IN THE COMPETITION APPEAL TRIBUNAL

Case Nos. 1275/1/12/17
1276/1/12/17

Victoria House,
Bloomsbury Place,
London WC1A 2EB

8th November 2017

Before:

PETER FREEMAN CBE QC (Hon)
(Chairman)
PAUL LOMAS
PROFESSOR MICHAEL WATERSON

(Sitting as a Tribunal in England and Wales)

BETWEEN:

FLYNN PHARMA LTD AND FLYNN PHARMA (HOLDINGS) LTD Appellant

- and -

COMPETITION AND MARKETS AUTHORITY Respondent

- and -

PFIZER INC. AND PFIZER LIMITED Appellant

- and -

COMPETITION AND MARKETS AUTHORITY Respondent

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HEARING – Day 6 - Redacted

A P P E A R AN C E S

Kelyn Bacon QC, Ronit Kreisberger and Tom Pascoe (instructed by Macfarlanes LLP)

Mark Brealey QC, Robert O'Donoghue QC and Tim Johnston (instructed by Clifford Chance LLP)

Mark Hoskins QC, David Bailey, Hugo Leith and Jennifer MacLeod (instructed by CMA)

Wednesday, 8 November 2017

(10.00 am)

THE CHAIRMAN: Good morning.

MS BACON: Sir, one housekeeping matter before I call Mr Williams. The tribunal, I hope, had a letter from my solicitors last night, responding to a query from Professor Waterson on day 2.

That concerned one of the products in the CRA graphs which was shown to be very loss-making on the cost allocation and I asked CRA to rerun their analysis using a revenue-based allocation and we have sent those figures to the tribunal last night and those figures should be now -- and with a covering letter -- in bundle N10.

THE CHAIRMAN: This is a follow-up to Macfarlanes' letter yesterday?

MS BACON: No, it is a completely different issue.

THE CHAIRMAN: Oh, right.

MS BACON: Macfarlanes sent a letter yesterday evening concerning a follow-up to Professor Waterson's query on day 2. Yesterday morning, I am sorry. So that is in N10.

THE CHAIRMAN: We cannot have stray letters wandering around the tribunal.

MS BACON: No, they have got to be placed in their

appropriate pigeonhole.

THE CHAIRMAN: They have, it is a big court.

MS BACON: Now, unless there is anything else...

MR HOSKINS: I have not had a chance to see N10 yet but if there is anything I need to say on it, I will say it probably tomorrow morning.

MS BACON: It does not relate to Mr Williams' evidence. If anything, it relates to Mr de Coninck's evidence, which will be tomorrow.

THE CHAIRMAN: I am glad it relates to something.

MS BACON: Sir, I will then call Mr Williams.

MR RICHARD WILLIAMS (affirmed)

Examination-in-chief by MS BACON

THE CHAIRMAN: Mr Williams, please sit down and make yourself comfortable.

A. Thank you, sir.

THE CHAIRMAN: I gather you are no stranger to the tribunal.

A. That is indeed correct, although I have not presented oral evidence to the tribunal, only written evidence some years ago in the Genzyme case.

MS BACON: Mr Williams, could you take bundle D, please. And could you turn to tab 10 -- 11. Do you see your report dated 2 December 2015?

A. I do.

Q. Is that your report?

A. It is indeed.
Q. I understand that you have one correction to paragraph 24 of that report.
A. I do, indeed. I am just turning to paragraph 24. Yes, the figure I quoted in paragraph 24 about the percentage of the NHS drugs bill accounted for by PPRS medicines, i.e. companies that were members of the PPRS, I quoted in that report at 80 per cent. Subsequent to the issuance of that report, the government prepared some further analysis, largely in connection with the passage of the 2017 NHS Medical Supplies (Costs) Act, that provided some further insight into the quantum of medicines that were supplied by PPRS members, as opposed to non-PPRS members and that figure is now between 50 and 60 per cent. So the percentage of medicines that is accounted for by PPRS medicines has fallen quite significantly since the figure I quoted.
Q. Could you turn to tab 12, please.
A. Yes.
Q. Is that your second report?
A. Yes.
Q. And could you look at page 19.
A. Yes.
Q. Is that your signature?
A. It is.

Q. Could you turn to tab 13.
A. Yes.
Q. Is that your third report?
A. It is.
Q. On page 26 is that your signature?
A. It is.
Q. And could you turn to tab 14.
A. Yes.
Q. Is that your fourth report?
A. It is.
Q. And I understand that you have a typographical correction to paragraph 23.
A. Yes, in paragraph 23 the passage in parentheses starting on line 2 says:

"... which represents the biggest proportion of the £9 million difference between the Williams/Harman common cost pools as set out in paragraph 17 above."

The figure should have read £13 million difference, not £9 million difference, which is clear from paragraph 17.

Q. And could you turn to the penultimate page of that report. I do not think it is numbered.
A. Yes.
Q. Is that your signature?
A. It is.

Q. Could you take up bundle F and turn to tab 5 and that is headed, "Joint statement of Mr Williams and Mr Harman." If you turn over a couple of pages to page 4 and you will see a column headed, "Mr Williams' position".

A. Yes.

Q. Does the content of that column represent your input into the joint report?

A. It does.

Q. Can you confirm that the opinions that you have expressed in the four reports and your part of the joint statement represent your true and complete professional opinions on the matters to which they refer?

A. I can confirm that.

Q. Thank you. Mr Hoskins will have some questions for you.

A. Thank you.

Cross-examination by MR HOSKINS

MR HOSKINS: Good morning, Mr Williams.

A. Good morning.

Q. Can I just start with the correction you made to your first report. So that is at bundle D, tab 11, at paragraph 24, page 7. D11, page 7, paragraph 24.

A. Yes.

Q. And you explain that you have stated in this statement, which is -- just looking at the date you made the statement, sorry. (Pause)

A. I believe it was December 2015.
Q. December 2015. And you said that there was new material relating to the 2017 Act that updated those figures. I just want to clarify: the figure of 80 per cent in this statement, therefore, refers to what period of time?
A. This was the generally accepted figure quoted by the ABPI. I have to admit I am not sure what particular time period it related to but it was probably 2011/2012, something like that, but certainly the figures I have quoted in my correction are from 2013/2014 financial year and 2014/2015 financial year. I believe that for 2014/2015, which is the more recent year, the PPRS proportion was slightly more than 50 per cent and for the preceding year it was slightly less than 60 per cent.
Q. Thank you very much. Start with some easy questions. You are a chartered accountant with a long experience of working in the pharmaceutical industry. That is clear from your reports?
A. That is correct.
Q. But you are not an economist?
A. No, I am not a professional economist although I did study economics at university.
Q. So you are an expert in economics?

A. No, I am not a competition economist.
Q. And you are not a lawyer?
A. I am not a lawyer.
Q. Can we go to bundle K, tab 17. Can I just explain: this is an email exchange between Macfarlanes, who are the solicitors instructed by Flynn, and the CMA and it related to -- if you turn through four pages, behind this tab, there is something called "Draft agenda for the joint meeting between Mr Williams and Mr Harman."
A. Yes, I have that in front of me.
Q. Were you involved in preparing this draft agenda --
A. I did indeed have input into the draft agenda.
Q. Have you seen this email exchange before, the one that begins immediately behind the tab?
A. It has been shared with me in the last few days, yes. I did not see it contemporaneously with -- 7 September.
Q. If we look at the email at the top of the page, so from Cameron Firth at Macfarlanes to John McInnes of the CMA, under "Attachments" it says:

"Agenda CMA version with changes accepted and our further changes applied."

So the CMA had obviously sent a version of some amendments and Macfarlanes have commented on it and made further changes to it. You see that from the heading?
A. Yes, I see that.

Q. And then Mr Firth says:

"Thank you for sending your proposed amendments. We attach a revised version. We thought the following would be helpful by way of explanation of the proposed changes. We have removed the choice of methodology section. Mr Williams is not an economist. Mr de Coninck of CRA is our economic expert. Mr Williams is an expert with experience of the pharmaceutical industry. He is not therefore in a position to comment on these questions."

If we look at the draft agenda, you see the choice of methodology has been struck out. Questions were:

"In principle is it correct that by their nature there is no cost causality associated with common costs?

"Are there a variety of ways in which common costs can be allocated in any given case?

"Is the fact that a party does not allocate common costs during the normal course of its business relevant to the choice of allocation method?"

Do you agree with Macfarlanes that those questions fall outside your expertise?

A. I think in relation to question 1.1, which states:

"In principle is it correct that by their nature there is no cost causality associated with common costs?"

I believe I do actually comment on that point in the joint report that you referred me to in bundle F, tab 5.

Q. I think there is a distinction, Mr Williams, because certainly you do comment on some of these issues and that is understandable given the task you have had to do but the distinction I am trying to make is whether these particular matters are actually within your expertise because the facts that you comment on them does not bring them within your expertise, it just means you have commented on them.

A. Yes.

Q. So I just wanted to check whether you agreed with Macfarlanes that points 1.1, 1.2 and 1.3 were matters of economic expertise and therefore did not fall within your realm even if you have in fact commented upon them.

A. Yes, my understanding is that these redactions were made in relation to the fact that the expert selected by Flynn to deal with economics was not myself and that to keep the joint meeting of experts, as instructed by the tribunal, to a manageable number of participants, it was appropriate that we did not include these within the meeting that took place between Mr Harman and myself.

Q. Do you agree it was appropriate to do that because you are not an economic expert?

A. I do.

Q. Then if we go back to Mr Firth's email, point 2:

"We have also removed the first general question in the sections on the CMA's approach and Flynn's approach for the same reason as in point 1 above."

So the same point and if we go back to the draft agenda, the issues they are referring to, you see volume based approach to costs allocation, CMA's approach at the top of the second page of the agenda and what has been removed is the question:

"Can a volume based approach be a reasonable approach to cost allocation in some cases."

So again, do you agree with Macfarlanes that that is an issue that falls outside your expertise because it is an economic issue?

A. I do.

Q. And similarly, with the first question under the next heading "Revenue based approach to cost allocation":

"Can a revenue based approach be a reasonable approach to cost allocation in some cases?"

Again, that falls outside your expertise?

A. I think my comments on both that and indeed 2.1 is that those are general matters of general economics whereas the question that has not been redacted is a question of -- specific to this case. And therefore I did believe that the questions revised 1.1 and -- sorry,

revised 2.1 and revised 3.1, which were specific to the Flynn case, were within my expertise.

Q. I will come back to that in a minute but just to finish up the -- just sort of clearing up on the agenda what is and is not within your expertise, cross-checks, 3.1, was not mentioned in the email but it was deleted by Macfarlanes and that question was:

"Is it appropriate to consider the use of different cross-checks in this case?"

Again, what is your position on that? Do you think that is or is not within your expertise as an accountant?

A. I think within my expertise as an accountant I think the use of cross-checks is appropriate. I do feel that is within my expertise but I think the idea of the agenda was to focus on the specific cross-checks that had been presented on behalf of the CMA rather than the generality of other cross-checks.

Q. When -- if you go back to the 2.1 and 3.1 and you explained to the tribunal a moment ago -- you said you agreed that 2.1 and 3.1 were outside your expertise because they were general questions of economics but you made the point that the following bullets which are now numbered 1.1 and 2.1 were within your expertise because they related to the case. I do not understand that

distinction because surely the question of whether a volume-based approach or a revenue-based approach is appropriate to assessing costs allocation is an economic issue, whether it is particular to this case or generally. It is always an economic issue.

A. But I think it comes down to -- the question, for instance, in 2.1 talks about costs allocation in some cases. That may not even be within the pharmaceutical industry. It may be within telecoms or utilities which is outside my expertise. I do feel, however, within the pharmaceutical industry, cost allocation is something I am experienced on and have a lot of experience of and therefore I do feel I am competent to comment on it.

Q. So you are obviously qualified to give expert evidence on actual practices in the pharmaceutical industry?

A. Correct.

Q. But when you express opinions on the appropriateness of volume-based approaches and revenue-based approaches, do you agree that the Tribunal should bear in mind that in doing so, you are doing so as an accountant and not as an economist?

A. I do agree with that.

Q. You can put that bundle away now, please. You can go back to your reports. That is bundle D. Your first report at tab 11. First of all, I would like to look at

paragraph 4(b). I want to pick it up six lines down in (b) where you say:

"The PPRS operates on a portfolio basis because it implicitly acknowledges the 'lifecycle management' approach adopted within the pharmaceutical industry, whereby companies typically have a portfolio of products, some of which are mature (and may therefore be highly profitable as they require minimal sales and marketing support) and some new (and less so due to the investment in market development and education in the early years of the life cycle)..."

I am going to come on to the PPRS later because that is one of the main reasons you are here. So trust me on that one. What I want to focus on first of all is what you refer to as "the life cycle management approach adopted within the pharmaceutical industry". So we will come to the technicalities of PPRS later. Life cycle management.

You are talking, are you not, in paragraph 4(b) about branded products?

A. I am.

Q. And if we go to paragraph 58 of this same report, you return to this notion of a life cycle. You say:

"On a more general point, taking individual product profitability within the portfolio of any pharmaceutical

company with a portfolio of products is likely to produce very divergent results on a ROS basis. It is generally accepted that in the life cycle of a pharmaceutical product, the mature stable of developed products that are well through their period of exclusivity, that is prior to but near their patent expiry, may be making high net returns because they require less support and marketing expenditure. The high returns on these products will enable a company to invest in product development, research and development and also marketing and market development of newer products."

You are dealing here with net margins and just so we are all on the same page, can you just explain what you mean by net margins.

A. By net margins I mean sales deducting direct costs and deducting sales and marketing costs and deducting an apportionment of general overheads.

Q. And you explain in paragraph 58 that:

"Products that are coming up to the end of patent expiry would generally make higher returns which in turn will allow the company to invest in R and D to develop new products."

We have seen that?

A. Yes.

Q. And that is the sort of pithy definition, is it not, of the life cycle management that you are talking about in this report, is it not?

A. It is. The life cycle management is effectively products typically have a period of exclusivity in the UK after approval of ten or so years. During the early part of their life cycle they will be requiring very heavy investment in sales and marketing and education of clinicians but in the latter part they will probably be requiring very little support in terms of sales and marketing and education because the market is well experienced with the product.

Consequently, the front end, they are typically less profitable as a net margin basis and at the back end of the life cycle they are more profitable.

Q. In the first sentence of paragraph 58 you say -- well, I have read it out already, you can refresh your memory. Just to confirm, what you are saying is the return on sales of individual branded products within a company's portfolios are likely to be very different. There will be a wide range, will there not, within a portfolio?

A. Yes, it is likely to be a wide range.

Q. Then if we go to paragraph 65 of this report, you may just want to read that to yourself, refresh your memory. (Pause)

A. Okay.
Q. Here you are dealing with gross margins. Again just to make sure we are all on the same page, what do you mean by gross margins?
A. Sales less direct costs, principally cost of sales.
Q. And you make a similar point in the final sentence, do you not? You say:
"Due to product life cycles, there is seldom a uniform gross margin in a company's portfolio."
So it is the same point: the gross margins on particular branded products in a company's portfolio will be divergent?
A. They will but maybe to a lesser extent than the net margins because the net margins are of course affected by selling and marketing costs which fall below the gross margin line. So gross margins can vary but I would suggest they vary by a smaller amount than net margins because of that point on sales and marketing.
Q. But you can still have a fairly wide spread within a company's portfolio?
A. It is possible to, yes.
Q. And then paragraph 69 of this report. You say:
"Within the portfolio of any mature pharmaceutical company, there would be new and old products, the former requiring extensive sales and marketing support and the

latter being products for which there may be lower direct costs involved other than in the supply chain and working capital."

This is the same point again, it is the life cycle point and it is the fact that companies' portfolios will be divergent?

A. It is indeed another way of looking at the same point.

Q. Then if we go to paragraph 32(a), please -- actually paragraph 32(a) and (b) and here we are dealing with generic drugs so we have moved from branded. Again you might want to refresh your memory of what you say in 32(a) and (b) about generic drugs. (Pause)

A. Yes.

Q. One of the points you are making here, are you not, is that the profile of individual generic drugs within a company's portfolio may be very different?

A. That is what those paragraphs say.

Q. Can we go to paragraph 16 of this report. It begins:

"Were Flynn to have joined Scheme M, then the DH would have been able to use the information and assessment mechanisms set out in Scheme M which are summarised below."

Then you actually -- I think that is -- you set out part of the Scheme M, do you not?

A. Yes, it is a cut and paste of paragraphs 29 and 30 of

Scheme M.

Q. In particular, first of all, paragraph 29 of Scheme M says:

"To allow the consideration of prices and reimbursement, a scheme member shall provide to the Department on reasonable request information such as the following: an analysis of the direct and indirect manufacturing and/or supply cost of the product or products which have increased in price and these costs should be supported by auditable evidence such as invoices/discounts offered and received, analyses of manufacturing costs and apportionment of overheads."

Then -- before we look at 30. What that is telling us is that pharmaceutical companies may be required to carry out some form of common costs allocation under Scheme M; correct?

A. Yes, that is the apportionment of overheads reference.

Q. And they would be required to do that even if they did not do so in the normal course of their business, if the DH requires them to do it they will have to?

A. On request from the Department, yes, they would.

Q. I think we can leave that. Let us go to paragraph 38. Again you refresh your memory on this but it is the sentence that -- it is the fourth sentence:

"The allocation in the PPRS of shared or common

costs was typically done by reference to revenue and splits permissible common costs between products covered by the PPRS (PPRS products) and all other products."

So this is a cost allocation exercise that can take place under the PPRS that you are describing, is it not?

A. It is.

Q. Can you just describe a bit more what the purpose of that cost allocation exercise is?

A. The PPRS is focused on assessing the profits a company is making on its branded medicine sales to the NHS. The PPRS has no interest in the profitability it is making on those medicines being exported or indeed non-PPRS medicines, so consumer medicines or veterinary medicines. So the PPRS requires a company initially to report through something called an annual financial return, which I always describe as a sort of audited P and L account of your business activities, split into three columns. The first one is NHS medicines that are sold in home market. The second one is those same medicines that are exported and the third one is non-PPRS medicines and, as I said, that could include devices or veterinary products or consumer products.

So there is a requirement, firstly, to put into these three individual columns sales and costs and sales and as far as possible costs that are directly

attributable. But then, of course, there will be likely in a business that has a number of business lines to be a rump of common overheads, finance being a good example, that have to be allocated between those three columns and that is really what I am referring to here. So the PPRS does require cost allocation at common cost level if a company has more business than just selling branded medicines to the NHS.

Q. So it is an allocation between the three categories of products you have identified. It is not an allocation between specific products?

A. Absolutely correct.

Q. We know that the CMA's approach to common cost allocation is based on volumes and particularly focused on the number of packs sold, whilst your view is that a revenue-based approach is the most appropriate approach. Does that set the scene sufficiently?

A. It sets it exactly.

Q. First of all, do you agree that revenue equals price multiplied by volume?

A. I do as long as the unit of volume is consistent. If it is not consistent -- and this is the problem one can get if one sells products in multiple pack sizes -- that can cause a problem.

Q. Can we go to Mr Harman's first report. So that is

bundle F, tab 1. If you could go to page 23, please, paragraph 3.33 and he says:

"A revenue-based allocation is subject to a number of challenges that Flynn raises in the context of volume-based approaches. For example, the inconsistency with how commercial decisions are made, common costs do not vary by volume and costs allocations are sensitive to changes in volume over time."

So basically what he is saying is some of the criticisms that Flynn has made of volume-based approach apply equally to a revenue-based approach and I have not been able to find where you have disagreed with that anywhere. I just want to check, do you agree, do you accept that these sorts of criticisms basically apply equally to revenue and volume-based approaches?

A. I think I would like to unpick the paragraph -- the statement in parentheses. The inconsistency with how commercial decisions are made. I actually think that commercial decisions in the pharmaceutical industry are very frequently based, if you are doing a product profitability analysis, on some absorption of common costs and I think that would be looked at most typically on a revenue basis. I do accept that common costs by and large do not vary by volume. By their nature you do not need two finance directors if your revenue doubles

and cost allocations are sensitive to changes in volumes over time. I think if you want me to agree that cost allocations are sensitive to changes in revenues over time, I would agree with that as well.

Q. Then if we go to paragraph 3.18, still in this report. Perhaps you would like to read that paragraph to yourself, refresh your memory. (Pause)

A. Yes, I have read that.

Q. You will see he makes really a very similar point, that the argument that it is not possible to set a forward-looking price for a drug based on a method of costs allocation which relies on historic sales data is a criticism that can be made equally of a revenue based approach and again I have not seen you disagree expressly with that. Do you agree with that point in Mr Harman's report?

A. I think it would equally apply if sales revenues could vary significantly in a short space of time.

Q. If we go to paragraphs 3.20 and 3.21, again feel free to refresh your memory.

A. Yes.

Q. The point that is really being made here is that the majority of Flynn's common costs or fixed costs do not vary by volume but please do re-read the paragraph.

A. Yes, I have read paragraph 3.20. I am just looking at

3.21. (Pause). Yes, I have read those two.

Q. So you see, the point that is being made here by Mr Harman is that as common costs are likely to be fixed costs, they will not vary directly with volume or revenue. Again I have not seen you take issue with that anywhere. Do you agree with that point?

A. I do agree that in the short term common costs are unlikely to vary with revenue or indeed volume. Of course, in the longer term, if a business grows rapidly, common costs could have to increase to accommodate a larger volume of work.

Q. Is that an argument that goes to the nature of fixed costs and the extent to which they will vary over time and the period over which they will vary?

A. Yes, that is the point I am making but in the short term I would accept they do not vary proportionately either to volume or to revenue.

Q. Stay in bundle F. I would like to go to the joint statement, which is behind tab 5 and if we could go to point 2.2, which begins at the bottom of page 9. We see the question that both of you pose to yourselves is:

"Does the use of a revenue-based approach in cases of potential excessive pricing risk a circularity bias?"

And again, at the bottom of page nine, "Mr Williams' position", you agree with that proposition?

A. Yes, I understand the concept of circularity and do indeed agree that if a product is excessively priced, it would attract under a revenue-based method of allocation an excessive proportion of common costs which is the main reason that I try to defuse that by doing sensitivity analysis to see what the impact would be with different levels of revenue based upon different -- well, two sensitivities that are presented in my report.

Q. I am going to come to your sensitivity or sensitised cost allocation methods in a minute. I just want to focus at the moment on a pure revenue-based approach. So we will come to the sensitivities. Just let us imagine a pure revenue-based approach. I wanted to ask you: are you aware that following the CMA's decision, both Pfizer and Flynn had to reduce their prices for Phenytoin capsules?

A. I am aware.

Q. If we stay in the joint statement -- it is actually the same point but at page 10 in Mr Harman's column, in the final paragraph Mr Harman says:

"Based on NHS drug tariff data, GH [that is Mr Harman] understands that the NHS drug tariff price of Phenytoin has been reduced by around 50 per cent to 80 per cent across different Phenytoin dosage strengths."

Does that accord with your understanding?

A. It does.

Q. And Flynn's common costs will not have altered as a result of that price reduction, will they?

A. No, their direct costs will have done but not their common costs.

Q. But if one were to apply a pure revenue-based approach, the result of this change in pricing was that less of Flynn's common costs would be allocated to Phenytoin?

A. Any adjustment in the revenue of Phenytoin will change the common cost allocation but this is really a question of judging the outcome having pre-determined that there is excessive pricing, imposed a requirement to change prices and then revisiting the common costs allocation again. I see that as -- itself as somewhat of a circular argument but I do accept the point that any changes in Phenytoin revenues would change my base case cost allocation quantum.

Q. And so what this demonstrates is that there is no necessary relationship between revenues and common costs?

A. I have accepted that there is no cost causality in common costs within Flynn.

Q. Can we go to page 8 of this joint statement, paragraph 2.1, and the question you are dealing with

here -- you see the heading "Revenue-based approach to costs allocation: Flynn's approach."

"2.1. Is a revenue-based approach a reasonable approach in this case?"

You agree.

Then it is your second paragraph, where you say:

"In particular, RW considers that it is reasonable for products that generate the highest revenue rather than volume, which may bear no relation to value, to bear the greatest amount of the business's common costs. It is no different from a progressive taxation regime with the broadest shoulders bear the highest burden. Even though their consumption of shared services provided by the state is likely to be no greater than those who pay the least."

The first question I wanted to ask you in relation to that is: do you accept that high revenue products do not necessarily generate the highest profits?

A. Correct.

Q. And indeed it is possible that a high revenue product could be loss-making?

A. It is indeed possible, depending on your relationship of direct costs to revenues.

Q. So it does not necessarily follow, does it, that the products with the highest revenues necessarily have the

broadest shoulders when it comes to bearing common costs, does it?

A. But within the Flynn portfolio we have a range of products, all of which were earning positive gross margins and therefore I do believe the issue of the outlier, which is a very large revenue, very low profit product, is not relevant.

Q. But you agree with the general proposition, I take it away from the specifics of Flynn's portfolio, that the products with the highest revenues do not necessarily have the broadest shoulders, as you describe it?

A. I think that has got to be the case.

Q. You mention the idea of progressive taxation. Under the idea of progressive taxation, high earners pay the most for common state services, which they almost certainly use the least; correct?

A. Yes.

Q. And low earners, by the inverse, will pay less for common services that they use the most. That is what progressive taxation involves, does it not?

A. It does.

Q. There is effectively an inverse relationship between the use of common services and the requirement to pay under such a system?

A. In taxation that will be the case.

Q. That might be good politics depending upon your colour but it is not obviously appropriate for the economic exercise we are engaged in, is it, which is to come up with an appropriate apportionment of common costs attributable to a particular product?

A. Any business has to cover the totality of its costs out of the totality of its revenues and profits. And therefore, in my view, it is normal practice to apportion to the more profitable products, the ones typically with the higher revenue, if by and large the products have a similar gross margin, a larger share of common costs. They can afford to bear or absorb a larger share than an unprofitable or very small -- yes, product. This is what I see companies to the extent that they ever do take an individual product profitability analysis doing, and it is also consistent, as I have mentioned before, with the approach that I have always seen adopted in the PPRS three column approach.

Q. Let us stick with commercial practice because Mr Walters' evidence and indeed your evidence in your reports is that generic companies do not generally do an apportionment of common costs. That is the normal position, is it not?

A. They are not required to do so under any PPRS or other

scheme. They would be if they were called under Scheme M to provide some product-specific data but in generality I do not see them apportioning common costs by product.

Q. As you say it and as Mr Walters says in his evidence, what companies -- generic companies tend to do is just make sure that they make more money than they are spending on costs; they take an across the board approach to their business?

A. Yes, but I do think they obviously focus on ensuring that the products that they are selling are profitable and are contributing to the business as a whole.

Q. If you go to -- stay in the joint statement, sorry. We are going to page 9. So it is still under issue 2.1.

A. Yes.

Q. It is the top of Mr Harman's column on page 9. He says:

"Whereas the PPRS allows a revenue-based approach, GH understands that this potential for a circularity bias is limited under the PPRS because the allowed return on sales (ROS) constrains prices by ensuring there is no excessiveness at the portfolio level. As a result, the circularity issue is less likely to arise in the context of the PPRS."

And you do not disagree with that either in the

joint statement or in your reports. Do you agree with Mr Harman's observation?

A. The first thing to say is that this comment by Mr Harman is really predicated on a company having a single line of business and certainly if it did have a single line of business selling branded medicines to the NHS, circularity is, as you say, less of an issue because all of the costs are going in the same column anyway. If, however, it has different lines of business, so, for instance, a branded business and a veterinary business, then, of course, the issue of circularity could arise and the Department are always keen to ensure that an appropriate and fair method of allocation has been adopted between columns.

Q. So if we restrict Mr Harman's observation to branded products that fall within the PPRS, you would agree with him?

A. Yes, because they are looking at the -- the Department of Health would be looking at a single column and therefore would not be looking at any individual products within that column.

Q. Can we turn over to page 11 of the joint statement, still under the heading "Revenue-based approach to costs allocation", issue 2.3 is:

"Do the approaches adopted by Mr Williams using his

sensitised methodologies remove the risk of circularity bias?"

In your column the second paragraph begins:

"RW believes ..."

I would like to pick it up for the moment six lines down where you say:

"The supply price charged by Pfizer to Flynn must in RW's view be fully taken into account in any reasonable and fair approach to calculating Flynn's costs for the purposes of calculating the reasonableness of Phenytoin's profits and hence its prices. Whether or not that supply price is considered to be excessive is in RW's opinion irrelevant. It is the supply price that Flynn actually paid and which therefore form part of Flynn's cost base during the relevant period."

It is correct, is it not, that the high price paid by Flynn to Pfizer is already taken account of in the CMA's analysis of -- cost plus analysis, if you know what I mean by that?

A. Yes --

Q. As a direct cost?

A. It is.

Q. So why should the high price, which is already taken account of as a direct cost, also be taken into account in the allocation of common costs?

A. The direct costs taken into account in the CMA's calculations were the actual prices paid. They led through to revenues and sales price being charged by Flynn and therefore on my revenue basis of allocation, I automatically will allocate common costs according to revenue or sensitised revenue. So I do not see there being -- the implication is that there is a sort of double count. I do not see that. I think revenues drive an allocation percentage, which I have used three of in my calculations.

Q. Let me use the contentious epithet for a moment: high direct costs. I think you have just confirmed that if you were to use your revenue-based approach and plug it into the CMA's cost plus approach, you would take account of the high direct costs as the direct costs and they would also then be taken into account again in the allocation of common costs. It is simply the point you have just made that it comes in twice in that way?

A. Flynn setting its prices at a premium to earn an appropriate margin above its direct costs will affect its revenue. It will therefore affect the common costs allocation.

Q. But I am talking here about the price that Flynn pays to Pfizer --

A. The price Flynn pays to Pfizer does inevitably impact

the price that Flynn is able to profitably sell the product to the NHS.

Q. And therefore is taken account as you explain in your revenue --

A. It is.

Q. -- based allocation of common costs.

So there is a section now where I need to refer to some figures and I think -- I would prefer to go into private both for me and for the witness because I am worried it will be a bit like a Carry On film otherwise with lots of nudge, nudge, wink, wink but neither of us actually able to refer to them --

THE CHAIRMAN: How long do you anticipate you need?

MR HOSKINS: It will be about, maybe, 20 minutes.

THE CHAIRMAN: I suggest we go into camera now, minus the Flynn -- the Flynn people can stay, am I right?

MR HOSKINS: That is right.

THE CHAIRMAN: Everybody else has to go.

(10.47 am)

(In private)

(11.04 am)

(A short break)

(11.17 am)

THE CHAIRMAN: We are back in public session and for the foreseeable future.

MR HOSKINS: Hopefully until the end.

THE CHAIRMAN: On we go, Mr Hoskins.

MR HOSKINS: Your third report, which I think we were looking at just before the break, tab 13, paragraphs 54 to 59. What you do here is you set out three further calculations of excess on Phenytoin and you produce three tables at 56, 57 and 58; yes?

A. Yes, that is correct.

Q. And what you have done here is you have used what I will call the genuine common costs pool but we must not refer to the figure. You understand what I am referring to?

A. I understand what you refer to, yes.

Q. So just to confirm, you are using what we have called the genuine common costs pool in these calculations?

A. I am.

Q. And these three tables all assume a ROS of 21 per cent.

A. They do.

Q. And if we look at paragraph 53 of your third report, if we count up eight lines from the bottom -- nine lines from the bottom, you say:

"Thus for the analysis that follows, I have used the 21 per cent ROS derived from non-manufacturing generic companies in Williams 2, annex 3 as an appropriate ROS benchmark."

Do you see that; yes?

A. I do.
Q. And if we look at that annex 3 -- so that is your previous report, behind tab 12. It is page 22 of that second report.
A. Yes, I have that open.
Q. This is the analysis that you were just referring to in paragraph 33 of third Williams, is it not?
Paragraph 53 --
A. It is.
Q. And you might want to just keep a finger in that but let us go into second Williams, the body of it, 39 to 40, because there you explain what you have done in annex 3.
Paragraph 39:
"I have also analysed the actual profitability of generic pharmaceutical companies more generally, both at a gross margin and at a ROS level, by reference to the audited accounts of several member companies of the BGMA. Whilst these companies all have differing portfolios, their association with the generic pharmaceutical sector (and this can include branded generics that are off-patent but are required for regulatory reasons to maintain a brand name) is evidenced from their association with the BGMA and the nature of their activities detailed in their accounts, general industry knowledge or their websites."

Then you say:

"In annex 3, I have summarised the ROS for an additional seven companies (in addition to Alliance and Martindale), all in the generics field. I have highlighted those with an element of in-house manufacturing and those that source products from affiliates or third parties. In aggregate, they represent sales of over £0.75 billion, so hardly a narrow sample."

So you explain to us what you have done in annex 3?

A. Yes.

Q. Then in paragraph 41 you draw some conclusions or present some summaries of what you draw from annex 3 and at paragraph 41(b) you say:

"The figures show the weighted average ROS for non-manufacturers of 21 per cent."

And that is the 21 per cent figure you have then used in your third report, is it not?

A. It is.

Q. Can we go back to annex 3 of -- forwards to annex 3, page 22. The sole criterion you have used to select the comparators you have used in third Williams is the absence of UK in-house manufacturing, is it not?

A. I have included in annex 3 both companies that have manufacturing and those that do not but I have then

split out a subset of those, the non-manufacturers, which is -- that subset that derived the 21 per cent that feed into my subsequent calculations.

Q. And that is the only factor you use to pick the companies that you use to come up with the 21 per cent figure. If they are non-manufacturing, you have used them and that produces the 21 per cent figure?

A. That is what I have done to pick the subset of that list of companies, yes.

Q. And you have not provided any breakdown in annex 3 of the types of product in these companies' portfolio, the crucial factor for these purposes, manufacturing and non-manufacturing. Is that correct?

A. Correct.

Q. Can we go back to bundle F, tab 1, which is Mr Harman's first report. So F, tab 1, page 66. Pick it up at page 65. We see it is paragraph 4.73.

A. Yes.

Q. Over the page at 66(4) Mr Harman -- he is dealing with some of the companies we have just been looking at in annex 3. He says:

"For example, ATNAHS states ..."

Sorry, let me start at the beginning:

"Some of the proposed comparator companies engage in product development activities."

So ATNAHS is one of the ones in your annex 3 and he says:

"It develops medicines in-house and its main risks relate to inter alia its ability to bring its developed medicines to market on a timely basis."

A. Could I just ask you to confirm where in annex 3 ATNAHS appears.

Q. Sorry, maybe that is my ... sorry, it is a wrong reference on my part. I am sorry. I do not need to deal with those questions, you are quite right.

A. I do not think ATNAHS was one of the companies that I looked at.

Q. So you are using the average ROS for these seven generic companies, average ROS being 21 per cent?

A. Yes.

Q. And you are using that as the appropriate ROS for Phenytoin in your third --

A. As a guide to the appropriate percentage, yes, which I then use mathematically in my third report.

Q. But as we have seen, you have made the point repeatedly in your statement that the profile of individual generic drugs within a company's portfolio may be very different?

A. Yes.

Q. And is it not the case, therefore, when you are trying

to determine a reasonable ROS, specifically for Phenytoin, it is not actually going to be very useful to look at the average ROS across portfolios in other generic companies, is it? It is a very rough and ready comparison at best?

A. It is a far better comparison than using the PPRS 6 per cent rate of return.

Q. But you are comparing an old, long off-patent product with Phenytoin with the averages across a portfolio?

A. Yes, these -- the 21 per cent is indeed an average across the portfolio. Many of these companies I know, I know the type of products that they make. They are many and varied but they are all generic or branded generic.

Q. Can I go back to the joint statement, which is in bundle F, tab 5. Issue 1.1, which begins on page 4. So the heading here is "Volume-based approach". 1.1, the question is:

"Is a volume-based approach a reasonable approach in this case?"

You disagree and you say in the first paragraph under your column:

"RW agrees that there is typically no causality associated with common or shared costs."

And you also agree that:

"There can be a number of methods whereby such costs can be absorbed across a business's different product lines or business segments."

What sorts of other methods or methods are you referring to here. You acknowledge there can be a number of methods but you do not identify what they might be?

A. So, for instance, if you are trying to allocate the costs of the IT department across a business, I have seen companies use the number of laptops, for instance, and the individual employees within each department. Likewise, I have seen space used if you are looking at a building that has a number of business segments in terms of saying, right, well, that is veterinary and that has so much space. That is branded medicines. That has so much space. So there are other methods other than pure revenue that I have seen used even under the PPRS.

Q. In this part of the joint statement, 1.1, you disagree that a volume based approach -- you disagree that it is a reasonable approach in this case?

A. I do disagree that it is a reasonable approach.

Q. Is your position that it is not reasonable even as a cross-check. You should not pay any attention to it?

A. I think it would be narrow-minded to eliminate from any

analysis cross-checks, even cross-checks on incremental costs, et cetera, even though you may then debate them and say whether they have value. So I would never say that you should as a matter of principle exclude any cross-check.

Q. Do you say it has any value in this case?

A. I do not think it does and I pointed out a number of flaws or problems that a volume-based approach can take in the pharmaceutical industry, where you have very different products that really do not -- they are not homogeneous in any sense, may have very different pack sizes, may have very different price per pack, may have very different volumes.

Q. Let us come on to that very issue because it is dealt with at point 1.2 of the joint statement. The question is:

"Are Flynn's products sufficiently homogeneous for a volume-based approach to be meaningful?"

You disagree with the proposition; Mr Harman agrees with the proposition. So there is a debate between you as to whether Flynn's products are sufficiently homogeneous for a volume-based approach to be meaningful; correct?

A. There is a disagreement between us on that point.

Q. And Mr Harman's position, as he sets out in the joint

statement, is he thinks Flynn's products are sufficiently homogeneous to apply a volume-based approach because he says all Flynn's activities relate to the sale and marketing of different types of drugs. That is his position, is it not?

A. It is.

Q. And he, for example, in his first report, contrasts Flynn with a company like Siemens, which he says if you look at Siemens, they sell such diverse products as trains and wind turbines, whereas Flynn sells one type of product, drugs?

A. Human pharmaceuticals.

Q. And your point is to say, well, Flynn's portfolio has a wide array of different drugs and presentations within it and that is why you say not sufficiently homogeneous?

A. Yes.

Q. The question of whether a company's products are sufficiently homogeneous to justify the use of a volume-based approach to common cost allocation for the purposes of this case, for an excessive pricing case is actually a question of economics, is it not?

A. I think it is important to look at what companies in the pharmaceutical industry do in practice and that has been one of the drivers in me choosing a revenue-based approach, rather than the necessary economic theory and

I would point out some of the idiosyncrasies that can arise if one does follow a volume-based approach. Within Flynn's own portfolio, for instance, they have a product that either sells in packs of 1 or packs of 10. You know, that would end up with the same cost allocation for a pack of 10 or on a pack of 1, whereas a revenue based allocation would take account of the fact that the pack of 10 is, unsurprisingly, ten times the price of the pack of 1.

I also point to observations in other companies that I have worked with, such as Bayer, where you can end up with a very unusual result if you adopt a volume approach, if you are taking a very high volume, very low value medicine -- and I use oral contraceptives as the example -- compared to some of their new very small volume but highly expensive oncology products. This is why typically I think volume is not helpful in the pharmaceutical industry where there are so many diverse products and Flynn's products are of course all human pharmaceuticals but they are in different presentations, they have different price points, they do not have different pack sizes.

Q. We are getting on quite well, at least in terms of being on the same wavelength because the next point I want to come to was joint statement 1.3, which really just deals

with the point you have just made:

"Is a volume-based approach flawed in this case because it can be affected by changes in pack size?"

We will see your position. You agree with the proposition and you say:

"RW considers that the use of a simplistic pack basis method of allocation could on Flynn's portfolio give rise to absurd results."

Then you give some examples to support your view. And we see Mr Harman's position in his second paragraph on page 6. He says:

"GH considers that it is reasonable to assume that the current volume of drugs per pack is based on some form of rational commercial logic, for example reflecting prescription practices. It is unclear whether the level of overhead should increase or decrease if the number of individual products in the pack subsequently changes. There is no compelling reason why the common costs allocation to a pack should change proportionally in response to a change in the number of individual products in a pack. While the level of variable costs attributable to that product would change, by their nature common costs would not. This could be explained intuitively as follows: a cup of coffee that is twice as large as a small cup of coffee

does not normally cost twice as much because the price of coffee is likely to include a fixed allocation of common costs per unit, for example, the rental of the premises and the staff and the variable costs, for example, the number of shots."

You yourself actually made a very similar point this morning. You referred to the fact that the mere fact that a company's -- I cannot remember exactly the way you put it so correct me if I am wrong, if a company's business increases in size twofold, it does not necessarily mean you need to appoint a second financial --

A. That is exactly what I said, yes.

Q. So you agree with -- effectively with the coffee example and you give your own example of the finance directors.

A. We had a good debate at the joint experts' meeting about Starbucks and the coffee analogy. I think this goes back really to the point that is agreed between both myself and the expert appointed by the CMA, Mr Harman, that there is not costs causality. I do not dispute that whatsoever.

THE CHAIRMAN: So this is accountancy firmly rooted in the facts.

A. I think we are a practical bunch, us accountants, yes, chairman.

MR HOSKINS: Again, it is obviously a theme that comes up here. Your evidence is as an accountant with practical experience and that is the basis of the evidence you give and Mr Harman is here as an economist and that is the basis of the evidence he gives but there is sometimes a disjunct between the two for that reason --

A. Yes, there may be.

THE CHAIRMAN: I have to say I think the borderline between accountancy and economics in cases of this kind is quite fuzzy. I am sure you have got that in mind.

MR HOSKINS: I do not disagree with that. I think it is important to put the evidence in context. I am sure the same will be done with Mr Harman when he takes the stand.

If we stay in Mr Harman's column but go on to the next page, page 7, there is a paragraph that begins:

"RW argues that the revenue based allocation methodology ..."

And Mr Harman concludes that paragraph by saying:

"No allocation method can be said to reflect economic reality given the absence of causality. Hence a key factor in the selection of cost allocation method is the absence of factors that are likely to bias the cost allocation in practice. That is objectivity."

If you keep that open but if we can go back to

bundle K, tab 17. This is the draft agenda for the joint meeting and paragraph 1 was the issue in principle:

"Is it correct that by their nature there is no cost causality associated with common costs?"

And that was a point that Macfarlanes said you were not qualified to comment on, so I think you have already accepted that this is a matter that is not within your economic expertise because you do not have any and it is an economic point?

A. I did.

Q. If we can go back -- you can put away bundle K now. Go back to bundle F. This is the joint statement behind tab 5. Page 5. Point 1.2. Remember, this was:

"Are Flynn's products sufficiently homogeneous for a volume-based approach to be meaningful?"

Mr Harman's position, second paragraph in his column, final sentence, he says:

"Flynn provides no quantitative analysis to show that the CMA's particular volume approach would actually lead to biased conclusions verses other approaches."

That is correct, is it not? You have not conducted any such quantitive analysis?

A. I have calculated all of my common cost allocations on a revenue basis or a sensitised revenue basis but I have

actually included within the calculations I have done calculations using the CMA's volume basis of calculation, using a 21 per cent return on sale.

Q. I think this statement is correct, is it not, you have not done a quantitative analysis to show that the volume approach would actually lead to biased conclusions; you have done an exercise to try and show that the revenue approach does not lead to a biased conclusion but there is a potentially separate exercise, which is to analyse a volume-based approach and see if on its own terms it is biased and you have not done that?

A. I have not done that.

Q. And we are about to go to something where the figures are confidential. Page 4 in this statement.

So again just to remind ourselves the question of the issues:

"Is a volume-based approach a reasonable approach in this case?"

Mr Harman's position -- and it is number 4. He says:

"Adopting this approach allocates X per cent of Flynn's common costs to Phenytoin..."

So that is a volume-based approach:

"... even though Phenytoin was one of Y products sold by Flynn in 2015."

You haven't disagreed, at least with that, as a calculation anywhere. Do you agree the figures are correct?

A. The figures are correct, but the implication that Y is a relevant method of allocating common costs is something I do not agree with.

Q. But again, what Mr Harman is doing is he is expressing his view as an economist and he says it is not an obviously unreasonable result and you are expressing your view as an accountant?

A. I am indeed.

Q. Still in the joint statement, this time issue 3.1 and this is moving into the realm of cross-checks. 3.1, the issue is:

"Is it appropriate to consider the use of different cross-checks in this case?"

And you agree that it is appropriate and you say:

"As a general principle it is difficult to argue against the use of cross-checks in this case although they need to be appropriate in the circumstances."

It is correct, is it not, that the PPRS does not require the use of cross-checks in annual financial returns when dealing with common cost allocation, does it?

A. The PPRS requires you to allocate your costs reasonably

between your different areas of business. There is no cross-check performed but you do have to disclose to the Department of Health, when you submit your annual financial return, the method you have used and, as I say, that is invariably in my experience revenue or sales, which is typically talked about in AFR notes and that is something that the Department of Health, I am sure would confirm. They have seen even more AFRs than I have.

Q. So it is acceptable under the PPRS just to use one method of allocation of common costs? It is not required but if you were to put in an AFR using one method, that would be acceptable?

A. And equally the Department of Health, were you not to follow that method, without good reason, would probably reject it and question why you had followed that method.

Q. But you accept that in this case it is difficult to argue against the use of cross-checks. That is what you say --

A. I accept that, I think, you know, one should not be narrow-minded. One should look at a range of cross-checks but not just on common cost allocations; I think one should look at gross margins, one should look at net margins, one should look at comparator generic companies. I think all of those are relevant cross-checks to take into account.

Q. I think it is fair to say then when dealing with this case it is not always your position that you have to adhere strictly to what happens under the PPRS because of the different context we are dealing with here, sometimes you might depart --

A. It is possible, yes.

Q. We have seen already that your base case -- in fact, I think all your analyses are revenue based analyses. So the ones we have looked at --

A. On the subject of common costs allocation, yes.

Q. Sorry, on the subject of common costs allocation, all revenue analyses.

Can we go to Mr Harman's first report. So this is still in bundle F, tab 1, at page 32. Paragraph 360, table 3.2 and this is where he sets out the results of the cross-checks that he has performed; yes?

A. Yes.

Q. And all of his cross-checks differ from your revenue-based approaches because he always uses the 6 per cent ROS as a reasonable return, does he not?

A. Yes, and he also uses the common cost pool that we cannot mention -- put it this way, the lower common cost pool, which I think is inappropriate in a PPRS model. Those are the two differences between Mr Harman and myself; different costs pool, different ROS.

Q. Let us leave that question of the appropriate ROS. There is a dispute between you on that. Let us leave aside the appropriate costs pool. There is a dispute between you on that. We have already seen that.

A. Yes.

Q. I am just going to focus on what are appropriate methods of cross-check. Paragraph 3.58 of Mr Harman's first report sets out the different approaches that Mr Harman has assessed as cross-checks. We see EPMU, incremental costs, stand alone costs, equal allocation.

And the only methodology in the joint statement that you accept might provide a reasonable cross-check is EPMU, which I believe stands for equi-proportional mark-up?

A. Yes.

Q. You agree that that is the only one you think might provide a reasonable cross-check?

A. That is my position.

Q. Let us deal first with EPMU. We see from paragraph 3.58(1) of Mr Harman's first report that EPMU allocates common costs in proportion to each product's directly attributable costs. That is the methodology; yes?

A. Yes.

Q. And then I am afraid we are going to have to flip back

to the joint statement behind tab 5. I think it is --

A. If you do not mind, I also want to make it clear that I accepted EPMU as an appropriate method for allocating common costs on the basis that the portfolio had broadly comparable gross margins.

Q. We are literally just coming to that.

A. Sorry, my apologies.

Q. I was just reassuring you. Bundle F, tab 5, 3.2 and the question is:

"Is the EPMU approach a reasonable cross-check in this case?"

It is page 4. 3.2:

"Is the EPMU approach a reasonable cross-check in this case?"

You agree and you say:

"RW has no particular difficulty with accepting an EPMU basis of cost allocation as where products are broadly similar in gross margin percentages, it gives a not dissimilar result to a revenue-based allocation."

So you are obviously, I presume, saying that it is not a suitable cross-check where products do not have broadly similar margin percentages. Is that your position?

A. If they vary widely. The reason why I say I think it can be an appropriate cross-check is that again it gives

a result that is really proportional to the contribution or profitability of the product and again it would lead to higher allocation of common costs to products that have, as I have used elsewhere the terminology broader shoulders.

Q. That is what you say in the last part of that first sentence I just read out. You say the reason you think it might be a reasonable cross-check is because it gives a not dissimilar result to a revenue-based allocation and as you have just described, the reason why you think this is valuable is because it has a similar basis to your revenue-based approach. That is why you like it; correct?

A. Yes, I think it does support -- indeed it has a consistent -- on the terms I have described it, with common levels or similar levels of gross margin, it is consistent with my revenue approach.

Q. Given what the EPMU is, the way you have described it, it is not surprising they tend to support each other?

A. Indeed, as a factor of mathematics, it would be unsurprising if they did not.

Q. Mr Harman in relation to EPMU says the following. I think we can pick it up in his second paragraph -- sorry, no, we need to pick it up in the first. He disagrees that it is a reasonable cross-check. He says:

"GH considers that a normal application of the EPMU may not be a suitable approach for Flynn in this particular case, but has included it as a comparator for completeness. GH considers the EPMU to be unsuitable because it would allocate a high share of common costs to Phenytoin as a direct consequence of the high (and allegedly excessive) prices charged by Pfizer. By adopting this approach, any excessiveness by Pfizer may conceal excessiveness by Flynn."

So again, given the similarity between the revenue-based approach and the EPMU approach, what Mr Harman is identifying is again the risk of circularity; correct?

A. Indeed.

Q. Then he goes on to say --

A. Can I just, sorry --

Q. Sorry, of course.

A. -- supplement that, sir? I think that is -- there can be circularity within Flynn itself and then, of course, there is the issue of the supply price it receives from Pfizer. I think in all the calculations I have done I am looking at the position of Flynn and I am therefore looking at the input prices from Pfizer as a given. So I do not believe in a sense the Pfizer to Flynn transfer price contributes to the circularity of the Flynn

revenue.

Q. Well, I think Mr Harman disagrees with you because he goes on to say -- this is the bit I was just about to read:

"However, regardless of the first point, the input price of Phenytoin is several times greater than the cost of a number of Flynn's other products."

The input price of Phenytoin he is referring to is the price that Flynn pays to Pfizer; correct? He says:

"Therefore the EPMU approach allocates a much higher level of common costs to Phenytoin than to Flynn's lower cost products."

Do you agree with that?

A. Yes, and it is entirely consistent with the fact, which I accept, that there is a higher allocation of common costs to Phenytoin under a revenue-based approach. It is exactly the same point.

Q. Then if we go back to Mr Harman's first report at page 32, so back to the table we were looking at, the cross-check table, so we see his results for EPMU and I cannot read out the percentages, they are confidential. So you see the results he put?

A. Yes.

Q. Again I think -- it depends what you say -- I only need to ask this question one more time: you have agreed it

is not within your expertise to express an opinion on whether these percentages indicate an excessive price or not from an economic or a legal standpoint, are you?

A. I am agreeing with your comment.

THE CHAIRMAN: In Mr Harman's words, that is an issue for the tribunal to determine.

A. Absolutely, absolutely.

MR HOSKINS: The next cross-check that Mr Harman uses is what he calls an EPMU adjusted for Pfizer excess. So that is line D in his table. And in that approach what he has done is he reduces the price paid by Flynn to Pfizer to remove the excess in Pfizer's prices that were found by the CMA. Is that correct?

A. That is my understanding of the approach he has taken.

Q. And then going back to the joint statement where you deal with this -- so that is tab 5, point 3.3. Just bear with me while I find my reference. (Pause)

It is your second paragraph:

"RW's comments on this latter point are set out in his response to question 2.3 above and RW3."

You contend that it cannot be appropriate to adjust an actual arm's length supply price downwards in the calculation of Flynn's cost calculations and resultant ROS measurement by using a supply price that was never charged.

But that is precisely what you did, was it not, in your first and second sensitised costs allocations? You made an adjustment --

A. But it was not on the basis --

Q. -- to prices actually charged?

A. No, it was not on the basis of the input price from Pfizer to Flynn. It was a sensitivity calculated on a what if Phenytoin revenues were equivalent to that supply price, which was sensitivity 2, or what if revenues were equivalent to the CMA's calculation of cost plus, which was sensitivity 1. It was not adjusting the input price.

Q. But for the purposes of your sensitivity analyses, you were happy to use revenue figures other than actual revenue figures?

A. Yes, I used two notional revenue figures.

Q. If we go back -- I am sorry, we have to keep flipping between them, for obvious reasons, back to first Harman, page 32 and line D. And we are not allowed to read the figures out but we see that the excesses indicated by the adjusted EPMU approach are similar and indeed sometimes greater than those indicated by the volume-based approach, do we not? So we are just comparing line D with line A?

A. Yes, we do.

Q. So this cross-check does provide some support for the volume-based approach, does it not?
A. The numbers are broadly similar. I do not know that it necessarily supports a volume-based approach.
Q. Next if we deal with the incremental approach, we find the incremental approach used by Mr Harman defined in this bundle at tab 2C, which should be a document entitled "Appendix 3: other cost allocation methodologies"?
A. Yes.
Q. So this is appendix 3 to first Harman and at paragraph A3.9, "Incremental cost based common costs allocation." And if you read that paragraph, you will see towards the bottom, when assessing the LRIC for any one product:

"All common costs are allocated to the other products in a company's portfolio."

And that is what is referred to as the incremental costs approach; it involves assigning no common costs to Phenytoin in this case, does it not?
A. It does.
Q. And then if we go to the joint statement at tab 5, paragraph 3.4, the proposition is:

"Is an incremental approach allocating common costs to all the other products in Flynn's portfolio

a reasonable cross-check in this case?"

You disagree with the proposition and effectively Mr Harman also disagrees with the proposition:

"Likely to be too strict for an assessment of excessiveness."

So actually there is a degree of agreement that has broken out between you on the incremental basis of the cross-check; correct?

A. Yes, that is correct.

Q. And the reason why it is not appropriate is because it is too unfavourable to Flynn because it does not take account of any common costs when assessing the appropriate return relative to the costs of Phenytoin?

A. Yes.

Q. And then back to first Harman -- actually, let us stay here. I will try and save you flipping. I am going to move on to the standalone approach and that is defined in tab 2C that we have just seen, paragraph A3.12. You see the heading, "Stand alone cost based common cost allocation." He says:

"The highest cost plus that a multiproduct firm can support for any individual product is given by the efficient stand-alone costs of that product in which all common costs are allocated to the product under assessment."

So that is what Mr Harman has used as the stand-alone basis:

"All common costs are allocated to Phenytoin for his cross-check; correct?

A. Yes, that is correct.

Q. And the problem with that approach is it is too generous to Flynn because it overestimates its cost base for the purpose of assessing the extent of any profits beyond a reasonable return. It is too generous to Flynn, is it not?

A. And nor would it be allowed under any PPRS model. There has to be fair and reasonable allocation of costs between business lines. So I would agree with you. Either allocating zero per cent or 100 per cent are outliers.

Q. If we go to the joint statement, tab 5. So the issue is:

"Is a stand-alone approach allocating common costs to a single product a reasonable cross-check in this case?"

In the second paragraph of your column it is recorded:

"GH [Mr Harman] asserts that the stand-alone approach 'forms the upper bound to cost plus'."

You say:

"This is true in relation to the proportion of common costs that are allocated to Phenytoin -- which at 100 per cent of GH's assessed common cost pool of Flynn, can never be greater. However, it is misleading to say it is the 'upper bound of cost plus', because the other elements of a cost plus calculation (and GH's calculated excess of [X] per cent) also depend on (a) the size of the cost pool ... and (b) the size of the chosen ROS."

Leaving aside the issue of the appropriate ROS and the size of the costs pool, you agree, do you not, that the stand-alone approach forms the upper bounds to cost plus? If you were to use your figures for the common costs within ROS, it would give you the upper bounds to cost plus, would it not?

A. For a given plus. And that is a big debate between us. Of course, if the larger of the two costs pools had been used and Mr Harman had run calculations allocating 100 per cent to Phenytoin, then we would simply -- I think we would probably have the upper bound to cost. The plus would then have to be debated as to whether 6, 6 plus MOT, or an ROS of 21 is the appropriate figure. So I think the implication that this is a very generous approach -- and the calculation has shown the absolute almost absurd position of allocating 100 per cent and I still have a very -- a large percentage excess -- the

implication is that there has been generosity in all aspects but indeed it is only on one, which is allocating 100 per cent of the smaller costs pool.

Q. But we are agreed that there is generosity on that one part of the equation that one has to look at as a whole?

A. Yes, 100 per cent of a disagreed number is allocated.

Q. Then equal allocation is the final cross-check that Mr Harman has applied. You deal with this at joint statement paragraph 3.6, page 18. And you have to pick it up at page 17 actually. You see the issue:

"Is an equal allocation approach, where costs are split equally based on the number of products in the portfolio, a reasonable cross-check in this case?"

And your position is that you cannot envisage this methodology ever being used in practice in a multiproduct pharmaceutical company. So you are not expressing a view on whether it might be a valuable approach economically; you are just saying this would not happen in practice?

A. I am saying it would not happen in practice because of the different revenue streams of different products. You could end up allocating a disproportionate amount of common cost to a product that may only have £1,000 worth of revenue because it has just been launched.

Q. Go back into your reports, so back to bundle D, your

first, tab 11, bundle D, paragraph 31. I said I would come back to the PPRS. I am now coming back to it. You will see the heading of this section of your report on page 7:

"The CMA's reliance upon the PPRS."

So that is the area we are now in; yes?

A. Yes.

Q. Paragraph 31. You say:

"The CMA has adopted a cost plus model. This is not reflective of paragraph 8.9 of the 2014 PPRS which explicitly states the industry accepts that the scheme is not a cost plus scheme."

Then you say:

"Cost plus guarantees a supplier a mark-up on its product costs, in effect a product guarantee. The PPRS does not do this in any circumstance and thus the CMA cost plus approach is therefore by definition inconsistent with the PPRS approach."

I would like to look at what the PPRS says about cost plus and guarantees. That is bundle H2, tab 33. So you see the heading -- this is the 2014 PPRS, is it not?

A. Yes.

Q. And if we turn through to paragraphs 8.8 and 8.9, 8.8:

"Any scheme member must be able to demonstrate that

costs or capital included in its AFR are appropriate to supply of NHS medicines in accordance with this scheme. Overhead costs and shared assets utilised in both NHS medicines and other products must be reasonably apportioned. Scheme members will provide reasonable details of costs and capital either directly allocated or apportioned to home NHS medicines together with an explanation supporting any apportionment."

Then 8.9:

"The industry accepts that the scheme is not a cost plus scheme and that the Department is entitled to satisfy itself that the costs and capital claimed for medicines supplied to the NHS are properly incurred in accordance with the scheme and they are reasonable in the light of accepted commercial practice. Excess costs and capital will be disallowed from the assessment."

I just want to be clear: the PPRS does allow a certain rate of return taking account of costs, does it not? That is the basis of the price part of the scheme. So in that sense it is a cost plus scheme, is it not?

A. The paragraph you quoted before to say that it is not a cost plus scheme, what the Department of Health and the ABPI agreed is that effectively the Department of Health will not pay a price for a medicine irregardless

of the underlying costs. So if a company is inefficient or spends more than the Department believes is justified on sales and marketing, it is not simply a question of presenting the Department of Health a bill, saying: this is what we spent, you give us 6 per cent and this is the profit we should charge. So that is what not a cost plus scheme means; it is not -- it is not simply that you will always make a profit irregardless of your cost base as a PPRS member.

Q. There is no guarantee?

A. There is no guarantee.

Q. So if you look back at paragraph 31 of your first report, it seems to conflate those two points because you are criticising the CMA, saying: the PPRS does not have this cost guarantee element. And then: so the CMA was wrong to adopt a cost plus model.

That is a wee bit unfair, is it not, because the CMA has never said or conflated itself the idea of a cost plus model using cost plus a reasonable rate of return with a price guarantee?

A. No, but I think from what all I have read the CMA does seem to have relied extremely heavily on the 6 per cent ROS that is quoted in the PPRS.

Q. We are going to keep coming back to the PPRS, so you might want to keep bundle H2 handy. But for the moment

I would like to go back to bundle D, tab 11, which is your first report. Do you want to get rid of some bundles? It is looking a bit crowded.

A. Do we need the joint report to refer to again? I have got plenty of space here.

Q. We do not because we have finished cost allocations, so ...

A. Can you just repeat the tab you were referring me to.

Q. Absolutely. Bundle D, tab 11.

A. Yes.

Q. Which is your first report and we are going to go to paragraph 24.

A. Yes.

Q. And we have seen this already because this was the subject of one of the corrections you made this morning. I do not need to revisit the first sentence. It is what follows:

"The PPRS is negotiated, not imposed and is intended to achieve a balance between reasonable prices for medicines prescribed for NHS patients and recognising the role of the pharmaceutical industry in the UK as a leading employer and investor in research and development."

I wanted to ask you: in what way does the PPRS recognise the role of the pharmaceutical industry in the

UK as a leading investor in research and development?

A. If you look at the principal objectives of the PPRS, which are set out in the scheme, it talks about the balance between fair and reasonable prices but also rewarding innovation, encouraging companies to bring new medicines to market. One of the most generous aspects of the PPRS is the fact that a company can offset fairly substantial amounts of research and development against its UK profits, probably actually in excess of the average it is incurring in its group as a whole and that is one of the key ways in which the PPRS encourages investment and research for bringing new medicines to market.

Q. So if we go back to the PPRS, which I hope you have still got open at H2, tab 33, page 51.

A. Yes.

Q. You see the heading "Levels of return and allowances?

A. Yes.

Q. "The scheme provides a framework for determining reasonable limits to the profits to be made from the supply of branded medicines to the NHS. In keeping with the principles set out in the introduction to the scheme, there is encouragement for the research and development (R&D) of new medicines, and a commitment to a minimum of interference with scheme members' freedom

to succeed in that activity.

"There will be one level of return on sales target (ROS) and one level of return on capital (ROC) target."

So does it follow from what you have just explained that the ROS target in the PPRS is set at a level which is intended to provide encouragement for the research and development of new medicines?

A. Only taking into -- if you also take into account the costs that are allowed in reaching the ROS. So the ROS itself -- what the PPRS is not saying is: 6 per cent is sufficient for you as a return to go away and develop all the new medicines for the future. The ROS is struck after deducting research and development expenses in particular and it is one of an interrelated set of allowances that ensure that a pharmaceutical company can be profitable and can actually invest in new medicines.

Q. But the 6 per cent figure that is chosen for the ROS, one of the purposes of choosing 6 per cent is this point we are discussing, which is the need to allow sufficient funds for companies to engage in R and D?

A. To be sufficiently profitable when taking into account the other profit in the PPRS chain, which I think was presented to the tribunal in Ms Bacon's opening statement. That chart that was presented in evidence.

Q. If we can go through to tab 35 in bundle H2, this is the

PPRS/DH, Department of Health, 12th report to Parliament dated April 2014. What is the purpose of this report? Why does the DH produce these reports to Parliament?

A. The Public Accounts Committee requires the Department of Health to periodically report on the operations of the scheme, I think in terms of just normal good Parliamentary governance.

Q. If we go to page 6 of this report, paragraph 2.2. You see it says:

"The major components of the 2009 PPRS were price adjustments and the list price of branded prescription medicine sold to the NHS, a target rate of return on capital of 21 per cent and a target rate of return on sales of 6 per cent. A more systematic basis for patient access schemes, action to support innovation so that patients had faster access to new medicines that are clinically and cost-effective."

So we see the broad scope of the PPRS but we see in the second bullet one of the components of the PPRS is a form of price control and the target rate of return on sales of 6 per cent was one of the major components of the 2009 PPRS. Would you agree with that view expressed by the DH --

A. Can you just clarify what you mean by price control? Is that in relation to bullet 1?

Q. No, I mean in terms of setting a figure of 6 per cent, companies then have to comply subject to MOT -- and we will come on to your transfer profit allowance, but companies are allowed to modulate their prices in order to arrive at the appropriate place?

A. Yes, so the PPRS is not a direct form of price control. It is a form of profit control and a company is allowed to set its prices within that profit envelope as it sees fit.

Q. And so do you agree that the target return of return on sales of 6 per cent was one of the major components of the 2009 PPRS --

A. It is a key component, yes.

Q. And it is also a key component in the 2014 scheme, is it not?

A. And preceding schemes to that. The 6 per cent has been around a long time.

Q. Can I come on to look at the margin of tolerance. So we will go back to tab 33, which is the 2014 PPRS. I want to look at annex 15, which is towards the end of that tab. It is page 107.

A. Yes.

Q. Annex 15:

"2014 PPRS schedule of rates and allowances."

And we have the ROCE target, the ROS target then

MOT, upper limit, 150 per cent; lower limit of 50 per cent. So the MOT works both ways, does it not? There is an upper limit and a lower limit, as we see?

A. Yes, so you cannot apply for a price increase simply because you are slightly below the target return on sales; you have to be materially below the target but that is only part of -- not only do you need to be materially below the target, you also are -- your P and L account, your AFR is recast with a different level of allowances that are taken into account if you are applying for an overall price increase, which is the difference between level 1 and level 2 allowances.

Q. The existence of an MOT, upward and lower, was the same under the 2009 PPRS except the limits were different, were they not?

A. Yes.

Q. The limit was 140 per cent, upper limit, and the lower limit was 40 per cent for the 2009 scheme?

A. Yes, correct.

Q. I would like to deal now with the transfer profit price allowance. We need to go back to -- keep the PPRS handy. We are going to go first of all, though, to your second report, bundle D, tab 12. Paragraph 18 on page 6. You say there:

"The second reason why PPRS ROS returns are higher

in practice than 6 per cent is the so-called transfer price profit allowance. This reflects the fact that in addition to a local profit target of 6 per cent, the PPRS also allows for a return, which can be expressed as a ROS on products purchased by the PPRS member from affiliates outside the UK, for example an entity manufacturing the product that sells it to the local UK entity, the PPRS member, at a transfer price which incorporates a profit element."

So the transfer profit price allowance only applies where PPRS members are purchasing products from an affiliated company outside the UK. That is correct, is it not?

A. No, it is not.

Q. Explain why.

A. The company can be within the UK and indeed the company can be a non-manufacturer but it does have to be a related party. So if you are buying from any member of your group, if you are the sales and marketing company and you were buying your product from any member of your group, you will be entitled to the transfer price profit allowance on the price that that member of your group charges the sales and marketing company for the purchase of the product.

Q. Well, I was taking it from your paragraph 18. You say:

"Typically outside the UK."

Why do you use the phrase "typically"?

A. Because that is the majority of cases, they are outside the UK. They are overseas manufacturing or procurement entities and they are typically offshore. In other words, of those I have seen, many more are offshore than are onshore but I have seen both.

Q. So the scheme is not limited to an affiliate outside the UK but that is the typical position that you have encountered?

A. Yes, that is correct.

Q. Did you come up -- did you help Flynn's team to come up with the worked example that Ms Bacon referred to in her opening submissions? Did you have input into that?

A. I did have input into that, yes.

Q. Because she suggested that a company such as Flynn, for example, could and would set up an affiliated procurement company if that allowed it to take account of the transfer profit price allowance. We are in a slightly unusual situation here because we are imagining Flynn being in the PPRS for the purposes --

A. And Phenytoin being a branded product, yes.

Q. Indeed. But presumably, you agree with the way Ms Bacon presented it, that if a company were distributing a profit, what it would do if -- it would -- in order to

gain advantage from the TPPA, it would just set up an affiliate and then it would claim the TPPA. Is that doing justice or am I being too --

A. No, I think you are doing reasonable justice. It would probably establish itself a procurement company that sourced all of its products within a single company and that procurement company would then sell to the UK affiliate for sales in the UK and maybe the German affiliate for sales in Germany, it is a very common structure.

Q. The suggestion seemed to be in opening that that would be done simply to take account of the TPPA. Is that your position or are you saying that as part of a general commercial decision-making process that might happen?

A. I think taking advantage of the structure of the PPRS, of which the TPA is a fundamental part would be one of the drivers of setting up that procurement entity, it can also be for logistical reasons as well. It could also be for tax reasons.

Q. So one of the drivers?

A. One of the drivers.

Q. What would the other drivers potentially be?

A. Well, it could be for putting all your procurement logistics in a single company. It could be for tax

reasons. In other words, there are reasons other than just the TPPA but I would say that the TPPA would be an important element of that decision-making process.

Q. Are you suggesting that it would be appropriate to set up an affiliate procurement purpose solely for the purpose of being able to benefit from the TPPA? Would a company be allowed to do that?

A. A company would be allowed to do that and indeed I have been at meetings with officials at the Department of Health where that has been discussed and even endorsed.

Q. Can we go back to the PPRS. So that is H2, tab 33.

A. Yes.

Q. At page 12. It says:

"All parties will operate the scheme in good faith and recognise that there should be compliance with the scheme. All parties to the scheme will use their best endeavours not to manipulate or undermine the scheme in a way which conflicts with the overarching purpose, principles and objectives set out in chapter 1 or in a way which makes the scheme ineffective as set out at paragraph 3.13. The mutual intent is that neither the Department, the ABPI, nor members of the scheme will seek to abuse this scheme."

So is your position that if a company were to set up an affiliate procurement company solely for the purposes

of taking advantage of the TPPA, it would still be operating within the confines of good faith set out in this paragraph?

A. I would and that is a generally understood methodology and structure with officials at the Department of Health and this is not -- this would not be done without full transparency because it would be very clear from the AFR that was presented about the group structure and the procurement model.

Q. If we look at the purpose, principles and objectives of the PPRS, that is on page 9 of the document. One of the principal objectives at the top of page 10 is:

"Support the NHS by ensuring that the branded medicines bill stays within affordable limits and deliver value for money for the NHS by securing the provision of safe and effective medicines at reasonable prices and encouraging the efficient development and competitive supply of medicines."

A commercial strategy, you are suggesting, would result in the NHS paying more for medicines, would it not?

A. No, I do not think it would. I think 1.4.2 is written in the context of what the Department sees as the total allowable profitability on the sales of medicines, of which a key component is the transfer price profit plus

the local profit. I think the Department would not be the first to say that they believe 6 per cent alone is sufficient to run an innovative and productive pharmaceutical industry in this or indeed any other country. I think the other point of 1.4.2 is it goes to the structure of the 2014 scheme, where the branded medicines companies that were members of the scheme actually made repayments to the Department of Health under the PPRS, which ensured that the medicines bill stayed within affordable limits.

THE CHAIRMAN: Mr Williams, I think the question you are being asked is whether there is some kind of colourability to a corporate restructuring which is solely for the purpose of obtaining more allowances within the scheme of the PPRS. In other words, does the Department regard the PPRS as a framework within which companies are allowed to structure their affairs so as to take advantage of the maximum --

A. I believe so, yes.

THE CHAIRMAN: Is that --

A. Yes --

THE CHAIRMAN: -- part of the overall objective?

A. And understanding of the way the PPRS works between Department officials and companies.

THE CHAIRMAN: Following from what you said earlier, is that

because you see the PPRS as not only trying to keep the drugs bill down but also trying to encourage research and development? Is that what you are saying?

A. Yes, absolutely and providing sufficient profitability to innovate and to market products and increase uptake of new innovative medicines.

THE CHAIRMAN: And you would see that as all within the overall purposes and objectives of the PPRS?

A. Yes, it is not simply a profit measure; it is also to encourage a profitable industry within this country and that has been reconfirmed recently by the industrial strategy review paper.

MR HOSKINS: Just to be clear, why would a company want to take advantage of the TPPA? What is in it for the company?

A. Because it gives an overall higher allowable profit.

Q. It makes more money?

A. It can make more money.

Q. And who is paying for that profit? It is the NHS, is it not?

A. As long as the company is operating within the agreed guidelines of profitability, ultimately that will reflect in its overall revenues and its profitability. So, yes, the NHS will be purchasing those products at -- incorporating those arrangements but that is what the

Department has agreed with the ABPI is an appropriate profit envelope for a company to operate within.

Q. If we go back to -- we are still in it, I hope -- the 2014 PPRS and go to page 53, paragraph 8.21, the PPRS provides:

"Where possible scheme members should seek to provide an independently reviewed breakdown of their transfer prices."

Then over the page:

"Where a scheme member provides no breakdown of transfer price costs it will be required to confirm that its transfer prices are at arm's length, to indicate the basis on which such arm's length prices are set and to confirm that the transfer prices reported in AFR are as will be reported in the member's corporate tax computation."

So a company seeking to rely on the TPA must either provide an independently reviewed breakdown of its transfer prices or confirm that its transfer prices are set at arm's length. Is that correct?

A. Yes, and indeed there is a requirement to confirm to Her Majesty's Revenue and Customs that prices are at arm's length as well, which is why there is the references to the Corporation Tax computation. So if a company is self-declaring that they are not at arm's length and

that the transfer price is different in the tax computations, that different number has to be used in the PPRS computations as well.

Q. So the transfer prices cannot just be plucked off the shelf to get the best position under the PPRS; they have to be justified to the DH, do they not? They have to have an objective basis?

A. Yes, and they have to be justified to the tax inspector as well. I should point out by the way that the reference to the independently reviewed breakdown of their transfer prices, I think the last time I saw one of those was in the last millennium. It is certainly for at least 20 years I have only ever seen the default mechanism used since 2000.

Q. Going back to paragraph 8.22, the final sentence. So:

"Where a scheme member has provided no breakdown of transfer price costs, it will be required to confirm that its transfer prices are at arm's length ..."

Et cetera. Then under the PPRS it is said:

"In such cases the Department will assume that transfer prices comprise 59 per cent manufacturing, 21 per cent R and D and 20 per cent profit."

Then it goes on to explain at 8.23:

"The maximum permitted transfer price profit allowed in the assessment is 25 per cent of accepted costs.

Accepted costs means the costs allowed after negotiation. In the case of a member assessed on the ROC basis, the allowed profit will be converted to an equivalent amount of assets using the scheme ROC target and added to the member's total capital employed."

Then:

"In the case of a member assessed on a ROS basis, the allowed profit will be added to the member's ROS profit target."

Just to clarify, the 20 per cent assumed profit that makes up the transfer price, which we see in 8.22, is what is referred to as the TPPA. Is that correct?

A. Yes, and it is equivalent to the 25 per cent of accepted costs as well because costs assumed -- if all costs are accepted within the transfer price, you have costs of 59 plus 21, which is 80 and 20 is 25 per cent of 80.

Q. If we go to page 58 of the PPRS, you see the heading "Small companies". It says:

"Any scheme member with total home sales of NHS medicines not exceeding £50 million in each financial year will be exempt from supplying financial information. However, the Department reserves the right to call for a full AFR if circumstances appear to warrant it."

Again let us keep the PPRS handy but I want to go to

your third report, D/13, paragraphs 10 to 11:

"The DH is entitled to ask for an ad hoc AFR to be produced by companies below the AFR threshold. However, save for cases where a non-AFR company is required to submit an AFR in support of a price increase based on inadequate profitability, I have only once seen this happen over the last 20 years of my involvement with the PPRS.

"This means that while the PPRS rules do still apply in principle to smaller companies, the measurement and enforcement of profitability for such companies is in practice non-existent."

Then over the page at paragraph 14, in the middle of paragraph 14 you say:

"The point is that the 6 per cent ROS is in practice never applied to a company like Flynn. It is only applied via an AFR."

Is it your experience that small companies which are exempt from the obligation to file an AFR do not comply in practice with the substantive requirements of the PPRS?

A. No, I think it is sensible governance for any company, even if it is below the £50 million limit, to do -- in fact I have been involved in many of these -- a sort of mock AFR to model their profitability to ensure that

they are still complying. I think it is important that even though companies do not have to submit an AFR, they are still bound by the rules of the PPRS.

Q. That is good practice?

A. Yes.

Q. But is it the general practice?

A. I think the practice gets more general as companies grow. I do not think a company with £2 million or £3 million sales is likely to do a mock AFR but the company that was approaching the 50 million or anywhere close to it probably would do.

Q. But we are agreed, I think, from what you said, the fact that a company is exempt from the obligation to provide an AFR does not exempt it from the substantive obligations in the PPRS, and you see that --

A. I agree with that comment, yes.

Q. -- paragraph 9.10 of the 2015 scheme; yes?

A. Yes, absolutely. It is not a blank cheque for small companies to ignore the PPRS.

Q. In your second report, tab 12, at paragraph 31 to 33, you say:

"The impact of this ..."

We are talking about the TPPA here:

"... can be seen in practice by a review of the data in the 12th report to Parliament. Table 2 of that

report is reproduced below."

So table 2 is cut and pasted from the 12th report that we saw earlier.

A. That is correct, yes.

Q. And the final row, return on sales, you have company columns and then outturn columns, and the outturn columns we see, for 2009, 2010 2011, give figures of 18.2 per cent, 18.5 per cent and 17.3 per cent, and at paragraph 33 of your second report you say:

"In each of the three years presented the outturn ROS assessed by the DH, excluding any profit within the TP, is between 17.3 per cent and 18.5 per cent."

I want to take you back to then the 12th report to Parliament. So that is back to bundle H2, tab 35. Can I ask you to turn to page 9. You will see that is indeed table 2 that you reproduced in your report, is it not?

A. It is.

Q. And paragraph 2.21 says:

"As in previous reports, the information submitted to the Department by companies is shown in the company columns, while the outturn columns show the position reached after assessment of the AFRs by the Department and negotiation with each company. Where companies purchase goods from affiliates and transfer prices,

these are reallocated between costs of goods sold, 59 per cent, R&D 21 per cent, and profit, 20 per cent."

And we saw the part of the 2014 PPRS where those assumed percentages come from, did we not?

A. We did.

Q. "This split of the transfer price has been agreed with the industry and is set out in sections 8.21 to 8.27 of the 2009 PPRS. The split was identical to that under the 2005 scheme. It is for this reason that R&D costs allowed in the assessment seem to be higher than those being claimed by the companies."

Then it says:

"The transfer price profit element of the transfer prices ..."

We have already established that that is the 20 per cent figure; yes?

A. Yes.

Q. "... is not treated as a cost in arriving at assessed profit but is added to target return and is the major reason why outturn profit is significantly higher than that apparently claimed by the companies in their submission."

So what that tells us is that the figures of between 17.3 per cent and 18.5 per cent in the ROS outturn columns do include the transfer price profit element.

That is correct, is it not?

A. Amongst other things, yes.

Q. Can we -- can you be given, please, bundle A. If you could turn to tab 3, you see this is a copy of the CMA's defence in these proceedings.

A. Yes.

Q. And there is a little tab B, hopefully.

A. Yes.

Q. Could I ask you to turn to that. We have seen this before because you have commented on it in your reports, as I will show you?

A. Yes.

Q. So this is an annex produced by the CMA to deal with the transfer price profit allowance. Paragraph 5 at the bottom of the page says:

"First, as explained in the outturn ROS, the affiliate's profit is stripped out of the transfer prices paid by the UK SMDC. This has the effect of reducing the UK SMDC's costs. The figures quoted by Mr Williams are therefore artificial figures calculated by adjusting for a proxy rather than the actual profit element of the transfer prices faced by these businesses."

Then the final sentence:

"Accordingly, the outturn ROS is not the ROS the UK

SMDCs actually earn."

Can you deal with that? Go to your third report. You want to keep Annex B out and open.

A. Yes.

Q. Third Williams, so D13. At paragraph 12(e), on page 4, you say:

"The CMA is therefore correct to say in Annex B to the defence that the transfer profit allowance is an adjustment based on a proxy rather than looking at the actual profit element of the transfer prices."

Your footnote 4 refers to CMA defence, Annex B, paragraph 5.

A. Yes.

Q. So are you agreeing that paragraph 5 of Annex B to the CMA defence is accurate?

A. Yes, it is a proxy because the 59, 21, 20 is not, to my knowledge, based on any actual analysis of underlying transfer price costs and profits.

Q. Then if we go back to the CMA defence, Annex B, turn over the page to paragraph 6. CMA says:

"Second, again as explained above, the transfer price profit element is added to the target return. This adjustment has the effect of including both the UK SMDC's actual profits as well as a proxy for the affiliates profit within the outturn ROS. As outlined

in second Williams, paragraph 28, under the PPRS the affiliate's profit on its sales to the UK SMDC is assumed to amount to 20 per cent of the transfer price. The outturn ROS is therefore much greater than the UK SMDC's actual ROS."

Do you accept that that is all accurate in light of what we have seen in paragraph 2.21 of the 12th report to Parliament?

A. Yes, because there is -- effectively, the company submitted data, and its profitability that they submit is increased by disallowing an element of their cost of sales. It is countervailed by, of course, the Department of Health then add it on the other side, which is the allowance. But certainly in terms of the outturn, that is one of the reasons that the outturn profitability here is higher than the company's submitted profitability. Well, indeed, as you can see, for two of the three years it was actually a loss that the aggregate companies submitted data showed.

Q. If we go back to your second report, so bundle D12, this time paragraph 28, you say:

"Taking an average transfer profit --

A. Transfer price.

Q. Transfer price, sorry:

"Taking an average transfer price of 65 per cent of

net selling price and applying the 20 per cent profit allowance within the TP means that the equivalent of 13 per cent, 65 per cent times 20 per cent of UK sales, is the profit allowed within the TP. The ROS equivalent of the allowed TP profit is therefore 13 per cent."

So the ROS equivalent of the allowed TP profit is therefore 13 per cent?

A. Yes.

Q. I want to hold that figure in our heads and I want to go back to the 12th report to Parliament, bundle H2, tab 35. Back to table 2, which is on page 9.

If we go to the return of sales outturn figures, if you strip out the transfer price profit element of around 13 per cent, expressed as a ROS, you would get figures of 5.2 per cent, 5.5 per cent and 4.3 per cent, would you not?

A. You would.

Q. And if we go back to the CMA's defence in bundle A, paragraph 7 --

A. Which tab?

Q. Sorry, this is bundle A, tab 3b.

A. Yes.

Q. The CMA said:

"As calculated in second Williams, paragraph 28 ..."

Which we have just seen:

"... taking an average transfer price of 65 per cent of net selling provision, the 25 per cent profit allowance leads to some allowed profit of 13 per cent. Therefore, to determine a more accurate reflection of the actual ROS earned by the UK SMDC, the outturn ROS should be reduced by 13 per cent. This means that the returns earned by the UK SMDC on their sales under the PPRS would actually be closer to 5 per cent."

Do you agree with that? It is the process we have just been through.

A. I understand the mathematics but unfortunately they are fundamentally flawed because the company column -- this is in the table 2, behind tab 35, page 9 of bundle H2 -- is not the profitability -- the aggregate profitability of the companies submitting AFRs, and the reason for that is that when you submit an AFR, you are allowed to do two things. The first thing is you are allowed to inject costs from outside your local entity to the extent that they relate to your local entity and a -- sorry, to the extent that they relate to the PPRS. So the most typical thing a company might do is have a sister company in the UK that is incurring R&D expenses and those R&D expenses can be claimed in the company column, even though they were not in that company, they were in a sister.

And perhaps even more significant, the vast majority of companies in this country that are members of the PPRS and that do incur research and development expenditure in the UK recharge that research and development expenditure to the parent company, not least so the IP sits in the ownership of the parent company.

The PPRS AFR allows a company to ignore the credit it receives for the recharge and do what I have described as grossing up the R&D. So this is why the company numbers presented are lower in the company column than the real company numbers, because the real statutory accounts of the company will reflect that income that it has received from recharging R&D, and it equally will not reflect any of those injected costs. So it is not -- it is not, unfortunately, as simple as saying I see 17.3 per cent as an outturn, Mr Williams says that 13 per cent is the typical transfer price profit, QED the right return, or the exact return, for the local SMDC -- sales, marketing and distribution company -- is only, you know, less than 5 per cent.

So, unfortunately, it is a flawed analysis.

Q. But, Mr Williams, you accept -- I think you must accept, given the exchange we have had in the last few minutes, that the figures in the outturn column in table 2 of the 12th report to Parliament also do not reflect the

returns actually earned by the UK SMDC in their sales, do they?

A. No, they do not because they reduce the cost of sales of the SMDC by the assumed transfer price profit. That is treated as a disallowed cost.

Q. And if we can go to your third report, so bundle D, tab 13 -- we have already been to it once -- paragraph 12(e) at the bottom of page 4. We saw the sentence:

"The CMA is therefore correct to say in Annex B to the defence that the TP allowance is an adjustment based on a proxy rather than looking at the actual profit element of the transfer prices."

But you go on to say:

"But the effect of that is to understate the actual profit earned by the group."

It is stating the obvious here, is it not, that Flynn and Pfizer are not part of same group, are they?

A. They are not.

Q. In your third report, at paragraph 15, you refer to something called "a limited risk distributorship" or "LRD model". That is an arrangement -- I will ask: is that an arrangement that is only available where there is a parent with UK sales, marketing and distribution company?

A. That is typically the case, yes. I cannot think of a -- someone has to take a risk in a limited risk distributorship model and it is typically a parent or an overseas affiliate.
Q. So to take advantage of the limited risk distributorship model, the companies have to be in the same group, do they not?
A. They do.
Q. And it is a tax arrangement that is agreed with HMRC, is it not?
A. It is, effectively. One does not specifically get the HMRC to write to you to say, "This is fine." You typically self-declare to tax returns these days that your arrangements with your affiliates are at arm's length. You normally get a firm of accountants to do that analysis, to conclude that your profitability is appropriate given industry benchmarks and that is -- if challenged by the HMRC, would be presented to them.
Q. And the limited risk distributorship model is nothing to do with the PPRS, is it? It is to do with tax affairs?
A. It is to do with tax affairs but it sits very comfortably with the PPRS because it leaves the profitability of the UK subsidiary at a low level which fits comfortably within the PPRS allowances.
Q. But it does not form part of the PPRS in any way, does

it?

A. No, it does not.

Q. Thank you, Mr Williams. I have no further questions.

THE CHAIRMAN: Ms Bacon?

Re-examination by MS BACON

MS BACON: I do have a couple of questions in re-examination. Can I start with the sensitivity analysis? Can you take up your third report, which is at tab 13, and go to paragraph 41, table 2. And you will see that you presented a number of figures -- we do not need to read them out. If you could look at the bottom line of table 2 and you will see the base case figure, the sensitised 1 and sensitised 2, and you can see the differences between the base case and the sensitised figures and you have described them in a couple of cases, including in paragraph 42.

What conclusions do you draw from the level of those differences about the validity of a revenue-based calculation?

A. I think the conclusions I draw that even with fairly significant sensitivities, the net result on the calculation is not very significant.

Q. What is the purpose of a sensitivity analysis on a base case in general terms?

A. I think just to test --

MR LOMAS: By that do you mean not significantly different?
A. Yes, yes.
MS BACON: What is the purpose of a sensitivity analysis on a base case in general terms?
A. I think in general to test the robustness of the base case to see if it is wildly wrong because the sensitivity produces a very different result and in this case it did not.
Q. Can you turn to the joint report, which is at -- I have lost it now -- bundle F, tab 5. Could you go to page 11. About half way down page 11 you will see on your column:

"RW believes both of his sensitised revenue-based allocations to be extremely conservative and in the case of his sensitised 2 calculation almost absurdly so."

Do you see those words?
A. I do, yes.
Q. What did you mean by that?
A. What I mean is that in my sensitivity 2, which is the one I describe as absurd, it is based on notional revenues delivering zero pounds profit whatsoever above direct cost and that is something no company would ever enter into an agreement where it was selling at no profit whatsoever.
Q. What do you mean by the extremely conservative because

you say you believe both of them to be extremely conservative?

A. In other words, they reduce my base case allocation percentage using conservative -- very conservative assumptions; in other words, taking the most aggressive approach I could possibly take to getting a revenue allocation.

Q. I see. And you say that you have -- you said in some of your responses to Mr Hoskins' questions that you had addressed a potential circularity arising from possible excessiveness at Flynn's level?

A. Yes.

Q. But you did not do so in relation to Pfizer's supply price

A. No, I took Pfizer's supply price throughout my calculations as a given.

Q. Why do you make that distinction?

A. Could you rephrase that question.

Q. Why do you make a distinction between circularity at Flynn's level and circularity at Pfizer's level?

A. Because I think my job here in all my reports has been to do calculations and present them in relation to only the question of whether Flynn's prices were excessive. Therefore, I believe circularity is relevant in my calculations only in relation to Flynn's prices.

Q. Thank you. You were asked about your sample of

companies in annex 3 of your second statement and you can look at that, if you need to. That is at tab 12 of bundle D, pages 22 and 23.

A. Yes.

Q. And you were asked about how you selected the non-manufacturing companies and you explained that. Can you explain how you chose the sample set as a whole?

A. I basically sourced it from the BGMA website. So these are companies that are members of the British Generic Manufacturers Association and I took -- I took the names from the website.

Q. What criteria did you use to select those companies?

A. I looked at companies that were selling a broad range of generic products, some of them, I accept, were of differing sizes but a number of them are fairly similar sized to Flynn, and, of course, a separate set of sample companies was looked at by another expert on the case and came to broadly similar figures. A lot of these companies, I know, you know, first hand, so I understand quite well what they do.

Q. And it was put to you that looking at a sample of companies, the products within that company are going to vary significantly within a portfolio, and you were asked then why the 20 per cent figure that you alighted on was a relevant figure to use and your response -- and

this is at page 48 of the transcript -- was that your 21 per cent figure was at least a far better comparison than the 6 per cent PPRS figure?

A. Yes, it was an average of these companies, I eliminated the manufacturers as that clearly would be a huge differentiating factor between Flynn and the sample and I felt that this was a representative sample of the returns being made on the generics industry of companies that sell predominantly medicines to the National Health Service.

Q. It might be obvious from your evidence but can you just explain why you think that is better than using a PPRS measure, which also looks at a portfolio?

A. Yes. Well, the PPRS measure of 6 per cent has got a whole host of problems within it. The first one, of course, it applies to brands and not generics, the second one it is a portfolio but I accept your point, Ms Bacon, that the 21 per cent is also a portfolio. But the third problem is I think what we have been discussing a little bit this morning which is the 6 per cent is not 6 per cent. It is -- the profitability allowed under the PPRS is very significantly in excess of 6 per cent.

MS BACON: I have no further questions.

Questions from THE PANEL

PROFESSOR WATERSON: Just as a matter of interest, you said -- you corrected a figure in your report. It was, I think your second report, paragraph 24, where you put in 80 per cent and you said that that was now accepted to be nearer 50 or 60 per cent that was in the PPRS.

A. Yes.

PROFESSOR WATERSON: Are you able to elaborate on the reasons why that has happened?

A. Yes, sir. There are probably two or three driving reasons about why the PPRS is now covering a smaller percentage of medicines. Reason number 1, generics have grown. Generics are now a more important part of the NHS drugs bill than they were when that 80 per cent figure was sourced and that is of course a function of the fact that we have had a number of fairly notable products, Lipitor being a good example, coming off patent in that period and are now being supplied generically.

The second reason is that parallel imports, certainly before the decision on Brexit, had increased fairly materially because the pound was quite strong at that point against the euro and of course those are part of the NHS drugs bill but they are not sold by PPRS members. They may be sold by their affiliates in Greece or Portugal.

1 And the third reason is that actually a number of
2 companies have elected not to join the PPRS and they are
3 controlled by something that is colloquially referred to
4 as the statutory scheme and there are two companies in
5 particular, Gilead and ViiV, who are large, growing very
6 rapidly and they are not within the PPRS. So they fall
7 outside. They do not have to submit AFRs. They have no
8 form of profit control whatsoever.
9 PROFESSOR WATERSON: And are not necessarily generics
10 companies?
11 A. No, both of those companies are branded companies,
12 almost exclusively, I think, they are branded.
13 THE CHAIRMAN: Sorry, I have one question. I should have
14 asked it earlier and I apologise for not doing so.
15 Mr Williams, we have discussed the 6 per cent return
16 on sales figure in the context of the PPRS?
17 A. Yes.
18 THE CHAIRMAN: I think you raised various objections to it.
19 If you assumed for one moment hypothetically that it was
20 legitimate for the CMA to look for a figure from the
21 PPRS that it could apply to Flynn, in this case, what
22 figure would you think that they could use, if they
23 cannot use 6 per cent?
24 A. I think the only figure, sir, that is mentioned in the
25 PPRS in relation to an ROS is the 6 per cent but then

the report says the MOT that one can add on to that. The transfer price profit allowances is referred to in the PPRS but it is not actually converted into an ROS. But I think the CMA should have looked more broadly at the real workings of the PPRS rather than the headline figure of 6 per cent.

THE CHAIRMAN: So you are not saying that if the CMA have looked carefully and taken account of the TPPA, for example, that it would have come out with a figure that you would have regarded as reliable?

A. I think the problem, of course, it deals with brands, so I think Ms Bacon presented a chart that showed you that the real ROS under the PPRS, allowing for the TPPA is probably, you know, closer to 27.5 per cent. That, of course, is predicated on the default transfer price assumption of 59 per cent manufacturing costs, 21 per cent R&D and 20 per cent profit. In my experience -- and I think I have set this out in one of my reports -- the reality is that the 59 per cent manufacturing cost assumption within the transfer price is actually probably extremely generous to the industry. The real underlying manufacturing costs of product is a fraction of that figure.

THE CHAIRMAN: Are you really making a broader point, that the PPRS is not an appropriate place to look for

a suitable measure --

A. Yes, sir.

THE CHAIRMAN: -- for a reasonable rate of return?

A. I am.

THE CHAIRMAN: Right. I think it is lunchtime. What happens next, Ms Bacon?

MS BACON: Our next witness is going to be Mr Davies, who is here.

THE CHAIRMAN: And that is all ready.

MS BACON: Mr Hoskins indicates that he is not likely to be much more than a couple of hours with him. I would propose in that case we finish with Mr Davies today and then we start with Mr de Coninck tomorrow. We have a normal start time and I am sure that we will be finished with Mr de Coninck tomorrow. Mr Hoskins is nodding but also grimacing.

MR HOSKINS: It has been a long couple of days.

MS BACON: We will be finished with Mr de Coninck tomorrow without needing to sit early, hopefully, or late, and that will then conclude the evidence.

THE CHAIRMAN: Right, and then we will resume with Mr Harman on Monday?

MS BACON: Yes.

THE CHAIRMAN: Okay, that sounds very sensible. We will see you at 2 o'clock.

(1.00 pm)

(The short adjournment)

(2.00 pm)

THE CHAIRMAN: For the record, I think I omitted to tell Mr Williams that he was discharged and could stand down, so I see he is not there. Can we take it that the record now does say that? Thank you.

MS KREISBERGER: Thank you, sir. I would like to call Mr Davies now, please.

MR ROGER DAVIES (affirmed)

Examination-in-chief by MS KREISBERGER

THE CHAIRMAN: Mr Davies, please sit down and make yourself comfortable. Counsel will have some questions for you.

MS KREISBERGER: Can I ask that Mr Davies is handed bundle D of the hearing bundle. Mr Davies, if I could ask you to turn to tab 5 in that bundle, please. Do you see there it says:

"Expert report of Roger Davies"?

A. I do.

Q. Could I ask you to turn to page 24 of that document. Mr Davies, is that your signature there?

A. Yes, it is.

Q. Mr Davies, you told me you would like to make a minor correction to your statement. If we turn to page 7, you

will see there table 1, which carries on over the page. I think you wanted to make a correction at the top of page 8.

A. Yes, that is correct. The line that reads:

"Pay CMO for stock shipped to pre-wholesaler."

In the columns to the right of that should say Flynn and Flynn, rather than Pfizer and other CMOs. It is a mistake and as a consequence of that, the numbers in the column to the left, instead of 2, 3, 4, become 3, 4, 5, ending with 13 at the bottom. And that carries on into the first sentence of paragraph 22, which says:

"Table 1 ... shows that there are [13] activities ..."

Not 12:

"... some of which (namely 7, 8 ..."

It will be 8, 9 and 10 now:

"... are driven by the requirements of being an MA Holder."

THE CHAIRMAN: It just shows what a lot of consequences one small error can make.

A. Yes, unfortunately, yes.

THE CHAIRMAN: Thank you.

MS KREISBERGER: Mr Davies, subject to that amendment, could you, please, confirm that the opinions expressed in this report represent your true and complete professional

opinions on the matters to which they relate.

A. I confirm that, yes.

Q. Thank you, Mr Davies. Mr Hoskins for Pfizer will have some questions for you -- I am so sorry, CMA. I think Pfizer will not have questions.

THE CHAIRMAN: Mr Hoskins, are you aware of your identity?

MR HOSKINS: Sometimes, sometimes. I am for the CMA, I think you probably gathered that already.

Cross-examination by MR HOSKINS

MR HOSKINS: Take up your expert report and begin at paragraph 12, please. I want to pick it up four lines down. You say:

"The starting point is that unbranded generic medicines in the UK are effectively allowed freedom of pricing. The DH specifically excluded unbranded generic drugs from the PPRS rules for agreement of reimbursement prices of medicine sold to the UK NHS. The rationale for this exclusion was that the supply prices of generic drugs would be determined by competition between companies supplying such products, subject only to intervention by the DH where competition was not working effectively."

Then you go on at paragraph 13 to explain:

"This has been a highly successful approach resulting in savings of hundreds of millions of pounds,

as patents for blockbuster drugs expire. The reason it has been so successful is because in a situation where there are multiple suppliers of the same medicine, generic companies compete on price to win market share."

So the regulatory approach to unbranded generic medicines, as you describe it here, was based on the premise that competition would control prices?

A. Yes, that is correct.

Q. So that premise would not hold for a particular generic drug if it faced no or limited competition?

A. Yes, that is correct.

Q. And what you say in paragraphs 12 and 13 is that where there was no competition, prices could only be controlled by intervention by the DH.

A. Yes, that is correct.

Q. Paragraph 3 of your report, you make a criticism of the CMA for not meeting with the British Generic Manufacturers Association, the BGMA. Can you just tell us what the BGMA is, please?

A. Yes, the British Generic Manufacturers Association is an association of generic companies that produce and supply products in the UK, unbranded generics, mainly.

Q. And you say in paragraph 3 that:

"The BGMA would have provided an important and relevant context to understand how the generic industry

works in the UK under the current pricing regulations and how Flynn compares to other similar companies."

So is it fair to say that you think that the BGMA is well placed to explain how the generic industry works in the UK under the current pricing regulations?

A. Yes, I do.

Q. Could you be given, please, bundle H2 at tab 42. You will see the heading towards the bottom of the page, "Health Service Medical Supplies Costs Bill," written evidence submitted by the British Generic Manufacturers Association, BGMA, and you will see at the top of the page that the date of this written evidence is 7 November 2016. Do you see that?

A. Yes, I see that.

Q. The first section is called "Overview". If you turn over the page to page 2, pick it up at paragraph 2, what the BGMA said was:

"Our arrangements with the Department of Health provide that the prices of most generic medicines in the UK are controlled by different manufacturers of essentially the same product competing for sales to community pharmacies principally on the basis of price. As acknowledged by the Secretary of State and others on all sides of the house at second reading, this system in the vast majority of cases works very well."

And that reflects what you yourself said in your report, which we have just seen; yes?

A. Yes, that is absolutely correct.

Q. And then paragraph 3:

"There have, however, been recent examples of a very small number of generic medicines that face limited competition marketed at very high prices."

Do you agree with the BGMA that the current pricing system for generic medicines has not worked for a small number of generic medicines that face limited competition and are marketed at very high prices?

A. Yes, I do agree with that.

Q. And effectively there is a gap in the system in relation to these medicines, is there not?

A. Yes, there is and I believe that the government have recently passed legislation to close that gap.

Q. And the reason that the gap exists is because the system works on the assumption that there will be sufficient competition to restrain prices. So when there is not sufficient competition, that is how the gap arises; correct?

A. Yes, correct, or in some cases, if there is a shortage of product, in which case then the prices change as well.

Q. And then the BGMA continues in paragraph 3 of its

evidence:

"Our arrangements with the Department of Health provide that they may intervene to set prices where competition is ineffective in protecting the NHS from high prices. We have earlier made proposals to the Department of how they could efficiently achieve this but we understand that they..."

That is the DH:

"... feel that they lack the powers to do so. The bill will rectify this and we welcome this change."

Do you agree that the system of intervention has not been effective in controlling high prices in some instances because the DH felt it lacked the necessary powers to do so?

A. I just do not know the answer to that.

Q. The Government has recently enacted the Health Service Medical Supplies (Costs) Act 2017 to give the DH greater powers, has it not?

A. I do not know the exact name of the legislation but I assume it is the recent --

Q. It was a 2017 Act of Parliament to give the DH greater powers. Is that right?

A. Yes.

Q. The Association of the British Pharmaceutical Industry, the ABPI, is another trade body. Can you just tell us

about that. How does its membership differ from that of the BGMA?

A. The ABPI is an association of pharmaceutical companies that operate in the UK but it is much more orientated towards the big multinational companies selling branded products and in fact there is another association in the UK which deals with the smaller manufacturers, called EMIG, and these various associations all represent the industry with Government and other bodies.

Q. I think you have still got bundle H2 there. Can you turn to tab 40, please. You should have a House of Commons library briefing paper dated 21 October 2016 and the title is, "The health service medical supplies costs bill". Do you have that?

A. Yes, I do.

Q. If you turn through to page 20, please, you see a heading, "2.3. Comment on the bill." It says:

"The pharmaceutical journal have reported that ABPI was currently looking at the bill to ensure the Government's response is proportionate and appropriately targeted. They include the following comment from the ABPI. 'The ABPI acknowledges the need for clarity on pricing on older medicines and has been calling on the Government to take action on the issue of significant price rises in a small number of those medicines, where

a competitive market is not working as effectively', says Richard Torbett, Executive Director of Commercial at the ABPI."

So do you agree that both the ABPI and the BGMA felt that the previous system, before the 2017 Act, was not dealing effectively with a small number of medicines which did not face effective competition?

A. Yes, I do agree with that.

Q. And is that your view as well? Do you agree that --

A. Yes, it is my view as well.

Q. Can we go back to your report. So that is bundle D, tab 5, and go to paragraph 36(a).

A. Sorry, paragraph?

Q. Paragraph 36(a), sorry.

You explain here:

"In the unbranded generic sector, the way pricing generally works is as follows: the first company to launch an unbranded generic product typically sets the price around at least 20 per cent lower than the reference product price."

I am sorry, I will just wait for the tribunal. Sorry, so we are at D5, paragraph 36(a):

"The reference product can be either a product coming off patent in the case of a product reaching patent expiry or an existing competitor product with the

same molecule indication, the share of supply captured by the first generic product against the originator can vary considerably but in my experience the originator usually estimates that it will lose around 40 per cent of its market share."

So that is looking at the situation. You have got what you call the reference product and one other competitor comes in?

A. Yes.

Q. And then over the page at (b):

"The second generic entrant will launch at a price around 10 to 15 per cent less than the first entrant."

So you go on to look at the situation where there are three players in the market; is that correct?

A. Yes, that is correct.

Q. And you say:

"Although this can vary depending on the strategy and aspirations of the supplier as the trade off between obtaining market share and maintaining price. At this point there may be three players in the market, namely the reference product and two competitors."

Then you say:

"If no further suppliers enter the market, the three companies will not usually seek to compete further on price because the increase in volume will be offset by

reductions in the price or will otherwise eventually result in a race to the bottom."

So is it fair to say that what you are explaining here is that three companies in the market will not usually be enough to provoke intense price competition?

A. That is correct.

Q. And then at (c) you explain:

"If a third generic entrant enters the market ..."

So we now have four players in the market; yes?

A. Yes.

Q. "... the price competition intensifies and prices go into a downward spiral as new suppliers seek to earn volume and existing suppliers seek to win market share."

So it is when one gets to four players in the market that one usually observes, if I use the phrase "intense price competition" to summarise what you said in (c). Is that fair?

A. Yes, that is absolutely fair.

Q. If you go to paragraph 39, the first sentence, it is clear from that you are treating Flynn as the first company to launch the unbranded generic Phenytoin sodium capsules. Is that right?

A. I am treating Teva's tablets as, if you like, the originator and Flynn as the first competitor.

Q. So Flynn is the first in relation to the capsules but

you are assuming competition with tablets?

A. Well, I am not sure exactly what you mean but what I was trying to say is that there was an existing product in the market that had the same indication, the same active ingredient and the same strength. That was in my mind the first product in the market.

Q. Sorry, just give me a second, Mr Davies. (Pause)

PROFESSOR WATERSON: Just while we are waiting, can I ask you: you do not mention parallel imports in this. Would that be like an equivalent of another competitor?

A. It is difficult to answer that. It is -- because it is an exact copy of the originator product, we have not got a competitor in the sense of somebody coming in with a lower price, as you would have normally. What we have is exactly the same product being imported by a wholesaler to compete with the original product. So it is not quite the same but it does have the same effect on the original product in the market, in that it loses market share, yes, that is correct.

PROFESSOR WATERSON: And possibly leads to a price response, or not?

A. Well, I think the industry nowadays -- the approach they adopt is to restrict supply if -- that they are allowed to do under EU law to -- to reduce the volume of parallel imports, rather than necessarily to reduce the

price, not least of all because with foreign exchange variations that parallel import issue may disappear overnight or increase overnight.

MR HOSKINS: Mr Davies, are you aware that the CMA's decision finds that Phenytoin sodium capsules and Phenytoin sodium tablets are not in the same product market.

A. I am aware of that, yes.

Q. And are you aware that that means that they are not considered to be sufficiently close substitutes in economic terms?

A. I am aware that that is the CMA's view, yes.

Q. And are you aware that neither Pfizer nor Flynn has challenged that finding in the CMA's decision?

A. I was not aware of that, no.

Q. So let us carry on the analysis on the basis of the unchallenged finding in the decision, which is that there is not sufficient degree of competition between tablets and capsules. So we are assuming that capsules are a separate market, putting tablets to one side.

A. Mm-hm.

Q. In relation to Phenytoin sodium capsules, there were only two players in the market at most at any one time, which was Flynn and NRIM; correct?

A. That is correct.

Q. And on the analysis that we have just seen in your paragraph 36, in your opinion that would not be enough to provoke -- I have used the phrase "intense competition" but that would fall into your paragraph 36(a), would it not?

A. Yes, that is correct.

Q. In paragraph 38 you say:

"In the case of Phenytoin, by the time Pfizer and Flynn negotiated the deal, Flynn was aware that there was already a competing product on the market, namely Phenytoin tablets and the competitor product NRIM capsules with the same molecule indication."

We have dealt with tablets. So let us put that to one side. You say:

"Therefore the scenarios in 36 (b) and (c) above were both possible, in which case prices could decline significantly post launch."

Now we have pushed tablets to one side, while 36 (b) and (c) were possible, neither actually eventuated, did they? The only competitors with capsules in the period we are looking at were Flynn and NRIM?

A. They were the only competitors, that is correct. In capsule form.

Q. Therefore, given the limited competition in the market for capsules, Phenytoin capsules were in the category of

drugs that fell into the gap in the existing regulatory system for unbranded generic medicines that we have identified, were they not, because there was not sufficient competition in the market to keep the price down?

A. Yes and no. What I mean by that is that it ignores the strategy that NRIM adopted when it launched the capsule product. Generic companies have two possible approaches. One is to seek to obtain a reasonable -- what they regard as a reasonable market share at a moderate discount to the lead product, if I could call it that in this case, and the other strategy is to place the product amongst many, many distributors and allow them to in effect compete on price for market share.

That is the volume strategy that some generic companies adopt, and the other one is, if you like, a balance between price and volume.

Q. You are saying that you have not actually covered the situation of Phenytoin capsules in paragraph 36 of your report then? Is it not covered? The point you have just made does not seem to be in your report.

A. I have mentioned in my report that the strategy of the generic company needs to be taken into account. Yes, in (b):

"Although this can vary depending on the ..."

Second row of paragraph 36(b):

"Although this can vary depending on the strategy and aspirations of the supplier as to the trade-off between obtaining market share and maintaining price."

Q. But -- in your scenario there are three players in the market and we are dealing with where there are only two players in the market, which is your paragraph 36(a), is it not?

A. Yes, but this was written on the assumption that the tablets were a competitor. You have put in a hypothetical position, where there were two, and that is why there is a difference in the wording. I could equally have put that sentence into paragraph (a).

Q. If the tribunal were to find that there were -- there was limited competition between Flynn and NRIM?

A. Yes.

Q. So you are making that assumption. Then Phenytoin capsules would fall into the category of drugs that fell into the gap in the existing regulatory framework, would they not, because there would not be the competition necessary to keep the prices down?

A. Could you explain what you mean by "limited competition".

Q. Well, I took you at the start to paragraph 12 and 13 of your report, so the bottom four lines of paragraph 12:

"The rationale for excluding unbranded generics from the PPRS was that the supply price of generic drugs would be determined by competition between companies supplying such products, subject only to intervention by the DH where competition was not working effectively."

So I am simply putting to you that if the tribunal were to find that there was not effective competition between NRIM and Flynn in relation to capsules, then it must follow from your opinion that they fell into the gap that we have identified in the system.

A. Yes, I think what -- what I think needs to be distinguished is effective competition where there are multiple suppliers, which in this case there was not effective competition because there were not multiple suppliers -- there were only two -- and the situation where there are just two companies but one decides to effectively compete with the other by significant price reductions to seek high volume market share.

Q. Were you here when Mr Walters gave evidence last Thursday?

A. No, I was not.

Q. Because he has given evidence that NRIM's business model, as is well known, was not to compete hard on price. Are you in a position to comment on that?

A. No, I am not.

Q. Can we go to paragraph 14 of your report. You say:

"To avoid this intense price competition arising from multiple suppliers, generic companies seek to obtain competitive advantages".

To a competition lawyer that is a bit confusing. You are saying to avoid intense price competition, companies seek to obtain competitive advantages because you appear to be saying that generic companies seek to gain competitive advantages by avoiding competition. Do you see the tension?

A. Yes, I think I understand what you mean.

Q. But would it be more accurate to rephrase what you said in paragraph 14 as:

"To avoid this intense price competition arising from multiple suppliers, generic companies seek to obtain commercial advantages over their competitors by..."

And then the following strategies? Is that a fair ...?

A. No, I would stay with the wording that I had, "a competitive advantage".

Q. And what do you mean by "competitive advantage"?

A. They are described in the three subsequent paragraphs -- three subsequent paragraphs.

Q. So let us look at those paragraphs. Paragraph 14(a).

Why is it attractive to generic companies to be the first to market for blockbuster drugs?

A. Okay, well, the reason is because the first to market obtains the initial, significant market share and the difficulty for -- in a blockbuster model, generic model, is that the second, third, fourth all have to in effect compete with the original blockbuster, generic competitor. So being first to market means that they can secure significant market share, which the others have to sort of try and take away from them.

Q. So they will be able to make more profits by being first to market as compared to second to market?

A. In the short term, yes, but the short term can be as short as one month.

Q. And can they generally charge higher prices, the first to market for these blockbuster drugs?

A. Yes, they would normally go in, as I mentioned under the paragraph on pricing. They would normally go in at a price that is, let us say, 20 per cent below the originator product.

Q. And then the next category of 14(b):

"Ensuring that pharmacists have an incentive to dispense the generic version of the drug supplied by the company, for example by offering competitive discounts on supply of the product."

Again, I imagine this is fairly obvious: generic companies behave that way because they think that will make them more profits. Is that fair?

A. They behave that way in order to either secure or maintain their market share. So if you are a second generic into the market, you may offer pharmacies bigger discounts than the first generic entry to secure some market share but if you were the first, you might offer pharmacists competitive discounts to maintain your market share.

Q. Market share is not an end in itself. The reason why they want to obtain market share is because it will increase their profits, presumably. They are commercial operations.

A. Well, I do not agree with that completely because market share is -- generates volume. Many of these generic companies have supply agreements that require them to deliver certain -- or to purchase certain volumes from those companies so that they are looking to ensure that they can meet those obligations.

Q. By meeting those obligations, they increase their profits. They are commercial operations --

A. They may not because the discount they have to give away to get the volume is not actually a higher profit than they would have had, had they had a lower volume. We

just do not know.

Q. So in some circumstances companies may have to offer discounts to avoid contractual penalties but generally speaking they are in business to make profit?

A. Of course, all companies are in business to make a profit.

Q. Then 14(c), your third example is:

"Launching niche generics, which are typically products with some initial barriers to entry for competitors. These barriers may be a lack of API suppliers, specialised manufacturing processes and/or patent or regulatory hurdles. Without multiple competitors driving down prices, the niche generic product supplier has a higher than average gross margin until the arrival of additional competitors who consider that the market value in the UK and/or other EU countries makes it worth developing a bioequivalent product."

So what we are dealing with here is the fact that generic companies look for niche products in relation to which there is limited competition because that allows them to charge higher prices and make higher than average gross margins. Is that correct?

A. Yes, that is correct, at least in the short term.

Q. You go on to say, after the sentence:

"... without multiple competitors driving down prices ..."

Et cetera. The next sentence says:

"As such, whilst in the short term a niche generic may not have any or many competitors, in the medium term it is likely to face greater competition based on price."

But if that possibility does not eventuate, if a product does not face greater competition in the medium term, the generic company will be able to continue charging higher prices and earning higher than average gross margins, will it not?

A. Yes, that is correct.

Q. And those are the sorts of drugs that ABPI and BGMA felt were not effectively regulated under the previous regime, or at least an example of those sorts of drugs?

A. I do not know which ones they meant but it would include those.

Q. Can we go to paragraph 16 and 17 of your report under the heading "Activities and risks of companies supplying unbranded medicines."

From reading paragraph 16 and 17, you do not appear to disagree with the statement that Flynn's actual involvement in the supply chain for Phenytoin sodium capsules was limited. But the point you want to make is

that that is fairly typical of generic companies. Is that a fair summary of your position?

A. Yes.

Q. If we go to paragraph 21, you say:

"In respect of operational activities, I have undertaken an analysis of all Flynn's operational activities to assess the relative weight of activities undertaken on post manufacturing supply chain and other activities, both on Phenytoin and other products, showing that Flynn's activities are not limited."

And your conclusion, having set out your findings in the table, is at paragraph 23 and you say:

"Flynn's non-supply chain activities are therefore equally or more important than its supply chain activities and the CMA's analysis is wrong to exclude these from its assessment of Flynn's activities."

But it is clear from the face of your report that you have not sought to place any financial value on Flynn's supply or non-supply chain activities, have you?

A. I have done some work to understand that the resources going into supply chain at Flynn are much less than the resources that are going into the other activities that every pharmaceutical company that is a marketing authorisation holder has to undertake.

Q. But you have not in your reports put a value on those

activities, have you --

A. No, because I have not got a value to put on it but I have calculated what I think are reasonable resource levels based on my understanding of what goes on in the industry and the costs that companies have to pay for things like pharmacovigilance, for medical information, for key account management, for finance, for administration and so on.

Q. So you have not been given access to Flynn's actual data --

A. I have some data from Flynn that -- for example, the pharmacovigilance costs are around £200,000 a year, which is equivalent to two to three full-time equivalents.

Q. But you said that your conclusions were based on knowledge that you had from the industry generally. You did not have sufficient information from Flynn to carry out that exercise, did you?

A. I think I have. I have first of all a general understanding of the industry from many companies I have worked in, budgets I have prepared, the understanding of actually managing myself these operations. I obtained from Flynn an estimate of the number of people they have in their supply chain, which is difficult to quantify but is around two. I know from the pharmacovigilance

number that I just quoted to you that there is at least two to three full time equivalents there and that is without adding in the resources to do with key account management, medical information, regulatory, quality and technical report, compliance and so on.

Q. Go on to paragraph 26 of your report and you say there:

"The major risk facing any company supplying a generic medicine is competition from other companies causing loss of volume and reduction in prices."

I have asked you questions on competition, so I am not going to come back to that. I want to put it in context when we come to paragraph 27, where you say:

"The second major risk is an interruption in supply of the drug or supply of faulty products caused by the manufacturer."

Then picking it up in the final sentence:

"I understand that Flynn held safety stock and took concrete steps to identify at least two other potential Phenytoin API suppliers, reflecting the importance of the manufacturing risk."

Is the information that you refer to there information that is provided to you by Flynn's solicitors or have you conducted some sort of independent assessment of your own?

A. No, I have not conducted any independent analysis, it

was what was in the Flynn document. So I assume that was correct.

Q. If we go to paragraph 28, I am going to pick it up at the second sentence. You say:

"As the MAH ..."

Which just to clarify is marketing authorisation holder. Is that correct?

A. Yes, that is correct.

Q. "As the MAH, the company is responsible for quality of the product and compliance with the regulations. The fact that the company uses a third party service provider does not absolve the company of this responsibility. For example, if there is a serious adverse event caused by a faulty product, the MAH is responsible even if it has a quality agreement with its manufacturer."

Have you been given copies of the contractual arrangements between Pfizer and Flynn? Have you seen the contracts?

A. No, I have not.

Q. Can you be given a copy of the decision, annex K, please. This is confidential. So you must not read it out. Annex K should be right towards the end. It is easier to start from the back, to be honest. Yes, there is no page number on it. It is literally about 12 pages

from the back, annex K. It is entitled "Flynn's responsibilities as an MA holder".

If you look at K5 -- sorry, you still do not --

A. Okay, I have got it now, thank you.

Q. So K5 -- I can read out the first bit:

"Flynn gained significant legal protection through the contracts that it had with Pfizer and other companies. In particular, clause 18 of the exclusive supply agreement between Pfizer and Flynn contains a broad set of indemnities given to Flynn by Pfizer which protect Flynn if it were found liable due to failures by Pfizer in the manufacturing process which would otherwise be one of the key sources of legal and commercial risk for Flynn."

Then if you could read the rest, because it is confidential and I cannot read it out.

A. I am sorry, I have not picked up the original reference.

Q. I am so sorry. So we are in annex K.

A. Yes.

Q. There is a paragraph called K5.

A. K5, I am sorry.

Q. Perhaps you would just read that to yourself.

A. Yes. (Pause)

Yes, I have read that.

THE CHAIRMAN: I think you have just read out stuff that is

marked "Confidential".

MR HOSKINS: I am told I have been given an updated version --

THE PRESIDENT: Really?

MR HOSKINS: -- and I have been told that the first few lines are safe but the bit I did not read out was not safe. So it was not blind on my part. I have a more recent version which is not all blue.

THE CHAIRMAN: The price of safety is eternal vigilance.

MR HOSKINS: I know, I understand. I apologise if there is an error but I think I am safe on this one.

THE CHAIRMAN: We are talking about Flynn's commercial arrangements.

MR HOSKINS: I understand, sir, absolutely.

If there is a problem, Flynn can raise it and we can perhaps do something about the transcript --

THE CHAIRMAN: I am not hearing any problem from Flynn.

MS KREISBERGER: It is fine.

THE CHAIRMAN: Right. You may proceed.

MR HOSKINS: Thank you. You were not aware of this before you wrote the report, were you?

A. No. Well, I knew there was a supply agreement.

Q. But not --

A. No, of course not, no.

Q. Can we go back to your report, bundle D, tab 5. You

say, the penultimate sentence of paragraph 28:

"In addition, any failure in compliance, for example in respect of pharmacovigilance, is the responsibility of the company."

Were you aware that Phenytoin was first marketed in the UK in 1938?

A. Yes, I am aware of that.

Q. Would you agree that the prospect of any previously unknown pharmacovigilance issue arising now in relation to Phenytoin capsules is very unlikely?

A. A priori, I guess, yes, but I do not know because of the narrow therapeutic index of the product and maybe there would be a lot of adverse events reported from people switching between tablets and capsules or capsules and capsules. I do not know the answer to that question.

Q. So you have not looked into whether there have been any pharmacovigilance issues arising in relation to Phenytoin capsules in order to prepare your report?

A. No, I have not.

Q. Go on to paragraph 35 of your report. I would like to pick it up six lines down, where you say:

"In terms of the forecast price, the buyer will seek to launch at the highest competitive level in relation to competing products' prices, in this case Phenytoin sodium tablets."

We have dealt with the tablets issue. I just want to understand, what do you mean by the highest competitive level in terms of a strategy?

A. What I mean by that is the maximum price that the company could achieve to achieve its target market share.

Q. What is the target market share? Explain how the price relates to the market share.

A. Well, in a generic market there is a direct relationship between price and volume. The lower the price, the higher the volume.

Q. But that only holds good, though, where there is effective competition, though, does it not?

A. Yes, that is correct.

Q. In paragraph 15 of your report.

A. 15?

Q. 15. You refer to the fact that Phenytoin has a narrow therapeutic index. What is the practical significance of a drug having a narrow therapeutic index? Do you know? Can you comment on that?

A. It means that the patients need to be monitored to ensure -- I am not a medical person so I cannot be precise but people have to be monitored to ensure that they do not under or overdose, that the dose is set for that patient, yes.

Q. But you are not a medical person. We have heard evidence on this --

A. Okay.

Q. So I will move on.

A. Thank you.

Q. Can we go to paragraph 37 of your report. You say:

"As explained above, at launch a company will not know which competitive scenario above is likely to occur and will therefore set the highest competitive level in relation to competing products' prices to recover its investment in developing or acquiring the product as fast as possible because in the short and medium term the company may no longer be competitive and will be forced to leave the market."

So is this a fair summary of what you are saying, which is a company will set as high a price as it thinks -- sorry to use a colloquialism -- it can get away with to try and recover as much in the short term to make sure it has covered its development and/or acquisition costs. Is that fair?

A. Yes, that is correct.

Q. And you are aware that Flynn did not incur any development costs in relation to Phenytoin sodium capsules, are you not?

A. Yes, I am aware of that.

Q. And it is a confidential figure so I cannot say it out loud but are you aware how much Flynn paid to Pfizer in return for the transfer of the marketing authorisations for Phenytoin sodium capsules?

A. Yes.

Q. You know the figure. So it is fair to say that Phenytoin sodium capsules do not fit into your description of what is normal in paragraph 37. And I say that because Flynn cannot justify high prices by reference to the development costs or acquisition costs, can it?

A. Well, the only thing I would say is that the fee that Flynn paid to Pfizer for the acquisition of the product is part of the total -- I mean, you know, my background in business development is quite extensive and I know from negotiations that the upfront fee is a combination of many different terms in the agreement and therefore to pay the -- the fee cannot be looked at in isolation, without trying to give too much away.

Q. Go to paragraph 48 in your report. You say:

"As regards Phenytoin specifically, it is necessary to compare the product's gross margin to that of companies who predominant supply generic medicines as opposed to branded medicine. This is because the gross margin of these companies is lower than that of

companies which supply branded medicines."

So I think you are stating quite clearly there, just to make sure I have understood, that companies that supply branded medicines generally have higher gross margins than companies that supply generic medicines?

A. In general that is true.

Q. And why is that the case?

A. Because -- well, as a percentage the -- the gross margin, as a percentage, is the difference between -- it reflects in effect the cost of sales percentage, so in a situation where you have got a tablet that costs a pound a pack, for example and you have got a price of, let us say, £10 a pack, you have got a 90 per cent margin and in the case where you have got a price of £2 a pack, you have got a 50 per cent margin and that is why generics, which have generally lower selling prices but similar cost of goods to brands, have a lower gross margin.

Q. If we can go on to paragraph 54.

A. 54?

Q. 54, yes. Pick it up in the second sentence. You say:

"In a commodity market such as unbranded generics, including products such as Phenytoin capsules, the business model relies on a portfolio of products, all of which will have different absolute gross profits and

gross margins."

Can you just expand a bit on what you mean by the business model relies on a portfolio of products?

A. Yes, in a typical generic company they can never be sure which of their generics will be successful in the marketplace and which ones will not because it will depend on how many different competitor companies enter with bioequivalent products. So what they seek to do is to have a range of products, a portfolio, that will allow them to ensure that the risk is reduced by not focused on one particular generic product.

Q. Does that mean they will try and have sort of different types of products, so, for example, if we go back to -- let me ...

If we go back to your paragraph 14 -- will try and have different products within these sorts of categories, will they? Is that one of the ways in which they spread the risk?

A. Sorry, could you repeat that.

Q. Yes, in paragraph 14 you identify a number of different types of strategy and drugs that a generic company might pursue and I am just asking whether, when you talk about the business model relies on a portfolio of products -- and as you described it that is in order to try and anticipate risks -- is this the sort of spread of

products we are talking about in a portfolio? Is this what companies would look to achieve?

A. Yes, B is not applicable. Basically, there are two types of unbranded generics, if you like, the big volume blockbuster generics, and the niche generics.

Q. Are there also more common and garden generics which do not fall into blockbuster or niche though? You have used the phrase "commodity", is that a third category?

A. Yes, that is correct.

Q. At table -- so -- sorry, to paragraph 48 of your report and table 3. What you have done there is you have set out reported gross margins for 13 UK companies, including Flynn. That is correct, is it not?

A. For 13 UK companies, including Flynn.

Q. And if we go to annex 3 at page 29 of your report.

A. Yes.

Q. You see it is headed, "Data sources for tables 2 to 5".

A. Yes.

Q. So this is annex 3 -- is where -- the basis on which you produce table 3. Is that correct?

A. That is correct.

Q. You say in annex 3, second paragraph:

"Data for 19 companies were collected. All the companies have a portfolio of generic and branded products."

But then you say:

"Some companies, such as Sandoz/Novartis are 100 per cent generic."

There seems to be an inconsistency between saying that they all have a portfolio of generic and branded and then saying Sandoz/Novartis are 100 per cent generic. Can you just explain what you mean there?

A. Sandoz is a generic subsidiary of Novartis, so it only sells generics. If you take another company in that list, you will find that some of the companies there, they sell a mixture of generics, branded -- unbranded generics, branded generics and what I would call speciality medicines. What I mean by speciality medicines are those that are unique in some way or another. It may be a drug delivery system but they are all sold under a brand name.

Q. So the companies that are in your data source have different profiles, as you have just described it?

A. By and large they are similar but they have variations, yes, that is correct.

Q. And other than Sandoz and Teva, you have not in the annex sought to indicate or describe the particular characteristics of each of the companies upon which you rely, have you?

A. I have not described it there but I know what they are.

Q. And you have not set out in your reports the percentage of generics and branded products, for example, for each company. You have not attempted a breakdown for each company?

A. No, because that data is not available to anybody other than the company.

Q. And again, just looking at what you have done, you have not conducted a product by product breakdown of the portfolio of each of these companies, have you?

A. No, because that information is confidential to the companies.

Q. Go to paragraph 64 of your report. You say:

"In most mature companies with a reasonable number of products, such as Flynn, 20 per cent of the company's products account for around 80 per cent of sales and gross profit. I refer to such products below as leading products. Based on my analysis of confidential information of four small to mid-sized companies supplying primarily unbranded generics, an average 20 per cent of each company's products account for 74 per cent of their sales and 80 per cent of their gross profit."

So you refer to the notion of leading products. I just wondered what sort of products might be described as leading products. Is it the sort of products you

identify at paragraph 14(a) and (c), for example? So they are blockbuster generics and the niche generics. What are we talking about here?

A. From memory -- and I have not got my notes in front of me -- I think most of them I would put in the category of niche or unique in some form. What I mean by that is that there is limited API supply, for example --

Q. Limited API supply?

A. I cannot be precise because I have not got my notes with me here.

Q. So you cannot tell us in relation to these four companies that you refer to, for example, what their leading products are?

A. I cannot tell you that anyway because this data is confidential.

MR HOSKINS: I do not have any further questions. Thank you for your time.

A. Thank you.

Questions from THE PANEL

THE CHAIRMAN: Mr Davies, there was a brief discussion about competition.

A. Yes.

THE CHAIRMAN: And what it does in the generic sector. It seemed to me that a lot of what was being said could be summed up by saying that behind every competitor is

a would be monopolist. Would you agree with that?

A. Behind every competitor is a would be monopolist?

THE CHAIRMAN: In the sense that you have to compete but you would quite like the others not to be there.

A. Absolutely correct, yes.

THE CHAIRMAN: It is one of the paradoxes of competition.

A. Yes, every company seeks to make a profit and one of the ways to protect that profit or develop it is to be in a monopolistic position. The big pharma companies have patented products that put themselves in that position and in the generic sector it is achieved by barriers to entry for other generic companies.

THE CHAIRMAN: Right. You were also discussing the price behaviour model that you described.

A. Yes.

THE CHAIRMAN: And you were starting with the originator and I think I am right in saying that for comparison purposes you were taking Teva as the originator in relation to Phenytoin.

A. Yes.

THE CHAIRMAN: Is that right?

A. Yes.

THE CHAIRMAN: Where does Pfizer as the originator fit into that model because they have been supplying this stuff up to 2012 for many years at a rather different price.

So how does that fit into your model?

A. It does not because Pfizer had exited, in my understanding, from the business and had transferred the marketing authorisation and the product to Flynn and therefore they were no longer competing in the marketplace.

THE CHAIRMAN: So you are taking them as having left --

A. Yes.

THE CHAIRMAN: -- and you are applying your model to the new situation.

A. Yes. In effect, they became the contract manufacturing organisation who handed over the product itself to Flynn.

THE CHAIRMAN: Finally -- I am doing you a gross injustice, but the gist of your evidence is that Flynn is just like any other generic company in relation to Phenytoin, which means that one should be looking at suitable points of comparison with other generic companies in order to draw conclusions about what profit it is making and whether it is right or not. Is that fair?

A. Yes, that is fair.

THE CHAIRMAN: What weight do you attach in that sort of analysis to the amount of competition that Flynn and the comparator companies face? Are you factoring that into your analysis or do you take that as a sort of neutral

factor which may or may not affect all of them?

A. I do not know how much the other companies are affected by competition. So I can only assume I have treated it as a neutral factor. I mean, I do know that some companies have less competition on some products and more on others, but to be able to undertake that analysis I would have to have detailed information which I do not have.

THE CHAIRMAN: It would be quite a considerable analysis, almost like a market investigation, dare I say.

A. It would be.

THE CHAIRMAN: Thank you, I think that is all.

MR LOMAS: I want to follow up on a point that the chairman made just two minutes ago. I think you said that the big pharma companies had patented products that put themselves in that position, which was the position to be able to make a profit and that in the generics sector it is achieved by barriers to entry for other generic companies.

A. Yes.

MR LOMAS: I do not know how much of the debate you have been following but we have had a lot of debate about the principle of continuity of supply in the light of the recommendations that people stabilised -- patients stabilised on one manufacturer's product should continue

to have that product prescribed for them or at least should continue to take that product even if not prescribed. My question was, is that principle of continuity of supply the type of barrier to entry that you would have had in mind in the answer you gave to the chairman's question?

A. Yes, it is.

MR LOMAS: Okay, thank you.

THE CHAIRMAN: Re-examination.

MS KREISBERGER: Sir, I have no re-examination.

THE CHAIRMAN: Right, well, Mr Davies, you may --

PROFESSOR WATERSON: There was one point that I wanted to raise --

THE CHAIRMAN: I must stop talking.

PROFESSOR WATERSON: I was just comparing the sample that Mr Williams spoke about this morning -- I do not know whether you have had access to Mr Williams' report, have you?

A. He wrote three reports. I am not sure --

PROFESSOR WATERSON: I am talking about his, I think, second report. Yes, his second report.

A. I am not sure if I have had access but if you ask me, I will...

PROFESSOR WATERSON: Okay. He has a sample of generic companies. Some of them are the same as yours and

others are different, which raises the question, I suppose, about quite how these samples are drawn. You obviously cannot speak for him.

A. No.

PROFESSOR WATERSON: But maybe you could tell us how your sample was drawn.

A. Yes, my sample was drawn by looking at companies of a comparable size to Flynn and so I took companies that were equidistant in value, if you like, sales around the Flynn point, so that we had a comparison of similar size companies because they have different business models to much bigger companies.

I also made sure that all those companies in that sample were companies that sold unbranded generics, because Phenytoin is an unbranded generic, and I also tried to segment it to identify companies, some companies, that had a mixed portfolio of brands, I mean speciality brands and generics. I do not know how Mr Williams --

PROFESSOR WATERSON: He may have placed some emphasis on whether they had in-house manufacturing facilities or not.

A. Okay. In my sample group in annex 3 there are three companies that had manufacturing in the UK. The rest -- some of them had manufacturing overseas and some of them

have a CMO model.

PROFESSOR WATERSON: And some of them have an asterisk. I do not see what was the meaning of the asterisk.

A. Yes, I apologise for the omission. The four companies with an asterisk are those that have a mixed portfolio.

PROFESSOR WATERSON: I see.

THE CHAIRMAN: Thank you very much. You are discharged. You may stand down.

A. Thank you very much, sir.

THE CHAIRMAN: Does that conclude the proceedings for today or do we want to crack on?

MS BACON: I think it would be very unfair on Mr Hoskins if I said I wanted to start again now. So I am very happy to start tomorrow morning.

THE CHAIRMAN: So I have given you the opportunity to be fair to Mr Hoskins.

MS BACON: And I have taken it.

THE CHAIRMAN: In that case we will finish for today and we will start the normal time tomorrow, 10.30?

MS BACON: Yes.

THE CHAIRMAN: Thank you very much.

(3.03 pm)

(The court adjourned until 10.30 am the following day)

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