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IN THE COMPETITION APPEAL TRIBUNAL

Victoria House, Bloomsbury Place, London WC1A 2EB Case Nos. 1275/1/12/17 1276/1/12/17

9th 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 7 - Redacted

# <u>A P P E A R AN C E S</u>

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

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

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

Thursday, 9 November 2017

2 (10.30 am)

1

3 THE CHAIRMAN: Good morning.

4	MR HOSKINS: Good morning, sir. Before Mr de Coninck is
5	called, I am going to take him to quite a few figures
6	that are all in the evidence and I thought it would
7	be the easy way to do it rather than trawling through
8	spreadsheets while he is in the box, was to produce
9	a cribsheet, which tells you where the particular
10	figures I am going to put to him come from. I have
11	given that to Ms Bacon and if there is any problem, they
12	can shout after the event. It's just to save time
13	whilst Mr de Coninck is in the box.
14	THE CHAIRMAN: Mr de Coninck is giving evidence about Flynn?
15	MR HOSKINS: Yes.
15 16	MR HOSKINS: Yes. THE CHAIRMAN: How are we on confidentiality?
16	THE CHAIRMAN: How are we on confidentiality?
16 17	THE CHAIRMAN: How are we on confidentiality? MR HOSKINS: We are going to do about the first third open
16 17 18	THE CHAIRMAN: How are we on confidentiality? MR HOSKINS: We are going to do about the first third open and then we will have to go closed because I will be
16 17 18 19	THE CHAIRMAN: How are we on confidentiality? MR HOSKINS: We are going to do about the first third open and then we will have to go closed because I will be referring to figures.
16 17 18 19 20	<pre>THE CHAIRMAN: How are we on confidentiality? MR HOSKINS: We are going to do about the first third open    and then we will have to go closed because I will be    referring to figures. MS BACON: I do not have an objection to this in principle,</pre>
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<ol> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> </ol>	<pre>THE CHAIRMAN: How are we on confidentiality? MR HOSKINS: We are going to do about the first third open     and then we will have to go closed because I will be     referring to figures. MS BACON: I do not have an objection to this in principle,     my only concern is that one can extract any number of     figures from a spreadsheet and just looking at</pre>

1	just suggest that if Mr de Coninck needs to or thinks it
2	appropriate, we could go to the original spreadsheet.
3	THE CHAIRMAN: Yes. Yes.
4	MS BACON: Other than that, I obviously have no objection.
5	THE CHAIRMAN: Mr de Coninck must give the evidence that he
6	feels he needs he has to give. This is, as I understand
7	it, an aid as much to us as anybody else.
8	MR HOSKINS: And to Flynn's team so they are not searching
9	around trying to find where the figures come from. It
10	is intended to help.
11	THE CHAIRMAN: I am sure they would rather search around and
12	get the right answer than not search around. Okay. So
13	we begin in open court.
14	MS BACON: Sir, so I call Mr de Coninck.
15	MR RAPHAEL DE CONINCK (affirmed)
16	Examination-in-chief by MS BACON
17	THE CHAIRMAN: Welcome to the tribunal, Mr de Coninck.
18	A. Thank you.
19	THE CHAIRMAN: Sit down, make yourself comfortable. Your
20	counsel will put some questions to you and then,
21	I suspect, Mr Hoskins.
22	MS BACON: Yes. Mr de Coninck, could you look at bundle D,
23	please, and could you turn up tab 1. Is that your first
24	report?
25	A. Yes, that is right.

1	Q.	And could you go to tab 2. Is that your second report?
2	A.	Yes, that is right.
3	Q.	Can you look at page 2 of that tab? Is that your
4		signature?
5	A.	Yes, it is.
6	Q.	Can you go to tab 3. Is that your third report?
7	A.	Yes.
8	Q.	And again can you look at page (iii).
9	A.	Yes.
10	Q.	Is that your signature?
11	A.	Yes, it is.
12	Q.	Could you go to tab 4. Is that your fourth report?
13	A.	Yes.
14	Q.	Could you go to page (iii) again. Is that your
15		signature?
16	A.	Yes, it is.
17	Q.	One more. Could you take bundle N and could you turn up
18		tab 10. The first couple of pages of that tab are
19		a letter to the tribunal. Can you go to the third page
20		of the tab and onwards and you will see a set of bar
21		charts. Can you confirm that those are prepared by you?
22	A.	Yes and my team.
23	Q.	And can you confirm that the content of your reports, as
24		well as these bar charts that you have submitted to the
25		tribunal, represent your true and complete professional

1		opinions on the matters to which they refer?
2	A.	Yes, I do.
3	Q.	Thank you. Mr Hoskins will have some questions for you.
4		Cross-examination by MR HOSKINS
5	MR	HOSKINS: Were you in the tribunal when Ms Bacon was
6		making her opening submissions to the tribunal?
7	Α.	No.
8	Q.	Have you read the transcript of those opening
9		submissions?
10	A.	I have, yes.
11	Q.	You have. So you may remember that Ms Bacon
12		submitted she said:
13		"In our event, our submission and I think the CMA
14		also says this at various points in its skeleton"
15		So Flynn's submission:
16		" is that a more accurate view is gained from
17		looking at the evolution of the market over the entire
18		period so trend lines is more instructive than looking
19		at individual peaks or troughs."
20		I should have said she is talking obviously about
21		defining the relevant product market. So Flynn's
22		submission from its counsel was a more accurate view is
23		gained from looking at the evolution of the market over
24		the entire period so trend lines are more instructive
25		than looking at individual peaks or troughs. Do you

1 agree with what Ms Bacon said about more accurate
2 approach?

3 So I think that if you are referring to data on shares, Α. 4 when we look at it on a monthly basis, we do see a lot 5 of variation. So I think that indeed one should not 6 focus on specific points where you have a spike or 7 a decrease because there is a lot of volatility from one 8 month to another and in that sense I do think it makes 9 more sense to look at what happens over time rather than 10 consider a specific point in time. 11 Are you restricting that point to volumes or is that for Ο. 12 volumes and prices? 13 Α. So I was making the point here with respect to shares 14 but the point with respect to prices is also correct, 15 that one should not look at price only at one point in 16 time but rather think about the evolution of price over 17 a longer period. 18 Q. You are obviously aware that the duration of the 19 infringement we are dealing with here is from 24 20 September 2012 until December 2016? 21 Α. Yes. 22 Can I go to your third report. That is bundle D, tab 3, Ο. 23 at paragraph 9. I will pick it up at the bottom of 24 page 2. So paragraph 9 begins:

25 "We disagree ..."

But I will pick it up with:

2		"On the contrary, we consider that the observed
3		price movements provide compelling evidence that at
4		least in respect of certain strengths of Phenytoin,
5		NRIM's capsules constrained Flynn's prices."
6		Then you go on to say:
7		"In particular, the graph below clearly shows a
8		material price response by Flynn in April 2014 in
9		respect of its 100 milligrammes but also 300
10		milligrammes capsules to the price reduction introduced
11		by NRIM."
12		Moving on a little bit to the penultimate sentence:
13		"This evidence strongly suggests that Flynn
14		considered NRIM to be a competitive threat not only in
15		respect of its 100 milligramme capsules but also its 300
16		milligramme capsules."
17		Your report does not consider any factual evidence
18		as to why Flynn reduced its prices in 2014, does it?
19	Α.	That is correct.
20	Q.	So in your analysis you are assuming that Flynn drops
21		its prices in April 2014 as a competitive response to
22		NRIM?
23	Α.	So here I think the point is made very much in relation
24		to a point that was raised by the CMA that looking at
25		price differences in price level as such is

1 informative about whether two products should be in the 2 same market and the point that was made here was that 3 one should not look at just a difference in price level 4 but one should think about the competitive pressure and 5 what is the price evolution that is seen following entry of a generic. So how has Flynn responded to 6 7 potential entry by NRIM rather than just focusing on 8 a price difference.

9 I think the answer to my question from what you've just Q. 10 said is yes because you accepted that you had not looked 11 at any factual evidence as to why Flynn reduced its 12 prices in 2014 and the question I asked was: does that 13 then follow that you are assuming that Flynn drops its 14 price in April 2014 as a competitive response to NRIM? 15 So what I am doing is looking at the data, looking at Α. 16 what the evolution of the data is. What I do see there 17 is that you have entry by NRIM, that you have a reduction in price by Flynn following this entry by 18 19 NRIM. If the question is have I considered every 20 potential possibility of why there may be a decrease in 21 price by NRIM. The answer is no. What I am doing here 22 is just describing the data, seeing what happens to the 23 price of Flynn following NRIM's entry.

Q. In your analysis here you specifically mention the pricereduction by Flynn in April 2014. But you do not appear

1		to take any account, at least on the face of the report,
2		of the dramatic increase in the selling prices of
3		Phenytoin sodium capsules that took place on
4		24 September 2012, do you?
5	A.	That is not the question I am addressing here. I am
6		just answering the question about whether one should
7		define different market when there is a difference in
8		price with time and I conclude that that is not the
9		right approach.
10	Q.	So you do not take account of the dramatic price
11		increase that took place on 24 September 2012?
12	A.	That is not the question I am addressing.
13	Q.	So you do not take account?
14	Α.	I am not looking at this question because that is not
15		the question I am addressing here.
16	Q.	And you do not take account of the guidance published by
17		the MHRA in November 2013. We do not see a reference to
18		that, do we?
19	A.	So the question that is of course I am aware of this
20		guidance and this is something that we think about, of
21		course, when looking at evolutions of the of the
22		volumes and maybe we will come back to that later. But
23		here what we are looking at is really what is the evolution
24		of prices, as in pure descriptive analysis.
25	Q.	You do not take account of the fact that Flynn's price

2

reduction in April 2014 came 12 months after NRIM had entered the market, do you?

A. I do not think it is a question of taking into account or not taking into account. I am just describing the data and showing the evolution of prices and of course there are a number of facts that happened through the periods.

Q. (inaudible) basing your analysis of the relevant product market on one event, which is the price reduction in April 2014. Looking at that, to define a market over a four-year period simply is not robust, is it? This is an afterthought. It came in your fourth report -sorry, your third report. This is just an afterthought, is it not? It is not a robust analysis?

15 Okay, so I think we should reput this in context so that Α. 16 the court understands this, that the point I am making 17 here is obviously not the focus of my analysis but it is 18 a response to an argument that is made by the CMA and 19 that, I think, is flawed, and I show this here. In 20 a very simple way, not -- you know, this is a very short 21 section of a report, just to address a particular point 22 and this is not the main analysis that has been 23 conducted (inaudible).

Q. Does it follow from that you accept this is nota sufficient basis upon which to draw a conclusion about

1		product market. It is not an attempt to produce
2		a complete analysis, is it?
3	A.	It is a response to a flawed argument in the CMA. And
4		it is useful evidence in this respect for a definition
5		of a market that I think should be taken into account.
6	Q.	But you have not attempted a complete analysis of market
7		definition, have you?
8	A.	Well, you know, market definition can be a very
9		a very complex exercise but I think this is relevant
10		information that informs market definition.
11	Q.	But is it complete in your view to lead to a robust
12		decision. If this was the only evidence that was before
13		the tribunal, would it be sufficient to draw
14		a conclusion on market?
15	A.	I think that is the I would say that is the best
16		evidence that I have seen in this case.
17	Q.	Move on to another topic. Can you be given the
18		decision, please.
19	THE	CHAIRMAN: Just before we move on, while we are on this
20		topic
21	MR	HOSKINS: I am going to come back to market definition in
22		closed there is some closed material I need to take
23		you to
24	THE	CHAIRMAN: You are going to come back to it? And NRIM
25		and Flynn's price comparative price behaviour?

1	MR	HOSKINS: I am going to come back to that but we need to
2		do that in closed.
3	THE	CHAIRMAN: Then I will not interrupt your flow.
4	MR	HOSKINS: If we could turn to paragraph 5.210, please.
5		You see from paragraph 5.210 the decision finds that
6		what it finds is that a rate of return actually well
7		below 6 per cent return on sales would be appropriate
8		for Flynn's capsules. Do you see that? Yes?
9	A.	Where are you?
10	Q.	Paragraph 5.210 on page 340. Would you like to re-read
11		that?
12	Α.	Ah, yes. (Pause)
13	Q.	While you are reading that, if you could also read
14		5.212; at the bottom of page 340. Sorry, you have got
15		different pages, have you?
16	A.	I do not know, which?
17	Q.	I have just asked you to read 5.210, which is under the
18		heading "Conclusion on reasonable rate of return."
19	A.	Yes.
20	Q.	Do you have it? So 5.210 and if you could also read
21		5.212. (Pause)
22		You seem to be struggling a little bit.
23	Α.	Yes, 5.210.
24	Q.	And 5.212. It is just at the bottom of the same page.
25	A.	Yes, it is 340 for me. (Pause) Yes.

1	Q.	So hopefully we can agree this, that first of all the
2		decision finds that a rate of return well below
3		a 6 per cent ROS would be appropriate for Flynn's
4		Phenytoin sodium capsules; yes? We see that in
5		paragraph 5.210?
6	A.	Yes.
7	Q.	And then in 5.212 the decision makes it clear that it is
8		not saying that a 6 per cent ROS would be suitable for
9		all generic medicines or even for Flynn's products other
10		than Phenytoin. Do you agree with that? Do you see
11		that in the decision?
12	A.	Mm-hm.
13	Q.	You need to say yes, sorry.
14	A.	Yes.
15	THE	CHAIRMAN: Sorry, are you agreeing with the conclusion
16		or are you agreeing that is what the decision says?
17	A.	No, that's what the decision says.
18	THE	CHAIRMAN: Keep that distinction in mind.
19	MR	HOSKINS: That was the basis of my question: does the
20		decision do you see what the decision says
21	THE	CHAIRMAN: Can Mr de Coninck read, was the question.
22	MR	HOSKINS: Absolutely. I wanted to set the scene.
23		We have heard a lot of evidence in the last few days
24		about the different factors that may affect the ROS of
25		pharmaceutical products. Let me give you one example.

1		If you stay in bundle D, where your reports are, and go
2		to tab 11, this is the first report of Mr Williams, who
3		was also an expert witness for Flynn. Have you read
4		this before?
5	A.	Yes.
6	Q.	And if we could turn through to page 8.
7	A.	Mm-hm.
8	Q.	You will see the heading, "Rates of return". Then you
9		might want to refresh your memory just by looking at
10		32(a) and 32(b).
11	A.	Mm-hm.
12	Q.	So Mr Williams identifies quite a large number of
13		factors that might affect the ROS of pharmaceutical
14		products. Do you agree that when you were seeking to
15		determine a reasonable return on sales, as we are in
16		this case, it is appropriate to consider the
17		characteristics and circumstances of a particular drug?
18	A.	So, I would first mention to you that the question of
19		what is a reasonable rate of return is a difficult one
20		but also one that introduces a lot of confusion in the
21		analysis, which is what I have tried to mention in the
22		report because the way it has been used by the CMA is,
23		of course, very different from thinking about what is
24		excessive and the use and the contribution of thinking
25		about what is the reasonable rate of return is quite

limited, especially if it is based on some arbitrary threshold and not based on comparators. So I think that it does -- of course, if one wants to consider what is reasonable, one has to look at other comparators, what other products rate of returns are and when one does that, one may, of course, want to consider the specific characteristics of the products.

8 Mr de Coninck, I do not want to stop you saying what you Ο. 9 want to say but it is really important that you answer 10 the question and then if you want to add to it, you add 11 to it. So if I ask you a question, please focus on what 12 I am asking you, answer it, preferably if you can with 13 yes or no, and then you can say whatever you want --14 Can you repeat. Α.

15 Q. I will, absolutely.

16 THE CHAIRMAN: I do not think there should be any pressure 17 on Mr de Coninck to answer yes or no. If he wants to 18 answer your question with a longer statement, he is 19 entirely free to do so provided he answers it. 20 MR HOSKINS: I am perfectly happy with that. I think --21 I will not say anything. You are right.

THE CHAIRMAN: I think we are on the same page, Mr Hoskins.
MR HOSKINS: Absolutely, we are. Do you agree that when you
are seeking to determine a reasonable ROS, it is
appropriate to consider the characteristics and

1 circumstances of a particular drug?

2	A.	So the answer is yes, if one considers returns on sales
3		one has to that is reasonable but again one has to be
4		careful about what we mean by that but one has to look
5		at comparator products and comparator products to the
6		extent that they can be found should be as close as
7		possible in terms of characteristics.
8	Q.	And in your reports you conduct a number of
9		profitability analyses of the products in Flynn's
10		portfolio in order to show that the profitability of
11		Phenytoin is not out of step with the profitability of
12		other Flynn's other products. That is what you do in
13		your report, is it not?
14	A.	That is right.
15	Q.	Can we look in your second report. That is bundle D,
16		tab 2. Could you turn to page 18 and the figures in
17		this table are confidential so we must not say them out
18		loud at the moment because we are still in open court.
19		Do you understand?
20	Α.	Yes, I do.
21	Q.	This is one of your updated analyses and your pool of
22		comparators, ie Flynn's products, is between 12 and 14

24 including Phenytoin. That is correct, is it not?

products in total, depending on the year and that is

5 1

25 A. That is correct.

Q. Do you agree that is not a very large pool for
 comparison?

3 No, I do not. I think that this is a reasonable pool Α. 4 for comparison. I think there is always -- there is 5 always a trade-off. You can have -- you can have 6 a larger pool with very, you know, different products or 7 you can have a smaller pool, which is here the ones that 8 are in Flynn's portfolio, so in that respect, you know, 9 it is all of the products in Flynn's portfolio 10 I consider that to be, you know, an appropriate pool and 11 I would not be concerned that this is a particularly 12 small pool or a pool that would prevent from reaching 13 a conclusion on the analysis. 14 Are you familiar with the expression quality not Q. 15 quantity? 16 Α. Yes. 17 Are you saying that even though this is on its face Ο. a relatively small pool, if the quality of the 18 19 comparisons that it provides are good enough, then that 20 is sufficient? Is that a fair way of summarising what 21 you are saying? 22 First, I did not say it was a particularly small pool Α. 23 but I think that, given that they are in -- the other 24 products in Flynn's portfolio, they are an appropriate

25 pool for comparison.

Q. Let us go to tab 3 in your third report, paragraph 50,
 on page 14. You say:

3 "In response to these criticisms we note that from 4 a practical perspective one has to accept that it is 5 very difficult to find companies whose product portfolio 6 exactly resembles Flynn's Phenytoin or any other 7 individual product for that matter."

8 Can you just explain why it is very difficult to do 9 that?

10 A. Well, first one has to have access to data and clearly 11 when one works for a -- as an economist for a company, 12 one can have access to the data that is available to 13 that company, which is the easiest way to think about 14 those questions, so the data that we have access to was 15 this data from Flynn.

16 ο. That is not the point you are actually making here, is 17 it, because you have to say it is very difficult to find 18 companies whose product portfolio exactly resembles 19 Flynn's Phenytoin or any other individual products. You 20 are not making a point about access to data. You are 21 making a point, which we have already touched on, which 22 is that generic companies have very varied portfolios. 23 It is hard to find two that are similar. That is the 24 point you are making here, is it not?

25 A. If you want to have an exact portfolio, of course, you

1		are never going to get the exact same portfolio.
2	Q.	And your reports do not contain any analyses of other
3		companies' portfolios. You have not attempted that,
4		have you?
5	Α.	No, I have not.
6	Q.	Your analysis of the products in Flynn's portfolio does
7		not look at the degree of competition faced by each of
8		those products, does it?
9	Α.	No, it does not.
10	Q.	And it does not consider the extent to which any of
11		those drugs might be considered innovative or at the end
12		of their life, does it?
13	Α.	It does not.
14	Q.	Your analysis does not assess which pricing regime each
15		of Flynn's products is subject to?
16	A.	No, it does not.
17	Q.	Do you know if any of the drugs in Flynn's portfolio
18		are protected by patent?
19	A.	I suppose they are not but I have not conducted that
20		analysis.
21	Q.	And you are obviously aware that Phenytoin is subject to
22		continuity of supply, are you not?
23	A.	Yes, I am.
24	Q.	You have not in your reports analysed the prescribing
25		regime applicable to each of Flynn's products, have you?

A. No, I have not. Q. Sir, we are at the stage where we need to go into private so I can refer to confidential materials. THE CHAIRMAN: Right. Can those outside the confidentiality ring other than Flynn, please leave. (10.55 am) (In private) (12.01 pm) (In further private session, confidentiality ring only) (12.38 pm) (The court adjourned until 10.30 am on Monday, 12 November 2017) 

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