 And then at 1390, which is over on page 320, next page on, this -- in respect of  
13 prospect of supplying the market, they simply say:  
14 "They would have remained a threat due to its advanced development of perindopril  
15 and absent the agreement would retain the competitive abilities and incentives and so  
16 forth." [as read]  
17 So they are not looking at this issue in the same way. That's why we think there's  
18 a gap between what we see on the Commission file and what we want to have.  
19 So we think there is likely that there are substantial numbers of relevant documents  
20 that are likely to have been generated and will not have been captured.  
21 Now, the reasons why we think EDQ and Disclosure Report are a helpful way of  
22 attacking this problem.  
23 I mean, the simple, broad point is the Rule 39 Defendants are likely to have a much  
24 better idea than we do of what documents they would have generated at the relevant  
25 point in time and where those documents are likely to have survived.  
26 In respect of the technical issues, they know what testing they in fact were doing, or

1 at least that would have been in the knowledge at the time, and they would have known  
2 how their normal records of production parameters and test results were kept.

3 In respect of both the technical and financial issues, they will know what their internal  
4 structure was and how information flowed within the company: what the management  
5 structure was, where documents were likely to have been generated, what the teams  
6 were, et cetera.

7 Now, if I can just show you the parts of the EDQ that we think will be potentially  
8 particularly useful with respect to this. The EDQ is in the authorities bundle. It's  
9 bundle J, tab 4. You can see "Question 1, Date Range"; that's fairly straightforward.  
10 Question 2 is "Identifying the Custodians or Creators Whose Repositories Should be  
11 Searched" [as read].

12 Now, they will know who in their companies were involved in trying to bring these  
13 products to market. They know what teams are involved. We have literally no idea.  
14 So that is an obvious example of a question where more focused requests for  
15 documents can be made once it is known who was involved.

16 Then similarly over on question 5, which is on page 3:  
17 "Identification of database systems including document management systems which  
18 were used, which may contain electronic documents." [as read]

19 Again, they'll know what their IT systems were and where technical documentation  
20 may have been kept, or financial documentation.

21 Similarly, question 6: "Proposals for Keywords". It's important, we think, that if  
22 keyword searching was to be done that the Rule 39s have to make some proposals to  
23 what keyword should be used. They will know, for example, internal project names,  
24 names of relevant custodians. Documents may be in different languages. We're  
25 dealing with suppliers in India, Hungary, various places. And they will know the  
26 relevant vocabulary in different countries, et cetera, and therefore for us to try and put

1 forward keywords -- it's all very well to say "perindopril", that may generate a lot of  
2 documents, but it would be very hard for you to do focused searches without them  
3 having input into keyword searching.

4 Then questions 10 to 12, these are also important. This is on page 5 -- opportunity,  
5 indeed an obligation, to set out specific concerns about the reasonableness of the  
6 search, problems with access to documents including, presumably, if things have  
7 become inaccessible -- that's question 11.

8 Now in a sense we're quite interested in hearing answers to those questions as well.

9 If we have a detailed proper account of what documents may have been created, and  
10 why these places have become inaccessible, we can then produce focused and  
11 proportionate requests for searches to be done. Whereas at the moment we're getting  
12 very broad assertions of, "Well, a lot of time has passed, some people have left".  
13 Those things are very hard to go behind. They didn't help us much to produce  
14 a focused request. Whereas if we have more specific information as to what actually  
15 has become inaccessible, that will be of significant assistance in bringing forward  
16 proportionate disclosure proposals. So you can see why this information as a whole  
17 will enable us to produce, together with the Commission file review, focused and  
18 realistic disclosure proposals.

19 Now, various objections are taken by the Rule 39 Defendants. I think generally these  
20 are all put in Ms Vandendorre's evidence. That is at bundle I, tab 25.

21 JUDGE MEADE: Right.

22 MR WOOLFE: She makes a statement on behalf of Viatris, but I think it summarises  
23 points generally on behalf of the Rule 39 Defendants. Now, she turns to paragraph 23,  
24 which is on page 7.

25 JUDGE MEADE: Yes.

26 MR WOOLFE: First of all, she complains that Servier has never been ordered to file

1 a Disclosure Report or EDQ. That's paragraph 23, we say there's nothing in that for  
2 several reasons. First of all, Servier has actually been ordered to provide standard  
3 disclosure on a number of issues. When you have a general obligation to give  
4 standard disclosure, all concerns about reasonableness of searches, in a sense, are  
5 put on the disclosing party. Whereas if you're having a structure like we're having for  
6 Rule 39 disclosure, where we're going to bring forward requests, it's a different  
7 dynamic. In any event, Servier was in fact ordered to give information as to its  
8 corporate structure in order that we could have some insight into that. In any event,  
9 the fact that Servier hadn't done something doesn't mean it's not sensible for the  
10 Rule 39s to do now.

11 Paragraph 24. She says that this is premature because we haven't finished reviewing  
12 the Commission file. Now, what we say is: this is when the CMC we have is. We've  
13 done a substantial job of reviewing the Commission file and indications coming out of  
14 it are that it doesn't contain the kind of information which we need, or at least not  
15 sufficient information. If we want the next disclosure CMC to be effective, we want to  
16 be coming back with more specific disclosure requests. We seek this information  
17 precisely in order to help us formulate reasonably targeted and proportionate requests.

18 At paragraph 26, over the page, she says that Viatrix may not have control over  
19 a material number of documents. That may well be the case, but that's precisely why  
20 ordering Disclosure Reports and EDQs is a good idea. Because if we simply start by  
21 identifying gaps in the Commission file disclosure, and broad -- very  
22 broad -- categories of documents that we think might be relevant, and start making  
23 a whole series of disclosure requests of Viatrix for documents by reference to that,  
24 they're going to have to search each time by reference to the broad requests.

25 Whereas if instead they proceed by giving us an understanding of what relevant  
26 repositories of documents did exist and what's now accessible, it may well become

1 | apparent that there's simply no point in pursuing certain requests against them, or we  
2 | could change the terms of the request to capture something more likely to be available.

3 | So simply a more useful way of proceeding.

4 | A fourth point is that disclosure of the Commission file remains ongoing. That's really  
5 | a repeat of the prematurity point.

6 | Then at paragraphs 28 to 29. What she really is supposed to be saying at  
7 | paragraphs 28 and 29 is that the Disclosure Report and EDQ are appropriate for the  
8 | start of a disclosure process, but aren't appropriate now that some disclosure has  
9 | taken place. We find this somewhat difficult to understand. Some disclosure has been  
10 | given from a pre-existing cache of documents, namely the Commission file. But the  
11 | fact that that disclosure has been given doesn't make it any harder to identify the  
12 | issues in the proceedings, nor does it make it any harder for the Rule 39 Defendants  
13 | to identify relevant repositories of documents they may have.

14 | In terms of an alternative, just to call attention to this -- this is at paragraph 32 -- what  
15 | she seems to suggest is -- paragraph 32 which begins on page 9 and runs onto  
16 | page 10 -- that we make targeted and specific requests addressed to particular issues  
17 | or topics. She mentions a Scott Schedule, I think what's meant is the  
18 | Redfern Schedule. But what's not clear is whether they are proposing that we  
19 | formulate requests in terms of issues -- documents relevant to the issue of particle  
20 | size, for example -- or whether they're suggesting we formulate specific descriptions  
21 | of documents.

22 | JUDGE MEADE: Or both, I mean --

23 | MR WOOLFE: Or both. But it's quite important because in a sense issues can be  
24 | identified we think, in some sense. But what's challenging, without having greater  
25 | insight of the type that a disclosure (inaudible) would give, is for us to produce  
26 | categories of documents that are going to be proportionate. What we're concerned

1 about is that if we frame broad descriptions of documents that we think are going to  
2 capture everything that could be there -- that could be relevant -- that we're going to  
3 be met by objections saying "This is disproportionate" and "They're a long time ago",  
4 and all these difficulties; "That's too broad".

5 If we try and go more narrow, we don't know what we're looking for. It becomes  
6 a game of battleships. So what we're trying to do is just give us more transparency in  
7 order that we can produce the focused requests. So that's essentially the point. It's  
8 trying to give us the transparency to produce focused requests.

9 JUDGE MEADE: I mean, this may be more a question for them than for you, but how  
10 long do you see it taking to produce an EDQ?

11 MR WOOLFE: Well, we have proposed in the order -- a composite order -- four weeks  
12 from this CMC.

13 JUDGE MEADE: I should say I'm not unsympathetic to the overall position you're  
14 taking, which is that there could well be things that are not covered in the Commission  
15 disclosure, I think that's obvious, and you've given a helpful example. So I'm not  
16 unsympathetic to that at all. So we're really talking about the tools that should be used  
17 to investigate the difference. So the question is, "Is the EDQ the right way to do it?"

18 MR WOOLFE: Yes.

19 JUDGE MEADE: My non-trivial but not enormous experience of EDQs is that they  
20 take quite a long time to do, especially in big organisations with a lot of repositories of  
21 documents. So I just question whether it's realistic to do an EDQ in this sort of  
22 circumstance in anything like four weeks.

23 MR WOOLFE: So the situation is we propose four weeks; Servier I think have  
24 proposed three months.

25 JUDGE MEADE: Yes.

26 MR WOOLFE: But the Rule 39 Defendants, who are the ones who actually would be

1 | doing it, haven't produced any counter-proposal. Obviously if they came back to us  
2 | and said "We need six weeks, not four weeks", for example, we're not going to argue.  
3 | JUDGE MEADE: Yes.  
4 | MR WOOLFE: But we don't have any counter-proposal from them.  
5 | JUDGE MEADE: No, sure. But I --  
6 | MR WOOLFE: Now, the four weeks --  
7 | JUDGE MEADE: Stop, stop.  
8 | MR WOOLFE: Sorry.  
9 | JUDGE MEADE: My instinct is that to do it properly would take a really long time,  
10 | especially because we're looking back to the distant past. If it would take a long time,  
11 | that's actually just a reason why this might not be very attractive to you, because then  
12 | you can't really get going until you've got the EDQ and the Commission disclosure,  
13 | and only then can you do your document requests. So just the sheer time of it is  
14 | something you need to turn your mind to. If it was going to be four weeks and if it was  
15 | only going to be a couple of weeks work for a couple of solicitors, well, that might give  
16 | the lay of the land a little bit, but I just question whether that's at all realistic.  
17 | MR WOOLFE: Well, this does then tie into the timing of the next CMC because we  
18 | said four weeks --  
19 | JUDGE MEADE: It does, yes.  
20 | MR WOOLFE: -- in the hope that we seem not unreasonable, and perhaps they come  
21 | up with different proposals, but that was with a view to our suggestion the next CMC  
22 | be in July and obviously we need to be in in time for us to have that.  
23 | Now, I was going to come to this a bit later on, but having reflected on your ruling  
24 | yesterday, we think we do need to have a disclosure CMC with a fixed date.  
25 | JUDGE MEADE: Yes.  
26 | MR WOOLFE: But obviously it does seem sensible to have a CMC after the General

1 Court judgment as well.

2 JUDGE MEADE: Yeah.

3 MR WOOLFE: If it were possible to combine them that would be --

4 JUDGE MEADE: Yes.

5 MR WOOLFE: So what we were going to propose on the timing of the CMC is  
6 that -- well, the last date the General Court could hand down judgment before the  
7 summer is 15 July, because the vacation starts on 16 July.

8 JUDGE MEADE: Right.

9 MR WOOLFE: Servier's sensible proposal is that any CMC following the General  
10 Court's judgment be no earlier than 2 months and 10 days after the --

11 JUDGE MEADE: Yes.

12 MR WOOLFE: -- (inaudible) deadline. That takes you to late September. So we  
13 would propose that if a disclosure CMC were to be listed for the earliest convenient  
14 date after Monday, 5 October.

15 But we have a fixed-date disclosure CMC that we know we're heading towards to give  
16 us a target to work towards in terms of formulating disclosure requests and so forth.  
17 Then, if the judgment is handed down before the summer, then that can also function  
18 as the General Court CMC as well.

19 JUDGE MEADE: Right.

20 MR WOOLFE: But if that's the case, then there is a longer period available before that  
21 CMC for disclosure, Disclosure Reports and EDQs.

22 Now, the other thing to mention (inaudible) a possibility, it's Ms Vandendorre that  
23 referred to Model C disclosure from Practice Direction 57AD -- I always get my letters  
24 confused.

25 JUDGE MEADE: Yes.

26 MR WOOLFE: And that Model C disclosure involves filling out a Disclosure Review

1 Document.

2 JUDGE MEADE: Yes.

3 MR WOOLFE: Which involves identifying the issues, and then there are some  
4 proposals about categories. But both sides have to collaboratively put forward the  
5 categories they're proposing. Then there is a set of questions in part 2, which do cover  
6 some of the same ground as the EDQ but maybe not quite the same depth. That  
7 might be another way to attack it but, in a sense, what we want to avoid is a situation  
8 where we're throwing darts at the dart board.

9 JUDGE MEADE: No, I understand that. You said that. But Model C is a much more  
10 issue-based approach; isn't it? Because the thing about the EDQ is that it just looks  
11 at documents as things to be found and it doesn't split it out by issue, really, does it?  
12 I mean, if they did an EDQ and you wanted to say to yourself -- you keep looking at  
13 the clock!

14 MR WOOLFE: Sorry. I was (overspeaking) distracted by that, sir.

15 JUDGE MEADE: No, no.

16 If they did an EDQ and somebody on your team wanted to say to themselves, "Well,  
17 now who are the custodians we should be looking to for the batch reports?" It doesn't  
18 actually tell you that, does it?

19 MR WOOLFE: It depends on --

20 JUDGE MEADE: Because it just lists all the custodians.

21 MR WOOLFE: It depends on how it's completed, but I can see it could --

22 JUDGE MEADE: Well, it doesn't require that; does it?

23 MR WOOLFE: No, it doesn't require that.

24 JUDGE MEADE: So it's not actually a very good tool for differentially scrutinising  
25 according to issue. So, as I say, I'm not deprecating your clients' general position that  
26 there has to be careful scrutiny of documents that are important but don't come from

1 the Commission disclosure. I'm just testing whether an EDQ is the way to do it.

2 MR WOOLFE: Yes.

3 JUDGE MEADE: I mean, for example -- this is a rather silly example -- if your  
4 disclosure review of the Commission documents concluded and the only thing missing  
5 was documents concerning the purity of production batches or something, we'd take  
6 one course. If that was there but some other thing, you know, correspondence with  
7 Servier was not, we'd take a totally different approach.

8 MR WOOLFE: Yes, I can see that. So, in that case, are you more attracted to  
9 something like the Model C?

10 JUDGE MEADE: Well, I'm not going to order Model C disclosure today. That's a very  
11 major step. But I do think whatever tool is used has to be calibrated to the issues and  
12 give you an insight to the disclosure on the issues, rather than just what is sometimes  
13 called the landscape of the documents without differentiating between the issues.

14 MR WOOLFE: Thank you, sir. I think in light of that indication, it would probably be  
15 helpful if I could take in some instructions from my solicitors on where we proceed  
16 next. Unless you want to hear submissions from the other parties immediately now.  
17 Might it be convenient to you if I were to do that, and then we could resume in --

18 JUDGE MEADE: Because I question whether an EDQ is really the way to pursue  
19 what I think is a very legitimate goal, I'm either going to order that or not order it, it  
20 seems to me.

21 MR WOOLFE: But I understand you're sympathetic to our point that we need more  
22 information about what underlined this. But you're concerned that an unfocused EDQ  
23 is not the right way to go.

24 JUDGE MEADE: Yes.

25 MR WOOLFE: So what I was wondering is if I could take instructions on the possibility  
26 of producing a more focused request to meet your concern, essentially. That's what

1 I was thinking of doing.

2 JUDGE MEADE: What I'm indicating, I think, is this: first of all, I question whether an  
3 EDQ is the right way to go.

4 Secondly, if it was or if I was going to do it in some modified form, I cannot believe that  
5 the Rule 39 Defendants can do it in a short time. I think it's a huge job.

6 MR WOOLFE: Yes.

7 JUDGE MEADE: Your suggestion for the date of a CMC to cover disclosure and  
8 possibly everything else sounds very sensible, but by then you will have finished  
9 reviewing the Commission documents, won't you?

10 MR WOOLFE: Yes.

11 JUDGE MEADE: So you could come back with at least a narrative description of what  
12 you have got, and the major things you haven't got. A point you've made very well is  
13 that you shouldn't be put in a cleft stick of having to grope around in the dark with  
14 things that are either too narrow or too broad.

15 MR WOOLFE: Yes.

16 JUDGE MEADE: But that would assume that you've only got one more chance at the  
17 next hearing and if you fall between Scylla and Charybdis you lose. Well, that's not  
18 going to happen because that would obviously be unfair. So my thinking is that, simply  
19 because the EDQs will (a) take too long and not be the right tool, and because  
20 a disclosure CMC is not realistic before October anyway, the practical way forward for  
21 you is to finish your review and come back with a more issue-based inquiry outline.  
22 The Rule 39 Defendants would have heard what I've said about the fact that I think  
23 you almost certainly are driving after an important thing, which is the delta between  
24 the Commission disclosure and the disclosure. Which is appropriate given the  
25 pleaded issues in the case.

26 MR WOOLFE: I think that, in a sense, we may well have enough to enable the parties

1 to move forward because we can carry on with our review. The Rule 39 Defendants  
2 have heard what's been said, although maybe they'll make some submissions about  
3 it now. And we can try to collaborate on formulating issues with a view to getting  
4 something, information of the broad type, the EDQ-like stuff --

5 JUDGE MEADE: Right.

6 MR WOOLFE: -- in relation to those issues by the time of the next CMC.

7 JUDGE MEADE: Well, I think the practical way forward is for me to hear from the  
8 Rule 39 Defendants and in particular whoever's taking the lead on this one, in case  
9 I've just completely got it around my neck and have been making ridiculous  
10 suggestions.

11 Yes.

12

13 Submissions by MR SAUNDERS

14 MR SAUNDERS: Just before the Rule 39 Defendants stand up, can I just say that  
15 we -- so, Servier supports the Claimants' application.

16 JUDGE MEADE: Right, yes. As long as you don't have to do it!

17 MR SAUNDERS: I won't comment on that my Lord.

18 But the point about the Disclosure Report, as it applies to Servier, we dealt with in  
19 paragraph 33 of our skeleton (overspeaking).

20 JUDGE MEADE: Right. Sorry, just give me one second then.

21 MR SAUNDERS: This is the point, that we've never had to file an EDQ ourselves.

22 JUDGE MEADE: Yes. Well, that's because of the duration of the proceedings, the  
23 different statuses.

24 MR SAUNDERS: There are (overspeaking) orders on this (overspeaking).

25 JUDGE MEADE: Yes.

26 MR SAUNDERS: For our part, we're not wedded to an EDQ in the form it's done. We

1 | hear what my Lord says about that. But we do think that there has to be a time where  
2 | the generics companies are going to explain, for example: their document retention  
3 | policies, who the potential custodians are, what repositories they've got, what they  
4 | keep, what they don't keep. That sort of information should be perfectly amenable to  
5 | being provided in some form. So we're a little bit hesitant about moving that debate  
6 | until potentially after a further CMC. But, you know, we're in your hands.

7 | JUDGE MEADE: Would it be all right if I had a good description of what's already in  
8 | the Commission documents?

9 | MR SAUNDERS: My Lord, it's a question of whether you're doing it by looking for the  
10 | delta between the Commission documents and other things that might be behind, or  
11 | whether you're doing that debate with some further information from the Rule 39  
12 | Defendants explaining what it is they've got. I mean, for example, if one of them says,  
13 | "Well, actually we have a policy and it's always been the company policy that we shred  
14 | all documents after 8 years", then we'll have to see where we go on that one. Having  
15 | that sort of information saves a lot of time, and that is something that could be  
16 | progressed now. An EDQ may not be the right vehicle anyway because, how much  
17 | of this is going to be electronic when we're dealing with things from 30 years ago is up  
18 | for debate.

19 | JUDGE MEADE: Well, quite.

20 | MR SAUNDERS: But the general principle of the Claimants' application we seek not  
21 | just for the cynical reason my Lord identified.

22 | JUDGE MEADE: Yes, okay. All right, thank you.

23 |

24 | Submissions by MR JOHNSTON

25 | MR JOHNSTON: Sir, I appear on behalf of the Third and Fourth Defendants, Viatrix.  
26 | I've been nominated to address this application first. Others may well follow me. My

1 first submission was going to be that this application is a very blunt, slow, and rather  
2 expensive tool by which to get to where the applicants say they want to go. Where,  
3 I think, you've reached in discussions with Mr Woolfe -- and I'll cut almost all of my  
4 submissions in light of that -- is very much where the Rule 39 Defendants have been  
5 sat in preparation for this CMC. What our position is, in short -- you heard it from  
6 Mr Woolfe this morning, you heard the word gap, delta, lacuna, and so on and so forth.  
7 The Rule 39 Defendants are not setting this up as some kind of binary: it's EDQs and  
8 disclosure, or no disclosure; of course they're not.

9 The Rule 39 Defendants' position is that the proper approach, in this somewhat  
10 unusual case that's been going on for a very, very long time, where the Claimants  
11 have just been provided with thousands of documents to review, is for the Claimants  
12 to do what Mr Tickner did in paragraph 44 of his witness statement that you just saw.  
13 Which was to identify specific documents in some cases. There are circumstances,  
14 and we see that in Mr Tickner's statement, it may be worth turning it up again. It's at  
15 I 15, page 19. So if you look at 44(4), we do say --

16 JUDGE MEADE: Just while you're on that, this system is excellent, but could you  
17 possibly change the file name so that, instead of 19 ... Tickner, you call it Tickner 19.  
18 Because --

19 MR JOHNSTON: There is much common sense in that. For search purposes.

20 JUDGE MEADE: Yes. Because, when I'm trying to find it in my tabs, all I can see is  
21 19.

22 MR JOHNSTON: Yes. That's --

23 JUDGE MEADE: It's not really a criticism, but it would improve what is already very  
24 good.

25 MR JOHNSTON: I'm grateful. I'm sure that can be picked up by somebody behind  
26 me.

1 JUDGE MEADE: Yes.

2 MR JOHNSTON: What you see in paragraph 44.4 there is Mr Tickner identifying with  
3 some precision some of the documents that he says are missing, and that -- coming  
4 back to the discussion you had with Mr Woolfe -- that's precisely where the Rule 39  
5 Defendants anticipate that we are going to be in these proceedings, which is that the  
6 Claimants may say: "There is a specific document that we are after. We are after  
7 witness statement of Mr X, or Ms X, on this date. Can you please go and search for  
8 it?"

9 Of course, there will be broader issue-based requests, and they can be refined in the  
10 course of correspondence, to the extent there's disagreement, there can be a Redfern  
11 Schedule, we can come to you, there can be a decision about what should or should  
12 not be ordered. But we do say -- and I take the Tribunal's indications, I'm not going to  
13 press the point at length at all -- but we do say that EDQs and Disclosure Reports are  
14 going to be really quite time consuming.

15 JUDGE MEADE: Yes.

16 MR JOHNSTON: In relation to -- I mean it's going to be an exercise in database  
17 archaeology, by reference to all the issues in the case. And that's the other thing about  
18 EDQs and Disclosure Reports, of course: they cover everything, and as you've heard  
19 very clearly from Mr Woolfe this morning, we don't need to cover everything. What we  
20 need to do is to identify the gaps -- if I can put it that way -- or the issues that are  
21 inadequately addressed in the contemporaneous documents. Then there needs to be  
22 a dialogue: what kinds of things might be searched for, where might you search  
23 keywords and so on and so forth.

24 Whereas ordering Rule 39 Defendants to go away and produce EDQs and, you know,  
25 for the avoidance of doubt, my instructions are absolutely consistent with your  
26 suggestion this morning, sir, which is that this is not something that could possibly be

1 done within four weeks. The proper approach is for the parties to have a dialogue and  
2 the Rule 39 Defendants are not pulling up the drawbridge and saying "No disclosure".  
3 Quite the contrary: they're saying doing a very broad, very general and rather  
4 expensive exercise isn't really going to cast very much light on the next stage of the  
5 process, which is what specifically are you seeking? And we say that much the more  
6 proportionate, much the more sensible approach is for the Claimants to read what they  
7 have -- which is rather a lot -- but quite possibly not everything they're after, and --  
8 JUDGE MEADE: Certainly not going to be everything after. I mean, it's quite clear it's  
9 not going to be everything they're after.  
10 MR JOHNSTON: Absolutely, that's right. And then to come back and for there to be  
11 a dialogue and for there to be a hearing, to resolve matters that can't be resolved by  
12 agreement between the parties.  
13 JUDGE MEADE: Right.  
14 MR JOHNSTON: What would be wholly disproportionate would be a very expensive,  
15 very broad, very general EDQ and Disclosure Report process that doesn't -- in my  
16 respectful submission -- take us very much further, because what they're told is there's  
17 a database in India and it dates from this date to that date. That doesn't tell them how  
18 they're going to find either (a) specifically evidence on this particular molecule and how  
19 it was developed, or (b) this particular witness statement of that person.  
20 And so we just say this is the wrong tool. It's going to be slow, it's going to be  
21 expensive and it's not going to get us where all the parties are keen to go. And we do  
22 stress -- sir, I don't know if you've had a chance to read Ms Vandendorre's statement.  
23 JUDGE MEADE: Yes, I have.  
24 MR JOHNSTON: I won't take you back to it though, but you'll recall from it that in the  
25 case of my client, the relevant subsidiary has been sold to a company called iQuest.  
26 My client has written to them and said, "We're going to need to make document

1 requests from you". But trying to do an EDQ or Disclosure Report effectively -- at the  
2 gift of a third party where every request is going to be imposing an additional burden  
3 on them, mapping out this exercise, saying, "Can you please tell us which repositories  
4 you have that we handed to you? We can't quite tell you what we handed to you  
5 because we don't necessarily know that in 2024. Can you search?" It's going to be  
6 extraordinarily difficult. What will be much more effective will be having had  
7 a conversation between the Claimants and the Rule 39s, us being able to go and say,  
8 "Can you search this particular document, or can you search for this particular  
9 category of documents by reference to these key words?"

10 So we do say this is layering over the top something that's going to be unhelpful and  
11 I take it from Mr Woolfe's submissions that he was coming around to that view in the  
12 course of his dialogue with you. So I won't press the point any further, save to say  
13 that we are -- maybe one more point very briefly before I sit down, which you'll have  
14 seen from the skeleton arguments, but just to sort of underscore it, there is an oddity  
15 about this application, which is that it's been made by the Claimants against the  
16 Rule 39 Defendants.

17 JUDGE MEADE: Yes, you've made that point in your skeleton.

18 MR JOHNSTON: Yes, it's in our skeleton. And so I won't develop it, reiterate it, in  
19 any great detail, given where we are. But it's worth recalling that the Claimants'  
20 proposal was to go to trial without any of this information. They've had years in which  
21 to sue the Rule 39 Defendants. They didn't. They're perfectly entitled not to, of course.  
22 Servier brought a claim against the Rule 39 Defendants. Servier hasn't made an  
23 application for the Rule 39 Defendants to file EDQs and Disclosure Reports.  
24 They've -- slightly latter-day basis -- discovered that there is support for the  
25 application, but they didn't make it themselves, let me put it that way.

26 And so we do say that rather goes to the force of the way the application was being

1 put in the first instance, which is: "This is absolutely essential. We must have this. We  
2 need to have very comprehensive overviews. Yes, it might be onerous, it might be  
3 costly, it might be time consuming, but nonetheless this is absolutely necessary." Well,  
4 part of the answer to that, my Lord -- at least contextually -- is this is actually an  
5 application by a party in this litigation against the party that they -- against which they  
6 had not brought a claim.

7 So we do say that goes some way to at least contextualising the application and some  
8 way to softening some of the force of it.

9 So there was plenty more that I was going to say, but I think we've reached a happy  
10 common ground, which is that where you've reached in discussion with Mr Woolfe is  
11 pretty much what my clients have been advocating for, which is: read the documents,  
12 tell us specific documents that you want and/or identify topics on which you want  
13 further discussions and further searches.

14 JUDGE MEADE: That's encouraging in a way, but you're not really squaring off the  
15 trap that Mr Woolfe doesn't want his clients falling into, which is how can they possibly  
16 say that they want such and such letter of such and such date when they don't know  
17 it exists on the one hand, or on the other hand, if they come back and they say they  
18 want everything you've got about purity, you say, "That's too broad". So, soothing  
19 words, but I can see a lot of debate downstream when your clients say, "Well, you've  
20 come up with your request, but they're all too broad or too narrow."

21 MR JOHNSTON: And so -- you know, I don't mean to be pouring -- you know, false  
22 soothing words into my submissions. The position is that in some respects, they can  
23 identify the specific documents that they want.

24 JUDGE MEADE: They can.

25 MR JOHNSTON: Because they've identified them. They say, "We want the witness  
26 statement of Mr X."

1 JUDGE MEADE: Yes.

2 MR JOHNSTON: And in those circumstances, it's going to be straightforward. Will  
3 there be differences between the parties as to the proportionality of some of the  
4 categories of documents sought?

5 JUDGE MEADE: Right.

6 MR JOHNSTON: Yes, that seems likely to me, because that's consistent with all of  
7 our experience of any litigation, litigation at this time. But that isn't a reason -- in my  
8 submission -- to order EDQs and Disclosure Reports, because EDQs and Disclosure  
9 Reports aren't going to remedy or remove or address that possibility, because it's not  
10 going to give them the kinds of information that would enable them to say, "Well  
11 actually, now, I can make a much more targeted request, because I know that there is  
12 a database in relation to 2003 to 2005", partially because the EDQs are going to be  
13 very broad, they're going to cover all the issues in the case -- not just the issues where  
14 there are lacunae or gaps -- everything. And secondly because they're not going to  
15 give the kind of precision that Mr Woolfe, I think, is hoping that they will. That's not in  
16 practice how they work, sir.

17 And that's why I don't propose to make any false promises as to whether at some point  
18 before you there will be --

19 JUDGE MEADE: Of course, but I'm talking about the structural question now about  
20 whether just simply leaving it to further requests after the Commission disclosure has  
21 been reviewed is just going to be met by -- you know -- the Rule 39 Defendants  
22 declining to engage because every single request is too narrow or too broad.

23 MR JOHNSTON: Well, I think it's unlikely to be any refusal if request is too narrow. If  
24 it's too --

25 JUDGE MEADE: Well, sorry --

26 MR JOHNSTON: Too broad is normally the complaint.

1 JUDGE MEADE: Yes, right. Impossible to make a sufficiently targeted one, and all  
2 the ones that they can make are too broad. The point we've been debating anyway.

3 MR JOHNSTON: And so that is the grift of disclosure disputes in cases of this kind.  
4 The question is whether or not the tool being advocated for by the Claimants' right  
5 gets us to a materially different point on a proportionate basis --

6 JUDGE MEADE: Right.

7 MR JOHNSTON: -- by reference to the really significant cost and time that's going to  
8 be involved in it.

9 JUDGE MEADE: Right.

10 MR JOHNSTON: And by reference to the fact that, unusually, in this case, they  
11 already have quite a large universe of documents and the way Mr Woolfe has been  
12 putting it to you this morning is: it's about delta, it's about gap, it's about lacuna. My  
13 submission is: in those circumstances, saying go away, do a lengthy, detailed,  
14 expensive process across all the issues in the case, very high level, then also providing  
15 us with, you know, all of the details that, you know, have to go into these reports, about  
16 how much is it likely to cost and so on and so forth.

17 We see that is not proportionate, for two reasons. Firstly, because it's going to be  
18 lengthy, expensive and time consuming, but also because we do say -- and I'm ending  
19 up developing many of the submissions I was going to make to you, albeit not in quite  
20 the order I would have done -- that there isn't likely to be an enormous amount here  
21 and I think we do need to be realistic about how much there will be 20 years later,  
22 beyond, what is in the Commission file. The Commission was asking itself  
23 adjacent -- not the same -- but it was asking itself the question: are you a potential  
24 competitor? That is not the same question as: when would you have entered the  
25 market?

26 JUDGE MEADE: It's clearly materially different, isn't it?

1 MR JOHNSTON: It's materially different, but nonetheless it is adjacent. So there are  
2 documents that have gone to the Commission at a point much closer to the time --

3 JUDGE MEADE: Right.

4 MR JOHNSTON: -- through a very exacting Commission process that will have gone  
5 to that. Will there be wider and further documents? We all hope so, sir, but when  
6 we're looking at the proportionality of this exercise, one of the things we do say is that  
7 we shouldn't be proceeding on the premise that there's this vast universe of additional  
8 material out there, because the Commission was asking itself: is there an infringement  
9 and were you an actual or potential competitor?

10 JUDGE MEADE: Yes.

11 MR JOHNSTON: And that is not wholly unconnected from the points that the  
12 Claimants are seeking to illuminate. So we do say that a good part of what is going to  
13 be the relevant disclosure in this case is in the Commission file.

14 JUDGE MEADE: Right.

15 MR JOHNSTON: We anticipate that's the case and it would be surprising if there was  
16 a vast body of material that goes wider than that and that we say goes against the  
17 proportionality in this disclosure.

18 JUDGE MEADE: So you've got your high level point of general importance about  
19 iQuest. It does --

20 MR JOHNSTON: Sorry, sir, I missed that.

21 JUDGE MEADE: About iQuest. Have I got the name right?

22 MR JOHNSTON: Yes, sorry.

23 JUDGE MEADE: Mr Saunders has made the general point that for some of the  
24 Rule 39 Defendants, they might be able to say, "Well, there's just no point going back  
25 behind year so and so, because we just won't have anything". And those high level  
26 indications, it seems to me, might be quite useful, at least to indicate that there's just

1 no point looking in some categories or some issues or some places.

2 MR JOHNSTON: That's likely to emerge in the course of the correspondence. I mean,  
3 actually, Mr Saunders pointed you to his skeleton argument and said, "Well, we didn't  
4 produce documents like this because we had an extensive dialogue between the  
5 parties and that fulfilled that function".

6 JUDGE MEADE: Yes.

7 MR JOHNSTON: Well, that's what the Rule 39 Defendants are proposing is that there  
8 would be a dialogue between the parties.

9 JUDGE MEADE: Right.

10 MR JOHNSTON: We are not, as I've said before, pulling up the drawbridge and saying  
11 "We're not looking and we're not prepared to look, that's the end of it". What we're  
12 saying is -- and the question for the Tribunal today is -- what's the most effective tool  
13 by which to move matters forward in circumstances where: (a) the Claimants haven't  
14 yet read all the documents given to them; (b) they have a really substantial body of  
15 documents; (c) all of the challenges that you've seen described in the skeletons? It's  
16 our very firm submission that an EDQ and a Disclosure Report is a wholly  
17 disproportionate way of moving disclosure forward.

18 But that is not said in a spirit of: "Because we're not prepared to do anything and we're  
19 not prepared to have a dialogue with you". It's said in a spirit of "We think this is just  
20 the wrong tool" given the particularities of this case. It's going to be very broad, very  
21 expensive, not hugely illuminating, but if at certain points in the future there is a request  
22 for a particular category of documents then it may well be that the Rule 39 Defendants  
23 then -- part of their response is -- "Well, actually, we've now identified the relevant  
24 database no longer exists". There's no part of the Rule 39 Defendants' position that  
25 they're going to sort of play dead, if I can put it that way, on disclosure. Quite the  
26 opposite. It's not a binary. It's not EDQs or, you know, playing dead on the path of

1 Rule 39 Defendants. What they're saying -- our submission is -- that this is just the  
2 wrong way of making progress in this particular case, given the peculiar circumstances  
3 of it.

4 Sir, I don't propose to address you on the next CMC and so on and so forth, I'm  
5 conscious that's something that might be dealt with separately. But if you want to hear  
6 submissions on that, I think some of us might need to take instructions because  
7 precisely how it's suggested by Mr Woolfe this morning was new at least to me.

8 JUDGE MEADE: Well, he just came up with a date, which was 5 October. No earlier  
9 than 5 October.

10 MR JOHNSTON: Yes. And you'll know that our position on that, coming into this  
11 CMC, was that the next CMC should follow from a judgment of the General Court.  
12 What Mr Woolfe is trying to do is to sort of triangulate those two possibilities together.  
13 I don't yet have instructions on what our position will be if they're not together; others  
14 may.

15 JUDGE MEADE: Right.

16 MR JOHNSTON: But that certainly has been our position hitherto, which has been:  
17 the sensible way of dealing with this is to have one CMC where it has a really clear  
18 purpose and we can decide, "Right, what do we do following the General Court  
19 judgment?" And that disclosure can form a part of that.

20 JUDGE MEADE: Okay. Can I ask you, in High Court litigation one important step  
21 would be a meeting about disclosure; is that worth considering?

22 MR JOHNSTON: A meeting between the parties?

23 JUDGE MEADE: Yes, yes.

24 MR JOHNSTON: I haven't taken instructions on that question. If I can turn my back  
25 for a moment.

26 JUDGE MEADE: Well, I think, but I think --

1 MR JOHNSTON: I'll hear from the other Rule 39 --

2 JUDGE MEADE: No, no. You can't quite say.

3 MR JOHNSTON: I'm delegated to go first before they all supplement or add their own  
4 points.

5 JUDGE MEADE: Okay. Well, let me hear specific points from other Rule 39  
6 Defendants then.

7 MR JOHNSTON: I'm very grateful, sir.

8 JUDGE MEADE: Okay. Thank you.

9 Yes, Ms Abram.

10

11 Submissions by MS ABRAM

12 MS ABRAM: Two short points from me. First, by way of hopefully reassurance on  
13 embarking on an issues based exercise in place of a full blown EDQ and DR, that is  
14 a very normal process in this Tribunal that all of those in this room will be very familiar  
15 with. For example, in the Trucks litigation it's the process that was followed. Of course  
16 there are disputes. Of course, that's why you have another disclosure CMC to deal  
17 with it.

18 But as a matter of practicality, to the extent specific documents can be identified then  
19 great. The extent that understandably the process needs to unroll by reference to  
20 issues, the Claimants clearly can identify the issues, or will be able to identify the  
21 issues. They will then say "We want you to produce known adverse documents, or  
22 documents that are readily available". Or "We think you should engage in a search in  
23 relation to those issues". We will come back and say "Yes", or we will say, "Well, we  
24 don't agree that we should do searches for this". Or "We accept that we'll do a search,  
25 but we're not going to search repository x or y, although it might in principle have  
26 relevant documents in because they're hardcopy documents that are 30 years old in

1 a storage facility". Or "We sold the business". Or whatever the point is. Then if there's  
2 a --

3 JUDGE MEADE: Could you say that again, please.

4 MS ABRAM: So the Claimants say "Do a search", and we might come back and say,  
5 "Well, we agree to do a search, but we don't think that we ought to search repository  
6 x or repository y". Then if there's a dispute about that, it will be for the Tribunal to  
7 determine.

8 JUDGE MEADE: Right. But you won't have described the repositories because you  
9 don't want to do an EDQ. So how does that work?

10 MS ABRAM: Well, depending on the context -- and that goes back to the point that  
11 you made about these kind of hard lines that some of the Rule 39 Defendants have  
12 where they say, "Well, we've sold the business and so we don't have access to this  
13 group of files anymore."

14 JUDGE MEADE: Okay.

15 MS ABRAM: It depends on the context. But it's not impossible that we might say there  
16 may be documents in a storage facility that we don't think we should have to go  
17 through in a fingertip search for this purpose. That then is something that can be  
18 considered by the Tribunal at a disclosure CMC and a ruling can be given on that. It's  
19 right that a kind of generic EDQ process is not going to illuminate the answers to those  
20 questions any more than an issue by issue type focused approach. So we say  
21 that that's the way of advancing this. It's what we've been proposing for a while.

22 JUDGE MEADE: Okay.

23 MS ABRAM: That's the first point. Second point is just to put down a marker. We are  
24 focusing today on disclosure from the Rule 39 Defendants. But of course it's important  
25 to be clear that there's no reason why there shouldn't be disclosure from other parties  
26 in relation to the issues raised by the Rule 39 Defendants' claims. I know there's no

1 suggestion that this process would be unidirectional, but of course there's no reason  
2 why it should be unidirectional either. It may well be that the Rule 39 Defendants have  
3 disclosure requests from Servier, who after all have sued us -- have brought us into  
4 litigation -- and potentially also from the Claimants. So it's important just to put that  
5 down --

6 JUDGE MEADE: As a marker, yes. Great. Thanks very much.

7 MS MACKENZIE: Nothing from me.

8 JUDGE MEADE: Okay.

9 MS LOVE: If I may, where you've come out of dialogue with Mr Woolfe, and  
10 Mr Johnston said it's effectively what we've been saying all along: we are very happy  
11 to engage in a constructive dialogue in due course.

12 JUDGE MEADE: Right.

13 MS LOVE: So indeed you'll have seen that there have already been documents that  
14 we've produced in response to requests from the parties, and in fact one that wasn't  
15 raised with us but we actually disclosed of our own accord because we read  
16 a complaint in Tickner 19 about the redacted version of a Lupin document and we said  
17 "Fine, have the unredacted version".

18 The question is whether a long and expensive, and quite frankly, given the state of the  
19 pleading in our case, in all likelihood uninformative EDQ, is the more expeditious way  
20 forward. For all the reasons that Mr Johnston's canvassed with you, then we say no.

21 JUDGE MEADE: Okay.

22 Mr Turner.

23

24 Submissions by MR TURNER

25 MR TURNER: I'm instructed that we have disclosed over 8,500 pages of documents  
26 on the Commission file, which neither the Claimants nor Servier have asked as yet for

1 copies of. We very much share the view of the other Rule 39 Defendants that they  
2 should first look at what all these documents say and anything they refer to and so on,  
3 and then come back with requests for tailored disclosure. That will move the case  
4 along.

5 We certainly accept and indeed rely on the point that the Commission's findings -- and  
6 it's research that led to those findings -- that the agreements affect potential  
7 competition is not conclusive of the issue of whether they cause damage and, if so,  
8 who was responsible for that damage? So there are other issues to be addressed.  
9 But they need to be addressed in an efficient and focused way. Once the Claimants  
10 and indeed Servier have had a proper look at the documents that are already  
11 available, then they can suggest other matters -- other issues -- that need to be  
12 focused on and request disclosure in relation to those. So that's very much our  
13 position, as indeed, sir, you suggested in the course of Mr Woolfe's submissions.

14 Can I also just address a point that Mr Woolfe made. He characterised all of the  
15 agreements in question as pay for delay agreements. In the case of the Krka  
16 agreements, they have not been characterised and are not pay for delay agreements.  
17 They were characterised by the EU Commission and the full EU court as market  
18 sharing agreements. Krka agreed not to continue trying to enter the UK in certain  
19 other markets whilst the patent 947 remained in force, but obtained a licence from  
20 Servier to market its perindopril product in its eastern European markets. That was  
21 a kind of market sharing agreement that was ruled, but it wasn't a pay for delay  
22 arrangement.

23 JUDGE MEADE: Mr Saunders, yes.

24

25 Reply submissions by MR SAUNDERS

26 MR SAUNDERS: My Lord, my client is delighted to hear that the drawbridge on castle

1 generics has not been pulled up on these points. But there is a danger of having too  
2 much of a debate about form over function. We are going to get to the next CMC, and  
3 there is going to be a debate about disclosure. The debate about disclosure may take  
4 the form of a debate about whether there are gaps between the Commission file and  
5 things, as you've already heard from Mr Woolfe, to the extent that documents are  
6 probably missing and you've heard some submissions on that already.

7 But one of the other things that we know is that the Claimants don't have some of the  
8 regulatory files with the MHRA when the drugs were approved. A big issue for us is  
9 going to be do the Rule 39 Defendants still have that stuff.

10 Now, one way to deal with this is to say, well, in advance of the next CMC, when  
11 everybody is preparing evidence, they should address whether they should give an  
12 outline of their document retention policies. Have they sold their -- we've heard about  
13 companies being sold off. We've heard about databases in India. It is not  
14 a disproportionate ask to ask for some of that material to be set out so that that CMC  
15 can take place on a slightly more informed basis, rather than us having then a further  
16 debate about it after the event. That may be a proportionate way to deal with some of  
17 these points.

18 As I say, we support the application -- the ground is shifting as we're obviously in  
19 court -- but we do say that when we come to that next CMC it is important that we've  
20 got the shape of what we might be asking for, and if there are barriers because actually  
21 we need to go and ask a third party. It's important we know that because we might  
22 have to go off and make some enquiries as to how we get hold of that or ask that  
23 relevant Rule 39 Defendant whether they have some agreement with the third party to  
24 get these documents.

25 JUDGE MEADE: Okay.

26 MR SAUNDERS: So it's that sort of stuff. We need to flush that out.

1 JUDGE MEADE: Okay.

2 Yes, Mr Woolfe.

3

4 Reply submissions by MR WOOLFE

5 MR WOOLFE: Just a few points. First of all, Mr Johnston implied that it was odd that  
6 we haven't sued the Rule 39 Defendants and we were willing to do without all this  
7 material. Obviously, where we have joint tortfeasors, we can sue who we like. We  
8 chose to sue Servier and we didn't have to sue anybody else. Once the Rule 39s  
9 come in to the proceedings, they're going to be turning up with witnesses saying, "It  
10 was very difficult. We couldn't get into the market", et cetera. At that point, we need  
11 disclosure from them to test that evidence. Since they're parties to the proceedings  
12 as well, it makes sense to request.

13 JUDGE MEADE: Yes, (overspeaking) but they're not the first party to a claim by you.  
14 It is a difference.

15 MR WOOLFE: There is a difference. But you can't infer from the fact that we didn't  
16 pursue them for third-party disclosure, which is a difficult process --

17 JUDGE MEADE: Yes.

18 MR WOOLFE: -- in a situation where they weren't going to be producing witnesses to  
19 trial before they rejoined. You can't infer from that that somehow this documentation  
20 is not important to the claim matters (overspeaking).

21 JUDGE MEADE: I certainly wasn't inferring that you don't want disclosure.

22 MR WOOLFE: That was the point that was made, so I just wanted to put that one to  
23 bed.

24 Now, to be clear: on his feet, Mr Johnston implied that we can come forward, having  
25 reviewed the Commission file documents, with the request for this particular document  
26 or that particular category of document.

1 JUDGE MEADE: Well, I've already said (overspeaking) that there's an obvious trap  
2 that you could be lured into there. I'm alert to that and I see the danger that your client  
3 sees about that.

4 MR WOOLFE: It's in that context, then, perhaps I can see the indication you've  
5 already given. We think an issues-based approach, we define issues as more  
6 workable than trying to come forward with requests for specific categories of  
7 documents in the absence of more information. So we are willing to collaborate with  
8 the other parties about --

9 JUDGE MEADE: Well, there might be a bit of both, you see. It might easily be a bit  
10 of both.

11 MR WOOLFE: Yes. You mentioned a meeting about disclosure. For our part, that  
12 kind of meeting is what happens in the High Court proceedings, a Disclosure Review  
13 Document, et cetera. If that's the sort of procedure we're going down, with  
14 collaboration on something like a Disclosure Review Document, then we're perfectly  
15 content to have the relevant meetings.

16 JUDGE MEADE: Yes. Well, I mean, Mr Woolfe, there's been quite a lot of mention of  
17 dialogue. A dialogue that only takes place in correspondence will be unbelievably  
18 slow --

19 MR WOOLFE: Yes, agreed.

20 JUDGE MEADE: -- and we could get to another CMC with the correspondence still in  
21 flux. So I'm strongly attracted to having something after the conclusion of the  
22 Commission document review and before the next CMC, so that the dialogue has  
23 progressed. The obvious route is, to me anyway a meeting along the lines of the sort  
24 of High Court disclosure meeting that there would be.

25 But you all need to take instructions about that before I go forward with it because  
26 some people might agree, some people might not. What I broadly now have in mind

1 is that you will all finish your review of the Commission documents, and I need a date  
2 from each of you for that. Then there will be a meeting, I suggest -- subject to  
3 indications from people who need to take instructions about it -- at which it seems to  
4 me reasonable that the Rule 39 Defendants should at least come along with an  
5 indication of high level, landscape in the sense of "We've sold our business to iQuest,  
6 we've shredded all the documents before such and such a date, in keeping with our  
7 ordinary procedures", that sort of high-level thing.

8 MR WOOLFE: And for our part, a statement of the issues. Documents (inaudible).

9 JUDGE MEADE: Yes. I mean, it will be down to you to work out what you bring to the  
10 meeting. But, yes. But I'm not going to just jump down saying it's all got to be issue  
11 based from now on when it might be some issue based and some document based.  
12 It's a very, very unusual and complicated landscape. So that is my broad sense and  
13 then we will think about the timing of the disclosure CMC and whether it should be at  
14 the same time as another CMC, post the General Court's decision, or not, once we've  
15 got a slightly better handle on actual dates. So we'll have a break. You can all take  
16 instructions to consider the option of getting a date for when you're going to finish your  
17 review, getting a proposed date for a meeting if people don't object to a meeting, or if  
18 they do object they can explain to me why. Then that will give us a framework for  
19 dates of a future CMC or CMCs. So we'll take a break for people to take instructions  
20 about that. We better take at least 20 minutes, I think.

21 MR WOOLFE: By my watch, it's 11.45 now. Shall we come back at 12.05?

22 JUDGE MEADE: 12.05, yes.

23 (11.44 am)

24 (A short break)

25 (12.12 pm)

26 JUDGE MEADE: Yes.

1 MR WOOLFE: Thank you, sir. Well, there's been much discussion over the break.  
2 Perhaps it would help if I set out our proposal for how things can proceed. What we  
3 would propose is that, just in terms of timings, the initial thing that has to happen is  
4 there has to be a stop date when all the Rule 39 Defendants have given disclosure of  
5 their material from the Commission file. Some of that is still outstanding. We  
6 understand from Niche that they should be in a position to provide their last list within  
7 2 weeks of today. Assuming that's correct and material stops coming in shortly  
8 thereafter, we would think it would be possible to have reviewed that Commission file  
9 documentation by around the end of July or the beginning of August. But what we  
10 would then propose is that we produce a list of the issues for disclosure informed by  
11 that review and say for which of those issues we are content to rely upon the  
12 Commission file disclosure, and identify those for which we think incremental  
13 disclosure is required, in the format of section 1(A) of the Disclosure Review  
14 Document that's used in the Business and Property Courts. We propose to do that by  
15 the start of September.

16 JUDGE MEADE: Right.

17 MR WOOLFE: There's a bit of a gap between completing the review and then doing  
18 what's a slightly different exercise of assessing the product of that review by reference  
19 to the list of issues, to decide what we think is sufficient.

20 Then we would propose that the parties aim to have a meeting -- and there's a fair bit  
21 of time -- in the first week of November. I say the first week of November is advisory,  
22 because what we say should happen in between our producing that list of issues and  
23 a statement of what we're content to put on the Commission file, is that the Rule 39  
24 Defendants should, by the end of October -- so roughly 2 months from when we  
25 provide them with that list of issues -- tell us what their proposals are, for what  
26 searches they think it would be reasonable for them to carry out by reference to that

1 list of issues.

2 We also think it would be helpful -- that's in a sense of what you normally get in  
3 section 1(B) of a Disclosure Review Document. We can also say specific searches  
4 that we definitely think would be necessary, but we think we also want something from  
5 them as to what is required to cover the issues.

6 JUDGE MEADE: But, sorry, this isn't prejudging that search-based disclosure is  
7 necessarily the right thing. This is just your requests about searches.

8 MR WOOLFE: This is our request about the searches. There should be a statement  
9 of issues.

10 JUDGE MEADE: Right.

11 MR WOOLFE: And then we can also identify, possibly, some specific searches that  
12 would be helpful on the basis that these are not exhaustive. I think that's very clear.

13 Then the parties can have a meeting in the first week of November at which these two  
14 sets of proposals are discussed. Shortly after that, anything that's not agreed can be  
15 in the form of an application to be made mid-November for CMC to take place in  
16 December. That is our proposal. And I have relayed this to counsel but only shortly  
17 before coming back into court in the last couple of minutes. So I'm not saying anybody  
18 else has signed up to that. I think they may be happier with, perhaps, the first bit of it  
19 than the remainder.

20 JUDGE MEADE: Okay. All right.

21

22 Reply submissions by MS ABRAM

23 MS ABRAM: I'll go next. So we agree with the broad outline of the structure in terms  
24 of the Claimants, of course, reviewing the Commission file, identifying the issues as to  
25 which they want to seek disclosure, there being a meeting and then there being  
26 another CMC.

1 JUDGE MEADE: Right.

2 MS ABRAM: But we do have some quite significant concerns about the way in which  
3 that process should unfold. There are two in particular.

4 The first is that it's really important that this process shouldn't lapse back into either  
5 a full EDQ and a DR on every issue, just because the Claimants say they want  
6 disclosure on a particular issue or, second, into an assumption that there's going to be  
7 search-based disclosure on every one of the issues.

8 JUDGE MEADE: Right. Well, that's what I just said just now. That's without  
9 prejudging that it'll be search-based disclosure.

10 MS ABRAM: That's it. So the Claimants might say, for example, "We'd like disclosure  
11 in relation to issue X because we don't think the Commission file is complete on that  
12 point, and we think that should be search based and we think that you should look in  
13 all of your available repositories". We might come back and say, "No, we just don't  
14 agree with that. We will disclose known adverse documents or we'll disclose the  
15 readily available documents" and there's no point having a conversation about what  
16 the repositories might be because it's just disproportionate to look at search-based  
17 disclosure. Because, otherwise, what could happen is the Claimants can ask for  
18 search-based disclosure on every single point and we have to give all of the same  
19 information that we would have had to give under an EDQ in any event. And so that --

20 JUDGE MEADE: That's a fair concern but I don't think Mr Woolfe's proposal involved  
21 any of that, because it just requires the Rule 39 Defendants to come forward with their  
22 proposals for searches. In an extreme case, that might be "We're not going to do any  
23 searches because none of this is --" I hope not. But his suggestion doesn't cut across  
24 your client saying "We'll do these two searches, but none of the others".

25 MS ABRAM: I'm grateful, and that is consistent with what we'd be content to do.

26 What set my spidey senses flashing on that point was references to the Disclosure

1 Review Document in the High Court form -- which is obviously used for lots of  
2 High Court disclosure -- which does presuppose that you're going to have this kind of  
3 mapping of the scope of disclosure, scope of potential searches for every issue. So  
4 if --

5 JUDGE MEADE: It doesn't potentially -- there's a column for what model you say it's  
6 going to be.

7 MS ABRAM: Yes.

8 JUDGE MEADE: That's why Mr Woolfe was clear, he was talking about the first  
9 column, which is the issue.

10 MS ABRAM: Yes and then there won't necessarily be full mapping of what every  
11 search could be -- that could be carried out, if one was to --

12 JUDGE MEADE: No, of course not, because participating in the process of preparing  
13 the form doesn't commit you to search-based disclosure at all.

14 MS ABRAM: Or indeed to providing information about what those repositories would  
15 be if you were going to do C, D, and E and disclosure.

16 JUDGE MEADE: No.

17 MS ABRAM: I'm grateful.

18 And the second point, that it's important to feed into the timetable is that -- I don't know  
19 if you clocked this, sir -- but part of the process that's going on, on disclosure, is that  
20 Servier has agreed to provide disclosure to the Rule 39 Defendants of 11,600  
21 documents. We haven't got those documents. The parties are in the process of  
22 setting up an inner confidentiality ring that will enable those documents to be  
23 disclosed. Servier haven't been able -- understandably, this point has only just  
24 arisen -- to tell me how many pages of documents that will involve. What we want to  
25 flag to the Tribunal is that we don't know now when we're going to get those documents  
26 first, or how long it's going to take us to review those documents.

1 JUDGE MEADE: Right.

2 MS ABRAM: And so there is a risk that, with the best will in the world, it's not possible  
3 to review -- for us to review those documents and formulate our disclosure requests in  
4 the light of them at the same time as the Claimants will have been able to review the  
5 Commission files.

6 JUDGE MEADE: No, sure. But it doesn't have to be at the same time and nor does  
7 this -- the Rule 39 Defendant discussion that we're talking about doesn't have to await  
8 your dialogue with Servier, I don't think, does it?

9 MS ABRAM: No, not necessarily. We are just mindful, though, of the huge collective  
10 cost of a hearing like this and the risk that -- or as the risk increases, that we'll need  
11 two CMCs rather than one.

12 JUDGE MEADE: Right.

13 MS ABRAM: The prospect that one needs to perhaps double those costs and I can't  
14 make the submission any more concrete than that at the minute, because I just don't  
15 know how much we're going to have to review, when we're going to get the documents  
16 or how long it's going to take us. But I just flag that there is a kind of inbuilt risk in the  
17 timetable --

18 JUDGE MEADE: Right.

19 MS ABRAM: -- and that's a concern for us.

20 And another point that it might also be worth just underlining just to loop back to where  
21 we were on the General Court earlier, is that we don't press for the disclosure CMC to  
22 be a certain amount of time after the General Court judgment. At present, that's not  
23 a submission I'm instructed to make now, but there is a potential side benefit to having  
24 the CMC when the General Court judgment is likely to be available, because that  
25 makes it more likely that one is going to be able to be more efficient in the next hearing  
26 and do more things.

1 JUDGE MEADE: Yes. Well, the timetable that Mr Woolfe's outlined now sounds, first  
2 of all, much more realistic, and secondly, much more likely to result in a CMC after the  
3 General Court's given its decision, because it's talking about December.

4 MS ABRAM: We respectfully agree, sir.

5 JUDGE MEADE: Yes.

6 MS ABRAM: And so I think that's everything that I wanted to say, save just to  
7 emphasise -- if it's not totally clear -- that we would be opposed to any order that  
8 required the Rule 39 Defendants to complete a full section 2 of the DRD and  
9 I understand that that's not what the tribunal --

10 JUDGE MEADE: That's not what's being proposed.

11 MS ABRAM: I'm grateful.

12 JUDGE MEADE: Okay. Do you have any comments to make about whether it's  
13 appropriate or possible for your clients to come to a meeting with a general idea of  
14 high level repository -- to use a not brilliant term -- information?

15 MS ABRAM: I should have covered that.

16 JUDGE MEADE: Yes.

17 MS ABRAM: Yes. So, although we do oppose the full section 2, we do not oppose  
18 that indication that you gave and it seems to me that the timetable that Mr Woolfe  
19 suggested would enable that to be accommodated. So the issues would be identified  
20 to the Rule 39 Defendants by the beginning of September and perhaps at the same  
21 time as we respond as to whether we agree to give disclosure on any of the issues,  
22 we would also give that high level indication of whether there are red lines in our  
23 disclosure.

24 JUDGE MEADE: But in good time for a meeting at the beginning of November.

25 MS ABRAM: Yes. I think Mr Woolfe proposed -- I'm not sure whether he said this in  
26 court, but he proposed to me that we would respond to the issues by the end of

1 October and then there'd be a meeting in November.

2 JUDGE MEADE: Yes. Well, also the -- yes, he phrased it to me just now as proposals  
3 for searches at the end of October. But I was going to ask you -- you need to respond  
4 to the list of issues as well, obviously, because that needs to be not just unilaterally  
5 decided by Claimants.

6 MS ABRAM: Yes. We were (inaudible) on whether they're appropriate issues for  
7 disclosure, for us to give more disclosure, on the nature of the disclosure that should  
8 be given and on the, I would say the red lines, where we say the disclosure shouldn't  
9 trespass beyond, for particular Rule 39 Defendants, because of points like having  
10 divested a business or --

11 JUDGE MEADE: All right. Okay.

12 MS ABRAM: I'm grateful.

13 JUDGE MEADE: Yes.

14 MR JOHNSTON: So nothing to add for my part. That's our position.

15 UNIDENTIFIED SPEAKER 1: Same, sir.

16 MS LOVE: Sir, I'm instructed that we are content with the proposal in relation to  
17 a meeting. I do just want to lay down a marker now about the issues for disclosure  
18 and the truncated version of section 1A, which is that obviously issues for  
19 disclosure -- and I'm looking at the DRD right now -- by reference to the statement of  
20 case and as we discussed yesterday, sir, the assertion is just that my client would  
21 probably have entered the UK market soon after April 2007. I don't want to prejudge,  
22 and it may be that there's nothing that Mr Woolfe's clients need to go beyond the  
23 Commission file for, but I am a bit concerned about the idea that we'll be confronted  
24 with some list of descriptions of issues that don't actually have a proper basis in the  
25 frankly minimal pleading, and we're then left grappling with it.

26 JUDGE MEADE: You're fully entitled to make those points when you respond to the

1 list of issues.

2 MS LOVE: Thank you, sir. As long as that's understood.

3 JUDGE MEADE: Yes.

4 MS LOVE: Thank you.

5 JUDGE MEADE: Nothing to add? Okay.

6 MR SAUNDERS: For my part, Servier's content with the Claimants' proposals.

7 JUDGE MEADE: Okay. All right.

8 MR WOOLFE: I've got one thing. In terms of the section 2, I can see that what you  
9 want to avoid is people filling out, having a hard obligation to give comprehensive  
10 information as to the section 2 of the review document, which looks like an EDQ; I can  
11 see that. However, as I understand it, it's not just the document under the practice  
12 direction in 57AD, the idea it's an evolving document and you begin with section 1A  
13 and you work from there and then to the extent that anybody is proposing  
14 search-based disclosure, then you go into section 2 and so forth.

15 JUDGE MEADE: Right.

16 MR WOOLFE: We think it would be helpful if such disclosure is being proposed, which  
17 will be clear by September.

18 JUDGE MEADE: Right.

19 MR WOOLFE: If people could -- in terms of coming with a high level understanding  
20 of what repository-based material there is, one option is people can come to that  
21 meeting having filled out -- so far as they can, as they reasonably can -- section 2, to  
22 give us what information they have readily available as to the repositories of  
23 documents. That would be a helpful and collaborative way to proceed.

24 JUDGE MEADE: Yes.

25 MR WOOLFE: And then if we're pushing forward for something more specific then  
26 the court could order at that stage a fuller response to specific questions, if that was

1 necessary.

2 JUDGE MEADE: Well, the way I conceive of it is that they will put forward their  
3 proposals for searches where they propose searches. So where they propose  
4 searches, they'll make clear what that is, where they're not proposing a search at all,  
5 they won't.

6 MR WOOLFE: Yes. (Pause)

7 If their information as to why searches are difficult is as specific as possible, that would  
8 be helpful.

9 JUDGE MEADE: Well, I think I've given -- I'm not going to make a formal order about  
10 this. I think I've given an indication that where they have sold the company, shredded  
11 the documents, whatever, suffered a flood at their data centre, they will tell you that.  
12 But that's the level of detail that I'm indicating and not more than that. If they come  
13 along with a positive suggestion for a search, then they've got to explain what the  
14 search is, but they haven't got to give their reasons in a tabular form about why they're  
15 not proposing searches, where they're not.

16 MR WOOLFE: Thank you, sir.

17 JUDGE MEADE: Okay, all right. So there's some drafting to do there for the order,  
18 but I think we've covered that now, okay. (Pause)

19 And that will enable an actual date to be put in for the meeting at least, because I can  
20 tell that we need an actual date, because a lot of people are going to have to make  
21 themselves available, and I should have said before, I'm not mandating that every  
22 single person has to be in the room for eight solid hours; I imagine there will be some  
23 side meetings and that's up to the good sense of the parties.

24 MR WOOLFE: Well, after this, we'll produce a draft with these dates in, but we are  
25 going to be proposing a meeting taking place in the week of, and then we can -- if  
26 there's disagreement, we sort it out immediately after this and then we can --

1 JUDGE MEADE: Right.

2 MR WOOLFE: So that's exactly right, sir.

3 JUDGE MEADE: It's obviously going to be a very, very important meeting and people  
4 will have to make themselves available.

5 MR WOOLFE: Yes. This going to set the framework for any applications that are  
6 made.

7 JUDGE MEADE: Yes, it is, yes.

8 MR WOOLFE: Understood. Thank you, sir. I think we've made some very helpful  
9 progress.

10 I think that takes us to the end of everything that concerns the Rule 39 Defendants  
11 directly, because we've dealt with the EDQ and Disclosure Reports matter and the  
12 timing of the next CMC. The remaining matters are PPRS disclosure, as between  
13 Servier and the claimants.

14 JUDGE MEADE: Yes.

15 MR WOOLFE: The RFI issue.

16 JUDGE MEADE: Yes.

17 MR WOOLFE: And our application in relation to the short form claim form.

18 JUDGE MEADE: Well, the short form claim form -- nobody's opposing that, right?

19 MR WOOLFE: Nobody's opposing, so if you're content to make the order, that's --

20 JUDGE MEADE: Yes.

21 MR WOOLFE: So in which case I don't know whether -- I don't know whether  
22 provision to deal with the RFI issue now and/or if the Rule 39 Defendants wants to  
23 leave.

24 MR SAUNDERS: My Lord, I'm not sure whether -- I assume the Rule 39 Defendants  
25 are all happy, but if not, now's the opportunity to say otherwise.

26 As far as the RFI is concerned, it would help if we had the short adjournment just to

1 deal with that, or at least a short ten minutes just to speak about that. I'm afraid we  
2 just haven't had an opportunity to see whether we can narrow this, so that we don't  
3 have to trouble --

4 JUDGE MEADE: Okay.

5 MR WOOLFE: Well, in which case we could fit in the PPRS issue probably before  
6 lunch.

7 JUDGE MEADE: Yes, let's do that then.

8

9 PPRS issue

10 MR WOOLFE: Thank you, sir.

11 MR PICCININ: It is my application.

12 MR WOOLFE: Well, we both have proposals in relation to it. If you want to go first, by  
13 all means.

14 Submissions by MR PICCININ

15 MR PICCININ: This application started life as a very modest request for a specific set  
16 of documents that we believe exist -- that may exist -- and it's morphed in the  
17 Claimants' response into something that we say has become quite disproportionate.  
18 But I just want to start, if I may, by showing you what the defence is. And so if we take  
19 that from our defence, which is in B1, tab 5, page 35.

20 JUDGE MEADE: Yes.

21 MR PICCININ: You can see at the heading L:  
22 "Set off for under delivery on the 2005 PPRS." [as read]  
23 I just note that although this does not appear as an amendment in the document, that's  
24 because we produced a consolidated defence.

25 JUDGE MEADE: Okay.

26 MR PICCININ: But it was introduced into the case by way of an amendment

1 (inaudible). The only reason I mention that is that, of course, this issue has not  
2 therefore been the subject of any disclosure orders. This is not covered by any of the  
3 disclosure orders that were made years ago when the claim was first pleaded.  
4 Although it is the case that lots of documents relating to the PPRS have been thrown  
5 up through the course of disclosure exercises that have been carried out in the case  
6 more generally. So it's not like we're starting from a blank page, from a disclosure  
7 perspective.

8 Now, I'm sure you know what the PPRS is and roughly how it works, so I'll take that  
9 quickly. But you can see we set that out in paragraph 117 and that we participated in  
10 the 2005 PPRS. In a nutshell, under that scheme we were required to set our prices  
11 for branded medicines across our portfolio in a way that would deliver savings against  
12 list price of 7 per cent in aggregate, in the period that ended up running through to  
13 31 August 2008. Our perindopril product, which is called Coversyl, was part of that  
14 scheme.

15 I'm sure you also know that the way it worked was that the companies had discretion  
16 as to how they achieved that aggregate saving and they could modulate their prices  
17 up and down across their products, as we say in paragraph 118.

18 Then as it happens, and this much is common ground, Servier underdelivered on that  
19 reduction target in that period. As you can see in paragraph 120 of the page, the  
20 Department of Health calculated the under-delivery at some 900,000 and asked us to  
21 pay them that.

22 JUDGE MEADE: Yes.

23 MR PICCININ: Paragraph 121 -- we disagreed, and you can see why we disagreed.  
24 But ultimately that led to a settlement where we agreed on a carry forward, essentially,  
25 into the next year of 500,000. That period that we're talking about here, 2005 to 2008,  
26 of course overlaps with the period in which the Claimants say, in the counterfactual,

1 "Generic entry would have occurred earlier than it actually did in the real world".

2 If that had happened, the Claimants' case is that we would have sold less Coversyl  
3 and there would have been more generic perindopril being sold. So if they're right  
4 about that, we say it follows that our under-delivery on the PPRS scheme would have  
5 been smaller. Indeed, if they're anywhere near right about what they say would have  
6 happened in the counterfactual, then we wouldn't have had to pay any of that money  
7 back to them at all. So we say that the damages should be reduced to that extent and  
8 that's --

9 JUDGE MEADE: Paragraph 123.

10 MR PICCININ: Exactly. That's paragraph 123(c). Then at paragraph 124 we say that  
11 even beyond that, generic perindopril, if the Claimants are right, would have resulted  
12 in us substantially overdelivering, so we would not have had to cut prices on other  
13 products to the extent that we actually did in the real world, and so that would need to  
14 be taken into account as well.

15 I also just want to show you the Reply so that you can see what is and is not in dispute.  
16 So that's B1, tab 2, page 17. It's paragraphs 33 to 35 over the page. If I can  
17 summarise, essentially they admit all of the details of what actually happened. But  
18 then beyond that, they plead a bare non-admission as to what we say would have  
19 happened in the counterfactual particular at paragraph 36. We say that's not really an  
20 adequate pleading, but I don't have an RFI before you, but one consequence of it is  
21 that they don't have a positive case on this issue, at least at the moment, proposing to  
22 advance at trial.

23 JUDGE MEADE: Yes.

24 MR PICCININ: So then coming on to disclosure, I just need to show you a small  
25 number of letters. If we could start at bundle H, tab 159, which is our letter of the  
26 5 December last year. (Pause)

1 JUDGE MEADE: I was just saying I hadn't really been using the bundles for  
2 correspondence like this.

3 MR PICCININ: Okay, right. We don't need to go through all of it, but it's just to bring  
4 you up to date essentially. In the second paragraph of this letter you can see that my  
5 solicitors refer back to an earlier incident in the proceedings back in 2023 when the  
6 Department of Health wrote to Servier directly -- so, not between solicitors --

7 JUDGE MEADE: Yes.

8 MR PICCININ: -- to say that they had received a request to release some of our  
9 historical information to Peters & Peters, the Claimants' solicitors, and  
10 Frontier Economics, the experts in these proceedings, and that this information came  
11 from the PPRS context. So to continue the story, back in 2023 we asked them to  
12 provide that to us as well so that we would be on an equal footing in the litigation. If  
13 you just follow this letter over the page, you can see that what's recorded there is that  
14 they refused essentially on the basis that it was not relevant to any pleaded issue in  
15 the case at that time.

16 Now, that's a bit odd because it wasn't relevant to anything in the litigation at all. One  
17 wonders why it was being provided to Peters & Peters and Frontier Economics.  
18 Presumably it was relevant to something. But in any event, once we'd introduced our  
19 PPRS defence into the case it seemed to us that it was even more obviously relevant,  
20 at least to that issue, and so we asked them to provide it. Then their response came  
21 in the letter at H 169.

22 JUDGE MEADE: Yes.

23 MR PICCININ: This is the letter of the 12 December. You can see in paragraph 2 that  
24 they provided us with copies of our modulation submissions over particular years.

25 JUDGE MEADE: Yes.

26 MR PICCININ: But they did not say whether that was all that they had been given by

1 the Department of Health.

2 JUDGE MEADE: Yes.

3 MR WOOLFE: So we wrote back to them on 15 January of this year. I don't think we  
4 need to turn it up, but just for reference, that's H 181. We effectively asked them that:  
5 whether it was or wasn't the whole lot.

6 Then their response came on 25 February this year, which is at H 212, that effectively  
7 they ignored that request. Instead, in paragraphs 5 to 6, they told us that they had  
8 embarked on their own little disclosure exercise of their own volition, which we didn't  
9 ask them to do, in which they've identified they say 17,000 documents covering  
10 a period going all the way back to 1999 and all the way on to 2016. Then in  
11 paragraph 8 of that letter they turned around and asked us what disclosure exercise  
12 we were carrying out in relation to this issue.

13 The next thing -- I think this is the last thing I need to show you -- is in particular 19 at  
14 paragraph 37 which is at I 15, 13. Towards the bottom of that paragraph is really the  
15 only response I think we've ever had to our request about whether they received  
16 anything else in 2023 other than just that modulation spreadsheet. Mr Tickner says  
17 that answering that question might encroach on privilege because the documents  
18 provided may tend to betray the advice sought. We say that that's a very puzzling  
19 response.

20 The ask we're making here is a very simple one in that there seems to have been  
21 a cache of documents; we don't actually know. It may just be that spreadsheet. But  
22 if there was anything else, then there was an identified cache of documents in 2023  
23 that were already in the possession of the Department of Health which were packaged  
24 up and provided to Peters & Peters and Frontier for the purposes of this litigation.  
25 Those are the documents that we want and there was absolutely no reason why they  
26 should refuse to provide them to us, because indeed anything they're providing to their

1 experts should be shared with us anyway.

2 Yet, as to the suggestion that privilege might attach, we say that's wrong because  
3 these are contemporaneous documents that were already in their possession and  
4 control. It could seem to us that what Mr Tickner had in mind was the principle in *Lyell*  
5 v *Kennedy* -- I don't know if that's one you've come across.

6 JUDGE MEADE: I don't know about the particular case, but I think I understand  
7 conceptually what they're saying the privilege would be and why giving the documents  
8 could betray their thinking.

9 MR PICCININ: Yes. So, the principle in *Lyell v Kennedy* is that if a party goes out  
10 and gathers a folio of documents from elsewhere -- from somebody else that were not  
11 in their possession in control -- then just taking copies of those documents, or  
12 translations or whatever it is, that those documents may be privileged if that selection  
13 that you've taken from somewhere else betrayed the trend of legal advice. But that  
14 only applies to documents that are being gathered from elsewhere that are not  
15 otherwise in your possession. So that's the *Sumitomo* case which we've got in  
16 paragraph 39 of that skeleton. I can take --

17 JUDGE MEADE: No, I get the point. Yes.

18 MR PICCININ: So on that basis we say that there can't be any privilege issue here  
19 and so it should simply be provided.

20 Now, moving beyond that to what else needs to be done, the wider exercise that the  
21 Claimants have already started and then are proposing for ourselves, which seems to  
22 be essentially standard disclosure, we say it's disproportionate to the scale of this  
23 issue and is inefficient. Really there are two points: one is that their own pleading  
24 consists only of admissions and non-admissions, and accordingly they're not actually  
25 advancing any positive case on this defence at all. I mean, it's also fair to say that this  
26 is a defence that by its nature is focused on documents that passed between us.

1 JUDGE MEADE: Right.

2 MR PICCININ: The other point is that the value associated with this defence is not  
3 very high in the scheme of things. So in those circumstances we don't understand  
4 why they've gone out and done this big 17,000 document review. Of course, we can't  
5 stop them from doing that if that's what they want to do. But of course we wouldn't  
6 accept that that was necessary or proportionate. There may be issues about  
7 recoverability of costs, if that ever goes forward, but if they want to look at those  
8 documents and then disclose some of them to us, of course they can do that. I should  
9 say --

10 JUDGE MEADE: I'm looking at your proposal according to the composite order, and  
11 that is, first, that they give disclosure of the documents previously disclosed to the  
12 solicitors and the economists. Secondly, they give any further disclosure by the end  
13 of July.

14 MR PICCININ: That was their proposal. What we're saying is, "If that's what you want  
15 to do, then go for it". I should say, we really don't want a dump of documents from  
16 them. There may be cost consequences if they do just dump a large load of  
17 documents on us. But if that's something they want to do, to go and do a further  
18 disclosure exercise, then they've built that into our final (inaudible).

19 JUDGE MEADE: Is the gist of what you're saying, then, that you think that the  
20 documents previously disclosed -- leave the economist to one side for a moment -- are  
21 likely to be what you really want, and that the further disclosure is (inaudible). Yes.

22 MR PICCININ: That's all we've asked for.

23 JUDGE MEADE: Right.

24 MR PICCININ: Now, beyond that they ask, "Well, what are we going to do?" To which  
25 we say effectively the most proportionate way to deal with this part of the case, at this  
26 point in time, is what in High Court proceedings is effectively called Model B. So we

1 give them the documents that we propose to rely on, and we've agreed to do that, and  
2 then adverse documents.

3 JUDGE MEADE: (Inaudible) documents.

4 MR PICCININ: Sorry?

5 JUDGE MEADE: And known adverse documents.

6 MR PICCININ: And known adverse documents. Then, if at that point there's  
7 something else that they want, then they can ask, and vice versa.

8 JUDGE MEADE: Right, yes. Okay. You don't particularly need to know whether the  
9 documents were or weren't given to the economists; do you?

10 MR PICCININ: No, I mean, they told us that --

11 JUDGE MEADE: You just want the bolus of documents.

12 MR PICCININ: Yes, I mean, they did tell us that --

13 JUDGE MEADE: I may have misunderstood, but there won't be documents that did  
14 go to the economists but not to the solicitors.

15 MR PICCININ: I see. No, I don't understand that.

16 JUDGE MEADE: Well, that's why the whole privilege thing gets sucked in; isn't it?  
17 Because if it was a subset of documents that went to the economists, that's where this  
18 privilege argument arises, I think, isn't it?

19 MR PICCININ: Well, it's not clear to me how the privilege argument arises at all.

20 JUDGE MEADE: Well, if it does, that seems that's where it is.

21 MR PICCININ: That's right. But there was a full set that was produced by the  
22 Department of Health. It may have only been one, we don't know. But whatever it  
23 was, it was provided, as we understood it, to Peters & Peters and Frontier.

24 JUDGE MEADE: Yes.

25 MR PICCININ: But they don't need to distinguish between them.

26 JUDGE MEADE: No.

1 MR PICCININ: That's the set of documents we're asking for. So it's fairly  
2 straightforward. And anything further that the parties need that is proportionate then,  
3 as you've said before, there's plenty of time for the parties to make targeted requests.  
4 But we certainly don't think an order for standard disclosure for the parties to go away  
5 and do custodial searches, which seems to be what they're now proposing, is  
6 a proportionate way of dealing with this issue.

7 JUDGE MEADE: All right. Thank you.

8 Submissions by MR WOOLFE

9 MR WOOLFE: I'll just begin by explaining how this issue did arise. As Mr Piccinin did  
10 say, this was added to Servier's defence as an amendment. So it wasn't previously  
11 pleaded and he's correct, the disclosure wasn't previously given on this issue.

12 Now, he did say something that was not correct, which is this is not covered by  
13 disclosure orders that are made. That's not right. In as much as Mr Justice Henderson  
14 ordered the Defendants to give standard disclosure on issues of causation and  
15 quantum. His order was made in 2016, it's bundle C1, tab 27, if you want to take  
16 a look at it.

17 JUDGE MEADE: So this would be before the amendment?

18 MR WOOLFE: This would be before the amendment, but it's an ongoing obligation of  
19 disclosure on that issue.

20 JUDGE MEADE: Right.

21 MR WOOLFE: So, in a sense, what Servier are doing now by saying they only wanted  
22 to give documents on which they rely on is to try to, in a sense, cut down their existing  
23 obligations. But more to the point, the reason why we are not comfortable with what  
24 they are proposing is -- can you look at the wording of their draft order? So that's  
25 at bundle A, tab 6. I should say this is the part of the order that was updated overnight.  
26 So therefore you may want to look online because I think they've missed off part of

1 | what they were asking for.

2 | JUDGE MEADE: Yes.

3 | MR WOOLFE: So the part that has been added overnight -- that won't be in your hard  
4 | copy -- is paragraph 2 which relates to their request that we disclose documents in  
5 | that 2023 package. That was unfortunately missed off the hard copy that you have,  
6 | so that's the bit that's been added.

7 | In terms of the wording of their disclosure obligation, (a) it cuts down relevant  
8 | documents and documents --

9 | JUDGE MEADE: Sorry, which part should I be looking at here? (Overspeaking).

10 | MR WOOLFE: 3(b) on their disclosure. Their proposal is that they disclose documents  
11 | in which they intend to rely and adverse documents. But they say they're not required  
12 | to undertake any further searches to identify any such documents. The difficulty with  
13 | that is that the searches to date will not have captured relevant documents.

14 | I can make this point by reference to Servier's skeleton argument for this hearing. If  
15 | you go to their skeleton argument, paragraph 42(d), it's on page 18 of their skeleton  
16 | argument. You can see what they say about the searches that have been undertaken  
17 | and why they think they are sufficient. So paragraph 42(d), the proposed Model B  
18 | disclosure. The last four lines, they said that:

19 | "The process they undertook included searches of documents belonging to three of  
20 | the Servier custodians proposed in our letter and, although PPRS was not the keyword  
21 | used, searches for perindopril and Coversyl were undertaken." [as read]

22 | They assert that this would likely have captured the vast majority of PPRS documents  
23 | related to perindopril. The flaw in this, is the PPRS is a deal that doesn't just cover  
24 | drug by drug. It's a deal between the DH as a whole, and drug companies about the  
25 | portfolio of their drugs, and about the moderation of the prices of their portfolio of  
26 | drugs.

1 JUDGE MEADE: Yes.

2 MR WOOLFE: So, therefore, it's simply not sufficient. If my learned friends are  
3 running this point -- this PPRS issue -- it necessarily involves the pricing of the other  
4 non-perindopril drugs.

5 JUDGE MEADE: Right.

6 MR WOOLFE: So simply saying, "We search for perindopril" is not going to have  
7 captured the relevant documents.

8 JUDGE MEADE: Okay.

9 MR WOOLFE: And that's our main concern with that proposal.

10 Also, they're relying upon this settlement agreement between the DH. Now that would,  
11 again, have been a settlement agreement across the piece between the Department  
12 of Health and Servier. Again, documents that are relevant to what that settlement  
13 would have been in the absence of this unlawful conduct are not necessarily going to  
14 be captured by perindopril and Coversyl. So that's our concern.

15 Turning to the other side of this, I think there's been something of a misapprehension.  
16 They're seeking that we disclose a specific set of documents, which the solicitors  
17 received.

18 JUDGE MEADE: Yes.

19 MR WOOLFE: And the concern that is raised by Mr Tickner, he doesn't say, "We  
20 refuse to disclose the actual underlying documents because they have somehow  
21 mysteriously become privileged mysteriously ". That is not what is being said. What  
22 he said was, "We don't want to respond to your question as to precisely what was sent  
23 on that date", because to respond to that question may betray the trend of legal advice.

24 JUDGE MEADE: Right.

25 MR WOOLFE: In the context where we are accepting that we will disclose all relevant  
26 documents, any relevant documents that are in that package --

1 JUDGE MEADE: Right.

2 MR WOOLFE: -- will be captured and will be provided. There's no refusal to provide  
3 any specific documents on the basis that the (inaudible) become privileged.

4 JUDGE MEADE: What's confusing me here, I think, is Peters & Peters got some  
5 documents and the economists got some documents. I'd been assuming that the  
6 economist documents was a subset of the Peters & Peters documents, because  
7 Peters & Peters made a decision about which ones to give to the economists and that  
8 was the basis of privilege being involved in some way.

9 MR WOOLFE: While I'm on my feet now, I'm not sure exactly what selection was or  
10 was not made. Our basic point is that we are content to provide any documents that  
11 are relevant, including any that are in that tranche. But what we don't want to do is  
12 hand over this separate tranche as a separate package. We propose that we simply  
13 provide all relevant documents to the PPRS issue. My learned friends will not miss  
14 out on anything if our --

15 JUDGE MEADE: No, it's just (overspeaking).

16 MR WOOLFE: (Overspeaking) they didn't get to find out what we sent on that date  
17 and --

18 JUDGE MEADE: What you sent?

19 MR WOOLFE: Sorry, what the Department of Health sent Peters & Peters on that  
20 date.

21 JUDGE MEADE: But why would that be privileged? Because if Peters & Peters writes  
22 to the Department of Health and say "Please can we have documents about  
23 this" -- I can understand why, you take 5000 documents, you choose four and you  
24 send them to the economists and that betrays your thinking because, if the other side  
25 see that those were the four, they can understand what you were thinking. But your  
26 external inquiry to somebody else about getting in a category --

1 MR WOOLFE: It's not an external inquiry, sir. The Department of Health has no  
2 separate legal personality separate from the Secretary of State.

3 JUDGE MEADE: Yes. But why -- sorry, go on.

4 MR WOOLFE: My client is the Secretary of State for Health, whose identity changes  
5 from time to time. The Department of Health is the ministerial department supporting  
6 that, has no separate legal personality from him.

7 Now, as a matter of practicality, my instructing solicitors may write to people within the  
8 Department of Health to obtain things, but that's just the communication, effectively,  
9 with the client. So that communication between the client and the solicitors is  
10 privileged and any communication between solicitors and experts, for the purpose of  
11 taking advice related to litigation, is privileged.

12 What we don't understand is why Servier have any legitimate motive for wanting to  
13 know precisely what was sent or received on that date, as distinct from receiving the  
14 actual documents themselves, which they will get.

15 JUDGE MEADE: Yes. It's just that, I don't know if it's set out in the evidence, but  
16 there's a strong suspicion that you got the ones that looked like they were going to be  
17 useful, and they want the ones that are going to be useful. They don't want it swamped  
18 by another 11,000 that you're currently looking through. It's as simple as that. They  
19 don't want to know the intricate thinking that went into getting in those documents and  
20 they don't care, and I don't particularly care, who the legal identity was. It's just there  
21 is a tranche of documents on a particular issue which might be the useful tranche, and  
22 they'd rather have those.

23 MR WOOLFE: That depends upon their speculation as to the thrust of legal thinking  
24 and inquiries that were ongoing before this defence was pleaded. In a sense, that  
25 shows precisely that what they're looking for is to understand what our relevant  
26 thinking was. If the order that we propose is made, we will give them all relevant

1 documents. They will have everything they're entitled to.

2 JUDGE MEADE: I understand that, but --

3 MR WOOLFE: And in a normal disclosure process, if you're being offered all relevant  
4 documents, you don't separately inquire as to what parcels of documents were sent  
5 when, between Claimants and solicitors.

6 JUDGE MEADE: Sure. But this is a special situation because there's this earlier  
7 tranche which, one's suspicion is, probably the core ones. They just don't want to  
8 waste their time looking through the other 11,000 on a dispute which involves an  
9 amount of money which is, you know, you could have a trial over it. But it's a very  
10 small amount of money compared to the overall amounts at stake in the proceedings.  
11 It just sounds very, very likely that there's a useful collection of documents that they  
12 could focus on and not on all the others.

13 MR WOOLFE: Our position is and remains that to hand over that separate tranche of  
14 documents would risk betraying the trend of advice sought and received by our client  
15 and that, therefore, handing over disclosure in that way -- as I emphasise, it's not that  
16 the documents themselves mysteriously become privileged --

17 JUDGE MEADE: No, I know. I've understood that.

18 MR WOOLFE: -- but requiring us to give disclosure in that particular manner, as  
19 opposed to giving disclosure more broadly, does risk trespassing on privilege.

20 Now, if your concern is that our proposal process is too broad, it could be perhaps cut  
21 down in some way. But what we object to is a request that we say what was provided  
22 on this particular date. We think it's better to provide relevant documents. The fact  
23 that we're reviewing a large number of documents doesn't mean to say, (a) we're going  
24 to hand over such a large number of documents, or (b) that they have to read every  
25 single one of them.

26 JUDGE MEADE: Well, how many are you going to hand over?

1 MR WOOLFE: Well, at the moment the review is ongoing, so that remains  
2 undetermined.

3 JUDGE MEADE: Right, okay. All right. Sorry, you need to also just cover what they're  
4 proposing to give -- oh, I see, your position on that is that Ms Justice Henderson's  
5 already decided that.

6 MR WOOLFE: Yes, and insofar as it needs to be covered by this order, it should be  
7 the order we propose in the composite order, which is both sides disclosing relevant  
8 documents.

9 JUDGE MEADE: Right.

10 MR WOOLFE: It's the green text in paragraph 3 of the composite order.

11 JUDGE MEADE: Right.

12 MR WOOLFE: On our proposed.

13 JUDGE MEADE: Okay. Yes, in the -- right, okay.

14 Reply submissions by MR PICCININ

15 MR PICCININ: In relation to disclosure from us, we say this issue cannot be covered  
16 by an order for disclosure that was made.

17 JUDGE MEADE: No. Well, I'm with you on that. And anyway, even if it was, I could  
18 revise it in light of what's transpired. It's obviously -- these are my reasons on that.  
19 This is obviously a dispute of modest value within the context of the proceedings as  
20 a whole, and even if Ms Justice Henderson's order had forward looking effect on to  
21 issues introduced by amendment, it must be open to me to vary that and for a dispute  
22 which is of obviously very modest financial significance in the context of the dispute.  
23 I'm sure that I ought to restrict what disclosures given by Servier now to documents  
24 relied on and known adverse documents and if the matter needs to be taken further,  
25 then it can, but that'll be the disclosure for now. So the question is what the Claimants  
26 ought to give.

1 MR PICCININ: Yes, and on that, really the only answer I heard to our request, what  
2 we're asking for, is one of privilege, which is contrary to Court of Appeal authority.  
3 Perhaps I do need to show it to you, sir, because it's --

4 JUDGE MEADE: Well, I think what's said is that because it's kind of like -- it's sort of  
5 like correspondence with their clients, but also not correspondence with their clients  
6 and at the moment it's only expressed in rather general terms. What I propose to do  
7 is to allow the Claimants to go forwards with the course they're on at the moment,  
8 which is to do their review, and we'll see how much that generates. Perhaps the review  
9 will only generate a relatively modest amount and it won't actually turn out to be  
10 important whether they give you the subcategory. And if we have to come back to it,  
11 we will, but if we do, then there needs to be much more detailed and cogent evidence  
12 from the Claimants about the privileged claim, because at the moment it doesn't sound  
13 to me completely insubstantial, but it also sounds to me very generic.

14 MR PICCININ: Well, sir, can I just show you Sumitomo? Don't even really need to go  
15 further than the headnote.

16 JUDGE MEADE: Okay, all right.

17 MR PICCININ: This has been decided.

18 JUDGE MEADE: Okay.

19 MR PICCININ: Yeah. So it's the bundle J, tab 8. (Pause)  
20 You can see it's a decision of the Court of Appeal.

21 JUDGE MEADE: Sorry, my thing's lagging. (Pause)  
22 Right, yes.

23 MR PICCININ: What the case was about was that the claimants' solicitors in that case  
24 had reviewed a large number of the claimants' own Japanese language documents  
25 and then they'd selected some of them for translation.

26 JUDGE MEADE: Yes.

1 MR PICCININ: And the proposal from the defendants was that each side should  
2 disclose the translations of foreign language documents that were already in their  
3 control, and the claimants objected on the grounds of privilege, because the ones that  
4 they'd selected for disclosure would obviously be the interesting ones, which would  
5 then betray the trend of their advice. And the first point that the court needed to decide  
6 was whether the translations are any different from photocopies.

7 JUDGE MEADE: Yes.

8 MR PICCININ: And the court decided: no, they're not. But the relevant bit to us today  
9 is at two --

10 JUDGE MEADE: Okay, so mine is not working.

11 MR PICCININ: It's not working?

12 JUDGE MEADE: If whoever's controlling it could scroll down to the two in the  
13 headnote. Please go down further. (Pause)

14 MR PICCININ: You got that?

15 JUDGE MEADE: No, we've gone into the short adjournment. I'll read this over the  
16 shortest adjournment when my screen comes back up and we'll pick this up at the end.

17 MR PICCININ: I'll just give you some paragraph numbers to look at while you're --

18 MR WOOLFE: I was going to suggest the same thing. So perhaps if you give your  
19 list and if there's another one I want to add. It's not long, sir.

20 MR PICCININ: So it's just the headnote, then paragraph 71, paragraph 72 and  
21 paragraph 76.

22 MR WOOLFE: Sir, from my part, can I suggest you read the whole of 71 through to  
23 79?

24 JUDGE MEADE: Sure. All right. We'll come back -- ah, it started again. But anyway,  
25 we'll start again at 2.05 and I will have read it by the time I come back.

26 (1.04 pm)

1 (The short adjournment)

2 (2.07 pm)

3 MR PICCININ: Yes, sir. I don't think there's a lot more for me to say about this. The  
4 paragraphs I referred you to before lunch make very clear that there's no privilege  
5 here.

6 JUDGE MEADE: Right.

7 MR PICCININ: Paragraphs 76 and 77 in particular and that's the only basis on which  
8 this disclosure is being resisted.

9 JUDGE MEADE: Okay. Let me hear from Mr Woolfe again. Thanks. Yes, I've read  
10 it, Mr Woolfe.

11 Further submissions by MR WOOLFE

12 MR WOOLFE: Sumitomo is about whether or not somehow by making a selection,  
13 the underlying documents become cloaked, privileged. We're not saying that they do.  
14 So that's -- it's just not really a point. What we are concerned with is the manner in  
15 which disclosure is ordered. Paragraph 79 is very clear, you have a discretion as to  
16 whether to order production of a section of the party's own client documents and in  
17 exercising that discretion, you shouldn't exercise it in a manner which would betray  
18 the trend of advice that was sought. They will receive all relevant documents, including  
19 any which happened to have been included in that selection that was made. (Pause)

20 In terms of that quote, I would draw attention to the last lines of that quote, that "The  
21 court is not powerless to control the terms upon which production inspection is  
22 ordered". But my point is this: we are not seeking to cloak any actual document with  
23 privilege and we just don't want to respond to the question, essentially, of exactly which  
24 documents were handed over on that particular date.

25 JUDGE MEADE: Right, and just show me the evidence that says that the (inaudible)  
26 submission that the selection would indicate the advice was given.

1 MR WOOLFE: So that would be in Mr Tickner's --

2 JUDGE MEADE: Yes, it'll be the 19th statement, but which -- just point me to --

3 MR PICCININ: Paragraph 37.

4 MR WOOLFE: Yes, I think that is correct.

5 JUDGE MEADE: Okay, now we have a look, but (inaudible). (Pause)

6 Right.

7 MR WOOLFE: And obviously in a sense I was just concerned about the generic  
8 nature of the assertion of privilege. But if you get into explaining, "Ah, these  
9 documents were sent to us for this reason because", that starts moving into  
10 immediately matters that are in fact privileged. (Pause)

11 But sir, we'd be content with what I think you were proposing before the short  
12 adjournment, which is we provide the relevant documents on our review and then if  
13 there is an issue, because the mass is too large to review, they can come back and  
14 make any appropriate application at that stage.

15 (2.10 pm)

16

17 Ruling

18 JUDGE MEADE: It is accepted that ultimately this is a question of my discretion,  
19 because Mr Woolfe accepts the thrust of Mr Piccinin's submissions. That privilege  
20 does not exist in the documents themselves and I am satisfied that *Sumitomo* stands  
21 for the proposition that making a selection from one's own documents does not allow  
22 an objection of privilege to the disclosure of that selection. In *Sumitomo*, the relevant  
23 documents were translations, which is not the case here, but that is not relevant to the  
24 underlying point. Since it is a question of discretion, I accept Mr Piccinin's submission  
25 that there is a danger of what is probably a useful bolus of documents being swamped  
26 by a much larger number currently being reviewed for reasons which are unclear.

1 Therefore I will order the claimants to give disclosure of the documents previously  
2 disclosed to the English solicitors. There is no point, to my mind, separately identifying  
3 the documents given to the economists, where I think it is easier to understand why  
4 an insight into that might be unnecessarily and unfairly intrusive, but the evidence that  
5 privilege is conceivably engaged at all is so generic that I do not think it can attract  
6 significant weight. So I am in favour of Servier on this point.

7

8

9 (2.12 pm)

10 TRIBUNAL USHER: I'm not too sure what's happening.

11 JUDGE MEADE: I thought it was me for a minute.

12 TRIBUNAL USHER: Hang on.

13 MR WOOLFE: Sir, I think that --

14 TRIBUNAL USHER: Might be wise to take a short break.

15 MR WOOLFE: Well, I was going to say there's not much left to do. I think it's the RFI  
16 where I think the position may have narrowed somewhat. We'll just pause.

17 (2.13 pm)

18 (A short break)

19 (2.19 pm)

20 JUDGE MEADE: Sorry, was it two or four, did you say? It was two? Right, thank you.

21 Okay, let me just read it to myself again. (Pause)

22 Right.

23

24 Submissions by MS EDWARDS-STUART

25 MS EDWARDS-STUART: And sir, just so we're clear, we're not pursuing the final  
26 clause of that which says "and provide all facts the matters that the Defendants intend

1 to rely on in support of it". So we're simply asking: insofar as a positive case is being  
2 advanced, can it be summarised? (Pause)

3 JUDGE MEADE: Right, yes.

4 MS EDWARDS-STUART: Okay. So in essence, we've just put a line through that  
5 part of the request, from the word "and provide all" through to the end of the sentence.

6 JUDGE MEADE: Yes.

7 MS EDWARDS-STUART: And so we say that it's only right and proper in order to  
8 understand the case we have to meet to know whether or not Servier are in fact  
9 advancing a positive case on any of the issues that are identified in requests 1(a) to (c)  
10 above, and if so, to tell us what that case is. We accept it's not a yes/no request, but  
11 obviously we ought to know any positive case that's being advanced by Servier.

12 But a further and other important reason that we're pressing for identification of those  
13 positive cases is because otherwise it runs the risk that the responses we in fact  
14 receive to requests 1(a) to (c) and 3(a) simply take the dispute, or the difficulties that  
15 we have, with the case as it stands, no further forward. As you may recall, the basis  
16 of the requests in respect of requests 1 and 3 is to address an apparent inconsistency  
17 in Servier's defence, in that they, on the one hand, deny that IR spectroscopy is able  
18 to definitively confirm the crystal form of a product, and are therefore unable to  
19 definitively distinguish between different crystal forms of a product, and also deny, in  
20 fact, they were using IR spectroscopy in order to confirm the crystal form of their  
21 batches.

22 And the pleaded basis for that second denial, that is, that they were in fact using it for  
23 that purpose is twofold. It's firstly that perindopril was subjected to IR analysis, not for  
24 the purposes of determining crystal form, but for some unspecified quality control  
25 purpose. The second is reliance on the first point that they've made, which is that IR  
26 analysis cannot definitively be used to distinguish between different crystal forms. So,

1 therefore, Servier can't have been using it for the purposes of ascertaining the crystal  
2 form of their batches. You can see that clearly in their defence at paragraph 72(d),  
3 which is at B1, tab 5, page 58.

4 But the inconsistency that all of these requests were intended to elucidate was that all  
5 of the disclosure we've seen indicates that Servier were in fact subjecting their  
6 perindopril batches to IR analysis for the very purpose of confirming that those batches  
7 were indeed in crystal form. Furthermore, that's exactly what they were telling the  
8 regulators that they had been doing. If you can remind yourself of the emboldened  
9 text at paragraph 29, subparagraph 2, 3, 4, and 5, which is on B1, tab 1, page 75.

10 (Pause)

11 There's some emboldened text within the subparagraphs of 29, which is at the bottom  
12 of that page. I think it's the very last word and it goes over. So that's subparagraph 2.  
13 Then over the page subparagraphs 3, 4, and 5, we say that Servier's defence simply  
14 doesn't engage with that potential inconsistency at all. Our real concern is that if  
15 Servier answer 1(a), (b), (c), and 3(a) without answering 2, we face the very real  
16 prospect of being met with an answer to each of 1(a), 1(b), and 1(c) being not admitted  
17 without knowing whether or not that admission is a mere non-admission or actually  
18 a denial. And then some response to 3(a) which simply says, "Oh, by 'definitively' we  
19 mean that you actually have to be able to ascertain what the crystal structure is. You  
20 can only do that with XRPD. All that IR does is measure how atoms in the sample  
21 absorb energy and the like", and that takes us no further forward from where we were  
22 in the defence at 72(d).

23 JUDGE MEADE: Okay.

24 MS EDWARDS-STUART: So for that reason we say that they ought to provide  
25 a response to request 2. It's not particularly difficult. They must know already whether  
26 or not they have a positive case in relation to each of those issues. If they do, they

1 should just summarise what that is.

2 JUDGE MEADE: Okay. Yes, Mr Saunders.

3

4 Submissions by MR SAUNDERS

5 MR SAUNDERS: Well, my Lord, (2) really begs a pseudo expert question you say.

6 Can I just step back and just address you on why we say -- I mean, as you will have

7 seen, our primary case was that we shouldn't be doing any of this right now, so there's

8 a question of timing on it. The background to this whole RFI was that we went

9 from -- in the previous pleading, before consolidation -- a pleading with six pages on

10 patent abuse to one with 48 pages on patent abuse. We responded with another,

11 whatever it was, 30-odd pages, 40 pages, of defence on it. This stuff is, as I think

12 possibly even getting a flavour from the pleadings, quite tricky and very factually

13 complicated and scientifically complicated because it all relates to analytical chemists

14 doing things 35 years ago and how they went about developing the drugs.

15 Now, we spent approximately £230,000 pleading back to the rather beefed up inverted

16 commas "consolidated pleading". In relation to a case where the underpinnings of the

17 case may evaporate if we win again in the General Court, then we're very reluctant to

18 expend any significant further money dealing with this now beyond some very high

19 level sorts of yes and no type questions that my Lord had in mind. If you take the

20 example of infrared spectroscopy, I mean, the position again -- my Lord's

21 familiar -- we've come across that previously in various things -- but essentially you

22 shine a torch on your molecules and make them vibrate in different ways and certain

23 bonds vibrate at different wavelengths of light. That lets you tell chemically what's in

24 there. It tells you the chemical composition of the gubbins that you've got inside your,

25 whatever they are, sodium chloride plates or whatever you're using. But it doesn't tell

26 you what the structure is. For that you normally use XRPD.

1 Now, it may be that the fingerprint that you get from a particular structure in infrared  
2 spectroscopy that it can be used to tell downstream, having done a structural analysis  
3 that you've got something chemically consistent, but these are the sorts of issues that  
4 these requests are touching on.

5 Why do the Claimants say they need a response to this now? In their skeleton they  
6 say, "Well, we want to elucidate the position on factual points". Well, that's a question  
7 for evidence in due course. In Mr Tickner's 18th statement in the run up to the CMC  
8 the Claimants explained for the first time, they said, "Well, we want Servier to answer  
9 this now because we need to determine the remit of expert evidence at trial". There's  
10 no application for experts at this stage, but we can help them out with this. You're  
11 going to need an expert on IR spectroscopy and X-ray powder diffraction.

12 JUDGE MEADE: That's obvious, yes.

13 MR SAUNDERS: This is tricky stuff actually, it really is. So that's not for today, but  
14 we can tell them that one for free. So what we say is, well, we can answer the  
15 request 1 and the other requests that we've provided, we accept that number 3(a),  
16 which isn't quite a yes/no type thing, but that's a question about our pleading, which  
17 quite properly we should explain.

18 Number 2, and it's helpful that my learned friend's just clarified that they're not seeking  
19 facts and matters and so on, but insofar as it relates to a particular development of  
20 a positive case in relation to the ability -- if you look back at 1(a) -- of IR analysis to  
21 distinguish certain things or whether IR spectra could or couldn't be used at certain  
22 points in time, and various other things, that is a very different kettle of fish to just the  
23 sort of yes or no type analysis.

24 We're not saying that they should be shut out from that inquiry. It's just that doesn't  
25 have to happen now, and let's get the General Court judgment and see where we are,  
26 because at that stage we're going to have to get into these expert issues in a lot more

1 detail if we have to develop them. So that's the position on this.

2 JUDGE MEADE: But if you admit any of 1(a), (b), or (c), you don't have to do anything  
3 else, right? If you don't, then this asks if you've, as I interpret it, currently got a positive  
4 case.

5 MR SAUNDERS: My Lord, yes. I mean, I suppose the extent is the extent of detail  
6 that's required by way of summary. But, you know, if you just take 1(a), the question  
7 is: can IR analysis distinguish crystals of particular polymorphs from each other? On  
8 one level the answer to that is no, but on another level it's a pseudo expert question  
9 about whether when it comes to perindopril particularly -- and you'll see the preamble  
10 to number 1 -- whether in fact those, when applied to those particular molecules in that  
11 testing process, you can see different traces for different absorption bands for IR that  
12 enable you to do a sort of backdoor polymorph cross-check as it were. These kinds  
13 of issues are quite -- well, they're technical issues, they're going to take a bit of time  
14 to get to the bottom of.

15 My Lord made the point in your judgment yesterday that part of the concern is not  
16 troubling people who have retired and would rather not have to get off their deck chairs  
17 with a contingent case, and this may well involve those kinds of discussions because  
18 we need to look back at the history of how these things were dealt with at the time.  
19 There's no point giving a state of the art 2026 version of this. We need to know how  
20 things were being done 35 years ago. That's the problem.

21 So these enquiries, although they look deceptively straightforward, they're not. We  
22 say this, we're not shutting out number 2, but just not now. That's something that if  
23 they want to press it they can do so at the December CMC.

24 JUDGE MEADE: Okay, thank you.

25

26 Reply submissions by MR EDWARDS-STUART

1 MS EDWARDS-STUART: Our position is that the requests that we've made at 1(a),  
2 1(b), 1(c) are actually requests of fact. In particular you can see --

3 JUDGE MEADE: (a) isn't. I mean, that's a question of scientific opinion, really.

4 MS EDWARDS-STUART: Arguably that's true in respect of (a). (b) and (c) are  
5 actually the questions of what they were in fact doing at the time.

6 JUDGE MEADE: Right.

7 MS EDWARDS-STUART: As I've said, the difficulty is that we see from their pleadings  
8 they have asserted a bare denial that they were using IR testing to determine the  
9 crystal form while simultaneously submitting to the regulators that that's precisely what  
10 they were doing. That inconsistency ought to be resolved. If they admit any of (a) to  
11 (c), the issue falls away. If they don't, we would, in essence, like to know, what are  
12 they advancing? Is it a mere non-admission? We can deal with that. Or is it a denial,  
13 in which case: what's the reason for that denial? That should have been already in  
14 their pleading in circumstances where those facts are denied.

15 JUDGE MEADE: Okay, thank you.

16 (2.33 pm)

17

18 Ruling

19 JUDGE MEADE: I now have to deal with a very modest outstanding disagreement  
20 about the claimants' request for further information on various technical matters, but  
21 in particular IR analysis. The dispute has come down to the first half of request 2,  
22 which refers back to request 1, which concerns whether or not the defendants admit  
23 three particular things. The first one, (a), is about the capacity of IR analysis. Then  
24 (b) and (c) are about particular acts said to have been performed by Servier. 2 says:  
25 "Insofar as any of 1(a) to (c) are not admitted and the defendants intend to advance  
26 a positive case in support of a denial of any of these allegations, please summarise

1 that positive case and provide all facts and matters that the defendants intend to rely  
2 on in support of it."

3 In discussion between the parties, which has proved to be helpful, and in further  
4 discussions before the Tribunal, the claimants have trimmed off the closing clause: the  
5 words beginning, "and provide all facts and matters". So now the request is only for  
6 any positive case the defendants intend to advance in support of a denial of 1(a) to  
7 1(c), seeking a summary.

8 Mr Saunders, KC for Servier, submits that all of these matters ought to await the  
9 decision of the General Court in case the patent abuse arguments all turn out to have  
10 failed. But, in my assessment, a decision has already been made long ago that the  
11 pleadings would progress so far as they have anyway, and they have done so. The  
12 argument for the claimants, made today by Ms Edwards-Stuart, KC, is that this is  
13 about whether the defendants have a positive case or not.

14 In my view, she is right about that and if a pleading is a true non-admission and merely  
15 puts the claimants to proof, then that is one thing. But if a non-admission conceals  
16 a positive case, then that is not a compliant pleading and it ought to be remedied.

17 I have to say that some of the requests are rather argumentative and this is one of  
18 them in the sense that it is founded on what is said to be an inconsistency in Servier's  
19 position, and that is not an appropriate use of a request for further information. But  
20 what is appropriate is to find out what is admitted and then to find out, if that conceals  
21 a positive case, what that positive case is.

22 If Servier is going to admit any of 1(a) to (c), then there will be no need to go any  
23 further. But I infer that there is a strong likelihood that Servier is not going to admit  
24 that and that a positive case will be advanced. Mr Saunders makes the reasonable  
25 point that these requests, if ordered, would start to trespass into what will, in due  
26 course, be the contents of expert reports. In my view, the right balance to strike is to,

1 first of all, require the defendant Servier to say whether they are admitting 1(a), (b), or  
2 (c). I suspect that they are not going to admit it but, in any event, they must do that  
3 first. Then, if they currently have positive matters to advance, those must be disclosed  
4 in a high-level summary. I emphasise "high level" because this is not to take the place  
5 or trespass into the sort of detail that would come into an expert report. I emphasise  
6 that this is to do with any positive matters that they currently know that they intend to  
7 advance. I think that will put the pleadings in an appropriately compliant state, which  
8 has been the strategy behind the directions given for these proceedings so far.  
9 So to summarise, my ruling on 2 is that it will say that, insofar as any of 1(a) to (c) are  
10 not admitted and the defendants currently intend to advance a positive case in support  
11 of a denial of any of the allegations, they must summarise that positive case at a high  
12 level.

13

14 (2.38 pm)

15 JUDGE MEADE: So if you come up with further points downstream, Mr Saunders,  
16 which I think is highly likely, then you're free to do that.

17 MR SAUNDERS: (Inaudible) once we get experts running, they'll --

18 JUDGE MEADE: They'll be much more detailed. But this requires you to show your  
19 hand, insofar that you're already aware of matters that you're going to run.

20 MR SAUNDERS: (Inaudible).

21 My Lord, the only other point was timing. I can't remember the date they asked for but  
22 that was fine by us.

23 MS ABRAM: I think it was 10 June.

24 MR SAUNDERS: Yes, I think that's fine. 10 June is fine.

25 MR WOOLFE: I think that's taken us through all the business in the CMC.

26 JUDGE MEADE: All right. Well, thank you very much everybody. Thank you very

1 much for the document management system. I think, actually, that such stuttering has  
2 there been has probably been a Wi-Fi issue more than anything else but, in any event,  
3 it's been extremely helpful and I'm very grateful for that and all of the other  
4 organisational effort that's taken place.

5 (2.39 pm)

6 (The court adjourned)

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### Key to punctuation used in transcript

--	Double dashes are used at the end of a line to indicate that the person's speech was cut off by someone else speaking
...	Ellipsis is used at the end of a line to indicate that the person tailed off their speech and did not finish the sentence.
- xx xx xx -	A pair of single dashes is used to separate strong interruptions from the rest of the sentence e.g. An honest politician - if such a creature exists - would never agree to such a plan. These are unlike commas, which only separate off a weak interruption.
-	Single dashes are used when the strong interruption comes at the end of the sentence, e.g. There was no other way - or was there?