Approved Judgment

Neutral Citation Number: [2019] EWHC 2545 (Ch)

Case No: HC-2015-005005

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS
INTELLECTUAL PROPERTY LIST (CHANCERY DIVISION)

Rolls Building
Fetter Lane, London, EC4A 1NL

Date: 4 October 2019

Before :

LORD JUSTICE ARNOLD

- -

Between :

(1) GLAXO WELLCOME UK LIMITED	**Claimants**
(2) GLAXO GROUP LIMITED	
- and -	
(1) SANDOZ LIMITED	**Defendants**
(2) SANDOZ INTERNATIONAL GMBH	
(3) AEROPHARM GMBH	
(4) HEXAL AG	
(5) SANDOZ AG	
(6) VECTURA GROUP PLC	
(7) VECTURA DELIVERY DEVICES LIMITED	

- -
- -

Simon Malynicz QC, Tom Hickman QC, Stuart Baran and **Stephanie Wickenden** (instructed by **Stephenson Harwood LLP**) for the **Claimants**
Martin Howe QC, Iona Berkeley and **Ashton Chantrielle** (instructed by **White and Case LLP**) for the **First to Fifth Defendants**
Iain Purvis QC and **Anna Edwards-Stuart** (instructed by **Bristows LLP**) for the **Sixth and Seventh Defendants**

Hearing dates: 10-11, 15-19, 22, 24-26 July 2019

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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LORD JUSTICE ARNOLD :

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Introduction

1. This case is about the colour purple. The Claimants ("Glaxo") have marketed a combination of salmeterol and fluticasone for the treatment of asthma and chronic obstructive pulmonary disease ("COPD") under the trade mark Seretide in a proprietary dry powder inhaler ("DPI") branded Accuhaler since 1999 and in a metered dose inhaler ("MDI") branded Evohaler since 2000. Both the Seretide Accuhaler and the Seretide Evohaler are coloured two shades of purple (in the case of the Evohaler, the shades vary with the dose of fluticasone) and both are sold in packaging featuring a shade of purple (again, the shade varies with the dose of fluticasone). On 20 November 2015 the First, Second and Fifth Defendants ("Sandoz") launched a branded generic competitor to the Seretide Accuhaler under the trade marks AirFluSal Forspiro. The Forspiro is a proprietary DPI designed by the Sixth and Seventh Defendants ("Vectura"). The AirFluSal Forspiro is largely coloured a shade of purple and is sold in packaging featuring a shade of purple. Glaxo claim that Sandoz have passed off the AirFluSal Forspiro as being (i) connected in the course of trade with Glaxo and/or (ii) equivalent to the Seretide Accuhaler through the get-up and packaging of the AirFluSal Forspiro. Although Glaxo's pleaded case also relies upon certain other aspects of the get-up and packaging, by the end of the trial the only feature Glaxo really relied upon was the use of purple. There is no dispute that Vectura are jointly liable for any passing off. Glaxo contend that the Third Defendant ("Aeropharm") and the Fourth Defendant ("Hexal"), which are members of the same group of companies as Sandoz, are also jointly liable.

2. Although Glaxo commenced these proceedings as long ago as December 2015, the claim has had an unfortunate procedural history which meant that it only reached trial in July 2019. Regrettably, both sides have approached the matter as if it were a State Trial: there was a great deal of interlocutory skirmishing which continued right up to trial, a large volume of both documentary and witness evidence was produced and I received extensive written and oral submissions. It is not necessary for me to refer to all of this material in this judgment, and large parts of the documentary evidence turned out to be of little significance for reasons that will appear.

The witnesses

3. Even though a number of witnesses were dropped, I received evidence from a large number of factual witnesses: six employees or former employees of Glaxo; four solicitors employed by Glaxo's solicitors; six employees or former employees of Sandoz, Aeropharm and/or Hexal; one former employee of Vectura; four respiratory consultants; one junior hospital doctor; seven general practitioners ("GPs"); 13 pharmacists (two of whom were independent prescribers and two of whom were employed by Clinical Commissioning Groups, "CCGs"); one nurse independent prescriber; one physician associate; one regulatory affairs consultant; and one data analyst.

4. I do not consider it necessary to identify all of these witnesses or to discuss their evidence individually, although I shall mention some in context. I should, however, note two points.

5. The first is that, prior to the trial, Sandoz sought permission to adduce expert evidence from a respiratory consultant, a GP and a pharmacist. This application was

successfully opposed by Glaxo, which contended that the relevant evidence could and should be given by factual witnesses giving so-called "trade" evidence (as to which, see in particular *Fenty v Arcadia Group Brands Ltd* [2013] EWHC 1945 (Ch), [2013] Bus LR 1165). Subsequently, the Defendants objected to the admissibility of substantial parts of the witness statements served by Glaxo on various grounds, but in particular that some of the statements were in substance expert evidence and that parts of others amounted to expressions of opinion, and in particular speculation by the witnesses as to the thought processes of other persons. At the pre-trial trial review I largely, although not entirely, upheld the Defendants' objections. This led to a cross-application by Glaxo to exclude parts of the witness statements served by the Defendants on similar grounds, which I partly upheld. At trial, by contrast, both sides repeatedly asked questions in cross-examination which were at least arguably inadmissible without objection from the other (although the Defendants did object to certain questions which were sought to be put by Glaxo to a couple of witnesses). In assessing the evidence, I have attempted to give weight to the witnesses' evidence of fact and not to their expressions of opinion.

6. The second point is that counsel for the Defendants pointed out that the witness statements of some of Glaxo's trade witnesses contained passages which cross-examination revealed did not accurately reflect their practices. As counsel accepted, this was probably not the witnesses' fault: they are busy people who perhaps assumed that the statements which had been drafted for them were accurate without checking this sufficiently carefully. It follows, however, that it is the oral evidence which matters.

7. In addition to the evidence of the factual witnesses, I received written and oral evidence from a number of market survey experts. I shall address their evidence in context below.

Factual background

8. The factual background to this case is of considerable complexity, involving as it does matters of medicine, regulation of medicines, the manner in which prescription drugs are prescribed and dispensed in the UK and the marketing of the rival products. Much of the background is undisputed, but there are certain disputes. The following account contains my findings of fact in the light of all of the evidence.

9. Two important points to note at the outset concern dates. First, both asthma and COPD are chronic diseases. Particularly in the case of asthma, patients may suffer from it, and be treated for it, for decades. Although there have been many changes in the medications and inhalers available for the treatment of asthma and COPD over the years, some of the staple treatments, such as salbutamol, have been on the market in one form or another since the late 1960s or early 1970s. Many patients will have used such treatments for many years. For this reason, the history of the treatment of asthma and COPD remains relevant. Secondly, for reasons that will appear, the two key dates are November 2015 and February 2017. Quite a lot of the evidence adduced was directed to the position at later dates, which although still relevant is less important. I will endeavour to be specific as to dates where it matters.

The licensing of medicines

10. *Requirement for a marketing authorisation*. The marketing of medicinal products in the UK is regulated by the Human Medicines Regulations 2012 (SI 2012/1916, "the 2012 Regulations") made under the Medicines Act 1968 and the European Communities Act 1972. The 2012 Regulations implement European Parliament and Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use ("the Medicinal Products Directive").

11. It is an offence to sell or supply, or to offer to sell or supply, in the UK a medicinal product that does not have a relevant marketing authorisation: see regulations 46 and 47 of the 2012 Regulations and Article 6(1) of the Medicinal Products Directive.

12. *Procedures for applying for marketing authorisations*. An application for marketing authorisation may be made:

    i) to one Member State, for authorisation in that Member State only (see Chapter 1 of Title III of the Medicinal Products Directive);

    ii) to two or more Member States, for authorisation in those Member States (see Chapter 4 of Title III of the Medicinal Products Directive); or

    iii) to the European Medicines Agency, for authorisation throughout the European Union (see European Parliament and Council Regulation 726/2004/EC of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency).

13. Where an application is made to two or more Member States, it may follow the "mutual recognition" procedure or the "decentralised" procedure. The former applies where a marketing authorisation has already been granted in one of the Member States concerned. The latter applies in other cases.

14. Under the decentralised procedure, the applicant applies to each of the Member States simultaneously, nominating one of them to act as the "reference" Member State or RMS. That Member State must prepare preliminary and draft assessment reports, a draft summary of product characteristics ("SmPC") and a draft of the labelling and patient information leaflet ("PIL") in relation to the medicinal product see Article 28(1)-(3) of the Medicinal Products Directive. These documents must then be approved by all of the other Member States concerned or CMSs: see Article 28(4) of the Medicinal Products Directive. There is a fixed timetable for the RMS and the CMSs to take the necessary steps, which allows some time for consultation between the applicant and the RMS and the CMSs. It is also possible for the RMS to stop the clock for a period to allow the applicant to supplement its dossier and respond to questions which have been raised.

15. The Medicines and Healthcare products Regulatory Agency ("the MHRA"), acts on behalf of the UK as a CMS. The MHRA is an executive agency of the Department of Health and Social Care and is responsible for the regulation of medicines, medical devices and blood components for transfusion in the UK.

16. A CMS may object to a positive assessment given by the RMS on the basis of a "potential serious risk to public health". Article 29 of the Medicinal Products

Directive lays down the procedure for resolving such a dispute. As required by the Directive, the European Commission has adopted guidance on the meaning of "potential serious risk to public health" in this context: *Guideline on the definition of a potential serious risk to public health in the context of Article 29(1) and (2) of Directive 2001/83/EC – March 2006* [2006] OJEU C133/05. The guidance states:

> "— A '**potential serious risk to public health**' is defined as a situation where there is a significant probability that a serious hazard resulting from a human medicinal product in the context of its proposed use will affect public health.
>
> — '**Serious**', in this context, means a hazard that could result in death, could be life-threatening, could result in patient hospitalisation or prolongation of existing hospitalisation, could result in persistent or significant disability or incapacity, or could be a congenital anomaly/birth defect or permanent or prolonged signs in exposed humans.
>
> …
>
> Therefore, a potential serious risk to public health in relation to a particular medicinal product can mainly be considered to exist under the following circumstances:
>
> — Efficacy: the data submitted to support therapeutic efficacy in the proposed indication(s), target population(s), and proposed dosing regimen (as defined by the proposed labelling), do not provide sound scientific justification for the claims for efficacy; adequate proof for bioequivalence demonstrated by generic medicinal products to the reference medicinal product is lacking.
>
> …."

17. Once granted, the marketing authorisation will record, among other things, the strength of the medicine (i.e. in the case of an orally inhaled product, the nominal dose delivered per actuation of the inhaler), the medicine's indication (i.e. the health condition the medicine is licensed to treat) and the patient group for whom the medicine is licensed (e.g. adults (18 years and over), adolescents (12 years to 17 years) or children (4 years to 11 years).

18. *Information that must accompany an application*. The Medicinal Products Directive provides three main pathways to the grant of a marketing authorisation for a medicinal product.

19. The first pathway is for originators. The applicant for a marketing authorisation for an originator product must supply the information prescribed in Article 8(3) of the Medicinal Products Directive, and in particular the results of "pharmaceutical

(physico-chemical, biological or microbiological) tests, pre-clinical (toxicological and pharmacological) tests, clinical trials".

20. The second pathway is for generics once the originator's so-called "data exclusivity period" of 10 years has expired. Article 10(1) provides that the applicant for a marketing authorisation is exempted from providing the results of pre-clinical tests and clinical trials "if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community".

21. Article 10(2)(a) defines a "reference medicinal product" to mean "a medicinal product authorised under Article 6, in accordance with the provisions of Article 8".

22. Article 10(2)(b) defines a "generic medical product" to mean:

> "a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. ..."

23. The key requirement for this pathway is demonstrable "bioequivalence" to the originator's reference product. Bioequivalence can normally be demonstrated by showing that, for example in the case of a tablet, the generic tablet gives rise to equivalent levels of the active ingredient(s) in the blood. Where bioequivalence is demonstrated, it is presumed that the safety and efficacy demonstrated by the originator product's data will apply also to the generic. Where a product meets that requirement and the other requirements in Article 10(2)(b), it can be said to be a "pure generic" of the originator product.

24. Where a product is not such a "pure generic", a third gateway is provided by Article 10(3), which provides:

> "In cases where the medicinal product does not fall within the definition of a generic medicinal product as provided in paragraph 2(b) or where the bioequivalence cannot be demonstrated through bioavailability studies or in case of changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product, the results of the appropriate pre-clinical tests or clinical trials shall be provided."

25. This pathway is sometimes termed the "hybrid" route to a marketing authorisation. It is the appropriate route for a product such as a DPI which dispenses a locally acting product and where therefore its action in the body may depend upon the pattern of distribution of the active ingredient as delivered into the patient's lungs: see guidance published by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human ("CMDh") entitled *CMDh Questions & Answers, Generic Applications* (CMDh/272, Rev. 2, April 2017), which explains in the answer to Question 11 "Legal basis for products for local use":

> "Locally acting products are products which are applied locally and are assumed to exert their effect at the site of the application. Examples are … inhalatory products like powders or aerosols for inhalation … It is necessary to show for locally acting products that the product to be approved (either a generic or a reformulated product) is therapeutically equivalent to the product already approved (based on a full dossier).
>
> In order to demonstrate therapeutic equivalence, clinical trials are in principle necessary, but other models may be used. For this purpose, depending on the situation, human pharmacodynamic studies, local availability studies, animal studies or in vitro can be used, provided that all studies used are adequately validated and adequate justification is given for the absence of data."

The answer goes on to refer to the Guideline for orally inhaled products discussed below.

26. *Therapeutic equivalence of orally inhaled products*. The European Medicines Agency has produced guidance on the clinical information that should be submitted in support of such an application where authorisation is sought in respect of an orally inhaled product: *Guideline on the requirements for clinical documentation for orally inhaled products (OIP) including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of asthma and chronic obstructive pulmonary disease (COPD) in adults and for use in the treatment of asthma in children and adolescents* (CPMP/EWP/4151/00, Rev. 1, 22 January 2009).

27. This guidance explains (among other things) how an applicant can demonstrate the required "therapeutic equivalence" between a reference medicinal product and a new product containing the same active substance. It defines "therapeutic equivalence" as meaning "[e]fficacy and safety profile of the test and reference products are sufficiently comparable so that a clinically relevant difference between products can be realiably excluded."

28. Section 9 of the guidance explains that children and adolescents present additional challenges when assessing the equivalence of orally inhaled products. For example, page 19 states:

> "The airway in the younger child differs from the airway in the adult and the amount of dose of an inhaled drug reaching the lower airway in an infant and in a young child will differ from the amount which would reach the lower airway in an adult. The child displays different breathing patterns and has differing tidal volumes, airway geometry, etc compared with adults. ….
>
> The characteristics of the delivery device may be such that the device is more difficult for a child to use than it is for an adult and therefore the child is less able to use the device correctly, or the child may use the device differently from an adult. Such

> differences in the handling of the product by a child may result in a changed risk/benefit relationship in the child compared with that seen in the adult. Examples include the following:
>
> …
>
> - The internal resistance of the DPI may be such that a child will find the inhaler more difficult to use than would an adult. Therefore when comparing two DPIs which may be equivalent in adults, equivalence may not be demonstrated in children who inhale with a lower PIF [peak inspiratory flow]."

29. *Requirement for brand name*. It is common ground between the parties that, in the case of an inhaler, the MHRA will require an applicant for a marketing authorisation under Article 10(3) to provide the product with a brand name. The reason for this requirement is that (as explained below) such products should be prescribed by brand and not by the generic or international non-proprietary name ("INN") of the active ingredient(s) even when the active ingredient(s) are generic ones.

Advertising of medicines

30. Prescription-only medicines ("POMs") (as to which, see below) cannot lawfully be advertised directly to patients. Regulations 282 and 284(1) of the 2012 Regulations provide that, in the case of "advertisements wholly or mainly directed at members of the public", "[a] person may not publish an advertisement that is likely to lead to the use of a prescription only medicine."

31. Publication of an advertisement is widely defined in regulation 277(1) as follows:

> "'publication', in relation to an advertisement, means the dissemination or issue of that advertisement—
>
> (a) orally;
>
> (b) in writing;
>
> (c) by means of an electronic communications network within the meaning of the Communications Act 2003; or
>
> (d) in any other way,
>
> and includes causing or procuring such publication by or on behalf of another person, and
>
> 'publish' has a corresponding meaning."

32. These regulations superseded regulation 3 of the Medicines (Labelling and Advertisement to the Public) Regulations 1978, made under section 95 of the Medicines Act 1968, which was to similar effect.

33. It follows that POMs can be promoted to patients only in limited and indirect ways, e.g. by persuading GPs to hand out non-promotional information leaflets to patients. According to guidance given in the MHRA's publication *The Blue Guide: Advertising and Promotion of Medicines in the UK* at section 7.6, "any such materials should provide a demonstrable benefit to the patient." The guidance goes on:

> "Patient materials may include alert cards for patients to carry, leaflets about the disease and the treatment or additional advice on how to take the medicine, for example a video showing how the product is prepared and administered. The materials should be factual and promotional claims must not be included. Consideration should always be given to whether this information can be included in the patient information leaflet which accompanies all medicines."

Prescribing

34. *Prescribing generally*. When a marketing authorisation is granted, the medicinal product must be classified as either subject to medical prescription or not subject to medical prescription: see Articles 70 and 71 of the Medicinal Products Directive. Furthermore, a UK marketing authorisation is required to include a term stating that the product is to be available either only on prescription or only from a pharmacy or on general sale: see regulation 62 of the 2012 Regulations.

35. Regulation 214 of the 2012 Regulations provides, so far as relevant:

> "(1) A person may not sell or supply a prescription only medicine except in accordance with a prescription given by an appropriate practitioner.
>
> …
>
> (3) The following are appropriate practitioners in relation to any prescription only medicine—
>
> (a) a doctor;
>
> …
>
> (c) a supplementary prescriber;
>
> (d) a nurse independent prescriber; and
>
> (e) a pharmacist independent prescriber.
>
> …"

36. The General Medical Council ("the GMC") has published guidance on *Good practice in prescribing and managing medicines and devices* (March 2013). Under the heading "Keeping up to date and prescribing safely", this states at paragraph 11:

> "You should take account of the clinical guidelines published by the:
>
> a NICE (England)
>
> b Scottish Medicines Consortium and Health Improvement Scotland (including the Scottish Intercollegiate Guidelines Network) (Scotland)
>
> c Department for Health, Social Services and Public Safety (Northern Ireland)
>
> d All-Wales Medicines Strategy Group (Wales)
>
> e medical royal colleges and other authoritative sources of specialty specific clinical guidelines."

37. *Branded vs. generic prescribing*. A prescription may be written by reference to either the proprietary (brand) name of a medication or its INN (generic name). It should be noted that generic versions of originator products may be sold under brand or generic names. As discussed below, in the case of inhalers, it is necessary to distinguish between the name of the medication and the name of the inhaler which delivers it: again, the latter may be generic or branded.

38. Generic prescribing is encouraged at all levels of the healthcare system, including by the Department of Health, NHS England, CCGs (or Health Boards in Wales, Scotland or Northern Ireland – for convenience, I shall just refer to CCGs) and the medical professions. This is for both clinical and financial reasons. The clinical reasons are that prescribing generically helps remind clinicians of the therapeutic action of the drug, enables greater certainty amongst healthcare professionals ("HCPs") when treating a patient (e.g. when the patient moves between care providers) and promotes dispensing flexibility (and hence speed). The financial reasons are explained below.

39. It is common ground between the parties that, as explained in more detail below, inhalers such as those in issue in this case should be prescribed by brand even if the active ingredients they contain are generic ones.

40. *"Off-label" prescribing*. Generally speaking, a prescriber is entitled to rely upon the fact that a drug has a marketing authorisation for a particular indication and patient group when prescribing that drug for that indication and group. In addition, however, prescribers can, in the exercise of their own clinical judgment and at their own risk, prescribe an authorised drug for an unauthorised indication and/or for an unauthorised patient group. Because it has been authorised, it should be generally safe (although care will need to be taken in relation to known side effects). Even if it has not been authorised for the indication and/or patient group in question, the prescriber may have reason for believing that the drug will be effective in treating that indication and/or group. This is commonly referred to as "off-label" prescribing.

41. The GMC's guidance on prescribing states:

> "68. You should usually prescribe licensed medicines in accordance with the terms of their licence. However, you may prescribe unlicensed medicines where, on the basis of an assessment of the individual patient, you conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient.
>
> 69. Prescribing unlicensed medicines may be necessary where:
>
> a There is no suitably licensed medicine that will meet the patient's need. …
>
> b Or where a suitably licensed medicine that would meet the patient's need is not available. …
>
> 70. When prescribing an unlicensed medicine you must:
>
> a be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
>
> b take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so
>
> c make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.
>
> 71 You must give patients (or their parents or carers) sufficient information about the medicines you propose to prescribe to allow them to make an informed decision.
>
> …
>
> 73 If you intend to prescribe unlicensed medicines where that is not routine or if there are suitably licensed alternatives available, you should explain this to the patient, and your reasons for doing so.".

Dispensing

42. A POM can only be sold or supplied in accordance with a prescription: see regulation 214 of the 2012 Regulations set out above. It is an offence to sell or supply it in contravention of regulation 214: see regulation 255 of the 2012 Regulations. It is also an offence to sell or supply a medicinal product which is not of the "nature or quality" specified in a prescription: see section 64 of the Medicines Act 1968.

43. Where the prescription is written generically, the pharmacist is free to dispense a branded drug or a generic one. Where the prescription specifies a particular brand,

however, the pharmacist must dispense that brand in order to avoid (a) breaching regulation 214 and (b) committing trade mark infringement and/or passing off.

The NHS Drug Tariff

44. The NHS Drug Tariff ("the Drug Tariff") sets out the main mechanism by which pharmacists are paid by the NHS for dispensing drugs against NHS prescriptions. The Drug Tariff sets out both the remuneration pharmacists receive for their services and the reimbursement price they receive for dispensing drugs. Part VIII contains a range of commonly used drugs. Part VIII is divided into five categories: A (readily available drugs, where the reimbursement price is calculated from a weighted average of the list price for four suppliers, provided that the drug is available from both of two of the suppliers or from one of those two and the other two), B (where usage has declined over time), C (price based on a particular brand or supplier), E (extemporaneously prepared) and M (the most widely available drugs, where the reimbursement price is calculated by the Department of Health in accordance with an agreement negotiated between the Department and the British Generic Manufacturers Association under section 261 of the National Health Service Act 2006). The Drug Tariff is produced monthly by the Pharmaceutical Directorate of the NHS Business Services Authority.

45. Where a product is listed in Category C, pharmacists can claim reimbursement by reference to the originator's list price if what is prescribed is the originator's brand or by reference to the branded generic's price if what is prescribed is a branded generic. In the case of a Category C product prescribed by reference to the INN, reimbursement is at the originator brand's list price regardless of the brand dispensed.

Asthma and COPD

46. Asthma and COPD are both respiratory conditions and share some symptoms, but there are some differences between them. Some patients may have both conditions.

47. Asthma is defined by the World Health Organisation ("the WHO") as:

> "a chronic disease characterised by recurrent attacks of breathlessness and wheezing, which vary in severity and frequency from person to person … During an asthma attack, the lining of the bronchial tubes swell, causing the airways to narrow and reducing the flow of air into and out of the lungs."

48. Asthma can affect all ages and population groups, and it is the most common chronic disease among children. If it is effectively diagnosed and treated, an asthma patient may experience few symptoms most of the time. Even then, however, the patient may experience occasional exacerbations due, for example, to lung infections or encountering specific allergens.

49. COPD is defined by the WHO as:

> "not one single disease but an umbrella term used to describe chronic lung diseases that cause limitations in lung airflow. The more familiar terms 'chronic bronchitis' and 'emphysema' are no longer used but are now included within the COPD

> diagnosis. The most common symptoms of COPD are breathlessness, or a 'need for air', excessive sputum production, and a chronic cough. However, COPD is not just simply a 'smoker's cough', but an under-diagnosed, life threatening lung disease that may progressively lead to death."

50. Whereas asthma is not a progressive disease (unless ineffectively treated, in which case exacerbations may cause irreversible damage), COPD is progressive and the purpose of treatment is to slow it down rather than to eliminate its symptoms. COPD is caused by external factors (most commonly, smoking) and therefore affects an older population than asthma. Most patients are at least 45 years old, and often much older. It is not a condition that affects children. As COPD patients are older and COPD arises from lifestyle factors, it is also very common for COPD patients to suffer from other conditions such as diabetes, cardiovascular disease or depression.

51. The symptoms of asthma and COPD are most frequently treated with medication delivered directly to the lungs through the use of inhalers. (It may be desirable for the patient to use a spacer device in conjunction with their inhaler, but for the purposes of this dispute spacers can be ignored.) It is important to try to ensure that as much as possible of the nominal dose of medication delivered by each actuation of the inhaler actually reaches the patient's lungs rather than being deposited on the patient's mouth or throat. Considerable skill and effort has gone into the design of inhalers over the years to achieve this. Even so, delivery of the full dose still requires the patient correctly to use the inhaler. I shall return to this point below.

The treatment of asthma and COPD with inhalers

52. There are two main classes of inhalers used in the treatment of asthma and COPD: those containing fast-acting medication taken as needed during an exacerbation of the condition for immediate relief of symptoms (often referred to as "relievers" or "rescue inhalers") and those containing long-acting medication taken regularly (for example daily or twice daily) in order to minimise and prevent symptoms and exacerbations from developing (often referred to as "preventers" or "maintenance inhalers"). The short-acting medications are short-acting bronchodilators which open the patient's airways rapidly, but whose effects do not last very long. The long-acting medications may be either long-acting bronchodilators or anti-inflammatories which reduce inflammation in the lungs.

53. The main categories of short-acting medications are:

    i) short-acting β2 agonists ("SABAs") such as salbutamol and terbutaline; and

    ii) short-acting muscarinic antagonists ("SAMAs") such as ipratropium.

54. The main categories of long-acting medications are:

    i) inhaled corticosteroids ("ICSs") such as beclometasone, budesonide and fluticasone;

    ii) long-acting β2 agonists ("LABAs") such as salmeterol and formoterol;

iii) long-acting muscarinic antagonists ("LAMAs") such as tiotropium;

iv) ICS/LABA combinations;

v) LABA/LAMA combinations; and

vi) ICS/LABA/LAMA combinations.

55. Patients prescribed an inhaler containing a long-acting medication are frequently also prescribed an inhaler containing a short-acting medication. This is because the long-acting medication does not work fast enough to combat acute breathlessness. Therefore asthma and COPD patients will often have more than one kind of inhaler.

56. There are two main types of inhaler device: MDIs and DPIs. MDIs were introduced in 1957. Although a DPI had been marketed before that, the first commercially successful DPI was the Spinhaler which was introduced by Fisons in 1971.

57. MDIs typically contain the pharmaceutical in liquid form combined with a propellant chemical compressed in a cylinder which when actuated forms aerosols which are sprayed into the patient's airways. MDIs require good mental and physical co-ordination by the patient in order to deliver the correct dose, because good technique is required to coordinate actuation and inhalation in order to prevent the medication being sprayed onto the back of the throat rather than taken into the lungs. MDIs are nevertheless well suited to emergency relief medication where a patient suffering a severe episode of breathlessness may not have the ability to inhale with sufficient force to use a DPI.

58. In a DPI the pharmaceutical compound is presented in a fine particulate dust and the patient is required to use their own breath to deliver the drug into the lungs through inhalation. This results in the patient needing to exert a good degree of inspiratory effort, but on the other hand results in a more efficient intake of the drug into the lungs.

59. For many years after their introduction, MDI devices (as opposed to the medications they contained) were not themselves branded. More recently, however, some branded MDI devices have been introduced, such as Glaxo's Evohaler. DPI devices have generally been branded since the Spinhaler was launched. Prior to the Accuhaler, Glaxo had a DPI called the Diskhaler.

60. For medications delivered by MDIs, generic prescriptions are generally acceptable because most MDIs are boot-shaped "puffers" which operate in very similar ways and require a near-identical inhalation technique. In recent years, however, more and more DPIs have been introduced which have different designs requiring different actuation and inhalation techniques on the part of the patient. This has led to guidance being issued which recommends branded prescribing for inhalers (see further below).

Prescribing guidelines for asthma and COPD

61. For both asthma and COPD, various national and international guidelines have been published aimed at assisting HCPs in determining the appropriate pharmacological intervention at different stages of a patient's condition.

62. *NICE Guidelines*. The National Institute for Health and Care Excellence ("NICE") has existed since 1999 when it was set up as a special health authority. It was established as a non-departmental public body by the Health and Social Care Act 2012. Its functions are set out in the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations SI 2013/259. They include "giving advice or guidance, providing information or making recommendations about any matter concerning or connected with the provision of … NHS services, … public health services, or … social care in England" (regulation 5).

63. NICE guidelines are developed by independent committees of experts based on the best evidence available of what works (and what it costs). The guidelines contain evidence-based recommendations on, *inter alia*, the care and services that are suitable for most people with a specific condition or need. Many recommendations are intended "for individual health and social care practitioners who should use them in their work in conjunction with their own judgment and discussion with people using services".

64. NICE has issued guidelines for HCPs with respect to the management of both asthma and COPD. These are:

    i) *Asthma: diagnosis, monitoring and chronic asthma management* published on 29 November 2017 ("the NICE Asthma Guideline"); and

    ii) *Chronic obstructive pulmonary disease in over 16s: diagnosis and management* published on 5 December 2018 ("the NICE COPD Guideline").

65. NICE also commissions and funds the development of Clinical Knowledge Summaries. These are "concise, accessible summaries of current evidence for primary care professionals" (such as GPs, nurses and pharmacists). They are developed using the best available evidence and provide "trusted information to support safe decision-making and improve standards of care". Clinical Knowledge Summaries have been developed for both asthma ("the Asthma CKS") and COPD ("the COPD CKS").

66. *BTS/SIGN Guidelines*. The British Thoracic Society ("BTS") and the Scottish Intercollegiate Guidelines Network ("SIGN"), part of NHS Scotland, have jointly developed guidelines on the management of asthma, namely the *British guideline on the management of asthma: A national clinical guideline* published in September 2016 ("the BTS/SIGN Guidelines"). These guidelines provide "recommendations based on current evidence for best practice in the management of asthma" targeted at "healthcare professionals involved in the care of people with asthma including general practitioners, consultants and specialists in respiratory medicine, nurses and pharmacists".

67. BTS and SIGN have also produced a Quick Reference Guide ("the BTS/SIGN QRG") which provides a summary of the main recommendations in the BTS/SIGN Guidelines.

68. *GINA guidance*. The Global Initiative for Asthma ("GINA") is an international organisation launched in 1993 whose objectives include improving the management of asthma and reducing asthma morbidity and mortality. GINA works to improve the

lives of people with asthma around the world "[t]hrough resources such as evidence-based strategy documents for asthma management".

69. GINA produces a report titled *Global Strategy for Asthma Management and Prevention*, last updated in 2018 ("the GINA Report"). This document is "intended as an evidence-based asthma management strategy, for the use of health professionals and policy-makers". It is based "on current best evidence and medical knowledge and practice at the date of publication".

70. GINA also publishes a *Pocket Guide for Health Professionals* which constitutes a "brief summary of the GINA 2018 report, for primary health care providers" ("the GINA Guidelines").

71. *GOLD guidance*. The Global Initiative for Chronic Obstructive Lung Disease ("GOLD") is an international organisation launched in 1997 whose objectives include "recommend[ing] effective COPD management and prevention strategies for use in all countries".

72. GOLD produces a report entitled *Global Strategy for Diagnosis, Management and Prevention of COPD*, last updated in 2019 ("the GOLD Report"), which is used worldwide as a tool to implement effective management programs based on local healthcare systems. GOLD also publishes a *Pocket Guide to COPD Diagnosis, Management, and Prevention* based on the Gold Report ("the GOLD Guidelines").

73. *Branded vs INN prescriptions*. The NICE Asthma Guideline and Asthma CKS and the BTS/SIGN Guidelines and BTS/SIGN QRG all state that generic prescribing of inhalers should be avoided because this may lead to patients being given an unfamiliar device which they are not able to use properly.

74. Similar advice is contained in various NHS publications, such as a *Right Care Bulletin* published by the NHS London Procurement Partnership in September 2016 headed "Advice on Prescribing Inhalers by Brand Name". The key recommendation is to "Prescribe Inhalers by BRAND name and specify the DEVICE so that patients get the right inhaler every time." The following reasons are given for this recommendation:

> "There is a significant continuing growth in the number of combination inhalers in the UK respiratory market.
>
> There is a significant chance that a generic prescription for a combination inhaler can result in the patient getting different devices on different occasions. Unfamiliar devices can result in poor adherence and sub-optimal treatment.
>
> The only way for a prescriber to make sure that the patient gets the specific inhaler product that they intended, is by specifying it by brand and device name.
>
> For example, if budesonide/formoterol is prescribed this could result in the Symbicort Turbohaler or DuoResp Spiromax being

> dispensed. These are different devices even though the drug components are the same.
>
> There are differences in licensed indications, e.g. Seretide Evohaler & Symbicort Turbohaler are an option for 12 years and over (all strengths). SirDupla pMDI & DuoResp Spiromax is an option for 18 years and over (both strengths).
>
> There are differences in strengths available e.g. SirDupla and DuoResp don't currently have the lower strengths. DuoResp is available in 200/6 & 400/12 and SirDupla is available in 125/25 & 250/25.
>
> There may be compatibility issues with spacers e.g. Seretide is to be used with a Volumatic or an Aerochamber Plus; SirDupla is compatible with an Aerochamber Plus only.
>
> When a combination inhaler is considered an appropriate option, NICE guidance recommends taking into account patient preference as well as cost. Combination inhalers are commonly category C in the drug tariff, so if the more cost effective inhaler is chosen by the patient & practitioner then savings will be seen every time it is prescribed by brand name."

75. *The importance of training and adherence*. The NICE Asthma and COPD Guidelines and Asthma and COPD CKSs, the BTS/SIGN Guidelines and BTS/SIGN QRG, the GINA Guidelines and the GOLD Guidelines all emphasise the importance of patients being trained to use their inhalers properly. Furthermore, the NICE documents state that patients should be advised about their technique "whenever a new type of device is supplied" (to quote the Asthma Guideline).

76. Furthermore, the NICE Asthma and COPD Guidelines and Asthma and COPD CKSs, the BTS/SIGN Guidelines and BTS/SIGN QRG, the GINA Guidelines and the GOLD Guidelines all explain that patient adherence to treatment is important, and the Asthma Guidelines also explain that poor adherence to treatment with preventers is a common problem with asthma patients.

77. *Downward titration in asthma*. The NICE Asthma Guideline and Asthma CKS, the BTS/SIGN Guidelines and the GINA Guidelines all recommend that, once a patient's asthma is under control, therapy, and in particular ICS therapy, should be reduced to the lowest level that keeps it under control. This is known as "downwards titration". The reason for this is that all medications, and particularly ICSs, have undesirable side effects, particularly when administered for long periods.

Local guidelines and formularies

78. Local areas, hospital trusts and CCGs often develop their own guidelines based on national recommendations and clinical evidence in order to guide the prescribing decisions of prescribers. These guidelines will often involve the use of a local formulary. This is a list of medicines approved for use in the local area and is designed to encourage more clinically-effective and cost-effective prescribing.

Whether or not a particular inhaler should be included within the formulary will usually be discussed at prescribing committees by a multi-disciplinary team of decision makers. The prescribing committees will assess all aspects of an inhaler. They will consider clinical evidence, any licensing limitations, safety and the viability of the device (e.g. in terms of ease of use and the stability of the active ingredient). The cost of the inhaler will also be taken into account, as will logistical considerations relating to the provision of the inhaler to dispensaries.

79. Generally, most CCGs encourage prescribers in their area to adhere to the prescribing recommendations in their local formulary. Prescribers can, however, prescribe non-formulary products.

The prescribing process for inhalers

80. Inhalers are POMs. The process by which they are prescribed can be summarised as follows:

i) Diagnosis: the first step is to diagnose the patient (apart from in a hospital setting where the patient has already been diagnosed in primary care or otherwise, in which case the patient's clinical history is reviewed). For patients with respiratory conditions, this would typically involve lung function tests (to measure and assess the airflow in the patient's lungs) and other tests (such as thoracic CT scans or a histamine challenge test) if necessary. The patient will also be asked about their medical history.

ii) Selecting the right drug treatment: following diagnosis, the prescriber will then decide what active ingredient or combination of active ingredients (and the dose of that active ingredient or combination) would be most appropriate to treat the relevant condition. This tends to be the primary factor in the decision-making process. The national and/or local guidelines are typically followed when making this decision.

iii) Selecting the right device: once the appropriate active ingredient (or combination) has been identified, the prescriber will decide which device is most suitable for the patient. Important factors which drive this decision may include licensed indications, the age and dexterity of the patient, the patient's inhaler technique, encouraging the patient's adherence and whether the patient is already accustomed to using a particular device.

iv) Generating the prescription: once the decision on the inhaler has been made, the prescriber must generate the prescription. Prescriptions can be generated by hand or, more usually, electronically using one of a number of different computer programs (such as SystmOne, OptimiseRx, Emis, Lorenzo, ScriptSwitch). These programs provide prescribing information and/or alternative recommendations at the point of prescribing. The prescribing information and alternative recommendations are locally authorised by the CCGs. Prescribers are free to either accept or decline a recommendation on the system. Some programs like ScriptSwitch can be set up to encourage prescribers to prescribe by brand.

81. Some prescribers will also provide their asthma patients with personalised asthma action plans ("PAAPs"). Many PAAPs are based on a template produced by Asthma UK. This includes sections on everyday asthma care, what to do when the patient is feeling worse and what to do in an attack.

82. The everyday asthma care section includes the following part for the patient to fill in:

> "My daily asthma routine
>
> My **preventer** inhaler (insert name/colour): ….
>
> I need to take my **preventer** inhaler every day even when I feel well
>
> …
>
> My **reliever** inhaler (insert name/colour): ….
>
> I take my **reliever** inhaler only if I need to".

83. The guidance on what to do in an asthma attack includes the following:

> "**Take one puff of your reliever inhaler (usually blue)** every 30-60 seconds, up to a maximum of 10 puffs."

Switching patients to different inhalers

84. During the prescribing process, patients can be switched to a new inhaler from what they were previously on, either because their treatment needs to be changed or because an inhaler is no longer recommended or because a cost-effective generic alternative has come onto the market. Sometimes, the switch will be CCG-led (see below). In the event of a switch occurring, affected patients should be, and generally are, informed that they will be given a different inhaler during a one-to-one consultation, over the telephone and/or in a letter.

CCG-led switching

85. CCGs can recommend to prescribers within their area that patients be switched to a different, perhaps more cost-effective, medicine. For example, a CCG may tell its constituent GP surgeries that they wish a cheaper generic to be prescribed instead of a more expensive originator medicine. In the event of CCG-led switching, steps will be taken to ensure that patients are properly informed.

Dispensing guidelines and Standard Operating Procedures

86. A pharmacy has to be licensed by the General Pharmaceutical Council ("GPhC") in order to dispense medicines. The GPhC sets out standards and codes of practice that pharmacists and pharmacies are required to adhere to and can inspect any pharmacy to ensure that a pharmacy is meeting the expected standards. In addition, in order to dispense NHS prescriptions, a pharmacy will need to have a separate licence with the NHS.

87. The Royal Pharmaceutical Society publishes an annual guide to help pharmacists to adhere to the standards set by the GPhC entitled *Medicines, Ethics and Practice: The professional guide for pharmacists*. Edition 43 was published in July 2019.

88. Each pharmacy is required to have its own set of Standard Operating Procedures ("SOP"), which are reviewed annually by a superintendent pharmacist employed by that pharmacy. The SOP sets out the steps in the dispensing process that should be followed, including what staff members must do when a patient comes in, what to look for on the prescription, how to check that a prescription is legal and valid, and how to process it. The National Pharmacy Association ("NPA") publishes templates for SOPs. Before starting work in a new pharmacy, a pharmacist would be required to read the SOP for that pharmacy and then to follow it. This will help minimise dispensing errors (as to which, see further below).

89. It is a pharmacist's professional responsibility to keep up to date with the medicines they dispense (again, see further below).

The dispensing process in community pharmacies

90. Although there are minor variations in practice in the dispensing protocols within the SOPs of different pharmacies, community pharmacies generally have similar protocols for dispensing. The following key steps will usually be taken:

    i) Receiving the prescription: the first step in the dispensing process is for the patient (or someone else on behalf of the patient) to submit the prescription to one of the pharmacy staff at the pharmacy counter. The number of staff will depend on the size of the pharmacy. The prescription can also be submitted electronically from the GP practice. The pharmacy staff will typically perform an initial check to ensure that the prescription is legal (for example signed and dated by the prescriber) and to ascertain whether it is an NHS or private prescription.

    ii) Choosing the inhaler: once checked, the prescription is provided to a dispenser (who may be a pharmacy assistant rather than a qualified pharmacist) to choose the inhaler which is to be dispensed. The dispenser will enter the prescription information into the pharmacy's computer system. If the prescription is branded, the brand name will be entered into the computer system and that inhaler will subsequently be selected from the pharmacy shelf. If the prescription has been written generically, the computer system will provide a list of the inhaler options that match the generic prescription and one of those inhalers will be selected from the pharmacy shelf. The considerations that may be taken into account when making this decision include costs savings/profit margins, pharmacy preference and whether the patient has been on a particular brand before.

    iii) Selecting the inhaler from the pharmacy shelf: the inhaler is then selected by the dispenser from the pharmacy shelf. The way in which pharmacies arrange their medicine stocks differs from pharmacy to pharmacy. For example, inhalers may be arranged alphabetically by brand name or by active ingredient.

iv) Clinical checking: the pharmacist will undertake a clinical check of the prescription which could happen at any stage during the dispensing process. With inhalers, this will typically involve ascertaining whether the prescription in question is a new prescription, whether the strength and frequency of dosage written on the prescription are correct, whether there are any licensing issues and what inhaler brand the patient was on before (which will be recorded on the pharmacy's computer system if the patient has had a prescription filled by that pharmacy before). A good pharmacist will also try to check whether the inhaler seems appropriate for the patient's condition. Since relatively few prescriptions indicate the condition the medication has been prescribed for, this will usually involve asking the person presenting the prescription. Since many prescriptions are presented by relatives or carers, that person may not know. In that case, the patient's electronic Summary Care Record ("SCR") can be accessed by the pharmacist to find out, but only if the patient has given consent. If the SCR cannot be accessed, the pharmacist could try telephoning the prescriber if the pharmacist has a concern, but this is likely to be difficult. (Communication may be easier if the pharmacy is located in the same premises.) Thus it will not always be possible even for a diligent pharmacist to check this.

v) Labelling: before dispensing the inhaler, the inhaler and/or the packaging is labelled. The label comprises the name of the patient, the date, the pharmacy's address, the strength of the medication, the administration regime and any warnings.

vi) Final check: the product and label are checked against the prescription by the pharmacist. The label is typically initialled by the pharmacist before it is handed to the customer, together with any instructions on how to take the medication.

Patient training and instruction

91. As discussed above, it is important for patients to be trained to use a new device in order to ensure that the patient is using the device correctly and thereby getting the correct dose of medication. The training may be carried out either by the prescriber or the dispenser. Some prescribers will physically show the patient how to use the device or do so by showing them a video, e.g. on the RightBreathe website. (RightBreathe is a website (and now app) launched in April 2017 covering inhaler and spacer devices licensed in the UK for treating asthma and COPD. It provides online assistance to GPs, primary care nurses and respiratory specialists in choosing the correct inhaler for their patient. It can also be used by patients to learn how to use their inhaler: the profile page for each product links to video clips for instructing the patient in the use and inhalation technique for each type of device. It was founded by Dr Azhar Saleem, a GP who was one of the Defendants' trade witnesses.)

92. When a patient is dispensed a particular inhaler for the first time, it is good practice for the pharmacist to ask whether they know how to use it and, if necessary, give training on how to use it. If the patient is dispensed an inhaler they have previously been dispensed and know how to use, then training is not typically needed. Some pharmacies periodically carry out "medical use reviews" where they check patient technique.

Dispensing errors

93. Pharmacists are trained professionals who are trained to be on their guard against dispensing errors. Further, as explained above, pharmacies have procedures in place to try and minimise dispensing errors. As Glaxo point out, however, it is clear from the evidence that dispensing errors do sometimes occur. For example, in April 2017 the NPA issued an *Inhaler identification checker* to assist pharmacists and their members of staff with selecting the correct inhaler for dispensing against generic prescriptions. The introduction to this document states:

> "Information received through the NPA's patient safety incident reporting system has identified incorrect dispensing of inhalers against generically written prescriptions as a common issue. Examples of this include:
>
> - Wrong drug(s) being supplied – for example, … Seretide®/fluticasone …
>
> - Wrong device(s) being supplied – for example, Evohaler®/Accuhaler®… "

94. The introduction goes on:

> "The licensed indications for inhalers vary and some may only be licensed for patients over a particular age – individual Summaries of Product Characteristics (SPCs) should be referred to when dispensing an inhaler on a prescription to ensure that it is licensed for the patient's age and indication. For example, AirFluSal® Forspiro® (salmeterol 50mcg/ fluticasone 500mcg) is only licensed for use in adults aged 18 years of age and older."

Ventolin

95. Salbutamol was first marketed by Allen & Hanburys Ltd, a predecessor of Glaxo, in 1969 under the brand name Ventolin. Ventolin continues to be marketed by Glaxo to this day. Ventolin was originally marketed in an unbranded MDI which was coloured blue. Since the introduction of the Accuhaler and the Evohaler, Ventolin has been marketed in the form of Ventolin Accuhaler (200 µg per actuation) and Ventolin Evohaler (100 µg per actuation). The inhalers are both coloured two shades of blue (a lighter shade and a darker shade) while the packaging of both inhalers features the lighter shade of blue and white.

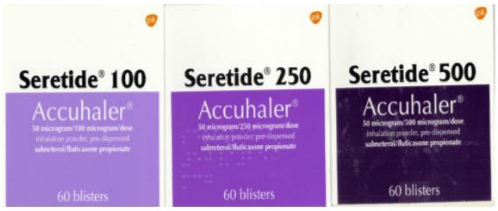
Serevent, Flixotide and Seretide

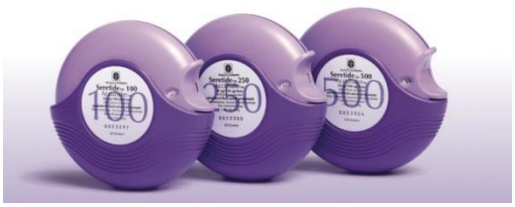
96. Glaxo have marketed salmeterol under the brand name Serevent since 1990. Glaxo have marketed fluticasone under the brand name Flixotide since 1993. Serevent and Flixotide were originally marketed solely in MDI form. In 1994 Glaxo introduced its Accuhaler device, and Serevent and Flixotide have been marketed in Accuhaler form since 1994 and 1995 respectively. The Accuhaler won awards for its design.

97. Serevent is and has always been marketed in inhalers coloured two shades of green and packaging coloured green and white. The same shade of green is used on the packaging of the Accuhaler and the Evohaler, and on the body of the Evohaler and the larger part of the Accuhaler, although the Evohaler delivers a 25 µg dose of salmeterol and the Accuhaler a 50 µg dose.

98. Flixotide is and has always been marketed in inhalers coloured two shades of orange and packaging coloured orange and white. The shade of orange on packaging varies with the strength of the medication: a pale orange for the 50 µg fluticasone Evohaler and 100 µg fluticasone Accuhaler; a mid orange for the 125 µg Evohaler and the 250 µg Accuhaler; and a dark orange for the 250 µg Evohaler and the 500 µg Accuhaler. The shade of orange used on the body of the Evohaler varies with the strength in the same way, while the cap is always a pale colour. The Accuhaler is the same two shades of orange regardless of strength, although the labelling differs.

99. In 1999 Glaxo launched the Seretide Accuhaler. It was the first product in the UK to consist of a combination of two preventers, a LABA and an ICS, in one inhaler. Three different strengths were and remain available: 50 µg salmeterol/100 µg fluticasone, 50 µg salmeterol/250 µg fluticasone and 50 µg salmeterol/500 µg fluticasone. In 2000 Glaxo launched the Seretide Evohaler. Again, three strengths were and remain available: 25 µg salmeterol/50 µg fluticasone, 25 µg salmeterol/125 µg fluticasone and 25 µg salmeterol/250 µg fluticasone. Seretide is and has always been marketed in inhalers and packaging coloured shades of purple. The pattern of the shades is similar to that for Flixotide, as shown in the case of the Accuhaler by the images below (note that, although the Accuhalers are shown "standing up" in the bottom photograph, they cannot in fact stand vertically unaided due to their shape).





100. It can be seen from the foregoing that Glaxo market, and have for many years marketed, Accuhalers and Evohalers containing four different active ingredients (or in one case a combination of active ingredients) which are differentiated both by the brand name of the active ingredient (Ventolin, Serevent, Flixotide and Seretide) and by the colour of the inhalers and packaging (blue, green, orange and purple). It can also be seen that, in the case of Flixotide and Seretide, the shade of the colour used on the packaging and on the Evohalers varies with the strength of the medication, with darker shades for stronger medication.

Marketing authorisations for Seretide Accuhaler

101. The different strengths of Seretide Accuhaler have at all material times had marketing authorisations for the following indications and patient groups:

i) 100 µg fluticasone– asthma in adults, adolescents and children;

ii) 250 µg fluticasone– asthma in adults and adolescents;

iii) 500 µg fluticasone– asthma in adults and adolescents, COPD in adults.

Sales of Seretide in the UK

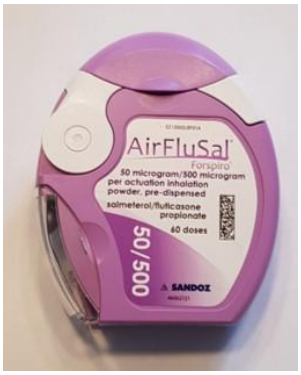
102. Seretide has been phenomenally successful. By 2014, over 113 million Seretide inhalers had been sold in the UK alone. Seretide is the second best-selling pharmaceutical product of all time in the UK. At its peak in 2010 and 2011, Seretide had over 42% of the UK inhaler market. Current UK sales still exceed £400 million per annum.

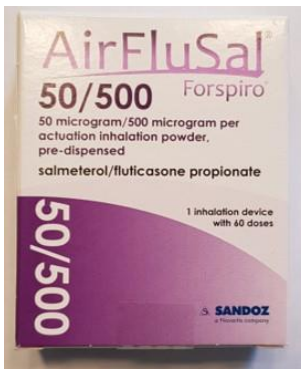
103. From 1999 to May 2015 Seretide Accuhaler and Evohaler were the only inhalers on the UK market coloured purple and sold in packaging coloured purple. This changed with the launch of Sirdupla and Aloflute in May 2015 (as to which, see below), but there is no evidence as to the extent to which Sirdupla/Aloflute had penetrated the market by November 2015.

The AirFluSal Forspiro product

104. AirFluSal Forspiro is a so-called "differentiated" generic because, although the active ingredients are generic pharmaceutical compounds, the ingredients are delivered by a proprietary inhaler. The Forspiro inhaler has a mode of operation which is quite different to that of the Accuhaler. The Forspiro has won several awards for its design. AirFluSal Forspiro is a Category C product under the Drug Tariff. For the reasons explained below, it is sold in a single strength, which corresponds to the strength of the strongest Seretide Accuhaler.

105. Both the AirFluSal Forspiro inhaler and its packaging feature the colours purple and white as shown in the images below (note that, although the AirFluSal Forspiro is not shown "standing up", it can stand vertically on its flat base). It can be seen from the pictures that the packaging and the label feature a graduated band of colour with a darker purple on the left which gradually became lighter as one moves to the right. (The design of the packaging also has some more subtle features which it is not necessary to mention.) What is perhaps less clear is that the shade of purple on the body of the Forspiro is intermediate in this range.





106. An aspect of the design of the packaging to which Glaxo drew attention at trial is that it features a Sandoz logo at the bottom right of all four faces (note that the front and rear faces are the same). Glaxo point out that this differs from the style of packaging used by Sandoz for many of their other products, which features a large S at bottom right in addition to the Sandoz logo. I am unimpressed by this: the whole of the AirFluSal pack design is different to the pack design traditionally used by Sandoz, and I see no reason to think that the absence of the S would make the packaging design more likely to deceive.

AirFluSal MDI products

107. The Defendants point out that, in March 2017, Sandoz launched an AirFluSal MDI inhaler in two strengths (25 µg salmeterol/125 µg fluticasone and 25 µg salmeterol/250 µg fluticasone). Both the inhalers and the packaging feature the colours purple and white, and the packaging features a darker shade on the stronger strength. No complaint has been made by Glaxo in respect of the AirFluSal MDI products. Glaxo have not explained why not. I note, however, that a greater proportion of both the MDI inhalers and their packaging is white: thus the bodies of the inhalers are white and only the caps are purple.

Marketing authorisations for AirFluSal Forspiro

108. Quite a lot of time was spent at trial investigating the process by which Sandoz obtained the UK marketing authorisation for AirFluSal Forspiro, and the outcomes of that process. It is not necessary for me to describe what happened in detail, but I must outline the key stages in the process.

109. Sandoz obtained the UK marketing authorisation by an application under the decentralised procedure in which Sweden was nominated as the RMS and the UK was a CMS. Sandoz have a Regulatory Competence Centre ("RCC") located in the Netherlands which handles applications under the decentralised procedure on behalf of the relevant national operating companies. Thus the RCC handled the UK application on behalf of the First Defendant, Sandoz Ltd.

110. The RCC submitted the UK application to the MHRA on 4 August 2014. The application was for two strengths of salmeterol/fluticasone: 50 µg/250 µg for asthma in adults and adolescents, and 50 µg/500 µg for asthma in adults and adolescents and COPD. Thus the initial application for AirFluSal Forspiro mirrored the licences of the corresponding strengths of Seretide Accuhaler. (An earlier plan to apply for all three strengths had been abandoned by that point.)

111. The MHRA raised two concerns in its assessment report on Day 100 of the procedure. First, it was of the view that the studies performed by Sandoz did not sufficiently demonstrate therapeutic equivalence of the ICS component (fluticasone) to that of the Seretide Accuhaler at the 50 µg/250 µg strength. Secondly, it considered that insufficient data were available for adolescents at both strengths. In absence of further data, the MHRA wanted a clear statement in the SmPC that the product should be not be used by adolescents.

112. Although some other CMSs (such as Ireland) were willing to (and did) grant marketing authorisations for both strengths of AirFluSal Forspiro, the MHRA maintained its position as the Day 210 deadline for completion of the assessment under the decentralised procedure approached. Accordingly, on 21 September 2015 the RCC on behalf of Sandoz Ltd withdrew the UK application for the 50 µg/µg 250 strength and amended the SmPC for the 50 µg/500 µg strength to include a statement that the product should not be used by anyone under 18. This led to the MHRA issuing a final assessment report on Day 209 (28 September 2015) concluding that the potential risks posed by those two aspects of the application had been resolved.

113. At the same time, however, the MHRA raised a new concern about the asthma indication for the 50 µg/500 µg strength, namely that it would not be possible to "titrate down" asthma patients from that strength while retaining them on the same inhaler device. The MHRA requested an amendment to the SmPC to address this. Because the assessment procedure was to terminate the following day, the RCC on behalf of Sandoz Ltd withdrew the asthma indication from the application and the application therefore proceeded to grant for COPD alone on 16 October 2015. The RCC intended to try to reintroduce the asthma indication later by a so-called "Type II variation".

114. On 29 July 2016 the RCC submitted an application for Type II variation on behalf of Sandoz Ltd seeking to add asthma in adults as a licensed indication to the marketing authorisation. In this application the RCC adopted the amended wording for the SmPC which had been requested by the MHRA. The application was granted on 3 February 2017.

115. At trial a dispute emerged as to the precise scope of the resulting marketing authorisation for AirFluSal Forspiro so far as it concerns asthma. Glaxo contend that marketing authorisation is limited to *severe* asthma, while the Defendants dispute this. There are also disputes as to whether this point is open to Glaxo and whether it matters which I shall consider below. So far as the facts are concerned, the Defendants point out that the question was not put, as it should have been, to Rebecca Clapson, Head of Drug Regulatory Affairs at Sandoz Ltd, who was the Sandoz witness who gave evidence about the application for the marketing authorisation and the subsequent variation (instead it was put to a different Sandoz witness). This is regrettable, but in my judgment this in itself is not a fatal objection to Glaxo taking the point, since it is essentially a question of interpretation of the relevant documents.

116. The starting point is the suggestions made by the MHRA in its Day 209 assessment report at page 4:

> "● The Applicant must define carefully the population of patients with asthma for whom this high strength would be prescribed

> within the Summary of Product Characteristics, Section 4.1 *Therapeutic Indications*
>
> - The Applicant will have to state clearly in the SmPC that this fixed-dose combination cannot be used in any of the situations and patient groups listed above and that in order to down titrate the dose of the inhaled corticosteroid component to attain the minimally effective dose to control asthma, a change to an alternative fixed-dose combination of salmeterol … and fluticasone…. will be required."

The "situations and patient groups listed above" include:

> "- there will be no rôle for this fixed-dose combination product in mild and mild to moderate asthma in adults and adolescents
>
> - there will be no rôle for use as initial maintenance therapy in adults and adolescents with moderate persistent asthma
>
> - there will be no rôle for use in children with asthma".

117. The Type II variation application was made by a letter dated 29 July 2016 accompanied by a proposed revised SmPC and PIL and a clinical expert statement of Dr Richard Russell (a consultant chest physician). The letter characterised the application as being for "Addition of a new therapeutic indication 'asthma' for the medicinal product AirFluSal Forspiro 50µg/500µg…". By contrast with the application, the supporting documents proposed that section 4.1 of the SmPC be amended to state that "AirFluSal Forspiro50µg/500µg is indicated in the regular treatment of adults with severe asthma where use of combination product (long-acting β_2 agonist and inhaled corticosteroid) is appropriate" and that section 4.4 *Special warnings and precautions for use* be amended to state:

> "AirFluSal Forspiro should not be used in patients with mild or mild to moderate asthma.
>
> AirFluSal Forspiro should not be used as initial maintenance therapy in adults and adolescents with moderate persistent asthma.
>
> AirFluSal Forspiro should not be used in children and adolescents less than 18 years of age with asthma."

118. In addition, the supporting documents proposed that section 4.2 of the SmPC Posology and method of administration be amended to state:

> "**In asthma patients, the dose should always be titrated to the lowest dose at which effective control of symptoms is maintained.**
>
> **To Note: AirFluSal Forspiro is available in the strength of 50 micrograms of salmeterol and 500 micrograms of fluticasone … per metered dose only.** Therefore, when it is

> appropriate to titrate down to a lower strength than is available for AirFluSal Forspiro, a change to an alternative fixed dose combination product of salmeterol and fluticasone … containing a lower dose of the inhaled corticosteroid is required."

119. Dr Russell's statement explained at pages 5-6 how asthma is managed in the UK. Having made the point that "[c]linicians understand that the goals of therapy change depending on the severity of the disease", he went on to say (references omitted):

> "The decision to step-down therapy will be based on the perceived risk-benefit for each patient. There is a cohort of severe patients in who[m] due to the high disease burden and the continued symptoms, stepping down is difficult to achieve … Consistency of therapy and regular use in an effective device is more important … "

120. The approval letter from the MHRA dated 3 February 2017 identified the "reason" for the variation as being:

> "To add a new therapeutic indication 'asthma' for the medicinal product. Consequently, the PIL and sections 3, 4.1., 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1 & 5.2 of the SmPC have been updated."

The amended SmPC and PIL approved by the MHRA largely accord with those submitted by the RCC, but include the following additional warning in section 4.4 of the SmPC:

> "AirFluSal Forspiro is for use in patients with severe asthma only."

121. Notwithstanding the references in the application letter and the approval letter to "asthma", in my judgment it is clear from the application documents and from the amended SmPC that, since 3 February 2017, AirFluSal Forspiro has only been licensed for the treatment of severe asthma.

Marketing of AirFluSal Forspiro in the UK

122. Sandoz's witness Dr Stephen Eder, who was the Managing Director of Sandoz Ltd from December 2013 to April 2017, explained that the market conditions at the time of the launch of the AirFluSal Forspiro in the UK meant that there were two possible sales channels.

123. The first was a branded channel or segment, driven by branded prescriptions. A practice of prescribing by brand name of a branded generic can afford that generic entrant a long-term, high-value market share. Dr Eder's evidence was that Sandoz regarded this as the most important part of the market. If a prescription is written specifically for AirFluSal Forspiro, the pharmacist has no alternative but to dispense the AirFluSal Forspiro product. This means that a branded prescription for AirFluSal Forspiro is a guaranteed sale for Sandoz. Therefore, Dr Eder explained that Sandoz

wanted the launch of AirFluSal Forspiro to be about building a brand, which would lead to prescribers prescribing by that brand name. In addition, Dr Eder explained that the branded segment is also a "sticky" market which means that, once it is built up, it tends to remain at about that level. For these reasons, it was Sandoz's objective to present the AirFluSal Forspiro as a unique alternative to the originator product, the Seretide Accuhaler, in that, although it contained the same active ingredients, the ingredients were delivered in a new device. In addition, of course, the AirFluSal Forspiro was significantly cheaper than the Seretide Accuhaler.

124. The second segment of the market was a retail/INN channel or segment, in which branded generics compete for INN scripts by supplying pharmacists (via wholesalers) at competitive prices to enable the pharmacists to realise profits on INN scripts. Given the way pharmacists are reimbursed for Category C products, they have an incentive to dispense the lowest cost product which satisfies the prescription when presented with an INN script. Dr Eder's evidence was that, since the retail/INN channel is subject to far higher downward price pressure and competition from subsequent generic entrants, and because the INN channel is much faster moving (as buyers react quickly to price changes), this channel was less important to Sandoz than building up branded prescriptions for the AirFluSal Forspiro.

125. An important part of Sandoz's marketing campaign was working with the CCGs. CCGs can actively influence prescribing practices in their local areas by adding AirFluSal Forspiro to their local formulary, and the CCGs can encourage prescribing by reference to AirFluSal Forspiro as a brand, for example by issuing guidance to prescribers or by implementing prescribing software changes. The CCGs can make savings by encouraging prescriptions to be written for a cheaper branded generic such as AirFluSal Forspiro (rather than prescribing by INN, which will not lead to a saving for the CCG for the reasons explained above). Similarly, it was also important that prescribers knew the brand name of the product and understood its advantages so that they were more likely to prescribe by brand name.

126. Dr Eder accepted, however, that the INN channel was important for Sandoz to begin with, since that was the quickest way to make sales. As Glaxo point out, in the event a large, albeit reducing, proportion of the initial sales of AirFluSal Forspiro were against INN prescriptions: 99% in 2015, 85% in 2016, 57% in 2017 and 50% in 2018.

Branded versus generic prescribing for salmeterol/fluticasone combination inhalers

127. The Defendants adduced evidence about the percentage of salmeterol/fluticasone combination inhalers in the UK market that are prescribed by brand rather than generically. The data presented represents NHS prescriptions written in the UK which have been dispensed in the community in the UK. This means that the data includes prescriptions written by GPs and other prescribers (such as nurses and pharmacists) who are attached to GP practices. The data does not include private prescriptions or hospital prescriptions. The data is available from April 2014 to October 2018. It shows that branded prescribing of 50 µg salmeterol/500 µg fluticasone DPI inhalers is becoming increasingly common: in 2015 54% of these inhalers were prescribed by brand, but by January-October 2018 this had increased to 78%.

128. Whether branded or generic, a very high percentage (around 95%) of prescriptions for both asthma and COPD are repeat prescriptions. Prescribers will generally review a

patient's prescription from time to time, say every 6-12 months, but the evidence suggests that the assiduousness with which this is done and the time which elapses between reviews varies between practices.

Sources of information for prescribers and pharmacists to check the licensing of an inhaler

129. Doctors and pharmacists can easily check the extent of the licence of an inhaler that they are considering prescribing or dispensing by consulting various sources. The most widely used is the British National Formulary (BNF). The BNF makes clear the indications for which each medicine licensed and the groups of patients (adult or children for example) who may receive the particular medication. Glaxo point out that, somewhat surprisingly, the BNF did not list the AirFluSal Forspiro until the September 2017-March 2018 edition, and even then listed it as being licensed for "asthma" (rather than severe asthma). There were in November 2015, and are, also other sources of relevant information, however. In particular, it was and is very easy to check the SmPC (as recommended by the NPA document quoted in paragraph 94 above) since this is available online and a simple search will locate it.

130. Glaxo nevertheless submit that the evidence shows that pharmacists do not always know, and do not always check if they do not know, what the precise scope of a particular inhaler's marketing authorisation is. I accept this.

Other salmeterol/fluticasone combination inhalers on the UK market

131. The AirFluSal Forspiro was of course not launched in a vacuum on the UK market and the other inhalers also launched on the UK market before and after it form part of the relevant context. Of particular relevance are other salmeterol/fluticasone inhalers.

132. In May 2015 Mylan launched an MDI for this combination in two strengths (25µg salmeterol/125 µg fluticasone and 25 µg salmeterol/250 µg fluticasone) under two brand names, Sirdupla and AloFlute. (There is no evidence which explains why Mylan chose to use two brand names rather than one.) The get-up of the Sirdupla and AloFlute inhalers and their packaging was very similar. Both featured two shades of reddish purple and white, a lighter shade for the lower dose and a darker shade for the higher dose. So far as the evidence goes, Glaxo made no complaint about these products. They therefore stand in a very similar position to the AirFluSal MDIs which Sandoz launched subsequently.

133. The Aerivio Spiromax, another salmeterol/fluticasone DPI (although shaped like an MDI), was launched by Teva onto the UK market in or around August 2016. This inhaler and its packaging are mainly white, but both bear reasonably prominent pink strips and elements of yellow (in the case of the inhaler, this includes a translucent yellow cap for the nozzle). As the Defendants point out, although most people would probably describe the colour of the strips, as I have, as pink, some might regard them as lying within the purple spectrum.

134. In around December 2016 Cipla (through its distributor Kent Pharmaceuticals) launched an MDI for this combination, again in two strengths, under the name Sereflo. These inhalers are coloured two shades of pink and white and the packaging is pink, two shades of purple and white. Again, the shade of purple corresponds to the

strength of the medication. Again, therefore, there are similarities with the Mylan and Sandoz MDIs.

135. In November 2017 Aspire launched an MDI for this combination, again in two strengths, under the name Combisal. These inhalers are coloured two shades of purple and white, while the packaging has two shades of purple, pink and white. Again, therefore, there are similarities with the Mylan, Cipla and Sandoz MDIs.

136. In April 2018 Orion launched a DPI for this combination in two strengths (50 µg salmeterol/250 µg fluticasone and 50 µg salmeterol /500µg fluticasone) under the name Fusacomb Easyhaler. These inhalers are coloured white and two shades of purple, but this time each strength features both shades of purple and the strengths are differentiated by subtle blue and green markings. Likewise, the packaging for both strengths features one shade of purple and white, together with green or blue corners.

137. As the Defendants point out, all of these salmeterol/fluticasone combination inhalers have purple and/or pink coloured elements on both the inhalers and the packaging. Furthermore, a number of them employ a lighter shade to indicate a lower strength and a darker shade to indicate a higher strength. The Defendants contend that these are both instances of two well-established and related phenomena: first, the tendency of colours to be associated with certain types of medication; and secondly, the tendency of generics to follow the colour conventions associated with originator products. I shall consider these phenomena further below.

Other LABA/ICS combinations

138. Three other LABA/ICS combinations were launched after Seretide and before AirFluSal Forspiro which are of some relevance. The first is AstraZeneca's Symbicort Turbohaler, a formoterol/budesonide DPI marketed in three strengths: 6 µg /100 µg, 6 µg /200 µg and 12 µg /400 µg. The inhaler is mainly white with some red, although text on the cap is printed in purple. The second is Chiesi's Fostair, a formoterol/beclomethasone MDI marketed in one strength, namely 6 µg/100 µg. This inhaler is coloured two shades which might be described as deep pink or burgundy or plum; some might well describe the darker shade as purple. (Subsequently Chiesi launched a DPI version called Fostair Nexthaler. This inhaler is coloured the darker plum colour and white, while the packaging is mainly white with elements in both shades of plum.) The third is Napp's Flutiform, a formoterol/fluticasone MDI marketed in three strengths: 5 µg/50 µg, 5 µg/125 µg and 10 µg/250 µg. The inhaler is mainly white and grey with the name Flutiform printed on an orange background, while the packaging is white and orange with blue, pink and grey stripes to differentiate the different strengths.

Colour conventions for inhalers

139. A significant area of dispute at trial was to the extent to which there are recognised colour conventions with respect to inhalers in the UK (as both sides acknowledged, the position is somewhat different in other countries). It is common ground that there is no official colour convention for inhalers in the UK. It is also common ground that the position has changed over time as more and more inhalers have been launched onto the UK market. The Defendants contend, however, that as at November 2015 there were certain informal, but widely recognised and longstanding, colour

conventions, whereby particular colours were associated with particular classes of medication. These conventions were most firmly established in relation to the colours blue (for relievers, particularly SABA relievers) and brown/orange/burgundy (for ICS preventers), but the Defendants contend that similar conventions were also recognised in relation to other colours.

140. The Defendants contend that the position was accurately described in an article by Linda Pearce (a respiratory specialist nurse) in the *Nursing Times* dated 14 September 2000 entitled "KNOW HOW Asthma inhalers", which the Defendants point out was sponsored by Glaxo. This article states:

> "**Colour coding of devices**
>
> In many cases, drug classes will be identified by the colour of the inhaler. The colour-coding is as follows: - Blue: short acting b2 agonist ('reliever'); - Brown/orange/burgundy: corticosteroid ('preventer'); - Green: long-acting b2 agonist; - Purple: long-acting b2 agonist/corticosteroid combination."

141. By the end of the trial there was a measure of common ground as regards the existence of a loose convention regarding at least blue, and to some extent brown/orange/burgundy, and to the reasons for this.

142. So far as blue is concerned, as explained above, Ventolin has long been marketed in blue inhalers and blue packaging. When the patent for salbutamol expired, generic salbutamol inhalers were marketed which were also, to a greater or lesser extent, coloured various shades of blue as was their packaging. Subsequently other kinds of reliever inhaler have also been marketed with elements of blue (such as a blue cap or actuator).

143. As a result, the evidence is clear that blue became firmly associated in the minds of HCPs and patients with reliever inhalers. Although Glaxo suggested that this convention had become less clear cut in more recent years, I find that it was still widely recognised in November 2015. It is recognised, for example, in the passage from the Asthma UK PAAP template quoted in paragraph 83 above. It is also recognised in the documents cited below.

144. It is also clear from the evidence that, as the Defendants point out, this particular convention had, and has, a safety aspect to it. This is because, as discussed above, patients frequently have more than one type of inhaler, typically a preventer to be used regularly and a reliever to be used only when needed, and in particular in the case of acute attacks of breathlessness. As discussed in more detail below, it is clear from the evidence that many patients find it convenient to differentiate between their different inhalers by reference to their colour. Thus patients generally know that their reliever inhaler is blue, and that if they suffer an acute attack the blue inhaler is the one they need to use. Again, this is clearly reflected in the Asthma UK PAAP template. It was for this reason that, in 2014, Glaxo changed the colour of the cap on their Relvar Ellipta inhaler (a fluticasone/vilanterol combination preventer inhaler) from blue to yellow following concerns raised by a number of HCPs.

145. Turning to brown and other "autumnal" colours, the position is similar. From 1972 to 2007 Glaxo marketed beclometasone under the brand name Becotide in brown MDIs and brown packaging. This was followed by generic ICS inhalers which adopted similar colours, and by Glaxo's own Flixotide. Thus it was possible for a long time for HCPs and patients to treat brown/orange/burgundy as denoting an ICS preventer inhaler. Again, Glaxo contend that this convention has faded more recently, but I find that it was still widely recognised in November 2015.

146. Even leaving aside the specific reasons for the blue = reliever, brown/autumnal = ICS preventer convention, there was, and remains, a sound medical rationale behind this practice of generics adopting similar colour schemes to the originator products, as it promotes familiarity amongst patients with their inhalers (for example, if a patient is switched between different brands of inhalers) and hence patient adherence to their drug regime. It is for this reason that the PAAP template encourages patients to write down the names and colours of their inhalers (see paragraph 82 above).

147. The Defendants contend that, when Glaxo launched Serevent and Seretide, whether by design or not, their green and purple colours enabled HCPs and patients conveniently to differentiate them from blue and brown/orange/burgundy. In that way, green and purple came to be regarded as signifying LABA and LABA/ICS inhalers as shown by the *Nursing Times* article even though at that time there was only one of each kind of product which was marketed by Glaxo.

148. As is common ground, in recent years there has been a proliferation of inhalers of different types, designs and colours on the market. Now there is an array of inhalers available, the Defendants accept that these colour conventions have started to erode. The Defendants maintain, however, that, as at November 2015, the colour conventions retained considerable vitality. In support of this contention the Defendants rely upon a variety of items of documentary evidence as well as the evidence of a number of the trade witnesses.

149. It is not necessary for me to refer to all of the documentary evidence the Defendants rely upon. It is sufficient to refer to two items which are representative. The first is a *Respiratory Inhalers Identification Guide*, two versions of which are in evidence. The first is Version 2 of the Guide, dated September 2013, produced by NHS Greater Glasgow and Clyde ("NHSGGC") together with seven pharmaceutical companies (including Glaxo) "as a service to medicine" and endorsed by the NHSGGC Respiratory Managed Clinical Network. The Contents page groups inhalers into five colour-coded groups: SABAs (blue), LABAs (green), SAMAs and LAMAs (beige), ICSs (brown) and what are described as "Compound [i.e. combination] preparations" (purple). Four examples of "compound preparations" are listed: Seretide, Symbicort, Fostair and Flutiform. The Guide contains a series of sections, which again are colour-coded, which depict and describe the various inhalers which were then available. The heading to the section on SABA inhalers, as well as being coloured blue, describes them as "blue/reliever" inhalers. The heading to the section on ICS inhalers, as well as being coloured brown, describes them as "brown/preventer" inhalers. The heading to the section on "compound preparations", which is coloured purple, describes them as "Corticosteroid/Long-acting $beta_2$ agonist".

150. Version 3, dated February 2017 and produced by NHSGGC without the collaboration of the pharmaceutical companies, is similar, but SABAs and ICS are no longer

described as "blue" and "brown", although the colour coding is the same. The Contents pages have an expanded purple-coded section which is still headed "Compound preparations" and sub-divided into "Corticosteroid/LABAs" and "LAMAs/LABAs". The corresponding section of the Guide has likewise been expanded and sub-divided, but the heading remains purple. The ICS/LABA sub-section begins with a fluticasone/ salmeterol group which now includes the AirFluSal Forspiro and the Sirdupla MDIs as well as Seretide Accuhaler and Evohaler.

151. The second item is a document which Glaxo themselves rely upon. This is a document produced by the Johnson & Johnson Global Strategic Design Office for the purpose of a collaboration with Vectura on 20 February 2015 entitled "Respivert/Jupiter Device Color Strategy". This states:

> "There is no consistent use of color to reference product type – short acting versus long acting or bronchodilators versus inhaled corticosteroids. While some markets seem to have certain color connotations (i.e. blue = short acting rescue inhaler in the UK), there are no longer clear standards in terms of color usage.
>
> Where in the past there were more general color guidelines (blue for short acting and brown for controller medications) the proliferation of newer types of drug products (and combinations) have led to a 'blurring' around the communication of color on the device in relation to drug type/class.
>
> That said, there are some colors that currently are represented by a single drug type/class – deep orange (ICS), beige/brown (ICS), purple (ICS + LABA), deep green (SAMA), light green (LAMA)."

152. The reason why Glaxo rely upon the document is that a different passage states:

> "A particular color can be representative of a particular brand – this is most clearly seen with GSK's Advair [the US brand name for Seretide] with their Diskus [Accuhaler] and MDI devices. Advair probably has the strongest brand association with a particular color (purple) in the inhalation device space."

153. It can be seen from the spellings and the references to Advair that this document is mainly concerned with the position in the US. Considering the evidence as a whole, I find that the first passage quoted accurately reflects the perceptions of HCPs in the UK in November 2015. As for patients in the UK, I find that they understood that the different colours signified inhalers containing differing types of medication for different purposes, although most patients would have had little idea as to what the different types of medication were.

154. Glaxo also rely, among other things, on a passage from the *Best Practice Guidance on the Labelling and Packaging of Medicines* issued by the MHRA in November 2015. Paragraph 4.4 states:

> "**Innovative pack design that may incorporate the judicious use of colour is to be encouraged to ensure accurate identification of the medicine**. … The primary aim of innovative design of packaging is to aid in the identification and selection of the medicine."

Contrary to Glaxo's contention, however, this is not inconsistent with the Defendants' case. On the contrary, the Defendants agree that "judicious use of colour" does "ensure accurate identification of the medicine".

155. Glaxo also rely upon the fact that some other salmeterol/fluticasone DPI inhalers marketed by third parties in the UK have not been coloured purple (Glaxo also rely upon one that was marketed outside the UK, but that is irrelevant). I am unimpressed by this. First, none was launched prior to November 2015. Secondly, the Sirdupla/Aloflute MDIs were purple (albeit reddish shades of purple). Thirdly, even taking into account inhalers launched subsequently, as discussed in paragraph 137 above, all of them have purple and/or pink elements.

The law

Basic principles

156. The basic principles of the law of passing off were summarised by Lord Oliver of Aylmerton in *Reckitt & Colman (Products) Ltd v Borden Inc* [1990] 1 WLR 491 at 499 as follows*:*

> "The law of passing off can be summarised in one short general proposition – no man may pass off his goods as those of another. More specifically, it may be expressed in terms of the elements which the plaintiff in such an action has to prove in order to succeed. These are three in number.
>
> First, he must establish a goodwill or reputation attached to the goods or services which he supplies in the mind of the purchasing public by association with the identifying 'get-up' (whether it consists simply of a brand name or trade description, or the individual features of labelling or packaging) under which his particular goods or services are offered to the public, such that the get-up is recognised by the public as distinctive specifically of the plaintiff's goods or services.
>
> Secondly, he must demonstrate a misrepresentation by the defendant to the public (whether or not intentional) leading or likely to lead the public to believe that goods or services offered by him are the goods and services of the plaintiff. Whether the public is aware of the plaintiff's identity as the manufacturer or supplier of the goods or services is immaterial, as long as they are identified with a particular source which is in fact the plaintiff. For example, if the public is accustomed to rely upon a particular brand name in purchasing goods of a particular description, it matters not at all that there is a little or

> no public awareness of the identity of the proprietor of the brand name.
>
> Thirdly, he must demonstrate that he suffers, or, in a quia timet action, that he is likely to suffer damage by reason of the erroneous belief engendered by the defendant's misrepresentation that the source of the defendant's goods or services is the same as the source of those offered by the plaintiff."

The relevant date

157. The date as at which the three elements identified above must be assessed is the date when the defendant commences the acts complained of: *Cadbury-Schweppes v Pub Squash Co* [1981] 1 WLR 193.

The need for deception

158. As Jacob J forcefully stated in *Hodgkinson & Corby Ltd v Wards Mobility Services Ltd* [1994] 1 WLR 1564 at 1569-1570:

> "I turn to consider the law and begin by identifying what is not the law. There is no tort of copying. There is no tort of taking a man's market or customers. Neither the market nor the customers are the plaintiff's to own. There is no tort of making use of another's goodwill as such. There is no tort of competition. …
>
> At the heart of passing off lies deception or its likelihood, deception of the ultimate consumer in particular. Over the years passing off has developed from the classic case of the defendant selling his goods as and for those of the plaintiff to cover other kinds of deception, e.g. that the defendant's goods are the same as those of the plaintiff when they are not, e.g. *Combe International Ltd v. Scholl (UK) Ltd* [1980] R.P.C. 1; or that the defendant's goods are the same as goods sold by a class of persons of which the plaintiff is a member when they are not, e.g. *Erven Warnink Besloten Vennootschap v. J. Townend & Sons (Hull) Ltd* [1979] A.C. 29 (the *Advocaat* case). Never has the tort shown even a slight tendency to stray beyond cases of deception. Were it to do so it would enter the field of honest competition, declared unlawful for some reason other than deceptiveness. Why there should be any such reason I cannot imagine. It would serve only to stifle competition.
>
> The foundation of the plaintiff's case here must therefore lie in deception…"

159. It is not enough if members of the public are merely caused to wonder. As Jacob LJ explained in *Phones 4U Ltd v Phone4U.co.uk Internet Ltd* [2006] EWCA Civ 244, [2007] RPC 5:

> "16. The next point of passing off law to consider is misrepresentation. Sometimes a distinction is drawn between 'mere confusion' which is not enough, and 'deception', which is. I described the difference as 'elusive' in *Reed Executive Plc v Reed Business Information Ltd* [2004] R.P.C. 40 . I said this, [111]:
>
> > 'Once the position strays into misleading a substantial number of people (going from 'I wonder if there is a connection' to 'I assume there is a connection') there will be passing off, whether the use is as a business name or a trade mark on goods.'
>
> 17. This of course is a question of degree—there will be some mere wonderers and some assumers—there will normally (see below) be passing off if there is a substantial number of the latter even if there is also a substantial number of the former.
>
> 18. The current (2005) edition of *Kerly* contains a discussion of the distinction at paras 15–043 to 15–045. It is suggested that:
>
> > 'The real distinction between mere confusion and deception lies in their causative effects. Mere confusion has no causative effect (other than to confuse lawyers and their clients) whereas, if in answer to the question: "what moves the public to buy?", the insignia complained of is identified, then it is a case of deception.'
>
> 19. Although correct as far as it goes, I do not endorse that as a complete statement of the position. Clearly if the public are induced to buy by mistaking the insignia of B for that which they know to be that of A, there is deception. But there are other cases too—for instance those in the *Buttercup* case. A more complete test would be whether what is said to be deception rather than mere confusion is really likely to be damaging to the claimant's goodwill or divert trade from him. I emphasise the word 'really'."

160. In order for there to be passing off, a substantial number of members of the public must be misled: see *Neutrogena Corp v Golden Ltd* [1996] RPC 473 at 493-494 (Morritt LJ). Furthermore, it is not enough that careless or indifferent people may be led into error: see *Norman Kark Publications Ltd v Odhams Press Ltd* [1962] 1 WLR 380 at 383 (Wilberforce J).

161. The correct approach to this question was well described by Jacob J at first instance in *Neutrogena* at 482:

> "The judge must consider the evidence adduced and use his own common sense and his own opinion as to the likelihood of deception. It is an overall 'jury' assessment involving a

> combination of all these factors, see *'GE' Trade Mark* [1973] R.P.C. 297 at page 321. Ultimately the question is one for the court, not for the witnesses. It follows that if the judge's own opinion is that the case is marginal, one where he cannot be sure whether there is a likelihood of sufficient deception, the case will fail in the absence of enough evidence of the likelihood of deception. But if that opinion of the judge is supplemented by such evidence then it will succeed. And even if one's own opinion is that deception is unlikely though possible, convincing evidence of deception will carry the day. The *Jif* lemon case (*Reckitt & Colman Products Ltd. v. Borden Inc.* [1990] R.P.C. 341) is a recent example where overwhelming evidence of deception had that effect. It was certainly my experience in practice that my own view as to the likelihood of deception was not always reliable. As I grew more experienced I said more and more 'it depends on the evidence.'"

162. It is not fatal to a claim for passing off that there is no evidence of actual confusion, but where the rival goods have been sold side by side for a long period the absence of such evidence is very material unless satisfactorily explained: see *Kerly's Law of Trade Marks and Trade Names* (16th ed) at 23-020.

Misrepresentation as to trade origin

163. The most common form of passing off involves a misrepresentation as to trade origin. Such a misrepresentation is normally made by the adoption of features of a name, mark or get-up which are distinctive of the claimant in the sense of indicating an exclusive trade origin. This form of misrepresentation does not require proof that the defendant's goods will actually be mistaken for the claimant's goods. It suffices if some customers think that the claimant is in some way responsible for the defendant's goods, or that they share a common (unknown) manufacturer.

Misrepresentation by shape and/or colour

164. It is common ground that, in principle, it is possible for a claimant to acquire a goodwill in the shape and/or colour of a product and/or its packaging such that use of the same or a similar shape and/or colour by a defendant leads to a misrepresentation as to trade origin. The authorities show, however, that it is difficult, although not impossible, for claimants to establish that the shape and/or colour of a product and/or its packaging are distinctive of them.

165. As Jacob J explained in *Hodkinson & Corby* at 1572-1573:

> "The plaintiff's problem of proof when there is no manifest badge of trade origin such as a trade mark becomes hard. This is so in the case of a descriptive or semi-descriptive word such as 'camel hair'. It is perhaps even more so where one is concerned simply with the appearance of the article with no self-evident trade origin frill or embellishment. For people are likely to buy the article because of what it is, not in reliance on

> any belief of any particular trade origin. This is so whether they buy it for its eye-appeal (e.g. glass dogs) or for what it does (e.g. the copy Rubik cube…
>
> The plaintiff's problem of proof lies in relation to the first two items of the trinity, which are related. It is not good enough for him to show that his article is widely recognised – has a 'reputation' in that general sense. …
>
> I believe that [Learned Hand J in *Crescent Tool Co v Kilborn & Bishop Co* (1917) 247 F 290 at 300-301] exactly encapsulates what must be shown when the plaintiff is complaining, in a passing off action, about a copy of his product as such. Is the public 'moved to buy by source?'
>
> It is, I think, because the difficulties of proof are so great that successful cases of passing off based on the shape of goods are so rare."

166. Similarly, Floyd J stated in *Numatic International Ltd v Qualtex Ltd* [2010] EWHC 1237 (Ch), [2010] RPC 25 at [39]:

> "It is recognised that it is more difficult to acquire a sufficient reputation and goodwill in the shape or get-up of a product. Whilst the principal function of a brand name is to denote origin, the shape and get-up of a product are not normally chosen for such a purpose. A member of the public seeing a product which looks identical to another (a red cricket ball is an example) does not necessarily, or even normally, conclude that they come from the same source. The claimant must prove that the shape of its goods has come to denote a particular source to the relevant public..."

167. The same point had previously been made in relation to colour by Walton J in *Rizla Ltd v Bryant & May Ltd* [1986] RPC 389. In that case the plaintiff sold fine, medium and heavy cigarette papers in red, blue and green packets and had a virtual monopoly of the market. The plaintiff applied for an interlocutory injunction to restrain the defendant from selling cigarette papers in packets coloured different shades of red, blue and green. Walton J refused the injunction, saying at 391:

> "The case for the plaintiffs can really be put thus simply: a potential customer will go into a shop and will ask for a packet of 'reds', meaning thereby a packet of Rizla 'reds' and the shopkeeper may supply him with a packet of Swan 'reds' and he may not notice the difference. As I have already said, that, I think, is just about conceivable. But it must be borne in mind first of all that it is by no means certain that when the customer asked for 'reds' he wants Rizla 'reds'. Up to the moment, he has had no opportunity in practical terms of obtaining any product other than a Rizla product. Therefore, in a sense, the manufacturer of the product has become, so far as he is concerned, an irrelevance, just like going to the post office one cannot get any other products than those which are made by the

> firm that supplies the perquisites therefor. But quite clearly what he does mean is that he wants a paper of a particular specification, a medium one in the case of the red packet."

168. Counsel for Glaxo relied heavily upon an old case concerning prescription pharmaceuticals, *Hoffmann-La Roche & Company AG v DDSA Pharmaceuticals Ltd* [1969] FSR 410, in which the Court of Appeal upheld an interlocutory injunction restraining the defendant from marketing generic chlordiazepoxide in black and green 10 mg capsules which were identical to those in which Librium was marketed by the claimant except they bore the name "DDSA" rather than "Roche". As counsel for Glaxo pointed out, the Court of Appeal found on the evidence that, if the defendant's product were marketed in different coloured capsules, it would be likely to meet with resistance on the part of patients who would demand the green-and-black ones they had had before. The Court of Appeal held that, as Harman LJ put it at 418 "because the public has always had CDP in a green and black form when they needed the 10 mg, it seems to me that that is a perfectly natural assumption to make, that all the green and black capsules emanated from the same manufacturer". Russell LJ said at 421 that he was "fully prepared to assume that there are many good reasons why it would be desirable that CDP 10 mg capsules should, from whatever source, have the same colour code", but held that this was not a defence to passing off.

169. As counsel for Glaxo rightly acknowledged, however, such cases always depend on their facts. I derive little assistance from this decision: not only was it a decision concerning an interlocutory injunction, but also it was not a case concerning inhalers. Moreover, the branded and generic prescription pharmaceuticals markets have changed out of all recognition since 1969, as has the organisation of the NHS.

Recognition and association is not enough

170. A point which Jacob J touched on in the passage from *Hodgkinson & Corby* quoted in paragraph 164 above is that it is not enough for the claimant to prove that the public recognise the shape and/or colour of the claimant's product and associate it with the claimant's product, particularly where it is the only product of its kind. He explained this further later in the same judgment at 1574:

> "Before turning to the evidence I would make one general observation. It was the Reverend Wm. Paley who said in Natural Theology (1784), ch. i: 'The watch must have a maker.' In that sense every manufactured article conveys a representation — that it had a maker. Now where an article has a readily distinguishable appearance and there has only been one maker, once the article becomes well-known in the market, consumers when they see an article like that may assume that it is made by the same maker as he who made the articles of that individual appearance which they have seen before. So, in the instant case, almost all those who casually saw the Flo'Tair cushion (or just a picture of it) reacted by saying, 'That is a Roho'. One more precisely said, 'That is a Roho or a convincing copy.' This sort of evidence alone can seldom, if ever, satisfy the legal test for passing off. It does not prove that

> anyone relies upon the appearance to get the product of the maker they want."

171. Jacob J returned to this point in the trade mark case of *Unilever plc's Trade Mark Applications* [2003] EWHC 2709 (Ch), [2003] RPC 35 at [46]:

> "I do not think it has been proved that the public use the shape as a badge of trade origin. Yes, a substantial proportion recognise the product as 'Viennetta', a Walls product. But no, it is not shown that they recognise the shape alone as a trade mark. An acid test may be, what would happen in real life? Suppose another trader sold a product identical to 'Viennetta' but using his own very different word trade mark. I do not actually know what the result would be. But the most likely reaction would seem to be no more than that 'Oh X are doing a Vienetta-like ice cream too'. …"

172. More recently, Kitchin LJ has elaborated on the same point in another trade mark case, *Société des Produits Nestlé SA v Cadbury UK Ltd* [2017] EWCA Civ 358, [2017] FSR 34:

> "77. Before assessing these rival submissions, I think it may be helpful to say a little more about a concept which is woven into the decisions of the CJEU, including the decision of the CJEU in this case, concerning the acquisition of distinctive character by an inherently non-distinctive three-dimensional shape mark such as the Trade Mark. As we have seen, the CJEU has held that it is not sufficient for the applicant to show that a significant proportion of the relevant class of persons recognise and associate the mark with the applicant's goods. However, to a non-trade mark lawyer, the distinction between, on the one hand, such recognition and association and, on the other hand, a perception that the goods designated by the mark originate from a particular undertaking may be a rather elusive one. Nevertheless, there is a distinction between the two and, as I shall explain in a moment, it is an important one.
>
> 78. The distinction is this. We are concerned here with a mark, the three-dimensional shape of a chocolate product, that has no inherent distinctiveness. A shape of this kind is not inherently such that members of the public are likely to take it as a badge of origin in the way they would a newly coined word or a fancy name. Now assume that products in that shape have been sold on a very large scale under and by reference to a brand name which is inherently highly distinctive. Assume too that the shape has in that way become very well-known. That does not necessarily mean that the public have come to perceive the shape as a badge of origin such that they would rely upon it alone to identify the product as coming from a particular source. They might simply regard the shape as a characteristic of products of that kind or they might find it brings to mind the

> product and brand name with which they have become familiar. These kinds of recognition and association do not amount to distinctiveness for trade mark purposes, as the CJEU has now confirmed in its decision in this case."

173. Counsel for the Defendants submitted, and I accept, that this distinction is equally applicable to other kinds of unconventional trade marks and also to passing off claims based on such indicia.

Misrepresentation as to equivalence

174. It is well established that the tort of passing off is not confined to misrepresentations as to trade origin. Thus suppliers of products of a particular description have succeeded in restraining rival traders from using that description, or a confusingly similar term, in relation to goods which do not correspond to that description, a type of action often referred to as "extended passing off". In the present case, Glaxo assert that the get-up of the AirFluSal Forspiro conveys a misrepresentation as to equivalence with the Seretide Accuhaler as well as a misrepresentation as to trade origin. In support of this contention, counsel for Glaxo relied in particular on the following authorities.

175. In *Combe International Ltd v Scholl (UK) Ltd* [1980] RPC 1 the plaintiffs marketed shoe insoles under the brand name Odor-Eaters which contained activated charcoal to adsorb odours. The product had been extensively advertised and the presence of charcoal was emphasised in the advertising and on the packaging. The defendant started to sell rival insoles under the brand name Scholl whose appearance was similar to those of Odor-Eaters in packaging whose get-up was somewhat similar to that of Odor-Eaters, and bore the words "Contains charcoal". This was a true statement, but the defendant's product did not contain activated charcoal, and the defendant's evidence did not explain what the purpose of the charcoal was. The plaintiffs applied for an interlocutory injunction contending that the defendant was misrepresenting that its product was the same as the plaintiffs' when it was not.

176. Fox J granted the injunction, stating at 8:

> "The question is whether the defendant's article is offered in such a way as to lead the public to believe that it is the same as Combe's when in fact it is admittedly different. On that issue, it seems to me that there is certainly a serious and substantial issue to be tried. Indeed, it seems to me that Combe makes out a prima facie case on the evidence which it now adduces. The actual product sold by the defendants is very similar indeed in appearance to Combe's, and it is sold in a way which emphasises the use of charcoal (where the charcoal used is not in fact activated charcoal) and it uses as its name the words 'Odour Destroying Cushion Insoles', which, less prominently it is true, are the ones used by Combe in its product."

177. In *Hodge Clemco Ltd v Airblast Ltd* [1995] FSR 806 the plaintiff was the leading supplier of equipment for shot blasting, and in particular supplied helmets from a US manufacturer which it modified to meet UK health and safety regulations. The

helmets were called Apollo helmets, but the name was not one in which the plaintiff could claim goodwill (presumably it was owned by the US company). The defendant set up in competition to the plaintiff selling unmodified parallel-imported Apollo helmets. They also sold tear-off lenses which they advertised as being "to suit Apollo blast helmets". Unlike the claimant's helmet, the defendant's products did not have Health and Safety Executive approval. Under the regulations, any offence would be committed by the users of the products and not the supplier.

178. The plaintiff applied for an interim injunction, as I understand it to restrain the defendant from stating that its lenses were "to suit" Apollo helmets. The plaintiff argued that this statement impliedly misrepresented that the defendant's lenses complied with the health and safety regulations. Although he refused an injunction on the balance of the risk of injustice, Jacob J held that the plaintiff had an arguable case of passing off, saying at 809-810:

> "The case even when it comes to trial involves the outer limits of the tort of passing off. There are many products which have to confirm to some sort of regulation and those whose products do so confirm can arguably say that their quality is different from rival products that do not so conform, and that there could be accordingly a class of plaintiffs who would be damaged by a misrepresentation by a defendant that in effect he is a member of that class.
>
> The difficulty with the limits of the tort is not difficult to articulate. What is difficult is to find out precisely where the limits go. Aldous J. in *SDS Biotech UK v. Power Agrichemicals* (1989), [1995] F.S.R. 797, indicated on an interlocutory application that this area of law was indeed one which is arguable one way or the other. Mr Hacon pointed out some of the difficulties with the notion of a tort as wide as this: how can a plaintiff say he is really entitled to part of a goodwill, the only goodwill, when all he has done is to comply with a certain standard? And how wide does the tort go? Would it, for instance, cover a motorcar manufacturer who wrongly claimed that his car would do 110 m.p.h. in a case where he was being sued by a manufacturer whose cars would do 110 m.p.h.? Mr Hacon hinted darkly that, if I were to find against him on this point, the courts might be flooded with applications by plaintiffs whose products comply with one regulation or another against defendants whose products did not so comply. Mr Hacon's argument went so far as to say that, even if the defendants in this case expressly and deliberately lied about their product saying, for example, 'our lenses when fitted to Hodge Clemco's helmets comply with HSE regulations', Hodge Clemco would have no cause of action. It is not necessary for me to decide the matter one way or the other today. I can well envisage that sooner or later this question is going to come fair square before the courts."

179. He went on at 810 to opine that it would not make any difference if the defendant did not expressly state that the lenses were "to suit" Apollo helmets:

> "It seems to me arguable that selling lenses to customers who need the products to comply with the regulations does convey to the customer, unless he is warned, a danger of the customer being misled, of the customer assuming that what he is buying he can lawfully use. It seems to me that just selling the lens may contain that representation. Looking at it from the point of view of a contract between the supplier and the customer, one could well understand a customer complaining if it turned out he could not use the product for the very purpose for which he had bought it, and for which the seller knew he was buying it. To my mind, there [is] no difference between advertising the lenses expressly saying they are 'to suit Apollo blast helmets' and simply selling the lenses for that purpose."

180. In *Schulke & Mayr UK Ltd v Alkapharm UK Ltd* [1999] FSR 161 the plaintiffs and the defendant were rival manufacturers of cleaning and disinfectant agents for dental instruments. The plaintiffs applied for an interlocutory injunction to retrain the continued publication by the defendant of an advertisement that contained claims about the properties of the defendant's Alkazyme product which were similar to statements made by the plaintiffs about their Gigasept product, but which the plaintiffs contended were false in the case of Alkazyme. Jacob J held that the plaintiffs had no arguable claim for passing off, saying at 166:

> "[Counsel for the plaintiffs] says that there can be or should be an extension of the law of passing off, taking it further than was taken in *Combe International Ltd and Others v. Scholl (U.K.) Limited* [1980] R.P.C. 1. In that case the plaintiff had extensively advertised its insoles as containing activated charcoal and educated the public that activated charcoal had the effect of destroying odour. The defendant put out an insole saying truly that it contained charcoal. But it was ordinary unactivated charcoal …. It was intended to deceive the public into believing that the defendant's products had the same properties as the plaintiff's. The false representation depended upon the plaintiff's product in the market having achieved a reputation of having [certain] properties.
>
> What [counsel] says here is that the two statements complained of are in effect a statement that the Alkazyme is the same as Gigasept. He points to some advertising which has been done by the plaintiffs, …, which describes [their] product ….. He says, therefore, along the lines of *Combe v. Scholl*, what the defendants are doing is representing their product to be the same as the plaintiffs.
>
> I do not think that the analogy is a good one. Passing off involves not only a false representation but a false representation related to the plaintiffs' product or goodwill, not

> a false representation in the air. This false representation does not depend, on the plaintiffs' case, on any representation concerning the plaintiffs' product at all; it is false (if it is in fact false) not because of the plaintiffs' product or goodwill but because it is inherently false. I do not think that there is a cause of action in passing off. It follows that the plaintiffs' claim will fail."

181. In the light of these authorities, counsel for the Defendants did not dispute that, in principle, a misrepresentation as to equivalence could be actionable as passing off, but submitted that it was necessary to consider with care what goodwill the claimant owned and whether any misrepresentation was made by the indicia complained of which was likely to damage the claimant's goodwill. I accept that submission.

The defendant's state of mind

182. Although the action for passing off evolved from the tort of deceit, it is not a necessary ingredient of passing off that the misrepresentation was deliberate. It is established by the highest authority that the misrepresentation may be an innocent one: see, for example, *A G Spalding & Bros v A W Gamage Ltd* (1915) 32 RPC 273 at 283 (Lord Parker of Waddington).

183. That said, it is also clearly established that the intentions of the defendant may have evidential relevance. As Lindley LJ put it in *Slazenger & Sons v Feltham & Co* (1889) 6 RPC 531 at 538:

> "… if you are driven to the conclusion that what is intended to be done is to deceive if possible, I do not think it is stretching the imagination very much to credit the man with occasional success or possible success. Why should we be astute to say that he cannot succeed in doing that which he is straining every nerve to do?"

184. The law was more completely stated by Earl Loreburn LC in *Claudius Ash Ltd v Invicta Manufacturing Co Ltd* (1912) 29 RPC 465 at 475:

> "It is said in this case that the Defendants intended to deceive – not that the goods were calculated even innocently to deceive – but that there was a fraudulent intention on the part of the Defendants. That is a material fact which would be weighed duly and to which doubt great weight would be attached by any Court if it were established, because no Court would be astute when they discovered an intention to deceive, in coming to the conclusion that a dishonest defendant had been unsuccessful in his fraudulent design. When once you establish the intent to deceive, it is only a short step to proving that the intent has been successful, but still it is a step even though it be a short step. To any such charge there must be, however, two conditions. The first is that it ought to be pleaded explicitly so as to give the defendant an opportunity of rebutting the

> accusation of intent. The second is that it must be proved by evidence."

185. The rationale for this principle was explained by Lord Simonds in *Office Cleaning Services Ltd v Westminster Window and General Cleaners Ltd* (1946) 63 RPC 39 at 42:

> "… if the intention to deceive is found, it will readily be inferred that deception will result. Who knows better than the trader the mysteries of his trade?"

186. In *United Biscuits (UK) Ltd v Asda Stores Ltd* [1997] RPC 513 Asda marketed a chocolate-coated sandwich biscuit called Puffin as a competitor to the well-known Penguin biscuit. Asda's witnesses gave evidence that the original artwork which had been designed for the Puffin packaging had been too close to the get-up of Penguin and had been changed in order to avoid confusion, which Asda wanted to avoid. Robert Walker J said at 531:

> "… it seems to me likely that [Asda's representatives] were, under advice, seeking to make only such changes as were needed to avoid what they judged to be an unacceptable risk of being attacked for copying while maintaining Puffin's position as an obvious competitor and parody, and (they hoped) a 'brand-beater'. I cannot escape the conclusion that, while aiming to avoid what the law would characterise as deception, they were taking a conscious decision to live dangerously. That is not in my judgment something that the court is bound to disregard."

Robert Walker J did not explain, however, why he considered that "a conscious decision to live dangerously" was of evidential relevance.

187. More recently, Kitchin LJ considered this in *Specsavers International Healthcare Ltd v Asda Stores Ltd* [2012] EWCA Civ 24, [2012] FSR 19:

> "114. Finally, I come to the 'living dangerously' point. Mr Mellor submitted that if a trader takes a decision to live dangerously he recognises a risk of a successful legal action and so also recognises a likelihood that his activity will deceive some people. This submission was founded upon an observation of Robert Walker J …
>
> 115. In my judgment it is important to distinguish between a defendant who takes a conscious decision to live dangerously and one who intends to cause deception and deliberately seeks to take the benefit of another trader's goodwill. It has long been established that if it is shown that a defendant has deliberately sought to take the benefit of a claimant's goodwill for himself the court will not 'be astute to say that he cannot succeed in doing that which he is straining every nerve to do' … A trader who has taken the decision to live dangerously is in

> a different position, however. He has appreciated the risk of confusion and has endeavoured to adopt a sign which is a safe distance away. All must depend upon the facts of the particular case. Further, it must be kept firmly in mind that the ultimate question whether or not the similarity between the trade mark and the sign is such that there exists a likelihood of confusion is one for the court to determine in the light of its global assessment of all material factors, of which the intention of the defendant, as a person who knows the market in which he is offering his goods or services, is only one.
>
> 116. In the present [case], the judge carried out precisely this assessment at [141] of his judgment which I have set out at [71] above. The judge considered that the evidence of Asda 'living dangerously' did not, in the circumstances of this case, amount to evidence of an intention to confuse. Asda had no wish for consumer to confuse one business for another and so the judge held its intention and conduct could not be relied upon as evidence of a propensity to confuse. I am entirely satisfied that the judge was entitled to reach this conclusion … "

188. Kitchin LJ was careful in this passage not to say that a conscious decision on the part of the defendant to live dangerously could never support a claim for passing off. Counsel for Glaxo submitted that the relevance of such a state of mind was that it showed that the defendant, as a person who knew the relevant market, was aware of the risk of deception and proceeded recklessly in the sense of not taking care to avoid that risk materialising. Counsel for the Defendants submitted that, if the defendant showed that he did not want his customers to be deceived, that was probative of a lack of a likelihood of deception. In my judgment this is precisely why Kitchin LJ said that it all depended on the facts of the case. If it is proved that the defendant was aware of the risk of deception and proceeded recklessly, then that is capable of supporting the conclusion that deception was likely even if the defendant did not intend to deceive. If, however, what is proved is that the defendant was aware of the risk, but thought that he had done sufficient to avoid it materialising, then that is not supportive of the conclusion that deception was likely, but rather of the reverse.

189. A separate point made by counsel for the Defendants is that an awareness on the part of the defendant that there was a risk that the claimant would bring proceedings is not the same as an awareness of a risk of deception. I agree with this.

Glaxo's case in outline

190. As noted above, Glaxo advance two claims of passing off. The first is that the get-up of the AirFluSal Forspiro makes a misrepresentation as to trade origin. Until the pre-trial review, Glaxo contended that both HCPs and patients were being deceived as to trade origin, but at the pre-trial review they abandoned the former contention. Accordingly, this claim is now confined to deception of patients. Glaxo's second claim is that the get-up of the AirFluSal Forspiro makes a misrepresentation as to equivalence with the Seretide Accuhaler. Glaxo contend that the AirFluSal Forspiro is not equivalent to the Seretide Accuhaler in three respects: (i) it was not licensed for

asthma prior to February 2017 and it is still not licensed for adolescents, (ii) it is only available at the 50 µg/500 µg strength, which means that the patient must be switched to a different inhaler for downwards titration and (iii) it has a different mode of operation, which means that the patient must be trained to use it.

191. Until shortly before trial, Glaxo were alleging that the Defendants intended to deceive HCPs and patients by the get-up of the AirFluSal Forspiro. Glaxo abandoned that contention, but maintain that the Defendants were reckless in the sense discussed above in adopting the colour purple.

Goodwill: the distinctiveness of the colour purple

192. In order to succeed in either of their claims, Glaxo must demonstrate that, at the relevant date, the feature of get-up they rely upon, namely the colour purple, was distinctive of Seretide in the mind of the relevant public, either HCPs or patients. For the purposes of the first claim, they must show that the colour was distinctive of the trade origin of Seretide. For the purposes of the second claim, they must show that the colour was distinctive of the relevant characteristics of the Seretide Accuhaler.

193. As the Defendants point out, in considering the question of distinctiveness, it is important to appreciate at the outset that Glaxo do not claim that any particular shade of purple (whether identified by Pantone reference or otherwise) is distinctive of their products. This is because, as described above, Glaxo do not use a single shade of purple in relation to the Seretide Accuhaler, but rather a range of shades, and this is even more true of the Seretide Evohaler. Moreover, the AirFluSal Forspiro features different shades of purple to those used on the Seretide Accuhaler (although the shade used on the Forspiro itself is not dissimilar to the lighter shade used on the Accuhaler). Thus Glaxo's claim is to distinctiveness of any shade of purple, and indeed of combinations of such shades. Although it is convenient to describe all the relevant shades as "purple", the claim encompasses shades which could equally well be described by other words, such as lilac, magenta, mauve, mulberry, violet and so on. Moreover, it encompasses shades which are likely to be perceived and described by different people in different ways (and even by the same person in different ways depending on the lighting and other factors).

194. As the Defendants also submit, the colour of a product and its packaging is generally devoid of distinctiveness, because consumers do not ordinarily identify the origin or characteristics of a product by reference to the colour of the product or its packaging. The Defendants do not dispute that, in principle, the colour of a product or its packaging may acquire distinctiveness as to trade origin through use, although they point out that this is difficult to prove for the reasons discussed above. Nor do the Defendants dispute that, in theory, the colour of a product and its packaging could also become distinctive of the characteristics of the product, but they contend that this is even less likely.

Distinctiveness as to trade origin amongst HCPs

195. The two main categories of evidence relied upon by Glaxo to establish that the colour purple was distinctive as to trade origin as at November 2015 are (i) evidence as to the use of purple on a substantial scale at the launch of Seretide and subsequently in marketing materials addressed to HCPs and (ii) surveys of GPs and pharmacists. As

the Defendants point out, neither category of evidence is of much relevance given that Glaxo no longer pursue their claim of origin deception amongst HCPs. In those circumstances I shall only deal briefly with the first category of evidence. I shall deal more fully with the second category, because it is also relied upon by Glaxo for other purposes as I shall explain. Moreover, quite a lot of costs have been incurred in relation to the surveys, and they raise some issues of wider significance.

Glaxo's marketing materials

196. Glaxo produced a considerable amount of evidence about their use of purple at the launch of Seretide and subsequently in marketing materials addressed to HCPs. The evidence about the launch included evidence about purple stands at trade shows, Glaxo representatives wearing purple ties, purple gifts and even purple food. As counsel for the Defendants submitted, this turned into something of a damp squib when it emerged that the Defendants' trade witnesses who were asked about the launch in cross-examination had (perhaps unsurprisingly given the passage of time) little recollection of it. More importantly, there is no dispute that, ever since the launch, Glaxo have made continuous and prominent use of the colour purple in marketing materials for Seretide. It is not necessary for the reasons already explained to go into details.

197. The only point that matters is that Glaxo do not now contend that HCPs would assume that AirFluSal Forspiro had the same trade origin as (or was otherwise connected in the course of trade with) Seretide because of the use of the colour purple. It follows that the colour purple was not at the relevant date distinctive of Glaxo's products in the minds of HCPs despite the extensive marketing to HCPs carried out by Glaxo featuring purple materials.

198. This accords with the evidence given by several of the Defendants' trade witnesses that they would not assume that any purple inhaler was Seretide, but would regard the colour purple as denoting the combination of salmeterol and fluticasone. That in turn accords with the colour convention discussed above.

Patient leaflets

199. Of greater relevance is the fact that Glaxo have distributed patient leaflets for HCPs to give to patients which are coloured purple. An example from 2015 is reproduced below. There is no evidence as to the extent of the distribution of such leaflets, however. In any event, it is difficult to see what these leaflets would add given patients' exposure both to the purple on the packaging of the Seretide Accuhaler and to the purple colours of the device itself, which they use twice a day. There is nothing in the leaflets to educate patients that the colour purple signifies the trade origin (or the scope of the marketing authorisation) of Seretide Accuhalers.

The surveys

200. In support of their case Glaxo relied upon four surveys. Two were carried out in March 2015, one of 200 GPs and one of 200 pharmacists. These surveys were devised and organised by Dr Almut Pflüger, a very experienced German expert in carrying out surveys for trade mark and unfair competition proceedings, using a methodology known as the "three-step test" which is accepted in Germany, a number of other EU Member States and the EUIPO. The results of these surveys were submitted to the UK Trade Mark Registry as evidence to support Glaxo's claim that the colour shade Pantone 2587C had acquired distinctive character through use in the UK and thus to support Glaxo's application number 3,108,001 to register that colour as a UK trade mark.

201. The 2015 surveys were criticised by Dr Anne Niedermann, another experienced German expert instructed by Sandoz, who were opposing Glaxo's application. As a result, Glaxo commissioned Dr Pflüger to devise and organise two more surveys in March-April 2016, one of 251 GPs and one of 252 pharmacists. These used a questionnaire based on one that had been employed in *Enterprise Holdings Ltd v Europcar Group UK Ltd* [2015] EWHC 17 (Ch), [2015] FSR 22, but with an additional question.

202. Glaxo submitted two reports (one concerning GPs and one concerning pharmacists) by Dr Pflüger dated 27 April 2016 to the Registry which summarised and commented on the results of all four surveys and responded to Dr Niedermann's criticisms. (So far as the 2015 surveys were concerned, these reports superseded two earlier reports by Dr Pflüger dated 22 April 2015.) In addition, Glaxo submitted reports from two English experts in market research with experience in surveys for trade mark and passing off proceedings, Graham Williams and Adam Phillips, who also commented on the results and on Dr Niedermann's criticisms. In response, Sandoz submitted a second report from Dr Niedermann replying to Dr Pflüger and a report from Louis Rothman, another English expert, replying to Mr Williams and Mr Phillips. In reply, Glaxo submitted further reports from Dr Pflüger, Mr Williams and Mr Phillips.

203. At that stage Glaxo applied for permission to use the survey evidence from the Registry proceedings for the purposes of these proceedings. That application was opposed by Sandoz. In support of their opposition, Sandoz relied upon a second report from Mr Rothman and a report from Philip Malivoire, who is probably the most experienced English expert in this field. In response, Glaxo served further reports from Dr Pflüger and Mr Phillips. In reply, Sandoz served a second report from Mr

Malivoire. By this point, therefore, the parties were between them relying upon no less than 15 expert reports from six experts.

204. The application came before Birss J at a hearing on 29 November 2017. He granted Glaxo permission to rely upon the surveys for the reasons he gave in a judgment dated 15 December 2017 ([2017] EWHC 3196 (Ch)). By an order dated 20 December 2017 he gave the parties permission to rely upon all the existing reports and upon oral expert evidence from each of the six experts. He also directed that the experts should meet and prepare a report setting out where they agreed and where they disagreed. Mr Phillips was unable to participate in the meeting due to illness, but the other five experts prepared a joint statement. Mr Phillips subsequently filed a further report commenting on the joint statement.

205. When the trial opened, the parties were proposing that all six experts be cross-examined during the course of one day. Having by then read all 16 reports and the joint statement, I observed that (unsurprisingly) the reports were quite repetitive and that it was likely that cross-examination of all the experts would be equally repetitive. I therefore proposed that only Dr Pflüger should give oral evidence for Glaxo and that only Mr Malivoire should give oral evidence for the Defendants, in accordance with the general principle that only one expert per discipline per side should be permitted. The parties agreed to this, with the proviso that they would still be entitled to rely upon the written evidence of the other experts. In the event, the cross-examination of Dr Pflüger and Mr Malivoire took most of a court day. I estimate that cross-examination of all the experts would have taken more like two days, and I do not believe it would have given me any greater assistance.

206. Before proceeding further, it is pertinent to observe that it appears that, at the time of devising the 2015 surveys, Dr Pflüger was not aware of the requirements of the English courts with regard to the documentation of surveys discussed below. Even at the time of devising the 2016 surveys, she does not appear to have been made fully aware of these requirements. As Mr Malivoire observed in his first report dated 27 July 2017, Dr Pflüger's initial reports did not properly describe the methodology employed in either the 2015 or the 2016 surveys. Moreover, although Dr Pflüger had provided further information in response to the second report of Dr Niedermann and Mr Rothman in her report dated 27 October 2016, the position at that stage was that there was no single document setting out the methodology. Rather, one had to look at several documents and even then the account was incomplete. It was not until Dr Pflüger's High Court report dated 28 September 2017 that some of the relevant information became available, and it can be seen from that report that Dr Pflüger had to obtain some of that information from other people. Leaving aside the question of whether, even now, the relevant guidelines have been complied with, it is clear that this procedure will have unnecessarily increased the costs of the survey evidence for both sides.

207. Two lessons should be learnt from this unfortunate history. First, parties who commission surveys should ensure that the methodology of the survey is fully described in a single document at the outset, and that the conduct of the survey is fully documented thereafter. Secondly, duplicative evidence from survey experts must be avoided. These points apply just as much to proceedings in the Registry as they do to High Court proceedings, and the Registry should not hesitate to use its case management powers to ensure that they are complied with.

The 2015 surveys

208. Respondents were asked initial screening questions to check that (in the case of GPs) they prescribed or (in the case of pharmacists) they dispensed inhalers for patients suffering from asthma or COPD "at least every now and then" and how often. Respondents were then shown a rectangular card bearing the colour Pantone 2587C (which corresponds to the shade used on the packaging of the Seretide Accuhaler 250 and to the shade used on the larger part of all Seretide Accuhalers) and asked the following questions. The interviewers were instructed to record responses to the questions using tablet computers.

209. The respondents were asked ("Step 1" in the analysis):

> "QO: What comes to your mind spontaneously when you see this colour in connection with inhalers?
>
> Q1: Have you already seen this colour used on an inhaler? Or do you think that you might have seen this colour used on an inhaler? Or have you not seen this colour used on an inhaler?"

210. Those who had said that they had seen the colour used or might have seen it were asked ("Step 2"):

> "Q2: Here are a few statements concerning inhalers that use this colour. First, please read all of them carefully and then tell me which statement represents your personal opinion.
>
> Inhalers that use this colour, for me …
>
> … come from **a particular** pharmaceutical company
>
> … come from **a number of different** pharmaceutical companies
>
> … tell me **nothing** about the pharmaceutical company **at all**".

The order of the possible responses was rotated so that each one was listed first in about a third of the cases.

211. Those who said that inhalers using the colour come from a particular pharmaceutical company were asked ("Step 3"):

> "Q3: Do you know the name of the pharmaceutical company or brand? Please answer this question only if you are sure about the name."

212. There were other questions later in the survey, but these are the key ones for present purposes.

213. In summary, 93% of pharmacists said that they had seen the colour on an inhaler and the remaining 7% considered it looked familiar. Of GPs, 92% said they had seen the colour on an inhaler and the remaining 8% considered it looked familiar. Of these,

92% of pharmacists and 93% of GPs considered that it indicated the origin of one pharmaceutical company and of these about 90% of pharmacists and 88.5% of GPs identified Glaxo or Seretide in one way or another.

The 2016 surveys

214. The methodology of the 2016 surveys was similar to that of the 2015 surveys except that interviewers were instructed to record anything respondents said even before the first question was asked and that respondents were asked the following questions:

> "Q1: Have you ever seen this colour before in relation to inhalers?
>
> Q2 Where have you seen this colour before?
>
> Q3: Is there anything else you can tell me about this colour in relation to inhalers?
>
> Q4: How do patients typically refer to the inhaler that you mentioned?"

215. 7% of pharmacists and 5% of GPs mentioned Glaxo/Seretide even before any question was asked. In answer to Q1, 100% had seen it before, with numerous respondents mentioning even at that stage that it was Glaxo or Seretide, before being asked where they had seen it. In answer to Q2, 63.9% of pharmacists said that they had seen it on Seretide, Glaxo or Accuhaler/Evohaler products and 75.7% of GPs said they have seen it on Seretide. The responses to Q4 suggest that patients refer to the inhalers by colour very frequently, and at least as much as they refer to them as Seretide or Accuhaler/Evohaler. In total 82.5% of GPs and 71.8% of pharmacists mentioned Seretide/Glaxo. References to third party brands at any point during the surveys were negligible.

No surveys of patients or surveys concerning equivalence

216. As the Defendants point out, on the face of it, the surveys relied upon by Glaxo cannot advance their case, because the surveys were designed to attempt to show that (a particular shade of) purple was distinctive of Glaxo's products in the minds of GPs and pharmacists, but Glaxo no longer contend that HCPs are deceived as to trade origin by the use of purple on the AirFluSal Forspiro. Glaxo do contend that patients are deceived as to trade origin, but no survey of patients was carried out in the UK. By contrast, Dr Pflüger explained that she had carried out patient surveys for Glaxo in other countries. Glaxo rely upon the answers to Q4 in the 2016 surveys as providing indirect evidence with respect to patients, but no corresponding question was asked in the 2015 surveys. Even for the purposes of Glaxo's claim of misrepresentation as to trade origin, therefore, the 2015 surveys and the answers to Q1-Q3 in the 2016 surveys appear to be of no relevance. Since Glaxo continued to rely upon all of the survey results in its closing submissions, however, I shall nevertheless consider them.

217. As for Glaxo's claim of misrepresentation as to equivalence, none of the questions asked in any of the surveys was designed to show whether the colour purple was distinctive of the specific characteristics of Glaxo's products that are in issue amongst GPs or pharmacists, let alone patients.

The law

218. It is well known that, in any form of survey or opinion polling, the wording of the questions has a very significant influence on the responses. In the context of surveys for the purposes of trade mark and passing off proceedings, this problem is compounded by the fact that trade mark and passing off law is concerned with people's unconscious assumptions. As soon as you start asking people questions designed to ascertain those unconscious assumptions, you risk the process distorting what you are trying to test. One of the well-known phenomena this gives rise to is respondents treating the questionnaire like a quiz, and searching for the answers they should give in the questions. These problems are rendered even more severe if the questionnaire seeks responses to an artificial stimulus (such as a colour sample rather than actual packaging). It is for these reasons that the courts of England and Wales have for a long time laid down guidelines which need to be followed by those carrying out such surveys if the evidence is to be relied upon. It does not matter for present purposes whether compliance with these guidelines is a requirement for admissibility or goes to weight, and I will assume the latter.

219. The basic guidelines, often referred to as "the Whitford Guidelines", were formulated by Whitford J as long ago as 1984 in *Imperial Group plc v Philip Morris Ltd* [1984] RPC 293 (an unsuccessful passing off claim concerning the use of the colours black and gold on cigarette packaging) at 302-303. More recently, these guidelines were endorsed by the Court of Appeal in *Interflora Inc v Marks & Spencer plc* [2012] EWCA Civ 1501, [2013] FSR 21. In that case Lewison LJ summarised the guidelines at [61] as follows:

> "i) if a survey is to have any validity at all, the way in which the interviewees are selected must be established as being done by a method such that a relevant cross-section of the public is interviewed;
>
> ii) any survey must be of a size which is sufficient to produce some relevant result viewed on a statistical basis;
>
> iii) the party relying on the survey must give the fullest possible disclosure of exactly how many surveys they have carried out, exactly how those surveys were conducted and the totality of the number of persons involved, because otherwise it is impossible to draw any reliable inference from answers given by a few respondents;
>
> iv) the questions asked must not be leading; and must not direct the person answering the question into a field of speculation upon which that person would never have embarked had the question not been put;
>
> v) exact answers and not some sort of abbreviation or digest of the exact answer must be recorded;
>
> vi) the totality of all answers given to all surveys should be disclosed; and

vii) the instructions given to interviewers must also be disclosed."

The Defendants' criticisms of the surveys

220. The Defendants contend that the surveys failed to comply with a number of the Whitford Guidelines. It is convenient to consider these in a different order to those set out by Lewison LJ.

221. *Guidelines (iii) and (vii)*. Surveys are a form of experiment. In the field of patent litigation, the English courts require that experiments be repeated in the presence of the opposing party. That is because experience has shown that it is only inspection that enables the opposing party, and hence the court, properly to understand and scrutinise the experiment. Furthermore, the requirement for repetition helps to ensure that the results are reliable. (As is now well known, one of the problems with the scientific literature is that it sometimes turns out that reported experiments cannot subsequently be repeated by others.) The English courts do not require repetition in the case of surveys, but they do insist on the next best thing, which is that the survey be fully documented and the documentation fully disclosed. This is so as to enable the opposing party, and the court, properly to scrutinise the manner in which the survey has been carried out. If the survey is not fully documented and the documentation fully disclosed, it cannot be regarded as reliable evidence.

222. Mr Malivoire, who as noted above is probably the most experienced English expert in this field, said that he could not recall any other survey where the documentation had been as spare as was the case with the surveys in the present litigation. Mr Phillips agreed that the surveys (in particular the interviewer briefings) should have been better documented. It is clear that the root cause of the problem is that Dr Pflüger had not been made fully aware of what was required. Accordingly, she did not ensure that all aspects of the survey were properly documented, and some aspects were not documented at all. This problem is compounded by the fact that Dr Pflüger did not personally oversee the conduct of the surveys. Part of the explanation for this was that Dr Pflüger was also instructed by Glaxo to carry out parallel surveys in a number of other countries, and clearly she could not be everywhere at once.

223. Dr Pflüger arranged for all the national surveys to be managed by the well-known market research company TNS Infratest (now Kantar TNS), which sub-contracted the field work in the UK to ACE International. ACE is a global market research company with headquarters in Cologne. For the 2015 surveys ACE appointed a project manager based in Cologne, who in turn recruited supervisors responsible for each region who in turn recruited interviewers in their respective regions. ACE was responsible for the conduct of 70% of the interviews. ACE pre-recruited the GP respondents and 30% of the pharmacist respondents by telephone from its call centre in Cologne. The remaining pharmacists were recruited by interviewers walking into pharmacies to find willing respondents. 30% of the interviews were sub-contracted to Exafield Ltd, a market research company specialised in the healthcare sector based in Macclesfield. Exafield pre-recruited the GP respondents and 30% of the pharmacist respondents by telephone from its call centre in London. For the 2016 surveys ACE appointed another project manager based in Cologne, but this time she was assisted by a project manager based in a branch office which ACE had by then opened in London. This time ACE London was responsible for the conduct of all the interviews, and recruited

the supervisors and respondents. Again, all the GPs and 30% of the pharmacists were recruited by telephone.

224. Neither the telephone recruitment of GPs and pharmacists nor the briefings given by supervisors to interviewers were documented. In neither case was a full script provided in advance, nor was any record kept of what had been said.

225. In the case of the recruitment process, Dr Pflüger disclosed a document setting out the screening questions which the recruiters were instructed to ask. But this document is plainly incomplete in at least three respects. First, there is no discussion at all of what to say to the receptionist in a surgery when trying to get through to a GP to ask the screening questions. Secondly, Dr Pflüger candidly explained in her reports that recruiters were instructed that, if necessary, they could offer respondents a small financial incentive to participate. Apparently, all the GPs and approximately 80% of the pharmacists required payment. But the instructions disclosed say nothing about this, and thus one does not know how or precisely when the incentive was offered. Thirdly, and relatedly, the instructions disclosed say nothing about making arrangements for the substantive interview (indeed, the introductory wording gives the impression that the substantive interview is to take place at the same time). When cross-examined on these points, Dr Pflüger said that she assumed that ACE would have had a more complete script, but admitted that she had not asked.

226. In the case of the interviewer briefing process, Dr Pflüger disclosed some rather cursory briefing notes which were supplied by ACE and Exafield to the interviewers. She also disclosed a much more detailed presentation on reporting adverse events which was provided to interviewers. These documents raise more questions than answers. For example, Dr Pflüger explained that ACE and Exafield had been instructed to recruit interviewers who were experienced in the medical field, rather than interviewers who were experienced in conducting surveys for legal purposes. She also said that it was standard practice to give interviewers carrying out pharmaceutical research training materials about adverse events. But the presentation makes it clear that the adverse events with which it is concerned are "an undesirable medical event which affects a patient to whom a product has been administered". The contents of the presentation had no relevance to the surveys, and in my view would have been likely to distract interviewers from the points that mattered. Dr Pflüger's estimate was that the briefing would have taken 45 to 60 minutes, but it is unclear how this time would have been spent apart from running through the questionnaire and receiving the training on adverse events. One has no idea what questions interviewers asked or how they were answered.

227. Dr Pflüger could not of course testify to what had been said by any of those involved, because she was not present. In cross-examination Dr Pflüger explained that she had relied upon the fact that she had instructed experienced market research organisations to carry out the work, who had recruited experienced interviewers, and that she was confident that the instructions which had been given both in writing and orally would have been adhered to. Mr Malivoire explained, however, that in his experience organisations and individuals who were experienced and competent in carrying out ordinary commercial market research could not be relied upon to adhere to the more exacting standards required for legal purposes unless they were specially recruited and trained. Moreover, his practice is not only to provide written instructions in advance, but also personally to attend interviewer briefing sessions. From my own

experience of market research carried out for trade mark and passing off cases, both at the bar and on the bench, I have no doubt that Mr Malivoire's approach is the correct one. I would add that, with modern digital recording technology, there is no reason why at least interviewer briefings should not be recorded. (Ideally, both recruitment interviews and survey interviews would be recorded as well, but this would require the consent of the respondents, which might well be problematic to obtain.)

228. Accordingly, I conclude that none of the surveys complied with Guidelines (iii) and (vii). This is not necessarily fatal to their being relied upon, but it reduces the extent to which the court can have confidence in their reliability, and hence their probative weight.

229. *Guideline (i)*. Addresses and telephone numbers for both GP practices and pharmacies were obtained from a list provided to ACE by Sample Solutions Europe. Dr Pflüger had no personal knowledge of this list, and her information about it came not directly from ACE but from TNS. According to that information, the list contained 90-95% of all GP and pharmacy addresses in the UK. This list was divided by region, and a quota applied to each sub-list based on the regional representation of GPs and pharmacies, but precisely how this was done Dr Pflüger did not explain. These sub-lists were used for recruitment until each quota had been fulfilled.

230. Mr Malivoire pointed out that, given that all the GPs had been recruited by telephone, it was likely that the recruiters would have had to get past a receptionist to speak to each GP. As discussed above, there is no evidence as to what would have been said at this point. Mr Malivoire speculated that it was likely that inhalers would have been mentioned. I agree with this. It does not follow that the survey respondents were unrepresentative, however.

231. The Defendants' experts pointed out, and Dr Pflüger accepted, that there had been no attempt to weight the samples of respondents by reference to the age, experience or gender of the respondent or the size of the GP practice or pharmacy. In principle, it would have been possible to use data from the GMC register and NHS Digital to try to construct appropriate quotas for GPs. It is less clear that equivalent information would have been available for pharmacists, but presumably some data could have been obtained from the GPhC. Mr Rothman's evidence was that there were statistically significant differences as to the age, experience and gender of respondents between the 2015 and 2016 surveys, suggesting that one or both was unrepresentative. Furthermore, only one GP or pharmacists from each practice or pharmacy had been interviewed, thus weighting the samples in favour of small practices and pharmacies and against larger ones.

232. Mr Phillips demonstrated, however, that, at least so far as age and gender are concerned, differences in the age and gender distribution of the respondents would have had little impact on the results of the surveys. Mr Malivoire accepted this, although he maintained that the sample should have been properly constructed. Similarly, Mr Malivoire was unable to think of any reason why the size of the practice or pharmacy should have made a difference to the results, although he considered that it should have been controlled for.

233. I conclude that Guideline (i) was not fully complied with, in that no attempt was made to obtain samples of respondents which were representative of the relevant

populations with respect to age, experience, gender and size of practice/pharmacy, but that there is no reason to think that this had any material impact on the results.

234. *Guideline (ii)*. There is no dispute that the sizes of the samples were adequate.

235. *Guideline (iv)*. The Defendants contend that the 2015 surveys do not comply with Guideline (iv). I agree with this. I acknowledge that courts in other countries regard these questions as acceptable, but in my judgment they do not comply with the standards required in this country. Q0 invites speculation. While this might not be so problematic if asked at a later stage (compare Q3 in the 2016 surveys), I do not consider acceptable to ask this question before Q1. Q2 is both leading and misleading. It is leading, because even though a choice of three different answers is proffered, it suggests to the respondent that the colour may denote the trade origin of the inhalers when that could well be a possibility that had never occurred to them before and would not occur to them if the question were not asked. It is misleading, because in March 2015 the only inhalers which used that shade of purple (or indeed any shade of purple to any significant extent whether on the device or on the packaging) were the Seretide Accuhaler and Evohaler. Thus purple could not indicate inhalers that came from a number of different pharmaceutical companies. Mr Malivoire's opinion was that, as result of these and other flaws, the 2015 survey was valueless. I agree with this.

236. As for the 2016 surveys, the Defendants do not criticise Q1-Q3, but they do criticise Q4, which was not included in the survey in *Enterprise v Europcar*. The Defendants contend that Q4 is flawed for three distinct reasons. First, they criticise the wording of the question as being vague (what does "typically" mean and in what context are the patients supposed to be referring to the inhaler?) and as requiring the respondent to try to remember what patients have said, possibly some time previously.

237. Secondly, and perhaps more importantly, they contend that Q4 does not comply with Guideline (v). Dr Pflüger explained that she was asked to add Q4 to the 2016 surveys and she agreed to do so on the basis that it would not influence the answers to any of Q1-Q3 since those questions would already have been asked. But the problem with Q4 is the converse one, namely the answers to Q4 are bound to have been influenced by the asking and answering of Q1-Q3, all of which mention colour. Moreover, from the beginning of the interview, the respondents had been given the show card of Pantone 2587C and kept hold of it or had sight of it throughout the interview. As Dr Pflüger admitted, if all one was interested in was answers to Q4, one would not need to show the participants any kind of colour card. Thus it is at least possible, and in my view probable, that respondents will have been biased towards mentioning colour, and specifically purple, in answer to Q4.

238. Thirdly, Q4 was asked of all participants of the survey whether or not they had referred to Seretide inhalers in answers to Q1-Q3 or not. Therefore, even if respondents had not referred to Seretide inhalers at all, their response to Q4 was still included within the results, which are being relied upon as indicating how patients refer to their Seretide inhalers. This, of course, is a defect in the sequencing of the questions rather than in Q4, but it is convenient to address it.

239. For all of these reasons, I agree with the Defendants that Q4 in the 2016 surveys does not comply with Guideline (iv) and the results cannot be regarded as probative.

240. *Guideline (v)*. The reason why Guideline (v) is important is that, as Lord Hoffmann said in another context, quoting Renan, *la vérité est dans une nuance*. This is particularly true when trying to ascertain people's unconscious assumptions from their responses to survey questions, and even more so when the survey is attempting to test whether unconventional subject-matter such as a colour has acquired distinctive character as a trade mark. The importance of this Guideline is enhanced in the present case when one comes to Q4 in the 2016 surveys because this question was attempting indirectly to ascertain patient perceptions.

241. The Defendants contend that this Guideline was not complied with. Dr Pflüger was adamant that the interviewers were all instructed to record answers verbatim and confident that they had done so. There are a number of reasons for believing that this is unlikely, however. First, the briefing notes to the interviewers do not mention this requirement. Nor, for the reasons explained above, is there is any evidence to confirm that interviewers were orally briefed about it. Secondly, the questionnaires for the 2016 surveys instructed the interviewers to write down verbatim anything the respondent said after being shown the show card and before Q1 was asked, but by contrast there was no such instruction in relation to Q1-Q4. Nor was there any such instruction in the questionnaires for the 2015 surveys. Thirdly, interviewers were required to record the answers on a specially-programmed tablet computer. It is unclear precisely how this operated, but it appears likely that the interviewers will have used the tablet's ordinary touchscreen keyboard to enter the answers. Dr Pflüger confirmed that they did not receive any training in how to record answers verbatim using such a keyboard. There is not even any evidence as to the extent to which any of them were able to touch type. Fourthly, Mr Malivoire's evidence was that, in his experience, it was difficult to get interviewers to record answers verbatim, since they were not used to doing it for ordinary commercial work where this was not required. This was one of the key reasons why they needed to be specially recruited and trained for legal work. Fifthly, Mr Malivoire pointed out that the recorded answers which had been disclosed tended be quite short, and shorter than was usual in his experience. More specifically, he showed that, on average, they were noticeably shorter than the answers in the *Enterprise v Europcar* survey. He was therefore, as he put it, "very sceptical that the reported responses represent the entirety of what respondents in fact said".

242. I found Mr Malivoire's evidence on points four and five entirely convincing. Taking all of these points into account, I am not satisfied that Guideline (v) was complied with. Rather, it appears likely that the recorded answers represent paraphrases by the interviewers of what the respondents said. Glaxo argue that, even if that is correct, it does not affect the reliability or evidential value of the results at least of the 2016 surveys, particularly given the high percentages of respondents who apparently associated purple with Seretide. Subject to the point discussed below, I am disposed to accept this so far as Q1-Q3 of the 2016 surveys are concerned. I do not accept it in relation to Q4, where I consider that capturing the answers precisely was more important for the reason explained in paragraph 240 above, but that question was flawed anyway for the reasons discussed in paragraphs 236-239 above.

243. *Guideline (vi)*. There is no dispute that this Guideline was complied with.

244. *Conclusion on compliance with the Guidelines.* For the reasons given above, I conclude that the 2015 surveys do not comply with the Guidelines in a number of

respects, and are of no value. As for the 2016 surveys, I consider that, despite the flaws in the surveys, the results of Q1-Q3 are reasonably reliable so far as they go, but Q4 was too flawed with respect to its position in the questionnaire, wording and lack of verbatim recording of the answers to be of value.

245. *Do the surveys demonstrative distinctiveness anyway?* Counsel for the Defendants submitted that, even taken entirely at face value, all that the 2015 and Q1-Q3 of the 2016 surveys established was recognition of Pantone 2587C on the part of the GPs and pharmacists and association of it with Seretide in the sense explained by Kitchin LJ. I accept this submission. All the surveys show is that GPs and pharmacists recognised the colour as a feature of Seretide inhalers. They do not prove that GPs or pharmacists would assume that another inhaler bearing that shade of purple (let alone a different shade capable of being described as purple) emanated from the same trade origin, let alone an inhaler of a different design bearing different word marks. As I have already noted, this is particularly true of the 2015 surveys when there was no other such inhaler on the market. Even in March-April 2016 the AirFluSal Forspiro had not been on the market for very long, and many of the respondents might not have encountered it. Sirdupla/Aloflute had been on the market for longer, but as noted above there is no evidence as to the extent of its market penetration by then.

246. As for the responses to Q4 in the 2016 surveys, counsel for the Defendants submitted that, even taken entirely at face value, all these showed was that patients frequently referred to their Seretide inhalers by colour. This was entirely consistent with patients finding it convenient to differentiate between their different inhalers by reference to their colour (their blue inhaler, their brown inhaler, their purple inhaler), which did not show that patients regarded the colour as being distinctive of inhalers having a particular trade origin (or as being distinctive of inhalers having specific characteristics). Again, I accept this submission. I will return to this point below.

Distinctiveness as to characteristics amongst HCPs

247. Glaxo's case is that, as at November 2015, purple denoted in the minds of HCPs an inhaler with the marketing authorisation (i.e. indications and patient groups), the strengths (or at least, titratability) and the delivery mechanism of the Seretide Accuhaler. As counsel for the Defendants submitted, however, there is simply no evidence to substantiate this case. None of Glaxo's trade witnesses said any such thing. And all of them were clear in cross-examination that they would never rely upon purple to indicate anything about (for example) the marketing authorisation of an inhaler. On the contrary, HCPs were well aware that generic versions of the same drug, including those presented in the same or similar colours, commonly have differing approved indications and patient groups. The Defendants' trade witnesses gave unchallenged evidence to the same effect.

248. I would add that there is an inherent flaw in this part of Glaxo's case anyway, namely that both Seretide Accuhaler and Seretide Evohaler are marketed in (broadly) the same shades of purple. The Accuhaler and the Evohaler differ in their delivery mechanisms, however, and so purple cannot denote any one mechanism. The Accuhaler and the Evohaler also differ in the doses of medication they deliver, and so purple cannot denote any specific range of doses. The most it could indicate would be a range of three. But in fact, for both the Accuhaler and Evohaler, different shades indicate different strengths. Furthermore, whereas the Accuhaler has different

licensed indications or patient groups for the three strengths, the Evohaler has the same licensed indications for all three strengths, which does not extend to COPD (the only difference is that only the lowest strength is licensed for children). Indeed, the SmPC for the Seretide Evohaler specifically warns that it is not indicated for COPD. It follows that, even leaving aside the different shades used, purple cannot indicate a particular set of extents of authorisation.

Distinctiveness as to trade origin amongst patients

249. As counsel for the Defendants pointed out, Glaxo have adduced very little evidence even to attempt to demonstrate that purple is distinctive of the trade origin of Seretide in the minds of patients. For the reasons discussed above, Seretide cannot lawfully be marketed directly to patients. Thus Glaxo's evidence of their marketing efforts does not assist them to show distinctiveness among patients. And as I have noted, Glaxo did not carry out any survey of patients. The nearest they came to this is Q4 of the 2016 surveys, which I have concluded is unreliable, but even if the results are taken at face value shows no more that patients use the colour purple to differentiate their Seretide inhaler from other inhalers of a different colour they have (or have had in the past).

250. The documentary evidence and the evidence of the trade witnesses of both sides at trial is entirely consistent with this being how patients use and perceive colour in relation to inhalers.

251. A document which counsel for Glaxo particularly relied upon is a GfK market research report prepared for Sandoz during their preparations to market AirFluSal Forspiro in May 2011. This contains a number of references to the purple colour reminding respondents (who were HCPs in various countries including the UK) of Seretide. But this simply shows that HCPs recognised purple and associated it with Seretide at a time when, as Glaxo themselves emphasise, there was no other purple inhaler on the market. It does not show that purple was distinctive of the trade origin of Seretide or of the Seretide Accuhaler even among HCPs, let alone patients. There is no documentary evidence which goes any further.

252. As for the trade evidence, the following extract from the cross-examination of Professor Rupert Jones, an Associate Professor at the University of Plymouth with a special interest in asthma and COPD and GP with 30 years' experience when he retired in 2014, is representative:

> "Q. It makes perfect sense, does it not, for them to distinguish those two inhalers which have different functions by their colours?
>
> A. Yes
>
> Q. So, when they are talking to health care professionals, that is really what is going on, generally they will be saying 'Yes I make sure I take my purple inhaler once a day, I have used my blue inhaler twice in the last week' or something like that?
>
> A. Yes I would agree

Q. That is the kind of interaction that you are talking about in paragraph 81 is it?

A. Yes. They do not always say purple, they might say mauve or they might say lilac.

Q. I see.

A. But purple is the one they usually state

Q. If they had two other inhalers, if they had the blue one and a different one, say Symbicort, they could easily use a colour to identify that one as well?

A. Yes and there is some published evidence that that is the case."

(Strictly speaking the last answer is probably inadmissible as being expert evidence - Prof Jones being one of the three Glaxo witnesses much of whose evidence I excluded on that ground - but neither side objected to it being admitted.)

253. As counsel for the Defendants accurately summarised the position, there is no evidence that in November 2015 patients would assume that any inhaler in a purple colour was an inhaler from the manufacturers of Seretide. They simply knew that their preventer (Seretide) inhaler was purple. The two propositions are quite different. Insofar as patients relied on the colour, it was for ease of distinction between different inhalers having different functions.

Distinctiveness as to characteristics amongst patients

254. I can deal with this shortly. There is simply no evidence to show that, in November 2015, the colour purple denoted an inhaler having specific characteristics in the minds of patients. The inherent flaw in Glaxo's case applies in this context too. And the evidence as to how patients used and perceived the colour purple does not show that purple was distinctive in this sense either. At most, it indicates that patients generally knew purple inhalers were prescribed to prevent their symptoms re-occurring (save for occasional exacerbations).

Facilitating switching

255. Before turning to consider Glaxo's claims of misrepresentation, it is convenient to consider two general points relating to all of them. First, Glaxo make much of the fact that the AirFluSal Forspiro is a substitute for (the strongest) Seretide Accuhaler. The Defendants do not dispute this. On the contrary, the Defendants fully accept that the AirFluSal Forspiro was always intended to be marketed, and has been marketed, as a generic alternative to (the strongest) Seretide Accuhaler. As the Defendants point out, generic alternatives to originator products are common, lawful and benefit the public.

256. Secondly, Glaxo contend that the use of the colour purple facilitates the switching of patients from the Seretide Accuhaler to the AirFluSal Forspiro. Again, the Defendants do not dispute this. As the Defendants contend, however, it is important to be clear as to the reasons for this. There are three inter-related reasons. First, the use of purple avoids other colours which might cause concern amongst patients as to whether they

are receiving the correct medication. Secondly, purple will be recognised by most HCPs as following the colour of the originator products and thus as indicating a generic salmeterol/fluticasone inhaler. Most HCPs support the general idea of "colour coding" inhalers according to their drug class. Thus the use of purple conforms with the expectations of HCPs. Thirdly, the use of purple encourages HCPs to prescribe and/or dispense AirFluSal Forspiro to patients who have previously had Seretide Accuhalers, because HCPs will not be concerned about patients who are used to distinguishing between their blue and purple inhalers having to learn a different colour distinction. As the Defendants submit, these are all legitimate aims which have nothing to do with passing off.

257. The contrasting positions of the parties is well illustrated by Glaxo's reliance upon evidence given by Vectura's witness Stephen Eason (as to whom, see further below), who is himself an asthma sufferer, that, if he was dispensed an inhaler which a different colour to the one he was used to, then it would raise a question in his mind and he would query it. Counsel for Glaxo said in their written closing submissions that this evidence encapsulated Glaxo's case. But it also encapsulates the Defendants' case. The key question, of course, is why Mr Eason would query the change in colour, which depends on what the colour signified to him. Mr Eason's evidence was that, so far as he was concerned, what the colour signified was the active ingredients delivered by the inhaler (see also further below).

258. Counsel for Glaxo also submitted that this evidence, and a number of other similar examples, showed that "by using the same colour, patients have an expectation that the product is the same as they have had before but just from a different company. A different colour gives a clear warning that this may not be correct". But this is precisely the Defendants' case.

259. There is also no dispute that some patients have indeed been switched from the Seretide Accuhaler to the AirFluSal Forspiro. In principle, switching can occur either at the prescribing level (typically CCG-led) or at the dispensing level (where a pharmacy is presented with an INN script and chooses to dispense AirFluSal Forspiro rather than Seretide Accuhaler). It should be noted, however, that there is no evidence of any CCG, GP practice or pharmacy switching patients who have been prescribed salmeterol/fluticasone for asthma (as opposed to COPD) prior to February 2017. Indeed, there is evidence that some CCGs declined to include AirFluSal Forspiro in their local formularies until it was licensed for asthma. Similarly, a number of large pharmacy chains declined to stock AirFluSal Forspiro until then (as to which, see further below). It should also be noted that the trade witnesses who gave evidence about it were clear that, at least at the prescriber level, switching would not be done without proper consultation with the patient.

<u>Misrepresentation to patients as to trade origin</u>

260. Given the absence of evidence that the colour purple had become distinctive of Seretide in the minds of patients by November 2015, it is not surprising that there is no evidence either of any actual confusion amongst patients in the period for more than 3½ years since AirFluSal Forspiro was launched.

261. Glaxo pleaded four alleged instances of confusion. As counsel for the Defendants submitted, however, upon analysis none of these instances did evidence confusion on

the part of patients. Since none of these were relied upon by counsel for Glaxo in closing submissions, it is unnecessary for me to go into details. The same goes for two other instances relied upon by Glaxo's witness Jonathan Crompton, who is a Marketing Director, in his witness statement.

262. It is clear that Glaxo put a great deal of effort and resources into searching for evidence of confusion, including (i) searching Glaxo's own documents, (ii) searching the Defendants' disclosure documents, (iii) asking their retail sales teams to look out for any instances of confusion and (iv) trawling through a series of websites and social media platforms. For example, the two additional instances of alleged confusion relied upon by Mr Crompton in his statement both came from patient forums hosted by a website called HealthUnlocked.

263. To his credit, Mr Crompton, after being cross-examined on the instances of alleged confusion to which he had drawn attention, gave a straight answer to the obvious question:

> "Q. Mr. Crompton, I am going to put to you if this is the best evidence of patient confusion that can be found after the kind of trawl of internet resources that we are looking at ----
> A. Mmm-hmm.
> Q. ---- it suggests very strongly that there is not any patient confusion going on at all; correct?
> A. Correct."

264. Mr Crompton's answer was realistic. Some 500,000 prescriptions for AirFluSal Forspiro have now been filled in the UK. As counsel for the Defendants pointed out, the ubiquitous use of social media makes it much easier than it used to be for instances of confusion to be publicised and for well-resourced claimants to find them. But in the present case the cupboard is entirely bare. There is not even any evidence of a single patient rejecting an AirFluSal Forspiro inhaler, whereas one would expect this to have happened on a substantial scale if Glaxo's case were well founded.

265. Counsel for Glaxo's only answer to this point was to rely upon the principle that evidence of actual confusion is not a pre-requisite to success in a claim for passing off, it is sufficient to show that there is a likelihood of confusion. In the present case, I am not persuaded that there is any likelihood of patients being confused into thinking that AirFluSal Forspiro comes from the same origin as Seretide. But if I was in any doubt, the state of the evidence would resolve it. Given the lengthy period during which AirFluSal Forspiro has been on the market, the substantial sales of AirFluSal Forspiro and the likelihood that, if there had been any confusion, Glaxo would have found evidence of it, I conclude that the reason why there is no evidence of confusion is, as Mr Crompton recognised, that there is no confusion.

266. It follows that Glaxo's claim for passing off by a misrepresentation to patients as to the trade origin of AirFluSal Forspiro must be dismissed.

Misrepresentation to HCPs as to equivalence

267. Not only is there is no evidence that the colour purple was distinctive of the relevant characteristics of Seretide Accuhaler inhalers amongst HCPs in November 2015, but

also there is no evidence that any HCPs have been, or are likely to have been, confused as to the characteristics of AirFluSal Forspiro due to the use of purple. As counsel for the Defendants submitted, the evidence at trial was flat contrary to Glaxo's case.

268. It is convenient to consider the three characteristics relied upon by Glaxo in reverse order. First, Glaxo contend that the use of the colour purple conveys a misrepresentation that the AirFluSal Forspiro has the same mechanism for delivering the active ingredients as the Seretide Accuhaler, and thus can be used by patients without re-training. As I have already pointed out, this case is inconsistent with Glaxo's own use of the same shades of purple on the Seretide Evohaler.

269. In any event, this is in my view a very far-fetched claim. Seretide Accuhaler patients use the Accuhaler twice a day every single day. It is very important to them, since it helps them live a normal life. They inevitably become intimately familiar with the device, including its precise colouration, and how it operates, even if for some reason they don't recall its name. It is absurd to suggest that such a patient (or their carer) could possibly think the AirFluSal Forspiro was the same product (or a new version of it). Apart from the very different name, packaging, shape and colour (both in terms of shade and configuration), the mechanism and the mode of operation of the two devices are radically different. A patient who received an AirFluSal Forspiro expecting the Accuhaler would find that instead of rotating a circular dial round to access the mouthpiece and then inhaling, they had to open a lid to access the mouthpiece, and then move a lever up and over to move the dose into position, before drawing the dose. Thus, even if they disregarded its name, packaging, shape and appearance, anyone who tried to use an AirFluSal Forspiro would instantly discover that it works differently.

270. There is no evidence whatsoever that HCPs would assume that the AirFluSal Forspiro works in the same way as the Seretide Accuhaler just because it is coloured (a different shade of) purple. On the contrary, the evidence demonstrates that, as one would hope and expect, HCPs were and are aware that different brands of DPI work in different ways, and therefore patients need to be trained to use each brand dispensed to them.

271. It is precisely because of this awareness that inhalers, and in particular DPIs, are increasingly prescribed by brand. Glaxo point out that, in November 2015, a higher percentage of inhalers was prescribed generically than now. But there are three answers to that. First, it seems likely that a good proportion of that higher percentage was represented by MDIs. Secondly, the fact that many prescribers had an ingrained habit of prescribing generically even when it came to inhalers does not prove any lack of awareness on their part that different DPIs functioned differently. Rather, it is at least equally consistent with an expectation that pharmacists could be relied upon to give any training the patient might need (or at least to direct the patient to a resource such as RightBreathe since that became available). Third, even in cases where the script was written generically, that does not mean that dispensers lacked awareness that different DPIs functioned differently. The evidence of the pharmacist trade witnesses is to the contrary.

272. Secondly, Glaxo contend that the use of the colour purple conveys a misrepresentation that the AirFluSal Forspiro exists in three strengths, thus permitting

patients to be titrated down using the same device. Again, there is a degree of inconsistency with Glaxo's use of the same shades of purple on just two strengths of Seretide Evohaler. In any event, this is an even more bizarre claim. Anyone prescribing or dispensing AirFluSal Forspiro cannot help but be aware that it comes in a single strength. It is therefore inescapable, as any prescriber or dispenser will instantly appreciate, that downwards titration, if required, will necessarily involve the patient being switched to another inhaler. Unsurprisingly, there is no evidence of any prescriber or dispenser being led by the colour purple to think that patients can be titrated downwards using the AirFluSal Forspiro. Again, the evidence of the trade witnesses is to the contrary.

273. Thirdly, Glaxo contend that the use of the colour purple conveys a misrepresentation that the AirFluSal Forspiro has the same extent of authorisation as the Seretide Accuhaler. This is the case that Glaxo pushed hardest at trial, and in particular the aspect of it that concerns the fact that AirFluSal Forspiro was not authorised for asthma, but only for COPD, prior to February 2017.

274. Even this aspect of Glaxo's case suffers from a fundamental difficulty, however. In order to amount to actionable passing off, any misrepresentation must be material, so as to cause damage to the claimant's goodwill. I find it difficult, however, to see how a misrepresentation that AirFluSal Forspiro was licensed for asthma could have been damaging to Glaxo's goodwill. The product did not change when Sandoz obtained the variation to the marketing authorisation in February 2017. Nor did Sandoz submit any further evidence of therapeutic equivalence to the Seretide Accuhaler. All that happened is that Sandoz agreed to the revised wording of the SmPC (and PIL) which the MHRA had requested. Glaxo point out that the basis of the MHRA's previous objection was a potential risk to public health. The fact remains, however, that the objection was resolved without any change to the product or the evidence of its efficacy and safety. It was purely a regulatory issue. Furthermore, before the product was licensed for asthma, it would have been open to prescribers to prescribe it off-label for asthma; and in my assessment it is likely that a few did so.

275. A related point concerns the way in which Glaxo articulated this part of their case at various points during the trial. This was that the colour purple conveyed a misrepresentation to patients that the AirFluSal Forspiro was suitable for treating asthma. Counsel for the Defendants submitted that this was not pleaded, whereas counsel for Glaxo submitted that it was. The relevant plea is in the following terms (despite the use of the present tense, it relates to the period from November 2015 to February 2017):

> "AirFluSal is only authorised for COPD sufferers and should not be taken by asthma sufferers … AirFluSal is therefore not equivalent to Seretide because the latter includes both indications (COPD and asthma) while AirFluSal is only authorised for COPD."

In my judgment this pleads that the AirFluSal Forspiro is not equivalent to the Seretide Accuhaler because it is not authorised for asthma. It does not plead that AirFluSal Forspiro is not suitable for the treatment of asthma. Accordingly, the only case which is open to Glaxo is the one considered above.

276. In any event, regardless of how the claim is formulated, as counsel for the Defendants submitted, the evidence does not support it. So far as suitability for the treatment of asthma is concerned, there is no evidence that AirFluSal Forspiro was unsuitable. For the reasons discussed above, the evidence is to the contrary. Indeed, counsel for Glaxo accepted that a prescriber could have prescribed AirFluSal Forspiro off-label for asthma without being negligent. He submitted that that would have required a clinical judgment by the prescriber based on his or her assessment of the individual patient; but that does not detract in any way from the suitability of AirFluSal Forspiro for treating asthma.

277. As to the scope of the marketing authorisation, only one of Glaxo's trade witnesses, Chinedu Nwanede, a pharmacist, stated in a witness statement that he had assumed that the AirFluSal Forspiro had the same approved indications as the Seretide Accuhaler due to its colour (until he was told the contrary when his statement was being prepared). When it was put to him in cross-examination that he had not given any thought to precisely what the licensed indications of AirFluSal Forspiro were, however, Mr Nwanede replied that he had assumed that AirFluSal Forspiro was "prescribed" for COPD. Although he used the word "prescribed", in context I understood him to mean "licensed". Thus his understanding appears to have been correct. Moreover, he said that he would not make any decision based on the colour of the inhaler, but rather he would presume that the prescriber had prescribed the right medication for the right indication.

278. Another of Glaxo's trade witnesses, Hannah Lubbeke-Brown, who was also a pharmacist, stated in her second witness statement (although not in her first) that she would expect an inhaler with the same active ingredients to have the same licensed indications. This, of course, had nothing to do with colour (or any other aspect of get-up) at all. In any event, in cross-examination, she accepted that she was aware that in fact inhalers were commonly licensed for different indications even though they contained the same active ingredients in the same dosages, and therefore she would always check when presented with a prescription for a product that was new to her for the first time.

279. All of Glaxo's trade witnesses were clear that they would not make any assumption about the marketing authorisations of inhalers based on their colour. Rather they would check the BNF, the SmPC, the product literature or some other resource. Moreover, the Defendants' trade witnesses were not challenged on their evidence that they would not do such a thing either.

280. Glaxo contend that it is probable that some asthma patients, including some adolescents, had received AirFluSal Forspiro prior to February 2017. I accept this so far as adult asthma patients are concerned, although I am doubtful about adolescents, but it does not establish passing off. In some cases this may have occurred due to off-label prescribing. It is also likely that some pharmacists assumed without checking that AirFluSal Forspiro was licensed for treating the condition the patient in question was suffering from, which was in fact asthma although the pharmacist did not know that. It is also possible that, even when they knew or had ascertained that the patient in question was suffering from asthma, some pharmacists assumed that AirFluSal Forspiro was licensed for asthma. But even in the last scenario, there is nothing to show that they did so because it was purple, rather than because it contained the same active ingredients in the same strength as the strongest Seretide Accuhaler.

281. Counsel for Glaxo particularly relied in this regard upon an internal email from two Sandoz representatives dated 13 November 2015 reporting their visit to Peter Glover, the Superintendent Pharmacist of the Day Lewis pharmacy chain. Mr Glover was recorded as having said:

> "When all the repeat prescriptions come in, the pharmacist won't know if it is for COPD or asthma. I would rather wait until you have all indications as it will cause confusion"

282. Counsel submitted that this showed that Day Lewis had declined to stock AirFluSal Forspiro until it was licensed for asthma because of a concern about confusion, and suggested that it was likely that other chains which had declined to stock it at that stage did so for the same reason. But there is nothing to suggest that Day Lewis, or any other chain, thought that confusion would be caused as to what indications AirFluSal Forspiro was licensed for because it was coloured purple. On the contrary, Mr Glover was also recorded as having said:

> "Are you following the colour code for Seretide? ([One of the representatives] explained the reason behind the colour purple) – That makes sense to me to do it that way."

283. Counsel for Glaxo also relied upon a comparison between the large percentages of AirFluSal Forspiro dispensed against INN scripts and the much lower percentages of Aerivio Spiromax dispensed against INN scripts (24% and 13%). The possible reasons for this difference were not explored with any witness, however. It is pure speculation to suggest that it had anything to do with the colour of the AirFluSal Forspiro, as opposed to factors such as CCG policies and pricing. Moreover, even if it did, it does not demonstrate any misrepresentation. An alternative explanation would be that pharmacists were more confident that patients would accept that AirFluSal Forspiro contained the correct active ingredients.

284. It remains finally to address the point raised by Glaxo at trial that AirFluSal Forspiro is only licensed for severe asthma, whereas the marketing authorisation for the 50µg/500µg strength of Seretide Accuhaler contains no such restriction. The first question is whether it is open to Glaxo on its statements of case to advance a case of misrepresentation as to equivalence based on the fact that AirFluSal Forspiro is only licensed for severe asthma. In my judgment it is not. As counsel for the Defendants rightly pointed out, paragraph 61.6 of Glaxo's Fifth Amended Particulars of Claim does not allege that AirFluSal Forspiro is not equivalent to Seretide Accuhaler 50µg/500µg because it is only licensed for severe asthma.

285. Even if the case is open to Glaxo, I do not accept it. As can be seen from the expert statement of Dr Russell quoted above, the clinical rationale which underpinned Sandoz's application for the variation to the marketing authorisation for AirFluSal Forspiro was that the 50µg/500µg strength would only be likely to be prescribed for patients with severe asthma who were unlikely to be titrated down to a lower dose, and hence the non-availability of lower strengths of AirFluSal Forspiro was not a significant issue (although patients could be switched to a different inhaler in any event). This accords with evidence given at trial by two of the trade witnesses, Dr Daniel Moore (a GP) and Tapiwa Mukori (a pharmacist who is an independent prescriber). Thus, no prescriber would be likely to think that AirFluSal Forspiro was

suitable for patients with mild to moderate asthma anyway, because of the high dose of the active ingredients (and in particular the high dose of fluticasone). As for the proposition that prescribers would be misled by the colour of AirFluSal Forspiro into thinking that it was suitable for patients with mild or moderate asthma, that is simply fanciful. And of course no pharmacist would dispense AirFluSal Forspiro to a patient who had not been prescribed 50µg salmeterol/500µg fluticasone.

286. For completeness, I would add two points. The first is that Glaxo pointed out that, as noted above, the BNF entry for AirFluSal Forspiro records the licensed indication as being "asthma" rather than "severe asthma". (The same is true of RightBreathe.) I agree that, strictly speaking, this is inaccurate, but the inaccuracy cannot be laid at Sandoz's door. Moreover, even if prescribers or dispensers were misled by this, it would have nothing to do with the colour of AirFluSal Forspiro.

287. The second is that Glaxo criticised Sandoz for not putting statements such as "Not for asthma" and "Only for adults" on the external packaging of the AirFluSal Forspiro prior to February 2017. Although the MHRA suggested this, Sandoz declined to accept the suggestion and the MHRA did not require it to be done. It follows from the conclusion above, however, that no such statement was necessary to avoid passing off. The same goes for Glaxo's criticism of Sandoz for not putting statements such as "Only for severe asthma" and "Only for adults" on the external packing since February 2017.

Misrepresentation to patients as to equivalence

288. As counsel for the Defendants submitted, it is inherently improbable that patients would make any assumptions as to the characteristics of AirFluSal Forspiro inhalers based on their colour. There is no reason why patients should make any assumption as to the delivery mechanism, and as discussed above they would find out that it was different as soon as they tried to use it even if they had somehow not been made aware of that before. Nor is there any reason for patients to be concerned as to whether or not there is more than one strength of AirFluSal Forspiro. Few patients would be aware of the need for downwards titration, and those that were aware would rely upon their prescribers and dispensers to ensure that they received the appropriate treatment. Equally, few patients would be aware of the existence and significance of differing marketing authorisations, and those that were aware would rely upon their prescribers and dispensers. It is therefore unsurprising that there is no evidence that any patients have been, or are likely to have been, confused as to the characteristics of the AirFluSal Forspiro, let alone that this is due to its colour.

289. Counsel for Glaxo submitted that evidence of confusion as to equivalence was unlikely to come to light. I accept that confusion as to equivalence is less likely to come to light than confusion as to trade origin. Given the extensive sales of AirFluSal Forspiro, however, I regard the absence of any evidence of confusion as confirmation that it is wholly improbable.

Recklessness

290. As a result of Glaxo's allegation of an intention to deceive, the Defendants gave extensive disclosure of the process by which the Forspiro device was designed by Vectura and the process by which the AirFluSal Forspiro product was developed by

Aeropharm and Hexal in collaboration with Vectura. Furthermore, the Defendants served detailed witness statements from witnesses who had been involved in the development process, which spanned a considerable period of time. Given the abandonment of the allegation of intent to deceive, this evidence is of little relevance. Accordingly, I do not propose to rehearse the history of the development in this judgment, but simply concentrate on points which matter to the case which was pursued by Glaxo.

291. As finally presented at trial, Glaxo's case that the Defendants were reckless as to whether members of the relevant public would be deceived into believing that the AirFluSal Forspiro was connected in the course of trade with Glaxo and/or equivalent to Glaxo's product was based on the following three allegations:

> "(1) the Defendants deliberately sought to make the AirFluSal product and packaging as similar as possible to the Seretide Accuhaler and they did so recognising that this would assist in switching patients from the Seretide Accuhaler to their product;
>
> (2) the Defendants identified and sought to exploit the high level of generic prescribing of the DPIs and the commercial opportunities of pharmacy substitution; and
>
> (3) the Defendants were aware of a risk that many patients and HCPs would take a purple-branded product to be associated in the course of trade with the Seretide Accuhaler and/or that it was equivalent to it."

292. Before turning to these allegations, it is convenient first to consider the Defendants' evidence as to why the colour purple was chosen for the AirFluSal Forspiro. The key witness on this topic was Kirsi Norvasuo-Huber, who at the relevant time was Senior Product Manager for Respiratory and Allergy at Hexal. On 23 May 2006 she sent an email to a number of colleagues in Hexal and Sandoz International GmbH attaching a picture of a Viani Diskus (Viani and Diskus are brand names used elsewhere in Europe by Glaxo instead of Seretide and Accuhaler) and making the following proposal (in English translation):

> "Our suggestion would be that we produce the Gyrohaler [later this became the Forspiro] in purple and label it normally (white). (The alternative would be to produce the Gyrohaler in the standard [i.e. Sandoz house] colour, e.g. dark blue, and to make the respective active ingredient recognisable by labelling it with an indicative colour, but in my opinion the label is too small for that.)
>
> Whether the purple tone is exactly identical to that of Viani does not matter (could also be protected). In any case, purple is now the indicative colour for the active ingredient combination fluticasone + salmeterol, which every doctor has certainly internalised.

> … We can determine later whether we want to have 2 different purple tones, like the originator. In that case, the protective cap, for example, could have a lighter tone. Of course this is also a question of costs."

293. The colour of the device was discussed at a meeting on 20 June 2006 attended by representatives of Aeropharm, Hexal, the Second Defendant Sandoz International GmbH and Vectura. The minutes of the meeting state:

> "Vectura have presented several design options for two colours provided (dark purple: Pantone 2573 C and light purple: Pantone 2603 C). The light purple combination for cap, top and bottom case (colour code: Pantone 2603 C) was agreed to be the preferred option and should be continued in the further development.
>
> Although there are lots of arguments in favour of this colour design (different device design, different colour purple, purple is the identification colour for this combination product) a fall-back position with different colour should be established. The back-up solution could have a light grey colouring."

294. Consistently with these documents, Ms Norvasuo-Huber's clear and firm evidence was that the reason for the choice of purple was that it was, as she put it, "the signal colour for this substance combination". (The reason for the "fall-back" option was in case Glaxo obtained an injunction restraining the use of purple, as indeed Glaxo did for a short period in 2014 in Germany.) Dr Jens Gross, who was at the time Project Manager Business Development and Licensing at Hexal, and Jan Tangermann, who was at the time Managing Director of Aeropharm, both gave largely unchallenged evidence supporting Ms Norvasuo-Huber's account of the colour choice. I have no hesitation in accepting this evidence.

295. As to allegation (1), the Defendants did not deliberately seek to make the AirFluSal product and packaging as similar as possible to the Seretide Accuhaler. One only needs to look at the products and packaging to see that this is so. The only similarity that Glaxo persisted in relying upon is the similarity in colour. In any event, however, as the Defendants submit, this is irrelevant. If there is no deception of HCPs or patients, then developing a product that would assist in switching patients from the Seretide Accuhaler to a generic is not passing off. In particular, it is not passing off if the similarity in colour merely re-assures patients that the AirFluSal Forspiro has the same active ingredients as the Seretide Accuhaler.

296. Counsel for Glaxo laid considerable emphasis on the fact that Sandoz had made prominent use of purple in its marketing materials (as illustrated below). Leaving aside that this point is not pleaded in support of the case of recklessness, it is perfectly consistent with Sandoz's reasons for choosing purple.

297. As to allegation (2), there is no dispute that Sandoz sought to make sales in the INN channel, since that represented (as of late 2015) around a half of prescriptions. It is unclear what is meant by "pharmacy substitution". If it is meant to refer to managed changeovers with appropriate patient training, then there is no dispute that Sandoz

intended to take advantage of that possibility, but they were fully entitled to do so as a generic entrant to the market. If it is meant to refer to pharmacists deliberately supplying a product they know the patient is unfamiliar with and is not expecting without warning or training, it is an allegation which is not open to Glaxo. Such an allegation would have to be expressly pleaded, but it is not.

298. The allegation in (3) of recognising the risk of origin confusion was only put directly to one witness, Mr Eason, who was employed by Vectura at the time that they developed the Forspiro device, but left in April 2017. Mr Eason rejected it:

> "Q. Did you at least consider that there was a risk that healthcare professionals and patients would think that a purple product would be a GSK product?
>
> A. Absolutely not, no. This is my baby, and I do not want anybody to think that it is produced by anybody other than Vectura and Sandoz."

Again, I have no hesitation in accepting this evidence.

299. A version of allegation (3) on equivalence confusion was put to Dr Gross. It was suggested to Dr Gross that he had recognised in 2006 that the shape of the product, and in particular the purple colour, would mean that there would be a high chance that the product would be recognised by HCPs and patients as a "substitute" for the Seretide Accuhaler. As counsel for the Defendants pointed out, that begs the question – what is meant by "substitute"? The product plainly was intended to be, and is, a substitute in the sense that it is the same combination of active ingredients in the same strength as Seretide Accuhaler 50 µg/500 µg and can be prescribed for the same indications (subject to the point on the scope of the marketing authorisation).

300. If what was meant was "you knew there was a risk that HCPs and patients would think the purple colour meant the product was equivalent to the Seretide Accuhaler in terms of the precise scope of the marketing authorisation, existence of lower doses of the same product, and no need for retraining", the question should have been put in those terms. It is clear that would have been rejected. Dr Gross was clear in his answer as to his actual intention:

> "My perspective, at that point in time, was there is a colour coding, essentially, and patients -- it is in the interest of the safety of the patient that he knows which drugs he is taking. So the colour was a helpful reminder [to] the patient that he is taking the salmeterol fluticasone product, which he has to take twice a day."

Again, I have no hesitation in accepting this evidence.

301. The closest Glaxo got to putting its pleaded case to the Sandoz internal witnesses was the following question that was put to Dr Eder about the position in the UK between November 2015 and February 2017:

> "Q. Did you recognise that risk at all at this point in time?

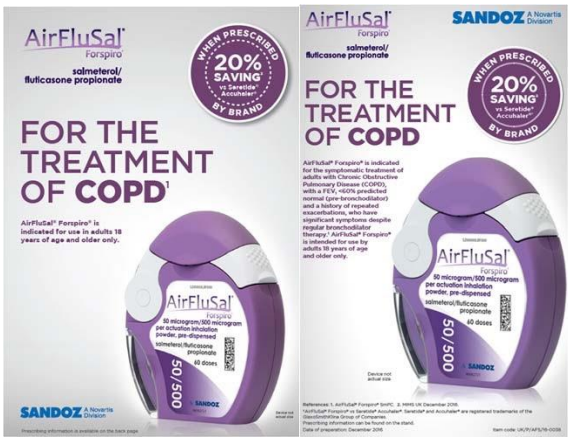
A. That there would be -- which risk?

Q. The risk that asthma sufferers, who were getting repeat generic prescriptions, would be dispensed your product?

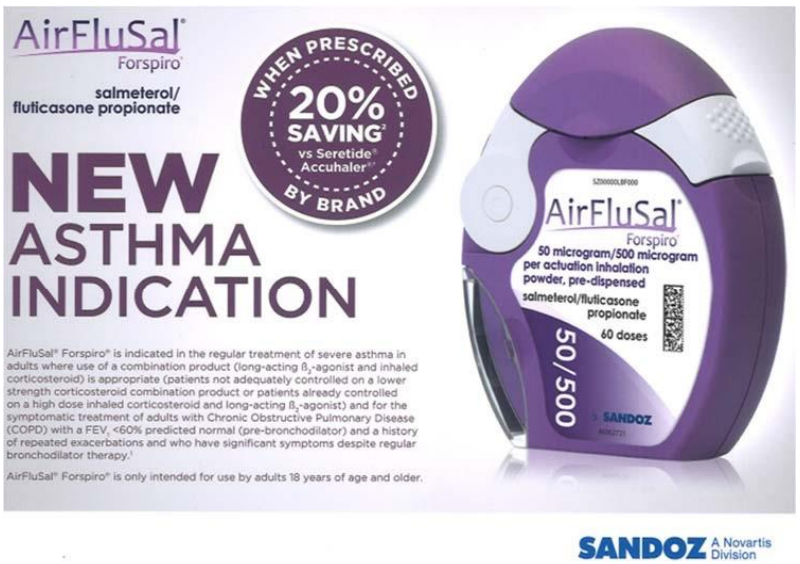
A. My Lord, I did not consider this a risk. We made it very clear what our product was for, namely for COPD. All our marketing materials were structured accordingly, and we communicated this to our customers."

302. As counsel for the Defendants submitted, it is unclear what the risk put to Dr Eder has to do with passing off. It would appear that, if such a risk exists at all, it is inherent in the regulatory system and in the way in which HCPs discharge their responsibilities in relation to a generic product with the same active ingredients as the originator but differences in the scope of its marketing authorisation. It was not even put to Dr Eder that this risk had anything to do with the purple colour of the AirFluSal Forspiro.

303. In any event, I accept Dr Eder's evidence that Sandoz made it clear in its marketing materials during this period that the product was for COPD, as can be seen from the example shown below.



304. By contrast, when AirFluSal Forspiro was licensed for asthma, Sandoz promoted the new indication, as can be seen from the example shown below.



In addition, this makes it clear that the new indication is for severe asthma.

305. It was also put to various witnesses that they were aware of a risk of being sued by Glaxo. As discussed above, however, that is irrelevant. This is particularly so given that their concern was of being sued for trade mark or design right infringement. Equally irrelevant is the fact that Vectura sought and obtained an indemnity from Sandoz in 2010.

306. Counsel for Glaxo also put a series of questions to Mr Eason which seemed to be intended to establish that various marketing materials were misleading. The cross-examination failed to establish any such thing, but in any event it was irrelevant to the pleaded case. It is therefore unnecessary for me to go into details.

307. The upshot is that I entirely acquit the Defendants of the charge of recklessness. There is nothing in the Defendants' state of mind at the time of developing and launching the AirFluSal Forspiro that lends any support to the claim of passing off. To the contrary, given that it is Glaxo's own case that Sandoz were knowledgeable about the relevant market, the evidence supports the case advanced by the Defendants at trial that the use of the colour purple on the AirFluSal Forspiro would be perceived by HCPs and patients as indicating the combination of active ingredients it contained. It can now be seen that there never was any proper basis for the charge of recklessness. It follows that, as the Defendants submit, the entire investigation into the Defendants' state of mind has been a complete waste of time and money.

Joint liability of Aeropharm and Hexal

308. Since I have concluded that Sandoz are not liable for passing off, the question of joint liability on the part of Aeropharm and Hexal does not arise. I shall briefly deal with it for completeness, however.

The law

309. There is no dispute as to the applicable principles, which were considered by the Supreme Court in *Fish & Fish Ltd v Sea Shepherd UK* [2015] UKSC 10 and by the Court of Appeal at an earlier stage of this case, *Glaxo Wellcome UK Ltd v Sandoz Ltd* [2017] EWCA Civ 227, [2017] FSR 32. In short, a defendant which is said to be jointly liable with a principal tortfeasor must be shown to have acted in a way which furthered the commission of the tort by the principal tortfeasor, and must have done so in pursuance of a common design to do or to secure the doing of the acts which constitute the tort - mere assistance or facilitation of a tort will not do.

Assessment

310. There is no dispute that both Aeropharm and Hexal were closely involved in the development of the AirFluSal Forspiro from the point at which Vectura brought the initial design of what was then called the Gyrohaler to the Sandoz group to the point at which the AirFluSal Forspiro was ready to be marketed. It is therefore unnecessary for me to go into details. The dispute centres on what happened after that in the UK.

311. In support of Glaxo's case that Aeropharm and Hexal are jointly liable for any passing off by Sandoz (strictly speaking, Sandoz Ltd, being the relevant operating company in

the UK, although Sandoz International GmbH and the Fifth Defendant Sandoz AG accept joint liability for any passing off by Sandoz Ltd), counsel for Glaxo relied strongly upon evidence given by several witnesses that the relevant companies, being part of the same group, were very closely interconnected and, in many respects, operated seamlessly together.

312. Counsel for Aeropharm and Hexal submitted that this evidence was insufficient to establish joint liability on the part of Aeropharm and Hexal because it did not establish that those entities were parties to a common design to launch and market the Airflusal Forspiro *in the UK*. It was not put to the relevant witnesses that either of those entities had any say in the decision to launch the AirFluSal Forspiro in the UK, let alone in a decision to launch it with one strength only and with only a COPD indication, or that they had any input into the marketing of the AirFluSal Forspiro in the UK.

313. Dr Jan-Torsten Tews, who was Head of the Global Respiratory Department at Sandoz International GmbH from November 2009 to September 2017, but is no longer employed by the Sandoz group, gave unchallenged evidence that the decision as to whether to launch the AirFluSal Forspiro in each country in Europe was ultimately down to the local businesses. Thus he explained that, although regulatory approval had been obtained for the AirFluSal Forspiro in many countries, some local businesses chose not to launch the AirFluSal Forspiro (for example the businesses in Italy, France, Belgium and Finland). By contrast, Dr Tews explained that, as far as he was aware, Dr Eder was always relatively clear that he wanted to launch in the UK. For his part, Dr Eder gave unchallenged evidence that it was Sandoz Ltd which was responsible for marketing of the AirFluSal Product in the UK. There is no evidence that either Aeropharm or Hexal (two German companies) had any involvement in the decision to market AirFluSal Forspiro in the UK or in the manner in which it was marketed in the UK.

314. In one line of questioning, counsel for Glaxo referred to the fact that Dr Michael Malaun, who was the Head of the Sandoz Development Regulatory Centre at Aeropharm, was aware that only the 50/500 strength of the AirFluSal Forspiro would be approved in the UK and that it would be approved only for COPD. As Dr Eder explained, however, it was the RCC, and not Dr Malaun or Aeropharm, which was responsible for taking relevant regulatory decisions on behalf of Sandoz Ltd in the UK. The fact that Dr Malaun was aware of the limitations of the UK marketing authorisation does not mean he had any input in the decision to launch in the UK, which was ultimately down to Sandoz Ltd.

315. I therefore conclude that, even if Sandoz are liable for passing off, Aeropharm and Hexal are not jointly liable.

Result

316. All of Glaxo's claims are dismissed.