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## **IN THE COMPETITION**

Case No. 1251/1/12/16-1255/1/12/16

### APPEAL TRIBUNAL

Victoria House, Bloomsbury Place, London WC1A 2EB

28 March 2017

Before:

# THE HON. MR. JUSTICE ROTH (President) MR HODGE MALEK QC DERMOT GLYNN

(Sitting as a Tribunal in England and Wales)

**BETWEEN**:

GENERICS (UK) LIMITED
GLAXOSMITHKLINE PLC
(1) XELLIA PHARMACEUTICALS ApS
(2)ALPHARMA LLC
ACTAVIS UK LIMITED
MERCK KGaA

**Appellants** 

- and -

COMPETITION AND MARKETS AUTHORITY

Respondent

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**HEARING** 

## APPEARANCES

- <u>Stephen Kon</u> and <u>Christopher Humpe</u> (instructed by MacFarlanes) appeared on behalf of the Appellant (Generics UK Limited).
- <u>James Flynn QC (Brick Court)</u>, <u>David Scannell (Brick Court)</u> and <u>Charlotte Thomas (Brick Court)</u> (instructed by Nabarro) appeared on behalf of the Appellant (Glaxosmithkline PLC).
- Robert O'Donoghue QC (Brick Court), (instructed by Clifford Chance) appeared on behalf of the Appellant (Xellia Pharmaceuticals APS (1) Alpharma LLC (2)).
- <u>Sarah Ford QC</u> (instructed by MacFarlanes) appeared on behalf of the Appellant (Actavis UK Limited).
- Ronit Kreisberger (instructed by DLA Piper) appeared on behalf of the Appellant (Merck KGaA).
- Jon Turner QC (Monckton), Marie Demetriou QC (Brick Court) David Bailey (Brick Court),

  Thomas Sebastian (Monckton), Ravi Mehta (Blackstone) and Elizabeth Kelsey (Monckton) appeared on behalf of the Respondent

1	THE PRESIDENT: Yes, Mr. Kon.
2	MR. KON: Good morning.
3	We have heard the submissions of Mr. Flynn and Mr. O'Donoghue, and I will seek in these
4	closing submissions not to repeat what has already been said, but inevitably on occasions
5	there will be some areas of overlap.
6	We are going to address, rather than simply follow our written closing, what appeared to us
7	to be the key questions that the Tribunal is likely to be considering in an assessment of this
8	case, and we will do so obviously with a focus on GUK.
9	We may jump from time to time between objects and effects, but I think that is the
10	inevitability in this case. We shall try not to take you to too many materials in the bundles,
11	but on occasions we may need to do so for which we are very much in your hands, sir.
12	There are seven questions which we would like to address and which are as follows: firstly,
13	what is the relevance to potential competition of an injunction and why we say on that poin
14	the CMA's case finds no support in Lundbeck?
15	I am afraid, sir, on several occasions I will be referring to Lundbeck although I note the
16	mutual sympathy we all have in relation to that.
17	We shall be very brief on this particular point of potential competition because we have
18	heard a lot about it already. Secondly, I wish to ask the question: what is the CMA's object
19	case and what is the importance to that case of, firstly, the strength of the patent, and
20	secondly, the size of the value transfer or payments in the case as advanced by the CMA?
21	Thirdly, does Lundbeck say that you can infer an anti-competitive object when a settlement
22	includes a payment above litigation costs and there is no independent entry? We say that
23	Lundbeck does not do that.
24	Fourthly, the question of wholesalers. Do they benefit from the agreements and, indeed,
25	were the wholesalers and competition at wholesale level, was that a benefit as a result of a
26	competitive process?
27	Fifthly, does it matter at all to these proceedings whether wholesalers actually passed
28	through the price reductions they received to pharmacies?
29	Sixthly, does the CMA have an effects case at all?
30	Seventh, very briefly, was the CMA over-cautious in its no grounds for action decision in
31	relation to IVAX?
32	Finally, we address one question on fines, which Mr. Humpe will address you on, which is
33	whether the infringement committed was intentional or negligent.
34	THE PRESIDENT: So eight questions?
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1 MR. KON: The eighth one is fines, which I guess moves away from, if you like, substantive 2 assessment per se. 3 First question: what is the relevance of potential competition? A key question which we 4 have heard a lot about is whether there can be potential competition when an injunction is in 5 place and whether Lundbeck supports the proposition that when an injunction is in place 6 that does not foreclose potential competition. 7 We do not want to spend a lot of time, as I have said, on that, but there are two brief 8 submissions we make. The first submission is a general submission. There can be no 9 potential competition when GUK was injuncted. This is despite the fact that GUK -- and 10 we acknowledge that, and as you have seen from our written closing we address it directly -11 - the fact that GUK has taken significant steps towards entering the market was 12 fundamentally changed by the grant of the injunction which closed the market to GUK. We 13 say quite simply that the market was not open to competition while the injunction was in 14 place. 15 The injunction in short created a blocking position. Mr. O'Donoghue took you to the 16 relevant paragraphs of E.ON. I will not do likewise unless you wish me to, but we believe 17 that supports entirely this submission. Really, the CMA has only had one response to that 18 submission, which is that the injunction was a temporary measure pending trial. 19 We consider that submission to be misconceived since the injunction would only avoid 20 becoming permanent in the event that GUK was successful in the patent litigation. Unless 21 and until that occurred, we were blocked. By describing the injunction as temporary, we 22 say that the CMA is in essence prejudging the outcome of the litigation. 23 We heard -- and I believe it was suggested by the Tribunal -- that the injunction may have 24 been short lived. We would respectfully submit that if that is a submission from the CMA, 25 that is an entirely speculative submission. We do not know how long the injunction --26 THE PRESIDENT: Well, the temporary injunction? You mean --27 MR. KON: The interim injunction. We have no idea --28 THE PRESIDENT: It was until trial. 29 MR. KON: But we do not know what the outcome of the trial was. 30 THE PRESIDENT: But the outcome of the trial would end an interim injunction. You are 31 making a separate point that if GSK had succeeded, then there would have been a 32 permanent injunction, but that would have been the end of the temporary injunction. 33 MR. KON: Yes. 34 THE PRESIDENT: So we know how long --

1 MR. KON: Perhaps let me put it this way, sir. The blocking position was entirely uncertain how 2 long that was going to remain, whether that was on the basis of a temporary injunction or a 3 permanent injunction. But it is clear that the only circumstance under which we would not 4 have been injuncted would have been if we had won the litigation, and that is the 5 speculative aspect of the CMA's position on this, that they are assuming that that injunction 6 would have been set aside and not replaced by a permanent injunction or continued until 7 any appeals. 8 THE PRESIDENT: Well, they are saying that is uncertain. That is the point. 9 There is a distinction. There is the temporary injunction, which is certain, it was there. We 10 know. It is a fact established and we know or can infer how long it would have continued, because I think you make the point, or someone made the point, even if you had won at trial 11 12 there might have been an appeal that would probably have been extended. An expedited 13 appeal. 14 MR. KON: Correct. We certainly made that point. 15 THE PRESIDENT: So we know that. What would have happened at trial in turn or on appeal for 16 the permanent position is uncertain. 17 MR. KON: Yes. 18 THE PRESIDENT: That is the uncertainty. 19 MR. KON: My point is a very simple one, which is that if GSK had succeeded in the appeal, an 20 injunction, whether you classify it as a permanent or temporary injunction, would have 21 remained in place and we would have continued to be blocked. Therefore, the only 22 circumstance under which we would have then become a potential competitor would have 23 been if the injunction had been lifted. We believe that the E.ON case is entirely supportive 24 of that position. 25 There is plenty of contemporaneous evidence --26 THE PRESIDENT: Is that the critical factor, do you say, which prevents GUK being a potential 27 competitor? 28 MR. KON: Yes. We are not postulating on this, as we say in our written closing. We accept that 29 up to the moment we were injuncted, it would have been correct to assess us as a potential 30 competitor because we had taken all the preparatory steps to enter. Indeed, at the core of 31 GUK's case is that it was faced with a very stark position. It had invested an enormous 32 amount to enter this market, it was injuncted, and whether one accepts the 33 contemporaneous correspondence or not -- that is something I will be saying something

about in a moment -- we were prevented from entering and we were legally blocked.

1 THE PRESIDENT: There might have been a distinction with IVAX. 2 MR. KON: I think it was fundamentally different for IVAX, which is one of the reasons why we 3 find the no grounds for action decision --4 THE PRESIDENT: But I mean, IVAX, the no grounds for action may be to do with blockage. I 5 am talking about potential competitors. But IVAX never had an injunction. 6 MR. KON: Yes. No, they never had an injunction and, indeed, I think some have questioned 7 exactly what its status was, whether it even had a product. We certainly had both, the 8 benefit of both for the purpose of these proceedings. 9 THE PRESIDENT: Yes. 10 MR. KON: On the second point on injunctions which, again, I think is a relatively 11 straightforward point, we say that Lundbeck provides no support to the submissions made 12 on the injunction by the CMA, and that is because the facts were fundamentally different in 13 the Lundbeck case. 14 We do not want to labour the points, but there is one fundamental difference in that regard that we believe distinguishes anything said on this subject and relied upon by the CMA 15 16 from Lundbeck, and that is that a fundamental finding of the General Court in Lundbeck was 17 that the market for citalogram was open to competition. 18 There were no injunctions, as we know, and please, sir, if you wish me to take you to 19 Lundbeck on any of these points I am of course happy to do so. There were no injunctions 20 in that case and it was more than doubtful that Lundbeck would have secured any 21 injunctions. As you know, that is a question that the General Court queried and, indeed, 22 doubted. 23 THE PRESIDENT: Yes. 24 MR. KON: Secondly, the Commission did not derive potential competition in that case merely 25 from the possibility of pursuing litigation, but it relied upon a number of factors, one of 26 which was that Lundbeck had acknowledged that there were a number of other processes 27 available to produce citalopram without infringing their patents. Therefore, again, the 28 market was open in that regard from the CMA's point of view in the way that it was not to 29 GUK once the injunction had been granted. 30 That is of course subject to the regulatory requirements being complied with, which they 31 were as far as most of the parties were concerned. Of course, all I say on Lundbeck is 32 without prejudice to whether it is rightly decided. 33 Thirdly, the court made it clear that they saw no genuine intention on the part of Lundbeck

to put its patents to the test. The court again, as you know, paragraph 127, insofar as you

wish to look at it, made it clear that Lundbeck actually did not have the stomach to do so because it doubted whether it had a decent patent case, indeed whether there were extant patents to cover an infringer.

So according to the Commission and the General Court, *Lundbeck* was essentially a case where there was nothing to stop generics from getting on the market, and that, from the General Court's point of view, was one of the most egregious aspects of the case in terms of its assessment of Lundbeck's conduct.

That is all that I wish to say on potential competition. We believe, both on the specific and the general by reference to *Lundbeck*, this case is a strong case that we were not potential competitors. Having said that, we obviously have to consider the possibility of you finding otherwise -- if we were a potential competitor where does that leave us in this case? -- since I think we are all agreed that that will require the CMA to establish that there was either an object or effect, or both, of a restriction of competition.

Our submission on that, which goes on to my next point, is, well, what is the CMA's case on that? We say the CMA's case fails.

In order to explain why we consider essentially on object, which is, as I say, although we will occasionally refer to aspects of the effects analysis but we want to focus on object at this point, we say quite simply this. We say the CMA's case goes beyond *Lundbeck*, it is much more extreme than *Lundbeck* and is actually more extreme than the so-called pay for delay inference that Professor Shapiro has advanced.

In opening -- and I am happy to take you to this, but perhaps I could read it to you for you to decide whether you wish to -- the case advanced by CMA by Mr. Turner was very, very clear, and I do not think Mr. Turner would resile from this given that he said it on Day 3 in opening.

#### He said:

"The CMA's case in the decision is based on a very simple and intuitive proposition. It is that if the owner of a patent protected product agrees to pay a potential competitor to induce it not to launch a rival product for the duration of the agreement, then that agreement is by its nature something which is antithetical to the competitive process."

It is a very simple proposition.

If I may just give you the reference to that, it is  $\{TR/3/3\}$ , Day 3 of the openings.

This is repeated to all intents and purposes at paragraph 178 of the CMA's closing. I will not read that to you, but I will say that the key aspects of what Mr. Turner says there is that

2 the words "unexplained reverse payment". 3 He says the Competition Authority is entitled to infer that that payment was consideration 4 for the acceptance by the generic of restrictions on its competitive entry. 5 He goes on to say, specifically in this case there was no legitimate explanation for that payment. So very, very simple, three steps, I think, almost, that is the way that Mr. Turner 6 7 opened. 8 So the CMA's case is all you need for an anti-competitive object, and it is important to bear 9 in mind at this stage that an anti-competitive object is an irrebuttable presumption of anti-10 competitive effects. That is essentially what an objects case is: by its very nature, it 11 constitutes the restriction of competition, and therefore it creates an irrebuttable 12 presumption. 13 THE PRESIDENT: That is all subject to paragraph 3? 14 MR. KON: Subject to paragraph 3, which I will come on to, absolutely. 101(1), because, of 15 course, if it is an objects restriction, essentially one of the three falls for consideration. But 16 my submission to you on that is going to be it is almost impossible to conceive, given the 17 way that Mr. Turner has put his case, that 101(3) could add very much relevance in this 18 case. That is something I am going to put to you. I recognise that others have submitted 19 otherwise. 20 MR. GLYNN: May I just ask, in referring to Mr. Turner's expression of the argument, rather than 21 the CMA decision, is there any significant difference between the way in which Mr. Turner 22 has put it and the way in which the CMA decision expresses it? 23 MR. KON: No, I think Mr. Turner's argument is consistent on this particular question with the 24 CMA's decision. 25 Going back, all you need for an anti-competitive object is a payment, an unexplained 26 payment of unexplained value transfer. From that you infer an inducement, and if there is 27 any form of entry restriction that, according to Mr. Turner, is valid. 28 The CMA does claim -- and this is Mr. Turner because of course Professor Shapiro was not 29 at least on the record in the CMA decision -- that its case is supported by Professor Shapiro 30 in his pay for delay inference. According to that, as we know it can be inferred from a 31 payment above litigation costs that the originator is buying off potential competition. 32 Now, while we acknowledge that Professor Shapiro to some extent is an advocate for his 33 own theories, that is not our submission in this regard because he does not dispute that there 34 are different views amongst economists, some of which have been aired before the

he refers to the presence of an unexplained reverse payment, and I would like to emphasise

1 Tribunal, that concerns the validity and strength of the inference. How significant is it? 2 How strong is it? The circumstances and conditions under which it could be relevant. 3 But the fundamental point is that Professor Shapiro has acknowledged that his inference can 4 produce the wrong result, because he accepts that his inference of anti-competitive effects 5 can be rebutted. On this, I should like to take you very briefly to the experts' joint statement 6 point, which is bundle  $\{I/1/15\}$ . 7 I take you to three lines from the top where Professor Shapiro says: 8 "When applying the pay-for-delay inference to cases where the value transfer takes a 9 non-cash form ..." 10 That clearly is at least in part the position here given the agreements: " ... it may be necessary to determine whether the arrangement comprising the value 11 12 transfer itself could be expected to lead to a meaningful increase in competition that 13 would predictably benefit customers." 14 No particular category of customers: customers. 15 Now, we say that that is a different emphasis and not as extreme as the position adopted by 16 the CMA. Professor Shapiro acknowledges that it is consistent with his evidence before you 17 that the presumption is rebuttable, and that applies to both cash and non-cash value 18 transfers. 19 But the CMA makes no such concession at all. Its case goes beyond that. Its case is one of 20 object, which as I have said is irrebuttable, and we rely upon Consten and Grundig for that 21 amongst others, which we do not need to go to. In that, as you know, the ECJ held that it is 22 not necessary to look at effects once it appears that the agreement has an anti-competitive 23 object. 24 Now, the CMA claims that it is always possible, as you raised a moment ago, Mr. President, 25 that it is also always possible the possibility of exemption always arises under 101(3). 26 But it is in fact, according to our submission, impossible to envisage how that may apply 27 because the indispensability requirement of Article 101(3) simply, it seems to us, if the case 28 made out by Mr. Turner is correct, cannot be satisfied. 29 I recognise it is an unattractive proposition for those relying upon 101(3), but I think what it 30 does is re-emphasise the stark nature of the proposition: if the case is characterised, as it is 31 by Mr. Turner, 101(3) really has no place, because he equates agreements such as this with 32 market sharing agreements. So the consequence of what the CMA is saying is this is a per 33 se prohibition, where a settlement involves a payment and is not accompanied by immediate 34 generic entry, it is per se unlawful.

So that in itself is a reason why we say the case is extreme. But it goes more extreme than that, and there are two matters that I would like to take you to in particular to demonstrate that. The first is in relation to what does he say, or what does the CMA say about patent strength. We say, and clearly Mr. Turner will reply to this if I am wrong, that in the CMA's case the strength of the patent as a relevant consideration forms no part of the CMA's case. The likelihood of the generics succeeding or not in the litigation is simply not relevant for Mr. Turner or the CMA. According to the CMA, all that is relevant is that the litigation has been interrupted. 

I must say, I mean, on occasions I found it perplexing in both the CMA's closing submissions, their written closing submissions and their cross-examination of Vivien West and Mark Reilly, that so much emphasis has been put on exploring the patent position, because ultimately GUK's belief in the strength or otherwise of its patents is simply not relevant to the case advanced by the CMA.

THE PRESIDENT: GSK's belief.

MR. KON: Sorry, by GSK. I do apologise.

The same applies to GUK's concerns that it will not prevail in the litigation. Again, that is not a relevant consideration as far as the CMA's case is concerned. I think Mr. Turner did explain this very clearly in opening, and again, I will read you the opening and I am happy to take you there.

The reference for the transcript references is {TR/3/61} and he said:

"The precise degree of belief in the strength of patent ... is neither here nor there ...

Our approach to the case is what matters is uncertainty, which is then removed by a reverse payment."

That is the submission he made.

Therefore, I am sure, having heard so much on patent strength, one can query why patent strength has actually figured so large. We acknowledge that the views that the parties had on patent strength may have formed part of motivation, and that goes to the question of whether the reverse payment is explained or unexplained, which is something I will come on to in a moment. But in terms of this Tribunal, it is a question that arose I think yesterday, being asked to actually assess the strength of the patent, we say actually all of the debate on that here is not relevant to the CMA's case.

So the second aspect of Mr. Turner's case is the payment. He says, and the theory advanced by the CMA is, that a payment in whatever form, whether cash or non-cash, is the evil that

1	converts a settlement into a restriction by object. That essentially converts the whole
2	agreement. It does not matter what form, and indeed, on his case it does not matter what the
3	size of the payment is.
4	The only way that you can actually, from the payment, induce that there is no restriction of
5	competition is if the generic would have settled for nothing; that is, it would have
6	capitulated.
7	MR. GLYNN: Forgive me, there is reference several times to the payment being sizeable, to the
8	point that size does not matter does not seem quite to square with other things we have
9	heard.
10	MR. KON: May I, sir, come back to that question?
11	MR. GLYNN: Of course.
12	MR. KON: The question of payment is clearly a relevant consideration, and our submission
13	essentially is that: that the payment is part of a balancing exercise, that there are a number
14	of motivations on both sides of the equation that are taken into account and the payment
15	clearly is a relevant consideration. But what we say is that it is not the exclusive
16	consideration, and we say that from Mr. Turner and the CMA's perspective the payment is
17	like the magic pill. It converts everything into an anti-competitive
18	MR. GLYNN: I just wanted to be clear. As I have understood it so far, it has been that the
19	payment has to be sizeable to have this
20	MR. KON: I do not think, sir, with respect, that that is the case which has been advanced against
21	us. If I am wrong on that I am happy for Mr. Turner to correct me when he replies. But I
22	believe that the case that has been advanced is that a payment of any size will actually
23	create an anti-competitive agreement if accompanied by the other criteria that go into what
24	is classified as an object infringement.
25	MR. MALEK: I thought certainly when we heard Professor Shapiro he was talking in terms of
26	payment, or whatever you want to describe it, in excess of the litigation cost?
27	MR. KON: Above litigation cost. That is the only carve-out, we say.
28	The way the CMA deal with that, we say, sir, is that they say if the payment is unexplained,
29	and the question is what does "explained" mean? But certainly in terms of quantum of the
30	amount, we do not believe that forms any part of the CMA's case.
31	MR. MALEK: Can I just go back a bit.
32	MR. KON: Sure.
33	MR. MALEK: Strength of payment, you say it is not relevant to the CMA's case but clearly it is
34	relevant on your case is it?

MR. KON: No --

MR. MALEK: Surely, look, if you just look at the effects case, for example, you may say, well, the strength of the patent is relevant because if you cannot show on the balance of probabilities the result would have been one way or another, you will say, well, there is no effect because the effect would have been the same as before, we still would have been out because we would have lost the litigation. So I thought that it may be relevant for that, but what I was trying to figure out is whether it is relevant to you for the objects case, and it is not clear to me.

You are saying it is not part of their case, but is it part of your case that for this to be a restriction by object, you do have to form a view as to the strength of the patent?

MR. KON: I think the answer is, from our perspective, the position -- I am going to move away from using the strength of the patent because that suggests that the people taking the decisions in this case were able to form their own view. I recognise everything that has been said in terms of legal advice etc. But essentially the position is, as far as we are concerned, that the patent position, the exposure under the patent, the potential exposure, is something that is relevant for our client clearly, because as we have seen from the contemporaneous correspondence, what was concerning our clients, what was motivating our clients was really how were we going to win this patent litigation, and there was significant doubt.

From that perspective it is a relevant factor in our overall motivation. But going to the question that the Tribunal asked yesterday is we do not think -- and I think the Tribunal was suggesting exactly this -- that it is necessary, therefore, to form a percentage chance of where we stood in relation to that. All I need to say, I think, is to say from an objects perspective there is good evidence to demonstrate that our motivation was partly -- not exclusively as we say in our written closing, but it was partly that we were exposed potentially on the patent side, and if we lost the patent case and there was a real prospect of that occurring according to what we believed, we were going to be in serious difficulty. So the answer is it is a relevant consideration in motivation, but not in determining were we going to win or lose definitively, but it is part of the overall circumstances.

What we say is that on the CMA's case, actually, that does not figure. On the CMA's case if you have the three magic elements that I have referred to -- you have a payment, you have a value transfer and you have any form of restriction -- unless the generic capitulates, that is enough and whatever the strength of the patent was, even if the generic thought they had a

1	90% chance of success, that would not change that overall proposition on which the CMA
2	relies.
3	MR. MALEK: Thank you very much.
4	MR. KON: No, thank you, sir.
5	THE PRESIDENT: Can I just ask you, on the size of payment point that Mr. Glynn asked, if one
6	looks at the decision at paragraphs 6.57, 6.58 dealing with your client, I thought quite a lot
7	of weight is put on the size of the payment.
8	MR. KON: The size of the payment is referred to in the decision.
9	THE PRESIDENT: It is relied on.
10	MR. KON: Would you like to refer me, sir, to exactly what
11	THE PRESIDENT: 6.57 in the decision, which is page {V/1/258}:
12	"By entering into the agreements, GSK committed to make value transfers to GUK
13	and the other generic companies that totalled at least £50.9 million, including value
14	transfers to GUK that totalled at least 21.3 million. The average annual value that
15	GSK committed to transfer to the Generic Companies was equivalent to 37% of its
16	annual UK paroxetine profits. These transfers were commercially rational for GSK
17	only on the basis that they would be used to induce the Generic Companies'
18	acceptance of entry restrictions and to delay their potential independent market entry
19	"
20	Then the next paragraph, 6.58:
21	"The fact that GSK chose to make substantial cash payments to GUK, and supply
22	GUK" demonstrates that, they perceived your entry to be credible, in other words,
23	that the patent was viable.
24	MR. KON: Yes. What we say to that, sir, is that if, on the case that has been advanced to this
25	Tribunal, the payments had been significantly less, it would make no difference at all to the
26	CMA's case. They obviously looked as part of the motivational factors at the value
27	transfers as one that was taken into account by the generics, by GUK.
28	THE PRESIDENT: But they did seem, from that, and I think there may be some other references
29	to focus on the size. I thought you said they did not regard the size as of any significance?
30	MR. KON: We say, sir, and I think it is consistent with what has been submitted to you by the
31	CMA here, is that as long as the value transfers, the payments are above litigation costs on
32	the CMA's case, of course, from the judicial point of view they are looking at the size of the
33	nayment but we say it is not necessary for that in order to make out the case

1 This is an objects case, and therefore the position of the value transfer and whether it is 2 actually a key element or not in that objects case in our view is fundamental. 3 I mean, if one wants to investigate the weighing up, and this is something that I am going to 4 come on to when I talk about the unexplained nature of the presence, then you can weigh in 5 the balance the size of the value transfer. THE PRESIDENT: They are doing it on the object. 6 7 MR. KON: That is what we object to. We say it is not part of their objects case advanced to you 8 here. We say the size of the value transfer -- I can only refer you back to how Mr. Turner 9 opened the case and the consistent submissions that he has made to you here over the last 10 four weeks or so. 11 Perhaps if I go on to talk about the unexplained nature of the payment that may add further 12 light on this. 13 The presence of an unexplained reverse payment suggests -- which is the point I have just 14 been making -- that the parties can come up with an explanation for the payment. We say, 15 however, that this is a device. We say that where the generic does not obtain unrestricted 16 access to the market, on the CMA's own case there would never be an explanation good 17 enough to trump the inference that where there is a payment, it is a payment for delay. 18 That, essentially, is the way we are putting our case on payment to follow on to the point 19 you make, sir. Whatever the reasons are that are driving the innovator and the generic to 20 settle, we know that these were different and diverging. But that is irrelevant for the CMA 21 on its own case because the reverse payment provides the magic bullet that trumps 22 everything else on the CMA's case, and that is very much the way they have put it in their 23 case. 24 In that regard, in terms of what the various diverse reasons were, we say in many respects, 25 therefore, on the CMA's own case much of the evidence from GUK from Messrs Hart, 26 Saynor and Self should not be strictly relevant, as indeed is the evidence from Mr. Urwin 27 about which there has been so much debate. Because the inducement, which is the key 28 element, of course, in the CMA's case and the anti-competitive harm, can be inferred from 29 the simple fact of there being a payment. 30 The inducement and anti-competitive harm emerges from the payment. That is the CMA's 31 case. Then obviously enormous time has been devoted to the CMA, to the evidence and, 32 indeed, to ourselves to show our motivation for entering into the settlements.

1 I am conscious that Mr. Turner has put before you a number of authorities on the approach 2 to be taken when a party does not call a relevant witness. I will deal with those in reply 3 because I do not know exactly how Mr. Turner is going to put it. 4 So far, I would like to remark on one particular matter: that nothing that is said so far by the 5 CMA in its closing, written closing, addresses the points made by GUK in its closing. But 6 it should not be open to the CMA to question the interview evidence and the sworn 7 evidence of Mr. Urwin. 8 Sir, I am working on the basis that you will recall the question of some of the 9 contemporaneous and witness evidence given by Mr. Urwin. 10 MR. MALEK: But the thing is, when an authority like the OFT and the CMA interview someone, 11 it is generally not a sort of a hostile process, it is an information-gathering process, which is 12 very different from calling someone as a witness and testing their evidence before the 13 Tribunal, is it not? 14 MR. KON: Sir, may I just put it to you in this way -- I understand that, I understand that point, 15 but let me perhaps put a counterpoint to you, which is that the sequencing of events is that 16 Mr. Urwin, as you said, was requested to give evidence, he did so, there is a transcript of 17 that evidence. This question of whether the comments he made in the relevant email 18 exchanges were or were not simply pretextual and, if you like, just trying to spin a yarn to 19 Sumika, our raw material manufacturer, that was never put to Mr. Urwin in his interview. If 20 one looks at the transcript of the evidence the word "Sumika" does not appear. 21 The next thing that we see is that in the Statement of Objections, the inference drawn from 22 that email that this was purely pretextual, it does not demonstrate at all a genuine concern 23 on any of the matters expressed in there which led him to settle. Mr. Urwin, therefore, 24 corrected that on the basis of a sworn witness statement. 25 That witness statement is, as you know, in the evidence, where he says: I have read what the 26 CMA have said in relation to that. So Mr. Urwin did not just sit back passively and say 27 nothing, and GUK did not acquiesce in that interpretation. 28 The next thing was that in his witness statement Mr. Urwin says -- a sworn witness 29 statement -- he says very, very clearly that that is not a correct interpretation. He says that what I was stating was exactly the situation, and he rebuts very clearly and unambiguously 30 31 what is said in the Statement of Objections. 32 The CMA could have called him back for further interview. They could have summoned 33 him here if they were still questioning that. They did no such things. We say we are entitled 34 to rely upon that sworn witness statement from Mr. Urwin in the absence of the CMA

1 preferring to draw an incorrect inference on a sworn witness statement from Mr. Urwin 2 rather than the CMA actually having sought to confirm themselves in any way during the 3 proceedings the incorrect interpretation. 4 After all, the witness statement was filed very shortly after the Statement of Objections. 5 They could have asked Mr. Urwin to attend the hearing, they could have called him back. 6 They did none of these things. We say we are entitled to rely upon that, and no effort has 7 been made to correct Mr. Urwin's interpretation or his statement of truth in relation to that. 8 All it has done is sought to rely upon an inference rather than on the witness himself giving 9 clear evidence. 10 Therefore, the question arises: would it be for us, in that situation, to call Mr. Urwin? We say it was unnecessary. His witness statement remained unrebutted other than on the basis 11 12 of an inference in the decision, which he has clearly said unequivocally is wrong. That is 13 my submission on that. 14 I understand the point you are making. What I would say is that in those situations, it is 15 quite clear from cases such as Napp, Mr. Urwin and therefore GUK is entitled to a 16 presumption of innocence. Any reasonable doubt there may be, when he swears a sworn 17 statement stating -- apart from Mr. Urwin remaining silent in this situation, this is not a case 18 where there is no contemporaneous evidence, this is a case where the meaning of 19 contemporaneous evidence has been explained by the author of that evidence. What the 20 CMA is choosing to do is draw inferences from that, and we say that is inappropriate and 21 that it really operates against the presumption of innocence which Mr. Urwin and GUK are 22 entitled to. 23 Sir, unless I can help you further on that point? 24 MR. MALEK: No. There is obviously a fair amount of law and learning on this. We will come 25 to it later once we hear Mr. Turner on that. 26 MR. KON: Yes, and if I may, I will reply at that point. 27 MR. GLYNN: Are you moving away from the point about the unexplained --28 MR. KON: In fact, that is my next submission, the unexplained nature. It is entitled "Explaining 29 the unexplained". No knowns and no unknowns, I suppose. 30 GUK's reasons for settling. Before actually considering the significance of the payment 31 etc, there were compelling reasons -- and I do not think many of these, as we say in our 32 written closings, were in dispute -- there were compelling reasons for GUK to settle. These 33 turned upon the fact that we were injuncted and, sir, if in relation to any of these you wish 34 me to take you to any supporting materials, do say.

The fact that GUK was injuncted, I do not think that is in dispute. The difficulty of establishing the non-infringement and, indeed, insofar as it was relevant, the invalidity of GSK's patent. The real concerns that GUK expressed in contemporaneous evidence that they would not prevail in litigation. GUK's significant financial exposure, which is referred to in our closing, and its assessment of the value that attached to being able to enter the market immediately. That is something that I think has been underestimated because GUK, as you know, had taken orders, they had customers standing by, they were then injuncted, and there is contemporaneous evidence that they were concerned as regards what those customers thought they were doing and whether they were ever going to come to market with the paroxetine product. I mean, customers clearly had an expectation that it would have a paroxetine product available. Then, a final consideration, which I will say a little bit more about in a moment, is the value of the cross-undertaking itself. We say that the motivational factors are clear. GUK wanted to get onto the market. It should not be underestimated that that was a prime motivating factor, and indeed it wanted to get onto the market with sufficient quantities. I know there have been a great deal of discussions about whether the numbers were right in the Urwin email we have seen before. It would be disingenuous for me to say that clearly he was concerned as regards the financial outcome of the settlement, but equally the numbers derived also refer to the fact that there is clear evidence in the proceedings that GUK was pushing back time and time again. There is, as you may recall, sir, a schedule in the decision, or rather a table in the decision which shows -- it is table 3.2 of the decision, which is at  $\{V/1/119\}$ . I am happy to take you there but I do not think it is necessary. Would you like me to, sir? But it shows that that on occasion after occasion GUK was pushing back on GSK to get more volumes, to enter the market more effectively. It sought to get the best supply terms and push GSK to get better terms. You can see there, time and time again, the 23rd, 26th November, each time GUK pushing back  $\{V/1/120\}$ . Eventually we got up to the 750,000 packs. I will say more about the 750 number in a moment. As I have already said, it had a contingent claim for a cross-undertaking. It has been suggested that the cross-undertaking had no role to play in the negotiations. That is clear

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from the evidence, clearly incorrect.

1 Here, I would like to take you to  $\{L/2/1\}$ , which is a Richard Saynor email. That is a bad 2 reference, I am sorry. {B1/18/1}, apologies. This is an email, as you can see, from Richard 3 Saynor to Simon Clark of IVAX because, of course, we were getting supplies. 4 THE PRESIDENT: It is a letter. 5 MR. KON: It is a letter, yes. Apologies. I said email. 6 In the final paragraph, this is his latest kind of demands on pack size. They wanted 1 7 million packs, as you can see. So GUK were pushing the boundaries all the time to try to 8 get more supplies. 9 As I said before and I shall say again, what Mr. Saynor did not recognise was that of course 10 both IVAX and GSK had restrained themselves and mutually agreed that GUK could not 11 get more supplies than IVAX was getting, but he says at the end of that letter: "Please note that this letter should be considered without prejudice except in relation 12 13 to any question that may arise in the litigation relating to costs or Generics UK's 14 claim for damages on SKB's cross-understanding (should we win at trial)." 15 So clearly the cross-undertaking was very much in Mr. Saynor's mind, and clearly it was a 16 factor that was in the negotiation pot as far as GUK was concerned. 17 Sir, we made it clear that we would be seeking value from the cross-undertaking from the 18 beginning, or throughout the negotiations, perhaps to put it more accurately. The 19 suggestion that it was not a relevant factor or it was not something that was part of the value 20 that GUK was intending to extract from the settlement is misconceived. 21 As, indeed, whatever the criticisms are made of Dr. Reilly by the CMA that the evidence 22 before this Tribunal and, indeed, throughout the CMA proceedings has been very clear that 23 GSK was unprepared, was not prepared to grant an early entry agreement. As I said, that is 24 quite simply because, if you look at Article 2.2 and Article 1 of the IVAX side letter with 25 GSK, essentially the limits were predetermined. The parties, neither IVAX nor GSK were 26 free to offer GUK better terms than the terms that existed under those arrangements. 27 So all of this is going to the first point. 28 MR. GLYNN: Excuse me for interrupting again. Is there any indication of the value that your 29 client attached to this cross-undertaking? 30 MR. KON: The answer is not, because obviously in valuing a cross-undertaking it depends how 31 long one is excluded from the market for. So there is no clear evidence as regards what the 32 value was. 33 But I think if you think even in the best case scenario, if GUK would have won the 34 litigation in, say, April of 2002, they would have been excluded from the market for 7

1 months. As the only generic on the market, which would have been their position at that 2 time, it would have been very significant. 3 THE PRESIDENT: Well, the value would be presumably to the date of the agreement. 4 MR. MALEK: You have got four and a half months. The injunction was 23rd October. The 5 settlement was 13th March. That is about four and a half months. 6 MR. KON: Yes, at that point. 7 THE PRESIDENT: That's --8 MR. MALEK: If you say I want to -- it is actually quite often very difficult to claim under a 9 cross-undertaking. 10 MR. KON: I have done it, sir, and I agree with you. 11 MR. MALEK: It is so hard to prove the actual loss. 12 MR. KON: I agree. 13 MR. MALEK: Let us say you would have been able to sell half a million pounds, then it is a loss 14 of profit on half a million pounds. 15 MR. KON: No, but, sir -- that is certainly one way of looking at it, assuming that the agreement 16 was in place. But of course if you look at the counterfactual world, GUK would have -- with 17 the argument I am sure that GUK would have mounted, would be that we would have been 18 actually not limited in the quantities that we could sell because we would have 19 independently entered --20 MR. MALEK: That is why I chose 500,000, because this letter is saying "our required demand of 21 1 million packs a year". 22 MR. KON: I see. 23 MR. MALEK: That is why I got --24 MR. KON: I see. Perhaps that is a fair way of assessing. I agree entirely that assessing damages 25 under a cross-undertaking is the general (inaudible) line of authority and all of that, that is 26 incredibly difficult. I agree entirely with you. 27 But I think my only submission, the only way I need to put this submission is that it would 28 have been a substantial claim, it would not have been a de minimis claim. It was not at the 29 margins of the value that GUK was trading. 30 MR. MALEK: Look, the value of the cross-undertaking, the strength of that value depends on the 31 likelihood of you winning. If you have a 10% chance of you winning, the value of the 32 cross-undertaking is pretty minimal. If you have a 50% chance of winning, then the value 33 of that cross-undertaking, it actually does have some value once you get to that level.

1	MR. KON: If I may put it to you this way, I think it a fair way of putting this proposition that the
2	settlement in a sense should be seen as a recognition that both sides were capable of
3	winning. That is the point of compromise: both sides recognise
4	MR. MALEK: I think Mr. Flynn put that quite well yesterday. He accepts that, and
5	MR. KON: Therefore, insofar as what you are trying to do is strike a bargain, it is not
6	unreasonable to assume that GUK would have said, well, our cross-undertaking is worth X,
7	we are losing certain benefits by not being able to enter directly, and therefore there would
8	be a give and take.
9	MR. MALEK: Yes.
10	MR. KON: So coming back to the CMA's case, where do they take all of this? They essentially
11	say, well, none of this background, none of these other considerations are relevant, they say,
12	because what they say is and the words used by Mr. Turner were: they say the payment is
13	an unlawful deal clincher. I refer you to the transcript, Day 3, internal page 4, lines 15 to
14	16. Unless you want me to, sir, I will not take you there, but those are the words used.
15	He said payment was a deal clincher, and he relies upon Lundbeck to support that
16	proposition.
17	The words "deal clincher" used by Mr. Turner are in fact taken directly from Lundbeck.
18	Those are words used. If I may very briefly take you to paragraph 361 of Lundbeck to
19	demonstrate that to you.
20	{W/1/76} The very bottom of paragraph 361:
21	"The payments thus served as a 'deal clincher' and were decisive in convincing the
22	generic undertakings to abandon their efforts to enter the market."
23	That is where Mr
24	MR. MALEK: But if we take out the pejorative term "unlawful", or whatever, do you accept that
25	the payment was a deal clincher?
26	MR. KON: No.
27	MR. MALEK: You do not?
28	MR. KON: No. My submission to you, sir, is the following: that we submit that the <i>Lundbeck</i>
29	case weighed a whole host of factors in the overall assessment of whether it was an object
30	infringement or not, they undertook a balancing exercise of them, and that actually the
31	conclusion that was drawn when they used the expression "deal clincher" in the court
32	what we say the General Court is saying is it was and I am coming on to this submission,
33	but everything else fell into the shade as a result of the reverse payment in that case.

1	If I may, sir, if I may make good that submission to you and then perhaps follow up on your
2	question. We believe that when Mr. Turner, in using the word "deal clincher" in this
3	context, what he means is that it was the payment and only the payment that one needs to
4	take into account in assessing the fact that this is an object restriction, for the reasons I have
5	already submitted to you. We say that is an incorrect reading of Lundbeck, that is not what
6	Lundbeck was saying and that is not the context in which they were using the expression
7	"deal clincher".
8	MR. MALEK: There are two things here. One is whether or not in fact you accept that this was a
9	deal clincher in the sense that without these so-called reverse payments there would have
10	been no deal, and the second is whether you accept the spin on it that Mr. Turner puts on it.
11	I fully understand why you do not accept the second, but I want to go back to the first.
12	MR. KON: Yes, the first, I think, sir, I addressed in opening and Mr. Turner in fact referred to
13	what I said on that.
14	What I said was clearly the payment was a consideration, I go so far as to say an important
15	consideration, in the overall assessment of GUK entering into this agreement.
16	MR. MALEK: That is very realistic, thank you very much.
17	MR. KON: It would be disingenuous for me not to agree to that, but the reason why I feel
18	confident in making that submission is that on the CMA's submission the payment is the
19	root of the evil and is actually the basis upon which, as I have already submitted to you, the
20	conversion process takes place into an unlawful object restriction.
21	As we understand it, the CMA's case is that there is an inducement even if the payment was
22	simply a factor amongst others in the decision to enter into a settlement. In other words, as
23	long as there is a payment settled, the other matters are simply not necessary for the CMA's
24	case.
25	We say that is not what <i>Lundbeck</i> says. In <i>Lundbeck</i> at paragraph 361, the reference is
26	made that the payments thus served as a deal clincher and:
27	" decisive in convincing the generic undertakings to abandon their efforts to enter
28	the market."
29	What we say is in this case, not withstanding the paragraphs in the decision to which the
30	President referred me, which I do not think make this point, we say that in this case they
31	were not decisive.
32	What we say is the only way that Mr. Turner can make that point is really by the extreme

proposition to which I have referred. In Lundbeck we acknowledge and agree and, as I say,

1 without prejudice as to whether the court is right or wrong, the payments were found to 2 have been the driving force that led to the settlement. 3 If I could take you to paragraph 366 to make that point good {W/1/77}. Just the first two 4 paragraphs: 5 "... in the present case, the Commission relied on a body of evidence in the contested 6 decision to demonstrate that it is principally the size of the reverse payments to the 7 generic undertakings which induced those undertakings to accept the limitations 8 governing their behaviour and not the existence of Lundbeck's process ..." 9 So the emphasis there is on the size of the undertaking, principally the size of the reverse 10 payment in *Lundbeck*. 11 As we heard yesterday, one of the other factors upon which reliance was placed was the 12 profits that the generics could have expected to earn by entering the market. That is 13 paragraph 362 of Lundbeck {W/1/76}, although I do not think I need to take you to that. 14 I do not think it is in dispute that in *Lundbeck* the actual profits assessment as regards what the generics would have earned if they had entered independently as against if they had 15 16 entered under agreements, was a relevant factor. That is in paragraph 362, which I will 17 leave you to read but I will not read to you. 18 So in the overall analysis of what drove the generics to settle, the court in *Lundbeck* agreed 19 with the Commission that it was the payments which overshadowed, and I would like to 20 take you in this regard to 336 of *Lundbeck*, please.  $\{W/1/70\}$ : 21 "In other words, according to the Commission, the agreements at issue transformed 22 the uncertainty in relation to the outcome of such litigation into the certainty that the 23 generics would not enter the market ..." 24 It refers back to recital 641 of the contested decision. 25 You may have seen, sir, that one of the authorities I added into the authorities bundle was 26 the French version of Lundbeck. That is not because I was --27 THE PRESIDENT: We have not seen the authorities added. 28 MR. KON: I would imagine that that would be de trop, as they say, to expect you to read the 29 French version. But the word used in the French language version for overshadows is 30 "éclipse". 31 What the court is saying in this paragraph, using the English word "overshadowed" or 32 perhaps using a better word, and of course the French text is the binding text, "éclipse", is 33 that the payment overshadowed, it basically wiped out all other considerations. No such 34 case is made here by the CMA.

1 We say that that is a fundamental flaw in Mr. Turner relying upon the deal clincher 2 argument, in trying to say this was a deal clincher, because that is not a case which the 3 CMA has made out, and we say that is not open to Mr. Turner to maintain that submission 4 in the light of what *Lundbeck* decided and, indeed, to rely upon *Lundbeck*. 5 He can make the submission, of course, and I am sure he will, but what he cannot do is rely upon Lundbeck for that because Lundbeck decided something different. 6 7 MR. MALEK: I think he does rely on Lundbeck. 8 MR. KON: Yes, he does certainly. 9 MR. GLYNN: Do we know what the orders of magnitude are for your client of expected profits 10 on entry and of the reverse payment? 11 MR. KON: Yes and no is the answer to that, sir. You may recall that a point we made in opening 12 and a point that has emerged, actually, I think through some of the witness evidence, is that 13 the CMA had argued in its Statement of Objections that the value transfer under the 14 settlement exceeded the amount that GUK could expect to earn by entering the market 15 independently. 16 I will refer you to the relevant authorities for that because GUK went back, as part of the 17 procedure before the CMA, and actually argued that that was misconceived, and actually it 18 was an incorrect assessment of the position. 19 Initially, if I can put it this way, the CMA sought to make their case that in fact the reverse 20 payment overshadowed or eclipsed the amount that generics would have earned, GUK 21 would have earned. They withdrew that from their final decision, and no part of that 22 decision refers to this point. 23 If I may give you the references for that, sir, since it would be quite a lengthy exercise to 24 take you through that, and I am happy at any subsequent stage of the proceedings to address 25 it for you. If you look at the Statement of Objections at paragraph 7.175, for which the 26 reference here is  $\{A1/4/441\}$ . Annex D of the decision, again, paragraph D.21, which is 27  $\{A1/4/674\}.$ 28 THE PRESIDENT: Sorry, annex D --29 MR. KON: Of the decision. I am sorry of the SO forgive me. Paragraph D .21. 30 Then, as I say, in its response to the SO, GUK demonstrated that these calculations were 31 flawed and that the profits that GUK would have expected to earn from entering with its 32 own product were far greater than the size of the alleged value transfer. I can refer you to 33 our response to the SO if that would be helpful, sir, without going there perhaps now.

1	The response to the SO is dated 31st July 2013 at page 73 at paragraph 5.10(c)(ii), that can
2	be found in the bundles at {A5/83/73}.
3	As I say, it is abandoned in the decision, this point, the CMA having originally obviously
4	tried to replicate what it believed to be the Lundbeck situation, although of course
5	Lundbeck was not known at this time, but SO was known and it was a point made in the
6	Lundbeck SO. If I can perhaps take you back to the decision on this point as regards how it
7	was left in the decision, sir, and that is at $\{V/1/284\}$ .
8	MR. MALEK: What did you say were the profits that you would have earned? It is in there
9	somewhere.
10	MR. KON: It is a very long and complex calculation which was put forward by our economist in
11	relation to that.
12	MR. MALEK: They said in the Statement of Objections it is between 1.06 and £1.13 million over
13	three years. Okay? So I just want to know what your side would say.
14	MR. KON: Sir, can I revert to that?
15	MR. MALEK: You can do that at any time.
16	MR. KON: Perhaps after the short adjournment I can give you that figure. But perhaps I can
17	finish this point by simply saying that in the decision I think that has now come up at
18	6.114:
19	"From GUK's perspective, its actions demonstrate that it had determined the value
20	transfers would provide it with sufficient compensation for its acceptance of the entry
21	restrictions. It can be inferred that GUK considered provided it with expected
22	returns and that were higher than those associated with continuing with its efforts to
23	enter the market independently of GSK."
24	Then you can see the various references to that. That is the sum total.
25	THE PRESIDENT: What does one get from 6.131 about your estimate of the damages?
26	MR. KON: 6 point?
27	THE PRESIDENT: Page {V/1/289} at the bottom.
28	MR. KON: Could you go to that page? Page 289, please. Thank you. At the bottom?
29	THE PRESIDENT: Yes:
30	"On the basis of GUK's own estimate of the damages that GSK avoided from GUK
31	not entering the market independently, which totalled £4.1 million"
32	They explain the calculation. That, they say, was your estimate.
33	MR. KON: That may well be the figure that in terms of I think that goes to the cross-
34	undertaking.

1 THE PRESIDENT: Well, it is used by reference to looking at what might a cross-undertaking be 2 worth, but the value of the cross-undertaking, of course, is based on what profits you might 3 have made. 4 MR. KON: That may well be the figure, sir. That may well be the figure which Mr. Malek just 5 asked me for. But perhaps I could check and see exactly what our --6 MR. MALEK: I know it could just be a blind alley, but if you look at page  $\{V/1/290\}$  at the 7 footnote, they say that the lost profits figure of 20.5 million --8 MR. KON: Is not reliable. 9 MR. MALEK: Is not reliable. 10 MR. KON: Sir, my point in relation to this is a very simple point, which is that what the CMA 11 does not say at any point was that the profits that we would have earned under the 12 agreement with GSK completely overshadowed, completely eclipsed exactly what we 13 would have earned under independent entry. It is a point it sought to make, but it withdrew 14 it. 15 MR. MALEK: But you can eclipse or overshadow something without necessarily meaning all 16 your anticipated profits have been covered. 17 MR. KON: You can, but my submission, as you would have heard, is that we accept that the 18 value transfer, the payment is a relevant consideration in the overall assessment. But what 19 we are saying is in *Lundbeck* they undertook a very careful weighting exercise, they did not 20 simply say per se whatever the outcome was of the payment that that wiped out everything 21 else and you did not need to consider it. That, we say, is exactly what the CMA is doing in 22 this case. 23 We are saying that the proposition put forward by the CMA is a binary proposition in that 24 regard. In summary, we say that an anti-competitive object cannot simply be derived from 25 a payment from the originator in excess of litigation costs. It is only where the size or 26 nature of the payment, we say, completely eclipsed all other considerations, and in 27 particular the assessment of the patent situation, that any inference can be applied along the 28 pay for delay inference of Professor Shapiro. We say that is not something that the CMA 29 has done and, indeed, as we said, its overall proposition in these proceedings is far more 30 extreme than that. 31 THE PRESIDENT: In the decision they look at the cross-undertaking: can it be explained by the 32 cross-undertaking? So they carry out that analysis. 33 MR. KON: They look at the cross-undertaking, but that is not the basis upon which they 34 established an object infringement.

THE PRESIDENT: They look at it to see if it can be explained. The unexplained point is
addressed by reference to litigation costs. They looked at that. Cross-undertaking, looked at
that. Then it looks at subjective intentions, and that is the process they go through.
MR. KON: It is looking at the overall motivation behind the agreements. That, as I have already
submitted to you, is correct. But what we say is that is not the case that is being advanced
to this Tribunal. That is not the case that Mr. Turner has advanced to you.
THE PRESIDENT: You are saying he is not relying on the decision for those points, is that what
you are saying?
MR. KON: We are saying that whether he is departing from it or whether he is explaining what
the decision says, that he has advanced a very extreme proposition to you which we say
goes beyond that of even Professor Shapiro and which actually means that none of these
other factors on his own submission are relevant factors for the conclusion that this is an
object restriction.
I am the first one to accept that looking at these factors go into an effects case, but I say to
you it is almost unparalleled that in a situation where, actually which is what I am going
to go on to, what I imagine would be after a short break that in a situation where there is
clear evidence that there were consumer benefits, that you need to look at all these
circumstances within the context of an overall effects analysis.
To posit this as an object infringement, as a per se infringement, essentially, the way he has
done that is to ignore all of these other considerations as
THE PRESIDENT: No, I understand what you say about the effects case. I did not get the
impression that the CMA are seeking to advance a different case from the decision.
MR. KON: Well, I can only refer you to what
THE PRESIDENT: If they are, it certainly was not made clear that they are not relying on the
decision.
MR. KON: That may well be because to some extent they have been seduced by Professor
Shapiro, because of course Professor Shapiro's evidence has been pretty fundamental in all
of this. But as it so happens, we say in fact that not only have they been seduced by
Professor Shapiro but they have taken the analysis far further than even Professor Shapiro.
Sir, would that be a convenient point on which to stop?
MR. MALEK: Before we move on, if you look at 6.113 {V/1/283}:
"From GSK's perspective, its decision to make value transfers totalling at least £21.3
million can only be explained by its desire to induce GUK's acceptance of the entry
restrictions and to delay its potential independent generic entry."

1	Is Mr. Turner not really using shorthand when he says it is a deal clincher or he used the
2	word "overshadowed"? Is that not what they really mean? He is not creating a new case, he
3	is just putting a label on something which is already there.
4	MR. KON: Yes, but what there is not evidence of in this decision perhaps if I put it this way:
5	that Mr. Turner and the CMA talks in terms of unexplained payment. The only explanation
6	that they settle upon is the value transfer. In other words, they discount the other transfers
7	because, as I submitted to you already, they say the value transfer trumps all. If there is a
8	value transfer, irrespective of the size or nature of that value transfer, or payment, that in
9	itself completely wipes out
10	THE PRESIDENT: It has to be unexplained.
11	MR. KON: No. With respect, all
12	THE PRESIDENT: Irrespective of the explanation, it does not matter
13	MR. KON: From their point of view, by definition, once there is a value transfer, that value
14	transfer means that it is an unexplained
15	MR. MALEK: You say it is a self-fulfilling prophecy. A big circle you can just go round and
16	round.
17	MR. KON: I could not put it better myself. It becomes an entirely circular proposition. Thank
18	you.
19	Would that be a good place to break?
20	THE PRESIDENT: Yes.
21	MR. KON: Thank you.
22	(11.20 am) (A short break)
23	(11.30 am)
24	MR. KON: Thank you.
25	Sir, may I go on to my fourth point. I will return to the questions that were asked, which I
26	have some answers to, but if I may I will do it at the end.
27	THE PRESIDENT: Yes. So this is the wholesaler benefit?
28	MR. KON: Precisely, the wholesaler benefit. The question is, did the wholesalers benefit from
29	the agreement, and if so, does that matter and was this a benefit of the competitive process?
30	As I think Mr. O'Donoghue submitted, you will be forgiven for thinking that in order to
31	assess the likely impact of the agreements, the wholesalers are a silent party in the CMA's
32	decision, and we submit that it is important to consider how the agreements affected the
33	customers of the generics, and of course the customers of GUK were wholesalers.

1 You look in vain in the decision to find any material reference to wholesalers, and the 2 effects of the agreements on competition at the wholesale level are almost entirely absent. 3 Now, the CMA has sought to plug that hole, as we heard yesterday, in relation to 4 wholesalers and wholesaler competition in these proceedings. It has done so by advancing 5 a number of arguments that essentially seek to trivialise or marginalise the role or 6 importance of wholesalers in this market and the positive impact of the agreements on them. 7 Yet it is common ground that significant benefits were conferred on wholesalers and that these derive directly from the agreements. It was not just a random accident. This was 8 9 something that was entirely predictable from the agreements. 10 Let us first of all look at the evidence on the positive wholesaler benefits and then deal with 11 how these are addressed by the CMA. All of the experts have agreed that the agreements created materially greater competition to supply wholesalers. 12 13 Sir, if you look at Ms. Webster. Again, I will not take you to the transcript, but if you look 14 at the transcript of Day 11, internal page 61, lines 10 to 14 {TR/11/63}, Ms. Webster says: "... I do not dispute that on the basis of the numbers and even with an adjustment to 15 16 the parallel import price that is up to 5%," which is of course something she argued 17 for, "adjustment to prices that are in the decision, we are still in a position where the 18 wholesalers would have been receiving a price for the generic ... product that was 19 materially, you know, of the order of 10% below that of the parallel import price." 20 Again, in the joint experts statement -- I will not read this to you, but if you look at the joint 21 experts' statement, which is at  $\{1/2/9\}$ , paragraph 3, again, there is a similar agreement 22 amongst all the experts that there were significant benefits on wholesalers. 23 So those are the financial benefits on wholesalers. In addition, it is common ground that the 24 generic product was substantially a better product than the parallel imports which were 25 overstickered and all that went with that, and we have heard the evidence of Dr. Reilly on 26 that. 27 I will just refer you to {TR/6/62} and, equally, Sellick on {TR/7/9}, line 33. 28 Equally, and this is an extremely important point, it is common ground that absent the 29 agreements wholesalers could only purchase paroxetine on the parallel market because 30 GUK had withdrawn the supply of Seroxat from wholesalers under its direct to pharmacy 31 models. So from a wholesaler perspective this enabled them to source, in the absence of 32 Seroxat, paroxetine in circumstances where they would not have done otherwise. So it 33 materially improved their position and increased their choice; all important indices of

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competition, we say.

This, again, is not being challenged by the CMA. There is no disagreement that the agreements led to a displacement of parallel import. In addition, there is no disagreement that Seroxat was displaced and that was not a sequential movement, not a sequential process. The only reasons that Seroxat would have been displaced is because pharmacists switched from buying Seroxat to buying the generic product, otherwise it would not have been displaced. Pharmacists would not have done that unless there was some benefit to them doing so. I will come on to that now.

I am not going to say a great deal about the drug tariff price because of course that is essentially a case made by GSK. But we do know that the drug tariff fell; that is not in dispute. Yesterday, sir, you raised the question of whether the pharmacists benefited at all given that they were reimbursed the drug tariff price.

I think the answer to this is given in paragraph 16 of Mr. Horridge. If I could just take you there because I think that explains quite a lot. It is at  $\{E/4/5\}$ , paragraph 16.

He explains that:

"Because the reimbursement value [that is the drug tariff] was usually (although not always) higher than the aggregated Contractors' purchase price ..."

The contractors are, I can take you to it, the pharmacists.

THE PRESIDENT: Yes.

MR. KON: "... this led to a `retained profit' for Contractors. It appeared to those of us outside the DH that this was tolerated to a degree because it incentivised Contractors to negotiate better prices with pharmaceutical companies with the objective that they could keep some of this gain for themselves. From time to time, there was ... "

What was called -- and I do not know if this is on your radar, sir, but from time to time there was:

" ... a discount inquiry to seek to 'claw back' as much of this excess profit as possible for the NHS. However, in my experience it was well understood that pharmacists were typically `one step ahead' and would always find a way to retain some profit."

You may recall, sir, that you chastised me during the cross-examination of Ms. Webster that I was actually making submissions; quite rightly, sir. This was the point I was putting to her, that there is an arbitrage that takes place between pharmacists and wholesalers. They are being reimbursed, as you rightly observed yesterday, the drug tariff price. Their deal is to try to get the best deal they can from their wholesaler price, and therefore they hope that this will not be clawed back. Mr. Horridge goes on to explain that the clawback is a very rough and ready instrument and it does not normally claw back the total profits that are

2	inquiry after paroxetine was launched generically.
3	I believe this does respond to the question you raised, sir, with Mr. Flynn yesterday.
4	THE PRESIDENT: Yes. Thank you.
5	MR. KON: How does the CMA deal with this evidence? I think it is dealt with and summarised
6	very well in paragraph 101 of the CMA's closing submission, where they say such lower
7	wholesale prices is not the result of any competitive process.
8	I will just read this to you I do not think I need to take you there:
9	"They were just the application of standard wholesaler percentage mark-ups to a
10	generic product that happened to have a high pharmacy price. The lower wholesale
11	prices were therefore just part of the swings and roundabouts [according to the CMA]
12	that wholesalers experienced across their portfolio."
13	So he says that Dr. Majumdar, the CMA says, was wrong to characterise the low generic
14	prices to wholesalers as reflecting an increase in competition, it was just a swings and
15	roundabouts exercise. It may have been there, it may not, but nonetheless there was clearly
16	a significant benefit.
17	In that regard, we say the CMA misses a fundamental point. There was competition
18	between the entrants and parallel importers to supply wholesalers. This is agreed by Ms.
19	Webster in the joint statement where she says where she agreed this is page 9 of the
20	second joint statement, paragraph 3 {I/2/9}:
21	" if it were the case that wholesalers were able to obtain the new source of
22	paroxetine at a material discount to parallel imports, this would imply that there is
23	greater competition to supply wholesalers."
24	That is on page 9, as I have said, and you can see it in Ms. Webster. Could somebody point
25	that out to me? Yes, there it is in subparagraph 3.
26	The CMA also tries to deal with this wholesaler point by claiming that the wholesaler terms
27	are standardised. But this is absolutely not true, at least so far as GSK is concerned.
28	Mr. Collier's evidence is very, very clear on this, and you may recall that I took Ms.
29	Webster to that. But if I could briefly take you to that for one moment, it is at $\{F/1/7\}$ .
30	Paragraph 20 of Mr. Collier's evidence.
31	This is in relation to GUK:
32	"In relation to GUK's argument that '[t]here is no basis to assume that [my evidence]
33	applies across the board and/or indeed bears any relevance to GUK's position' my

gained by the pharmacists. Equally, he goes on to explain that there was in fact no discount

1 recollection is that, unlike Alpharma, GUK did not have a scheme in place at the time 2 and therefore its prices to wholesalers may have been individually negotiated." 3 We have seen this paragraph before. 4 THE PRESIDENT: Yes. 5 MR. KON: But it clearly is not correct for the CMA to suggest that there is no competition 6 because everything is standardised. 7 On this basis we do not see any response to the wholesaler competition point, which the 8 CMA has -- as I say, they endeavoured to trivialise it. They come up with a number, we 9 say, of entirely misconceived submissions to try to explain that this is not real competition. 10 We say that on this basis alone, this could not possibly be an object infringement case. As I 11 have already said, we do not consider these are matters for 101(3), for the reasons I have given you. These issues of wholesaler competition go directly to the question of restriction 12 13 by object. 14 We say that where an agreement delivers significant benefits to direct customers, that agreement cannot be said to reveal in itself a sufficient degree of harm to competition and 15 16 further analysis is required. 17 That analysis can only take place on the basis of an effects assessment. The only reason 18 that is being offered, we say, to justify finding an objects infringement is essentially that 19 more competition could have prevailed in the event of independent generic entry. But that 20 essentially requires a counterfactual analysis, that more competition could have prevailed. 21 A failure to create more competition, we say, cannot be an object infringement. If the CMA 22 wants to run a counterfactual case, they can do so, but then they have to engage in a proper 23 effect counterfactual analysis. But this can only be done on that basis, and we say that they 24 have singularly failed to do that, and clearly that is a further submission that I shall be 25 making shortly. 26 They have not undertaken a proper effects analysis. Our next submission is does pass-27 through matter, because of course given the characterisation by the CMA this is not real 28 competition at the wholesaler level, it begs the question as regards pass-through. 29 GUK, as we said, sold almost exclusively to wholesalers. Therefore, the extent to which the 30 significant benefits GUK conferred upon those wholesaler customers was passed on or was 31 not passed on is really not a matter for GUK. It was ultimately the decision of wholesalers 32 whether and to what extent to pass through the price reductions to pharmacies. Therefore, 33 we say it would be entirely unprecedented, and we would go as far as to say absurd, to find

that GUK breached competition law, because the significant benefits that GUK conferred

upon wholesalers were not passed on by those wholesalers, over whom obviously it had no influence, to pharmacies. We say that is simply not something you would expect or want GUK to be concerned with.

In any event, the evidence is that the price to pharmacists went down. It is in dispute as regards by how much. So far as Ms. Webster is concerned, departing from the decision, she endeavoured to rely upon Mr. Collier in order to find that there was a relatively modest pass-through to pharmacists. In fact, as we have said, Mr. Collier made it clear that he had no idea what actually the terms were that GUK was passing on to pharmacists, so there is no way they can establish that.

Dr. Majumdar, as you know, estimated that pass-through at 7%. We do not believe that Ms. Webster had any reply to that. I refer, if I may refer you there, to the second joint experts' report, point 5.1, issue 14, page 68.

In their closing, the CMA criticised Dr. Majumdar's evidence by asserting that he had no sound economic basis by which the benefits of the settlement could be expected to reach pharmacists. But, with respect, it is not for GUK to assess the level of pass-through, but for the CMA to do so, and both Professor Shapiro and Ms. Webster acknowledged that the best way to investigate the question of pass-through was by the CMA undertaking its own empirical assessment of pass-through from data, which it could have easily obtained from wholesalers on the price but which they failed to do for reasons that only they can tell you. If I could refer you to -- I will not take you there given that I am already going to run over by a few minutes -- Professor Shapiro, {TR/9/60}, internal page 58, lines 5 to 6. He says:

"... the best thing would be to look at the data? I think it is obvious."

That is in cross-examination.

Webster similarly, in {TR/11/72}, line 5, she said:

"If one can get the data it is helpful to look at the data."

But the CMA, it would appear, failed to take any steps to get the data and preferred rather than that to simply make a series of assumptions in relation to the data, which Ms. Webster tried her valiant best to explain, but which actually is not in any way part of the CMA's decision and which we say, in any event, is drawing inferences where what the CMA should have done is to produce the data to this Tribunal.

THE PRESIDENT: Was this point you make about the wholesalers made in response to the SO?

32 MR. KON: I am sorry, sir?

THE PRESIDENT: Was the point that you are addressing us on now, about the benefit to -- pass-through from wholesalers to pharmacies, was that made in response to the SO?

- 1 MR. KON: The answer is at the time the CMA was not arguing in its statement of objections the
- 2 same issues as it is making now as regards prices not having moved.
- 3 | THE PRESIDENT: But you are saying these agreements brought a benefit to wholesalers.
- 4 MR. KON: Yes.
- 5 THE PRESIDENT: And to pharmacists as a result.
- 6 MR. KON: Yes.
- 7 THE PRESIDENT: That is your argument.
- 8 MR. KON: Yes.
- 9 THE PRESIDENT: Therefore, there is a benefit under the agreement, a competitive benefit.
- 10 MR. KON: Certainly GUK made the point that there were benefits conferred by these
- 11 agreements.
- 12 THE PRESIDENT: On wholesalers?
- 13 MR. KON: Yes, because wholesalers were our only customers.
- 14 MR. MALEK: But did you make the point that those benefits would have passed through from
- the wholesalers --
- 16 THE PRESIDENT: To the pharmacists.
- 17 MR. MALEK: -- to the pharmacists?
- 18 MR. KON: As I say, the CMA made a slightly different case in its own statement of objections.
- 19 THE PRESIDENT: But in your case, you were responding to an allegation of the agreements --
- 20 MR. KON: Sir, I will need to refresh my memory.
- 21 THE PRESIDENT: You do not have to answer it straightaway, but at some point it would just be
- 22 helpful to know, I think.
- 23 MR. KON: Sure. Sir, on objects that is all I have to say.
- 24 My next question -- I think it is my fifth -- is: does the CMA have an effects case?
- 25 THE PRESIDENT: Your sixth?
- 26 MR. KON: It is my sixth, I do apologise. It is numbered paragraph 7 in my notes, which makes
- it particularly confusing. That is because I have an introduction.
- 28 | MR. MALEK: Well, I am on point 8 now. As I say, I do not know how I managed that.
- 29 MR. KON: We say that the CMA's cupboard is entirely bare on its effects case. It is bare on
- pricing because it does not at all address the reduction of prices to wholesalers, as we have
- discussed, and that is an effects analysis. It focuses almost entirely on prices to
- 32 pharmacists, and therefore on that ground alone it has no -- it has not made out an effects
- case from the point of view of pricing to wholesalers, which we say on any basis is relevant.

1 The second reason why we say the effects cupboard is bare is because the CMA has not 2 undertaken any meaningful counterfactual analysis, and this is something you heard from 3 Mr. O'Donoghue on yesterday. Its case on the counterfactual analysis is that an anti-4 competitive effect can be derived from the mere fact that absent the agreement there was a 5 possibility that more competition would have materialised. 6 That essentially is its case, absent the agreement --7 THE PRESIDENT: That converts almost every objects case into an effects case, does it not? 8 MR. KON: Well, potentially every objects case is an effects case. 9 THE PRESIDENT: Well, it might be, but just because it is an objects case it is not, therefore, an 10 effects case as well. 11 MR. KON: No, but for reasons we have submitted that we do not believe this is a case that can 12 possibly be in the objects box for the reasons I have already submitted, and therefore, given 13 that the -- if you look obviously at Lundbeck, the Commission did not seek to make an 14 effects case. 15 THE PRESIDENT: Yes. 16 MR. KON: In Servier, of course, we know it does. It does both in terms of 101. Therefore, the 17 CMA took the decision to actually cover both objects and effects and take the decision that 18 this was an infringement by both objects and effects. What we say is it essentially did not 19 undertake a full and proper effects analysis. It was open to it to do so. It most probably had 20 much of the material to do so, but in some key areas it simply abstained from doing so. The 21 essential case being put forward by the CMA, I think, is based on the Visa case. 22 He sought to overcome the essential absence of a counterfactual analysis by saying that the 23 loss of a chance of entry is sufficient to establish anti-competitive effects. Mr. O'Donoghue 24 did submit to you on Morgan Stanley Visa yesterday -- the case as Mr. O'Donoghue 25 submitted to you was fundamentally different. In that case there was no question that 26 Morgan Stanley had the ability to enter the merchant enquiry market. The only question 27 was whether it intended to do so, and I can take you to pages of Visa given the shortage of 28 time. 29 MR. MALEK: I think Visa was dealt with --30 MR. KON: Visa was dealt with quite fully yesterday --MR. MALEK: I think it was. 31 32 MR. KON: -- and I agree. All I would say is, here, the situation is the reverse of Visa. GUK's 33 intention and wish to enter the market is not in doubt. As I have said, in Visa the real issue

was that Morgan Stanley did not have a real intention.

Just very briefly, the point in Morgan Stanley was they wanted to actually issue Visa cards, but there was severe doubt in the minds of Visa whether they wanted to acquire the merchant acquirer as well. So they questioned their intention. Here, there is no question that we intended to do -- that is exactly what drove us to enter the supply agreements, because we were prevented, as I have already submitted to you, from entering the market. So we say that Visa does not support the proposition that the mere possibility or a chance of being able to enter a market can establish a sufficient counterfactual, which is the argument, as far as I understand it, that Mr. Turner put to you. Then, when you look at the actual counterfactuals put forward, we say, again, these do not bear scrutiny. The first counterfactual is the better terms counterfactual, but this is not sustainable in the way it is advanced by: nothing of substance is advanced in the decision to support this counterfactual and it is based no more than on a hypothesis that absence of value transfer, the parties could have entered into a royalty agreement, with unrestricted volumes or some other form of agreement providing for early entry. Not only is there no evidence that this was the case -- and indeed, one thing I would like to point out to you is that there is evidence that GUK was prepared to contemplate a royalty agreement. If I could refer you to the decision -- I will not take you there unless, again, you wish me to, but it is the decision at paragraph 3.289, which is  $\{V/1/121\}$ . There is also an email from Howard Rosenberg to Mike Urwin and others dated 29TH November 2001, which is  $\{A5/90/1\}$ . But what is clear is that GUK did actually consider a royalty agreement, which, as we have heard already, and it is not something that GSK has resiled from in these proceedings, they were not willing to grant such a licence. Now, Dr. Reilly put forward the integrity of the patents being undermined, and that is something you heard Mr. Flynn on yesterday and I do not have anything further to say on that as regards what GSK's thinking may be, distinguishing between a distribution agreement and a royalty agreement. But of course there is one other fundamental reason, from a GSK perspective, that was not done. It is because the pre-existing IVAX agreement which we were bound to mirror, although, as I said before, we did not know this at the time, that defined exactly what GSK could offer and could not, and a royalty agreement was not that. It was simply not possible for GSK to offer us that.

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So that counterfactual breaks down completely, and the second counterfactual equally breaks down completely. This comprises no more and no less than the same old arguments advanced in the objects infringement that interfering with the process of competition by not continuing the litigation to the bitter end in itself constitutes a restriction of competition. Now, we do not resile from the fact that settlement of litigation is part of a competition process. That would be foolish for us to do that. But clearly, if you continue litigation firstly as a counterfactual, you could win or lose, as we have discussed. It may be, as the President said -- I recognise that he said, well, if you lose, that is the product of competition. But what we say is that litigation is not the sole basis of competition, and if you are going to take a view on a counterfactual basis, in looking at the effect of the litigation you have to take in terms the length of the litigation process, when GUK could have entered the market and any incremental benefits on competition that are likely to have been caused by GUK's independent entry. In short, the CMA fails to provide any reason to expect that the distant possibility of greater competition in the future and the speculative effect of litigation was a viable counterfactual.

It may be that the CMA could have achieved this in a counterfactual analysis, but it does not do this in the decision, and it does not do it because essentially it is simply repackaging its objects case, which of course does not depend on a counterfactual analysis.

In closing on the counterfactual, there is one other point I would like to mention. The CMA seem to be suggesting a third alternative counterfactual in their closing, and that is that GUK could have taken a route and other generics could have taken a route of introducing a paroxetine product by using a different salt -- I do not know whether this resonates with the Tribunal -- and they mention the mesylate salt. It is at paragraph 163 of the CMA's closing. Sir, I can take you there if you wish me to? Perhaps I can continue and if you wish to go there I shall do so.

I mean, essentially what they say -- perhaps one can go there {M/6/67}, paragraph 163. He refers to *Lundbeck* and talks about different routes to market, and he said this includes litigation, which is of course the counterfactual I have been talking about:

"In the present case, GUK and Alpharma were engaged in litigation, whereas the evidence of Ms. West shows that a different route was to introduce a paroxetine product that did not infringe patents GSK's patents ..."

That submission is fundamentally misconceived for two reasons. First of all, the *Synthon* case is fundamentally different. I have put in the bundle the House of Lords judgment in the *Synthon* case.

1 Synthon had its own mesylate patent and there was a significant patent dispute between 2 Synthon and GSK in relation to mesylate, which began at fist instance before Mr. Justice 3 Jacob, because following Synthon prosecuting its own patent, GSK prosecuted its own 4 patent for a paroxetine mesylate salt and that was challenged successfully at first instance 5 by Synthon. Therefore, Synthon would have been able to come on to the market with its own mesylate product without infringing GSK. 6 7 Subsequently, Mr. Justice Jacob's judgment was overturned by the Court of Appeal. That was subsequent to that on 7th March 2001. Forgive me, I am sorry. The Jacob judgment 8 9 was 3rd December 2002. Then it was overturned subsequently in 2003 by the Court of 10 Appeal. Then, ultimately, on 20th October 2005, the revocation of the patent, the SB patent 11 was confirmed by the House of Lords. In other words, the Court of Appeal judgment was 12 overturned. 13 Therefore, if one strips that back until October 2005, the patent situation was at large in 14 those situations and it took Synthon some eight years to overcome GSK's patent challenge. 15 There is actually an even more fundamental reason why Mr. Turner's alternative 16 counterfactual here is wrong, and if I may I would like to just take you to a judgment of the 17 CJEU, the Court of Justice, in relation to that. 18 THE PRESIDENT: Just before you do that, you said you put the House of Lords judgment in the 19 bundle. 20 MR. KON: The House of Lords judgment is in the bundle. 21 THE PRESIDENT: Can you give us a reference. 22 MR. KON: The House of Lords judgment is at {Auth-P/1/3}. 23 THE PRESIDENT: We do not need to see it now, just to get the reference. 24 MR. KON: As I say, there is an even more fundamental reason why this counterfactual is entirely 25 misconceived, and that, if I may, sir, I would like to take you to. 26 If I could take you to the bundle {Auth-P/2/5} and paragraph 16 of the CJEU judgment. 27 Sir, I will take you to the paragraph in a moment, but just to contextualise this. 28 THE PRESIDENT: Sorry, just one moment. This is P. I am a bit old-fashioned on the 29 judgments. 30 MR. KON: I am very much the same, which is why I can never find it when I look on screen. 31 THE PRESIDENT: This case is called? 32 MR. KON: It is *Synthon*. This is the *Synthon* European Court of Justice judgment.

THE PRESIDENT: This is European Synthon.

1 MR. KON: The background to the case was that Synthon applied for marketing authorisation for 2 its mesylate salt, as I am sure Mr. Turner would have encouraged them to do, and that 3 marketing authorisation was rejected by the licensing authority. That was challenged by 4 Synthon before the provisional court by way of judicial review. 5 The case was referred to the ECJ as regards whether the rejection of that marketing approval was lawful or unlawful. Really, I do not need to take you to the judgment, but I 6 7 will tell you what it did decide. 8 But the key point is paragraph 16, where it says: 9 "By letter of 19th January 2001, the Licensing Authority informed Synthon that it 10 would not accept its application for mutual recognition. That decision was based on 11 the Licensing Authority's general policy pursuant to which medicinal products containing different salts from the same active moiety could not be considered to be 12 13 essentially similar." 14 As you know, the basis for granting a marketing authorisation for a generic -- the legal test -- is the generic essentially similar. 15 16 So Mr. Turner is actually suggesting as a counterfactual a situation where at the relevant 17 time it would have been not possible to get a marketing authorisation for an alternative salt, 18 and therefore that offered no counterfactual at all. That offered no option at all. 19 MR. MALEK: Was this option even referred to in the decision? 20 MR. KON: No, that is why I put it forward as an alternative counterfactual. Absolutely not. But 21 given that Mr. Turner considers this to be a counterfactual, I think it is -- just by way of 22 interest, if nothing else, Synthon won its challenge before the European Court and 23 subsequently was successful in getting a further judgment of the European Court that the 24 licensing authority committed a serious breach of community law to give it a right for 25 damages against the licensing authority. 26 MR. MALEK: I see who the legal team was. 27 MR. KON: Thank you, sir. 28 So to move on, and finally -- this is very quick -- we have dealt with objects, we have dealt 29 with effects, and the final question really, because I would not want it to be overlooked, is 30 whether the no grounds for action decision in relation to IVAX was over-cautious or 31 correct. 32 We say quite simply we rely upon the submissions we have already made. It is very, very 33 easy to lose sight of this VAEO point. We think it is an important point. We think there is

no reason why, if IVAX was correctly decided, the same should not apply to the GUK

1 agreements. In that regard, the only difference identified by the CMA, you will recall, is the 2 horizontal aspects of that decision. 3 We have already made it clear that (a) we think that a non-compete such as in issue here is 4 something that is covered by the block exemptions, the EU block exemptions and is not 5 unusual in a distribution agreement to have a non-compete. We would only note that in Mr. Reilly's cross-examination, which is relied upon by the CMA in its own written closing, Mr. 6 7 Reilly noted, and this is relied upon by the CMA, that it was not envisaged that IVAX 8 would enter the market independently alongside the agreement as they were on the market 9 selling a product, so why would they challenge GSK from a legal perspective? That is 10 paragraph 64 of the CMA's closing. 11 That just reinforces, in our view, the submissions we made in opening as regards why what 12 is good for the goose is good for the gander, and as far as we are concerned we are entitled 13 to not be -- I think the way Mr. Malek put it -- significantly disadvantaged compared to 14 IVAX. 15 Certainly we believe we are in an identical position to IVAX, and we would urge you, 16 despite obviously all the other important issues in this case, not to lose sight of that 17 fundamental but, we say, very simple way of addressing this case. 18 Sir, I am going to hand over to Mr. Humpe for literally a few minutes to deal with fines. I 19 do have some answers to the questions you raised, if I may. 20 THE PRESIDENT: Yes sure. 21 MR. KON: I will try and deal with them now. 22 The first one is the question raised by Mr. Malek, which is: the cross-undertaking damages, 23 was it valued? Actually, this is addressed in the decision in terms of what GUK valued it at 24 etc. You may wish to go there or you may just wish me to refer you to it, but it addresses 25 exactly the points that Mr. Malek had in mind. It is footnote 946 on page 287 of the 26 decision. The reference for that is  $\{V/1/287\}$ . 27 Sir, perhaps I could leave you to read that yourself rather than me read it to you. 28 As you can see, the significant point about it is that GUK valued the cross-undertaking 29 exactly as Mr. Malek suggested it might be, at £20.5 million. But then if you discounted it 30 on the basis that GSK had a very good chance of winning the litigation by 80%, that is 31 where the £4.1 million figure came along that I think Mr. Malek referred to. 32 MR. MALEK: Then you have to look at page 290, at the footnote 952 as well. I think you have 33 to read them both of them together.

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MR. KON: Yes.

THE PRESIDENT: Just while we are on that, was the 4.1 million, which is the figure the CMA 1 2 came up with on the basis explained in footnote 946 --3 MR. KON: It was an estimated figure based on an 80% discount, yes. Starting from the 20.5 4 million figure. 5 THE PRESIDENT: Yes. Was that challenged in the Notice of Appeal? 6 MR. KON: No. 7 THE PRESIDENT: That is not. 8 MR. KON: Sir, it is based on -- you may recall -- the second point which was raised, which was 9 what was the likely profits that GUK was going to make. These figures are based on the 10 annex 1 of the confidential response submitted by GUK to the Statement of Objections, 11 which is at  $\{A2/6/1\}$ . It may be worthwhile going there. If one could go to internal 12 numbering 27. 13 THE PRESIDENT: This is A2/6, page 1? 14 MR. KON: This is  $\{A2/6A/28\}$ . 15 THE PRESIDENT: Thank you. 16 MR. KON: I will not take you through the whole document, but the question raised was how did 17 the economists approach the question of the profit GUK would have earned as against the 18 profit that it obtained or was likely to obtain under the settlements. As you can see there is 19 a number of hypotheses depending on cost of capital and various other elements and 20 depending on how long the agreement went to. 21 That is also where the cross-undertaking question came in, but because this aspect of the 22 Statement of Objections was not pursued by the CMA, it forms really -- other than in the 23 footnotes that you referred -- it does not form the material part of, if you like, the 24 assessment in the decision. 25 THE PRESIDENT: Except on valuing the cross-undertaking. 26 MR. KON: Except on valuing the cross-undertaking, exactly. 27 THE PRESIDENT: Yes. 28 MR. KON: Then the final point you raised was in relation to -- well, perhaps this is a point that I 29 am just coming back for more on: the deal clincher point. 30 The one point I would make in relation to the deal clincher, you could argue, sir, on the deal 31 clincher point in response to Mr. Malek's question to me earlier that another reason why it 32 would be wrong to consider the reverse payment as a deal clincher was, of course, this was 33 a settlement that occurred at the doors of the court just as we were about to go in to settle

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the litigation.

1 So if you had to identify what a predominant motive was on a temporal basis, arguably the 2 timing of the settlement, one would argue that at least as important as anything else were 3 the litigation concerns that I referred you to. 4 Sir, unless I can assist you further. 5 MR. MALEK: Just one thing. Can someone give me by the end of today the reference to the document on page  $\{V/1/290\}$ , the last document referred to. It has a "document 0955" on 6 7 it. 8 THE PRESIDENT: Subparagraph (iii) of footnote 952. 9 MR. MALEK: Yes. 10 MR. KON: I am sorry, sir, which footnote is that? 11 THE PRESIDENT: It is footnote 952, (iii) {V/1/290}. It is just a cross-referencing. 12 MR. MALEK: Thank you. 13 MR. KON: Sir, Mr. Humpe will say a few words on fines. 14 THE PRESIDENT: Can I just ask you one thing. Under the agreement you made, and if the --15 you, I mean your client obviously, GUK -- if BASF had succeeded fully at trial, and indeed 16 on appeal, and the patent had been completely invalidated, you still could not enter before I 17 think June 2004, even though there was no patent obstacle. You had agreed to keep out 18 other than as a --MR. KON: Well, sir --19 20 THE PRESIDENT: How does one explain that in terms of -- compared to an anti-competitive 21 object? 22 MR. KON: I think there are two points to make. Firstly, that of course if that had occurred, the 23 IVAX agreement would have terminated, and while there were alternative -- because that 24 was provided for in the Norton IVAX agreement, if I remember rightly. 25 THE PRESIDENT: The IVAX agreement with whom? 26 MR. KON: With GSK. Therefore, we would have had no distribution agreement with IVAX. 27 Sir, in practical terms I believe that under the terms of the agreement it would have been an 28 entirely impractical proposition for us to continue to operate under the IVAX agreement. 29 The question would arise whether GSK would then insist on supplying --30 THE PRESIDENT: Yes, were you not entitled then to supply from GSK direct? 31 MR. KON: We were entitled to supply from GSK direct, and as I say, the question would be: 32 would GSK at that particular point do so? There are provisions in the agreement whereby 33 in the event that GUK would walk away from the agreement, in other words would breach 34 the agreement, there were certain provisions to cover that, which was a kind of form of

1 liquidated damages assessment. While, of course, it is an undesirable proposition on the 2 one hand to say if the agreement collapsed GUK would have walked away from that 3 agreement, I think almost inevitably that is the result, and the result would have been that, 4 as you heard from GSK and from Mr. Flynn yesterday, in the event that had occurred, 5 and if one is looking at a counterfactual world at least, then the same would have applied, 6 which is GSK would not have pursued the litigation in those circumstances in the same way 7 as it did not at the --8 THE PRESIDENT: I am not really looking at counterfactual. I am looking at it by object. You 9 may say an agreement which is ostensibly anti-competitive should not be regarded as such 10 if the parties might have breached it and not enforced it. 11 MR. KON: I understand. 12 THE PRESIDENT: That is a difficult argument, I think. 13 MR. KON: I do not think that in any sense that detracts from my primary proposition that what 14 the GSK agreement did was to allow GUK to bring onto the market a more competitive 15 product. That is why we say it cannot actually be an object restriction. 16 It is very difficult to know what the outcome would have been. I mean --17 THE PRESIDENT: If you look at it, at the date of the agreement, what it says, you are allowed to 18 bring on a certain volume of paroxetine sourced from GSK. 19 MR. KON: Yes. 20 THE PRESIDENT: Whatever happens to the patent, you cannot source your own and come in as 21 a fully competitive generic before June 2004. You make that agreement at the time when a 22 trial which will test the patent is about to start. 23 Looking at it as at that date, I do not think it is a question of counterfactuals. How does one 24 look at that in an object sense? 25 MR. KON: I think one looks at it on two levels. One level one looks at it is that clearly 26 reinforces the advice and the position I believe that Mr. Urwin's correspondence reflects. 27 You will recall it was something you addressed me on in my opening when Mr. Urwin said 28 we have been advised that we are unlikely to get onto the market until the end of 2003. You 29 will recall that email from Mr. Urwin. 30 I think what it does do, it reflects a very realistic assessment by Mr. Urwin that in terms of 31 the give and take of making a settlement, that that enabled -- I mean, GUK wanted -- the 32 one thing GUK cannot be criticised of is not trying to get onto the market. It is the only 33 company that went to court on a full hearing of an interim application to get onto the 34 market.

Rightly or wrongly, Mr. Urwin took the view as a commercial man, not as a patent lawyer and not as an expert in relation to these matters, that he was not going to be able to get onto the market, whatever the outcome of the litigation was, until about the end of 2003. He was also trying to get the maximum possible volumes from GSK, and you have seen the decision where he keeps pushing back on the volumes that he is getting and he does not get the volumes he wants.

My response, sir, is quite simply that it was not in any sense an anti-competitive object in the sense that Mr. Urwin would have any recognition that he was going to, so to speak, behave in an anti-competitive manner against his own company, but rather it was the give and take of the negotiations which took place with GSK where, rightly or wrongly, he formed an assessment, which we all do from time to time and get it wrong, that I believe we are going to be out of this market for three years.

It is an interesting question of why GSK insisted on a three-year term or whether it did, or whether it was just part of the give and take of the negotiations. We would say it is part of the give and take of the negotiations, and there was nothing anti-competitive about it. It was simply, as I say, a recognition, rightly or wrongly, by Mr. Urwin that he was not going to get onto the market until about then in any event, and so better he had the protection for the duration because, who knows, GSK may not renew etc. It was a commercial decision.

THE PRESIDENT: Yes. Thank you. Closing submissions by MR. HUMPE

MR. HUMPE: I would like to briefly address you on the question of fines, if I may.

THE PRESIDENT: Yes.

MR. HUMPE: Our primary submission on fines is that the statutory test of intention and negligence has not been met in relation to the alleged infringement. We also made some submission in our Notice of Appeal that goes to the level of the fine, but we do not intend to repeat those here. I intend to focus on the question of intention and negligence.

It is common ground that in order to establish intention or negligence, the CMA must demonstrate that GUK must have been aware, or could not have been unaware, or at least ought to have known, that its conduct would restrict competition.

We say that it is not possible in this case to sustain that GUK could have known or foreseen that the settlement would be deemed to restrict competition. We say this for three reasons. My first submission on this goes to the question of novelty of the alleged infringement.

The CMA does not dispute that at the relevant time there was no precedent that this specific form of agreement wasn't competitive. There was not a single case, 15 years ago, in which a settlement of a patent litigation had been found to restrict EU or UK competition

law. That was despite the fact that patent settlements were quite common. We therefore submit that there was nothing to alert GUK to the possibility that its conduct could be deemed to restrict competition. That is particularly so, in my submission, when you consider the novelty element in conjunction with three factors. The first factor is that the settlement did not exceed the scope of the patent. The second factor is the one we have been discussing a moment ago, which is that the settlement involved a supply agreement that enabled GUK to get on to the market. The third factor, which is equally important, is that GUK had a cross-undertaking in damages, and therefore there was a good reason for GUK to get compensation for releasing GSK from its liability. In fact, my submission is that a payment was entirely legitimate in these circumstances. That is also something that Professor Shapiro I think has conceded in his evidence. In fact, it would have been very odd not to have a payment in those circumstances. But our submission is that GUK could not have foreseen that a payment would in these circumstances be anti-competitive. So that is the first submission around the novelty of the alleged infringement. The second submission which reinforces the point on novelty is the treatment of the IVAX agreements in comparison to the GUK agreement. We have heard a lot about this already, but in my submission the fact that the IVAX agreement, which to all intents and purposes is largely identical to the GUK agreement, was found by the CMA to fall within the scope of a block exemption reserved for what were at the time considered to be benign vertical agreements, also underscores why it cannot seriously be maintained, in our submission, that GUK ought to have known that its conduct would be deemed to restrict competition. My third submission is that in looking at the question of intention or negligence, it is also very important to take into account the circumstances in which the settlement was entered into, and we have heard about these circumstances today, so I will be brief. But in my submission, there are at least four important factors to consider here, and the first is that GUK had made significant investment in its product but it was injuncted. That, of course, then leads to the second factor, which is that GUK was financially exposed, and so long as the injunction remained in place it could not enter the market, while of course at that time IVAX was already on the market. The third factor which led in to the decision to enter into the settlement was that the litigation was complex, and despite vigorously pursuing its litigation against GSK, GUK had a real concern that it would not prevail.

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That leads me to the fourth factor, which is also one of the driving forces behind the decision to enter into the settlement, which is that from GUK's perspective, the settlement unlocked access to the market and gave GUK the means to immediately supply paroxetine to its customers. The evidence which we have discussed today has established that those customers, the wholesalers, derived very significant benefits from the agreements, and that is not in dispute. So, in my submission, there is nothing in these circumstances which I have outlined from which an anti-competitive motivation can be inferred. I would add that GUK could also not have anticipated at the time that not pursuing its own litigation any further could in itself be deemed to restrict competition, and that is particularly so when, on the date when GUK settled, BASF was walking into court to pursue its own challenge on the validity of its own anhydrate patent. In fact, I would submit to you that had BASF gone on to win that litigation and invalidated the anhydrate patent, we would probably not be here today. THE PRESIDENT: You say that you would not be here. That is on the assumption that GSK would have allowed you to walk away from the agreement. MR. HUMPE: I say that in my submission because if BASF had been successful in its litigation and invalidated the anhydrate patent, then for all intents and purposes the dyke would have been breached, others would have come onto the market, the IVAX agreement would have fallen away, and ultimately that would have unravelled the very foundation of the GUK agreement. THE PRESIDENT: Because when the dyke was breached, you still could not get onto the market for seven months? MR. HUMPE: Yes, but ultimately the agreement unravelled. THE PRESIDENT: No, it did not unravel, you terminated as soon as you could. But you could not get onto the market. You wanted, no doubt -- as Mr. Kon has just said, you were very keen to get onto the market, but you were contractually prevented so that even when the dyke was breached, you had to stay out for another six or seven months. MR. HUMPE: Yes, but in those circumstances generic entry would have occurred. THE PRESIDENT: Well, it did occur, but I am saying you had signed an agreement which prevented you from competing. MR. HUMPE: That was the give and take. THE PRESIDENT: That is no doubt how it came about. Of course there is a commercially negotiated agreement, but in terms of competitive effect, you as an important competitor

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1	and a significant generic supplier, the fact that others were on the market does not mean that
2	your agreement does not intend to restrict an element of competition.
3	MR. HUMPE: I suppose my point is that that restriction was necessary at the time to enter into
4	that supply agreement and the supply agreement was the way for GUK to get onto the
5	market.
6	THE PRESIDENT: But then on BASF, of course the fact that BASF lost does not mean that you
7	would have lost because infringement was not an issue.
8	MR. HUMPE: I suppose my submission is that if BASF would have won on validity, the patent
9	would have fallen away.
10	THE PRESIDENT: Yes, I am just saying (Pause)
11	MR. HUMPE: Once the anhydrate patent
12	THE PRESIDENT: I am saying the fact that BASF did not win completely does not mean that
13	we do not know whether you would have won or not.
14	MR. HUMPE: We do not know what the position would have been on the infringement, but I
15	think one also has to bear in mind that GUK not only faced infringement action on the
16	anhydrate patent, but also on the hemihydrate patent.
17	THE PRESIDENT: That never got anywhere, did it?
18	MR. HUMPE: My submission is that the evidence on the hemihydrate patent shows that there
19	was, at least from GUK's perspective, a real concern.
20	But in summary, for all those reasons, my submission is that a finding that GUK acted
21	intentionally or negligently would not be sustainable in the factual circumstances of this
22	case.
23	THE PRESIDENT: Yes. Thank you very much.
24	MR. HUMPE: Unless I can assist you further. Closing submissions by MS. FORD
25	MS. FORD: Sir, I am going to start off by making some submissions on what I have called the
26	CMA's pay for delay track in my written submissions. I am going to move on to address
27	what I say are the correct tests to apply at each stage of the analysis, so potential
28	competition, objects and effects analysis, and how they apply in the context of Actavis'
29	appeal, and I am going to finish by addressing the criticism that has been advanced by the
30	CMA about not adducing witness evidence in support of this appeal.
31	I do maintain my other grounds of appeal, but I do not propose the same thing orally about
32	them. I have also dealt with penalty in my written submissions and I am content, subject to
33	the Tribunal's views, to rely on what I have said in my written submissions together with
34	adopting what others have said.

1	THE PRESIDENT: Yes.
2	MS. FORD: So the pay for delay trap. This is something that I have sought to illustrate at
3	{M/4A/1}. It arises, in my submission, because the CMA has applied a very low threshold
4	test at each of the relevant stages of the analysis.
5	Potential competition, object infringement and effects infringement. What I have sought to
6	illustrate by this diagram is, first of all, the very limited conduct which is required on the
7	part of a generic undertaking before it finds itself accused of having engaged in a quasi
8	criminal competition law violation.
9	Secondly, the very limited analysis that is required on the part of the CMA or on the CMA's
10	case before it can establish such a violation.
11	Thirdly, the very limited options which are left open to a generic undertaking to extract
12	itself from this trap.
13	You can see from the first box at the top of this page that the conduct that causes the generic
14	to fall initially into the trap is that it takes certain initial preparatory steps towards
15	independent entry onto the market. In Alpharma's case the steps in question were obtaining
16	a marketing authorisation and sourcing its paroxetine product. That then triggers the
17	originator to commence infringement proceedings against the generic.
18	In opening, counsel for the CMA emphasised that the patent challenges, the infringement
19	proceedings, are to be considered part of the competitive process and they are, it was said,
20	the very expression of potential competition in this sector. I have cited that in the second
21	box.
22	Once the generic has taken sufficient steps to prompt the originator to commence
23	infringement proceedings against it, it is likely to find itself characterised as a potential
24	competitor.
25	How can it escape from the trap at this stage? Well, if you look at the first green box on the
26	left, we gather from the CMA's defence that what it could do is drop hands or walk away
27	from the litigation. If it does not either drop hands or walk away, then it ends up being
28	characterised as a potential competitor. Those are the two options.
29	THE PRESIDENT: Are you not already a potential competitor when you get your marketing
30	authorisation and source the products with a view to entering onto the market? I mean, it
31	would be irrespective of whether the originator starts proceedings.
32	MS. FORD: In my submission, that is not enough because the test for potential competition is
33	that you have to be able to show a real concrete prospect of getting onto the market, and if
34	you have patents which may potentially prevent you from getting onto the market, in

1	addition from naving sourced your product and got a marketing authorisation there is a
2	further step that has to be taken, which is you have to have a way onto the market which is
3	lawful. So you have to engage in some sort of process of patent challenge in order to have a
4	concrete
5	THE PRESIDENT: You might think you have a non-infringing product so you are not going to
6	challenge anyone.
7	MS. FORD: One means that Lundbeck identifies is you can enter at risk. That is one way round
8	the patent stage.
9	THE PRESIDENT: Once you enter at risk you are a competitor, you are not a potential
10	competitor.
11	MS. FORD: In my submission, it is not enough where there are patents in place simply to say
12	you have a market authorisation and the product, because you have to find some way
13	through the patent thicket. Lundbeck tells you the various ways you might do that. You
14	might enter at risk, you might challenge
15	THE PRESIDENT: When you enter at risk are you not then a competitor? I mean, you are
16	selling on the market looking for customers. You are not a potential competitor, are you?
17	You are an actual competitor.
18	MS. FORD: You are quite right, sir. My point is that that is a further element in addition to
19	having the MA and having the product. You have to have some way of getting round the
20	patent situation.
21	THE PRESIDENT: I am just thinking, once you have entered at risk you are a competitor. If you
22	have not done that yet but you have got the authorisation, you have got the product, I mean,
23	you would not go and get the product if you were not intending to do something with it
24	because you are spending money on it, investing and so on. Are you not at that stage a
25	potential competitor?
26	MS. FORD: In my submission, that is not enough. It does not satisfy the real concrete prospect
27	tests. You can see that from <i>Lundbeck</i> , because <i>Lundbeck</i> tells you that patent challenges
28	are potentially a source of competition in this market and in this sector.
29	The reason for that must be that it is not enough just to have your product. You have to
30	have a route-to-market product. If there is a potential that you could be excluded from the
31	market lawfully by means of the assertion of a patent, then you have to have some means of
32	getting round that in order to be a potential competitor.
33	THE PRESIDENT: If you enter at risk
34	MS_FORD: That is one of those ways

1 THE PRESIDENT: It is not a way round it, it is a risk. You are taking the risk. You are 2 prepared to do it, but you have not found a way round it. 3 MS. FORD: But you have entered. It is a route to market. You are prepared to enter at risk. 4 Alternatively, you might wait until you have challenged validity, or you might wait until 5 you have challenged infringement. But the key is the test for potential competition is to 6 find a route to market, real concrete chance of a route to market. 7 THE PRESIDENT: I see, yes. Well, I have got the point. 8 MS. FORD: So we are at the stage where you have been characterised as a potential competitor. 9 Then the question is: what are the generics' options at that stage? 10 The generics' options, according to the CMA, are set out in the second green box on the left 11 and they really are extremely limited. The generic has to either continue the litigation to the 12 bitter end or it must capitulate completely, or it must adopt what Mr. Turner describes in the 13 CMA's opening as the third way, which is to settle without a value transfer. 14 Those are the options open to the generic at that stage. 15 The other step that it can adopt, the generic settles and accepts a value transfer from the 16 originator. That, on the CMA's case, automatically leads to the generic finding itself having 17 committed both an object infringement and an effects infringement. 18 Dealing first with the objects infringement route, which is the route which takes you down 19 the left-hand side of this diagram, I have highlighted in my written closing submissions that 20 the CMA's position on object infringement on the test that is applicable for an object 21 infringement was somewhat ambiguous. In that respect, I am slightly less charitable than 22 Mr. Kon was because I do say there is some ambiguity in what the CMA says is the relevant 23 test. 24 At times it appeared that the CMA accepted that there was a causal requirement that it had 25 to satisfy, that it had to be able to show that the payment by the originator actually induced 26 delay by the generic as a question of fact. An example of that submission was where Mr. 27 Turner said that the term "pay for delay" requires each of those three elements together and 28 that each of those three words does work. He then went on to define what we are to 29 understand by the word "for" and he says it means "which causes or contributes". 30 So for our part, if the CMA accepts that it has to show as a question of fact that there is a 31 causal relationship between the pay and the delay, then we would have no objection to that 32 as a test. 33 However, in other parts of Mr. Turner's opening, he seems to suggest that the mere fact of a 34 value transfer from the originator to the generic, which exceeded litigation costs, could be

1 presumed to be anti-competitive. That is the test that I have cited in this blue box on the 2 left-hand side of the diagram, and it is also the quote that Mr. O'Donoghue took you to in 3 the transcript yesterday. 4 This is the Statement of Case, where Mr. Turner said: 5 " ... an unexplained reverse payment in a patent settlement agreement allows you to infer that this is a deal that disrupts the competitive process." 6 7 {TR/3/54} 8 What, in my submission, is the ambiguity in the CMA's case as to what is the applicable test 9 is not resolved by the CMA's closing submissions. 10 If you look at  $\{M/6/64\}$ , paragraph 152, this is the paragraph which is setting out what is 11 the applicable test. You can see it says "the applicable principles are well established". 12 Then it cross-refers back, under "object", footnote 61, to what is said in the decision, the 13 defence and the skeleton. 14 I have looked back at those cross-references, but in my submission they do not answer this 15 key point, which is, is the CMA accepting that it has to satisfy a causation requirement, or is 16 it relying on an inference? It does not resolve that ambiguity. 17 If we go back to the pay for delay trap,  $\{M/4A/1\}$ , I have proceeded on the basis of the 18 CMA's articulation that it is entitled to rely on an inference. 19 THE PRESIDENT: As I understood it, are they not saying not that there is an ambiguity, they are 20 saying they have to show a causal relationship, which you accept. Then they say we can 21 show that causal relationship, we can infer it from the unexplained payment. So that is how 22 they show it. They say they are entitled to show it that way. Is that not what they are 23 doing? So they are not two different ways; the one feeds into another. I appreciate you say 24 you cannot make that inference, but I think that is the way I understood it is being reasoned. 25 MS. FORD: It may be you can square the circle in that way, in which case, as you anticipate, sir, 26 I accept you have to show a causal relationship and I do not accept you can resolve it by 27 means of an inference. 28 The inference is made in the form shown on this diagram, and the point I make is once you 29 are characterised as a potential competitor, once you get to this box here, there is very little 30 conduct that you as a generic then engage in which causes you to find yourself in the object 31 infringement box. On that case basically you have a value transfer in excess of avoided 32 litigation costs and you have the acceptance of an entry restriction, and of course every 33 settlement of patent litigation is going to be an entry restriction in the sense that it amounts

to a suspension of your efforts to enter the market independently.

1	That is all that is required for you to find yourself accused of an object infringement. It is
2	also contemplating only very limited analysis on the part of the CMA in order to show that
3	object infringement. It says: if we show a value transfer, if we show an entry restriction,
4	and if we satisfy ourselves that that value transfer is unexplained, that is the end of the
5	inquiry. That is all I have to show to show an anti-competitive object infringement.
6	MR. GLYNN: Could you say a little more about the difference in your mind between
7	establishing causality and drawing an inference. What is the difference?
8	MS. FORD: I can certainly come onto that just to encapsulate what I say.
9	In my submission, the correct test is you have to show that the generic was induced by the
10	payment to accept restrictions on entry it would not otherwise have accepted.
11	Now, I understand the CMA's case is that if you see a payment in excess of avoidable costs,
12	that in itself gives rise to an inference that that payment has induced you to accept the entry
13	restriction, and I say that is not enough. You have to show as a question of fact that the
14	generic has been induced to accept restrictions on market entry.
15	MR. MALEK: An inference, you still end up with the same thing, which is a fact.
16	MS. FORD: In my submission, it is not open to the CMA to rely on an inference to discharge this
17	burden.
18	THE PRESIDENT: Other than the person who signed the agreement saying "I was induced by
19	this payment", how can you ever show what induced someone to do something? You have
20	to look at the surrounding circumstances and say, well, what can one infer from that?
21	MS. FORD: If we look at <i>Lundbeck</i> , you can see a case where the Commission was satisfied that
22	the facts in that case demonstrated inducement. I do intend to come to the two paragraphs
23	that the CMA relies on to say that Lundbeck permits an inference. I will make the
24	submission that actually it does not.
25	What is happening there is the circumstances in <i>Lundbeck</i> were considered sufficient to
26	discharge the burden as a question of fact.
27	THE PRESIDENT: But I mean, it is still an inference, is it not, or deduction? Are you not saying
28	that you need a lot more than just an unexplained payment to permit the inference to be
29	drawn, that that is what induced the settlement?
30	MS. FORD: Yes, I can accept that formulation.
31	THE PRESIDENT: To say you have to prove it, you cannot use a inference, there is always
32	going to be an inference. It is really: what is sufficient to establish the inference? Is that not
33	really the point?
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1 MS. FORD: I think that is a fair point, sir, yes. The point that I take against the CMA's case is it 2 is not enough simply to point to a payment and say that suffices to give rise to the 3 inference. 4 THE PRESIDENT: Or that it is unexplained by litigation costs and cross-undertaking. That does 5 not go anything like far enough. 6 MS. FORD: It does not go far enough. 7 MR. MALEK: You accept there are reverse payments. You also accept there is a restriction 8 within those agreements that you cannot, during the period of those agreements, have any 9 independent entry. 10 MS. FORD: Yes. 11 MR. MALEK: Do you also accept that unless there were going to be expansion payments to your 12 client there would not have been a settlement at all? 13 MS. FORD: I say two things. I say, first of all, on the face of the contemporaneous documents 14 you can see that the change in the merits of the litigation prompted Alpharma to seek 15 settlement, and I put to Professor Shapiro -- I am going to come on to this in detail -- that in 16 circumstances where a generic has already resolved to settle, you do not get the causal 17 relationship between the payment and the agreement of the entry restriction. 18 MR. MALEK: Everyone has a price. Look, unfortunately you did not call any witnesses so it 19 could not be put to them, but there are various scenarios that you can have. One is that we 20 will settle as long as we are going to get a small fortune from GSK. The other is it is settle 21 at all costs, we do not really care what the terms are as long as we are out of this litigation. 22 It is very difficult for you to say it is the second without calling any witnesses. 23 MS. FORD: Sir, I say two things. The first is that you can see on the face of the 24 contemporaneous documents that Alpharma had reached a point where it resolved to engage 25 in settlement negotiation. That is the first point. 26 MR. MALEK: Yes, I understand the first point, that there are settlement negotiations, and that is 27 fair enough. But it is a settlement at any cost that I am really asking you about. 28 MS. FORD: That is where the second point comes in. Where there are valid reasons for 29 Alpharma to be seeking a payment from the originator to Alpharma, then the fact that 30 Alpharma is not willing to settle at any cost, the fact that it feels that it is entitled to a 31 payment, does not mean that Alpharma is receiving a payment in return for not entering the 32 market. 33 One of the key points that I intend to rely on is the existence of the cross-undertaking in 34 damages. I will make the submission that when you look at the documents, what Alpharma

was doing was saying "Look, we are entitled to a payment under this cross-undertaking and we expect you to make that payment if you are going to reach a settlement". That, in my submission, is not saying "We expect you to make a payment in order that we agree not to enter the market". THE PRESIDENT: But are you not then saying, not disputing the premise of the CMA but saying look at the facts, there is a good explanation for the payments? These are not unexplained payments. MS. FORD: That is the second half of my case. I say first of all if Alpharma has resolved to come to the table and settle and it is entitled -- and Professor Shapiro agreed that it was axiomatic that in that circumstance it would try to obtain the best possible settlement that it could, in those circumstances it is not right to say, well, the fact that you managed to obtain payment in your favour must be understood as meaning that you agreed not to enter the market. The second point is insofar as there are legitimate reasons for Alpharma to think it is entitled to a payment then, again, the fact that it is receiving a payment does not lead to any sort of conclusion that it is agreeing not to enter the market in return for that payment. THE PRESIDENT: I think on the second one if you make that good, that there are good reasons, you satisfy the CMA's own test. You do not have to knock down the test, you say "Apply it and you will find that this is not by object anti-competitive". MS. FORD: Yes, they would say that means it is not unexplained under their test. THE PRESIDENT: You say "We have a good explanation". That is what you will say. MS. FORD: Yes. THE PRESIDENT: The cross-undertaking is something you have considered and no doubt you will say they did not get it right. But the first point, parking that aspect, which I can understand, but the first point when you say if you have resolved to settle, and therefore you get a payment, it cannot be aside from a cross-undertaking and so on, it cannot be anticompetitive, that will only be if you resolve to settle at all costs. That goes back to Mr. Malek's point. We are in no position, unless you can say there is in the contemporaneous documents something that establishes that, to reach that view. MS. FORD: Sir, I do not make that submission, but I do say the two interrelate because if you resolve to settle, not necessarily at all costs but considering that you are entitled to certain payments, then both of those factors go to the conclusion that you are not accepting a

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payment in return for exiting the market.

It is not simply saying, well, the payments that I received were legitimate. There is a further element to it, which is to say if you have internally resolved that this is a case where you do not want to take the risk and you want to settle, you are not accepting the payment in return for an agreement not to enter.

- MR. MALEK: If you look at the agreement you have agreed not to enter and that you are being paid, and so surely you are being paid in part for agreeing not to enter, are you not?
- MS. FORD: Well, no. That is precisely the thing that we say you cannot make simply from the presence of a payment and an entry restriction. You have to look at did the payment actually induce the acceptance of the entry restriction. We say it would not do if (a) you had already resolved to settle, and (b) you consider you are entitled to payments for other legitimate reasons other than accepting an entry restriction.
- MR. GLYNN: You would add, I think, to what you said earlier (c), that if you saw there was a lot of money that you could get out of the other party, somehow that would just be a fruit worth plucking.
- MS. FORD: You are entirely entitled to do so.

- Sir, just to finish the point on the pay for delay trap, I make a similar point in relation to the right-hand box, which is the routes that you find yourself going down in relation to an effects infringement. The vice there we have heard is that you are essentially curtailing the competitive process of patent litigation.
- Again, the submission I make is that look at the very minimal conduct that is supposedly required on the part of this generic undertaking to find itself having committed an effects infringement. Once it is characterised as a potential competitor, essentially, curtailing that potential competition is itself said to give rise to the requisite effects. Obviously the CMA adds in that you have to do so in return for a value transfer, but again, the point I make is there is very minimal conduct required for the generic to find itself in this position and very minimal analysis on the part of the Competition Authority in order to establish purportedly that infringement.
- MR. GLYNN: Do you agree that there is a potential for serious anti-competitive behaviour in the context of a patent settlement?
- MS. FORD: I absolutely have to concede that, yes. I say in order to show that you have to discharge the right test, and that test has to be more demanding in my submission than this flow chart here, because what I am trying to illustrate is that a huge swathe of potentially perfectly commonplace settlements are outlawed by virtue of this process on the basis of very limited conduct and very limited analysis.

1	MR. MALEK: I understand you do not accept that any payment was made for you not entering
2	the market. But do you accept that if a payment was in fact made in return for you not
3	entering the market independently, that would be an infringement by object?
4	MS. FORD: I do, yes. I would say that that discharges the causal obligation to show that a
5	payment has induced the acceptance of an entry restriction.
6	MR. GLYNN: The kind of evidence that would count in your mind to establish that would be
7	evidence of the intent of the parties at the time, that kind of thing?
8	MS. FORD: I do not think you need to necessarily limit the potential evidence that could go to
9	that. I think if you had evidence of intention that would be potentially relevant. We know
10	that in <i>Lundbeck</i> the Commission considered it had sufficient evidence to make that factual
11	finding. I would not necessarily want to prescribe the sort of things that can be taken into
12	account; I would simply say it is necessary to show the causal relationship, and I say it is
13	not sufficient simply to point to the presence of a value transfer and the presence of a
14	restriction and say that that suffices.
15	MR. GLYNN: To be fair, it is not just the value transfer, it is the value transfer that cannot be
16	explained in any legitimate way.
17	MS. FORD: It is.
18	MR. GLYNN: That is the difficulty you face.
19	MS. FORD: Well, I intend to address that difficulty.
20	THE PRESIDENT: You are about to explain it.
21	MS. FORD: I will do my best.
22	Sir, I am coming on to deal with what we say on potential competition, object and effect. I
23	do not know if you want me to push on for another few minutes, or
24	THE PRESIDENT: Well, we will do whatever you find most convenient, or more convenient.
25	Would you like us to break? Would you think it is helpful
26	MS. FORD: I could deal with potential competition very briefly.
27	THE PRESIDENT: Let us go on and deal with that.
28	MS. FORD: We have essentially already discussed that the test is real concrete possibilities to
29	enter the market.
30	We have seen from Lundbeck, and it has been discussed in opening, that the fact of
31	challenging patents is capable of constituting an expression of potential competition. The
32	only additional point I would make is the one essentially that we have already debated,
33	which is that you do not treat litigation as a substitute for the test of real concrete
34	possibilities. It is one way in which essentially that test is satisfied, but you do not simply

2 possibilities test is satisfied. 3 In my submission, that test sits somewhat oddly with the facts of Alpharma's case. Firstly, 4 Alpharma itself never challenged the validity of GSK's patents. So we have seen, and I 5 made submissions in opening, its strategy was that it sat back and it waited for others such 6 as BASF and Apotex to challenge validity. 7 So on my view you cannot treat Alpharma as a sort of potential competitive challenge on 8 the question of validity. 9 THE PRESIDENT: Was there a counterclaim in the Alpharma litigation? I think Mr. 10 O'Donoghue referred in his written closing to a counterclaim. 11 MS. FORD: I would need to check that. 12 THE PRESIDENT: I do not think it featured in the preparation for trial. Anyway, perhaps you 13 could have a look. 14 MS. FORD: I will check. 15 Obviously, sir, I will be making the point that it makes no sense to treat Alpharma as a 16 source of potential competition in relation to the validity question. 17 In relation to the infringement question, obviously Alpharma did not set out to demonstrate non-infringement, but GSK started proceedings against it and there is no dispute that it did 18 19 defend those proceedings. 20 But in my submission, you do have to still ask: do those proceedings give rise to the 21 requisite real concrete possibilities of entry? This comes down to the point that Mr. 22 O'Donoghue made yesterday, which is that in the case of Alpharma, you cannot show real 23 concrete possibilities of entry any earlier than in fact occurred. 24 You have got a trial which was due to take place in the Alpharma litigation in December 25 2002 and you have got the Competition Authority's finding, the CMA's finding that the end 26 of its effects case is November 2003. 27 In between that period of time there has got to be a trial, a potential appeal and a resolution 28 of that appeal. 29 THE PRESIDENT: What was the trial estimate? How long was the trial for? 30 MS. FORD: That is another point on which I will have to come back to, I am afraid. 31 THE PRESIDENT: If you could, that would be helpful. 32 MS. FORD: Sir, the simple point I make is there is an artificiality in treating Alpharma and the 33 Alpharma litigation as a source of potential competition when, as Mr. O'Donoghue pointed

point to litigation and say potential competition. You still have to show the real concrete

1 out yesterday, ultimately it was not likely to result in entry any earlier than actually 2 occurred in the factual case. 3 But I do say as well, insofar as the Tribunal is minded to apply a relatively low threshold 4 test for potential competition, then because of the pay for delay trap that I have outlined, 5 that would tend in favour of a more rigorous test at the stage of object and effect infringement because of the interrelationship between the two. Once you find that you are 6 7 characterised as a potential competitor, the test to be applied as to your conduct has to be 8 one that is sufficiently rigorous to weed out settlements which are entirely lawful and 9 settlements which are not. 10 THE PRESIDENT: Yes. 11 MS. FORD: Sir, that is a convenient moment. 12 THE PRESIDENT: Thank you very much. 2 o'clock. 13 I think we are well on target are we not, Ms. Kreisberger, Ms. Ford, to finish comfortably 14 this afternoon? 15 MS. KREISBERGER: I was assuming I may take up to my allocated two hours, certainly no 16 more. 17 THE PRESIDENT: Yes. You will be through in an hour by 3 o'clock? 18 MS. FORD: I anticipate so, yes. 19 (The short adjournment) (1.03 pm)20 (2.00 pm)21 THE PRESIDENT: Yes, Ms. Ford. 22 MS. FORD: Sir, you asked two questions before the short adjournment. One was how long was 23 the trial likely to be. We have found a reference in the decision,  $\{V/1/147\}$ , which is citing 24 a document where Alpharma is saying that the trial should take three to four days. This is 25 the quote at the top of this page. 26 THE PRESIDENT: Yes, it was then refixed for December. 27 MS. FORD: It was, yes. This is as far as we got, I am afraid, in terms of identifying the length. 28 THE PRESIDENT: Yes. 29 MS. FORD: The other query related to the counterclaim that Mr. O'Donoghue mentioned. He 30 has kindly agreed to check on that point and revert. Under duress. 31 THE PRESIDENT: Thank you very much. 32 Thank you, Mr. O'Donoghue.

1 MS. FORD: I am turning to the question of the test for object infringement and in particular the 2 point that was raised before the short adjournment about whether it is enough for the CMA 3 to rely on an inference that a payment coupled with an entry restriction is anti-competitive. 4 In opening, the CMA identified particular paragraph in *Lundbeck* which it said permitted 5 such an inference, and that paragraph was paragraph 352, which is at  $\{W/1/74\}$ . As I understand the way the case is put for the CMA, it says: 6 7 " ... where a reverse payment is combined with an exclusion of competitors from the market or a limitation of the incentives to seek market entry, the Commission rightly 8 9 took the view that it was possible to consider that such a limitation did not arise 10 exclusively from the parties' assessments of the strength of the patents but rather was 11 obtained by means of that payment ..." 12 I understand the case being put is that the words "it is possible to consider" give rise to an 13 inference in the sense that where these two features are present, then you are entitled to 14 consider that such a limitation did not arise exclusively for the parties' assessment for the 15 strength of the patents. 16 In my submission, that is a misreading of this paragraph and that all the court is actually 17 saying there is that the Commission was entitled to reach a conclusion. It was a conclusion 18 that it was open to the Commission to reach on the facts before it. 19 It is not saying, in my submission, that the presence of these two factors gives rise to a 20 presumption of anti-competitive effect. 21 I am supported in my submission in that. If you look at the recital of the Commission's 22 decision that the court is approving there, it is referring to recital 604 of the contested 23 decision, which is {Auth-F/16/201}, hard copy 10, 16, 201. 24 This is quite a long recital, so it might make sense if the Tribunal simply reads it. But this is 25 the recital that is being approved by the General Court. 26 (Pause) 27 THE PRESIDENT: Yes. 28 MS. FORD: In my submission, what the Commission is doing there is setting out its theory of 29 harm as to why the pay for delay agreements are not problematic. What it is not doing, in 30 my submission, is seeking to rely on any sort of inference that the presence of a payment 31 and an entry restriction can automatically be deemed to give rise to anti-competitive

So, in my submission, the correct reading of paragraph 352 of the General Court's decision,

which is approving this,  $\{W/1/74\}$  is that the Commission was right, it was entitled to take

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consequences.

1	the view that it was possible to consider that such a limitation did not rise exclusively from
2	the strength of the patents. That was a conclusion it was open to the Commission to reach.
3	If we turn over the page to $\{W/1/75\}$ , you can see that the General Court goes on to
4	emphasise this is a recital that we have seen a number of times before various other
5	factors that the Commission also relied on in addition, in order to reach its conclusion.
6	In my submission, the fact that the court goes on to identify other factors tells you that the
7	Commission is not just relying on any sort of inference because otherwise any other factors
8	would be immaterial.
9	In my submission, the relevant paragraph that CMA has identified as entitling it to rely on
10	an inference does not support that position.
11	The other basis on which the CMA relies is, of course, the economic theory
12	THE PRESIDENT: Before you go on, 355 you say must be read with 354.
13	MS. FORD: Yes.
14	THE PRESIDENT: Saying they are relevant factors in establishing, but not sufficient on their
15	own. Is that what you are saying?
16	MS. FORD: That seems to be what the court was saying having, in 354, referred to "other
17	factors".
18	THE PRESIDENT: Yes.
19	MS. FORD: It is saying quite clearly in 354:
20	"It must be noted, in that respect, that the Commission did not find, in the contested
21	decision, that all patent settlement agreements containing reverse payments were
22	contrary to Article 101(1)"
23	It goes on to identify the several other factors.
24	That reasoning, in my submission, is inconsistent with 352 being read as a pure inference.
25	THE PRESIDENT: Equally, it does not say that and this is why we are all trying to sort of pass
26	this judgment as though it were a statute it was necessary to find all those other factors to
27	reach the conclusion.
28	MS. FORD: It does not, but in my submission, the fact that the court is emphasising the presence
29	of other factors in itself suggests that it is not endorsing an approach which relies solely on
30	an inference based on the presence of a payment and the acceptance of an entry restriction.
31	The very fact it goes on to talk about other factors suggests that that is not enough.
32	THE PRESIDENT: One is of course the fact that the generic is not allowed to launch, during the
33	agreement, their own product.
34	MS. FORD: Yes.

1 THE PRESIDENT: Which of course we have got here as well. 2 So one of the factors we have got, although we certainly have not got the third one, beyond 3 the scope of the patents. 4 MS. FORD: No. 5 THE PRESIDENT: Whether or not we have a first one is perhaps a bit unclear. Yes, well, there 6 it is. 7 MS. FORD: I am making a more simple point, sir, which is that the mere fact that the court goes 8 on to talk about "other factors" is not consistent with it being sufficient merely to rely on the 9 inference that the CMA seeks to read in paragraph 352. 10 MR. MALEK: You have paragraph 500, which Mr. Flynn took us to. 11 MS. FORD: Indeed, yes. 12 THE PRESIDENT: Yes. 13 MS. FORD: Sir, the other source of a purported inference is of course Professor Shapiro's pay for 14 delay inference, and I gratefully adopt everything that has been said so far by the appellants 15 as to why that is problematic. But I do add one particular point of emphasis on behalf of 16 Alpharma, which is that the pay for delay inference is problematic because it looks solely at 17 the motivations of the patent holder. That became very clear when Professor Shapiro was 18 explaining and asking questions such as what does the patent holder get for this payment? 19 What does he hope to achieve? It is looking solely at the patent holder's perspective. 20 In my submission, that cannot be determinative of the key question of whether the value 21 transfer induced the generic to accept entry restrictions which it would not otherwise have 22 accepted. 23 I put to Professor Shapiro a simplified scenario which, in my submission, illustrated that 24 point. I asked him to consider the situation where a generic had independently reached a 25 decision to settle no matter what the circumstances. Essentially, it would have been 26 prepared to accept no payment, but it went into negotiations hoping to maximise the 27 recovery that it made. 28 In that situation, if the generic has already independently determined it is not going to 29 enter, then any payment that it is able to extract from the originator does not induce that 30 generic not to enter because it has already independently reached that decision. So it cannot 31 be said that that payment is itself damaging to consumers or to competition. 32 The same goes, if you turn it round, if the generic were obliged to settle without its value 33 payment, consumers and competition are no better off than they otherwise would have been 34 because the generic would not have entered even if it had obtained a value payment and it

1 would not have entered if it did not obtain a value payment. So the value payment is not 2 causative of any competitive problem in that market. 3 That was a point that I put to Professor Shapiro, and he did not dispute any of that theory 4 that I put to him. What he said was, aha, but actually it may have been possible for the 5 generic to enter into some or sort of agreement instead which may have had pro-competitive 6 consequences, which is still problematic. 7 But in my submission, once you have disposed of the question of whether the payment has 8 caused you to agree not to go into the market, it is completely irrelevant that you could 9 possibly have reached an agreement that might be more pro-competitive. There is no 10 obligation as a matter of competition law that when you enter into an agreement with 11 somebody you have to make sure you maximise the competitive consequences of your 12 agreement. 13 So once you have disposed of the question of whether you were induced, it is no answer in 14 my submission for Professor Shapiro to say, well, there might have been a better agreement 15 that you could enter into. 16 MR. MALEK: What you are saying, then, if the object of the patent holder is to get you to agree 17 to keep off the market and he is going to do that by making a large payment to you, there is 18 nothing wrong with that if the person who is paid was not going to go in the market in any 19 event. Is that what you are saying? 20 MS. FORD: Obviously I in no way accept that that is a correct characterisation of this case, but in 21 an extreme situation it is not enough to look at the motivation of the patent holder in making 22 that payment. So yes, I am saying that. You have to also look at was that generic induced to 23 accept a restriction it otherwise would not have accepted? 24 The criticism I make of Professor Shapiro's inference is that it does not look at that side of 25 the equation. It only looks at what was the motivation of the originator. So it cannot tell 26 you about whether the generic was induced or not. 27 MR. MALEK: Let us say you can pay a public official a bribe to get a contract, and the defence 28 would be, well, you were going to get the contract in any event. He was going to give it to 29 you anyway. 30 MS. FORD: I think the considerations of bribery are different to the considerations of whether 31 there is an object or effect to restrict competition. 32 MR. MALEK: But if the object of the patent holder is to keep you out of the market and he is

going to do that by way of a payment, it seems rather extreme to say, well, it is a complete

1	answer if the generic was not going to enter the market in the first place, he did not have to
2	agree.
3	MS. FORD: The test of the object is an objective inquiry. So it is not an answer to say, well, the
4	subjective intention of the patent holder was X. You have to inquire what is the object of
5	this agreement.
6	In my submission, you do not establish that the objective of the agreement, in the
7	competition law sense, is market exclusion unless you can show that the generic has
8	accepted payment in consideration for not entering onto the market.
9	MR. MALEK: So even though there is a large payment here and there is a restriction in the
10	agreement, you say that does not amount to an object unless you link the two together?
11	MS. FORD: I say you are not entitled to rely on an inference merely arising from those two
12	factors.
13	MR. MALEK: Yes.
14	MR. GLYNN: I think you have to have in the mind of the people accepting that they are
15	accepting because of the money, so you are into the intention of the recipient of the money?
16	MS. FORD: Again, that is a subjective enquiry which is not necessarily the answer as to what is
17	the objectively defined object of the agreement. But I do say that it is not enough to look
18	solely at the originator's side of the equation in order to show essentially the generic has
19	been induced.
20	THE PRESIDENT: Are you not then, effectively, looking at the subjective intention of the
21	generic to defeat the object, if object is an objective question, you say. But if subjectively
22	the generic has decided "We are not going to get in anyway", then you cannot have this
23	objective object?
24	MS. FORD: I certainly rely on that to say why Professor Shapiro's influence is flawed
25	inference is flawed.
26	THE PRESIDENT: Yes, perhaps both.
27	MS. FORD: Yes, seductive though he is. I advance this as a simplified example of why the
28	inference, the pay for delay inference, is not an answer to the inquiry that the Tribunal
29	should be making.
30	THE PRESIDENT: You make a more basic point that one has to look at both sides not just from
31	the perspective of the originator.
32	MS. FORD: I do.
33	THE PRESIDENT: I understand that. Whether the subjective intention of the generics, how that
34	comes in, on that I am not sure.

1	MS. FORD: Sir, those were the two, as I understand it, origins of the possibility that CMA can
2	rely on this limited inference.
3	In my submission, that is insufficient. The CMA has to show, as a question of fact, that you
4	have here essentially a pay for delay case. You cannot rely on an inference.
5	I am turning to look at the facts of Alpharma's case. The first point I make is the one that I
6	made in opening, which is that in the light of the objective change in circumstance, the
7	change in merits of the Alpharma litigation, it is clear that Alpharma essentially went to the
8	table and resolved to settle with GSK. It was the one that approached GSK.
9	THE PRESIDENT: Yes.
10	MS. FORD: But I also go on to say that Alpharma did not treat the sums that were paid under the
11	Alpharma-GSK agreement as payments for agreeing not to pursue its independent entry.
12	I say, first of all, that certain of those sums were referable to the cross-undertaking, and
13	Professor Shapiro, when I asked him, agreed that in principle a discharge of the cross-
14	undertaking in damages would be a legitimate explanation for a payment to be made by an
15	originator to a generic.
16	In my submission
17	THE PRESIDENT: I think you have got the support of the decision. I mean, I think they say that
18	too, do they not? The decision says insofar as it
19	MS. FORD: They concede in principle.
20	THE PRESIDENT: relates to the cross-undertaking that is a good explanation.
21	MS. FORD: In my submission, when you look at what actually happened it is very clear that
22	Alpharma considered it was entitled to payment under the cross-undertaking, and that was
23	what it was negotiating for from GSK.
24	I am looking at a document that the Tribunal has looked at before. It is at {A9/184/81}.
25	This is the head of the email.
26	You can see this is the email account of the meeting that took place between Alpharma and
27	GSK on 11th October 2002.
28	THE PRESIDENT: Sorry, this is? This is 11th October. Perhaps if you would just identify
29	perhaps we should go back a page to see the start of it.
30	Who is it from?
31	MS. FORD: It is from Torben Laursen. If you see at page 82 you can see it is signed "Torben".
32	THE PRESIDENT: Laursen to everyone else. Yes. Right. Then in the middle he says (Pause)
33	{A9/184/81}
34	MS. FORD: He is setting out Alpharma's opening position:

1	initially we stated that a settlement must have elements of compensation for.
2	"The loss we have suffered since early July. We said the value was £2.5m a month as
3	our gross margin foregone."
4	They make the point that will continue well into January with the December trial dates.
5	He identifies other heads of damages: inventory, attorney fees, image loss by not launching
6	and relationship loss with Delta.
7	They say the total value that they asked from GSK was in the region of 20 million. In my
8	submission, what is clearly going on here is that Alpharma is asking for payment under its
9	cross-undertaking. It is saying "We have suffered loss by reason of being kept out of the
10	market and we would like you to pay for that loss".
11	Now, as would be expected in any commercial settlement, the amount that they sought got
12	negotiated down heavily.
13	THE PRESIDENT: Just a second.
14	MR. MALEK: It does not mean that their loss was actually 2.5 a month, but that is just what they
15	told the other side.
16	MS. FORD: Certainly, that is true or that is the estimate they put forward to GSK as what they
17	considered their loss to be.
18	In my submission, it is clear that what they are doing here is saying "We are entitled to
19	payment under the cross-undertaking for being kept out".
20	THE PRESIDENT: This is in October.
21	MS. FORD: Yes, this is relating to a meeting on 11th October.
22	THE PRESIDENT: Yes.
23	MS. FORD: Now, in opening, the CMA sought to place heavy reliance on the passage which is
24	further down in this email, where it is recorded as saying:
25	"GSK will offer a lump sum and/or monthly payment which can be turned into either
26	a cross-undertaking as part of the settlement or a promotional fee. We clearly have to
27	negotiate this further, and decide the minimum we can accept."
28	Then there is key issues to evaluate down the bottom and an indication they are going to be
29	thinking about the sum in question.
30	It was submitted on behalf of the CMA. What you gather from this, at this point, they are
31	still deciding what is the minimum to make the numbers right. So they use the language of
32	GUK.
33	So the submission was made that what is going on here is that Alpharma is weighing up
34	how much it is prepared to receive not to enter the market. But in my submission, if

Alpharma is entitled to some sort of payment under the cross-undertaking and that is what it considers it is negotiating, then the fact that it is weighing up what it is prepared to accept is not equivalent to saying: we are prepared to accept a payment not to enter the market. It is essentially saying: we are considering how much we are prepared to accept in consideration for discharging the cross-undertaking in damages. THE PRESIDENT: They are taking it up to January on the basis that the trial is in December. I think that is what they are doing, is it not? MS. FORD: I think they are saying: if we assume we were to win the December trial, we would have been kept out for the period from July to January. Now, we know that actually the amounts that they managed to negotiate were quite substantially smaller than that, but the sums that are eventually settled on are not sums that were plucked from thin air. They are sums referable to legal fees that Alpharma had actually incurred, production costs. So they are essentially elements of costs incurred that would have been recovered in some form or other in a cross-undertaking, possibly on the basis of a profit measure rather than a cost measure. But these are not sums that were plucked out of thin air. Sir, I took you in opening to various other contemporaneous documents which also make reference to the cross-undertaking. There was the document that Alpharma amended, the draft agreement that was amended to make specific reference to the cross-undertaking. That was then subsequently deleted by GSK. It was the Alpharma-GSK agreement itself which contains a draft order which provides for the discharge of the undertakings. Then there is a confidential schedule to that agreement which records that GSK and the GSK group shall be under no liability to Alpharma under the undertaking in damages, given pursuant to the orders of Mr. Justice Jacob. In my submission, what you can see on the face of the contemporaneous documents is that Alpharma considered that it was entitled to some payment from GSK in respect of its crossundertaking in any event, and that is what it was negotiating. THE PRESIDENT: What is not clear from that proposal is how long they were promising to stay out for under the 20 million. MS. FORD: Well, the agreement was for an initial period of a year. THE PRESIDENT: That is what they ended up with. This is what they were asking, and then they say GSK want the following, and they will offer on the basis that we can launch when

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our competitors at a later stage have penetrated their defences.

MS. FORD: Yes, which is, in my submission, entirely consistent with their strategy throughout, which is we wait until somebody else has essentially established the invalidity of the patent, then we enter as soon as possible. THE PRESIDENT: Yes. I mean, that is what GSK are proposing. MS. FORD: Sir, the next element of the payment that was made was a promotional allowance. There is a document which dates from the time where Alpharma were considering whether to renew the Alpharma agreement, which shows that the way they treated the promotional allowance was as a discount from the cost price of the paroxetine to be supplied under the IVAX agreement, rather than as any payment in return for not entering the market. That document is at {A9/184/127}. You see this dates from 2003. They are considering whether or not to renew the Alpharma agreement. If you see the paragraph commencing "Helen", it says: " ... can you do a new business case Delta vs GSK volume, revenue and profit from Nov 03 until Dec 04. Look at cost price from Delta vs cost price from GSK with and without the £100k contribution." So in my submission, what is going on there is that they are saying the 100k marketing promotional allowance is to be treated as a discount from the cost price of the paroxetine they got under their agreement. THE PRESIDENT: The business case -- delta is that they would go in with Delta and not renew, and then go in as an independent generic? MS. FORD: Yes. MR. GLYNN: Therefore, to compare the price with Delta with the price from GSK and knock off the 100,000. MS. FORD: Yes, they are taking into account the promotional allowance as a factor which goes to the price of their supply. THE PRESIDENT: But that would be entry at risk? MS. FORD: It would be. THE PRESIDENT: So they are clearly contemplating it. They are weighing up the benefits. MS. FORD: They are at the renewal stage. But the key point here is when you look at the role of this payment, this particular element, the promotional allowance, you can see what they are doing with it. The role they consider it plays is it is a discount of their supply price. They

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are not treating it as a payment for not entering onto the market.

MR. GLYNN: To be fair, they are just viewing it as money they are getting, and in considering an alternative option through the other source of supply, it is perfectly reasonable for them to say it is equivalent to a reduction from the --MS. FORD: It is reasonable. MR. GLYNN: It is equivalent, but it is just money they are getting from one deal to another. There is not much more to say other than that, really, is there? MS. FORD: Save that insofar as this shows them treating it as a discount, they are not treating it as a payment for not entering. They are saying "We understand this to be a discount of our supply price". The third element of the payment under the GSK-Alpharma agreement is the IVAX supply agreement itself, and the CMA has advanced a case based on expert evidence and, in my submission, ex post rationalisation that what was going on there was purely a value transfer from GSK to Alpharma. In my submission, there is no evidence to suggest that that was how Alpharma perceived the supply agreement that it was being offered. It of course weighed up the profit that it hoped to make from supplying GSK's products. Of course it did. That is what you would expect if you were being offered an authorised generic. You would not take it without trying to calculate whether or not the terms you were being offered were profitable or unprofitable. In my submission, the CMA pointing to emails where Alpharma tries to calculate whether or not it can make a profit on this do not show that it is treating it as an inducement not to enter the market. I made submissions in opening about what a valuable opportunity it was for Alpharma because their strategy had always been to wait until the patent was invalidated before they entered, and now they are being offered an opportunity to enter even before the patent was invalidated. So before they otherwise would have done. That, in my submission, is the way they treated this opportunity, not as an inducement not to enter independently. THE PRESIDENT: Although at this point, at least by June 2003, their strategy does not seem to be: we will not enter until it is invalidated, we will see whether entry at risk might be more profitable and they will balance it out and work out how much they might get from it, as opposed to how much they might get with the volume from GSK. MS. FORD: Certainly they are doing the exercise. THE PRESIDENT: Well, you would not do the exercise if you decided no way would we enter at risk. It just would not be considered. But it looks as though from this they treat two as just

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alternatives that look at potential profits.

1	We do not have any more than the email.
2	MS. FORD: No, and you can see:
3	"I will speak to Brendan Magrab to assess the patent risk if we go with Delta."
4	THE PRESIDENT: Yes, so they
5	MS. FORD: So they are considering the patent risk of entering at risk.
6	THE PRESIDENT: They are obviously aware of that.
7	Can we just look, while we are in this, at the one you also quote in your closing I think in
8	the same bundle {A9/184/75}, which is to this Mr. Carlsson about the proposal they were
9	going to make.
10	MS. FORD: Yes, this is when they are saying internally we need to approach GSK.
11	THE PRESIDENT: Then what they are suggesting is we will offer to delay until somewhere in
12	between what was then the trial date and their assumed appeal, and that GSK will then not
13	pursue us on its patents when we enter in April.
14	MS. FORD: Yes.
15	THE PRESIDENT: That was their starting point.
16	MS. FORD: This is the document that Mr. Turner said was the third way, if we had sought this
17	but had not sought the accompanying payment as well. His submission was this was the
18	third way that you could accept it.
19	THE PRESIDENT: They are saying we should get a payment as well.
20	MS. FORD: Yes.
21	THE PRESIDENT: Because we are giving them six months exclusivity.
22	MS. FORD: If I recall correctly, this is a document I had an exchange with Mr. Malek on,
23	because in my submission what you see from the subsequent meeting is when they go in
24	they are saying "We have been kept out, we are entitled to compensation for that".
25	So Alpharma are thinking "How can I negotiate a good settlement with GSK?"
26	THE PRESIDENT: Yes. Thank you.
27	MS. FORD: Sir, I have addressed the three heads of payment that were made under the
28	agreement. In my submission, none of them go far enough to establish that Alpharma
29	received those payments and treated them as an inducement not to enter the market.
30	THE PRESIDENT: Yes.
31	MS. FORD: It will be recalled that it is essentially the CMA's burden to show that. The CMA
32	seeks to rely on an inference which I say is insufficient, and I say on the face of the
33	contemporaneous documents you cannot show that Alpharma was induced not to enter the
34	market.

1 I am moving on very briefly to deal with the position on effects. There is a similar debate 2 about the correct tests for the purposes of effects, whether or not you simply show that there 3 has been curtailment of the competitive process of patent litigation or whether you actually 4 have to show a realistic counterfactual that is more pro-competitive. Others have really 5 traversed this ground quite completely. I gratefully adopt the submissions that have been made on, for example, the Visa Europe 6 7 case and why it does not assist. One point I do want to address is a point that Mr. Glynn raised yesterday to Mr. 8 9 O'Donoghue about whether, if the litigation results in GSK's patents being upheld, might 10 you not say that that is also a pro-competitive outcome? 11 As I understand the point you were putting, that would mean that you would not have to 12 show as a counterfactual that the generics would succeed in their litigation because you 13 would have a pro-competitive outcome even if they lost? 14 MR. GLYNN: That is correct, yes. 15 MS. FORD: In my submission, there are two answers to that point. The first answer is that it is 16 not the case that was put in the CMA's decision. In the decision what you see is an 17 explanation of the benefits of generic competition, which is absolutely pinned on the need 18 to show prices falling caused by generic entry. 19 Just to give a couple of examples of that: the decision at paragraph 3.59  $\{V/1/40\}$ . This is a 20 description of the benefits of generic competition. 21 You can see that: 22 "The process of generic competition is expected to lead to lower prices and reduced 23 market shares for the branded supplier in the following way ..." 24 Then it goes on to give various bullet points as to why that might be. 25 Similarly if you look at decision 7.66, which is at  $\{V/1/359\}$ , this is the section where the 26 CMA is setting out why it says the Alpharma-GSK agreement restricts competition by 27 effect. What you see is that the CMA is relying on the context that Alpharma did not enter 28 and true generic competition did not emerge, as set out in paragraphs 6.34 to 6.39: 29 " ... had true generic competition emerged, such competition was expected to result in 30 significant decreases in paroxetine prices ..." 31 In my submission, the CMA is relying on saying that that the pro-competitive effect that 32 they are looking at is generic entry. They are not saying it would be pro-competitive merely 33 to clarify that GSK's patents were indeed valid and that therefore generic entrants could be

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kept out.

MR. GLYNN: I also read from the decision that there was a lot of emphasis on what they call "true generic competition". In some of the writing that was what they had in mind. The reason why I am interested in this point particularly is their first counterfactual they suggest, which is the continued litigation, I do not think can be read to mean simply continued litigation ad infinitum. I think it has to be read to mean continued litigation until there is a resolution.

Since they do not say that they assume that the result of that litigation would be in favour of the generics, it has to be that they are contemplating either result. So the continued litigation counterfactual, as I understand it, would encompass either a result that favoured the originator or the generic.

Given that, and that that is being regarded by the CMA -- I will be corrected if I have got this wrong -- that is being regarded as a counterfactual which would be a competitive outcome against which the actual effects of the agreements can be measured. Then as a matter of the internal logic the CMA must be thinking that an outcome which included confirmation of the patent rights would be competitive.

I add to that the other points that I raised very early in these hearings, which is that if you think about what we should understand as the Tribunal by the proper working of a competitive process in the field in which patents are terribly important, it would be very, very odd indeed, I would think perhaps plainly wrong, not to include the confirmation of valid patents as part of the way in which a properly working competitive market should operate.

So for those two reasons, that was why I put the point yesterday. Thank you.

MS. FORD: I would respond to those point as follows. First of all, in my submission on a true construction of this decision the CMA is not treating upholding GSK's patents as a competitive outcome. What you have identified in my submission is a flaw in the decision, because as you say, the continued litigation counterfactual cannot just be treated as litigation going on ad infinitum and a loss of a potential chance at the end of it. That is unsatisfactory. What the CMA should have done, given that, as we have seen, the outcome it is looking for is generic competition and lowering prices, what it should have done is undertaken a proper assessment of the probability that that might be the outcome, and the dichotomy that you have identified is, in my submission, a flaw in the decision. But there is a second point which supports that, which is a good reason why the decision does not treat simply upholding GSK's patents as a pro-competitive benefit in itself, and you can see that from the Commission's horizontal guidelines.

1 They are at {Auth-K/10/8}. I am looking at the heading starting at paragraph 26, but in 2 particular paragraphs 27 and 28: 3 "Restrictive effects on competition." 4 27: 5 "For an agreement to have restrictive effects on competition within the meaning of 6 Article 101(1) it must have, or be likely to have, an appreciable adverse impact on at 7 least one of the parameters of competition on the market, such as price, output, product quality, product variety or innovation." 8 9 If we then go over to the following page, paragraph 28 {Auth-K/10/9}, you see: 10 "Restrictive effects on competition within the relevant market are likely to occur 11 where it can be expected with a reasonable degree of probability that, due to the 12 agreement, the parties would be able to profitably raise prices or reduce output ..." 13 So the relevant anti-competitive effect under Article 101 has to be some sort of impact on 14 one of the margins of competition, one of these factors of competition such as price. 15 You do see that if you prevent an outcome which would have led to generic entry, because 16 what you are doing there is preventing something which is likely to lead, as the CMA has 17 explained in its decision, to price falls. 18 You do not see that, in my submission, if the only consequence is that you prevent the 19 clarification that GSK's patents were valid. So while in the abstract you can see that there 20 might be some validity in clarifying the patent position, it does not in my submission give 21 rise to a relevant anti-competitive effect for the purposes of Article 101. 22 Sir, the application of the effects case to Alpharma is also something that has been traversed 23 fairly extensively, so I do not propose to say much more than that. In our submission, there 24 is no counterfactual which is materially more competitive than the outcome of the 25 Alpharma-GSK agreements, taking into account the point that Mr. O'Donoghue made vesterday about the likely timing of any realistic entry by Alpharma, even if it was 26 27 successful in its patent litigation. 28 I am turning to the final point that I indicated I would deal with, which is a factual basis of 29 Actavis' appeal. Much has been made in the CMA's written closings about the fact that 30 Actavis has not called any witness evidence in support of its case. 31 In my submission, the answer to that lies in looking at how the CMA has responded to 32 Actavis' appeal and what is really in dispute between Actavis and the CMA on these 33 appeals.

1 So Actavis in its Notice of Appeal, starting at  $\{A/4/4\}$ , set out a detailed summary of what 2 was submitted to be the factual background to the appeal. This is paragraphs 4 to 65. So it 3 went on for some time. It made submissions. 4 You can see, for example, paragraph 4: 5 " ... the decision does not set out anything approaching the full or proper background to the Alpharma-GSK agreement ..." 6 7 You can see in paragraph 64  $\{A/4/23\}$ , the submission that the decision contained a partial 8 and incomplete account of the factual background. 9 In its defence, the CMA completely failed to deal with Alpharma's case as to the factual 10 background or with the assertions that had been made about the adequacies of the decision, 11 and it certainly did not make any criticism at that stage of Alpharma's decision not to call 12 any witnesses. 13 When Alpharma then served its skeleton argument, at  $\{S/4/2\}$ , there was a further 14 exposition of the factual background as we saw it, and the submission was made that there 15 were eight respects in which it was said the decision provided an incomplete and partial 16 account of events. 17 If you look at the CMA's responsive skeleton again, you do not see any engagement either 18 with the account of facts we gave or with the criticisms of the decision we advanced. 19 Again, we do not see any objection to Actavis' failure to call any witnesses. That was an 20 objection that only arose for the first time in the context of the hearing before the Tribunal, 21 and it arose in a different context, namely Actavis' ground of appeal about delay. 22 Even then, when the CMA then opened, there was not really any concerted attempt to 23 engage with the factual account that Actavis put forward in opening. You saw the CMA 24 take the Tribunal to certain documents that it considered particularly helpful to its case, but 25 that really was the extent of it. 26 So stepping back, in my submission, if you ask: what is in issue between these parties? 27 What are they actually disputing about? It is not the sort of dispute where we are engaging 28 about who said what to who, when. Actavis has made submissions based on what can be 29 seen on the face of the contemporaneous documents. What is really being disputed is what 30 test the CMA should be applying to determine whether or not this agreement is anti-31 competitive and what conclusions can and cannot be drawn from the facts as they emerge 32 from the contemporaneous documents.

1 In those circumstances, in my submission, the criticisms that have been made of the fact 2 that we have not relied on witness evidence are simply not relevant because they do not go 3 to the key issues that are in dispute between these parties. 4 MR. MALEK: If you had Mr. Laursen and the others as witnesses, they could have given 5 evidence and said, look, we do not accept this pay for delay inference because as a matter of 6 fact there was no pay for delay. We got the consideration for other things and it had nothing 7 to do with any restriction on entry. They could have said that and they would have been 8 cross-examined. 9 MS. FORD: The important thing to remember is that the burden is on the CMA, and the way that 10 the CMA has chosen to discharge that burden, as you see from the defence and from their 11 skeleton, is not to engage in that sort of factual debate, it is to engage in a dispute about what is the appropriate test and how do you show an infringement by object and an 12 13 infringement by effect. 14 MR. MALEK: But you are saying as a matter of fact there was no inducement. They are saying, 15 well, you can infer there was inducement by looking at the terms and the size of the 16 payment. If you had the people who negotiated the agreement, they could have said "It is 17 not a question of inference, as a matter of fact there was no inducement". So there is an 18 evidential void. You may blame them for it, but you could have called a witness to deal 19 with that. 20 MS. FORD: Certainly it may be that I could have been in a better position, but in my submission, 21 the CMA could not be in a better position because the CMA is the one who bears the 22 burden. The CMA has tried to dispose of that burden by relying on an inference. 23 MR. MALEK: Correct, yes. 24 MS. FORD: Either it is entitled to do that, in which case it wins. Or it is not. If it is not, then it 25 has not done enough, in my submission, to discharge the burden that is on it. 26 MR. MALEK: I fully accept the burden of proof is on the CMA. 27 MS. FORD: Sir, those are my submissions. 28 THE PRESIDENT: Can I ask you one other thing that deals with the last part of your closing on 29 duration, which of course only arises if there is a penalty. We all appreciate that, and if you 30 succeed in everything else, there is not. 31 But on duration, I am not so interested on whether it should be 12th February or 13th 32 February, it does not seem to me to matter much. But is there not perhaps another point that 33 -- I mean, even if it is an object case, one still, for penalty, looks at effect when deciding a 34 penalty because one is looking at -- it seems to me.

1 Here this is treated, the duration, as being the length from the agreement, date of the 2 agreement, until, for some reason, the date, I think, of your notice terminating, became 3 effective, in February 2004, which is therefore the -- I think that is what they have done, 4 from November 2002 to February 2004. 5 MS. FORD: Yes. THE PRESIDENT: Because that was the date of the agreement that you made, 12th November. I 6 7 thought it was 12th November. No, it was 20th November, I am sorry. 8 MS. FORD: The IVAX agreement was the 20th. 9 THE PRESIDENT: The IVAX agreement was the 20th. 10 MS. FORD: The original agreement was the 12th. So the point being made under (a) is since the 11 conclusion of the IVAX agreement was the condition precedent --12 THE PRESIDENT: My point was a rather different one. If you had pursued the case to 13 judgment, trial in December, a four-day trial, I think it is reasonable for a four-day 14 expedited trial judgment, maybe February, possibly January, but certainly February 2003, 15 and an expedited appeal June/July 2003. If you had succeeded, that would be the earliest, 16 which is not the timeline Mr. O'Donoghue has put forward, which I think for a four-day 17 expedited trial would be most unlikely. 18 The earliest you would have reasonably come in is round about July 2003, and the fact the 19 agreement was made earlier, does it matter? When one is looking at duration, is one not 20 looking at the duration of the effect? 21 MS. FORD: I think there are two separate points. The CMA has found an effect only until --22 they say at least, but essentially the cut-off point they have identified is 30th November 23 2003. 24 THE PRESIDENT: Whether it is 30th November or whether it should be --25 MS. FORD: In my submission, it is really a series of quite aggressive assumptions that you, sir, 26 need to make in order to get us in any earlier than that. It has come down to how soon you 27 could have essentially accomplished a trial, a judgment and an appeal, and the outcome of 28 the appeal. 29 THE PRESIDENT: Yes. 30 MS. FORD: That is a process that Alpharma originally envisaged might take around a year. 31 THE PRESIDENT: That is what I am having regard to. The period they have taken is the period 32 from the agreement.

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MS. FORD: They have.

THE PRESIDENT: I am saying should it not be confined to the period when the agreement
would have had an effect of restricting entry, which might be said to be from July 2003, but
not from November 2002? The fact you make the agreement (inaudible), is that really
relevant?
MS. FORD: I am happy to accept a point in my favour.
THE PRESIDENT: But I am asking that because normally when you look at duration, even on an
object case, the duration point, when you come to penalty, I thought you look at then you
start to look at effect and you could have an agreement say a patent expires on 31st
December 2017, you make an agreement now in return for a larger payment that you are not
going to enter the market until 31st December 2018. Well, the agreement is made today,
but actually you are never going to enter at risk, you have not even got a marketing
authorisation, there is no question of it. The fact you make the agreement today, when one
thinks of duration, one would say the period when it bites, I would have thought, which is
the one year, is it not?
MS. FORD: It would be the period from in the counterfactual when we would be expected to
enter the market.
THE PRESIDENT: I mean, that has a rather more significant effect on duration. It might apply
to GUK as well, but in your case has a more dramatic effect than the calculations you put
forward here.
MS. FORD: It does, sir. That is of course on the assumption that you could get from a December
trial to resolving an appeal in our favour in that very short timescale. That is, in my
submission, quite an ambitious prospect.
THE PRESIDENT: Not sure. For infringement only, a four-day trial, sure to appeal, it is nothing
like the validity cases which are much more complicated.
But, yes, I just wanted to ask you that. Thank you very much.
MR. MALEK: I have one point arising from paragraph 181 of your Notice of Appeal where you
deal with penalty $\{A/4/58\}$ .
It seems to me from there that on the penalty you are just merely challenging the amount of
penalty, whereas if you look at, for example, GUK, GUK say they should not have been
fined at all because the CMA have not been able to approve that the infringement was
committed intentionally or negligently.
Is that a point you are taking on?
MS. FORD: Sir, if you look at paragraph 182 we have asked the Tribunal to remove and/or
reduce the penalty. So we have asked for it to be removed in totality.

1	MR. MALEK: The point I am making is there is no explicit challenge let us say the starting
2	point, the infringement must have been committed negligently or intentionally. For
3	example, if you look at GUK, that is their first point. They start off by that and then they
4	challenge the figures. It looks to me looking at 181 that you seem to be challenging the
5	figure and not dealing with the first step. I just want to know what your case is, really.
6	MS. FORD: I think the way we have put it is one which can be put under virtually any of those
7	heads. It is the same point that comes up. It is the novelty point. It is the intention point.
8	The parties are all making the same point under various different guises.
9	MR. MALEK: I will put you down as challenging that you should not have been fined at all on
10	the ground that the CMA have failed to show that the infringement was committed either
11	negligently or intentionally.
12	MS. FORD: I am grateful.
13	MR. MALEK: Okay.
14	THE PRESIDENT: As we are going until 5 o'clock we have been asked to take two breaks. It is
15	sensible to take a 5-minute break now.
16	(3.07 pm) (A short break)
17	(3.15 pm)
18	Closing submissions by MS. KREISBERGER
19	THE PRESIDENT: Yes, Ms. Kreisberger.
20	MS. KREISBERGER: Thank you, sir. I would like to start by saying now for something
21	completely different, but I think that is probably a little ambitious at this stage.
22	MR. GLYNN: We would love it though.
23	MS. KREISBERGER: I will do my best. Given the expert submissions of my friends, I may
24	struggle.
25	I was proposing to address the two topics of object and effect. The Tribunal has my written
26	closing submissions on penalty, so unless I can assist you with any questions on that I was
27	not going to address that in oral closings.
28	Turning to infringement, Merck's case is, in summary, that on object the CMA has not
29	proven that the purpose of the GUK settlement wasn't competitive, based on the evidence
30	cited in the decision and the theory of harm, which fixes on the payment.
31	Secondly, that the CMA has not proven that anti-competitive effects were likely because the
32	counterfactual of alternative settlement has not been proven as likely or realistic. I do not
33	think I need to address on you that. That has been thoroughly covered.

1 But I will say a few words on the counterfactual of continued litigation, which, in my 2 submission, is fundamentally defective, and that has led to a general failure of analysis on 3 effects. 4 As in openings, I will focus on the tests applied. I gratefully adopt Mr. Kon's submissions 5 on the facts. Before I turn to my submissions on each of those topics, just two prefatory 6 remarks. 7 The first is that Merck's position on the factual evidence has been clear from the outset, 8 which is that the factual evidence deployed at trial does not impinge on Merck's case. In the 9 Notice of Appeal we said that Merck does not challenge primary findings of fact. We of 10 course challenge the deductions drawn, the inferences made and the pricing analysis, but 11 not the primary facts set out in the decision, and of course the key finding of fact which we 12 have already heard a lot about is uncertainty. We accept that finding. We bank it, we do 13 not need to go behind it. 14 We agree that neither party knew the outcome of litigation. 15 MR. MALEK: You do challenge inferred facts? 16 MS. KREISBERGER: We do, absolutely. 17 MR. MALEK: The primary facts that you accept, and what you deduce from those primary facts 18 you do not accept necessarily. 19 MS. KREISBERGER: That is correct, sir. That is precisely our case. So the CMA attacks, for 20 instance, on GSK's precise level of confidence in its patents are not to the point in our case. 21 That leads me to my second prefatory remark. I fear it is not a new one. I think Mr. Flynn 22 already referred to this, but perhaps it is just worth emphasising that the CMA is not entitled 23 to alter its case at the appeal stage in fundamental ways. That is a well-established 24 principle, the decision fixes the case and we see that laid down in the Napp case. Really 25 just for your note that is paragraphs 77 to 78 at {Auth-B/1/29}. It is also cited in Merck's 26 opening skeleton at 98A, which is at 553. I do not think we need to turn to that now, but 27 you have it there. It fixes the CMA's case. 28 I will return to that point, but of course my fundamental submission on that is that the CMA 29 is not entitled at this stage to alter the fundamental conceptual underpinnings by running a 30 weak patent case. 31 It does not purport to in terms, but one does see shades of that if one looks a little more 32 closely on occasion at the tenor of the CMA's argument. In my submission, the CMA is 33 not entitled to make that shift now as to how it attacks the patent settlements. It can do that

in another case, but not in relation to these settlements.

THE PRESIDENT: By "a weak patent case", you mean an inference that GSK thought its patents were weak? MS. KREISBERGER: That is right, sir, I am grateful. It is shorthand. So turning first to restriction by object. If I may, I will address the Tribunal on three broad topics: first, the legal principles; secondly, the evidence; and thirdly, the inference. Now, I already addressed the legal principles in openings and I am not going to duplicate, but I fear I may be disappointing Mr. Malek here because I do need to come back to the legal test. The CMA is perhaps less keen to; there is no mention of it in closings. I am talking about the legal test for restrictions by object. There is not much mention of it in the decision. That is the test that needs to be satisfied. They need to hit the sufficient degree of harm threshold to make out a case on anti-competitive purpose. Now, Lundbeck purports to apply that test, but Lundbeck may be overturned. Cartes Bancaires is the law. Now, I think what was said against me in opening -- paraphrasing -is that there is no need to get caught up with the sufficient degree of harm standard or the restrictive approach once you have identified an anti-competitive purpose. In particular, the objection taken by all of the appellants that according to at least one counterfactual the settlement is benign and pro-competitive is not to the point. That is the CMA's case. If something, anything anti-competitive is intended, in the sense of it being the purpose of the agreement, the box is ticked and one does not need to worry about counterfactuals and establishing a sufficient degree of harm. Now, in my submission that sets the bar too low. The Cartes Bancaires framework is relevant, it is relevant to how you get to a finding of anti-competitive purpose. Now, Mr. Glynn and I had an exchange on the need to establish purpose in opening, and I think it is important for the Tribunal to have the correct analysis in the forefront of its mind, in my submission. If the allegation is anti-competitive purpose, which it is, then the legal test is whether the purposes revealed by the agreement by virtue of its wording, taking account of admissible features of the surrounding context, demonstrate that the agreement reveals a sufficient degree of harm. Now, the principles laid down in *Cartes Bancaires* are relevant to ascertaining purpose, and therefore relevant to that which the Tribunal has to determine here. This point is briefly

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1 addressed in my written closings at paragraph 8, and that is at  $\{M/5/4\}$ . But I would like to 2 develop the point for you now, if I may. 3 At this point we turn to {Auth-I/51/14}, and that is in hard copy volume 19. I would ask 4 you to just keep this open in front of you or on the screen. 5 If I could ask you to turn to paragraphs 67 and 68 on page {Auth-I/51/14}. This is where the Court of Justice address the ascertainment of objectives. 6 7 They say: 8 "In addition, the General Court pointed out ... that the Commission had stated that the 9 function attributed by the Grouping to MERFA ..." 10 MERFA are the pricing formulae: 11 " ... namely an incentive to expand acquisition, 'was inconsistent with the existence of 12 interchange fees which encouraged issue ... and by the fact that the supplementary 13 membership fee and the [dormant] member fee penalised banks that had not issued a 14 sufficient number of cards in the recent past'." 15 Paragraph 68: 16 "The General Court inferred from this ... that the object of the measures at issue, like 17 those ... in BIDS, is to impede the competition of new entrants on the market for the 18 issue of payment cards in France, since they require the banks subject to them either 19 to pay a fee or to limit their issuing activities." 20 So in other words, the General Court looked at what the group said was the purpose of the 21 formulae of MERFA and they said the purpose was said to be the incentive to expand 22 acquisition. 23 The General Court then said that stated purpose, the expansion of acquiring activities, does 24 not fit with the purpose of interchange fees because their purpose is to encourage or expand 25 issuing. 26 So the General Court inferred from the disconnect between the stated purpose and what the 27 General Court thought was the purpose, inferred from that disconnect that the actual aim 28 was to limit entry into the issuing market. So they made an inference as to the purpose. 29 That is an inference that was not clear on the face of the agreement in that case, and the 30 Court of Justice attacked that, they criticised it. It said the General Court's inference was 31 wrong on the facts and the essential reason it was wrong on the facts was because the 32 correct analysis is while the formulae are certainly capable of restricting competition for all 33 the reasons that the General Court set out in its judgment, that was not their purpose. That 34 is at paragraph 69 on that page.

1 If one turns to paragraph 80 later on in the judgment, it is clear and relevant for present 2 purposes {Auth-I/51/16} that it was not merely a restriction that they were capable of giving 3 rise to, these formulae, they might not simply limit the ability of banks to compete, but it 4 could even exclude new entrants. So there was a possibility of excluding players in this 5 market. 6 Contrary to one of the CMA's core submissions here, the mere possibility that the restriction 7 could lead to the exclusion of an actual or a potential competitor was not enough in Cartes 8 Bancaires for establishing purpose. 9 Now, I anticipate that the CMA might try and draw a distinction here and say "But in this 10 case it does lead to exclusion and there they just said it could lead to exclusion". But the 11 point is not the level of certainty of outcome. What the court is trying to get at here is what 12 was the purpose of the provision rather than its effect. 13 The Court of Justice says in terms, and this is highly relevant for our purposes, at paragraph 14 70 {Auth-I/51/14} the fact remains that the restrictive object must be established. 15 If one reads that paragraph in full, they accept that you can have an anti-competitive object 16 purpose even where you also have a legitimate objective. So I accept that point. But 17 nonetheless, that anti-competitive purpose has to be established on the facts, and it cannot 18 be done by reference to the effects of the measure. In the following paragraphs they look at 19 what the General Court did and they say the General Court got it wrong and they assessed 20 potential effects and so on. 21 What is interesting for my purposes is if one goes to paragraph 74 on the next page {Auth-22 I/51/15}, notwithstanding what they say at paragraph 70 that in theory you can have a 23 legitimate objective, it does not stop you having an anti-competitive objective at the same 24 time. In principle that is correct, but actually on the facts of this case the legitimate 25 objective of combating free riding was dispositive because what they say at paragraph 74 is 26 that the General Court failed to give proper account to the fact that it was a two-sided 27 market which opened up the scope for free riding. That was the legitimate objective which 28 the banks were claiming. 29 So they said, well, given this legitimate objective, the General Court failed to establish an 30 anti-competitive purpose. So what is one to take from this? If I could summarise it in the 31 following propositions. 32 If you are looking at purpose, it must be clear on the face of the agreement considered in its 33 context. Second point, the presence of a legitimate purpose does not itself preclude a finding

of anti-competitive purpose, it is not a knock-out blow, but in practice it does make things

1 rather difficult if it means that the purpose and/or the effects of the agreement are in fact 2 ambivalent. 3 That presents problems under the restrictive approach because if in doubt as to purpose, you 4 need to establish anti-competitive effects. In my submission, that is the whole point of the 5 restrictive approach. You tread with care on purpose. 6 Turning back to the settlements and applying these principles --7 THE PRESIDENT: Just before we leave Cartes Bancaires, it is right, is it, also that one can look 8 at the parties' subjective intentions? I think you accept that. 9 MS. KREISBERGER: Yes, it is dealt with at paragraph 88 of the judgment. 10 THE PRESIDENT: I was looking at 54, but you say 88. 11 MS. KREISBERGER: I think they actually cross-refer to each other, sir. 12 THE PRESIDENT: It is the legal principles at paragraph 54. 13 MS. KREISBERGER: Yes. 14 THE PRESIDENT: So it is not necessary, but it can be taken into account. 15 MS. KREISBERGER: That is right. Then I think at 88 they refer to the principles at 54 and they 16 apply those principles at 88 on the facts. 17 I am going to actually come on to that point in relation to the settlements, but I was going to 18 touch on it briefly. But that is right, subjective intention alone is not enough. But I will say 19 a word on how that might feed into the analysis here. 20 So the fundamental premise of my argument is that one looks at these settlements and one 21 sees the clear purposes of settling litigation and effecting early entry. That is on the face of 22 the agreements. So for these purposes early entry is not to be relegated to a 101(3) analysis 23 because you are looking at object. 24 These are clear legitimate and pro-competitive objectives, including settlement, which it is 25 generally accepted to give rise to efficiencies. Clearer than Cartes Bancaires. In Cartes 26 Bancaires you have to delve a little deeper to see free riding, but this is in the wording. 27 So the question is then: can you say, notwithstanding those legitimate purposes, that 28 nonetheless there is a clear anti-competitive purpose just on the basis of the terms of the 29 settlement considered in context? 30 Of course, the CMA says yes, because you can draw an inference from the payment. I will 31 come on to that, of course. My response is the mere presence of a payment alone is not 32 sufficient for these purposes because it does not distinguish between legitimate settlements 33 and settlements designed to have an anti-competitive purpose.

1 But the whole thrust of this judgment is that you look at the face of the agreement. So take 2 care with inferences; they might signal a need to conduct an effects analysis. 3 As is well known, we say the inference is based on an unreliable hallmark and so cannot 4 meet the strictures of the Cartes Bancaires test. No one is precluding an effects analysis. 5 Those are my submissions on the overarching legal principles, the approach to take to anti-6 competitive purpose. 7 Now turning to the application of that to the facts of the GUK settlement in particular, I 8 would like to address three separate topics on this point: the nature of the evidence; the 9 relevant threshold; and I will say a word as well on legal advice. After that I will come on 10 to talk about the inference. 11 If I could take you to paragraph 4 of the CMA's closing, which is at  $\{M/6/3\}$ . 12 The CMA says there, and I quote: 13 "... there is such strong evidence in this particular case concerning the parties' 14 objectives that the Tribunal is left in no doubt as to the anti-competitive nature of the agreements ..." 15 16 So the Tribunal should not stay its hand. 17 On its face, that would meet the test that I just laid out, at least potentially, very strong evidence of anti-competitive objectives. So it is a bold statement. But in my submission, 18 19 the CMA there mischaracterises its own case on purpose, which has little to do with 20 evidence. 21 So we ask ourselves what is the evidence on which the CMA relies? Well, if one turns to 22 the decision, I think this is a paragraph that the Tribunal will be familiar with, but 23 paragraph 6.86, and that is at {V/1/268}. I can deal with this briefly because I do not think 24 this is a contentious point, but it summarises the CMA's case. 25 If we start on 268 and then go over the page, it is very clear and it has been confirmed by 26 everything the CMA has said in terms in this trial: the case is GUK accepted restrictions, GSK made cash payments and other transfers, and the objective aim of the transfers was to 27 28 induce acceptance. You see the basis on which the CMA advances its case. 29 This is the inference. The CMA, the decision, does not rely on clear evidence of anti-30 competitive motives in the ordinary meaning of that term. It relies on the inference. 31 I will turn back to the inference in a moment, but I do just want to address the CMA's 32 assertion that it has a good case on the evidence on anti-competitive objective purpose 33 because I agree, this is not an inference which can replace evidence in order to establish 34 purpose.

Cartes Bancaires says we should start with the agreement. I have already touched on this. The agreement is not good evidence of anti-competitive purpose because it is distinct from a written agreement that provides for an export ban or an information exchange mechanism between competitors, to give some examples. Those are the agreements where you look at the agreement and you know on its face it is malign. You would not normally need to go to context even. Here, we do not have that. So you go to the contextual evidence. I will deal with this briefly because it has been touched upon. But this is what the CMA says in its written closing at paragraph 41 {M/6/17}. The CMA decision has relied on a body of clear contemporaneous evidence showing that GUK required sufficient financial inducement from the GSK to persuade it to cease its efforts to bring an independent product to market and accept entry restrictions. Mr. Kon has already addressed this point in substance. What the CMA means here is that GUK settled for the best terms it could extract from GSK. Mr. Glynn made the point it was fruit worth picking. This statement does not make GUK's actions anti-competitive. I will come back to this, but the pejorative language of inducement and ceasing efforts to make independent entry do not illuminate the issue. This is just about profit-maximising behaviour. One sees that. It is reflected in the decision at 6.136, which is at  $\{V/1/292\}$ . Precisely the same point: "GUK's internal documents demonstrate that, during its negotiations with GSK its intention was to maximise the profits that it would receive from GSK ..." It is certainly naked capitalism, but one has to ask oneself: what if GUK had not sought to maximise its profits when bargaining with GSK? Would that have made it a benign settlement? At what point was profit-maximising the bright line? I am only addressing purpose. MR. MALEK: Look, the agreement itself contains a restriction on independent entry. Are you saying that the payment had absolutely nothing to do with that? MS. KREISBERGER: No, I am not, sir, and I will come on to that. But if I could perhaps just pick you up on language, which has sort of developed a life of its own in this case. Professor Shapiro referred to it as a restriction on competition. I agree with your formulation, sir, it is a restriction on entry. We do not know whether it is a restriction on competition because one has to bear in mind there may have been no lawful right to enter at

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1 all. But no, I am not. I will address payment directly. What I am doing here is simply 2 looking at the evidence which the CMA says is so strong. 3 MR. MALEK: Do not let me take you off your point. 4 MS. KREISBERGER: I will come back to it later. 5 MR. MALEK: Come back to it later, thanks. 6 MS. KREISBERGER: I think that really deals with the question of evidence. 7 I want to turn, just before I get onto payment and inference, to the question of threshold 8 which I have addressed in written closings. That is at paragraph  $18 \{M/5/7\}$ . 9 Because my submission is that it is instructive to consider -- I have addressed the point that 10 we do not have evidence of anti-competitive motive here. What might one be looking for? 11 What kind of evidence would have justified the CMA's claim that the evidence of anti-12 competitive purpose is, in their words, so strong? I say profit maximising does not get you 13 there. 14 This is where I was going to refer to Cartes Bancaires, but I think you have the point about 15 subjective intention, sir. That could be a legal hurdle in itself. I would accept for these 16 purposes that going to contemporaneous evidence of subjective evidence on both sides is 17 capable of confirming that a payment had an anti-competitive goal. For these purposes I am saying we are now going beyond the agreement, there is a payment. 18 19 Payment alone is not enough, but payment plus evidence might get you there, can get you 20 there, if the evidence is right. 21 The heart of my case is that there has to be strong and compelling evidence that the 22 settlement was deliberately designed, as far as each of the settling parties was concerned, to 23 restrict competition. 24 Now, what does restricting competition mean in this context? It is to preserve by agreement 25 a patent which was expected to fall down at trial because it was granted in error or it was 26 not infringed. So it was an agreement to preserve an unlawful monopoly to stop a hopeless 27 legal challenge in its tracks. 28 Now, in written closings at paragraph 18, which you have in front of you, I suggest the 29 threshold should be along the lines of no realistic prospect of the patent being upheld as 30 infringed at trial because this is a defensible, conceptual bright line. It will distinguish truly 31 anti-competitive settlements from genuine settlements, remembering that we are just on 32 purpose, not effects. 33 Now, the Tribunal does not have to come to a landing on this. I am proposing this to assist 34

in the spirit of a contrast to a case that you do have before you. But I hope it is of some

1 assistance. I am conscious that you will not find my suggested formulation in *Lundbeck*, for 2 instance. You will have seen my submissions. 3 I say the General Court's version of the facts in *Lundbeck* are perfectly consistent with my 4 case. They do not use this language, so I do not put it any higher than that. I say that 5 Lundbeck can be factually distinguished, and what one has here is an exciting opportunity 6 for the Tribunal to take the right approach rather than being in thrall to *Lundbeck* I will 7 come back on that point to the language of inducement. 8 So, in my submission, this would strike the right balance and respect the restrictive 9 approach. It is appropriate for a finding of purpose as distinct from effects, remembering 10 that purpose is a shortcut. It is a way of getting at obviously malign agreements. It is not a 11 way of getting at restrictions that are too difficult to prove. Again, just pausing there. I say that the issue of the counterfactual is relevant here for 12 13 precisely that reason. I accept, of course, it is right that the CMA does not need to establish 14 effects by reference to the counterfactual otherwise the object category would simply serve 15 no purpose, it would blur the distinction. I said this before, but that is because it is obvious 16 that certain arrangements infringe compared to but for price fixing versus free play of 17 competitive forces. 18 But if it is not obvious because there are two plausible counterfactuals, according to one you 19 have restriction, according to the other no restriction at all, that is relevant to the object 20 analysis. I am not saying it excludes an object finding because I proposed a threshold, but I 21 think you do need to set the threshold in a way that respects that so that you do not capture 22 settlements in the latter category. 23 So that is why I suggest no realistic prospect. 24 MR. MALEK: It is quite brave, is it not, to put your head above the parapet and actually suggest 25 where the line should be drawn? 26 MS. KREISBERGER: As I say, I am not suggesting that your judgment needs to address this, but 27 it was a question raised by the President in opening, in the CMA's opening I think, as to 28 what are you saying the threshold is. 29 MR. MALEK: Yes. 30 MS. KREISBERGER: I am concerned that there is -- well, I want to make my submission that 31 we should not be in thrall to Lundbeck. I do not accept the inducement test laid down in 32 Lundbeck. I do not think it is a problem because it applies to those facts. I would also say I 33 do not think it is such a bold submission because it is so obvious.

1 If one steps back, what one is trying to achieve is to get at the weak patent cases. I think we 2 have to accept that. Those are the cases where one might have effects. If the patent is not 3 weak, one does not have effects. 4 MR. MALEK: What you are saying is it is easy to envisage an objects case where there is a weak 5 patent, but where the patent is moderate or strong, you are saying it is very hard to get into 6 that --7 MS. KREISBERGER: I think you need to look at effects I mean, perhaps if I put it like this: how 8 are you going to distinguish between bona fide settlements and settlements that are anti-9 competitive in purpose? 10 It seems to me that there is a large range of bona fide settlements. Now, you might look at 11 those settlements and say "Actually, I think those settlements were on balance likely to have effects on competition. We will deal with them in the way that Actavis deals with them. 12 13 We deal with them on an effects analysis." But to say we are not going to even look at the 14 effects, we do not need to do that, we are just going to condemn you on the basis of 15 payment, my submission is twofold: you need to get the threshold right and you need to 16 look at the surrounding evidence. 17 THE PRESIDENT: On an effects analysis, are you not also going to have to look at strength of 18 patent? 19 MS. KREISBERGER: I agree, yes. I am going to make that submission. 20 THE PRESIDENT: You say then you look at effects. You get to the same position because if it 21 is not obviously a weak patent, unless one can conduct a mini patent trial, you do not know. 22 There you do need a clear counterfactual, I think, when you are into effects. 23 MS. KREISBERGER: Absolutely. I think one should be sceptical of arguments that tell you you 24 do not need a counterfactual for a start, on difficult cases like this. I absolutely accept that. 25 There is no getting away from patent strength, but there may be different ways of cracking 26 that nut. I am not saying you need to conduct a patent trial. But I think, you know, it is 27 important to adopt a correct analytical approach and the correct approach is examining 28 effects. I do not think we should adopt a fictional construction of purpose based on an 29 inference that is not supported by evidence. 30 MR. GLYNN: It is clear that the effect of the agreement is to extinguish the chance of the patent 31 not being held, or the other way round. That is very clear and that is in the counterfactual 32 and quite difficult for you, is it not? 33 MS. KREISBERGER: I was going to come on to that in effects, but I think that is one of the 34 weaker aspects of the CMA's case because -- it has been said many times now in many

2 extinguishing a possibility, however small that possibility may be. 3 So I --4 THE PRESIDENT: Well, a realistic uncertainty. 5 MS. KREISBERGER: I would say on effects you need to --THE PRESIDENT: Sticking to object. 6 7 MS. KREISBERGER: But sticking to object. 8 THE PRESIDENT: You say one has to have some concept of effect. Well, that is the concept, 9 that the uncertainty is removed. 10 MS. KREISBERGER: So I do not accept that that sets the test at the right threshold because it will invariably -- I mean, it must capture benign settlements, and perhaps this is best dealt 11 12 with when I talk about payment --13 MR. GLYNN: Let me stick with the idea that the unexplained payment has to be substantial. So 14 you have a substantial payment which cannot be explained in some way that is legitimate, 15 and you have the fact that the risk or the chance of either outcome of the patent litigation 16 being extinguished, then are you not there in terms of an object case? 17 MS. KREISBERGER: Can I come back to that point because I would like to address that in 18 relation to the inference, and if I haven't answered you satisfactorily. Just because I would 19 like to take it in order and I am going to deal with that head on. 20 THE PRESIDENT: Do it in your own order. Before you get onto effects. 21 MS. KREISBERGER: I will deal with it in the context of object dealing with the inference. But I 22 can skip forward, but I think it might --23 MR. GLYNN: As you prefer entirely. 24 MS. KREISBERGER: So I was just going to really finish off on that point about the evidence. 25 The CMA place a great deal of emphasis on the March 2002 email from Mike Urwin, which 26 Mr. Kon addressed. But that email is, in my submission, a very useful one because he 27 makes the point that GUK may not prevail in the patent case. So his hope for the best 28 terms, which I have discussed, and extracting the best deal did not undercut his belief, or 29 does not contradict his belief, in the possibility of losing. I say there is evidence that this is 30 not a purpose case. 31 Really, just finishing up on the evidence, I just note that in the CMA's closings -- I just give 32 you the reference for your note, paragraphs 48 to 68,  $\{M/6/19\}$  under the headings: What 33 were the payments?.. What did the business people expect to happen? You would expect 34 that section to deal with anti-competitive purpose, the type of evidence I was talking about.

different ways -- that will always be the case. There must be something more than merely

You will not find a single mention of documents from GUK there. So really, I would say that omission speaks volumes. One is left with the impression that the facts here do not fit the theory.

If I could just say a word on legal advice and then I am going to turn to the inference itself. It is just a final evidential point. I act for Merck so I am not privy to whether legal advice was sought or not. We do not know. But even if it did exist, like Mr. Kon I agree that its disclosure would not have advanced matters in any material way. I raise this for the point that it brings out really, which is that the CMA's finding of uncertainty really makes this point redundant.

I think it is helpful conceptually just to distinguish between risk on the one hand and uncertainty on the other. I understand that economists often draw that distinction. I would be tempted to take you to some economic literature on the point, but I will refrain from doing that.

THE PRESIDENT: We accept your assertion.

- 15 MS. KREISBERGER: I think we can make the distinction as a matter of basic English.
  - MR. MALEK: If it was your case or any of the appellants' case that they had a subjective belief that they were going to win the litigation or they were actually going to lose the litigation in a positive way, then the legal advice would have been highly relevant, and that is why in the Australian cases where you try and rely on your subjective belief the cases say, well, you cannot raise privilege, you cannot say if part of the reasoning that would have led to that belief is legal advice, you cannot on the one hand say, court, believe my subjective belief at the same time not disclosing the material.
    - If your case is "We are not saying what our subjective belief was, whether we win or lose", then I agree with you, the legal advice will not take you anywhere.
  - MS. KREISBERGER: My case is that it is entirely redundant because of the finding of uncertainty in the decision. I make this point by reference to legal advice, but I am really making a broader point, which is risk is quantifiable, uncertainty is simply a state of not knowing.

The precise level of risk will not advance the question of uncertainty. Lawyers are a risk averse bunch themselves. You might get something between 30% and 70%, I do not know. Any point in that range is consistent with the CMA's own finding that the position was uncertain. So the CMA does not attempt to quantify risk. There is, therefore, no reason for the appellants to do so. Certainly on my case we accept the finding of uncertainty, we do not need to look at quantifiable risk.

1 Had the CMA said, like in *Lundbeck*, we think there is a 60% chance that this patent would 2 have failed or not failed, then this evidence might suddenly become relevant. But they 3 made the specific factual finding that the parties were in a state of uncertainty; the precise 4 degree of risk does not take you any further unless one were looking to challenge that 5 finding of uncertainty. THE PRESIDENT: Well, we did get some submissions that appeared to. Not from you. 6 7 MS. KREISBERGER: But they do not affect my case. 8 THE PRESIDENT: They do not affect your case, (inaudible) to challenge it and I think that is 9 how it arose. 10 MS. KREISBERGER: If I could then move on to inference, and I hope I will deal with the 11 Tribunal's questions. 12 Given what I have said so far, the question I would pose is whether the inference can be 13 substituted to plug the evidential gap and, sir, the sole premise of a finding of anti-14 competitive purpose. 15 I have four responses as to why that cannot be done here, which relate to threshold, the 16 unprecedented nature of the inference, that is a responsive point to the CMA's closings, and 17 then I will get to the problems with the inference itself. I have a collection of points at the 18 end concerning fairness and enforcement concerns. 19 Starting with threshold. If I am right as to my bold submission about the need to distinguish 20 between legitimate settlements on the one hand and those designed to prop up a weak 21 patent, then the inference does not help because that requires evidence of motives, of malign 22 intent because no one, including Professor Shapiro, suggested that the inference tells you 23 that. The inference does not tell you that this was a hopeless patent; no one claims that. So 24 I can say you can throw inference into the mix perhaps, but it does not get you there on its 25 own. 26 If I am right about threshold, I win on object. 27 I have already said in the absence of evidence of the sort I have set out, then one would 28 need to go on to look at effects. Competition law is not stymied, it is not shut out like 29 under the scope of the patent test, it is just that there is no shortcut. 30 There was considerable debate with my friend Ms. Ford as to the *Lundbeck* formulation that 31 a payment which induces delay is anti-competitive by object. We do not accept that 32 submission because my case is that the language of inducement is not helpful. It does not

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elucidate matters.

It is very difficult, I would say, to separate out causation of settlement and causation of delay. That is why I would prefer the test I have proposed, which genuinely differentiates between the two. But given that there are, in my submission, settlements where payment was necessary, where there was genuine uncertainty and the terms of settlement, including the payment, facilitated settlement and there is no reason to think that that settlement harmed consumers -- that is putting aside the mere extinguishing of possibilities for a moment -- did the payment induce delay? I do not think that tells you anything.

If the payment was necessary to achieve settlement and the settlement terms included a restriction on entry, because the generic has agreed to respect the patent, inducement does not help. You might be able to describe that settlement as a settlement in which payment induced delay because payment was a necessary component of that settlement, but that, on my case, is not a distinguishing feature of anti-competitive purpose.

It is not a fruitful enquiry to ask the question whether payment induced delay. The better question is: was this settlement designed to evade competition? If so, one can identify an anti-competitive purpose. In my submission, that is a workable test.

Now, I would like to come to my next heading which I set out was that the probabilistic approach is unprecedented to show anti-competitive motives.

The CMA says in closings at paragraph 93 {M/6/35}:

" ... inferences of the sort referred to by Professor Shapiro ... are not uncommon in competition law."

That submission is plainly wrong. The application of this particular inference as the only premise for a finding of anti-competitive purpose is completely unprecedented. There is no Article 101 case where the extinguishing of mere possibilities of competition, however small, are in themselves anti-competitive aims.

I have already discussed *Cartes Bancaires*. There, the possibility of excluding new entrants was not sufficient to support an object finding. But what is interesting here is the CMA relies on two case to support its proposition. One is *Toshiba* on market sharing and the other is *AKZO*. You have those there on the screen.

I am grateful to the CMA because actually I think these authorities support my approach to the need for inference and evidence, or the need for evidence if you are going to rely on an inference.

Taking each in turn very briefly. *Toshiba* is at hard copy volume 16, {Auth-G/33/33}. It should be paragraph 231. This is an easy case. If Siemens and Hitachi agree not to invade each other's home markets, it is a safe assumption that the purpose of the agreement was to

1	stop them doing precisely that, otherwise why bother? It really belongs in the category of
2	stating the obvious.
3	Putting Toshiba, this market sharing agreement, into the Cartes Bancaires analytical
4	framework, it clearly had a single purpose which was malign: market sharing. That is what
5	they were doing here. Although it is notable, if you look at the paragraphs which follow,
6	the Commission actually went on to refer to evidence that Hitachi was supplying in Europe.
7	So they did not in fact just rely on an assumption, it was supported by evidence even where
8	you have that single malign purpose.
9	Here we have benign pro-competitive purposes. You cannot assume a malign purpose in
10	the way that they do in <i>Toshiba</i> is justifiable. So that provides no support.
11	Then turning to AKZO, which is at hard copy volume 18 {Auth-I/22/16} and going over the
12	page to paragraph 71 and 72. This is the well known AKZO test for predatory pricing. I
13	say this provides especially interesting confirmation of Merck's approach in a very different
14	context because they focus on the evidence.
15	What you have is the two-part test for predatory pricing, above AVC and below ATC.
16	Prices below AVC, the court says, each sale generates a loss. So the only credible
17	explanation is the elimination of competitors. There is no other objective or credible
18	explanation for pricing below AVC. There is a single malign purpose.
19	Then you look at what they say on prices between ATC and AVC. They say, well, these
20	will be characterised as abusive if they are determined as part of a plan to eliminate a
21	competitor. So what you need is evidence, otherwise there might be an alternative
22	explanation or objective for that pricing. You are not entitled to make an assumption where
23	there is a potentially benign explanation.
24	So the court goes on to look at the threats made by AKZO made in that case to support the
25	allegation of predatory pricing. It is exactly the same. Payment alone cannot get you there.
26	If there is compelling evidence that the goal is not settlement and it is stopping a weak
27	patent case in its tracks, then you can find it restricts by its nature. So neither case is like
28	this inference.
29	While I am on the lack of precedent, I have made the point in written closings about Actavi
30	that is at paragraphs 43 and 44 $\{M/5/15\}$ that there they rejected the presumptive
31	approach and insisted on a rule of reason analysis.
32	I think I can move on from that point to finally get to the economic inference and the points
33	that we were discussing, aware of the time.
34	THE PRESIDENT: Would that be, then, a sensible point for our second break?

1 MS. KREISBERGER: I think it would. 2 THE PRESIDENT: We will take just 5 minutes. 3 (4.10 pm)(A short break) 4 (4.20 pm)5 THE PRESIDENT: Yes. MS. KREISBERGER: So moving on, sir, to the inference and the economic evidence on the 6 7 inference. 8 My overall submission is that it is not an inference which works in every case, and therefore 9 it is not an inference which is appropriate to support without more a finding of anti-10 competitive purpose. You need to have a proper factual inquiry, you can take proper 11 account of the payment, just as they found was the right approach in Actavis, but it is not simply purpose and no more, no need to go to effects. I say if you are going to effectively 12 13 abandon evidence, this inference is not good enough. 14 Now, Merck is the party that has put forward economic evidence from Dr. Jenkins, and her evidence shows that the core assumption of Professor Shapiro's theory, which is an 15 16 otherwise unexplained payment must have brought about a restriction of competition, that 17 core assumption breaks down when you consider the realities of settlement negotiations or, 18 putting that a different way, the theory, it is an elegant model, but it requires theoretical 19 assumptions of perfectly symmetrical information, efficient bargaining and risk neutrality. 20 I set out in closings at paragraph 27, and I do not think it is a controversial proposition --21 that is at  $\{M/5/10\}$  -- I think everyone has said this in one way or another -- that the 22 settlement range is a function of originator downside at one end, potential generic upside at 23 the other. The CMA does not disagree with that and that is reflected at paragraph 6.1 to 6.9 24 of the decision at  $\{V/1/240\}$ . We do not need to dwell on them now. 25 But the thrust of the economic evidence that Merck has adduced is that a payment can be 26 necessary to bridge the gap between the parties' differing conceptions of the likely upside 27 and downside of the generic entry. Parties often do not negotiate in conditions of perfectly 28 symmetrical information and they are often willing to pay more to avoid risk or to avoid the 29 loss of something they already owe. 30 THE PRESIDENT: If we take your example, you refer to paragraph 27, I think, of your closing. 31 Is that right? 32 MS. KREISBERGER: That is right, sir. 33 THE PRESIDENT: You give there that illustration. When you say a patent worth 10 million to

the originator, I assume you mean that is saying that it makes 10 million more profits than if

1	it was without a patent, having to compete in what has been referred to as a genericised
2	market? Is that right that is what it means?
3	MS. KREISBERGER: That is right.
4	THE PRESIDENT: That is the way I understood it. On that example, the patent holder might say
5	to the generic, right, I will pay you 1 million to drop your challenge to my patent, and of
6	course the generic will take it. Then another generic comes along and says, okay, you are
7	like generic number 1, I will pay you 1 million, go away, and it says of course I will, that is
8	all the profit I would have made, and the third one comes along and it says I will pay you 1
9	million and so that one goes away.
10	Yes, he has lost 3 million, but it is clearly in the interests, commercially, of the patent
11	holder because it keeps 7 million which it would not otherwise make. It is in the interest of
12	each generic because they each get all the profit they could have made, and the patentee has
13	bought off any challenge to the patent and keeps competition off the market, any chance of
14	competition. If I have understood it correctly you are saying there is nothing anti-
15	competitive about that at all.
16	MS. KREISBERGER: That is not my submission. My submission is that is not sufficient to
17	establish anti-competitive purpose.
18	THE PRESIDENT: Why not?
19	MS. KREISBERGER: Because the patent may be valid and
20	THE PRESIDENT: Well, it may. I am taking all your facts as hypothesised: 70% chance of
21	winning or maybe 60% chance on the other view, but between 60% and 70% chance it is
22	valid.
23	MS. KREISBERGER: I would like to make two points in response to that. First of all, the first
24	sentence of the next paragraph at paragraph 28 is:
25	" where the parties have significantly differing conceptions of the merits such a
26	payment may represent the only feasible means of achieving settlement."
27	That is a significant sentence.
28	So if you do not have perfect symmetry of information, payment may be your only route to
29	settlement.
30	The reason that is significant for the purposes of this inference is that you knock out
31	alternative settlement, and there is good evidence on the facts and that has been ventilated.
32	THE PRESIDENT: That is a different point, is it not?
33	MS. KREISBERGER: No.

1	THE PRESIDENT: It is not to bridge the gap between 30% and 40%. It is saying the profit you,
2	the generics, make in clearly a genericised market is so much less than the profit the
3	patentee makes in a protected market that it is commercially in the interests of the patentee
4	to pay the generic its entire profit. Nothing to do with different perceptions of patent
5	strength.
6	It would be the same if their perception was the same and the patentee thought his prospects
7	of winning were 60%. He would still say it: I will pay you the entire profit.
8	MS. KREISBERGER: So my submission is that that is not sufficient to find an anti-competitive
9	purpose, it simply arises out of the differing conceptions, the dynamics of the game, if you
10	like.
11	THE PRESIDENT: Well, it is commercially rational for both of them.
12	MS. KREISBERGER: It is not anti-competitive if the originator is confident about its prospects
13	at trial and there is a symmetry in that regard between the originator and the generic. It is
14	not anti-competitive.
15	THE PRESIDENT: Let us assume no asymmetry. Let us assume that instead of 70%, the
16	patentee said his prospects of winning are 65% and the generic estimates his prospect of
17	winning at 35%. So there is no asymmetry. It is still in the interests of the patentee to pay
18	the generic its entire profit because it keeps him out of the market and avoids any challenge
19	to the patent.
20	MS. KREISBERGER: But we would say then you need to look at the effects. You cannot
21	condemn the parties simply for entering into a settlement that makes commercial sense.
22	You need to have a closer look at the level of the payment.
23	We are not saying that competition law is excluded from looking at that settlement, what we
24	are saying is you should not assume purpose which is a high threshold and they could both
25	have bona fide intentions of achieving a settlement. You need to do some more work. I
26	think those were Dr. Jenkins' words.
27	THE PRESIDENT: What work would you do?
28	MS. KREISBERGER: You need to look at the level of the payment and you need to take a view
29	on what would have happened in the counterfactual. One has to do that.
30	MR. GLYNN: But in this case, on your example, we know exactly what the counterfactual would
31	have been, which is a 65% chance of the patent surviving.
32	MS. KREISBERGER: Then the settlement survives. So it is not anti-competitive.

1 THE PRESIDENT: That is what I mean. You can buy off, protect any chance, the 35% chance 2 of your monopoly profits being struck down, by just paying off the generic all the profit 3 they would have made. 4 MS. KREISBERGER: When you say just paying off the generic, yes, it is a settlement on terms 5 that involve a payment in relation to what we know is a valid patent. 6 THE PRESIDENT: No --7 MR. GLYNN: It is not a valid patent. 8 THE PRESIDENT: It has a 65% chance of success. 9 MS. KREISBERGER: This is where we get to thresholds on effects. On effects I am certainly 10 not aware of any case where one can go below a 50% threshold. I mean, think of it this 11 way: what is the precedent value? What are the precedent implications of a judgment in this 12 case that says: the exclusion of the possibility of competition below a 50% threshold is 13 sufficient to render this anti-competitive by purpose? 14 That might have really quite significant implications for a whole raft of cases where it has always been assumed that you have to show restrictive effects are more likely than not. 15 16 THE PRESIDENT: That is on an effects basis. 17 MS. KREISBERGER: That is right. 18 THE PRESIDENT: I understand that. But on an object basis where the object is to buy off the 19 chance of any challenge to a patent of which the validity is uncertain. That is really what is 20 being said, that the explanation for the payment is not legal cost, it is not cross-undertaking. 21 I mean, I know that Ms. Ford said it is and I think on the CMA's case, if it were, their case 22 would fail. It is to achieve protection of a payment to achieve a protection of the market 23 which would have a not insignificant but uncertain risk of being struck down. 24 MS. KREISBERGER: I mean, I do not shy away from this aspect of the argument. In my 25 submission, that is not sufficient to make out an anti-competitive purpose which avoids any 26 scrutiny of effects, and I will come on to the point about the distinction between doing this 27 prospectively and retrospectively. But you have two parties engaging in a settlement. Now, 28 I would ask you to take my version, which is you cannot achieve settlement except by 29 payment and the originator thinks his patent is valid. 30 MR. GLYNN: Could I put it in the terms in which I imagine the CMA argument is coming, 31 which is that you can have an inference or a rebuttable presumption, therefore you can be 32 looking for explanations. In your view, if, in the example you have, the payment were 65%

the payment or would that be an anti-competitive payment?

of 10 million or up to that amount, would that, do you think, count as a valid explanation for

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2 MR. GLYNN: It is perhaps an unfair question. 3 MS. KREISBERGER: I think what I am suggesting is that one should undertake an effects 4 analysis. 5 MR. GLYNN: Forgive me, we do know here that the effect of the agreement is to extinguish the 6 35% probability of the outcome. 7 MS. KREISBERGER: Okay, understood. 8 MR. GLYNN: We know because the market with the patent is worth 10 million, to simplify your 9 example, without the patent at generic prices it is worth 1 million. So that is the difference 10 in price that is at play here. 11 Clearly if you apply 35%, or whatever the appropriate number is that would reflect the 12 outcome of the litigation, to the 10 million you come to a number which is enormously 13 higher than the probabilities applied to the lower number. 14 The CMA are saying there is an inference of anti-competitive behaviour unless there can be 15 an acceptable, in competition terms, explanation for the payment. 16 My question, as I say it may not have been a fair one at all, is: do you think that a payment 17 effecting the probability of the outcome of litigation to the 10 million is anti-competitive or 18 not? 19 MS. KREISBERGER: If it is, on this hypothetical scenario, below the 50% threshold for patent 20 strength --21 MR. GLYNN: You have given us the 70% and 40%. 22 MS. KREISBERGER: Sorry, 70%, so you have extinguished 30%. 23 MR. GLYNN: Yes. Or to follow the President's -- simplifying it even further, if we go to, say, 24 65% and 35%. So they both agree on what the chances are of the patent being upheld, so 25 we have got rid of that problem and we have reached the point that the percentage applied 26 to the in patent price or the patent foundation price is very much more than the same 27 percentage applied to the generics' price. The question in those circumstances is: is a 28 payment that would be above 35% of the generic price but below the same percentage 29 applied to the thing, is that, in your view, an acceptable payment as a valid explanation of 30 the transfer value or not? 31 MS. KREISBERGER: I do not think it is a payment which supports a finding of anti-competitive 32 object, which I think is the long way of saying yes. I do not think you can treat the payment 33 as anti-competitive in those circumstances.

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MS. KREISBERGER: I think one --

1 I think it is important to step back and remind oneself that, at least in my submission, what 2 one is trying to get at, and this comes out very clearly in FTC v Watson, are the weak patent 3 cases. 4 Those are the ones that Professor Shapiro, he says it is inherently suspicious and he says in 5 terms I think GSK's patents were vulnerable. That is no part of the CMA's case because 6 my starting point is competition law should not strike down settlements under valid patents, 7 and it certainly should not do that by finding an anti-competitive purpose --8 MR. GLYNN: Could I then repeat the President's line of questioning. 9 Supposing a payment in that wide range was accepted and then it was repeated for the next 10 generic and the next, you could afford to buy off quite a number of potential generic 11 entrants on line of thought. Sorry, I do not mean to use the term "buy off" to assume what I 12 think the answer should be. 13 But the repeated gain line of thought is, again, another way in which one might see anti-14 competitive behaviour. 15 MS. KREISBERGER: I mean, obviously it is difficult because one is dealing with a hypothetical. 16 It may be quite difficult to construct an example in the real world where there is a strong 17 patent and so many generics to be bought off, I do not know. 18 MR. GLYNN: I should think that quite likely, actually. 19 MS. KREISBERGER: I think you need a defensible bright line to distinguish the weak patent 20 cases. We are shading into effects. On effects, we say clearly it should be 50%. So if you 21 look at the example and if you can get down to the numbers and it tells you that the patent 22 is more likely valid than not, you do not have a good case on effects. It is as simple as that. 23 MR. MALEK: You quoted Professor Shapiro, that he thought these patents were vulnerable. I 24 think they were vulnerable. Your point is that the test is weakness, is it not? 25 MS. KREISBERGER: Yes, agreed. It is not quite clear what he meant by --26 MR. MALEK: Because I do not think there is any dispute that these patents were vulnerable 27 either on invalidity or lack of infringement. Your case is that unless the CMA can show the 28 patents were weak in the sense that they had a less than 50% chance, they do not get to first 29 base. 30 MS. KREISBERGER: That is my submission. 31 MR. GLYNN: You do not accept that the extinguishing of a risk, never mind if it is 50% or not, 32 could be part of an anti-competitive object? 33 MS. KREISBERGER: I do not understand why that is only relevant where there is payment. If

that is genuinely the objection, why, and if it is not about weak patent cases, then why is

that okay where one has, for instance, early entry time and no payment? One is still in a settlement where the generic agrees to respect the patent for a period. There is still the extinguishing of the possibility of a legal challenge in that settlement with no payment.

- MR. GLYNN: The point is that if you exclude, as I understand it, the possibility of the payment, then the nature of the settlement has to be one which departs from the high -- well, we will call it high, but the in patent price.

  Let us say there was a 50% chance of a patent being extinguished and everyone agreed that
  - Let us say there was a 50% chance of a patent being extinguished and everyone agreed that, and the settlement were to be it is a ten-year patent but we will let you in after five years, leaving aside discounting and things like that. Then that would be a settlement which would give the consumer and the patent holder half the benefit of the existing patent price which is, as I have read the CMA's case, as what they would see as a competitive outcome, or the CMA/Shapiro's view, that would be a competitive outcome.
- MS. KREISBERGER: That is the logical consequence of this. So one has -- I think Mr. Kon makes this point in closings. One has the patent holder having to give up part of its lawful monopoly because it is not entitled to make a payment.
- MR. GLYNN: The guts of the case that you are discussing with this value transfer coming in is that if you pay that money, rather than allow the patent to be diminished by whatever the probabilities are that mean that it is appropriate that it should be diminished, getting rid of that chance, but you allow the value transfer in, then you are allowing the high price to be continued. Or in terms of your example, you are applying the percentages to the 10 million rather than the 1 million. That is why the value transfer raises the rebuttable presumption, as I think of it, of anti-competitive object.
- MS. KREISBERGER: I think there were a number of assumptions lying in that. The first is that the assumption is the goal is to have earlier generic entry within the duration of the patent.
- MR. GLYNN: Again, forgive me, if one thought that the goal was not that, set aside for a moment the way in which the CMA wrote its decision on that thing, which I agree with some of the points you made on that. But set that aside and suppose that our objective was to reach the outcome which properly reflects the strength of the patent and that that would be revealed if the case went through patent litigation and the outcome was whatever it was. If the parties were to reach an agreement on, for example, early entry or on the licence payment, then the acceptable terms of such an agreement would be equivalent in terms of the reduction of price from the patented level towards the generic level to the one we would have reached through patent settlement.
- MS. KREISBERGER: If that settlement could be achieved.

MS. KREISBERGER: Which will depend on the facts. MR. GLYNN: Yes, I agree with you. Well, then, so the question is that if you can show that the settlement could not be achieved other than for some clear reason, that would be one major point. MS. KREISBERGER: For instance, lack of symmetry. Perhaps if I could put it like this, and I will come on to make some broader points which relate to this. What Professor Shapiro says is the incentives to delay are so strong -- that is the premise of what he describes as the wider inference -- that if you take away the payment you will always get a better outcome for consumers. That is the premise. But that is not a fair assumption for two reasons. The first is alternative settlement may not be achievable. We have evidence here that that is the case. Professor Shapiro accepts in terms that if the evidence does not show that that is likely, you discard that counterfactual and you are in the world of continued litigation. Then we get to the nub of it. Can you assume that continued litigation is better for consumers without engaging with the question of patent strength? If I take Mr. Glynn's premise, I cannot make that submission, but I do not accept the premise that litigation in itself is less restrictive of competition, remembering -- the test was not consumer welfare, overall impact on consumer welfare, the test is: let us look at this on an effects basis, the test is the CMA has to show a restriction by reference to the counterfactual. So I would say that means you have to engage with patent strength to some degree in order to -- so remembering we are in the world where we have dispensed with alternative settlement, which I say is the case on these facts. You cannot assume that continued litigation is better on the basis of a 1% prospect or a 10% prospect. You have got to pick a threshold. That is how counterfactual assessments work. You have to pick the 50% threshold. You have to engage with patent strength. It is interesting that all the economists agree that if you have pro-competitive benefits on one side of the scales, even Professor Shapiro agrees if you have -- he does not accept them on this case -- but he accepts, if you have them, then you have to engage with patent strengths and he says that is not easy. I would say that is an economist looking at the problem from the perspective of overall consumer welfare. But the question for the Tribunal is whether a restriction of competition is proven. There is no reason why you should not have to conduct that balancing exercise

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MR. GLYNN: If that settlement can be achieved.

2 there are in this case. Even without them, you need to assess. 3 I say the fundamental premise of the inference is not correct because you cannot simply 4 assume that continued litigation will be better. 5 MR. MALEK: But do you accept Professor Shapiro, the bit that you quoted, which is that there is a strong incentive on the originator, ie GSK, to delay independent generic entry? 6 7 MS. KREISBERGER: You brought me neatly onto my next point, which is my second criticism. 8 If you accept his premise that there is a strong incentive, the logical consequence, which he 9 accepts and he promotes really in his writings, is that the parties will always negotiate to the 10 end of the patent and you will always observe lock-out to patent expiry. So if you accept 11 his starting point, that is your end point. You will always obvious lock-out to patent expiry 12 because it will always be in their mutual incentives to pay more and more until patent 13 expiry. 14 I think that shows the difficult foundations of his inference. There is a conceptual difficulty 15 here because, factually, we do not observe that in practice. I do not need to put lots of 16 empirical evidence before you to make that out, although Dr. Jenkins does refer to some in 17 her report, but we do not observe that here. In fact, not only do we observe payment for a 18 short period, three years, but also other benefits. One might ask, if the mutual incentive is 19 so strong, let us just have payment. 20 MR. MALEK: No, but the question is do you accept that GSK had a strong incentive to delay 21 independent entry? That is a simple question, is it not? 22 MS. KREISBERGER: I do not accept the framing of the question because I think that one is 23 looking at a settlement. I cannot speak for GSK's incentives but what I would say is the 24 proof is in the pudding. So Professor Shapiro says, parties will always have an incentive to 25 delay and pay as necessary until patent expiry. That is his answer to your point. 26 I say that must suggest there is something wrong with the theory and my response, based on 27 Dr. Jenkins' evidence, is his theory is based on perfect conditions of bargaining efficiency. 28 So I do not accept that parties operate in the way that Professor Shapiro assumes them to 29 because undertakings -- pharmaceutical companies are made up of people and people do not 30 function like robots; they have biases; they value things more they have than they do not 31 (sic); they bargain imperfectly; and so they settle on terms which they think are better than 32 going to court, irrespective of the precise quantification of the risk factor. 33 I am conscious that is a long response. I cannot really answer for GSK's incentives --

on this side of the scales, irrespective of offsetting pro-competitive benefits, which we say

1	THE PRESIDENT: It does not have to be GSK. If you just take an originator with a valuable
2	pharmaceutical patent.
3	MS. KREISBERGER: You do not need me to tell you that an originator has an interest in
4	preserving their patent. I do not think there is an anti-competitive purpose if they believe
5	their patent is valid and strong. There may be an anti-competitive effect but you have to
6	look at it. There is no shortcut and you should not not look at it because it is too difficult to
7	look at.
8	THE PRESIDENT: The only way you can look at it is by assessing the strength of the patent?
9	MS. KREISBERGER: Yes, but that does not necessarily mean conducting the mini patent trial.
10	It may mean looking at the surrounding evidence, the contemporaneous evidence, and
11	interrogating the size of the payment against the profitability and so on. There has been a
12	debate about whether that has happened here. It is certainly not the way in which the CMA
13	have put their case and I would like to make, if only one point, one point on the effects
14	counterfactual.
15	My point is the inference is imperfect. I do not need to make the submission that it is of no
16	utility. I do not make that submission, but I do say it is not reliable for purpose. I think you
17	can look at effects. Again I come back to Actavis where they say the magnitude of the
18	payment, it is all relevant. If I might skip ahead.
19	MR. MALEK: Yes.
20	MS. KREISBERGER: The problem is that they have not reflected that in the litigation
21	counterfactual.
22	Perhaps I could make one last point on object and that very brief point on the litigation
23	counterfactual, if I may.
24	My last set of reasons as to why the Tribunal should reject the object approach, and these
25	are, in my submission, important, Professor Shapiro and the CMA as well have been very
26	open about the fact that certainly his views are driven by the specific policy concern that
27	settlements should not escape the purview of anti-trust. It is an enforcement gap concern. It
28	is addressed in my closing at paragraph 58.
29	That is obviously not a relevant consideration for the Tribunal. I say there are three points
30	that should override that in the Tribunal's determination.
31	One is a consideration which I say should be dispositive, which is that GUK could not have
32	foreseen that the CMA would, so many years later, adopt this inference.

2 category -- these are the words of Advocate General Wahl. I will give you the reference 3 {Auth-H/6/6}, paragraph 35. Advocate General Wahl says this --4 THE PRESIDENT: Sorry, which case is this? 5 MS. KREISBERGER: Sorry, Cartes Bancaires. Assuming it is the only case I care about. It promotes legal certainty so that undertakings know the legal consequences of particular 6 7 conduct and they can modify their conduct. 8 In my submission, this is a real problem for the CMA's case because GUK has had no 9 opportunity to do that. You have been positing hypothetical scenarios and postulating about 10 consumer welfare. Well, that is something that may be relevant on a prospective basis, but 11 not on a retrospective basis. I think a real unfairness would result and that is not the premise of the object category. GUK has had no opportunity to modify its conduct. 12 13 I make the point in my written closings that some settlements on this approach will not 14 escape settlement at all. It is genuinely irrebuttable even under 101(3). So it is unacceptable 15 to condemn a party on that basis for retrospective behaviour. 16 MR. MALEK: So what you are saying is that even if we think it is a good theory, we say that and 17 that can be a warning for the future but it should not be for the past? 18 MS. KREISBERGER: I agree. What the CMA could have done is run a robust effects case. 19 There is no objection to that, and they could use the inference in that. You will remember I 20 have addressed you before on experience. One might say that something is not 21 presumptively unlawful the first time it is looked at, something difficult and complex. But 22 over time it may move to the object category, quite rightly, for this very reason. But it 23 should not be condemned the first time on this basis, if I am right that it could not have been 24 foreseen. 25 I say that is a knock-out blow. If the concern is really consumer welfare, one needs to be 26 careful about is competition law a procrustean bed? Does it not fit within competition law? 27 Are we really trying to engineer a perfect consumer welfare outcome? If that is the case, 28 regulation on an ex ante basis is the right approach. 29 But I make a less ambitious submission, which is you can get at this on an effects analysis. If you are not with me on effects, that is not a bar to these difficult points being addressed. 30 31 That brings me on to my very last point on object. 32 The inference applying it in the way the CMA apply it involved rewriting patent law. This 33 is what the CMA said in their closing at 59(b) {M/6/37}:

Now, that is relevant not for effects but for object, because the whole point of the object

1 "Dr. Jenkins was wrong to say that the brand has the right to exclude. All the 2 originator has is the right to assert its patent rights in court." 3 That is a bare assertion; it is unsupported. But in my submission, the CMA has just 4 redefined the patent right in bringing its case. I would call this competition law overreach. 5 If you ask an IP lawyer what a patent is, I think they are likely to say it is an intellectual 6 property right, a lawful monopoly and a right to exclude others. 7 If I could, just for your note, perhaps draw your attention to my Notice of Appeal, which is 8 at {A/5/46}. At paragraph 121, I cite the Commission's pharmaceutical report on what is a 9 patent. 10 I do not think, in my submission, any IP lawyer would tell you it is just a right to go to 11 court. It is a property right which can be challenged at court and may be found to have been granted in error, or may be upheld. That means settlements can have effects on competition 12 13 where a patent granted in error is preserved by agreement. 14 But the implication of the probabilistic approach that we were just debating is that any settlement which extinguishes any level of risk and so replaces litigation uncertainty is 15 16 presumed anti-competitive by nature. 17 If that is your approach, you have downgraded the patent from a property right to a right to 18 go to court --19 THE PRESIDENT: I see the point you are making, but I think a patent lawyer would accept it is 20 not a right to exclude a non-infringer. 21 MS. KREISBERGER: I agree. That is precisely why I have said it is a right which is capable of 22 challenge. 23 THE PRESIDENT: You are not challenging the right, you are saying I do not engage the right. 24 MS. KREISBERGER: That is of course right. Absolutely. 25 THE PRESIDENT: Which is one of the points, of course, as usual, they were all making, that we 26 do not infringe. 27 MS. KREISBERGER: This is exactly why you cannot throw your hands up and not engage with 28 the merits based on this inference. I completely accept that point. 29 That is it from me on object. Can I make one very confined point on effects on the 30 continued litigation counterfactual, which I will not labour at all. 31 My main submission on that is that the counterfactual is defective. So they could have done 32 the work -- this is on the case I have advanced before you -- and they could have looked at 33 the evidence, looked at the payment, looked at the underlying merits if appropriate. There 34 might be some easy cases, but I do not think this is the one, but you look at all the factors in

1 the round, which is precisely what the Supreme Court says in Actavis, and then the CMA in 2 the light of that needed to formulate a counterfactual. 3 My submission is that continued litigation with no more is not a valid counterfactual. They 4 needed to engage with patent strength. 5 Let me give you one reference. Paragraph 115 from the CMA's closings at {M/6/47}. The 6 CMA says, I think halfway down: 7 "As Professor Shapiro explained ... it must be that GSK anticipated that the 8 probability of it losing the litigation was sufficiently high to justify transferring 9 additional cash to the generics ..." 10 That is getting to a degree of risk which I touched on quite a lot earlier. If the CMA is 11 making findings about degree of risk, that needed to be reflected in the counterfactual. 12 MR. GLYNN: I am sorry, which paragraph are you reading from? 13 MS. KREISBERGER: Sorry, 115. I hope that is a correct reference. 14 MR. GLYNN: Yes. 15 MS. KREISBERGER: I sort of skipped ahead. So it is sort of the third line. 16 MR. GLYNN: Thank you. 17 MS. KREISBERGER: That is why I started by saying the CMA cannot change its case at this 18 stage. It could have run an effects case, but this one fails. 19 THE PRESIDENT: But to be successful, if I understand it, you say the effects case would have to 20 be on the basis that the likelihood of GSK prevailing in court was less than 50%? 21 MS. KREISBERGER: That is my answer if you ask me what I think the answer should be. But 22 we do not need to arrive at that answer because, in my submission -- I say this in the written 23 closings -- they have not identified any threshold. I do not think that is sufficient to say any 24 degree of risk gets you there. 25 If the CMA wanted to run a case that 30% is sufficient, okay, we might then address that. 26 But in my submission it ought to be on the balance of probabilities. It has to be that a 27 restrictive effect was more likely than not. 28 THE PRESIDENT: Because you have to look at the counterfactual and say we have to do a direct 29 comparison. So it seems to me difficult -- I think they do say that the loss of a chance is 30 sufficient. 31 MS. KREISBERGER: They say any degree. 32 THE PRESIDENT: But I am struggling with that. 33 MS. KREISBERGER: So, you know, if these are the conceptual difficulties in the effects case, 34 then one should be very cautious about finding a malign object.

2 malign cases. 3 THE PRESIDENT: Yes. 4 MS. KREISBERGER: Sir, those were my submissions unless I can be of any further assistance? 5 THE PRESIDENT: I only really wanted to ask you the same question that I asked Mr. Kon. This agreement with GUK, which gives effect to Merck was on the day before, or I think it 6 7 is now said the morning -- I thought it was the day before the trial which then continued with BASF. If BASF had won, and maybe then there would still have been an appeal and 8 9 won the appeal, but GUK had agreed to stay out for quite a bit longer, although the patent 10 had now actually been, in accordance with the approach you advocate, shown to be not just 11 weak, but bad, and yet --12 MS. KREISBERGER: Or not infringed. 13 THE PRESIDENT: No, BASF had won so it was just all the claims were invalid, not just the 14 product claim. Yet we have an agreement made before that saying even then there is no 15 chance to come in unless everybody then revokes the agreement, I suppose. Does that 16 indicate an anti-competitive object? It is not tied to patent validity. 17 MS. KREISBERGER: My first answer may not be the one you are looking for, but --18 THE PRESIDENT: I am just looking for your answer. I am not looking for any particular 19 answer. 20 MS. KREISBERGER: Only because I may be accused of not answering it is what I am saying. 21 I started out by saying the CMA is fixed by the decision. So shall I say rather than not 22 answering it, the easy answer is that is not the premise, that is not the finding in the CMA 23 decision. So fortunately for me I do not need to get into that. 24 THE PRESIDENT: Yes, okay. 25 Thank you very much. That was very helpful, Ms. Kreisberger. 26 MS. KREISBERGER: Thank you, sir. 27 MR. KON: Sir, it seems a very long time ago now, but Mr. Malek asked one question which he 28 asked for a reference for. 29 MR. MALEK: A footnote on. 30 MR. KON: Exactly. Footnote 952 on page 290. It was subparagraph (iii). The reference is 31 {Z/155/1}. I think when you look at that you will discover that it does not quite say what 32 the CMA says it says, but I will leave that for you. 33 MR. MALEK: I can look at it when I have time. 34 THE PRESIDENT: Page 155.

As I said, it should not be a substitute for a difficult case. It should be reserved for the most

1	MR. O'DONOGHUE: To complete the sweep-up, I am happy to confirm that Alpharma had no
2	counterclaim. We were reliant on the counterclaims in the BASF ase and to
3	THE PRESIDENT: Right, so you did not have a counterclaim. I think there was a reference in
4	your closing.
5	MR. O'DONOGHUE: It was paragraph 12. I may have been over exuberant for my part.
6	Sir, the second point, I do not think the Tribunal has received my solicitor's letter today. I
7	will hand that up now. It is to give a couple of the references which Mr. Glynn indicated
8	yesterday might be of assistance. (Handed)
9	THE PRESIDENT: Thank you very much.
10	So we will resume at 10.30 am tomorrow for the start of the closings by the CMA.
11	MR. TURNER: Yes.
12	THE PRESIDENT: Thank you very much.