

Neutral Citation Number: [2019] EWHC 1528 (Pat)

Case No: HC-2015-005005

## IN THE HIGH COURT OF JUSTICE BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES INTELLECTUAL PROPERTY LIST (ChD)

The Rolls Building
7 Rolls Buildings
Fetter Lane
London EC4A 1NL

Date: Wednesday, 12th June 2019

Before:

## MR. JUSTICE ARNOLD

**Between:** 

(1) GLAXO WELLCOME UK LTD (t/a ALLEN & HANBURYS) (2) GLAXO GROUP LIMITED

**Claimants** 

- and -

(1) SANDOZ LIMITED (2) SANDOZ INTERNATIONAL GMBH

(3) AEROPHARM GMBH

(4) HEXAL AG (5) SANDOZ AG

(6) VECTURA GROUP PLC

(7) VECTURA DELIVERY DEVICES LIMITED

**Defendants** 

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MR. SIMON MALYNICZ QC, MR. TOM HICKMAN QC and MS. STEPHANIE WICKENDEN (instructed by Stephenson Harwood LLP) for the Claimants

MR. MARTIN HOWE QC, MS. IONA BERKELEY and MS. ASHTON CHANTRIELLE (instructed by White and Case LLP) for the 1<sup>st</sup> to 5<sup>th</sup> Defendants

MR. IAIN PURVIS QC and MS. ANNA EDWARDS-STUART (instructed by Bristows LLP) for the 6<sup>th</sup> and 7<sup>th</sup> Defendants

## **Approved Judgment**

(Transcript of the Stenograph Notes of Marten Walsh Cherer Ltd., 1<sup>st</sup> Floor, Quality House, 6-9 Quality Court, Chancery Lane, London WC2A 1HP. Telephone No: 020 7067 2900. Fax No: 020 7831 6864 DX 410 LDE)

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## MR. JUSTICE ARNOLD:

- 1. This is the pre-trial review in these proceedings. The principal item of dispute, having dealt with a number of minor items, is an application by the Defendants to exclude parts of the Claimants' evidence.
- 2. In a nutshell, the claim advanced by the Claimants ("Glaxo") is that the sale by the First Defendant ("Sandoz") of its AirFluSal Forspiro inhaler for medication for the treatment of asthma and COPD amounts to passing off in that the relevant public are deceived by virtue of the get-up in which it is sold (and in particular, but not by way of limitation, the use of the colour purple) that the AirFluSal Forspiro is Glaxo's Seretide Accuhaler product or is otherwise associated with Glaxo or its Seretide Accuhaler product and/or that the AirFluSal Forspiro is equivalent to Glaxo's Seretide Accuhaler product. Glaxo also allege that the get-up of the AirFluSal Forspiro was adopted with the deliberate intention of deceiving the relevant public that the AirFluSal Forspiro is Glaxo's Seretide Accuhaler product and/or that the AirFluSal Forspiro was equivalent to Glaxo or its Seretide Accuhaler product. Glaxo allege that the other Defendants are jointly liable with Sandoz.
- 3. The matter has been pending for a considerable period of time, but is now listed for trial beginning on 8 July 2019. A substantial volume of evidence has been served on each side. Objection is taken by the Defendants to various parts of Glaxo's evidence on various grounds.
- 4. The point is made on behalf of Glaxo that, so Glaxo contend, many of the objections raised by the Defendants are equally applicable to the Defendants' own evidence. There may be some force in that contention. However, there is no application on the part of Glaxo to exclude any of the Defendants' evidence. In those circumstances. I do not consider that it is relevant to enquire as to the extent to which the objections raised by the Defendants are equally applicable to their own evidence.
- 5. The evidence that is objected to falls into three main categories which I will take in turn. The first category consists of the witness statements of three eminent clinical academics, Professors Rupert Jones, Paul Jones and David Thomas. These three witness statements are objected to by the Defendants in their entirety, on the basis that, as a matter of substance and reality, the witness statements constitute expert evidence and Glaxo does not have permission to adduce such expert evidence.
- 6. Before proceeding further it is necessary to record that, at an earlier stage of the proceedings, the Defendants sought permission to adduce expert evidence to address three topics. First, the medical conditions treatable by the use of inhalers, including the types of inhalers and the active ingredients which they contain which are employed for the treatment of such conditions. Secondly, the practice of healthcare professionals, including general practitioners, in relation to prescribing inhalers. Thirdly, the practice of healthcare professionals, including general practitioners in relation to the dispensing prescriptions relating to inhalers. Ultimately the Defendants sought permission to adduce evidence from three experts, namely a respiratory specialist, a general practitioner and a pharmacist, to address these topics.
- 7. Glaxo's position was that permission to adduce expert evidence should be refused. Glaxo contended that, to the extent that these topics needed to be addressed in evidence,

and I do not think Glaxo disputed that they did need to be addressed, it was both possible and preferable for those topics to be addressed through the medium of factual evidence, and in particular evidence from "trade" witnesses, that is to say, witnesses in the relevant professions speaking from their own personal knowledge. The Chief Master accepted that submission, and accordingly he refused the Defendants permission to adduce expert evidence. There was no appeal by the Defendants against his order.

- 8. Against that background, I turn to consider the evidence of the three witnesses in question. As someone who has spent his entire career, both at the bar and on the bench, reading large numbers of expert reports, particularly in patent cases, but also in other kinds of cases, I am bound to say that, having read each of the documents in question from end to end, I am in no doubt whatsoever that as a matter of substance and reality they do constitute expert reports. Put simply, they are documents authored by experts, expressing their experience and opinions as experts.
- 9. In each case the witness begins with a fairly lengthy recitation of his qualifications and experience to give the evidence that he gives, in exactly the same way one would expect from any expert producing an expert report. So they set out in each case their qualifications, the posts that they have held, their role in advisory bodies, their role on scientific committees, research that they have done in relevant areas and so on. They then go on to address, exactly as one would expect expert witnesses to do, the topics that they have been asked to address. They do so in part from their own personal experience as clinicians in the field, and in part by reference to relevant materials such as industry guidelines (such as those published by NICE) and academic research carried out in some cases by themselves and in some cases by other academics. They express their opinions on various points as well as recording factual matters. In short, as I say, these are, in my view, plainly expert reports.
- 10. Glaxo seek to defend the admissibility of these three witness statements on a number of bases. First, they contend that the evidence is not expert evidence, but trade evidence. They rely upon the fact that the witnesses all refer to their personal experience as supporting the contention that this is trade evidence. I do not accept that submission. Any expert witness will rely, among other things, upon their own experience in the field in question as supporting the conclusions which they draw. That is precisely what these witnesses do. It is not at all the same thing as a witness speaking to their own personal knowledge and their own personal actions in a narrative manner. That is not what these witnesses have done.
- 11. It is a fallacy to suppose that expert evidence is limited to the expression of opinions. Expert evidence, as has often been held, includes evidence which on its face is expressing a fact. If it requires expertise for the person in question to be able to state that fact, it is expert evidence. That is what in many places these witnesses are doing.
- 12. Next, Glaxo contend that the matters covered by the witnesses should be uncontroversial. That, of course, is entirely beside the point. If there was no issue, there would be no need for the evidence. It would be inadmissible on the grounds that it was irrelevant. However, there is no dispute that there are relevant issues, and that is not the objection that is made by the Defendants.
- 13. Next, it is submitted that the fact that the witnesses refer to relevant materials, such as industry guidelines, academic research that they have carried out and research carried

- out by others, does not make the evidence expert evidence. Again, I do not accept that submission. It seems to me that it confirms what the witnesses are doing is expressing expert evidence.
- 14. Accordingly, the conclusion I reach in respect of these three statements is that prima facie they are inadmissible on the ground that in substance and reality they are expert reports for which Glaxo have not obtained permission.
- 15. Counsel for Glaxo submitted that it would be contrary to the spirit of Chief Master Marsh's order for such evidence to be excluded. In my view the converse is true. I consider that Chief Master Marsh, having, at Glaxo's behest, refused the Defendants permission to adduce expert evidence of this kind, would be utterly horrified at the prospect that Glaxo were now seeking to adduce precisely the same sort of expert evidence before this court.
- 16. It remains for me to consider whether there is any part of the evidence of these three witnesses which is properly admissible. The difficulty with that is that the way in which they are drafted is as expert reports and that makes it very difficult to isolate admissible passages from their evidence. If the evidence had been drafted in a different way, the task might be easier. As it is, however, it seems to me that all I can do is to seek to identify whether there are any discrete passages in the evidence which are admissible, notwithstanding as a generality that the evidence is not.
- 17. In my view there are a number of passages which pass that test. The first is to be found in the witness statement of Professor Rupert Jones. At paragraphs 79 to 82 inclusive he sets out his own personal experience with respect to Seretide. As a generality I consider that that passage in his witness statement is factual evidence which is admissible. There are one or two sentences in it where he expresses opinions which I am dubious he is in a position to express as a factual witness, but nevertheless on the whole it seems to me that that passage in the witness statement falls on the right side of the line and I will therefore allow the admission of those four paragraphs. The same goes for paragraphs 31-32, 99-100, 104-105 and 115 of the witness statement of Professor Paul Jones and paragraph 121 and the first two sentences of paragraph 122 of Professor Thomas' witness statement.
- 18. Another passage is to be found at end of the Professor Thomas' witness statement. In section P of that statement in paragraphs 135 through to 136.6, Professor Thomas gives evidence about a meeting that he personally attended on 20 September 2011. As he relates, he does not remember every specific detail to the meeting, but he has refreshed his memory from the minutes of the meeting and he gives evidence on that basis. That, in my view, is plainly factual evidence which is admissible and it is a discrete part of his witness statement. Accordingly, notwithstanding that the generality of the statement is expert evidence, that section, it seems to me, can be admitted.
- 19. I move next to consider the next category of evidence which is objected to by the Defendants. This consists of a number of witnesses who do fall into the category of trade witnesses. The Defendants do not dispute that, consistently with the ruling of Chief Master Marsh, such evidence is properly admissible. The Defendants contend, however, that the evidence which the trade witnesses can give is restricted to factual evidence based on their own personal knowledge and experience and that they cannot stray into expressing opinions, particularly opinions constituting expert evidence, and that they

cannot speculate upon matters outside their own knowledge and they cannot advance argument or opine in any meaningful way upon the ultimate issue with which the court is concerned.

- 20. Accordingly the Defendants take objection not to the entirety of the witness statements of the witnesses in question, but to specific identified passages where, so the defendants contend, the witnesses have gone beyond that which is properly admissible. Glaxo's position is quite simply that none of the witnesses in question has gone beyond what is properly admissible and none of the passages that have been identified are objectionable. In particular, Glaxo contends that any expressions of opinion are admissible by virtue of section 3 of the Civil Evidence Act 1972, which permits factual witnesses to state opinions if that is done as way of conveying facts personally perceived by them. It is therefore necessary to take the witnesses one by one and consider the passages that are objected to.
- 21. The first statement is from Chinedu Nwanede, who is a pharmacist. Mr. or Ms. -- I do not know which is the appropriate designation -- Nwanede gives evidence based on his or her personal experience as a pharmacist. There is no dispute that most of his or her evidence is admissible. Objection is taken to three specific passages in the statement. The first begins at the end of paragraph 16 and continues through to the end of paragraph 19. In this passage the witness is relating an incident which happened where, as he puts it, AirFluSal Forspiro was almost dispensed to a patient with a branded prescription for the Seretide Accuhaler. In brief, a mistake was made, but then it was detected and averted.
- 22. No objection is made to the historical account save in one respect, but objection is made as to what the witness says in retrospect about it. The objection starts with the last sentence in paragraph 16 where the witness says: "I did not ask the dispenser the reason why the mistake had been made but I thought at the time that the similarity of the boxes would have been the cause." Objection is take to the second half of that statement. In my view the second half is not objectionable. It is a record of what the witness says he thought at the time. That is a pure question of fact and the evidence is admissible.
- 23. In paragraphs 17, 18 and the first sentence of paragraph 19, however, the witness goes on to give his opinion as to why he thought that at the time and why the other pharmacist made the mistake that he did. That is not factual evidence from this witness; it is a combination of opinion and speculation. As such, in my judgment, it is inadmissible. Accordingly I will admit the objected to part of paragraph 16, but not the objected to parts of 17, 18 and 19.
- 24. In paragraph 23 the witness is dealing with the question of patient confusion. Having set out in the previous paragraph his own experience, or lack thereof, he expresses an opinion as to what regular users of Seretide are likely to assume when confronted with AirFluSal Forspiro. That is objected to on the basis that it is speculation as to the thought processes and reactions of others and/or as inadmissible opinion evidence. In my view that evidence is not factual evidence from this witness and it is inadmissible.
- 25. Finally, objection is taken to the last sentence of paragraph 30, where the witness expresses an opinion as to what assumptions would be made by other pharmacists. Again that is objected to on the basis that it is speculation as to what other people would

assume and/or as expert opinion evidence, for which no permission has been granted. Again, in my judgment, that evidence is inadmissible.

- 26. The next witness is Anthony Dysart, who is a general practitioner. As with the previous witness, the Defendants do not object to the bulk of his statement, but specific passages are objected to. First, there is an objection to paragraph 22 in which the witness gives his opinion as to what asthma or COPD patients are likely to do. That is objected to on the basis that it is speculation on his part as to what other persons will think and do and/or is expert evidence for which no permission has been granted. In my judgment that paragraph is inadmissible.
- 27. Similarly, in paragraph 29 the witness states his opinion as to what a community pharmacist who dispenses inhalers would do. Again, this is objected to on the basis that first Mr. Dysart is a general practitioner who has no expertise to give opinions about what community pharmacists will or will not do; and, in any event, even if he did have such expertise, this would be expert evidence for which there is no permission. In my judgment those objections are well founded.
- 28. Paragraphs 33 and 34 are paragraphs in which the witness comments upon a briefing issued by the NHS Greater Manchester and Bolton Pharmaceutical Committee and also a related poster. The witness admits that he was not sent the briefing and was not aware of these matters. He nevertheless comments on the documents because he has been asked by Glaxo's solicitors to do so. In my judgment, the Defendants are right to object that that is plainly not factual evidence from this witness. It is commentary on documents which he has been shown for the purposes of the litigation and/or expert opinion evidence for which no permission has been granted. It is therefore inadmissible on both grounds.
- 29. Next, objection is taken to a single sentence in paragraph 36. In that paragraph the witness is mainly expressing his own outlook on prescribing considerations and no objection is taken to that. However, in the second sentence he says: "Based on my experience I think other GPs and pharmacist would make the same assumption." Objection is taken to that partly on the basis that he is not qualified to give that evidence in relation to pharmacists and, in relation to GPs, that this is speculation and/or expert opinion for which there is no permission.
- 30. It seems to me the objection in relation to pharmacists is well taken for the reason that I gave earlier. So far as what he say about other GPs, it seems to me this is very much a borderline question. As I acknowledged in my judgment in *Enterprise Holdings Inc v Europear Group UK Ltd* [2015] EWHC 16 (Ch) at [32], there is a difficult line to be drawn as to the extent to which trade witnesses can express views based on their own personal experience as to what other people would or would not do. In the case of the objected to part of Mr. Dysart's statement, while I am dubious as to whether this is really admissible and of weight, I consider that it is just about on the right side of the line and I will therefore allow it in.
- 31. Finally, objection is taken to paragraph 42, where the witness expresses an opinion as to what asthma and COPD patients would think when confronted with the AirFluSal Forspiro device. That is objected to on the basis that it is speculation on the part of the witness on the ultimate question with which the court is concerned and/or expert opinion evidence. In my judgment the objection is well taken.

- 32. So far as the next witness is concerned, Alexander George, he is a junior locum doctor. Again the Defendants accept that the bulk of his evidence is unobjectionable, but object to certain specific passages. The first is half a sentence at the end of paragraph 16 where the witness says: "Patients build up trust in their inhaler and, in my experience, become loyal to their brand of inhaler." The words from "and, in my experience" are objected to on the basis that this is speculation and/or expert opinion. I disagree. In my view the witness is there stating his personal experience as a locum doctor and I consider that that half sentence is, therefore, admissible.
- 33. Next, objection is taken to paragraph 23 in which the witness expresses views said to be based on his experience as to what patients will or will not do. Objection is taken again on the basis that this is speculation on the ultimate question for the court and/or inadmissible experience opinion. In my view the objection is well-founded for the most part. However, there is one sentence in this paragraph which, in my view, is unobjectionable, where the witness says: "I find that patients often trust their HCPs to dispense them the right device". That is a statement by the witness of his own personal experience. That is factual evidence which is admissible.
- 34. Next, objection taken to a sentence in paragraph 25 where the witness is talking about what happens with respect to repeat prescriptions. He says in the objected-to sentence: "As far as I am aware this shows up on the pharmacist's system as a repeat prescription, e.g. four of six allowed, so the pharmacist is likely to assume that the patient already knows how to use the device dispensed." That is objected to on the basis that the witness is not qualified to give that evidence and/or if it is it is expert opinion for which no permission has been granted.
- 35. In my view the sentence falls into two parts. I think the first half of the sentence where he is setting out to the best of his awareness what happens on the pharmacist's system, that is factual evidence and the extent to which he is aware of what happens in pharmacists' systems can be explored in cross-examination. So that part of the sentence I consider is admissible. When he goes on, however, to express his opinion as to what the pharmacist is likely to assume, in my judgment, that is inadmissible.
- 36. Finally, objection is taken to a few words at the end of paragraph 27 where the witness expresses an opinion as to what patients he has treated think. That is objected to on the basis that it is speculation on the ultimate question that the court is concerned with and/or expert evidence. In my judgment, that objection is well founded.
- 37. Next there is the witness statement of David Jackson who is a Consultant Respiratory Physician. Again the Defendants accept that the bulk of this evidence is admissible, but they object to specific passages. First of all there is a passage in the second half of paragraph 11 and the first half of paragraph 12 where the objection is made that the witness is speculating as to the motivations and behaviour of pharmacists and the possible impact of that on their patients. Accordingly, that is speculation and/or expert opinion for which there is no permission. Again, I think that objection is well founded.
- 38. Similarly, objection is made to what the witness says about GPs in two parts of paragraph 14 and again I think the objection is well-founded.
- 39. Next, objection is taken to parts of paragraphs 22 and 23 where the witness is expressing opinions as to the views of patients and pharmacists. Again, objection is made on the

- familiar basis that he is speculating about others and/or this is expert opinion for which no permission has been obtained. Again I think those objections are well founded.
- 40. Finally, objection is taken to paragraphs 25 and 26, again on the basis that he is expressing opinions as to the thought processes of patients, and again, therefore, speculating and/or expressing expert opinions. Again, I think the objection is well founded.
- 41. Next, there is the evidence of Jonathan Laird, who is a GP pharmacist. Again the Defendants accept that the bulk of this evidence is admissible, but objection is taken to various parts. In the first place, objection is taken to paragraph 42 where the witness gives his opinion on the risk of confusion on the part of pharmacists and/or patients. Objection is taken that this is speculation on his part as to the thought processes oaf others and/or expert opinion. Again, I think the objection is well founded.
- 42. At paragraph 43 the witness refers to a report by the Department of Health issued in 2018. This is objected to on the same basis and also on the basis that what the witness is doing is commenting upon a document. I think the objection is well founded on all grounds.
- 43. Similarly, at paragraphs 45 and 46 he refers to a document published by the National Pharmacy Association in 2017. In this case the witness is explicit that he was not previously aware of this document and only became aware of it because he was shown the document by Glaxo's solicitors when they were preparing his statement. This is blatantly inadmissible.
- 44. Next, there is paragraph 27 where the witness refers to a product called the Aerivio Spiromax. The first sentence of this paragraph is inadmissible because it follows on from the inadmissible evidence about the document issued by the National Pharmacy Association. The second sentence, however, simply states that the witness is familiar with the Aerivio Spiromax in his practice and he expresses the view that it is different in appearance to the Seretide Accuhaler. In my judgment, that evidence is plainly admissible, not inadmissible, because he is stating his own personal experience and views.
- 45. Next, objection is taken to paragraphs 55 and 56 where again the witness has been asked to comment on a document, this time a study reported in Expert Review of Respiratory Medicine. It is not terribly clear from what the witness says whether this was a document he was previously familiar with or not. If he was not, then it is plainly inadmissible as a commentary on documents; even if he was previously familiar with it, in substance, this is expert evidence for which there is no permission.
- 46. Likewise, at paragraph 61 where the witness refers to research published in The Pharmaceutical Journal. Again, this is either commentary on documents or expert opinion and either way it is inadmissible.
- 47. In paragraphs 63 and 64 the witness discusses Sandoz documents that he has been shown and asked to comment on. This is blatantly inadmissible.
- 48. At paragraphs 65 and following through to paragraphs 70, the witness discusses another document. This is The UK National Review of Asthma Deaths published in May 2014.

Again, it is not clear from what the witness says whether he was previously familiar with this document or not. If he was not familiar with it he is just commenting on the document. If he is, then, in substance, this is expert evidence and either way it is inadmissible.

- 49. Then there is objection to part of paragraph 72 and as to that the witness is talking about what happens in pharmacies. This is objected to on the basis that this is speculation by this witness as to what other pharmacists will think and do and as to the effect on the patient and/or its expert opinion. I agree that this evidence is inadmissible.
- 50. Then objection is taken to a passage at paragraph 79 where the witness sets out under the heading of "Patients' Perspective" a melange of his own experience with his patients and his speculation as to what patients in general will think and assume. This passage, in my view, is quite difficult because some of it falls on the right side of the line and some of it is inadmissible. Differentiating between the two is not easy and the course I propose to take is to err in favour of Glaxo in terms of where I try and draw the line.
- 51. Adopting that approach, I will admit paragraphs 79 and 80 since, on balance, I think those two paragraphs are mainly directed to the witness's own experience. Paragraph 81, I think, falls on the other side of the line: this is speculation as to a patient's thought process rather than anything that the witness can speak to from his own experience. Paragraphs 82 and 83, again, I think are somewhat difficult as constituting a mixture of the patient's own experience and a degree of opinion. Nevertheless, on balance, I think the better course is to admit those two paragraphs in their entirety rather than trying to disentangle the two.
- 52. Next in this category, there is Hannah Lubbeke-Brown who is a pharmacist. Once again, the Defendants accept that the bulk of her written statement is admissible, but object to specific parts. As to that, the first objection is taken to part of a sentence in paragraph 12 and the final sentence, in both of which the witness is expressing an opinion as to other pharmacists and as to patients. Objection is taken on the familiar bases. In my view, again, the objection is well-founded. Similarly, the last sentence in paragraph 24 is objected to where the witness is expressing an opinion as to what a busy pharmacist will think. Again, in my view, that sentence is inadmissible.
- 53. Likewise in paragraph 32 an objection is taken to a sentence in which the witness expresses an opinion as to what patients are likely to do. In my judgment that is inadmissible. In paragraph 36 objection is taken to the whole paragraph, short though it is, on the basis that it is expressing an opinion about patients. Again, in my judgment, that is inadmissible.
- 54. In paragraph 41 objection is taken to the bulk of the paragraph which is concerned with online pharmacies and the witness's speculation as to what the thought processes and reactions of patients are. In my view the passage objected to is inadmissible except for the first sentence where the witness sets out, to the best of her awareness, what happens as a matter of fact as between an online pharmacy and the patient. So that sentence will be admitted and she can be cross-examined as to the extent to which she is aware of what happens.
- 55. Finally, objection is taken to small parts of the witness statement of Gregory Lawton, who is a pharmacist. Objection is taken to the last sentence of paragraph 25 and the last

- sentence of paragraph 30, in both of which the witness expresses opinions about what other people think. That evidence is inadmissible.
- 56. I turn, therefore, to the third category of evidence to which objection is taken and this consists of witness statements from Glaxo witnesses. The first objection relates to the witness statement of Peter Daley-Yates. He is the Director of Clinical Pharmacology and Experimental Medicine for the GlaxoSmithKline group of companies. Objection is taken by the Defendants to the entirety of his witness statement on the basis that, in substance and reality, it is an expert report for which Glaxo have no permission.
- 57. As Dr. Daley-Yates explains in his statement, he deals with three topics: first, the regulatory process for the approval of medicines; secondly, the concepts of pharmaceutical equivalence, bioequivalence and therapeutic equivalence; and, thirdly, marketing authorisations held in respect of both Seretide and AirFluSal and the extent to which this means that they are equivalent.
- 58. In the first section of his statement Dr. Daley-Yates sets out his understanding of the procedures which apply to the authorisation of medicines as to market them in the UK. As he explains, these derive from European law and Dr. Daley-Yates sets out his understanding and interpretation of the relevant provisions. As the defendants contend, this is plainly expert evidence and, not only is it expert evidence, Dr. Daley-Yates has no apparent expertise to give it since it is legal expert evidence and not medical expert evidence.
- 59. In section II, Dr. Daley-Yates describes various types of equivalence and he also deals with the concept of substitutability and interchangeability. He gives his opinion as to the meaning of the use of terms and his opinion on the assertion by Sandoz that AirFluSal Forspiro is the therapeutic equivalent of Seretide. The Defendants object to this on the basis that it is essentially expert evidence and, to the extent that it is not, it is essentially argument. In my judgment that objection is also well-founded.
- 60. In section III of his statement, Dr. Daley-Yates comments upon the various marketing authorisations and their significance and, in particular, comments upon what happened during the course of Sandoz's application for marketing authorisation. He refers in the course of that passage in his evidence to exchanges between Sandoz and MHRA and draws conclusions. This is objected to on the basis that this is, in substance, expert evidence, but it is also objected to on the basis that a large part of it consists of Dr. Daley-Yates's commentary on exchanges between Sandoz and MHRA and therefore not something of which he has any personal knowledge whatsoever. In my judgment both objections are well-founded.
- 61. Accordingly, it seems to me that the Defendants are correct to say that the entirety of Dr. Daley-Yates's witness statement is inadmissible.
- 62. The point was made by counsel for Glaxo that the Defendants, notwithstanding their objection to Dr. Daley-Yates's evidence, have served evidence in response to it from a Mr. Marshall. It is submitted on behalf of Glaxo that it can be seen from Mr. Marshall's witness statement that a lot of what Dr. Daley-Yates says is uncontentious. In my judgment, even if that is correct, it did does not justify the admission of Dr. Daley-Yates's statement. As counsel for Sandoz pointed out, the Defendants' position is that if, as they contend, Dr. Daley-Yates's evidence is inadmissible, then they

- are content to withdraw the responsive parts of Mr. Marshall's statement. Other parts, so the Defendants say, are directed to a different issue.
- 63. I turn next to the statement of Wendy Adams, who is GSK's Vice President, Head of Market Supply & Distribution Quality. Fifty-seven out of 58 paragraphs in this statement are not objected to. The only objection that is raised is to the final paragraph, paragraph 58, which is in the following terms:

"I believe that if there was a recall of AirFluSal Forspiro, there is a risk that this could cause problems for the Seretide brand, if patients see information about the AirFluSal recall and are confused into thinking that it is a recall of Seretide, or news and social media outlets re-publish incorrect information."

- 64. The Defendants object that this is plainly inadmissible opinion evidence. I agree.
- 65. Next is the witness statement of Benjamin Murray, who is GSK's Head of Payer Strategy & Solutions, UK Pharma. The bulk of his statement is not objected to, but certain passages are. First, paragraph 21, where the witness comments on AirFluSal Forspiro marketing materials from the parties' disclosure and gives his opinion upon them. This is objected to, first, on the basis that this is a commentary by the witness on documents, not something he has personal knowledge of and, in any event, this is opinion and/or argument. I agree with all of those objections. This evidence is inadmissible.
- 66. Next, objection is raised to what the witness says in paragraph 28. Having referred to minutes of a meeting, at which he says he was not present, he then speculates as to the thought processes of those who were present. This is objected to on multiple bases: it is a commentary on a document when he no personal knowledge; that it is speculation as to the thought processes of others; that it is argumentative; and it is expert opinion. In my judgment, this evidence is plainly inadmissible.
- 67. Next, objection to taken to paragraphs 29 through to 32 where the witness comments upon internal Sandoz documents which have been disclosed in the proceedings. This evidence is all plainly inadmissible as being matters of which he has no personal knowledge.
- 68. Next, objection is made to paragraph 38 where the witness comments on his understanding of the reason for a policy adopted by the NHS. This is objected to on the basis that this is either expert opinion evidence, for which there is no permission, or argument. In my judgment, the objection is well founded.
- 69. Finally, objection is taken to paragraph 41 where again the witness is commenting on internal Sandoz documents. That evidence is plainly inadmissible.
- 70. Next there is Derek Moriarty, who is GSK's Head of Regulatory (Europe Mid-Sized and Cluster Markets). Again, no objection is taken to the bulk of this statement, but objection is taken to various passages. First, objection is taken to a passage in paragraphs 12 and 13 where the witness expresses opinions about the interchangeability of inhaler devices. Objection is taken primarily on the basis that this is expert opinion evidence for which there is there is no permission. In my judgment, that objection is well founded. Objection is also raised that this is argumentative. I am less convinced that that objection

- is well-founded although there is undoubtedly an element of argument in the witness's evidence. But, in any event, the first objection is well founded.
- 71. Next, objection is taken to paragraphs 25 through to 31. The objection here is a rather unique one, namely, this evidence is wholly irrelevant because it is all about the position in Ireland, not the position in the United Kingdom. That objection, in my judgment, is well founded. That evidence is inadmissible on the simple ground that it is completely irrelevant.
- 72. Next, objection is taken to a passage at paragraphs 36 through to 39 where the witness is setting out, in effect, GSK's company policy. So far as the first paragraph is concerned, where the witness is recording GSK's policy in the past, that seems to me to just about fall on the right side of the line. The extent to which the witness is in a position, from his own personal knowledge, to articulate GSK company policy can be explored in cross-examination, but on the face of it he is giving evidence about the company's past concerns. By contrast, paragraphs 37 through to 39, which are objected to on the basis that the concerns expressed by the witness are pure argument, that objection seems to me to be well founded.
- 73. Next, objection is taken to paragraphs 42 through to 47 on the basis that these paragraphs are commenting on internal Sandoz documents. In my judgment that objection is well founded and the evidence is plainly inadmissible.
- 74. Next, objection is taken to paragraphs 48 through to 58 on the basis that what the witness is doing here is testifying to instances of apparent confusion experienced by Glaxo. However, the witness admits that he had no personal involvement in the instances in question. His evidence is based, on the face of it, primarily upon documents to which he refers. He also says in footnotes that he has spoken with unidentified personnel within GSK who were involved in the instances in question. Objection is taken on the basis that, on the face of it, the witness is commenting on documents without having any personal knowledge. Furthermore, it is pointed out that it appears from what the witness says that there are other unidentified employees of Glaxo who are in a position to give first-hand evidence of the matters in question.
- 75. In my judgment, this objection is well founded. I find it very odd that Glaxo, despite having served evidence from so many witnesses, have not served evidence from the relevant witnesses who are in a position to deal with the instances in question. If and in so far as Glaxo wishes to rely upon the documents as hearsay, that is another matter; but the evidence from this witness is inadmissible because he has no personal knowledge.
- 76. Finally, there is the witness statement of Jonathan Crompton, who is a Marketing Director within GSK. His witness statement runs to no less than 147 pages and 270 paragraphs. Objection was raised to various parts of this statement, although by no means the entirety. Glaxo have accepted that various parts of the statement are inadmissible on the ground that they constitute commentary upon Sandoz documents. However, there remain parts which are objected to by the Defendants and in respect of which Glaxo do not accept that the objection is well founded. Accordingly, it is necessary for me to consider the areas to which objection is taken.
- 77. The passages in question have helpfully been identified and grouped by counsel for the 6th and 7th Defendants ("Vectura"), in paragraph 47 of his skeleton argument where he

identifies the relevant paragraphs. I do not propose to lengthen this judgment still further by reading out all the relevant paragraph numbers. The first objection is taken to a group of paragraphs on the basis that the witness is expressing opinions which amount to speculation on the ultimate question before the court. I agree that those paragraphs are inadmissible on those grounds.

- 78. Next, objection is taken to various paragraphs on the basis that they are commentary on internal Sandoz and/or Vectura disclosure documents. The point is made on behalf of the Defendants that there is an inconsistency between Glaxo's acceptance that parts of Mr. Crompton's statement constitute inadmissible commentary on documents and their refusal to accept that other parts of the statement which do exactly the same thing are also inadmissible. In my judgment, the Defendants are entirely correct to point out that inconsistency. These passages are equally inadmissible for exactly the same reason.
- 79. Finally, objection is taken to various passages on the basis that these constitute argument rather than any statement of fact of which the witness has personal knowledge. In my judgment, that objection, again, is well founded. Those passages are also inadmissible.
- 80. In conclusion, therefore, it seems to me that, in large part, the Defendants' objections succeed but, to the extent that I have indicated, there are parts where the objections are not well founded and I will therefore admit those small parts of the evidence to which objection is taken.

(For continuation of proceedings: please see separate transcript)

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