INTELLECTUAL PROPERTY OFFICE

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19 December 2012

COUNCIL REGULATION (EC) 469/2009 CONCERNING THE CREATION OF A SUPPLEMENTARY PROTECTION CERTIFICATE FOR MEDICINAL PRODUCTS

APPLICANT	GlaxoSmithKline Biologicals S.A.
ISSUE	Whether SPC application numbers SPC/GB/08/046 and SPC/GB/11/043 complies with Article 1(b) and may be granted
HEARING OFFICER	C L Davies

DECISION

Introduction

1 This relates to two applications for a supplementary protection certificate (SPC) which were filed by GlaxoSmithKline Biologicals S.A. ("the applicant") and accorded the numbers SPC/GB/08/046 and SPC/GB/11/043. The applicant seeks the grant of these SPCs relating to novel adjuvant systems under the Regulation (EC) No 469/2009 ("the Regulation"). Both applications rely on the marketing authorization ("MA") EU/1/08/453/001 dated 14 May 2008 for Prepandrix (RTM) but refer to separate basic patents. Prepandrix (RTM) is a pre-pandemic influenza vaccine (split virion, inactivated, adjuvanted). It consists of a split influenza virus inactivated, containing antigen equivalent to A/Indonesia/05/2005 like strain used (PR8-IBCDC-RG2), adjuvanted by a combination of substances collectively referred to as AS03.

2 The following table adapted from one provided by the applicant in their skeleton argument filed on 1 October 2012, summarises the applications at issue:

SPC/filing date	Product	Basic patent	proprietor
SPC/GB08/046 10/10/08	An oil in water emulsion comprising squalene, DL-α-tocopherol and polysorbate 80	EP (UK) 0868 918 B1	GlaxoSmithKline Biological S.A.
SPC/GB11/043	An adjuvanted influenza vaccine comprising an	EP (UK)	GlaxoSmithKline Biological S.A.

18/8/2011	influenza virus component which is an influenza virus antigen from an influenza virus strain that is associated with a pandemic outbreak or has the potential to be associated with a pandemic outbreak, wherein the adjuvant is an oil in water emulsion comprising squalene, DL-a-tocopherol and polysorbate 80	1618889 B1	& GlaxoSmithKline Biologicals Niederlassung der SmithKline Beecham Pharma GmbH & Co. KG

The main claims of the basic patents read as follows:

EP (UK) 0868 918 B1 - An adjuvant composition comprising an oil in water emulsion of the following composition: from 2 to 10% squalene, from 2 to 10% alpha tocopherol, and from 0.3 to 3% TWEEN80^{TM}.

EP (UK) 1618889 B1 - A monovalent influenza vaccine composition comprising an influenza virus component which is a low dose of influenza virus antigen from an influenza virus strain that is associated with a pandemic outbreak or has the potential to be associated with a pandemic outbreak, in combination with a suitable adjuvant, wherein said low antigen dose is less than 15ug of haemagglutinin per dose or no more than 15ug per combined dose of vaccine, and wherein said adjuvant is an oil-in-water emulsion carrier comprising squalene, alpha tocopherol and Tween 80.

3 The Examiner, Dr. Philip Mountjoy, raised two main objections in his pre-hearing report dated 4 September 2012:

"(1) In my opinion the AS03 adjuvant (comprising squalene, D-L-α-tocopherol and polysorbate 80) for which an SPC is sought is not an active ingredient for the purposes of Article 1(b) of the Regulation. Adjuvants, whilst having a biological effect, cannot be considered active ingredients for the purposes of Article 1(b) of the Regulation in light of the CJEU's judgment in MIT (C-431/04).

(2) … once the product definitions were amended to overcome the objections raised all three applications would ultimately have to relate to the same product. Given that Article 3(2) of the Plant Protection Regulation (which is relevant to the Medicinal Regulation by virtue of Recital (17) of the Plant Protection Regulation 1610/96) precludes the grant of more than one certificate for the same product to a patent holder, I explained that it was likely that you would have to decide which of the aforementioned applications you wished to have granted and withdraw the others. "

Originally, a third application SPC/GB08/045 was due to be considered at the hearing but in a letter dated 19 October 2012, the applicant withdrew it therefore I will consider it no further.

4 The applicant requested a hearing in their letter dated 9 July 2012 and the matter came before me on 16 October 2012. The applicant was represented by Ms Marjan Noor and Mr Andrew Hutchinson of Simmons & Simmons. Also in attendance were Dr James Robertson and Dr Marcus Dalton of GlaxoSmithKline. The hearing was also attended by the Examiner, Dr Mountjoy and Dr Jason Bellia.

5 Prior to the hearing, the applicant submitted skeleton arguments dated 1 October 2012 which formed the basis of the hearing and hence the framework of my decision.

Issues to be decided

6 The issues to be decided are thus:

Whether the adjuvant AS03, is a product in its own right or when combined with the antigen, wherein the term "product" has the meaning set out in Article 1(b) of the Regulation, i.e. the active ingredient or combination of active ingredients.

As subsidiary issues, whether SPC/GB11/043 may be stayed pending resolution of questions concerning the interpretation of Article 3(c) referred to the Court of Justice of the European Union "CJEU". [The applicant requested I decide on this matter in their letter dated 19 October 2012.]

I will also consider whether or not the applicant may be awarded more than one SPC, as this was raised in their skeleton arguments (paragraphs 54-58) and in their letter dated 19 October 2012.

Relevant Law

7 To assist me in reaching my decision, I will set out the provisions of the Regulation which are relevant to the issues I must decide. I am mindful that when interpreting the provisions of the Regulation, I must do so teleologically, that is when seeking to find the meaning of its provisions, I must look to its underlying general principles. In that I am aided by its recitals, I quote these where I find them relevant as follows:

> (2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.
>
> (3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.
>
> (4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.
>
> (5) This situation leads to a lack of protection which penalises pharmaceutical research.
>
> (6) There exists a risk of research centres situated in the Member States relocating to countries that offer greater protection.
>
> (7) A uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the functioning of the internal market.
>
> (8) Therefore, the provision of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorisation has been granted is necessary. A regulation is therefore the most appropriate legal instrument.
>
> (9) The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community.

(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.

8 I can now turn to the provisions of the Regulation which were referred to during the hearing and which are central to the issues I must decide, again I only reproduce the sections relevant to the issues before me:

Article 1

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(a) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

(b) 'product' means the active ingredient or combination of active ingredients of a medicinal product; …

Article 2

Scope

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

Article 3

Conditions for obtaining a certificate

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the product is protected by a basic patent in force;
(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;
(c) the product has not already been the subject of a certificate;
(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

Article 10

Grant of the certificate or rejection of the application for a certificate

> 1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9(1) shall grant the certificate.
>
> 2. The authority referred to in Article 9(1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.

9 By way of recital 17 of the Plant Protection Regulation (EC) No 1610/96 I am also required to consider the impact of an additional condition for obtaining a certificate. Recital 17 of Regulation (EC) No 1610/96 refers to Regulation (EEC) No 1768/92 - this has since been codified under Regulation (EC) No 469/2009, so is relevant to the Regulation under which the applications were filed. I quote recital 17 and this further condition Article 3(2) of Regulation (EC) 1610/96:

> (17)Whereas the detailed rules in recitals 12, 13 and 14 and in Articles 3 (2), 4, 8 (1) (c) and 17 (2) of this Regulation are also valid, mutatis mutandis, for the interpretation in particular of recital 9 and Articles 3, 4, 8 (1) (c) and 17 of Council Regulation (EEC) No 1768/92,
>
> Article 3(2)
>
> The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.

10 Central to the consideration of the present applications is *C-431/04 Massachusetts Institute of Technology* (hereafter "MIT"). This case concerned a medicinal product Gliadel (RTM) comprising a combination of polifeprosan (a polymeric biodegradable excipient) and carmustine, a known active ingredient with a therapeutic use in chemotherapy. The questions referred to the CJEU were as follows:

> *1. Does the concept of "combination of active ingredients of a medicinal product" within the meaning of Article 1(b) of Regulation [No 1768/92] mean that the components of the combination must all be active ingredients with a therapeutic effect?*
>
> *2. Is there a "combination of active ingredients of a medicinal product" also where a combination of substances comprises two components of which one component is a known substance with a therapeutic effect for a specific indication and the other component renders possible a pharmaceutical form of the medicinal product that brings about a changed efficacy of the medicinal product for this indication (in vivo implantation with controlled release of the active ingredient to avoid toxic effects)?*

Argument and analysis

11 The applicant addressed me on 4 points of argument. I will now address them as they were discussed at the hearing and as they appear in the skeleton argument. The applicant submits that AS03 is a product within the definition of Article 1(b) for the following reasons:

(1) MIT is not relevant authority for whether an adjuvant is an active ingredient. The case was concerned with an excipient. An adjuvant is fundamentally different to an excipient.

(2) MIT is not authority that a substance must have a therapeutic effect of its own (in the sense that it is a requirement that the substance has a therapeutic effect when administered alone) to be covered by the concept of 'active ingredient'. It is sufficient that a substance has a therapeutic effect within the medicinal product in question, such as Prepandrix in this case.

(3) However, even if it were correct, there is no basis for taking a narrow approach to the concept of 'therapeutic effect' in the MIT case and the approach proposed by the Examiner is inconsistent with the definition of 'medicinal product'". An adjuvant which when administered alone has a physiological effect should be considered an active ingredient within the definition of Article 1(b)

(4) A narrow interpretation of the meaning of 'active ingredient' under the SPC Regulation so as to exclude novel adjuvants, as proposed by the Examiner, would be inconsistent with the underlying rationale of the SPC regime.

I will now take each of these points in turn. However, with regard to point (2), I will address the two sentences of this query separately as (2a) and (2b) (see below).

(1) MIT is not relevant authority for whether an adjuvant is an active ingredient.

12 In distinguishing the facts of the present cases from MIT, the applicant argues at paragraph 26 of their skeleton that:

"*MIT should not be considered as having wider application than on the issue of whether an excipient substance which does not have any therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product should be regarded as an active*."

Their reasoning for limiting the teaching of MIT to excipients alone is, they argue, supported by the facts of the case and paragraphs 19, 21 and 25 of the MIT judgment. Furthermore it was explained to me that question 1 referred to the Court had not actually been answered but that the Court had instead chosen to limit their answer to a more specific question (set out in paragraph 14 of the MIT judgment), this question being closer to the circumstances of the application that prompted the reference. I was also advised that it was important to consider the question in paragraph 14 of the MIT judgment holistically.

13 Whilst it is of course true that the combination of substances in MIT is that of polifeprosan, a polymeric biodegradable excipient and carmustine, an active ingredient already used in intravenous chemotherapy (as set out in paragraphs 6, 7 of the judgment) this does not determine whether the teaching of the judgment is intended to extend only as far as excipients. The references to passages in the judgment are bound to refer to the circumstances of the application that prompted the reference, without them the judgment would lack context or may fail to clearly spell out how the national court should apply it.

14 Furthermore, if it had been the Court's intention to relate the judgment more closely to the facts of the case, it could have elected to decide the case in relation to original question 2, which specifies the facts of how the excipient changes the medicinal product

"(in vivo implantation with controlled release of the active ingredient to avoid toxic effects)". The Court notably removed this qualification in the question of paragraph 14 of the MIT judgment. Surely, if the Court had intended the teaching of the case to extend only to excipients it would, in my view, have felt the need to define its answer in relation to the term "excipient" either providing a definition, or at least using the term in the operative parts of the judgment such as paragraphs 25-27, 29 and 31.

15 In relation to the other passages that the applicant quotes in support of their interpretation of MIT, namely 19 and 21, I believe both these passages merely exemplify excipients as but one of the substances that does not form part of the "product". In my view it is not intended to be an exhaustive list, so that finding excipients in this list we should not conclude that this and no more is intended to fall outside the notion of what is an active ingredient.

16 Indeed, these passages also indicate that the product should be understood to mean active substance in the strict sense. This to my mind implies a narrow interpretation of what is an active substance, and correspondingly a broad interpretation of what is a non-active. This is not consistent with the applicant's view that the active substance should be interpreted more broadly. Accordingly, it is my view that the reference to active substance in the strict sense is consistent with a broad interpretation of what is meant in the question of paragraph 14 of the MIT judgment, rather than the narrow one offered by the applicant.

17 Perhaps most importantly, by framing the question in paragraph 14 in functional terms of what the substances do rather than what they are named, it is clear to me that the teaching of the judgment is also defined by what the substances do in the medicinal product. Therefore I do not believe that the teaching of MIT should be limited only to determining if an excipient is an active ingredient, so MIT may have relevance to determining if an adjuvant is an active ingredient. I will now go on to consider the applicant's second point 2a in order to determine MIT's relevance to the present applications.

(2a) MIT is not authority that a substance must have a therapeutic effect of its own (in the sense that it is a requirement that the substance has a therapeutic effect when administered alone) to be covered by the concept of 'active ingredient'.

18 Clearly, in order to determine whether MIT is relevant authority, I need to construe what the limits of its teaching are or at least, if it can be correctly said to apply to adjuvants. I will now consider the question posed in paragraph 14 of the MIT judgment in its entirety and as set out below, to assist me in determining how the Court intended it to be applied.

> *"With these two questions, which should be examined together, the referring court is essentially asking whether Article 1(b) of Regulation No 1768/92 must be interpreted so as to include in the concept of 'combination of active ingredients of a medicinal product' inter alia, a combination of two substances, only one of which has therapeutic effects of its own for a specific indication, the other rendering possible a pharmaceutical form of the medicinal product which is necessary for the therapeutic efficacy of the first substance for that indication."*

19 At the hearing the applicant explained that it made no difference that the term excipient was not defined or explicitly indicated in paragraph 14 of MIT because the question found in this paragraph is correctly interpreted as excluding from the notion of active ingredient only substances that change the pharmaceutical form of the medicinal product.

To help show what the applicant explained to me to be the teaching of MIT, I refer to paragraph 31 of MIT which reads as follows:

> *"In those circumstances, the answer to the questions referred must be that Article 1(b) of Regulation No 1768/92 must be interpreted so as not to include in the concept of 'combination of active ingredients of a medicinal product' a combination of two substances, only one of which has therapeutic effects of its own for a specific indication, the other rendering possible a pharmaceutical form of the medicinal product which is necessary for the therapeutic efficacy of the first substance for that indication."*

20 Taking into consideration this passage and also my understanding of what I believe the applicant said about it, the applicant found that MIT teaches only in respect of substances that render possible a particular pharmaceutical form. That in a combination of substances found in a medicinal product, a substance that renders possible a pharmaceutical form of an active ingredient, enabling the combination to demonstrate therapeutic activity, is not itself an active ingredient. The clear implication the applicant suggested was that in the present applications the adjuvant did not merely "render possible a pharmaceutical form of the medicinal product which is necessary for the therapeutic efficacy" whereas polifeprosan in Gliadel (RTM), the subject of the MIT case, clearly did. To illustrate, the applicant drew me to paragraphs 21 and 25:

> *21. In fact, it is apparent from that memorandum that the pharmaceutical form of the medicinal product, to which an excipient may contribute, as noted by the Advocate General in point 11 of his Opinion and the French Government at the hearing, does not form part of the definition of 'product', which is understood to mean an 'active substance' or 'active ingredient' in the strict sense.*
>
> *25. In the light of the foregoing, the inevitable conclusion is that a substance which does not have any therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the concept of 'active ingredient', which in turn is used to define the term 'product'.*

21 These passages were used to explain that the important point is that the "excipient" or *"substance that does not have any therapeutic activity of its own"* is linked to the "pharmaceutical form", so that the operative part of the judgment says that if a substance, in the context of a medicinal product, renders possible a pharmaceutical form of another substance, it is not an active ingredient. The obvious example being that polifeprosan renders possible a pharmaceutical form of carmustine as it changes its form.

22 In my view, this interpretation is rather selective as it emphasises the importance of the pharmaceutical form and de-emphasises the functional definition, namely what the substances do to the efficacy of the medicinal product. In this way the applicant does not consider paragraph 14 of the MIT judgment as a whole and so alters its meaning. The change in pharmaceutical and even physical form is undeniable from the facts of MIT. But as I have said, merely because this narrow interpretation fits the facts of the case, it does not mean this is all the Court had to say on the matter. I think there is a better interpretation that is consistent with the entire question of paragraph 14, which I will now explain.

23 In my opinion the final clause of the question of paragraph 14 of the MIT judgment qualifies what the Court finds to be a non-active ingredient; it is a substance that has no

therapeutic effect of its own but renders the medicinal product in a pharmaceutical form that is efficacious. In my view the pharmaceutical form that is rendered possible by combining the active and the other substance need not be changed in any other way than that it is made efficacious. So what is important is not merely that the pharmaceutical form is changed, as the applicant would have it, but that a substance that has no therapeutic effect of its own renders the medicinal product in a form that is efficacious.

24 I find support for my view from paragraph 25 of the MIT judgment when it is seen in conjunction with the subsequent paragraphs 26 and 27:

> *25 In the light of the foregoing, the inevitable conclusion is that a substance which does not have any therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the concept of 'active ingredient', which in turn is used to define the term 'product'.*
>
> *26 Therefore, the alliance of such a substance with a substance which does have therapeutic effects of its own cannot give rise to a 'combination of active ingredients' within the meaning of Article 1(b) of Regulation No 1768/92.*
>
> *27 The fact that the substance without any therapeutic effect of its own renders possible a pharmaceutical form of the medicinal product necessary for the therapeutic efficacy of the substance which does have therapeutic effects cannot invalidate that interpretation.*

25 The latter paragraph 27 of the MIT judgment completes the idea begun in paragraph 25 and underlines the fact the determinative aspect of the judgment relates to substances that do not have a therapeutic effect of their own but render possible a form that has therapeutic efficacy. Relying as the applicant does on paragraph 25 in isolation merely begs a different question, what is necessarily different about the "certain pharmaceutical form" that means a non-active substance falls outside the definition of article 1(b). Without the answer provided in paragraph 27 there is no clear way to interpret what paragraph 25 means and thereby how MIT should be applied.

26 To conclude my view of the applicant's argument in 2a, I consider it does not truly reflect the test embodied in the MIT judgment. In my opinion the MIT judgment teaches that a combination of active ingredients of a medicinal product is not intended to include a substance that has no therapeutic effect of its own for a specific indication but renders the medicinal product in a pharmaceutical form that is efficacious for that indication.

27 I will now apply the teaching of MIT as I interpret it to the facts of the present applications, and in so doing pose the following question:

> Is the adjuvant AS03 a substance that has no therapeutic effect of its own for a specific indication but that renders possible a pharmaceutical form of Prepandrix (RTM) which is necessary for the therapeutic efficacy of the influenza vaccine?

28 To help determine this question, I need to consider what AS03 does, alone and in combination with the vaccine, when it is administered to a patient. To do so, I refer to the expert evidence the applicant helpfully provided before the hearing: The witness statement provided by Professor Dr. Geert Leroux-Roels, Founding Director and Principal Investigator at the Centre for Vaccinology at Ghent University Hospital Belgium, in his role as an expert in the art of immunology and vaccinology.

29 At paragraphs 59-63 of his witness statement he provided his view on the mode of action

of AS03 when administered alone: he did this by reference to 2 papers:

> *59. The mode of action of AS03 was investigated in an in vivo mouse model and human in vitro cell assays and reported in a recent paper by Morel et al (2011) (Exhibit GLR-5)[1].*
>
> *60. Following intra-muscular injection of AS03 (alone) in mice, local pro-inflammatory cytokines and chemokines increased as compared to a PBS (no adjuvant) control (Figure 3b) or Alum (Figure 3c). This led to increased cell recruitment (e.g. monocytes and dendritic cells) to the injection site and draining lymph nodes in the experiment with AS03 as compared to PBS (no adjuvant) or Alum controls (Figure 4). It was also shown that a-tocopherol modulates the cytokine response (primarily mediated via macrophages and monocytes) as compared to the control o/w emulsion (Figure 5).*
>
> *61. Following injection of AS03 (containing a-tocopherol) the uptake of antigen (a fluorescent ovalbumin) per cell by monocytes and dendritic cells was measured and shown to be higher compared to the controls of an o/w emulsion (AS03 without a-tocopherol), Alum adjuvant or no adjuvant (Figure 6b).*
>
> *62. When injected with hepatitis B antigen, the inclusion of a-tocopherol increased the levels of antigen-specific antibody production as compared to the control o/w emulsion (Figure 7).*
>
> *63. The mechanisms of action of AS03 are shown well in Figure 5 of Garcon et al 2012 (ExhibitGLR-6)[2], which is reproduced below.*

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[1] *Morel S, Didierlaurent A, Bourguignon P et al. Adjuvant System AS03 containing a-tocopherol modulates innate immune response and leads to improved adaptive immunity. Vaccine 29(13), 2461–2473 (2011).*

[2] *Nathalie Garçon, David W Vaughn and Arnaud M Didierlaurent. Development and evaluation of AS03, an Adjuvant System containing α-tocopherol and squalene in an oil-in-water emulsion. Expert Review of Vaccines, March 2012, Vol. 11, No. 3, Pages 349-366.*

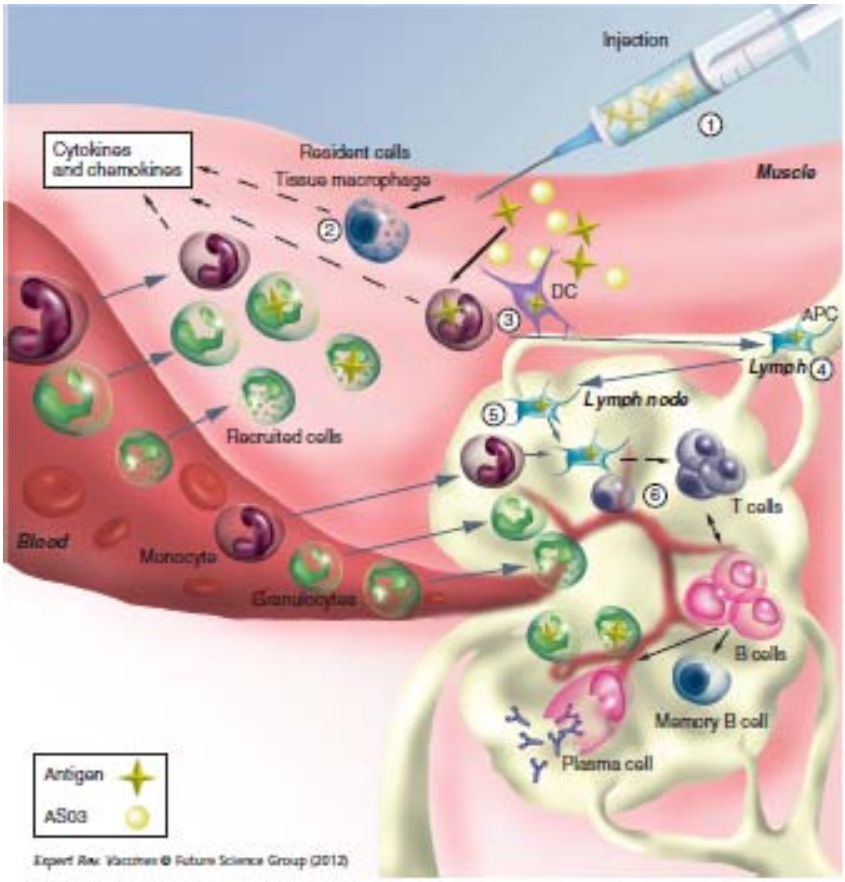

Figure 5. Model of AS03 mechanism of action. (1) AS03 needs to be colocalized with the antigen at the injection site. **(2)** AS03 induces a transient NF-κB, cytokine and chemokine response and an increased recruitment of innate immune cells out of the bloodstream to the site of injection. **(3)** Mainly monocytes are activated to become APCs. **(4)** Activated APCs loaded with the antigen migrate to draining lymph nodes. **(5)** AS03 enhances recruitment of innate immune cells at the local draining lymph node. **(6)** APCs activate naive CD4+ T cells. Activated CD4+ T cells interact with antigen-specific B cells, inducing high numbers of memory B cells and antibody secreting plasma cells. APC: Antigen-presenting cell; DC: Dendritic cell.

30 Having given careful thought to the witness statement and the supporting papers, it is my opinion that the expert evidence shows that AS03 recruits cells involved in eliciting an immune response to the site of vaccine delivery. It also enhances their uptake of antigen and increases the amount of antibody expressed as compared to conventional adjuvants, such as alum. It enhances the immune response when the recruited "antigen presenting cells" reach the lymph nodes- they in turn recruit other cells such as CD4+ T cells and B cells to induce memory B cells and secrete antibodies from plasma cells.

31 Having considered this process, I can now answer the question posed in paragraph 27 above. I do not conclude that AS03 has a therapeutic effect of its own, be that against a specific indication or any indication. The effects it has, although necessary in ensuring the efficacy of the medicinal product that contains AS03, are general and non-specific. The effects of AS03 on the immune system are involved with potentiating and enhancing the effect of the antigen, irrespective of the actual antigen and the immunological protection sought. AS03 confers no immunity of itself.

32 Furthermore in relation to the teaching of MIT to the present case, I now go on to consider an additional question:

Does AS03 render possible a pharmaceutical form of Prepandrix (RTM) which is

necessary for the therapeutic efficacy of the influenza antigen?

To help determine this question, I again refer to the expert evidence provided by Professor Dr. Geert Leroux-Roels. At the hearing, I was taken to two passages - the first concerning the increase or potentiation of the immune response, in paragraphs 46-48 of the witness statement:

> *46. The first human clinical study to examine the use of AS03 in (pre-)pandemic influenza vaccinedevelopment was published by my group in the Lancet enclosed as Exhibit GLR-7[3]) (although the name 'AS03' was not being used at the date of this paper). This study assessed the safety, immunogenicity and cross-reactivity of a recombinant H5N1 split-virion vaccine formulated with AS03.*
>
> *47. The adjuvanted formulations were significantly more immunogenic than the non-adjuvanted formulations at all antigen doses and met or exceeded the thresholds of the FDA and EMA CHMP licensure criteria at even the smallest dose. This is demonstrated by the data in Table 3 on p584, which assesses the following variables:*
>
> *a. GMT – Haem Agglutination Inhibition (HAI) Geometric Mean Titres – a measure of the titres of haemagglutination-inhibiting antibody responses.*
>
> *b. Mean geometric increase – the ratio of GMTs after and before vaccination.*
>
> *c. SCR – Sero Conversion Rate – the percentage of subjects (sera) with negative prevaccination HAI titre and post-vaccination titre of at least 1:40 or, for sera with positive pre-vaccination HAI titre, at least a four-fold increase in HAI titre. The CHMP licensure criteria for which is 40%.*
>
> *d. SPR - Sero Protection Rate – the percentage of subjects (sera) with post vaccination titre of at least 1:40, the CHMP licensure criteria for which is 70%.*
>
> *48. As can be seen in Table 3, all of the adjuvanted vaccines surpass the 40% HAI SCR threshold for immunogenicity after the second dose and in some cases (at doses of 7.5, 15 and 30 µg) even after a single dose. Significantly, after a single dose, none of the non-adjuvanted vaccines met the threshold of immunogenicity required by the CHMP and after two doses, only the highest 30 µg dose surpassed that threshold. Further, only the adjuvanted vaccines (and all of them after the second dose) surpassed the 70% SPR threshold whereas all of the non-adjuvanted-vaccines failed to surpass this threshold.*

The second was to a part of the witness statement relating to the cross reactivity that AS03 enabled, in paragraphs 51 and 52 of the witness statement:

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3 *Leroux-Roels I, Borkowski A, Vanwolleghem T, Dramé M, Clement F, Hons E, Devaster J-M, Leroux-Roels G. Antigen sparing and cross-reactive immunity with an adjuvanted rH5N1 prototype pandemic influenza vaccine: a randomised controlled trial. Lancet, August 2007, Vol. 370, Pages 580-589.*

51. In order to investigate further the cross-reactivity results reported in Leroux-Roels et al 2007 above, sera from the same individuals vaccinated in that study were used in experiments to analyse the cross-reactive potential in the same sub-c1ade (2.1) as in Leroux-Roels et al 2007 and in addition, two, more recent, sub-c1ades of the H5N1 influenza virus (sub-clades 2.2 and 2.3). These experiments were published in Leroux-Roels et al 2008 (enclosed as Exhibit GLR-8)[4]. The results showing cross-clade immunity are shown in figures 1 and 2 (on p3), which are reproduced below.

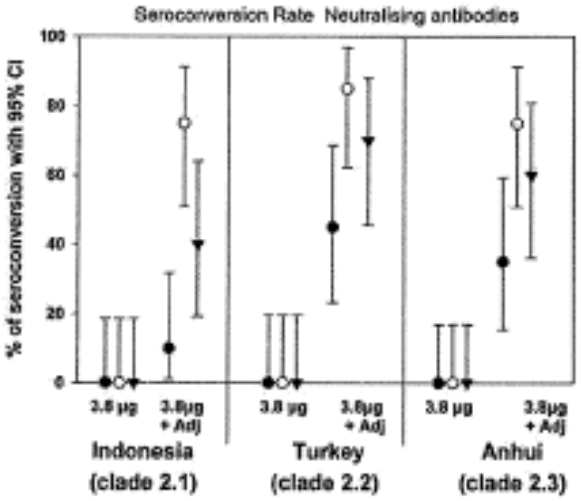

Figure 1. Neutralising seroconversion rates to the heterologous recombinant A/Indonesia/5/2005, A/Anhui/1/2005 and A/turkey/Turkey/1/2005 strains following vaccination with A/Vietnam/1194/2004 NIBRG-14 vaccine.
doi:10.1371/journal.pone.0001665.g001

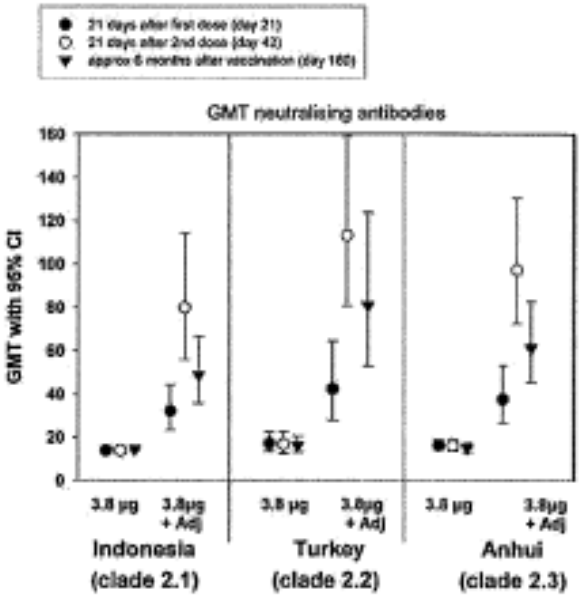

Figure 2. Neutralising geometric mean titres (GMTs) to the heterologous recombinant A/Indonesia/5/2005, A/Anhui/1/2005 and A/turkey/Turkey/1/2005 strains following vaccination with A/Vietnam/1194/2004 NIBRG-14 vaccine.
doi:10.1371/journal.pone.0001665.g002

52. As shown by the right hand side of each of the 3 parts of each figure, the GMTs and SCRs were significantly higher for adjuvanted compared to the non-adjuvanted vaccines. Significantly, SCR rates were zero for the non-adjuvanted vaccines and cross-reactive SCRs were only recorded with respect to the adjuvanted vaccines. High level of cross-immunity (75-85%) against all three sub-clades was evident after the second dose of adjuvanted vaccine (shown by the clear circles).

33 It was explained to me that cross reactivity is the ability of a vaccine to protect against related strains or clades such that immunity is provided against more than the specific strain used in the vaccine.

34 I agree with the witness that this data shows that a threshold of therapeutic efficacy is exceeded by the adjuvanted vaccines and not by the non-adjuvanted vaccine forms. It would also appear that in the adjuvanted form the vaccine meets a necessary criterion for authorisation as assessed by the EMA CHMP (the European Medicines Agency

[4] *Leroux-Roels I, Bernhard R, Gérard P, Dramé M, Hanon E, et al. (2008) Broad Clade 2 Cross-Reactive Immunity Induced by an Adjuvanted Clade 1 rH5N1 Pandemic Influenza Vaccine. PLoS ONE 3(2): e1665. doi:10.1371/journal.pone.0001665.*

Committee for Medicinal Products for Human Use). In light of these conclusions I believe I can now determine the answer to my question posed in paragraph 32 above.

35 In my opinion, AS03 is a substance that renders possible a pharmaceutical form of Prepandrix (RTM) which is necessary for the therapeutic efficacy of the vaccine. This answer is predicated on the understanding that the H5N1 antigen is the substance which has therapeutic effect of its own in Prepandrix (RTM).

36 I conclude that MIT is relevant to the facts of the present applications and shows that AS03 is not an active ingredient in the sense of a "combination of active ingredients" of Article 1(b) of the Regulation.

(2b) It is sufficient that a substance has a therapeutic effect within the medicinal product in question, such as Prepandrix in this case.

37 I will now consider the applicant's alternative view of MIT, that I should determine if part of the therapeutic effect can be attributed to the adjuvant AS03. It was put to me at the hearing (see page 25 of the hearing transcript):

> *"what we say MIT does is that you look at what the medicinal product is actually doing and ask yourself "what is that excipient" or whatever it is you are looking at, doing to the therapeutic effect of the medicinal product"*

and at page 23 of the hearing transcript:

> *"..that is the test it is whether AS03 has an effect on the therapeutic outcome"*.

In my view this is not correct because I consider the applicant has been rather selective with what MIT teaches. In paragraphs 19-22 above, I explained that it was my understanding that the applicant had emphasized the change in pharmaceutical form as the determinative factor. In this line of argument, the applicant proposes a different notion that I also find contrary to the teaching of MIT as I have interpreted (see paragraph 26 above). The fact that a substance has no therapeutic effect of its own but potentiates the therapeutic effect arising from the active ingredient is in my view the important factor in showing that a substance is not active, not as the applicant would have it, that modulating the effect of the active ingredient is enough to show that it is active.

38 I find support for my view in paragraphs 25-27 of the MIT judgment as quoted above in paragraph 24 above and the fact that polifeprosan, the non-active substance in the MIT case, had a similar effect on the therapeutic outcome but the finding was nonetheless against MIT in that judgment.

39 The fact that AS03 improves the quantitative therapeutic effect of the antigen and changes the qualitative therapeutic effect by way of the improved cross reactivity is clearly made in Professor Dr Geert Leroux-Roels witness statement. In more general terms i.e. pertaining to adjuvants in general, similar points are made in the "Concept paper on the development of a committee for proprietary medicinal products (CPMP) note for guidance on requirements for the evaluation of new adjuvants in vaccines" and in relation to the resulting approved guidelines – "Committee for medicinal products for human use (CHMP) Guideline on adjuvants in vaccines for human use" dated 20 January 2005[5] I do not propose to quote from both of these as the point to be made is the same, but only from the latter:

[5] available from: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003809.pdf

"Adjuvants should be chosen based on the type of immune response desired…" as found in the 4th paragraph of the introduction on page 4

"The major means by which adjuvants may exert their activities are: …(iv) Immune potentiation/modulation which includes activities that regulate both quantitative and qualitative aspects of the ensuing immune responses." as found in the 5th paragraph of the introduction on page 4.

So for adjuvants in general and for AS03 in particular, it is clear that the therapeutic effect of the antigen is changed both quantitatively and qualitatively.

40 It is my view therefore that the therapeutic activity flows from the provision of the antigen component, without it there could be no quantitative or qualitative change to the therapeutic efficacy. I do not agree with the applicant that I should consider the therapeutic effect to be, for example, the qualitative change in therapeutic efficacy that arises against cross clades when the antigen is administered with the adjuvant. In my view, this salami slices the notion of therapeutic efficacy which I find contrary to the teaching of MIT, as I have explained in paragraph 26 above. If I were to conclude that AS03 has a therapeutic effect, it would only be because of the efficacy that arises from the active ingredient and these are the effects that I consider MIT tells me are not in the concept of a combination of active substances.

41 To conclude, it is my view that it is not consistent with the teaching of the MIT judgment to consider the notion of therapeutic effect as broadly as the applicant has suggested (see paragraph 37 above) - to encompass changes to the therapeutic efficacy of the medicinal product that nonetheless rely on an active ingredient for their existence.

42 I now consider the applicant's third line of argument:

(3) However, even if it were correct, there is no basis for taking a narrow approach to the concept of 'therapeutic effect' in the MIT case and the approach proposed by the Examiner is inconsistent with the definition of 'medicinal product'". An adjuvant which when administered alone has a physiological effect should be considered an active ingredient within the definition of Article 1(b)

I agree with the applicant's view that the passages quoted above in paragraph 29, from paragraphs 59-63 of Professor Dr. Geert Leroux-Roels witness statement, demonstrate that AS03 has a physiological effect, but I will now determine if this is enough to deem it is an active ingredient as defined in Article 1(b).

The applicant argued that the definition of medicinal product may be satisfied by:

"… any substance or combination of substances which may be administered to human beings or animals with a view to… restoring, correcting or modifying physiological functions in humans or in animals;" (taken from Article 1(a) of the Regulation).

43 The applicant explained that it therefore follows that a substance that has a physiological effect is a product, as the active ingredient in the medicinal product is the product as defined in Article 1(b). It was explained to me that it was by this reasoning that an SPC was granted for AS03 by the Austrian Patent Office. The applicant characterised this decision in that the Austrian Office did not feel itself bound by the MIT judgment as it was inconsistent with the definition of medicinal product to apply MIT to the facts of this case. I consider that such a conclusion offends the purpose of the Regulation.

44 I will explain why in relation to some of the other evidence presented to me, for example at the hearing. The applicant brought to my attention a number of SPCs for products that do not have a therapeutic effect, like those for a diagnostic agent and a contraceptive pill, to further substantiate that something less than a therapeutic effect such as a physiological effect had already been shown to be sufficient for the grant of an SPC.

45 Whereas these SPCs may, like AS03, concern products that do not have a therapeutic effect, they differ from AS03 in one important respect - they required a MA that approved their use for these purposes. This is of course a vital pre-requisite for the grant of an SPC.

46 At the hearing the applicant made the point that the requirement for a MA does not necessarily matter because what needs to be determined is whether an adjuvant is an active under the SPC regulation:

"we do not think it follows that just because something is an active in the SPC regulation, it makes it an active in the regulatory legislation…" (at the head of page 18 of the hearing transcript).

47 To my mind this is contrary to the purpose of the Regulation as set out in the proposal for a council regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products COM (90) 101 dated 11 April 1990 (explanatory memorandum).

In the third sub paragraph of item 28:

> *"For the purpose of the certificate, which lies at the interface of the two systems, the term product has been chosen as a common denominator, the exact meaning given to it is defined in Article 1, which is based on the definition of a medicinal product laid down in directive 65/65/EEC. However, the qualifier "active" is added to the term "substance" in order to include the concept of an active ingredient or "active substance" used in patent law."*

This shows that a precisely defined link "the product" is established between the regulatory and patent systems, and that the "product" and thereby the "active substance" or the equivalent term "active ingredient" is intended to be common to the regulatory and SPC systems.

48 With regard to adjuvants in general and AS03 in particular, I do not believe that the regulatory bodies consider them to be active ingredients, as such because of the link I indicate in the preceding paragraph - adjuvants comprise part of the medicinal product as defined in article 1(a) and not the product as defined in article 1(b) of the Regulation. I find support for this view from the "Concept paper on the development of a committee for proprietary medicinal products (CPMP) note for guidance on requirements for the evaluation of new adjuvants in vaccines[6] CPMP/BWP/6622/02 dated 25 April 2002". The second paragraph under the section headed "problem statement" states:

"for the reasons above and because the adjuvant is not the active ingredient, it is an individual vaccine /adjuvant combination which will be licensed",

[6] available from http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003885.pdf

Furthermore Annex 1 to Directive 2001/83[7] on page 135, in referring to the 'Qualitative and quantitative particulars of the constituents', requires that a description should be provided of:

> *-the active substance(s),*
>
> *-the constituent(s) of the excipients, whatever their nature or the quantity used, including colouring mater, preservatives, adjuvants, stabilisers..." (emphasis added).*

So clearly in this respect, an adjuvant is not considered in the same way as an active substance.

Furthermore, in the MA for Prepandrix (RTM) the adjuvants are either listed with the excipients (section 6.1 of the Summary of product characteristics [SmPC] – list of excipients) and separately from the active and the excipients (section 2 of the SmPC).

49 I was also asked to consider how AS03 was described in other documents such as the labeling and package leaflets but I do not find these instructive as they are not part of the SmPC which the applicant is required to submit with their SPC application.

50 The most important point is not to my mind where an adjuvant appears on authorisation documents but how the adjuvant is assessed by the regulatory body. In the applicant's skeleton at paragraph 29, I was told in relation to the CPMP and the annex to 2001/83 documents that:

"GSK acknowledges that there is a distinction between an active substance and an adjuvant in terms of the regulatory requirements that each has to satisfy…"

51 It would appear that the applicant admits that an active ingredient and an adjuvant are not assessed by the regulatory authorities in the same way and that the process is less onerous for an adjuvant than an active ingredient. If it were nonetheless right that an SPC should be granted, it would mean that there would be different grades of SPC, some wherein the product had not of itself required a rigorous regulatory procedure because the regulatory body did not consider it an active ingredient, and others where it did, but they would all receive the same SPC "reward". Such a system would not be fair.

52 In respect of Prepandrix I was informed at the hearing that it had been necessary to obtain a full authorisation for this medicinal product:

> *"James has just reminded me, of course, that the flu vaccine was known before and GSK applied for a new marketing authorisation following the full procedure because its product was going to be a combination of the flu vaccine and this adjuvant. So it required a marketing authorisation. So it is not an insignificant amount of work that has to be done, and in fact it needed a new marketing authorisation."* (taken from page 18 of the hearing transcript).

53 However, it does not appear possible to obtain an MA for an adjuvant alone (see quote from CPMP document in paragraph 48 above) and it would appear that the criteria the regulatory body uses for assessing an adjuvant is lower than for an active substance. When I contacted the applicant for clarification as to whether or not AS03 was assessed

[7] available from: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0083:20110721:EN:PDF

as an active ingredient by the regulatory authorities, I was informed in their letter of 9 November 2012 that it was not relevant:

> *"We do not consider that whether or not the adjuvant has the same type of authorisation procedure as an 'active ingredient' under the regulatory legislation is relevant on the issue of whether the adjuvant can be the subject of an SPC"*

This follows the same reasoning as the applicant explained at the hearing and that I have quoted in paragraph 46 above. Therefore, I can only conclude that in so far as adjuvants are not subject to the same regulatory process as an active ingredient (see paragraph 50 above), AS03 would not have required the same regulatory scrutiny as the antigen, so even though it is part of an authorized product it is not itself a product within the definition of Article 1(b).

54 I was reminded by the applicant that CJEU in case C-322/10 "Medeva" teaches that a MA for products A+B can be used to support an SPC application for A. This is of course true but in Medeva all of the components were active ingredients and had been authorised on this basis. I do not find anything in the judgment to suggest that the Court intended it to be applied to combinations including not only actives but something other than active ingredients like adjuvants. To illustrate, I quote from the answer to question 2 in Medeva which clearly relates to active ingredients and no other components of the medicinal product:

> *"2. Article 3(b) of Regulation No 469/2009 must be interpreted as meaning that, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a supplementary protection certificate for a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the application for a special protection certificate contains not only that combination of the two active ingredients but also other active ingredients."*

55 In my opinion therefore, AS03 is not an active ingredient in its own right because the regulatory process is less onerous for an adjuvant than for an active substance wherein that distinction is determined by the regulatory authorities, and as such I conclude AS03 is not an authorised product within the meaning of Article 2 but a component of the medicinal product which does not of its self require an authorization. It is not relevant that AS03 has a physiological effect. On these grounds it does not appear appropriate that an SPC is granted for either AS03 or a combination comprising AS03.

56 I was not directly addressed on the possible line of argument that the antigen has no therapeutic effect of its own unless it is combined with an adjuvant and as such it may fall outside the scope of the teaching of MIT. I am not convinced that this argument is tenable: it is clear that non-active ingredients that potentiate a therapeutic effect may act by degrees and that a potentiator may increase a therapeutic effect already present without it or render a substance that is of no use for a particular indication into a therapeutically active form, as would appear to be the case for Prepandrix. Just because an active ingredient cannot actually be used in therapy until another substance is provided does not mean it is not an active ingredient. I am again persuaded that what is the active ingredient is what is authorised as such - the antigen component of Preprandrix was clearly the active in this case, so such a line of argument would not mean that these cases would fall outside the teaching of MIT. I now turn to point 4.

(4) A narrow interpretation of the meaning of 'active ingredient' under the SPC Regulation so as to exclude novel adjuvants, as proposed by the Examiner, would be inconsistent with the underlying rationale of the SPC regime.

57 The following were quoted in the applicant's skeleton arguments: recitals 2-5 (see paragraph 5); recital 13 of the plant protection regulation; paragraph 29 of the explanatory memorandum to the proposal for a Council Regulation (EEC); and *Neurim Pharmaceuticals (1991) Ltd v the Comptroller General of Patents [2011] EWCA Civ 228* (at paragraphs 18 and 28-30). Whilst I have given careful thought to these references, I do not cite them further as I find they all have no bearing on the present case. All these references take as their starting point the provision of an active substance or product. I have not found this to be the case for the present applications therefore I do not find they help instruct how I should consider the circumstances of the present case.

58 The applicant's skeleton arguments also took me to *Generics (UK) Ltd v Daiichi Pharmaceutical Co Ltd, Daiichi Sankyo Co Ltd [2009] EWCA Civ 646* ("Generics") and I was quoted passages at paragraphs 46 and 63.

> *46. And it was a new product as a matter of commercial and practical reality too – no-one, without the invention, could make it. And from the medical point of view it was a new and better medicine. Obviously before it could be marketed it would have to go through trials – its properties (including for instance important characteristics such as bioavailability – which depends or may depend on solubility – and toxicity) had to be established. So it needed a new marketing authorisation. In sum it was a new product from all practical points of view.*
>
> *63. Mr Carr submitted that ofloxacin should be regarded in the same way: as no more than levofloxacin with an impurity. But I think that is wholly unrealistic: they are not regarded as such by patent law (hence the novelty of the patent for the enantiomer), or by the law controlling the marketing of medicines. Why should the law about SPCs, built as it is on those two branches of law, go off in a different direction? There is every reason in logic and policy as to why not.*

59 From these passages, the applicant drew the following teaching at paragraph 52 of their skeleton: if *"it [the substance in question] was deserving of its own patent and [had] to satisfy regulatory requirements, then it should be entitled to an SPC"*. However the facts of *Generics* show that levofloxacin, which was the product of the disputed SPC, had obtained a MA, in short it was considered an active ingredient that needed to be approved by the regulatory authorities. This is not the case for AS03 therefore I do not think it should benefit from the SPC system. I find support in what Justice Jacob said in paragraph 63 of *Generics*, (above in my paragraph 58), in that he drew attention to the link established between the SPC and regulatory laws and warned against their divergence. It is just such a divergence that the applicant seeks in these applications (see paragraph 46 Generics quoted above). I also find support from the Explanatory Memorandum which at paragraph 11 which states: *"a product being understood to mean active substance in the strict sense"*. In my view, this passage when read in light of the passage from the Explanatory Memorandum quoted in paragraph 47 above, establishes that the Regulation was founded on a narrow interpretation of the meaning of active ingredient.

60 To conclude, I can find nothing in the applicant's observations to dissuade me from the view that a narrow interpretation of the meaning of active ingredient is consistent with the underlying rationale of the SPC regime.

61 For the reasons set out above, it is my opinion that AS03 is not an active ingredient either in respect of its combination with an antigen or in its own right. I find therefore that SPC/GB08/046 may not be granted an SPC.

62 With respect to SPC/GB11/043, in light of my finding that AS03 is not an active ingredient either in respect of its combination with the antigen or in its own right, I find that AS03 should not form part of the product definition, so that as it stands SPC/GB11/043 should not be granted an SPC.

The applicant is entitled to more than one SPC and possible amendments

63 I was also asked at the hearing to consider if the applicant may be entitled to more than one SPC. There is at least potential for the product defined in both of these applications to be amended to relate to the antigen alone, such a product definition would *prima facie* comply with Article 1(b). If the applicant amends both applications in this way they would relate to a common product but rely on separate patents, and as such Article 3(2) of Regulation 1610/96/EEC may be relevant, as the examiner indicated in his prehearing report (summarized as point 2 in my paragraph 3 above). This is a matter I could refer back to the examiner, relying as it does on what product definition the applicant and examiner can agree on in both applications.

64 Furthermore, I note from a review of the correspondence that the precise definition of the product has not been agreed in respect of the wording to define the pandemic virus strain. I find this too could be remitted back to the examiner to determine what the precise definition should be.

Is a stay of SPC/GB11/043 justified?

65 I was also asked in the agent's letter of 19 October 2012:

> *"in the event the Hearing Officer decides that the Adjuvant AS03 cannot be considered a product within the meaning of Regulation 469/2009 we hereby request a stay of this application [SPC/GB11/043] pending an appeal against the refusal of SPC/GB08/046. We submit that a stay of this application is justified given that pending referrals to the CJEU on the interpretation of Art 3(c). High Court in Activis v Sanofi ([2012] EWHC 2545 (Pat)) and by the Dutch court in Georgetown University v Octrooicentrum Nederland (Case AWB 10/4769)"*

I have read these cases but do not understand how they are relevant to the present applications. Article 3(c) does not appear relevant. I quote one of the proposed questions in *Sanofi* to illustrate:

> "Does [the Regulation], more specifically Article 3(c), in the situation in which multiple products are protected by (the claims) of a basic patent, preclude the proprietor of the basic patent being issued a certificate for each of the products protected?"

66 I am satisfied that SPC/GB08/046 or indeed any of the other SPCs that have already been granted for pre-pandemic influenza vaccines do not rely on the same basic patent as SPC/GB11/043. As such, there appears no reason to stay proceedings in SPC/GB11/043 pending the culmination of these references. Indeed, in order to be fair to all, it is reliant on me to expedite processing wherever possible in order that third parties can be aware of the status of an SPC at the earliest date, therefore I do not allow SPC/GB11/043 to be stayed.

Conclusion

67 I conclude that SPC/GB08/046 and SPC/GB11/043 are not allowable with the product definitions as they currently stand, as neither of these definitions comply with Article 1(b). I nonetheless provide the applicant with an opportunity to amend either or both of the product definitions in these applications, as I believe there are amendments that would allow at least one of these applications to proceed to grant.

I order therefore that the applicant has until 31st January 2013 to provide product definition(s) to the satisfaction of the examiner.

If the applicant does not provide a satisfactory product definition for either SPC/GB08/046 or SPC/GB11/043 by 31st January 2013, I order that the remaining application be rejected having regard to Article 10(2).

If the applicant does not respond to this order by 31st January 2013, I order that both applications be rejected having regard to Article 10(2) of the Regulation.

For the avoidance of doubt, I have not determined if both SPC/GB08/046 and SPC/GB11/043 may be granted SPCs in the event that their product definitions are amended to the same product and an acceptable form (see paragraph 63 above).

Regarding the staying of SPC/GB11/043, I do not allow this.

Appeal

68 Under the Practice Direction to Part 52 of the Civil Procedure Rules, any appeal must be lodged within 28 days.

C L Davies

Deputy Director acting for the Comptroller