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Case No: A3/2010/0295

IN THE HIGH COURT OF JUSTICE
COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE CHANCERY DIVISION (PATENTS COURT)
MR JUSTICE KITCHIN
2010 EWHC 68(PAT)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 23 June 2010

Before :

THE CHANCELLOR OF THE HIGH COURT
LORD JUSTICE ETHERTON
and
LORD JUSTICE ELIAS

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RE: MEDEVA'S SPC APPLICATIONS
RE: COUNCIL REGULATION (EC) NO.469/2009

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MR COLIN BIRSS QC & MR MILES COPELAND (instructed by **Rouse Legal**) for the **Appellant**
MR TOM MITCHESON (instructed by **Treasury Solicitors)** for the **Respondent**

Hearing date : 28 April 2010

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JUDGMENT

The Chancellor giving the judgment of the Court

Introduction

1. Council Regulation (EC) No.469/2009 ("the Regulation") enables the competent industrial property office of a member state (in the United Kingdom the Intellectual Property Office) to grant a certificate called a supplementary protection certificate ("SPC") to the holder of a patent or his successor in title extending the rights conferred by his patent but subject to the same limitations and obligations for a period. That period, not exceeding five years, is equal to the period which elapsed between the date on which the application for the patent was lodged and the first authorisation to place on the market in the European Union a medicinal product, as defined, protected by the patent less five years. The purpose of such a certificate, as recorded in recital (4), is to extend the period of protection conferred by the patent so as to enable the patentee to cover the cost of the necessary research.

2. On 20th April 1990 the appellant, Medeva BV ("Medeva"), filed an application for a patent for a method of making acellular vaccine compositions against whooping cough (bordetella pertussis) by combining two antigens, pertactin (69kDa protein) and filamentous haemagglutinin (FHA), to produce a synergistic effect such that a third antigen, pertussis toxin (LPF) is not required. The patent was granted on 18th February 2009 and expired on 26th April 2010. It is not suggested that its expiry affects the issues with which we are concerned.

3. Medicinal products must be approved in accordance with The Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994, made under s.2(2) European Communities Act 1972, before they are put on the market in any member state of the European Union. The first commercial vaccine made in accordance with the invention and duly authorised comprised all three antigens but was combined with diphtheria toxoid and tetanus toxoid so as to be effective against whooping cough, diphtheria and tetanus. It was launched in 1996. In and after 2000 larger combinations, similarly approved, were launched comprising vaccines against whooping cough, diphtheria, tetanus, meningitis (haemophilus influenzae type b) and polio. By 2004 the combined vaccine against all five diseases, DTPa-IPV/Hib, was routinely recommended as the primary immunisation for babies.

4. On 17th April 2009 Medeva filed five applications for SPCs. Three of them relate to vaccines against all five diseases (DTPa-IPV/Hib). The other two omitted the vaccine against meningitis (Hib). These applications came before Dr Cullen, the Hearing Officer acting for the Comptroller General of Patents, following an examination by Dr Patrick Purcell. In his decision dated 16th November 2009 Dr Cullen rejected all five applications. In the case of four of them he concluded that the active ingredients included some, namely the vaccines against diseases other than whooping cough, which are not protected by Medeva's patent. In the case of the fifth, though the active ingredients were limited to those protected by Medeva's patent the market authorisation covered a combination vaccine which included vaccines against the other four diseases. In other words, in the case of all five there was a mismatch between the active ingredients protected by the

patent and the active ingredients in the vaccine or medicinal product for which the relevant market authorisations had been given.

5. Medeva appealed. The principal ground (at least with respect to the four applications) was that the Comptroller had wrongly construed the meaning of a "product protected by a basic patent" in Article 3(a). This should, it was submitted, extend to any product which could be subject to successful proceedings for infringement of the patent ("the infringement test."). For the reasons given in his judgment dated 27th January 2010 Kitchin J dismissed Medeva's appeal but gave Medeva permission to appeal to this court. In considering the papers before the hearing commenced on 28th April 2010 it appeared to us that there might be a need for a reference of certain questions on the interpretation of the Regulation to the Court of Justice of the European Union. Accordingly we invited counsel to confine their arguments, in the first instance, to that issue. Having heard that argument we concluded that such a reference should be made. We indicated that we would give our reasons in our judgments to be handed down in due course and invited counsel to revise the draft questions they had helpfully provided in advance of the hearing. We were informed that counsel acting for other interested parties were attending the hearing. We asked counsel for the parties before us to take account of the views of the latter in considering the form of the questions and let us have their revised draft on or before Friday 7th May.

6. What follows are our reasons for considering that this court should refer to the Court of Justice the questions mentioned in paragraph 34 below. To explain them it is necessary to set out the relevant Articles of the Regulation, consider further certain parts of the basic patent and refer to some of the decided cases both in this jurisdiction and in the EU.

The Regulation

7. The Regulation came into force on 20th July 2009. It was a consolidation of the previous Regulation 1768/92 and all subsequent amendments. Accordingly cases decided on the earlier regulation are equally applicable to this one. It recites that pharmaceutical research plays a decisive role in the continuing improvement in public health (recital 2) but that (recital 4) the period between the filing of a patent application for a new medicinal product and the grant of the requisite authority to put it on the market "makes the period of effective protection under the patent insufficient to cover the investment put into the research".

8. Articles 1, 3, 4 and 5 provide:

"***Article 1***

Definitions

For the purpose 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;

.....

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

Article 4

Subject-matter of protection

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 authorised before the expiry of the certificate.

Article 5

Effects of the certificate

Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations."

9. Article 7 imposes time limits on applying for an SPC. They are six months from the date of the marketing authorisation referred to in Article 3(b) or, where such authorisation precedes the grant of the patent referred to in Article 3(a), six months from the date the patent is granted. Article 13 provides for the SPC to take effect from the end of the term of the basic patent and to be effective for a period equal to that which elapsed from the application for the basic patent and the date of the first authorisation less five years. The duration of the SPC may not exceed five years.

10. The issues with which we are concerned relate to the proper interpretation and application of Articles 3(a) and (b). To explain them it is necessary to consider the basic patent and the market authorisations relied on.

The basic patent

11. The relevant application was filed on 26th April 1990 and granted on 18th February 2009. We gratefully adopt the summary of it contained in paragraphs 4 to 6 of the judgment of Kitchin J in the court below. He said:

> "4. The Patent describes and claims a method of making acellular vaccine compositions against Bordetella pertussis, more commonly known as whooping cough. The specification discloses that a combination of two particular antigens known as pertactin (or the 69kDa protein) and filamentous haemagglutinin (or FHA) produces, surprisingly, a synergistic effect which is such that a third antigen called pertussis toxin (or LPF) is not required to produce an effective dose of vaccine.
>
> 5. This, explains the specification, was an important discovery. Prior to the invention there was a general understanding that pertussis toxin was an essential part of any acellular vaccine. But it was also believed that some of the adverse effects associated with pertussis vaccination were related to this antigen. Accordingly, the synergistic combination of pertactin and FHA meant that pertussis toxin need no longer be used, and consequently the risk of adverse reactions could be reduced. Additionally, a bivalent vaccine containing only pertactin and FHA would be cheaper to produce.

6. The relevant claims reflect the disclosure in the specification. Claim 1 is directed to a method of making the synergistic combination of the pertactin and FHA antigens and reads:

> "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 provide a synergistic effect in vaccine potency."

7. And claim 2 is directed to a vaccine which does not contain pertussis toxin:

> "A method according to claim 1 wherein the vaccine is devoid of the B. pertussis toxin."

12. It is clear from this description that the method protected by the patent relates to a mixture of the two or three antigens referred to in the claims. It does not, in terms, include the other antigens incorporated into the vaccines against diphtheria, tetanus, meningitis (haemophilus influenzae type b) and polio.

Combined vaccines and marketing authorisations

13. We have referred, in general terms, in paragraph 3 to the growth in the practice of combining the ingredients of vaccines against other diseases. This is described in greater detail by Kitchin J in paragraphs 8 to 10 of his judgment:

> "8. Despite the teaching in the specification, no vaccine containing only pertactin and FHA has ever been produced. The first commercial vaccine made in accordance with the invention contained pertactin, FHA and pertussis toxin. It was launched in 1996 as a combination with diphtheria toxoid and tetanus toxoid (DTPa) and was effective against the three diseases: pertussis, diphtheria and tetanus.
>
> 9. The desirability of combining vaccines against different diseases was something that had been appreciated for many years, so it was natural to develop even larger vaccine combinations from DTPa. But each time a new antigen is built into a combined vaccine there is a risk of an increase in the frequency of existing side effects or of a reduction in the immune response to certain antigens. So extensive clinical testing is required.
>
> 10. It was therefore not until 2000 that the first such larger combination (DTPaP-Hib) was approved. This included antigens against haemophilus influenzae type b, an agent which causes

> meningitis. It was followed in 2001 by the approval of a combination which included inactivated polio virus vaccine (DTPa-IPV) and then, in 2002, by the approval of the ultimate goal in the UK for childhood vaccines, namely DTPa-IPV/Hib, which provides a measure of protection against pertussis, diphtheria, tetanus, polio and meningitis. By 2004, DTPa-IPV/Hib was routinely recommended as the primary immunisation for babies."

14. Such combination vaccines required a market authorisation covering the combination, not just separate authorisations in relation to the individual vaccines. On 17th April 2009 Medeva filed the five applications for SPCs with which this appeal is concerned. They are numbered 015, 016, 017, 018 and 019. Each application specified, as required by the Regulation, the marketing authorisation for the medicinal product relied on and the active ingredients contained therein. The various combinations are helpfully set out in the table produced by counsel for the Comptroller General of Patents at the hearing before Kitchin J and reproduced in Appendix I to this judgment.

15. A detailed examination of the table reveals the problem. In the case of application 015, 016, 017 and 019, as shown in line 7, there were more active components or ingredients than those used in the method the subject matter of the basic patent. In the case of application 018, as shown in line 8, though the active components or ingredients were restricted to those used in the method described in the basic patent, namely pertactin (69kDa protein) and filamentous haemagglutinin (FHA), the marketing authorisation was not limited to a product containing those ingredients alone but included all the others indicated in the column headed MA. In these circumstances, as recorded by Kitchin J in paragraph 12 of his judgment:

> "...the Deputy Director concluded that the Patent did not protect the product the subject of applications 09/015, 09/016, 09/017 or 09/019 for the purposes of Article 3(a) of the SPC Regulation. Further, he concluded that marketing authorisation PL 06745/0120 for Pediacel was not, for the purposes of Article 3(b) of the SPC Regulation, a valid authorisation to place the product the subject of application 09/018 on the market as a medicinal product."

16. Kitchin J agreed with those conclusions. Before referring in more detail to his reasons we should refer to the decided cases he considered. They are, in chronological order, **Farmitalia Carlo Erba SRL's SPC Application** [1999] ECR I-5553, **Re: Takeda Chemical Industries Ltd's SPC Applications** (No.3) [2004] RPC 3; **Re: Gilead Sciences Ltd's SPC Application** [2008] EWHC 1902 and **Astellas Pharma Inc v Comptroller General of Patents** [2009] EWHC 1916.

The Decided Cases

17. In **Farmitalia Carlo Erba SRL's SPC Application** [1999] ECR I-5553 ("**Farmitalia**") the basic patent was for alpha-anomer of 4-Demethoxydaunomycin (also known as idarubicin), its manufacturing process and the medicament containing that substance. Farmitalia obtained a market authorisation for medicinal products called Zavedos 5 mg and Zavedos 10 mg containing the salt idarubicin hydrochloride and, as an ancillary ingredient, dehydrated lactose. Farmitalia applied for an SPC for "idarubicin and salts thereof including idarubicin hydrochloride". The German Patent Office granted an SPC for only "the medicament Zavedos containing as its active ingredient idarubicin hydrochloride". It considered that Article 3(a) was not satisfied because the basic patent did not protect all salts of idarubicin but only idarubicin hydrochloride and Article 3(b) was not satisfied either because idarubicin hydrochloride was the only active ingredient in the medicinal product covered by the marketing authorisation.

18. Farmitalia appealed to the Federal Court of Justice and that court, pursuant to Article 177, sought a preliminary ruling on the following questions:

> (1) Is it a condition of the application of Article 3(b) that the product in respect of which the grant of a protection certificate is sought is described as an "active ingredient" in the medicinal authorisation?
>
> Are, then, the terms of Article 3(b) not satisfied where only one individual salt of a substance is stated in the notice of authorisation to be an "active ingredient", but the grant of a protection certificate is sought for the free base and/or for other salts of the active ingredient?
>
> 2. If the questions at (1) are answered in the negative:
>
> According to which criteria is it to be determined whether the product is protected by a basic patent within the meaning of Article 3(a), where the grant of a protection certificate is sought for the free base of an active ingredient including any of its salts, but the basic patent in its patent claims mentions only the free base of this substance and, moreover, mentions only a single salt of this free base? Is the wording of the claim for the basic patent or the latter's scope of protection the determining criterion?"

19. Advocate General Fenelly, in his opinion delivered on 3rd June 1999 considered that both questions turned on the proper interpretation of the word 'product' in Articles 3(a) and (b) of the Regulation. Before he dealt with that issue he made four general observations of which we should quote the first three. In paragraphs 19 to 21 the Advocate-General said:

> "19. ....First, both of the questions referred by the national court relate to the conditions for the grant of an SPC set out in Article 3 of the SPC Regulation. What is at issue is not whether or not a certificate

should be granted, but its terms. The criteria for the grant of a certificate are procedurally and substantively distinct from those which determine the effective scope of the protection it confers. The latter are applied when it is sought to enforce the SPC in infringement proceedings, whereas the former are considered by the competent national industrial property office at the time of application for the award of a certificate.

20. Secondly, and in spite of this distinction, the conditions for the grant of an SPC cannot be construed in isolation from the general scheme established by the Regulation and, in particular, from the provisions governing the scope and effect of the protection it encompasses. These two elements of the scheme combine to determine in practice the extent to which patentees can recover investment in research, which is the essential purpose of the Regulation.

21. Thirdly, although the SPC regime creates a distinct, new form of intellectual property right, rather than simply extending the period of protection guaranteed by existing patents, it is, nonetheless, closely connected with the national systems under which pharmaceutical patent rights are initially granted and protected. Thus, in substantive terms, a certificate can only be granted if a product is protected by a basic patent and the protection conferred by a certificate must be within the limits of that conferred by the basic patent. The certificate holder enjoys the same rights and is subject to the same limitations and obligations as affected the basic patent. The Regulation replicates the basic procedural model of distinct phases for the administrative grant and judicial enforcement of patents which is common to all the Member States."

20. In paragraph 25 the Advocate General gave a number of possible interpretations to the meaning of the term "product" as it applies in Article 3(a) and (b):

"The term `product' is open to a number of possible interpretations, none of which can be excluded on purely textual grounds. The term `active ingredient ... of a medicinal product' is not defined in the SPC Regulation. On the one hand, it would be possible to construe the term `product' as being the particular form of a patented pharmaceutical, for example the particular salt of a free base which is the `active constituent' referred to in a marketing authorisation. An alternative approach is to interpret the term `product' as referring, broadly speaking, either exclusively to the parent compound or variants expressly referred to in the patent claims, or to the ensemble of the parent compound and its pharmaceutically acceptable derivatives for which patent protection can be secured in infringement proceedings."

21. After considering various arguments in favour or against these possible approaches, he expressed his own views in paragraph 35 in the following terms:

> "I would construe an active ingredient as being the pharmacologically active free base or parent compound underlying a medicinal product which is subject to a marketing authorisation. Different salts and esters can normally be understood as being simply variants of the active ingredient and, thus, of the product, rather than as being either products in their own right or distinct elements of the product. As a result, and in view of the fact that the patent claims will normally be phrased, as in the present case, in terms of the free base, these can be taken as defining the product and, therefore, as dictating the terms in which a subsequent SPC is granted. In my view, therefore, the certificate should be granted in the same terms as the patent claims. This would have the advantage of establishing a uniform criterion for the grant of a certificate, which could not easily be arrived at on the basis of the scope of protection of the basic patent, and of permitting national competent authorities to grant certificates without having to engage in an inquiry into the likely additional scope of protection of the patent and of the certificate, which is alien to their normal function. Furthermore, it would preserve the normal division of functions between those authorities and the national courts, permitting the latter to decide the ultimate scope of protection of a certificate worded in terms of the patent claims on the basis of the same principles of national law as are applied to the patent itself (subject always to the caveat required by Article 4 that the certificate's scope be limited to authorised medicinal uses of the product). Thus, manufacturers of generic pharmaceutical products would enjoy no greater freedom than under the basic patent, and infringement proceedings could be conducted on broadly the same procedural lines as those in respect of a patent, with the same balance of advantage between the parties."

22. It is plain therefore that the Advocate General was rejecting the first possible construction identified in paragraph 25; the SPC should extend beyond the particular salt identified in the marketing authorisation and cover the different salts or esters which are really variants of the product. That dictated his answer to the first question. This meant that he had to consider how one should define the scope of these products. In paragraph 25 he had identified the two ways of doing this; either it could be done by reference to the patent claim itself, or the competent authorities could themselves determine the scope of the parent compound and the pharmaceutically acceptable derivatives for which patent protection could be secured in infringement proceedings. He preferred the former for the reasons he gave, and that dictated his answer to the second question. It is far from clear, however that the alternative approach which he rejected was the infringement test as it has been advanced in this case. In our view there is real doubt whether he intended the reference to "pharmaceutically acceptable derivatives" to include any product whose manufacture could be restrained by

infringement proceedings, bearing in mind in particular that he was considering a very different factual situation from the present case.

23. Accordingly he answered the two questions in paragraph 36 as follows:

> "my recommended approach to the definition of the product would result in a negative answer to both parts of the first question regarding the definition of the active ingredient and, as should already be clear, in the second question being answered in favour of the use of the wording of the patent claims rather than the use of the scope of protection of the basic patent to define the product in question and, thus, to determine whether it is protected by a basic patent."

24. On the application of Article 3(b) the Court of Justice concluded that (paragraph 22)

> "where a product in the form referred to in the marketing authorisation is protected by a basic patent in force, the certificate is capable of covering that product, as a marketing product, in any of the forms enjoying the protection of the basic patent."

Thus in that case it was not an objection to the grant of the SPC sought that it would cover all salts of idarubicin and was not limited to the particular salt named in the medical authorisation, idarubicin hydrochloride.

25. In relation to the second question relating to Article 3(a) the Court of Justice stated:

> "[23] By its second question, the Bundesgerichtshof is, in substance, asking what are the criteria, according to Regulation 1768/92 and in particular Article 3(a) thereof for determining whether or not a product is protected by a basic patent.
>
> [24] In that connection, it should be noted that one of the conditions for obtaining a certificate is that the product should be protected by a basic patent in force.
>
> [25] As indicated in the seventh recital in the preamble to Regulation 1768/92, the patent concerned may be either national or European.
>
> [26] As Community law now stands, the provisions concerning patents have not yet been made the subject of harmonisation at Community level or of an approximation of laws.
>
> [27] Accordingly, in the absence of Community harmonisation of patent law, the extent of patent protection can be determined only in the light of the non-Community rules which govern patents.

> [28] As is clear in particular from paragraph [21] of this judgment, the protection conferred by the certificate cannot exceed the scope of the protection conferred by the basic patent.
>
> [29] The answer to be given to the second question must therefore be that, in order to determine, in connection with the application of Regulation 1768/92 and, in particular, Article 3(a) thereof, whether a product is protected by a basic patent, reference must be made to the rules which govern that patent."

Thus, having agreed that the product protected by the SPC could extend to any of the forms enjoying the protection of the basic patent, the court did not accept the Advocate General's recommendation that the scope of the protected products should be defined by the terms of the patent claims. Indeed, the Court did not expressly engage with his analysis at all. Rather the Court said that the scope should be determined by the national rules which govern the patent. We are therefore far from clear that either the Advocate General or the Court had in mind the particular issue that has arisen in this case, namely whether the SPC should extend to any product which could itself be the subject of infringement proceedings because it contained the antigen or antigens protected by the patent. That was not the factual scenario with which they were concerned. Not surprisingly, therefore, although the domestic courts have on occasions since **Farmitalia** had to engage with that very issue, they have not treated the Court's ruling in that case as determining the answer.

26. The first of those decisions is that of Jacob J in **Re: Takeda Chemical Industries Ltd's SPC Applications** (No.3) [2004] RPC 3. In that case ("**Takeda**") 6 SPCs were sought in relation to combinations of the anti-ulcer agent lansoprazole with two antibiotics selected from clarithromycin, amoxycillin and metronidazole. In the case of three of them the basic patent related to lansoprazole only. In the case of the other three the basic patent claimed the use of lansoprazole for the manufacture of a medicine for preventing or treating infectious diseases caused by Helicobacter pylori. All six applications were refused for failure to comply with Article 3(a), notwithstanding, as the applicant submitted, that the sale of the combinations would infringe the patents for lansoprazole. As Jacob J put it, with characteristic clarity, in paragraph 10 of his judgment:

> "The so-called "combination" of lansoprazole and an antibiotic would only infringe because of the presence of the lansoprazole. In truth, the combination is not as such "protected by a basic patent in force". What is protected is only the lansoprazole element of that combination. It is sleight-of-hand to say that the combination is protected by the patent. The sleight-of-hand is exposed when one realises that any patent in [counsel for the appellant]'s sense protects the product of the patent with anything else in the world. But the patent is not of course for any such "combination"."

After referring to a decision of Swedish Courts to the like effect Jacob J refused to make a reference to the European Court of Justice on the basis that the point was acte claire.

27. A similar point arose in that case in relation to compliance with Article 3(b) in that the marketing authorisations were for lansoprazole with various indications as to the conditions for which it was effective. Jacob J considered (paragraph 13) that Article 3(b) was not satisfied because:

> "The licence, both in its original form and its varied form, is for lansoprazole as such. It is that chemical compound which has a marketing authorisation. The product or products to be used for indications are not what is licensed. Putting it another way, it is not this product licence which permits the marketing of the antibiotic component. That would have to have its own marketing authorisation."

28. In **Re: Gilead Sciences Ltd's SPC Application** [2008] EWHC 1902 Kitchin J was concerned with the condition for the grant of an SPC contained in Article 3(a). In that case ("**Gilead**") the basic patent disclosed new antiretroviral compounds useful in the treatment of HIV and other diseases. Claim 1 covered a class of such compounds including tenofovir. Claim 25 was directed to tenofovir alone. The marketing authorisation was for a medicinal product comprising as its active ingredients tenofovir and another antiretroviral called emtricitabine. The application for an SPC described the product as a composition containing both tenofovir and emtricitabine. The examiner rejected the application on the ground that the basic patent did not protect that product. His decision was upheld by Kitchin J.

29. Before Kitchin J counsel for the applicant claimed that **Takeda** had been wrongly decided. He contended that as s.60 Patents Act 1977 would have enabled the patentee to prevent the manufacture or sale of the combination of tenofovir and emtricitabine such combination was "protected by a basic patent" within the meaning of Article 3(a). In paragraphs 24 to 30 of his judgment Kitchin J said:

> "24. There are, however, other matters which bear on this issue and which do not appear to have been explored in argument before the court in *Takeda*. The first is the decision of the European Court of Justice in Case C-392/97 *Farmitalia Carlo Erba Srl's Supplementary Protection Certificate* [2000] RPC 580. This primarily concerned the question whether the Regulation requires an SPC to be restricted to the particular form of the active ingredient described in the medicinal authorisation. The Court held it does not and that an SPC is capable of covering the product, as a medicinal product, in any of the forms enjoying the protection of the basic patent. As a secondary question the Court was asked, in substance, what are the criteria for determining whether or not a product is protected by a basic patent? The Court answered that, in the absence of Community harmonisation

of patent law, the extent of patent protection can be determined only in the light of non-Community rules which govern patents. As both parties before me were disposed to accept, this ruling suggests I must determine whether the product is protected as a matter of English law.

25. Second, s.125 of the Patents Act 1977 defines the extent of protection of a patent as being that specified in a claim as interpreted in the light of the specification. For this purpose the Protocol on the Interpretation of Article 69 of the EPC applies and this too refers to the extent of protection conferred by a patent and how it is to be understood. These two provisions make it clear that a product is protected by a patent within the meaning of the Act if it falls within the scope of a claim.

26. Third, no other provision of domestic law addresses the issue of protection of a product by a patent. This suggests the Court of Justice in *Farmitalia* must have had the infringement test and, for Contracting States to the EPC, Article 69 in mind. Anything less would have required the Court to interpret the term "protected" in the context of the Regulation as having a particular and different meaning, and that was something it declined to do. Certainly that appears to be the understanding of a number of other Member States, including Germany, as illustrated by the decision of the Federal Supreme Court in Case X ZB 12/00 of March 12, 2002.

27. Fourth, it must be remembered that the monopoly conferred by an SPC for a product consisting of both tenofovir and emtricitabine would be narrower and comprised wholly within a monopoly for tenofovir alone. It would be, in effect, a monopoly for tenofovir only when used with emtricitabine.

28. Fifth, I can envisage circumstances where the application of the *Takeda* test may produce a harsh result. For example, the holder of a patent for a new pharmaceutical may have chosen to market it *only* in combination with another active ingredient and duly secured a marketing authorisation for the medicinal product containing those ingredients. In such a case the product would appear to be the combination of active ingredients (Article 1(b)) for which authorisation has been obtained (Article 3(b)). Yet, upon an application of the *Takeda* test, it would not be protected by the basic patent and hence the inventor would be deprived of an opportunity to secure any SPC at all.

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.

30. These are difficult questions and they raise a serious issue as to whether the decision in *Takeda* is correct. I believe they merit further consideration by a higher court and perhaps even the Court of Justice. In that latter regard, it is my understanding the Court of Justice has not yet considered how the requirements of the Regulation are to be interpreted in the case of a medicinal product consisting of a combination of active ingredients where only one is claimed in the basic patent. It may require a development of the reasoning in *Farmitalia*. But in this case and in the light of my conclusion on the second submission advanced by Gilead, it is not necessary for me to express a final conclusion and, in the circumstances, I prefer not to do so."

30. A similar problem faced Arnold J in **Astellas Pharma Inc v Comptroller General of Patents** [2009] EWHC 1916. In that case ("**Astellas**") the basic patent disclosed emodepside, but not praziquantel or a combination of emodepside and praziquantel, for the treatment of cats with roundworm. A marketing authorisation had been obtained for a veterinary medical product called Profender comprising both emodepside and praziquantel. Astellas sought an SPC for Profender. This was refused on the ground that the basic patent did not protect the combination of emodepside and praziquantel. Arnold J referred to **Farmitalia**, **Takeda** and **Gilead.** He quoted the paragraphs from the judgments of the Court of Justice, Jacob J and Kitchin J I have already referred to. Before him it was also contended that the judgment of Jacob J in **Takeda** was wrong. He concluded, in paragraphs 34 and 35:

"34. I am not convinced that *Takeda* is wrong. To my mind, Jacob J's reasoning remains persuasive. Furthermore, I agree that there is a distinction between the scope of protection and the question of infringement. As to *Farmitalia*, it is not clear to me that the ECJ either endorsed or rejected the infringement test in that case. Nevertheless, I agree with Kitchin J that there are arguments in favour of the infringement test which do not appear to have been considered in *Takeda* and which merit consideration by a higher court and perhaps the ECJ.

35. I have considered whether it is appropriate to refer this question to the ECJ. If I were confident that the Court of Appeal would refer it, I would avoid delay by making a reference now. I am not confident that the Court of Appeal will refer it, however. I conclude that the decision whether to refer should be left to that Court."

This appeal

31. In this case Kitchin J described the argument before him in relation to all the applications except 018 as involving the contention that the basic patent protected all the active ingredients in the relevant product shown on line 7 in the Table in Appendix I within the meaning of Article 3(a) not because Takeda and the subsequent cases were wrongly decided but because vaccines are a special case distinguishable from the products with which the earlier cases dealt. The argument, as described by Kitchin J in paragraph 27:

> "...has two strands. The first is that a combination vaccine is a medicinal product which comprises a group of antigens directed at multiple diseases. They are, in effect, operating independently and in parallel. Accordingly, it is said, the product is indeed protected by the Patent within the meaning of Article 3(a). The second is that the implementation of the invention by Medeva in the form of combination vaccines directed at multiple diseases has been driven by national health policy and, unless vaccines are treated as a special case, Medeva will be deprived of any opportunity to secure an SPC in respect of any product covered by the Patent."

32. Kitchin J rejected both arguments. With regard to the first he pointed out that the evidence established that the combined vaccines did not operate independently and in parallel even though directed at different agents responsible for diverse diseases (paragraph 29). In relation to the second strand Kitchin J pointed out that the problem related to all combination products and not only vaccines. Accordingly he considered that vaccines could not be treated as special cases.

33. In relation to application number 018, as shown on the table, Article 3(a) was satisfied. The issue related to Article 3(b) given that the marketing authorisation did not relate to a product containing only those active ingredients. Kitchin J agreed (paragraph 33) that in those circumstances Article 3(b) was not satisfied.

34. On this appeal the issues are wider than they were before Kitchin J. They may be summarised in the form of the following four questions:

> (1) What is the test by which to determine whether "the product is protected by a basic patent in force" for the purposes of Article 3(a)?
> (2) Should a different test be applied in cases where the product is a multi-disease vaccine?
> (3) Is it sufficient for the purposes of Article 3(a), in the context of a multi-disease vaccine, that the basic patent in force protects one aspect of the product?
> (4) For the purposes of Article 3(b) may the product be limited to that part of a multi-disease vaccine as is protected by the basic patent in force?

The first three questions, on their face, raise questions as to the proper interpretation of Article 3(a), the fourth as to the proper interpretation of Article 3(b).

35. Counsel for Medeva, whilst not actively opposing a reference, submits that the relevant answers to the first three questions have been supplied by the Court of Justice in its decision in **Farmitalia** to which we have referred in paragraphs 17 to 25 above. We do not agree. We suggest with some diffidence that the judgment has been misunderstood. First, for reasons we have given, it is far from clear that either the Advocate General or the Court addressed the issue arising in this case. Second, even if the Court intended to leave to the national courts the determination of the precise scope of the protection afforded by the patent, the submission advanced by the appellant in this case has very extensive ramifications. There must be a real question whether it is compatible with EU law to interpret the phrase "product protected by the basic patent" in Article 3(a) as extending to any product with respect to which proceedings could be successfully brought in any national court for infringing the patent. Third, the very fact, as considered by the Court of Justice in paragraph 27 of its judgment, that there has been no EU harmonisation of patent law indicates the need for the concept of 'protection by a basic patent in force' in relation to a 'product' as defined in Article 1(b) to reflect a European concept separate from its meaning in any particular system of national law.

36. There is no suggestion that there is any decision of the Court of Justice determining whether there is or should be any special consideration or treatment of multi-disease vaccines when determining the proper meaning and application of Articles 1(b) or 3(a) to such products. Nor does any party submit that the fourth question posed in paragraph 34 above has been determined. As with the issues relating to Article 3(a), the proper meaning of 'a valid authorisation to place the product on the market as a medicinal product' is a matter of EU law. The extent to which 'the authorisation', 'the product' and 'a medicinal product' must be co-extensive would seem to call for the application of a concept of EU law. The possible justification for treating them differently is that they are in a special market. Although they do not necessarily face the problem identified in recital 4, namely the lack of sufficient time to cover the investment put into the research, nevertheless the market is dictated by governments who are continually seeking to combine vaccines where possible. So there is no market for the patented vaccine if provided on its own and the research costs may not be recovered.

Should this court make a reference to the Court of the European Union?

37. Under Article 267 of the Treaty on the Functioning of the European Union this court is entitled "if it considers that a decision on the question is necessary to enable it to give judgment" to make a reference of that question. In our view that test is amply satisfied in this case. First, there is substantial doubt whether the judgment of the Court of Justice in **Farmitalia**, answered any of the questions which we consider now arise. Second, though Jacob J in **Takeda** considered the issues on Article 3(a) to be acte claire because of the decision of the Swedish Courts to which he referred this may not now be the position in Norway or Germany. Third, both Kitchin J in **Gilead** and Arnold J in **Astellas** considered

that at least some of the issues which arise on this appeal are not acte claire. Fourth, the repeated emergence of these or similar issues in this jurisdiction, notwithstanding the judgment of the Court of Justice in **Farmitalia** indicates the need for the definitive answers which only the Court of Justice can give. Fifth, **Farmitalia** was in any event decided ten years ago and this is a rapidly developing area of jurisprudence

38. For all these reasons we will make a reference to the Court of Justice for a preliminary ruling on each of the questions posed in paragraph 34 above. The parties helpfully produced revised draft questions before this judgment was completed. We have attached their draft as Appendix II. We invite counsel to reconsider their revised draft in the light of all the foregoing and produce a draft reference for our consideration.

Appendix I

Combination of Active Ingredients	SPC/GB									
	/09/015		/09/016		/09/017		/09/018		/09/019	
Marketing Authorisation PL	10592/0216		06745/0120		06745/0121		06745/0120		10592/0209	
Medicinal Product relied upon	Infanrix-IPV+Hib (DTPa/IPV/ Hib)		Pediacel (DTPa/IPV/ Hib)		Repevax (DTPa/IPV)		Pediacel (DTPa/IPV/ Hib)		Infanrix IPV (DTPa/IPV)	
Marketed by	GSK		Sanofi		Sanofi		Sanofi		GSK	
Current UK use	1^{o} vaccine		1^{o} vaccine		Booster		1^{o} vaccine		Booster	
Expiry of SPC	26.06.12		25.04.15		25.04.15		25.04.15		06.08.11	
# of active components for SPC	9		9		9		2		8	
# of active components in Medicinal Product	9		11		9		11		8	
	SPC	MA	SPC	MA	SPC	MA	SPC	MA	SPC	MA
Filamentous Haemagglutinin	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pertactin	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pertussis toxoid	✓	✓	✓	✓	✓	✓	-	✓	✓	✓
Pertussis Fimbrial Agglutinogens 2 and 3	-	-	-	✓	✓	✓	-	✓	-	-
Diphtheria toxoid	✓	✓	✓	✓	✓	✓	-	✓	✓	✓
Tetanus toxoid	✓	✓	✓	✓	✓	✓	-	✓	✓	✓
Inactivated poliovirus type 1	✓	✓	✓	✓	✓	✓	-	✓	✓	✓
Inactivated poliovirus type 2	✓	✓	✓	✓	✓	✓	-	✓	✓	✓

Inactivated poliovirus type 3	✓	✓	✓	✓	✓	✓	-	✓	✓	✓
Haemophilus influenzae type b capsular polysaccharide-Tt conjugate	✓	✓	✓	✓	-	-	-	✓	-	-
Haemophilus influenzae type b polyribosylribitol phosphate	-	-	-	✓	-	-	-	✓	-	-

Appendix II

On Article 3(a)

1. In the absence of Community harmonisation of patent law and recognising, amongst other purposes identified in the recitals, the need for the grant of an SPC by each of the Member States of the Community to holders of national or European patents to be under the same conditions, as indicated in recitals 7 and 8 of Regulation 469/2009 (the Regulation), what is meant in Article 3(a) of the Regulation by "the product is protected by a basic patent in force"?

2. In a case like the present one concerning vaccines, in which the vaccine the subject of the marketing authorisation comprises a number of antigens larger than two in a single composition:

(a) is it sufficient in order to satisfy Article 3(a) of the Regulation for the patent holder to establish

(i) that the vaccine the subject of the marketing authorisation comprises the two antigens identified specifically in the relevant claim of the patent, and

(ii) that the protection conferred by the patent according to section 60(1)(c) of the 1977 Patents Act extends to the vaccine, and

(iii) that the vaccine could not lawfully be placed on the market in the UK without the permission of the patentee?

(b) if not, are the following further factors material (and if so how):

(i) is it necessary for each antigen in the single vaccine composition to be identified in the claims of the basic patent?

(ii) is the fact that the vaccine is directed against multiple diseases relevant?

(iii) is it necessary for each antigen directed against one disease to be identified in the claims of the basic patent?

3. In a case like the present one involving a medicinal product comprising more than one active ingredient, what are the criteria according to Article 3(a) of the Regulation for determining whether or not a product is protected by a basic patent in force?

On Article 3(b)

4. Does the SPC Regulation and in particular Article 3(b) permit the grant of a Supplementary Protection Certificate for a single active ingredient or combination of active ingredients where:

> (a) a basic patent in force protects the single active ingredient or combination of active ingredients within the meaning of Article 3(a) of the SPC Regulation; and
> (b) a medicinal product containing the single active ingredient or combination of active ingredients together with one or more other active ingredients is the subject of a valid authorisation granted in accordance with Directive 2001/83/EC or 2001/82/EC which is the first marketing authorization that places the single active ingredient or combination of active ingredients on the market?

IN THE COURT OF APPEAL

ON APPEAL FROM THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

CH/2009/APP/0493

BEFORE THE CHANCELLOR OF THE HIGH COURT
LORD JUSTICE ETHERTON
And LORD JUSTICE ELIAS

COURT 16
Appeal No.

A3/2010/0295

B E T W E E N

MEDEVA BV

APPELLANT

- and -

THE COMPTROLLER GENERAL OF PATENTS

RESPONDENT

ON READING the Appellant's Notice sealed on 10 February 2010 filed on behalf of the Appellant on appeal from the order of Mr Justice Kitchin dated 2 February 2010

AND ON HEARING Mr Colin Briss QC and Mr Miles Copeland of counsel on behalf Appellant and Tom Mitcheson of counsel on behalf Respondent

AND finding that in order to enable the Court to give judgment in this case it is necessary to resolve questions concerning the interpretation of European law and that it is appropriate to request the Court of Justice of the European Union(CJ) to give a preliminary ruling thereon

IT IS ORDERED that

1. The questions set out in the Schedule to this Order be referred to the CJ for a preliminary ruling in accordance with Article 267

TFEU

2. All further proceedings in this appeal be stayed until the CJ has given its ruling on the said questions or until further order
3. The Senior Master shall forthwith and without waiting for time to appeal against this order to expire transmit to the Registrar of the CJ pursuant to CPR Pt 68 this order and Schedule thereto accompanied by a copy of the Court of Appeal's Judgment dated 23 June 2010
4. The costs herein are reserved
5. Liberty to apply

SCHEDULE

REQUEST FOR A PRELIMINARY RULING UNDER ARTICLE 267 TFEU BY THE COURT OF APPEAL (CIVIL DIVISION) OF ENGLAND AND WALES

A. Introduction

1. This reference concerns questions on the interpretation of Council Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products ('the SPC Regulation').

2. The reference in particular concerns the correct interpretation of Articles 3(a) and 3(b) of the SPC Regulation and whether a) the basic patent protects the 'product' which is the subject of various applications for Supplementary Protection Certificates (SPCs) and b) there is a valid authorisation to place the 'product' the subject of an SPC application on the market as a medicinal product. The issues arising in this reference have been summarised by the Court of Appeal in the following questions:

   (1) What is the test by which to determine whether "the product is protected by a basic patent in force" for the purposes of Article 3(a)?

   (2) Should a different test be applied in cases where the product is a multi-disease vaccine?

   (3) Is it sufficient for the purposes of Article 3(a), in the context of a multi-disease vaccine, that the basic patent in force protects one aspect of the product?

   (4) For the purposes of Article 3(b) may the product be limited to that part of a multi-disease vaccine as is protected by the basic patent in force?

3. The five SPC applications at issue were filed on 17 April 2009 under the following application numbers[1]: SPC/GB 09/015; SPC/GB 09/016; SPC/GB 09/017; SPC/GB 09/018; and SPC/GB 09/019.

4. The SPCs relate to vaccines against multiple diseases. Medeva is primarily seeking SPCs to cover a vaccine for 'DTPa-IPV/Hib'. That expression refers to a vaccine which is aimed at:-

   D (Diphtheria);
   T (Tetanus);

[1] In this reference and in the various Judgments, each application is identified using the last three digits of the application number.

Pa (Pertussis i.e. whooping cough)[2];
IPV (Polio – IPV refers to Inactivated Polio Vaccine); and
Hib (Haemophilus influenzae type B - a cause of meningitis).

5. The combination of active ingredients sought to be protected for each application and the combination of active ingredients approved by the relevant marketing authorisation are set out in the table in Appendix I to this reference.

6. In the case of applications '015, '016, '017 and '019, as shown in row 7 of the table, there were more active components or ingredients than those used in the method the subject matter of the basic patent. In the case of application 018, as shown in row 8, though the active components or ingredients were restricted to those used in the method described in the basic patent, namely pertactin (69kDa protein) and filamentous haemagglutinen (FHA), the marketing authorisation was not limited to a product containing those ingredients alone but included all the others indicated in the column headed MA[3].

B. The SPC Regulation and Relevant Case Law

7. The SPC Regulation came into effect on 6 July 2009 and codifies the various amendments made to Regulation 1768/92. Articles 1, 3, 4, 5 and 19 are particularly relevant to the present reference.

8. The following provisions of the UK Patents Act 1977 are also relevant:

> **Meaning of infringement**
> 60.-(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that
> is to say -
> (a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;
> (b) where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;
> (c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.
>
> (2) Subject to the following provisions of this section, a person (other than

[2] The letter "a" in "Pa" refers to the use of "acellular" components rather than the older "whole cell" pertussis components (known as Pw)
[3] The two discrepancies in relation to '016 are not material. The parties agree that these are curable by amendment to the SPC application.

the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom.

Relevant Case Law

9. The relevant cases in the United Kingdom are:

   (i) Takeda Chemical Industries Ltd's SPC Applications No.3 [2004] RPC 3 (in the Patents Court following appeal from the Patent Office[4])

   (ii) Gilead's SPC Application [2008] EWHC 1902 (Pat) (Patents Court following appeal from the IPO)

   (iii) Astellas Pharma Inc v Comptroller-General of Patents [2009] EWHC 1916 (Pat) (Patents Court following appeal from the IPO)

   (iv) Generics (UK) Ltd v Daiichi Pharmaceutical Co Ltd [2009] FSR 335 (Court of Appeal)

10. The *Daiichi* case (the only Court of Appeal case) primarily concerned a question of interpretation of Article 3(d). However in answering the question of what was the "product" the subject of a marketing authorisation, Jacob L.J. held at §58 that the answer was clear. In that case it was the racemic mixture (as opposed to one of the enantiomers) on the basis that if there are two active ingredients, the "product" is the pair of them.

11. In respect of the UK Patents Court level cases, which address the issue under Article 3(a) as to whether a patent for ingredient A can be said to protect an SPC product consisting of A plus B, the current state of the authorities is that *Takeda* stands for the principle that an infringement test (that is an application of the national law of infringement) is not sufficient. In other words, the fact that a patent for A would permit a patentee to prevent the sale of a medicament consisting of A plus B - because of the presence of A - is not enough. As Kitchin J. put it at §23 of *Gilead*:

[4] The Patent Office in the UK is now referred to as the Intellectual Property Office (IPO) of the UK. See *Takeda Chemical Industries Ltd's SPC Applications No. 1* [2004] RPC 1 for the Patent Office decision.

> "…that is precisely the argument rejected by Jacob J in Takeda. It would mean that the holder of a basic patent could first obtain an SPC for the active ingredient the subject of the patent, so giving him perhaps one or two years of protection beyond the life of the patent, and then, some years later, obtain another SPC for a combination of the same ingredient together with another active ingredient and so gain protection for a full five years beyond the life of the patent. That, it may be said, is contrary to the purpose of the Regulation which is to provide an effective period of protection for the invention the subject of the patent and so encourage research, and not to provide an extension of protection based upon the adoption of another, possibly quite different, ingredient. I believe this reasoning underpins the decision in Takeda and it plainly provides powerful support for the Comptroller's position."

12. The result of this reasoning is that the relevant test requires consideration of something further than the law of infringement i.e. not everything that infringes can be said to be protected by the basic patent within the meaning of the SPC Regulation. In the decision in the *Gilead* case at the Patent Office level[5], this something further was described as the need for a "clear pointer" that the actual SPC product in question (in this case A plus B) was identifiable with the invention[6].

13. In the *Gilead* case in the Patents Court Kitchin J considered both this "clear pointer" test and the test applied in the *Takeda* case at the Patent Office level, where the Hearing Officer had asked himself if the product and subject of the SPC application was "identifiable with the invention" of the basic patent. Kitchin J decided that both these tests were problematic because they are not precise and do not find any foundation in the SPC regulation or the Act. He then went on to propose a different test which he expressed in the following terms (in paragraph 33 of the decision):

> "….Thus 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."

This does not mandate that the patent actually has to have a claim drafted to "A plus B" to be satisfied. Kitchin J found that the Gilead patent contained a claim which in effect called for "A plus optionally any other therapeutic agent"

5 See decision BL O/006/08 at http://www.ipo.gov.uk/pro-types/pro-patent/pro-p-os/p-challenge-decision-results-bl?BL_Number=O/006/08
6 see further discussion of this point in Gilead decision at paragraphs 18-20.

and held that this protected A plus B even though B itself was not mentioned expressly, because A plus B was within the scope of protection of the patent.

14. However, Kitchin J also set out, at paragraphs 24–28, five matters which bear on the first question being referred and which did not appear to him to have been explored in argument before the court in *Takeda*. His conclusion was that they merit further consideration by a higher court:

> "24……..The first is the decision of the European Court of Justice in Case C-392/97 *Farmitalia Carlo Erba Srl's Supplementary Protection Certificate* [2000] RPC 580. This primarily concerned the question whether the Regulation requires an SPC to be restricted to the particular form of the active ingredient described in the medicinal authorisation. The Court held it does not and that an SPC is capable of covering the product, as a medicinal product, in any of the forms enjoying the protection of the basic patent. As a secondary question the Court was asked, in substance, what are the criteria for determining whether or not a product is protected by a basic patent? The Court answered that, in the absence of Community harmonisation of patent law, the extent of patent protection can be determined only in the light of non-Community rules which govern patents. As both parties before me were disposed to accept, this ruling suggests I must determine whether the product is protected as a matter of English law.
> 25. Second, s.125 of the Patents Act 1977 defines the extent of protection of a patent as being that specified in a claim as interpreted in the light of the specification. For this purpose the Protocol on the Interpretation of Article 69 of the EPC applies and this too refers to the extent of protection conferred by a patent and how it is to be understood. These two provisions make it clear that a product is protected by a patent within the meaning of the Act if it falls within the scope of a claim.
> 26. Third, no other provision of domestic law addresses the issue of protection of a product by a patent. This suggests the Court of Justice in *Farmitalia* must have had the infringement test and, for Contracting States to the EPC, Article 69 in mind. Anything less would have required the Court to interpret the term "protected" in the context of the Regulation as having a particular and different meaning, and that was something it declined to do. Certainly that appears to be the understanding of a number of other Member States, including Germany, as illustrated by the decision of the Federal Supreme Court in Case X ZB 12/00 of March 12, 2002.
> 27. Fourth, it must be remembered that the monopoly conferred by an SPC for a product consisting of both tenofovir and emtricitabine would be narrower and comprised wholly within a monopoly for tenofovir alone. It would be, in effect, a monopoly for tenofovir only when used with emtricitabine.
>
> 28. Fifth, I can envisage circumstances where the application of the *Takeda* test may produce a harsh result. For example, the holder of a patent for a new pharmaceutical may have chosen to market it *only* in combination with another active ingredient and duly secured a marketing authorisation for the medicinal product containing those ingredients. In such a case the product would appear to be the combination of active ingredients (Article 1(b)) for which authorisation

has been obtained (Article 3(b)). Yet, upon an application of the *Takeda* test, it would not be protected by the basic patent and hence the inventor would be deprived of an opportunity to secure any SPC at all.

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.

30. These are difficult questions and they raise a serious issue as to whether the decision in *Takeda* is correct. I believe they merit further consideration by a higher court and perhaps even the Court of Justice. In that latter regard, it is my understanding the Court of Justice has not yet considered how the requirements of the Regulation are to be interpreted in the case of a medicinal product consisting of a combination of active ingredients where only one is claimed in the basic patent. It may require a development of the reasoning in *Farmitalia*. But in this case and in the light of my conclusion on the second submission advanced by Gilead, it is not necessary for me to express a final conclusion and, in the circumstances, I prefer not to do so.

15. In *Farmitalia*, the German Federal Court of Justice referred the following questions to the European Court:

> (1) Is it a condition of the application of Article 3(b) that the product in respect of which the grant of a protection certificate is sought is described as an "active ingredient" in the medicinal authorisation?
>
> Are, then, the terms of Article 3(b) not satisfied where only one individual salt of a substance is stated in the notice of authorisation to be an "active ingredient", but the grant of a protection certificate is sought for the free base and/or for other salts of the active ingredient?
>
> 2. If the questions at (1) are answered in the negative:
>
> According to which criteria is it to be determined whether the product is protected by a basic patent within the meaning of Article 3(a), where the grant of a protection certificate is sought for the free base of an active ingredient including any of its salts, but the basic patent in its patent claims mentions only the free base of this substance and, moreover, mentions only a single salt of this free base? Is the wording of the claim for the basic patent or the latter's scope of protection the determining criterion?"

16. On the application of Article 3(b) the Court of Justice concluded that (paragraph 22):

> "where a product in the form referred to in the marketing authorisation is protected by a basic patent in force, the certificate is capable of covering that product, as a medicinal product, in any of the forms enjoying the protection of the basic patent."

17. Thus in that case it was not an objection to the grant of the SPC sought that it would cover all salts of the active ingredient and was not limited to the particular salt named in the marketing authorisation.

18. The operative portion of the ECJ's decision in the *Farmitalia* case relevant to this referral is paragraphs 23 – 29:

> 23. By its second question, the Bundesgerichtshof is, in substance, asking what are the criteria, according to Regulation No 1768/92, and in particular Article 3(a) thereof, for determining whether or not a product is protected by a basic patent.
>
> 24. In that connection, it should be noted that one of the conditions for obtaining a certificate is that the product should be protected by a basic patent in force.
>
> 25. As indicated in the seventh recital in the preamble to Regulation No 1768/92, the patent concerned may be either national or European.
>
> 26. As Community law now stands, the provisions concerning patents have not yet been made the subject of harmonisation at Community level or of an approximation of laws.
>
> 27. Accordingly, in the absence of Community harmonisation of patent law, the extent of patent protection can be determined only in the light of the non-Community rules which govern patents.
>
> 28. As is clear in particular from paragraph 21 of this judgment, the protection conferred by the certificate cannot exceed the scope of the protection conferred by the basic patent.
>
> 29. The answer to be given to the second question must therefore be that, in order to determine, in connection with the application of Regulation No 1768/92 and, in particular, Article 3(a) thereof, whether a product is protected by a basic patent, reference must be made to the rules which govern that patent.

19. In the last UK case - *Astellas* - Arnold J decided that on the facts before him the SPC did not satisfy Kitchin J's test of whether the product falls within the scope of a claim of the basic patent because the claim (in effect to an agent comprising compound A) did not *disclose* an agent consisting of A plus B. He drew the distinction between the claim in *Gilead* (effectively for "A plus optionally any other therapeutic agent") and the claim before him (effectively for "an agent comprising A") and concluded that in *Gilead* the basic patent specifically disclosed and claimed a combination of active ingredients whereas the basic patent before him did not (see paragraphs 22-30).

20. Arnold J was also asked to consider the correctness of the *Takeda* decision. He had previously set out the operative portions of the ECJ's judgment in the *Farmitalia* case as above, which he referred to in declining to apply the infringement test (see paragraphs 32-35 of *Astellas*).

> 32. Counsel for Astellas supported the five reasons given by Kitchin J in *Gilead* for questioning the correctness of *Takeda.* In particular, he submitted that *Takeda* is inconsistent with the ECJ's ruling on the second question in *Farmitalia* that to determine whether a product is protected by a basic patent reference must be made to the national law governing the patent. He argued that this must mean determining whether the product falls within the scope of protection of the patent in accordance with section 125 of the Patents Act 1977 and Article 69, and the Protocol on the Interpretation of Article 69, of the European Patents Convention. He also submitted that, in the light of Kitchin J's judgment, it could not be said that it was *acte clair* that the infringement test was wrong and that this question should be referred to the ECJ.
>
> 33. Counsel for the Comptroller submitted that none of the five points identified by Kitchin J justified the conclusion that the infringement test was the right test. In particular, she submitted that there is a distinction between the scope of protection of a patent and infringement: the scope of protection is limited to that specified in the relevant claim properly construed, whereas infringement is not so limited. A product which includes all the elements of the claim infringes, but so does a product which also includes additional elements which are not specified in the claim at all. Accordingly, she argued, it is the scope of protection which matters, not whether a product infringes. She also submitted that consideration of the Opinion of Advocate General Fennelly in *Farmitalia* leads to the conclusion that the ECJ rejected the infringement test in that case. Finally, she submitted that the matter remained *acte clair*. She acknowledged, however, that it is the Comptroller's understanding that at least one Member State of the Community, namely Norway, applies the infringement test.
>
> 34. I am not convinced that *Takeda* is wrong. To my mind, Jacob J's reasoning remains persuasive. Furthermore, I agree that there is a distinction between the scope of protection and the question of infringement. As to *Farmitalia*, it is not clear to me that the ECJ either

endorsed or rejected the infringement test in that case. Nevertheless, I agree with Kitchin J that there are arguments in favour of the infringement test which do not appear to have been considered in *Takeda* and which merit consideration by a higher court and perhaps the ECJ.

C. The factual background to the dispute

The Patent

21. The Patent (EP 1666057) was filed on 20 April 1990, with a priority date of 8 May 1989. It was granted on 18 February 2009, that is to say just over one year before it was due to expire. The Patent expired on 25 April 2010.

22. Claim 1 and 2 are relevant. Claim 1 is to:

> 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 provide a synergistic effect in vaccine potency.

23. Claim 2 is to:

> A method according to claim 1 wherein the vaccine is devoid of the B. pertussis toxin.

24. The so called "69kDa antigen" is what is now called pertactin.

The Vaccines

25. The acellular paediatric vaccines for whooping cough in this case contain antigens for *Bordetella pertussis*. The particular antigens are called "pertactin", "filamentous haemagglutinin antigen" (FHA) and pertussis toxin. Pertactin and FHA are subjects of the relevant basic patent.

26. The first commercial vaccine made in accordance with the invention and duly authorised in the UK comprised all three antigens but was combined with diphtheria toxoid and tetanus toxoid so as to be effective against whooping cough, diphtheria and tetanus. It was launched in 1996. In and after 2000 larger combinations, similarly approved, were launched in the UK comprising vaccines against whooping cough, diphtheria, tetanus, meningitis (haemophilus influenzae type b) and polio. By 2004 the combined vaccine

against all five diseases, DTPa-IPV/Hib, was routinely recommended in the UK as the primary immunisation for babies.

27. Vaccines, as other pharmaceutical products, require considerable investment to develop, but unique considerations apply to their marketing. Governments buy paediatric vaccines and favour vaccines which can be administered in combination with vaccines for other diseases so that maximum protection against these diseases is achieved in as small a number of patient interactions as possible. Vaccine manufacturers are, in effect, required by government policy to aim towards large combinations of vaccines wherever possible.

28. The desirability of combining vaccines against different diseases was something that had been appreciated for many years, so it was natural to develop even larger vaccine combinations from DTPa. But each time a new antigen is built into a combined vaccine there is a risk of an increase in the frequency of existing side effects or of a reduction in the immune response to certain antigens. So extensive clinical testing is required. On one view the market is dictated by governments who are continually seeking to combine vaccines where possible, for the public policy reasons discussed above. In such circumstances there may not be a market for the patented vaccine if provided on its own, and the research costs may not be recovered before expiry of the basic patent.

D. Procedural History

29. In the Comptroller's decision of 16 November 2009 he concluded that the Patent does not protect the product the subject of applications '015, '016, '017 or '019 for the purposes of Article 3(a) of the SPC Regulation. Further, he concluded that marketing authorisation PL 06745/0120 for Pediacel is not, for the purposes of Article 3(b) of the SPC Regulation, a valid authorisation to place the product the subject of application '018 on the market as a medicinal product.

30. In a judgment of 27 January 2010, reported as *Medeva BV v The Comptroller General of Patents* [2010] EWHC 68 (Pat), Kitchin J, sitting in the Chancery Division of the High Court of England and Wales, agreed.

31. The decision of Kitchin J was appealed to the Court of Appeal which is now making this reference in view of:

(i) The Court's substantial doubt whether the judgment of the Court of Justice in *Farmitalia,* answered any of the questions arising in this reference.

(ii) The apparent divergence of understanding between the courts of different Member States as to the proper interpretation of article 3(a) of the Regulation. Though Jacob J in *Takeda* considered the issues on Article 3(a) to be acte claire because of the decision of the Swedish Courts in AB Hassle to which he referred, this may not now be the position in Norway or, possibly, Germany.

(iii) Dicta by both Kitchin J in *Gilead* and Arnold J in *Astellas* which supports the Court's consideration that at least some of the issues in this reference are not acte claire.

(iv) The repeated emergence of these or similar issues in the UK notwithstanding the judgment of the Court of Justice in *Farmitalia.* This indicates the need for the definitive answers which only the Court of Justice can give.

(v) The fact that this is a rapidly developing area of jurisprudence and *Farmitalia* was decided ten years ago.

E. Summary of submissions of the parties

Medeva BV's submissions

32. Medeva's primary case is that the approach adopted by the UK Patents Court to date is wrong. It contends that the principle of what is protected by a patent is a matter for national law, and that in the UK that means an application of infringement law.

33. That the principle of what is protected by a patent is a matter for national law is apparent from the SPC Regulation itself but more importantly, has already been confirmed by the ECJ in *Farmitalia* which requires that in order to determine whether a product is protected by a basic patent "reference must be made to the rules which govern that patent". In the UK these rules are contained in the Patents Act 1977 where the only principle as to whether a

product is protected by a patent is whether or not the product infringes the patent.

34. In support of its primary case, Medeva:

(i) contends that for the purpose of determining what is protected by the patent in Article 3(a) there is no distinction between extent of protection and infringement.

(ii) distinguishes the facts of *Takeda* and contends that the "clear pointer" test as developed and applied in *Gilead* and *Astellas* is unclear, unsatisfactory, leads to anomalies and harsh results. It contends that the reasoning applied in *Gilead* in respect of a claim effectively to "A plus optionally any other therapeutic agent" also apples to a claim to an agent 'comprising' A in combination with something else.

(iii) relies on the proposition that the purpose of the SPC Regulation, as per recital 3, should not be applied in such a way as to frustrate that purpose.

(iv) points to the fact recorded in paragraph 33 of the *Astellas* judgment quoted above, that the infringement test is applied in at least one other Member State of the Community.

35. Even if the general approach adopted by the Patents Court to date is not wrong for all cases, Medeva contents that it is nonetheless not applicable in the special case of multi-disease vaccines. Medeva relies on the particular set of circumstances which arise from the development of such vaccines and the way the market for them (driven by UK Government health policy) operates.

36. Medeva submits that if the special features of multi-disease vaccines and their market are not taken into account then on one view no SPC is ever granted despite the fact that the basic premise of the SPC system applies - that time recouping the investment is lost in obtaining marketing authorisation(s). The effect of this approach is to deny an SPC to Medeva and that for this reason the infringement test should apply, if not generally, then to the special case of multi-disease vaccines.

37. Medeva also raises, in the alternative to the arguments above, the point that the basic patent protects the pertussis component of the overall multi-disease vaccine on the basis of the approach adopted by the Patents Court to date, and that this should be sufficient to satisfy Article 3(a) at least in a vaccine case. Medeva draws an "additive" versus "independent" combination distinction and submits that it applies at the level of disease in question. For the purpose of this alternative argument only, Medeva accepts that the case law must be satisfied in relation to the *pertussis* component of the combination vaccines. However it is submitted that that is as far as the law should require.

Article 3(b)

38. The application number '018 approaches the matter in a different way. Here the SPC "product" is defined simply by reference to the two antigens called out by claim 1 of the '057 patent. There can be no doubt that the patent does indeed protect that product and therefore that Article 3(a) is satisfied. However the decision adverse to Medeva is on the basis that a different ground - Article 3(b) is not satisfied because the relevant marketing authorisation (which includes all the antigens against the other diseases) is not a marketing authorisation to place that SPC Product in the market - as a result of all the other antigens. This reasoning is the counterpart of reasoning addressed above and is supported by *Daiichi* in the Court of Appeal as well as others. Medeva does not contend that it can have an SPC on both bases at the same time. However it is submitted that to the extent that it is unlikely that Medeva will be granted an SPC based on the alternative '018 route this supports its case in relation to the '015, '016, '017 and '019 applications.

The Comptroller General of Patents' submissions

39. The Comptroller's case is that the approach adopted by the UK Patents Court to date is correct and whilst the principle of what is protected by a patent is a matter for national law, the Courts have determined that for the purposes of the Regulation in the UK that does not mean the application of infringement law. Instead, what is important is to identify the active ingredients which are protected by the patent in question.

40. The identification of the active ingredient is fundamental to the SPC legislation. The SPC system is designed to extend a patent monopoly only in respect of an active ingredient or ingredients for which marketing authorization has taken time to obtain. The system is not designed to extend different monopolies. The fact that a combination product containing additional active ingredients to those specified in the claims of the basic patent might infringe the monopoly given by the patent is irrelevant on a proper understanding of the scope and purpose of the SPC legislation.

41. So too here – the monopoly sought under the SPC is for FHA and Pertactin together with other pertussis components and various components of additional vaccines. Yet the invention in the basic patent is only concerned with FHA and Pertactin. The fact that the wider combination might "infringe" the claims of the basic patent does not bear upon the question of whether it took time to obtain a marketing authorization for the invention concerning the active ingredients FHA and Pertactin. Bearing in mind the purpose of the SPC legislation, the relevant question is whether the active ingredient(s) of the product are the same as those sought to be protected by the relevant claim of the basic patent.

42. It is submitted that this is a clear approach which is straightforward to apply and reflects the intention of the drafters of the SPC Regulation. This formulation gives protection both for single active ingredients and combinations of actives where such combinations are the subject of the patent (as here for Pertactin and FHA). What it does not do is allow SPCs to be granted based on products which go beyond the original invention made (i.e. Pertactin, FHA, other pertussis components and other vaccines). It is delay in commercialising the specific active ingredients which are the subject of a patent as a result of the regulatory regime that justifies the grant of an SPC. Compensation should not be awarded for the commercialisation of products going beyond the claimed invention, or which are the fruits of general research and not the exploitation of inventions which are patented.

43. Medeva's problem in this case is that amongst the present applications there is no definition of product which is simultaneously protected by the basic patent in force and agrees with the first authorisation to place the product on the market as a medicinal product. There is either a mismatch between the SPC application and the Patent (applications SPC/GB/09/015, 09/016, 09/017 and

09/019) or between the SPC application and the marketing authorisation (SPC/GB/09/018).

44. Consistent with the definitions used in the Regulation as set out in Article 1, the term "product" must be strictly construed – see §68 of *Daiichi* [2009] FSR 335, which reflects the findings of the ECJ in *MIT* (Case C-258/99) and *BASF* (Case C-431/04). Further, where there is more than one active ingredient, the product is the combination of active ingredients. It is for this reason that it is impermissible for the Appellant to rely on the argument that the commercial formulations in the present case are "independent" combinations in an attempt to overcome the Article 3(a) objection.

45. The invention in the present case is a bivalent vaccine containing FHA and Pertactin, and there is no basis in the Patent for concluding that the relevant disclosure goes any wider than this when the claims are construed correctly in the light of the *Takeda, Gilead* and *Astellas* decisions. The Patent merely protects the combination of pertactin and FHA; it does not protect the combination of this with the other active ingredients which go to make up the marketed products. By relying on a combination of active ingredients which is not disclosed by the Patent, the Appellant is attempting to "stretch" the invention in the patent to cover material going beyond the actual invention. This is contrary to both the letter and spirit of the SPC Regulation.

46. The Comptroller acknowledges that there may be particular public policy considerations which might justify a different approach being adopted to SPCs in the vaccine field but submits that this is a matter for governments, not the Courts. If changes to the approach to vaccine SPCs are justified, this is something which ought to be lobbied for by the pharmaceutical industry at national and/or European level in order to engineer amendments to the primary legislation but there is no comparative basis for applying a different rule to the class of vaccine products.

47. In the meantime, it is submitted that it would be contrary to both the letter and spirit of the Regulation to attempt to carve out concessions for a particular class of product. It is likely to lead to lack of clarity, divergence between member states and uncertainty for third parties, all of which would be contrary to the purpose of the SPC Regulation. In particular, it is not accepted that all vaccines amount to "independent" combinations, and the

difficulty of carving out a subset of vaccine products is even more apparent. Moreover, the identification of one or two harsh examples does not justify the relaxation of the rules applicable to an entire class of products, both for "floodgate" reasons, and because such a change will no doubt lead to harsh examples on the part of third parties going the other way.

Article 3(b)

48. In the '018 application it is accepted that the product as defined in the SPC, FHA and Pertactin, is protected by the Patent. However, the mismatch in this instance is between the product specified in the application and the marketing authorisation relied upon which includes a number of foreign antigens. This is neither the same product as is protected by the Patent, nor is it the first authorisation to place the product protected by the Patent onto the market. Even though the later products needed their own marketing authorisations, the reason for that was not the presence of pertactin and FHA, the subject of the claims. It is the length of time which it took Medeva to get permission to market the original DTPa combination vaccine product which ought to be taken into consideration when evaluating the validity of any SPC applications – not the length of time which it took to authorise the multiple combinations which are not the subject of the invention in the Patent. Accordingly, and again consistent with both the words of the SPC Regulation and the policy underlying it, '018 falls foul of Article 3(b).

49. Medeva's problem is not that it cannot get an SPC at all, but that the particular applications presently before the Court do not meet the conditions of the Regulation. Medeva appears to accept that had the bare combination of Pertactin and FHA been sold, an SPC would have been available. The reality is that the market Medeva is in is fast moving and/or the claims of the Medeva patents do not coincide with commercial reality, and so the protection afforded by an SPC which it is permissible to grant does not protect Medeva's current commercial products. None of this justifies the allowance of an application which is otherwise impermissible under the Regulation.

F. Questions referred under Article 267

50. In view of the need for a consistent and certain approach to questions of interpretation of the SPC Regulation the Court of Appeal, pursuant to Article 267 TFEU, requests the Court of Justice of the European Union to make a preliminary ruling on the following questions of EU law:

On Article 3(a)

1. Regulation 469/2009 (the Regulation) recognises amongst the other purposes identified in the recitals, the need for the grant of an SPC by each of the Member States of the Community to holders of national or European patents to be under the same conditions, as indicated in recitals 7 and 8. In the absence of Community harmonisation of patent law, what is meant in Article 3(a) of the Regulation by "the product is protected by a basic patent in force" and what are the criteria for deciding this?

2. In a case like the present one involving a medicinal product comprising more than one active ingredient, are there further or different criteria for determining whether or not "the product is protected by a basic patent" according to Article 3(a) of the Regulation and, if so, what are those further or different criteria?

3. In a case like the present one involving a multi-disease vaccine, are there further or different criteria for determining whether or not "the product is protected by a basic patent" according to Article 3(a) of the Regulation and, if so, what are those further or different criteria?

4. For the purposes of Article 3(a), is a multi-disease vaccine comprising multiple antigens "protected by a basic patent" if one antigen of the vaccine is "protected by the basic patent in force"?

5. For the purposes of Article 3(a), is a multi-disease vaccine comprising multiple antigens "protected by a basic patent" if all antigens directed against one disease are "protected by the basic patent in force"?

On Article 3(b)

6. Does the SPC Regulation and, in particular, Article 3(b), permit the grant of a Supplementary Protection Certificate for a single active ingredient or combination of active ingredients where:

(a) a basic patent in force protects the single active ingredient or combination of active ingredients within the meaning of Article 3(a) of the SPC Regulation; and

(b) a medicinal product containing the single active ingredient or combination of active ingredients together with one or more other active ingredients is the subject of a valid authorisation granted in accordance with Directive 2001/83/EC or 2001/82/EC which is the first marketing authorization that places the single active ingredient or combination of active ingredients on the market?

APPENDIX I

Row		SPC/GB									
		/09/015		/09/016		/09/017		/09/018		/09/019	
1	Marketing Authorisation PL	10592/0216		06745/0120		06745/0121		06745/0120		10592/0209	
2	Medicinal Product relied upon	Infanrix-IPV+Hib (DTPa/IPV/ Hib)		Pediacel (DTPa/IPV/ Hib)		Repevax (DTPa/IPV)		Pediacel (DTPa/IPV/ Hib)		Infanrix IPV (DTPa/IPV)	
3	Marketed by	GSK		Sanofi		Sanofi		Sanofi		GSK	
4	Current UK use	1^{o} vaccine		1^{o} vaccine		Booster		1^{o} vaccine		Booster	
5	Expiry of SPC	26.06.12		25.04.15		25.04.15		25.04.15		06.08.11	
6	# of active components for SPC	9		9		9		2		8	
7	# of active components in Medicinal Product	9		11		9		11		8	
8		SPC	MA	SPC	MA	SPC	MA	SPC	MA	SPC	MA
9	*Filamentous Haemagglutinin*	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
10	*Pertactin*	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
11	*Pertussis toxoid*	✓	✓	✓	✓	✓	✓	-	✓	✓	✓
12	*Pertussis Fimbrial Agglutinogens 2 and 3*	-	-	-	✓	✓	✓	-	✓	-	-
13	*Diphtheria toxoid*	✓	✓	✓	✓	✓	✓	-	✓	✓	✓
14	*Tetanus toxoid*	✓	✓	✓	✓	✓	✓	-	✓	✓	✓
15	*Inactivated poliovirus type 1*	✓	✓	✓	✓	✓	✓	-	✓	✓	✓
16	*Inactivated poliovirus type 2*	✓	✓	✓	✓	✓	✓	-	✓	✓	✓
17	*Inactivated poliovirus type 3*	✓	✓	✓	✓	✓	✓	-	✓	✓	✓
18	*Haemophilus influenzae type b capsular polysaccharide-Tt conjugate*	✓	✓	✓	✓	-	-	-	✓	-	-
19	*Haemophilus influenzae type b polyribosylribitol phosphate*	-	-	-	✓	-	-	-	✓	-	-