GSK's passing off claims dismissed

A summary of the High Court judgment of 4 October 2019 in Glaxo Wellcome UK Ltd (t/a Allen & Hanburys) v Sandoz Ltd and Vectura

I. Executive summary

- GSK's claim relates to its Seretide Accuhaler dry-powder inhaler(DPI) (which is known as the Viani Diskus in some EU jurisdictions and Advair Diskus in the US) and the Sandoz dry-powder inhaler, the AirFluSal Forspiro. As the Judge noted, this case was essentially about the colour purple.
- Vectura (for whom Bristows acted successfully) was involved in the design and development of the AirFluSal Forspiro. Vectura was therefore joined as a defendant to these proceedings.
- Images of the two inhalers at issue are shown below.

GSK's Seretide Accuhaler

Defendants' AirFluSal Forspiro

- Sandoz launched the AirFluSal Forspiro in November 2015. It is a competitor to the Seretide Accuhaler 50/500 inhaler. The AirFluSal Forspiro contains the same active ingredients as Seretide Accuhaler (Fluticasone propionate + Salmeterol) but the active ingredients are delivered by a proprietary inhaler. There are differences in the marketing authorisations of the two products.
- It was alleged that Sandoz had 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.[1]

- Judgment was handed down on 4 October. Each of GSK's claims were dismissed.
- Manufacturers of generic asthma/COPD inhalers will note that Mr Justice Arnold commented that there is *"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…and hence patient adherence to their drug regime"*.[2]

II. Generic inhalers, prescribing practices and the NHS Drug Tariff

Generic inhalers:

- Generic DPIs are commonly referred to as "hybrid" generics as opposed to "pure generics" because it can be difficult for generic DPI devices to demonstrate bioequivalence to originator products.

Prescribing practices:

- In the UK a prescription may be written by reference to either the proprietary (brand) name of a product or by reference to its active ingredient (generic name).
- If a product is prescribed by brand then a pharmacist has no option but to dispense the branded product. However, if a prescription is written generically, a pharmacist can dispense either a branded product or a generic product.
- On the whole, generic prescribing is encouraged across the healthcare system in the UK.
- However, in the case of inhalers, particularly DPIs the guidance is to prescribe by brand name rather than generic name, primarily to ensure patients receive a device they are familiar with.
- As a result of this, inhalers, including generic inhalers, are required by the Medicines and Healthcare products Regulatory Agency to have a brand name. In the case of DPIs, it is common for the drug and the inhaler device to have respective brand names, for example AirFluSal (drug) and Forspiro (device).

The Drug Tariff and Category C:

- The NHS Drug Tariff sets out the primary mechanism by which pharmacists are reimbursed by the NHS for dispensing drugs against NHS prescriptions..
- DPIs such as the Seretide Accuhaler and AirFluSal Forspiro fall into Category C of the Drug Tariff**.**

[1] GSK commenced its claim in December 2015 on the basis of passing off and infringement of its registered trade mark. However, the registered trade mark which was relied upon was declared invalid in 2016 following a counterclaim made by Sandoz.

[2] Paragraph [146]

- In Category C if a product is prescribed by brand a pharmacist is reimbursed at the list price of that branded product, however in the case of Category C products prescribed by reference to a generic prescription, pharmacists can dispense a generic medicine but be reimbursed by the NHS at the list price of the originator product, which is typically more expensive than the generic.
- The way reimbursement works under Category C was an important factor in the case as there is a monetary incentive for pharmacists to dispense generic medicines against a generic script. A key element GSK's case (which was described by the judge an allegation without any basis) was that the get-up and colour of the AirFluSal Forspiro was adopted deliberately to facilitate patients being switched from Seretide Accuhaler to AirFluSal Forspiro by pharmacists dispensing against a generic prescription.

III. The allegations made by GSK

GSK alleged that the colour, shape and packaging[3] of the AirFluSal Forspiro was likely to deceive the relevant public in the following ways:

1. that the AirFluSal Forspiro is Glaxo's Seretide Accuhaler product or is otherwise commercially connected with Glaxo or its Seretide Accuhaler (the **"Origin Claim**"). The Origin Claim was pursued originally in relation to both healthcare professionals and patients, but at trial GSK only pursued the claim against patients. This was because Glaxo had no evidence that healthcare professionals would consider the two inhalers to be coming from the same source. GSK alleged that the AirFluSal Forspiro might be assumed by patients to be a design evolution of the Seretide Accuhaler.

2. that the AirFluSal Forspiro is *"equivalent"* to the Seretide Accuhaler (the "**Equivalence Claim**"). The Equivalence Claim was pursued in relation to both patients and also healthcare professionals. GSK's alleged that the AirFluSal Forspiro is not equivalent to the Seretide Accuhaler (and therefore that its get-up amounts to a misrepresentation) for the following reasons:

    i. The AirFluSal Forspiro has a narrower marketing authorisation than the Seretide Accuhaler because it was only licensed for COPD (not asthma) until February 2017. It is still not licensed for adolescents whereas the Seretide Accuhaler is;
    ii. The AirFluSal Forspiro is only available in the highest strength (50/500), whereas the Seretide Accuhaler is available in three strengths. This allows patients to be titrated down when their symptoms are under control; and
    iii. Patients require training when they first use the AirFluSal Forspiro even if they have previously used a

[3] Whilst GSK's case pleaded to the get-up of the AirFluSal Forspiro in general terms, the Judge noted that "*by the end of the trial the only feature Glaxo really relied upon was the use of purple*" paragraph [1].

Seretide Accuhaler. This is because the two inhalers have different methods of operation.

IV. The Court's findings

Both of GSK's claims were dismissed. An outline of the reasons are set out below.

The Origin Claim

Mr Justice Arnold found that there was no evidence that the colour purple had become distinctive of Seretide in the minds of patients by November 2015 (the date of the launch of the AirFluSal Forspiro).[4] He therefore found it unsurprising that there was no evidence of any actual confusion amongst patients (or anyone else).

GSK's Origin Claim was therefore dismissed.

The Equivalence Claim

Mr Justice Arnold also dismissed GSK's Equivalence Claim.

He held that there was no evidence that the colour purple was distinctive of the relevant characteristics of the Seretide Accuhaler and also that there was no evidence that any HCPs have been or are likely to have been confused as to the characteristics of the AirFluSal Forspiro due to the use of the colour purple.[5]

Mr Justice Arnold addressed each of the three limbs of GSK's Equivalence Claim. A summary of his findings in relation to each limb is set out below:

i. Scope of Marketing Authorisation: There was no evidence to suggest that confusion would be caused amongst pharmacists as to the scope of the AirFluSal Forspiro's marketing authorisation. Importantly, each of the HCPs were clear that they would not make any assumption about the marketing authorisation of an inhaler based on its colour.[6]

ii. Availability of AirFluSal Forspiro in only one strength: Mr Justice Arnold described this claim as "bizarre". He found that any HCP cannot help but be aware that the AirFluSal Forspiro is only available in one strength and so any patient who needed to be titrated down would need to be switched to a different device at that point. Arnold J. concluded that *"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*".[7]

iii. Method of operation: Mr Justice Arnold described it as "far-fetched" and "absurd" that HCPs would assume, as GSK claimed, that the AirFluSal Forspiro works in the same way as the Seretide Accuhaler just because it is coloured (a different

[4] Paragraph [260].
[5] Paragraph [267].
[6] Paragraph [279].
[7] Paragraph [272].

shade of) purple.[8] He held that HCPs would notice the radically different mechanisms and modes of operation, even if they had not noticed the different brands, packaging shape and colour.

In relation to patients, Arnold J held that it is inherently improbable that patients would make any assumptions as to the characteristic of AirFluSal Forspiro inhalers based on their colour, and that the absence of any evidence of actual confusion in this regard was confirmation that it is "wholly improbable".[9]

V. Colour conventions for inhalers

Given that this case was essentially about the chosen colour of a generic inhaler, Mr Justice Arnold's judgment looked closely at the history of the use of colour for inhalers, and what patients and HCPs understood those to mean.

In particular, the Court considered how GSK's blue Ventolin inhaler was followed by generic Salbutamol inhalers which were also blue or which were sold in blue packaging. Similarly, GSK's Becotide was followed by generic beclometasone / budesonide inhalers which were brown. Whilst Mr Justice Arnold accepted that there was now a blurring of colour conventions, he found that there are still some colours that currently represent a single drug type or class, namely: deep orange (ICS), beige/brown (ICS), purple (ICS + LABA), deep green (SAMA), light green (LAMA). Manufacturers of generic inhalers will also be comforted by Mr Justice Arnold's comment that *"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."*

This judgment will therefore provide comfort to those generic manufacturers who choose to adopt a colour or colour scheme for their asthma and COPD inhaler which will be familiar to patients who are being treated by the originator product.

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[8] Paragraph [270].
[9] Paragraphs [288-289].