

3. In each application the product in respect of which an SPC is sought comprises a combination of active components. However, the combination defined as the subject of protection is different in each application. This is summarized in Table 1 below. The marketing authorisations supplied in support of these SPC applications are different for three of the applications, whilst two applications rely upon the same marketing authorisation. Table 2 summarises the active ingredients of the medicinal products which have been authorised in the UK. The combinations for which the SPCs are sought all comprise active ingredients that play a role in the vaccine field to improve immunity to particular diseases, especially providing protection against Pertussis, commonly referred to as Whooping Cough.

Table 1: Summary of combinations of active ingredients in the SPC applications made by Medeva B.V.

| Combination of Active Ingredients | SPC/GB | | | | |
|--|------------------|---------------|---------------|---------------|---------------|
| | /09/015 | /09/016 | /09/017 | /09/018 | /09/019 |
| <i>Diphtheria toxoid</i> | ✓ | ✓ | ✓ | - | ✓ |
| <i>Tetanus toxoid</i> | ✓ | ✓ | ✓ | - | ✓ |
| <i>Pertussis toxoid</i> | ✓ | ✓ | ✓ | - | ✓ |
| <i>Filamentous Haemagglutinin</i> | ✓ | ✓ | ✓ | ✓ | ✓ |
| <i>Pertactin</i> | ✓ | ✓ | ✓ | ✓ | ✓ |
| <i>Inactivated poliovirus type 1</i> | ✓ | ✓ | ✓ | - | ✓ |
| <i>Inactivated poliovirus type 2</i> | ✓ | ✓ | ✓ | - | ✓ |
| <i>Inactivated poliovirus type 3</i> | ✓ | ✓ | ✓ | - | ✓ |
| <i>Haemophilus influenzae type b capsular polysaccharide</i> | ✓ | ✓ | - | - | - |
| <i>Pertussis Fimbrial Agglutinogens 2 and 3</i> | - | - | ✓ | - | - |
| Total # of active components for SPC | 9 | 9 | 9 | 2 | 8 |
| Marketing Authorisation | PL 10592/0216 | PL 06745/0120 | PL 06745/0121 | PL 06745/0120 | PL 10592/0209 |
| Medicinal Product | Infanrix-IPV+Hib | Pediacel® | Repevax® | Pediacel® | Infanrix IPV |
| # of active components in Medicinal Product | 9 | 11 | 9 | 11 | 8 |

4. The combination for which protection is being sought in application SPC/GB/09/015 is defined as “*Diphtheria toxoid, Tetanus Pertussis toxoid, Filamentous Haemagglutinin, Pertactin, Inactivated poliovirus type 1, Inactive poliovirus type 2, Inactivated poliovirus type 3, Haemophilus influenzae type b capsular polysaccharide*” and the first authorisation in the United Kingdom supplied is PL 10592/0216 for the medicinal product “*Infanrix-IPV+Hib*”. A French marketing authorisation NL 22370 for the medicinal product “*Infanrix Quinta*” is supplied as being the first authorisation to place the product on the market in the European Community (hereafter, the Community).

Table 2: Combinations of active ingredients listed in the UK Marketing Authorisations provided by Medeva B.V. in support of SPC applications SPC/GB 09/014-019.

| Medicinal Product | Pediacel ® | Repevax ® | Infanrix IPV | Infanrix- IPV+Hib |
|--|----------------|----------------|-----------------|----------------------|
| UK Marketing Authorisation PL/ | 06745/ 0120 | 06745/ 0121 | 10592/ 0209 | 10592/ 0216 |
| <i>Tetanus toxoid</i> | ✓ | ✓ | ✓ | ✓ |
| <i>Diphtheria toxoid</i> | ✓ | ✓ | ✓ | ✓ |
| <i>Pertussis toxoid</i> | ✓ | ✓ | ✓ | ✓ |
| <i>Pertussis Filamentous Haemagglutinin</i> | ✓ | ✓ | ✓ | ✓ |
| <i>Pertussis Fimbrial Agglutinogens 2 & 3*</i> | ✓ | ✓ | - | - |
| <i>Pertactin 69kDA</i> | ✓ | ✓ | ✓ | ✓ |
| <i>Poliomyelitis Inactivated virus type 1</i> | ✓ | ✓ | ✓ | ✓ |
| <i>Poliomyelitis Inactivated virus type 2</i> | ✓ | ✓ | ✓ | ✓ |
| <i>Poliomyelitis Inactivated virus type 3</i> | ✓ | ✓ | ✓ | ✓ |
| <i>Haemophilus influenzae type B polyribosylribitol phosphate</i> | ✓ | - | - | - |
| <i>Haemophilus influenzae type B polysaccharide-Tetanus toxoid conjugate</i> | ✓ | - | - | ✓ |
| Total # of active components | 11 | 9 | 8 | 9 |

* Counted as 1 component in combination

5. The combination for which protection is being sought in application SPC/GB/09/016 is defined as “*Diphtheria toxoid, Tetanus toxoid, Pertussis toxoid, Filamentous Haemagglutinin, Pertactin, Inactivated poliovirus type 1, Inactivated poliovirus type 2, Inactivated poliovirus type 3, Haemophilus influenzae type b capsular polysaccharide*” and the first authorisation in the United Kingdom supplied is PL06745/0120 for the medicinal product “*Pediacel (RTM)*”. This authorisation is also supplied in support of application SPC/GB/09/018 which defines a simpler two component combination “*Filamentous Haemagglutinin, Pertactin*” for which protection is being sought. Although no earlier marketing authorisation to place the product first on the market in the Community is identified in application SPC/GB/09/016, the French marketing authorisation NL

22370 for the medicinal product “Infanrix Quinta” is supplied as being the first authorisation to place the product on the market in the Community in support of application SPC/GB/09/018.

6. The combination for which protection is being sought in application SPC/GB/09/017 is defined as “*Diphtheria toxoid, Tetanus toxoid, Pertussis toxoid, Filamentous Haemagglutinin, Pertactin, Pertussis Fimbrial Agglutinogens 2 and 3. Inactivated poliovirus type 1, Inactivated poliovirus type 2, Inactivated poliovirus type 3*” and the first authorisation in the United Kingdom supplied is PL06745/0121 for the medicinal product “Repevax (RTM)”. A German marketing authorisation for the medicinal product “Repevax” is supplied as the first authorisation to place the product on the market in the Community.
7. In application SPC/GB/09/019 the combination is defined as “*Diphtheria toxoid, Tetanus toxoid, Pertussis toxoid, Filamentous Haemagglutinin, Pertactin, Inactivated poliovirus type 1, Inactivated poliovirus type 2, Inactivated poliovirus type 3*” and the first authorisation in the United Kingdom supplied is PL 10592/0209 for the medicinal product “Infanrix IPV”. A French marketing authorisation for the medicinal product “Infanrix DTCaP” is supplied as the first authorisation to place the product on the market in the Community.
8. Although each application seeks to protect a different combination of active ingredients, there are two common active ingredients present in each defined combination, these being the Filamentous Haemagglutinin and Pertactin components.
9. The examiner, Dr Patrick Purcell, in his substantive examination reports on applications SPC/GB/09/015, 09/016, 09/017 and 09/019 objected that, in each of these applications, the product is not protected by the basic patent as required by Article 3(a) of Council Regulation (EC) 496/2009 (hereafter “the Regulation”). The basic patent does not protect a composition including a combination of active ingredients other than the Filamentous Haemagglutinin and Pertactin active ingredients. The examiner also objected that the product definitions in applications SPC/GB/09/015 and 09/016 did not agree with the active ingredients present in the marketing authorisations supplied.
10. In his examination report on application SPC/GB/09/018 the examiner objected that the product for which protection is sought is not subject to a valid authorisation to place the medicinal product comprising that product on the market as required by Article 3(b) of the Regulation. He also noted that the French authorisation supplied as the first marketing authorisation for the product in the Community did not correspond with the authorisation in the United Kingdom and so should not be used to calculate the duration of the certificate.
11. The applicant was given a period of four months in which to rectify the defects that had been identified in all the applications.

Preliminary Issue

12. In correspondence with the examiner, the applicant gave notice that they considered his report dated 31 July 2009 to be a 'final decision' on these applications and, as a consequence, that they would bring this 'final decision' to refuse these SPC applications as an appeal before the Patent Court. The examiner wrote back on 1 September 2009 indicating that this examination report did not constitute a final decision, that a response to the examination report was awaited and that, if the applicant did not have further arguments or observations on these applications, they could request a final decision on these applications from the Office, either at an oral hearing, or if they wished to expedite matters, on the basis of the papers currently on file. The applicant replied on 9 September 2009 waiving their right to be heard and indicating that they would like a decision based on the papers currently on file so that the status of these applications could be resolved before expiry of the basic patent in April 2010.
13. However, this request was made without prejudice to the ongoing question over whether or not it is appropriate to launch an appeal based on an examination report. While the Office agreed to the applicants request for a decision from the papers, it also indicated that it would reserve its right to seek an order to have this appeal application struck out on the ground that there was no decision of the Office to appeal from at that date.
14. At present, this preliminary issue is still outstanding. The decision below relates only to the substantive issues regarding whether or not these SPC applications meet the requirements of Article 3 of regulation 469/2009.

Substantive Issues

15. The primary issues to be decided are, firstly, whether the basic patent "protects" the product for which an SPC is sought as required by Article 3(a) of the Regulation and, secondly, whether the marketing authorisation relates to the product for which protection is sought as required by Article 3(b).

The Relevant Law & its Interpretation

16. Article 3 of the Regulation provides:

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 (b) is the first authorisation to place the product on the market as a medicinal product.*

17. Article 1 of the Regulation provides the following definitions:

"For the purposes of this Regulation:

- (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;*
- (c) 'basic patent' means a patent which protects a product as defined in (b) as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;*
- (d) 'certificate' means the supplementary protection certificate.*
- (e) 'application for an extension of the duration' means an application for an extension of the duration of the certificate pursuant to Article 13(3) of this Regulation and of Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use.*

18. Article 10 of the Regulation provides:

- 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.*
- 3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.*
- 4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.*
- 5. Member States may provide that the authority referred to in Article 9(1) is to grant certificates without verifying that the conditions laid down in Article 3(c) and (d) are met.*
- 6. Paragraphs 1 to 4 shall apply mutatis mutandis to the application for an extension of the duration.*

19. Article 13(1) of the Regulation states:

The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years.

20. For the purposes of the Regulation, Article 1(b) defines the term “product” as meaning the active ingredient or combination of active ingredients of a medicinal product whilst the term “medicinal product” is defined by Article 1(a) as meaning any substance or combination of substances presented for treating or preventing disease in human beings or animals. This makes clear that certificates are not granted for the medicinal product but rather for the active ingredients present in a medicinal product. Article 1(c) further makes clear that the basic patent must protect the product.

21. The interpretation of Articles 1(a) and (b) was set out in *Draco A.B.’s SPC Application* [1996] RPC 417. The importance of the definitions provided by Articles 1(a) and 1(b) and the role of the marketing authorisation was considered by Jacob J as he then was. He noted that the distinction made in these definitions must also be applied in reading recitals 8 and 9 of the Regulation and thus makes clear that the protection granted by a certificate is strictly confined to the active ingredient which is presented for treatment. At page 438, lines 30 to 35 of his judgment, he stated:

"It will be noted that the two recitals use both the phrase medicinal product and product. Without more there could be ambiguity. This is because authorisations typically are not for active ingredients as such. They are much more tightly drawn, generally to dosage and formulation or presentation. That has to be so because the actual performance of an active ingredient depends on these matters in addition to the active ingredient itself."

22. He went on to note that the authors of the Regulation had thought about the difference between the active ingredient and the actual formulation, and in so doing had defined "medicinal product" and "product" in Article 1. He then stated at page 439, lines 1 to 5:

"I have no doubt, nor do I think anyone else would have any doubt, that recitals 8 and 9 must be read as using these definitions. So strictly confined to the product which obtained authorisation means: strictly confined to the active ingredient of that which is presented for treatment."

23. As a result the protection afforded by a certificate extends only to the product (the active ingredient or combination of active ingredients) covered by the authorisation to sell the corresponding medicinal product. Thus, it is clear that a marketing authorisation for a medicinal product which comprises a plurality of active ingredients does not meet the condition for grant laid down by Article 3(b) in the situation where an SPC is sought for just one of these actives.

24. More recently, Lord Justice Jacob has again considered the interpretation of the Regulation and Article 1 in the Court of Appeal decision in *Generics UK v Daiichi*, 2009 EWCA CIV 646. At paragraph 58 he states:

"58. In the Regulation "product" means "the active ingredient or combination of active ingredients" (Art.2(b)) [sic]. Clearly that must be read with the words "as the case may be" at the end. If you have two active ingredients the "product" is the pair of them. And ofloxacin is a combination of significantly active ingredients. So it is that combination which was the subject of the 1990 and 1985 authorisations. The authorisation for levofloxacin was the first authorisation for that active ingredient alone."

25. It is clear that Jacob LJ considers that when a medicinal product is a combination of actives then for the purposes of the Regulation it is that combination which is the product as defined by Article 1(b) and for which a certificate could be granted.

26. Further Article 4 of the Regulation defines the subject matter of protection of a certificate in the following terms:

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate.

Thus whilst the protection is within the limits of the patent, it *"extends only to the product covered by the authorisation..."* and so it is apparent that it is not possible to break up a combination into its component parts.

27. The ECJ has previously considered the interpretation of Article 3(a) in *Farmitalia Carlo Erba Srl's SPC Application* (C-392/97) [2000] RPC 580 and the court concluded that the question of what is protected by a patent is not harmonised at EC level and is therefore a matter for national law.

28. Section 125 of the Patents Act 1977 determines how the scope of an invention is to be determined. The relevant subsections read as follows:

"(1) For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.

(2)...

(3) The Protocol on the Interpretation of Article 69 of the European Patent Convention (which Article contains a provision corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that Article."

29. Both Article 69 of the EPC and section 125(1) of the Act should be construed in the light of the Protocol on the Interpretation of Article 69 of the EPC, which reads:

"Article 1: General Principles

Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties".

Article 2: Equivalents

For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims."

30. Therefore the case law on the interpretation of these provisions which governs precisely how patent claims should be construed establishes the principle that patent claims have to be read in the light of the description. Thus whilst claims may not always be accorded their literal interpretation the purpose of the claims in a patent is to delimit the scope of the monopoly conferred by the patent, and the law on claim construction has developed with that in mind.

31. The interpretation of the Regulations that concern the grant of SPCs has also been the subject of case law. The scope of Article 3(a) has been considered in detail by the Courts. The question of what is protected by a basic patent under Article 3(a) in respect of combinations of active ingredients was first considered in *Takeda Chemical Industries Limited's Application* BL O/002/02. This case concerned several SPC applications for different combination products of lansoprazole and two other antibiotics. The specified basic patents concerned lansoprazole, making no reference to a combination and it was therefore held that they did not protect the product as required by Article 3(a) of the Regulation. This was upheld in the Patents Court [2003] EMHC 649 (Pat) where Jacob J. (as he then was) observed that

“The SPC system is to provide supplementary protection to that provided by the patent- to extend the relevant part of the patent monopoly. It is not a system for providing protection for different monopolies. Here Takeda’s monopoly is in lansoprazole. The monopoly which they seek is a combination of lansoprazole and an antibiotic. The fact that that combination might infringe the monopoly given by the patent simply because one component infringes is irrelevant.”

32. The question of what the term ‘protected by the basic patent’ in Article 3(a) means was further considered in *Gilead Sciences SPC Application* [2008] EWHC 1902 (Pat). In this decision Kitchin J commented *in obiter* on whether the approach of *Takeda* was correct and he did not disagree with it. Rather he found that

“33. ... I believe a test emerges from Takeda which is clear and can be applied without difficulty to a product comprising a combination of active ingredients. It is to identify the active ingredients of the product which are relevant to a consideration of whether the product falls within the scope of a claim of the basic patent. It is those ingredients, and only those ingredients, which can be said to be protected within the meaning of the Regulation. So, in the case of a product consisting of a combination of ingredients A and B and a basic patent which claims A, it is only A which brings the combination within the scope of the monopoly. Hence it is A which is protected and not the combination of A and B.”

33. The question of whether a patent protects an active ingredient has recently been considered further by a hearing officer in *Astellas Pharma Inc.*, BL O/052/09. In this decision he referred to the decisions of the Court in both *Takeda* and *Gilead*, and found that a claim to a single active ingredient, empodepside, did not protect a combination of active ingredients, empodepside and praziquantel, present in a medicinal product Profender. This decision was appealed in *Astellas Pharma Inc* [2009] EWHC 1916 (pat). In his judgment Arnold J upheld the decision of the hearing officer and found that where the basic patent does not disclose and claim a combination of active ingredients that combination cannot be considered to be protected by the basic patent within the meaning of Article 3(a). He held in paragraphs 26-27 that a claim to an active ingredient which used the term “comprises” means the claim covers products which include substances other than the compounds without having to disclose them. However, he found in paragraphs 28-30 that although the combination may be covered by the claim it is not protected by the claim when applying the test set out in *Gilead*:

“26. I therefore accept that the effect of the word "comprises" is that claim 19 on its true construction covers products which include substances other than the compounds of claims 1-11 and 14. These may include an excipient, but they may also include another compound with anthelmintic activity. This conclusion is supported by the use of the wording "an active ingredient".

27. I do not accept that it follows that claim 19 discloses a combination of a compound of claims 1-11 and 14 with another compound with anthelmintic activity. A claim may cover a product without disclosing it: see *A.C. Edwards Ltd v Acme Signs & Displays Ltd* [1992] RPC 131

28. Accordingly, I accept that Profender is covered by claim 19. If one asks oneself what brings Profender within the scope of claim 19, however, it is clear that it is the presence of the empodepside. It is not the presence of the praziquantel, any more than it is the presence of the BHA.

29. Applying the test articulated by Kitchin J in *Gilead* at [33], namely "to identify the active ingredients which are relevant to a consideration of whether the product falls within the scope of a claim of the basic patent", I consider that the answer in the present case is that it is only empodepside which is relevant. Accordingly, Profender is not protected by claim 19 of the Basic Patent within the meaning of Article 3(a) of the Regulation as interpreted in *Gilead*.

30. To put the same point another way, the present case is to be distinguished from *Gilead*. In that case the basic patent specifically disclosed and claimed a combination of active ingredients, whereas in this case the Basic Patent does not."

34. Arnold J also considered an alternative position that if no SPC could be granted for a combination of active ingredients then the applicant was entitled to an SPC for a single active. However he found that the applicant was not entitled to such a certificate stating, in paragraph 48:

*"An application for such an SPC would not comply with Article 3(b) of the Regulation since Astellas has not been granted a marketing authorisation for emodepside as opposed to Profender: see the recent decision of the Court of Appeal in *Generics (UK) Ltd v Daiichi Pharmaceutical Co Ltd* [2009] EWCA Civ 646, in particular at [57]-[58]."*

Discussion

35. Claim 1 of the basic patent is for:

"1. A method for the preparation of an acellular vaccine, which method comprises preparing the 69kDa antigen of Bordetella pertussis as an individual component, preparing the filamentous haemagglutinin antigen of Bordetella pertussis as an individual component, and mixing the 69kDa antigen and the filamentous haemagglutinin antigen in amounts that provide the 69kDa antigen and the filamentous haemagglutinin antigen in a weight ratio of between 1:10 and 1:1, so as to produce a synergistic effect in vaccine potency."

36. Considering this claim 1 it is clear that this covers a vaccine composition comprising a combination of two active ingredients, Filamentous haemagglutinin and Pertactin active ingredients (it should be noted that Pertactin is the alternative name that has been given to the 69kDa antigen). However, neither this claim nor its three dependent claims define or disclose the use of the claimed compounds with any other active ingredient. Indeed, claim 2, reproduced below, defines a method of producing a vaccine which specifically lacks a further component:

“2. A method according to claim 1 wherein the vaccine is devoid of the B. Pertussis toxin.”

37. The specification of the basic patent further states:

“[0015] The present inventors have found, that a combination of 69kDa [Pertactin] and FHA [Filamentous Haemagglutinin Antigen of B. pertussis] together is, surprisingly more potent than the aggregate effect of the individual components. The synergistic combination of 69kDa and FHA is advantageous since LPF [Pertussis toxin] is not required, and consequently the chances of adverse effects are reduced. Additionally, a bivalent vaccine containing only 69kDa and FHA will clearly be easier and cheaper to manufacture than a trivalent vaccine containing LPF as well.”

38. I note that all of the marketing authorisations supplied in support of these SPC applications list Pertussis toxoid as one of the active components – see Table 2. From a consideration of the basic patent one might conclude that a vaccine comprising only the Filamentous Haemagglutinin and Pertactin active ingredients would be easier to make and more effective than a vaccine including the Pertussis toxoid in addition to these two components. Thus, using these marketing authorizations which refer to medicinal products which include Pertussis toxoid and a further Pertussis ingredient - see Table 2 – would appear to be surprising.

39. I can find no reference in the specification of the basic patent nor in its claims to teach that the invention consists of anything other than the method of producing the combination of the Filamentous Haemagglutinin and Pertactin active ingredients defined in claim 1. Where, for example, any other active ingredient such as Pertussis toxoid is referred to in the specification, it is to show the synergistic effectiveness of the combination of the invention compared to this component, rather than as exemplifying or suggesting any further components that may be present in the combination.

40. The examiner in his substantive examination reports on applications SPC/GB/09/015, 09/016, 09/017 and 09/019 objected that in each of the applications the patent did not protect the product for which protection was being sought as required by Article 3(a) of the Regulation. As set out in paragraphs 4-8 above the product in each of these applications contains a combination of active ingredients which include Filamentous Haemagglutinin and Pertactin active ingredients as well as a number of other identified active ingredients. Each of the respective product definitions in these SPC applications agrees with the active ingredients listed as being present in the authorized medicinal product.
41. The case law on the interpretation of Article 3(a) of the Regulation considered above sets out the tests used to determine what is the meaning of “protected” in this Article of the Regulation. This case law has taken into account the relevant sections of the Act and the Protocol. Applying a purposive construction to the present claim 1, I find that the skilled person would not have understood the patentee to have intended to include any active ingredient other than those defined in the claim. By applying the test articulated by Kitchin J in *Gilead* “to identify the active ingredients which are relevant to a consideration of whether the product falls within the scope of a claim of the basic patent”, which was confirmed by Arnold J in *Astellas*, I find, in the present case, that it is only the Filamentous Haemagglutinin and Pertactin active ingredients which are relevant of any of the combinations for which protection is being sought as it is only these that are protected by the basic patent. Accordingly, none of the combinations of active ingredients in the medicinal products “Repevax”, “Infanrix IPV+Hib”, “Infanrix IPV” or “Pediacef” are protected by claim 1 of the Basic Patent within the meaning of Article 3(a) of the Regulation as interpreted in *Gilead* and confirmed in *Astellas*. Therefore none of these four SPC applications comply with Article 3(a) of the Regulation.
42. The examiner further objected in applications SPC/GB/09/015 and 09/016 that the product definition supplied did not agree with the active ingredients listed in the relevant marketing authorisations and so did not clearly identify the product for which protection is sought. It is clear when comparing the product definitions supplied with the active ingredients listed in the relevant marketing authorisations that these are not in agreement. However, these differences would appear to be merely typographical in nature and they can be addressed, as suggested by the examiner in his reports, by amendment of the product definition should the above objection under Article 3(a) be overcome.
43. By applying the test set out in *Gilead* to the product defined in application SPC/GB/09/018 which is “*Filamentous Haemagglutinin, Pertactin*”, I find that both the active ingredients are relevant and are protected by the claim 1 of the basic patent within the meaning of Article 3(a) of the Regulation.

44. However, the marketing authorisation supplied in support of this application is for the medicinal product “Pediacef” which comprises a combination of more than these two active ingredients Filamentous Haemagglutinin and Pertactin, identified as being the subject of this application. The active ingredients present in “Pediacef” are identified at section A, page 1 of the marketing authorisation as being the 11 separate active ingredients summarised in Table 2. The examiner objected that this authorisation did not meet the requirements of Article 3(b) of the Regulation.
45. Compliance with Article 3(b) requires considering the subject matter of the marketing authorisation and comparing this with the product for which the SPC is being sought. However, applying this principle and following the decision in *Astellas* which referred to the decision *Generics (UK) Ltd v Daiichi Pharmaceutical Co Ltd* regarding the interpretation of Article 3(b) I do not find agreement between the subject of the marketing authorisation and the product for which the SPC is being sought. The Regulation and the case law interpreting it do not require that the active ingredients present in a medicinal product have to act upon the same or similar disease conditions, nor that there is any synergistic effect of the combination. The United Kingdom marketing authorisation PL 06745/0120 relates to a product that is identified as containing eleven separate active ingredients and not merely the two active ingredients identified as being the product for which protection is sought by this application. Consequently, I find that the applicant is not entitled to an SPC for “*Filamentous Haemagglutinin, Pertactin*”. Therefore an application for such an SPC does not comply with Article 3(b) of the Regulation.
46. Furthermore I do not find agreement between the subject matter of the French marketing authorisation NL 22370 for “Infanrix Quinta”, the United Kingdom marketing authorisation PL 06745/0120 for “Pediacef” and the product for which the SPC is being sought. The medicinal product “Infanrix Quinta” authorised by the French marketing authorisation comprises nine active ingredients, not the eleven present in the medicinal product “Pediacef” authorised by the United Kingdom marketing authorisation. Consequently, considering the subject matter of these two authorisations I find they do not agree and so the French authorisation is not the first marketing authorisation in the Community for the combination of active ingredients present in the authorised medicinal product “Pediacef”. Consequently, this French authorisation does not form an authorisation that can be used under Article 13(1) to determine the duration of any certificate that may be granted.
47. The consequences of these interpretations of the Regulation were considered by Kitchin J at para 28 of *Gilead*. He recognised that the Regulation may produce in some circumstances a “*harsh result*” so that not every application for a certificate was successful. However, when he considered, in para 29, the possibility of breaking up a combination of active ingredients into individual actives that each might be protected, he recognised that this was “hard to reconcile” with Article 4 and the definitions set out in Article 1 of the Regulation:

“29. A possible answer, canvassed briefly before me in argument, is to regard such a medicine as containing, effectively, three products, that is to say the two active ingredients separately and in combination. In such a case an SPC could then be granted for the ingredient claimed by the basic patent. This solution has its attractions and would permit the holder of the basic patent claiming only one of two active ingredients to secure an SPC for that particular ingredient, assuming, of course, it is not already the subject of a certificate (Article 3(c)) and the authorisation is the first authorisation to place that ingredient on the market in a medicinal product (Article 3(d)). However, it must depend upon the proper interpretation of, at least, Articles 1(b) and 4 and it is my initial impression that it is hard to reconcile with the words of Article 4 which specify that protection shall extend only to the product covered by the marketing authorisation.”

48. He too recognised also that, although it is possible to interpret the wording of the Regulation in a number of ways, there is a need for consistency in this, especially when considering the other articles of the Regulation. As Kitchin J further noted in *Gilead* at paragraph 39:

“The scheme of the Regulation is to provide a simple and straightforward system for the grant of SPCs based only upon a consideration of the requirements laid down in the Regulation. Such is also apparent from the Commission Proposal COM (90) 101 of 11 April 1990 which says in terms at paragraph [16] that the proposal provides a simple transparent system which can easily be applied by the parties concerned and does not lead to excessive bureaucracy.”

49. In upholding the decision in *Astellas*, Arnold J also considered a second ground of the appeal, whether *Takeda* was wrongly decided and that the correct test to apply under Article 3(a) is an infringement test. Whilst he was not convinced that *Takeda* was wrong, he agreed with Kitchin J that there were arguments in favour of the infringement test which had not be considered in *Takeda* and that these would merit further consideration by a higher court and perhaps the ECJ. However he decided that such a course of action was a matter for the higher court (and not he) to decide.

50. None of the decisions referred to above relate to active ingredients and medicinal products that are in the vaccine field. It may well be that there are specific requirements from a wider public policy perspective in relation to the development, authorisation and use of vaccines, in particular those for use in children, that have a bearing on this case. However, this is not an issue that is discussed in the papers currently on file other than as an assertion and I am unable to comment further. However, if this present decision is appealed, this is an issue that a higher court might want to explore. For example, should factors such as how the vaccine is to be administered to a patient have any relevance? Are multiple combinations of active components preferred as a means to minimise the number of interventions required to provide immunity in the population and, if so, what impact does this have. Furthermore, many of these

combinations do not have any synergistic effects as the individual components are put together for delivery rather than efficacy purposes and, in fact, the active ingredients may never be marketed as individual components. Thus one might consider that vaccine products could be regarded as different and distinguishable from other medicinal products.

51. However, in the absence of any specific guidance to distinguish vaccine products from other medicines in relation to the granting of SPCs, I must base my decision on the current framework in the UK for doing so outlined above. This requires me to treat these vaccine products in the same way as other medicinal products for the purposes of granting an SPC. As a consequence, I see no reason to come to different conclusions to those I have reached below.

Conclusion

52. Taking account of all of the above, I conclude that the basic patent does not “protect”, for the purposes of Article 3(a) of the Regulation, the product which is the subject of applications SPC/GB/09/015, 09/016, 09/017 or 09/019.

53. Furthermore, I conclude that the marketing authorisation PL 06745/0120 for “Pediacef” is not, for the purposes of Article 3(b) of the Regulation, a valid authorisation to place the product which is the subject of application SPC/GB/09/018 on the market as a medicinal product. In addition, I conclude that the French marketing authorisation NL 22370 for “Infanrix Quinta” supplied in support of application SPC/GB/09/018 is not the first authorisation in the Community for the purposes of Article 13(1) of the Regulation.

54. Since, in accordance with Article 10(3), an opportunity to correct the irregularities with these SPC applications has already been given, as required by Article 10(4), I reject these applications.

Appeal

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

Dr L Cullen

Deputy Director acting for the Comptroller