# OPINION OF ADVOCATE GENERAL TRSTENJAK delivered on 13 July 2011[1]

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## I — Introduction

1. The present references for a preliminary ruling under Article 267 TFEU concern the grant of supplementary protection certificates for medicinal products under Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products. [2] The referring courts request the Court to clarify the conditions for the grant of supplementary protection certificates in respect of multi-disease vaccines.

2. The distinguishing characteristic of multi-disease vaccines is that they contain a number of active ingredients. In that context, by the omission or addition of individual active ingredients a multitude of multi-disease vaccines with varying composition can be developed and placed on the market as medicinal products on the basis of a single patented active ingredient or a single patented combination of active ingredients. Against that background, the Court must decide in the present proceedings inter alia whether and, if so, under what conditions a supplementary protection certificate (SPC) may be granted for multi-disease vaccines in which only part of the underlying active ingredients is the subject-matter of a patent. In answering that question, the Court is faced with the challenge of including partially patented multi-disease vaccines within the scope of Regulation No 469/2009 in a manner consistent with its objectives, without in so doing jeopardising the balance achieved in that regulation between the various interests at stake in the pharmaceutical sector.

## II — Legal context

### A — *Union law* [3]

3. The supplementary protection certificate for medicinal products was introduced into the European Union legal order by Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products. [4] Because Regulation No 1768/92 was substantially amended several times after its entry into force, it was codified, in the interests of clarity and rationality, by Regulation No 469/2009. There are no significant

2 — OJ 2009 L 152, p. 1.

3 — In accordance with the terms used in the EU Treaty and in the FEU Treaty, the expression 'Union law' will be used as an umbrella expression for Community law and European Union law. Where individual provisions of primary law are relevant hereinafter, the rules which are applicable ratione temporis will be cited.

4 — OJ 1992 L 182, p. 1.

substantive differences between the two regulations.

4. The preamble to Regulation No 469/2009 states:

'…

(2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.

(3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.

(4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.

(5) This situation leads to a lack of protection which penalises pharmaceutical research.

(6) There exists a risk of research centres situated in the Member States relocating to countries that offer greater protection.

(7) A uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the functioning of the internal market.

(8) Therefore, the provision of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorisation has been granted is necessary. A regulation is therefore the most appropriate legal instrument.

(9) The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a

patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community.

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

…'

5. Articles 1 to 7 of Regulation No 469/2009 read as follows:

'*Article 1*

— Definitions

For the purposes of this Regulation:

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

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

(c) "basic patent" means a patent which protects a product as 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 2*

— Scope

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for

human use [OJ 2001 L 311, p. 67] or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products [OJ 2001 L 311, p. 1] may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

*Article 3*

— Conditions for obtaining a certificate

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

(a) the product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

(c) the product has not already been the subject of a certificate;

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

*Article 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.

*Article 6*

— Entitlement to the certificate

The certificate shall be granted to the holder of the basic patent or his successor in title.

*Article 7*

— Application for a certificate

1. The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted.

2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.

…'

6. Article 13 of Regulation No 469/2009 provides, under the heading 'Duration of the certificate':

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

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.

…'

B — *The European Patent Convention* [5]

7. Article 69 of the European Patent Convention (EPC) reads, under the heading 'Extent of protection':

'(1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

(2) For the period up to grant of the European patent, the extent of the protection conferred by the European patent application shall be determined by the claims contained in the application as published. However, the European patent as granted or as amended in opposition, limitation or revocation proceedings

5 — Convention on the Grant of European Patents of 5 October 1973, as amended by the Act revising Article 63 EPC of 17 December 1991 and by the Act revising the EPC of 29 November 2000.

shall determine retroactively the protection conferred by the application, in so far as such protection is not thereby extended.'

8. The Protocol on the Interpretation of Article 69 EPC of 5 October 1973, as revised by the Act revising the European Patent Convention of 29 November 2000, reads as follows:

'*Article 1*

— General principles

Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.

*Article 2*

— Equivalents

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

C — *National law*

9. Section 60 of the United Kingdom Patents Act 1977 provides:

'(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.

…'

11. Patent claim 1 reads as follows: 'A method for the preparation of an acellular vaccine, which method comprises preparing the 69kDa antigen of *Bordetella pertussis* [= pertactin] 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.'

12. Claim 2 reads: 'A method according to claim 1 wherein the vaccine is devoid of the *B. pertussis* toxin.'

## III — Facts and references for a preliminary ruling

### A — *Medeva*

10. On 20 April 1990, Medeva BV ('Medeva') filed a European patent which protects the antigens 'pertactin' and 'filamentous haemagglutinin antigen' ('FHA'). Those antigens are usable in vaccines against whooping cough. The patent was granted on 18 February 2009 and expired on 25 April 2010.

13. In 1996 the first commercial vaccine was made in accordance with that invention and duly launched in the United Kingdom. As active ingredients it contained the antigens pertactin, FHA and pertussis toxin, in combination with diphtheria toxoid and tetanus toxoid so as to be effective against whooping cough, diphtheria and tetanus. In and after 2000, larger multi-disease vaccines were similarly approved and launched in the United Kingdom, comprising active ingredients against whooping cough, diphtheria, tetanus, meningitis (Haemophilus influenzae type B) and polio. Since 2004 the combined vaccine

against all five diseases, DTPa-IPV/HiB, [6] has been routinely recommended in the United Kingdom as the primary immunisation for babies.

14. On 17 April 2009, Medeva applied for five supplementary protection certificates under application numbers SPC/GB09/015, SPC/GB09/016, SPC/GB09/017, SPC/GB09/018 and SPC/GB09/019 ('SPC applications 09/015, 09/016, 09/017, 09/018 and 09/019'). Those supplementary protection certificates relate to five different multi-disease vaccines which are effective against whooping cough, diphtheria, tetanus, polio and in some cases also against meningitis (haemophilus influenzae type B) and contain the antigens pertactin and FHA. Those multi-disease vaccines also contain a number of further active ingredients.

15. SPC applications 09/015 and 09/017 specifically relate to multi-disease vaccines with nine active ingredients, the application relating to all those active ingredients. SPC application 09/019 concerns a multi-disease vaccine with eight active ingredients, and likewise relates to all those active ingredients. SPC applications 09/016 and 09/018 concern multi-disease vaccines with eleven active ingredients, whereas SPC application 09/016 relates to the antigens pertactin and FHA and seven further active ingredients and SPC application 09/018 only to the antigens pertactin and FHA.

16. It is apparent from that overview that SPC applications 09/016 and 09/018 relate only to part – nine out of eleven and two out of eleven respectively – of the active ingredients of the corresponding multi-disease vaccine. SPC application 09/018 is also the only application which relates only to the active ingredients pertactin and FHA which are used in the process described in the basic patent. SPC applications 09/015, 09/016, 09/017 and 09/019, on the other hand, cover more active ingredients than are used in the method which is the subject-matter of the basic patent.

17. Valid authorisations exist to place the five multi-disease vaccines to which the SPC applications in question relate on the market as medicinal products. Because those authorisations relate to the complete combination of active ingredients of the respective multi-disease vaccine, SPC applications 09/016 and 09/018 relate to fewer active ingredients than the marketing authorisations for the corresponding multi-disease vaccines. By contrast, in the case of SPC applications 09/015, 09/017 and 09/019, the combinations of active ingredients in the SPC applications are coextensive with the combinations of active ingredients of the corresponding multi-disease vaccines.

6 — This abbreviation is made up of the letters 'D' for diphtheria, 'T' for tetanus, 'Pa' for pertussis, that is, whooping cough, 'IPV' for polio (IPV stands for 'inactivated polio vaccine') and 'HiB' for haemophilus influenzae type B, a cause of meningitis.

18. By a decision of 16 November 2009, the Comptroller-General of Patents rejected SPC applications 09/015, 09/016, 09/017, 09/018 and 09/019 on the ground that the conditions for obtaining certificates as laid down in Article 3 of Regulation No 469/2009 were not satisfied. He concluded in particular in that regard that the products to which SPC applications 09/015, 09/016, 09/017 and 09/019 related were not protected by the basic patent for the purposes of Article 3(a) of that regulation. He further concluded that the marketing authorisation for the medicinal product to which SPC application 09/018 related was not, for the purposes of Article 3(b) of Regulation No 469/2009, a valid authorisation to place the product described in SPC application 09/018 on the market as a medicinal product.

19. The High Court of England and Wales, Chancery Division, confirmed that view by judgment of 27 January 2010. An appeal against the decision of the High Court was lodged before the referring court.

20. Because the referring court has doubts with regard to the interpretation of Article 3(a) and (b) of Regulation No 469/2009, it has referred the following questions to the Court of Justice for a preliminary ruling:

'1. Regulation No 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 proprietors 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"?

6. Does the 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 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 authorisation that places the single active ingredient or combination of active ingredients on the market?'

B — *Georgetown University and Others*

21. The central question in *Georgetown University and Others* is whether a number of SPC applications by Georgetown University, University of Rochester and Loyola University of Chicago satisfy the requirements of Article 3(b) of Regulation No 469/2009.

22. The SPC applications in question relate to one or more active ingredients of the vaccines Gardasi' and 'Cervarix', which provide protection against the human papillomavirus (HPV). The human papillomaviruses are classified according to various types which are identified by numbers. In that context, the vaccine 'Gardasil' provides protection against human papillomavirus types 6, 11, 16 and 18. The vaccine 'Cervarix' provides protection against human papillomavirus types 16 and 18.

1. The SPC applications of Georgetown University

23. Georgetown University is the proprietor of a European patent for the recombinantly produced protein L1 of the human papillomavirus, which can produce neutralising antibodies against the virions of that papillomavirus. The patent was applied for on 24 June 1993 and granted on 12 December 2007. It expires on 23 June 2013. Patent claims 9 and 16 concern a vaccine for the prevention of infections with the human papillomavirus.

24. On the basis of that patent, Georgetown University applied for eight supplementary protection certificates with the numbers SPC/GB07/070 to SPC/GB07/074 and SPC/GB07/078 to SPC/GB07/080 ('SPC applications 07/070 to 07/074 and 07/078 to 07/080').

25. Five of those SPC applications are based on the marketing authorisation for the medicinal product 'Gardasil':

— SPC application 07/079, which relates to the product 'recombinant L1 protein of HPV 6';

— SPC application 07/073, which relates to the product 'recombinant L1 protein of HPV 11';

— SPC application 07/080, which relates to the product 'recombinant L1 protein of HPV 16';

— SPC application 07/078, which relates to the product 'recombinant L1 protein of HPV 18' and

— SPC application 07/074, which relates to the product 'combination of the recombinant L1 protein of HPV 6, HPV 11, HPV 16 and HPV 18'.

26. SPC applications 07/079, 07/073, 07/080 and 07/078, which relate to only one active ingredient of the medicinal product 'Gardasil', were rejected by decision of the UK Intellectual Property Office ('the UKIPO') of 29 December 2009 because evidence of valid authorisations to place the products concerned on the market as referred to in Article 3(b) of Regulation No 469/2009 had not been produced. SPC application 07/074 was granted in principle by the UKIPO by letter of 22 January 2010. However, at the request of Georgetown University, the grant of the supplementary protection certificate was deferred pending the conclusion of the current court proceedings.

27. Georgetown University also applied for three supplementary protection certificates on the basis of the marketing authorisation for the medicinal product 'Cervarix':

— SPC application 07/071, which relates to the product 'recombinant L1 protein of HPV 16' and was subsequently slightly amended;

— SPC application 07/070, which relates to the product 'recombinant L1 protein of HPV 18' and was subsequently slightly amended;

— SPC application 07/072, which relates to the product 'combination of the recombinant L1 protein of HPV 16 and HPV 18'.

28. SPC applications 07/071 and 07/070, which relates to only one active ingredient of the medicinal product 'Cervarix', were rejected by UKIPO decision of 29 December 2009 because evidence of valid authorisations to place the products concerned on the market as referred to in Article 3(b) of Regulation No 469/2009 had not been produced. SPC application 07/072 was granted in principle by the UKIPO by letter of 22 January 2010. However, at the request of Georgetown University, the grant of the supplementary protection certificate was deferred until the conclusion of the current court proceedings.

2. The SPC applications of University of Rochester

29. University of Rochester is the proprietor of a European patent for a purified recombinant human papillomavirus-like particle or capsomere. The patent was applied for on 8 March 1994 and granted on 25 May 2005. It expires on 7 March 2014. Patent claim 7 concerns a vaccine for the prevention of an infection with the human papillomavirus.

30. University of Rochester applied for three supplementary protection certificates with the numbers SPC/GB07/018, SPC/GB07/075 and SPC/GB07/076 ('SPC applications 07/018, 07/075 and 07/076).'

31. Two of those SPC applications are based on the marketing authorisation for the medicinal product 'Cervarix':

— SPC application 07/075, which relates to the product 'virus-like particle of the recombinant L1 protein of HPV 16' and was subsequently slightly amended;

— SPC application 07/076, which relates to the product 'combination of the virus-like particles of the recombinant L1 protein of HPV 16 and HPV 18'.

32. SPC application 07/075, which relates to only one active ingredient of the medicinal product 'Cervarix', was rejected by UKIPO decision of 29 December 2009 because evidence of a valid authorisation to place the

product on the market as referred to in Article 3(b) of Regulation No 469/2009 had not been produced. SPC application 07/076 was accepted by the UKIPO and the supplementary protection certificate was granted on 5 October 2009.

33. SPC application 07/018 of University of Rochester, which relates to the product 'combination of the virus-like particles of the recombinant L1 protein of HPV 6, HPV 11, HPV 16 and HPV 18' and is based on the marketing authorisation for the medicinal product 'Gardasil', was accepted by the UKIPO and the supplementary protection certificate was granted on 4 October 2009.

3. The SPC applications of Loyola University of Chicago

34. Loyola University of Chicago is the proprietor of a European patent for recombinantly produced papillomavirus-like particles. The patent was applied for on 9 October 1995 and granted on 10 May 2006. It expires on 8 October 2015.

35. Loyola University of Chicago applied for two supplementary protection certificates with the numbers SPC/GB07/069 and SPC/GB07/077 ('SPC applications 07/069 and 07/077'). Both applications are based on the marketing authorisation for the medicinal product 'Cervarix'.

36. SPC application 07/069, which relates to the product 'virus-like particle of the recombinant L1 protein of HPV 16' and was subsequently slightly amended, was rejected by UKIPO decision of 29 December 2009 because evidence of a valid authorisation to place the product concerned on the market as referred to in Article 3(b) of Regulation No 469/2009 had not been produced.

37. SPC application 07/077, which relates to the product 'combination of the virus-like particles of the recombinant L1 protein of HPV 16 and HPV 18', was accepted by the UKIPO and the supplementary protection certificate was granted on 5 October 2009.

4. Question submitted by the referring court

38. In the main proceedings, the referring court is required to assess the lawfulness of the UKIPO's decisions by which the abovementioned SPC applications were rejected in all cases in which the product to which those applications related contained fewer active ingredients than the combination of active

ingredients of the medicinal product which was the subject of the marketing authorisations as referred to in Article 3(b) of Regulation No 469/2009.[7]

39. Because the referring court has doubts regarding the interpretation of Article 3 of Regulation No 469/2009, it has made a reference to the Court for a preliminary ruling on the following question:

'Does Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products 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 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 authorisation that places the single active ingredient or combination of active ingredients on the market?'

## IV — Procedure before the Court

40. The order for reference in *Medeva* was received by the Court on 5 July 2010 and the order for reference in *Georgetown University and Others* on 27 August 2010. By order of 12 January 2011, the two cases were joined for the purposes of the oral procedure and the judgment.

41. The European Commission and the Portuguese Government submitted observations in the written procedure in both cases. Medeva and the Latvian and Lithuanian Governments and the United Kingdom Government submitted observations in *Medeva*. Georgetown University, University of Rochester and Loyola University of Chicago submitted observations in *Georgetown University and Others*. In accordance with Article 54a of the Rules of Procedure, the parties were asked to provide written answers to a number of questions. Medeva, Georgetown University, University of Rochester, Loyola University of Chicago, the United Kingdom Government and the Portuguese Government replied to those questions in writing. At the hearing on

7 — The main proceedings thus concern SPC applications 07/070, 07/071, 07/073, 07/078, 07/079 and 07/080 of Georgetown University, SPC application 07/075 of University of Rochester and SPC application 07/069 of Loyola University of Chicago.

12 May 2011, the Portuguese Government, the United Kingdom Government, Medeva, Georgetown University, University of Rochester, Loyola University of Chicago and the Commission made oral submissions and answered questions put by the Court.

## V — Arguments of the parties

### A — *Questions 1 to 5 in* Medeva

42. By Questions 1 to 5 in *Medeva*, the referring court asks in essence for clarification concerning the application of Article 3(a) of Regulation No 469/2009 to an SPC application which relates to a combination of active ingredients which, although not the subject-matter of a patent as such, nevertheless enjoys protection under patent law because a valid patent exists in respect of one or more of the active ingredients used in the combination of active ingredients. In that regard, the referring court wishes in particular to know whether such a combination of active ingredients is to be regarded as being 'protected by a basic patent in force'. The referring court also enquires whether Article 3(a) of Regulation No 469/2009 applies differently to medicinal products with more than one active ingredient or multi-disease vaccines, on the one hand, and to medicinal products or vaccines with only one active ingredient, on the other.

43. The question whether a combination of active ingredients which includes both patented and non-patented active ingredients can be classified in its entirety as a 'product … protected by a basic patent in force' within the meaning of Article 3(a) of Regulation No 469/2009 is answered in the negative by the *Commission*, the *Portuguese Government*, the *Latvian Government* and the *Lithuanian Government*. *Medeva* and the *United Kingdom Government*, on the other hand, answer that question in the affirmative. The question whether Article 3(a) of Regulation No 469/2009 applies differently to medicinal products with multiple active ingredients or multi-disease vaccines, on the one hand, and to medicinal products or vaccines with only one active ingredient, on the other, is in effect answered in the negative by all the parties.

44. In the view of the *Commission*, in a case such as this, the referring court is required to determine, in accordance with Article 3(a) of Regulation No 469/2009, whether the product within the meaning of Article 1(b) is protected by a basic patent within the meaning of Article 1(c). For this purpose, the referring court must establish which active ingredients are protected by a patent under national law

and not which forms of commercial activity the patent proprietor can prohibit third parties from engaging in. In that regard, Article 3(a) should be applied to SPC applications for medicinal products or vaccines with multiple active ingredients in the same way as to SPC applications for medicinal products or vaccines with only one active ingredient. That solution applies both to multi-disease vaccines containing multiple antigens, in which only one antigen is protected by a basic patent in force, and to multi-disease vaccines containing multiple antigens, in which all the antigens against one of the diseases are protected by a basic patent in force.

45. In the view of the *Portuguese Government*, for the purpose of interpreting Article 3(a) of Regulation No 469/2009, the starting premiss must be that the determination of the extent of protection of basic patents must be made in accordance with national law. Under the national laws of the Contracting States to the EPC, the extent of protection of a patent is determined by the patent claims. It must therefore also be established on the basis of those patent claims whether a product is protected by a basic patent in force within the meaning of Article 3(a). It is also true to say of medicinal products with more than one active ingredient and of multi-disease vaccines that a combination of active ingredients is protected by a basic patent only where that combination of active ingredients is specified in the patent claims. Against that background, a multi-disease vaccine which contains multiple antigens, only one of which is protected by a basic patent in force, does not satisfy the requirements of Article 3(a). Likewise, a multi-disease vaccine which contains multiple antigens protected by a basic patent satisfies the requirements of Article 3(a) only where the combination of active ingredients corresponds completely with the patent claims.

46. In the view of the *Lithuanian Government*, it is apparent from the recitals in the preamble to and from the provisions of Regulation No 469/2009 that the grant of a supplementary protection certificate presupposes not only that the product concerned is protected by a basic patent and that a valid authorisation to place that product on the market as a medicinal product exists, but also that the active ingredient of that medicinal product is covered by the patent claims. That is true irrespective of the nature of the medicinal product in respect of which a supplementary protection certificate is being applied for. The *Latvian Government* likewise starts from the premiss that the question whether a product is protected by a basic patent must be answered on the basis of the patent claims. Only the product described in the patent claims is protected by the basic patent. This also applies to multi-disease vaccines or medicinal products with multiple active ingredients.

47. In the view of the *United Kingdom Government* and *Medeva*, on the other hand, Article 3(a) of Regulation No 469/2009 must

be interpreted as meaning that a combination of active ingredients is protected by a basic patent in force where at least one of its active ingredients falls within the extent of protection conferred by a patent as specified in the patent claims and the entire combination of ingredients thereby enjoys the protection conferred by the patent against the marketing of identical products. That rule applies without restriction to medicinal products with more than one active ingredient or multi-disease vaccines. Where, therefore, a multi-disease vaccine contains multiple antigens, one of which is protected by a basic patent in force, the multi-disease vaccine must also be regarded as being protected by that basic patent. The same must apply where a multi-disease vaccine contains multiple antigens against one disease and all those antigens are protected by a patent in force. In the alternative, Medeva submits that its interpretation of Article 3(a) of Regulation No 469/2009 must in any event apply to multi-disease vaccines.

B — *Sixth question referred in Medeva and sole question referred in Georgetown University and Others*

48. By the sixth question referred in *Medeva* and the sole question referred in *Georgetown University and Others*, the referring courts request clarification concerning the application of Article 3(b) of Regulation No 469/2009. In that regard, they wish in essence to know whether the condition laid down in that provision for obtaining a supplementary protection certificate can be satisfied where the medicinal product which is the subject of the marketing authorisation also contains, in addition to the active ingredient or combination of active ingredients specified in the SPC application, still further active ingredients.

49. In the view of the *Commission*, *Georgetown University*, *University of Rochester*, *Loyola University of Chicago* and *Medeva*, this question should be answered in the affirmative. However, Medeva formulates this proposed answer only in the event that the Court does not agree with its proposed answers to the first five questions referred in *Medeva*.

50. In the view of the *United Kingdom Government*, the *Portuguese Government* and the *Latvian Government*, on the other hand, Article 3(b) of Regulation No 469/2009 is to be interpreted as meaning that the medicinal product which is the subject of the marketing authorisation must have the same combination of active ingredients as the product in respect of which a supplementary protection certificate is applied for. The *Lithuanian*

*Government* submits that the active ingredient of the medicinal product in respect of which a marketing authorisation has been granted must correspond to the active ingredient specified in the patent claims.

## VI — Legal assessment

### A — *Questions 1 to 5 in Medeva*

51. By Questions 1 to 5 in *Medeva*, the referring court asks in essence for clarification concerning the application of Article 3(a) of Regulation No 469/2009 to an SPC application relating to the combination of active ingredients of a medicinal product which is not in its entirety the subject-matter of a patent, but nevertheless enjoys protection under patent law against production and distribution by third parties because a valid patent exists in respect of part of the combination of active ingredients.

52. Although the referring court has made reference, in its formulation of these questions, only to Article 3(a) of Regulation No 469/2009, it raises, by its reference for a preliminary ruling, the question of principle as to whether and, if so, how and under what conditions supplementary protection certificates may be applied for and granted in respect of medicinal products with multiple active ingredients where their combination of active ingredients is only partially the subject-matter of a patent. To date, the Court has not yet comprehensively ruled on that question of principle. Against that background, it seems to me to be necessary to analyse below, first, the issues surrounding the applicability of Regulation No 469/2009 to medicinal products with a partially patented combination of active ingredients. That will then enable a meaningful answer to be given to the questions referred concerning the application of Article 3(a) of Regulation No 469/2009 to such medicinal products.

53. In order to answer the question concerning the applicability of Regulation No 469/2009 to medicinal products with a partially patented combination of active ingredients, I shall first analyse Regulation No 469/2009 in terms of its wording and scheme. I shall then assess the result of that textual interpretation in the light of the objectives of Regulation No 469/2009. Against the background of the teleological considerations arising from that assessment, I shall then answer the questions referred.

1. Interpretation of Regulation No 469/2009 on the basis of its wording and scheme

(a) The subject of the supplementary protection certificate

54. Under Article 2 of Regulation No 469/2009, a product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83 or Directive 2001/82 may, under the terms and conditions provided for in that regulation, be the subject of a supplementary protection certificate.

55. The precise conditions for the grant of such a certificate are laid down in Article 3 of Regulation No 469/2009, in accordance with point (a) of which the product must be protected, in the Member State in which the application is submitted and at the date of that application, by a basic patent in force.

56. The meanings of the terms 'medicinal product', 'product' and 'basic patent' are specified in Article 1 of Regulation No 469/2009. According to Article 1(a), a 'medicinal product' is any substance or combination of substances intended for treating or preventing disease in human beings or animals. A 'product', according to Article 1(b), is the active ingredient or combination of active ingredients of a medicinal product. The 'basic patent', according to Article 1(c), is a patent which protects a product as such, a process to obtain a product or an application of a product.

57. With regard to the content of the terms 'product' and 'medicinal product' and their relationship to each other, the Commission observed in the Explanatory Memorandum to its proposal for Regulation No 1768/92 [8] that the concept of a medicinal product as used in everyday speech is difficult to define in a legal context. Furthermore, the definition of a medicinal product in pharmaceutical law is not necessarily exactly the same as that in patent law. For the purposes of the supplementary protection certificate, which lies at the interface of the two systems, the term 'product' was chosen as a common denominator. [9]

58. When adopting the regulation, the legislature thus sought to distinguish by way of definition between the terms 'medicinal product', 'product' and 'active ingredient' and in so doing to bridge the conceptual gap

8 — The Commission's Explanatory Memorandum to the proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final – SYN 255), reproduced in Schennen, D., *Die Verlängerung der Patentlaufzeit für Arzneimittel im Gemeinsamen Markt*, Cologne, *Bundesanzeiger*, 1993, p. 92 et seq.

9 — Ibid., point 28.

between the spheres of pharmaceutical law and intellectual property law. Although the definitions contained in Article 1 of Regulation No 469/2009 also appear to contain clear interpretative requirements in that regard, a certain ambiguity is apparent, on detailed analysis of the wording of Regulation No 469/2009, in the use of the terms 'product' and 'medicinal product', and it is not always clear to what extent those terms are or are intended to be coextensive in content.

59. A first example of this is provided by a comparison of the title of Regulation No 469/2009 with Article 2 of the regulation. According to its title, the regulation concerns the supplementary protection certificate for 'medicinal products'. However, Article 2 states that the supplementary protection certificate is to be granted for a 'product' protected under patent law.

60. A further example is provided by the wording of Article 2 of Regulation No 469/2009, which provides that a supplementary protection certificate is to be granted for a 'product' protected by a patent, which was subject, prior to being placed on the market 'as a medicinal product', to an administrative authorisation procedure as laid down in Directive 2001/83 or Directive 2001/82. Article 3(b) of the regulation also talks about an authorisation to place 'the product' on the market 'as a medicinal product'.

61. An overlap in content between the terms 'product' and 'medicinal product' also finds expression in the definition of 'product' in Article 1(b) of Regulation No 469/2009. In the various language versions of the regulation which distinguish between the definite and indefinite article, the product has been defined as 'the' active ingredient or combination of active ingredients of a medicinal product. [10] The product thus corresponds to the whole active or effective part of the medicinal product, which turns the latter into a preparation for preventing or treating disease and thus into a medicinal product. [11] Viewed in terms of the wording, 'an' active ingredient, which together with other active ingredients is only part of the combination of active ingredients of a medicinal product, therefore does not constitute a product within the meaning of Article 1(b) of Regulation No 469/2009. [12]

10 — In the different language versions, that definition reads, inter alia, as follows: French: *le* principe actif ou *la* composition de principes actifs d'un médicament; German: *der* Wirkstoff oder *die* Wirkstoffzusammensetzung eines Arzneimittels; Dutch: *de* werkzame stof of *de* samenstelling van werkzame stoffen van een geneesmiddel; Spanish: *el* principio activo o *la* composición de principios activos de un medicamento; Italian: *il* principio attivo o *la* composizione di principi attivi di un medicinale.

11 — In Case C-431/04 *Massachusetts Institute of Technology* [2006] ECR I-4089, paragraph 25, the Court has already held that a substance which does not have any therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the concept of 'active ingredient', which in turn is used to define the term 'product'.

12 — The definition of the 'product' as the whole active or effective part of a medicinal product in Article 1(b) of Regulation No 469/2009 also ultimately explains why the terms 'product' and 'medicinal product' are sometimes treated alike in Regulation No 469/2009.

62. The latter conclusion regarding the wording of Article 1(b) of Regulation No 469/2009 is of particular relevance to the present references for a preliminary ruling. It actually means that, in the case of a multi-disease vaccine, only the combination of all the active ingredients constitutes the product within the meaning of Regulation No 469/2009. According to the wording of Article 1(b), on the other hand, a single active ingredient of a multi-disease vaccine cannot be subsumed under the concept of product in Regulation No 469/2009.

(b) Issue raised: No supplementary protection certificate for medicinal products with multiple active ingredients, the combination of active ingredients of which is only partially patented?

63. According to the wording of Article 1(b) of Regulation No 469/2009, a single active ingredient or combination of active ingredients which is part of the larger combination of active ingredients of a medicinal product does not constitute a product within the meaning of the regulation. A literal interpretation of Regulation No 469/2009 therefore leads to the conclusion that, in the case of medicinal products with multiple active ingredients, a supplementary protection certificate may be granted only in relation to the entire combination of active ingredients. That is because, according to the wording of Article 1(b), only the combination of active ingredients as such constitutes the product in respect of which a supplementary protection certificate may be granted.

64. However, that literal interpretation at the same time implies that, in the case of medicinal products with multiple active ingredients, only part of which is the subject-matter of a patent, no supplementary protection certificates may be granted. In the case of such medicinal products, it would actually, as a rule, be de facto impossible for the basic patent within the meaning of Article 1(c) of the regulation – required under Article 3(a) of Regulation No 469/2009 – to exist.

65. That follows from the definition of a basic patent in Article 1(c) of Regulation No 469/2009.

66. Under Article 1(c) of Regulation No 469/2009, the basic patent is a patent which protects a product 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. That definition refers to the three

major categories of patent into which the basic patent can fall, namely:(1) patents relating to a physical entity; (2) patents relating to a process; and (3) patents relating to the application of an object or a process. [13]

67. In the three categories of patent referred to in Article 1(c) of Regulation No 469/2009, the subject-matter of the basic patent is always the product within the meaning of Article 1(b) of that regulation and therefore 'the' active ingredient or (the) combination of active ingredients of a medicinal product. It follows from this that a patent for 'an' active ingredient or 'a' combination of active ingredients which forms only part of the combination of active ingredients of a medicinal product cannot constitute a basic patent within the meaning of Article 1(c) of Regulation No 469/2009. That is because, on a literal interpretation, only the combination of active ingredients of that medicinal product in its entirety, and not the patented part of that combination, can be described as a product within the meaning of Article 1(b).

68. Nor is that conclusion altered in any way by the discussion conducted in the main proceedings in the context of Article 3(a) of Regulation No 469/2009, on the distinction between the subject-matter – or extent of protection – and the protective effect of the basic patent. That debate concerns, in particular, the question whether the fact that an active ingredient which is the subject-matter of a patent is an integral part of a combination of active ingredients and, as a consequence, that entire combination of active ingredients may not be produced or placed on the market without the consent of the patent proprietor (that is the *protective effect* of the patent) implies that the combination of active ingredients is deemed to be protected by a patent in force.

69. The decisive consideration in that context is the fact that the definition of the basic patent in Article 1(c) of Regulation No 469/2009 takes as its basis the *subject-matter* of the patent, and not its *protective effect*. A basic patent within the meaning of Regulation No 469/2009 must therefore be understood as one whose *subject-matter* comprises either a product as such, a process to obtain a

13 — See, with regard to these categories of patent, Melullis in Benkard, G. (ed.), *Europäisches Patentübereinkommen*, Munich, 2002, Art. 52, points 105 and 106, who points out, in the context of the EPC, that patents relating to an object cover substances, compositions, machines and apparatus. Patents relating to a process may concern manufacturing processes, test methods, applications, etc. A usage patent protects the usage of an object or process, generally known to be in line with the state of the art. Such a patent is therefore based on the discovery of a new potential use of a state-of-the-art product or process.

product or an application of a product within the meaning of Article 1(b) of Regulation No 469/2009.

70. In the absence of harmonisation of patent law in the European Union, the question whether a product as such, a process to obtain a product or an application of a product within the meaning of Article 1(b) of Regulation No 469/2009 forms the subject-matter of a national or European patent must, as Union law now stands, be answered on the basis of the national rules governing that patent. [14] Nevertheless, the definition of the basic patent laid down in Article 1(c) of the Regulation [15] requires that, in the application of that definition, regard is always had to the *subject-matter* of the patent in question, and not to its protective effects.

71. At the same time, that definitional requirement of Article 1(c) of Regulation No 469/2009 also reduces the risk that the absence of harmonisation of substantive patent law in the European Union could lead to differences in the protection conferred by certificates in the Union. [16]

72. In the light of those considerations, it would not, in my view, be compatible with the mandatory requirements of Article 1(c) of Regulation No 469/2009 for a national court, relying on national patent law, to invoke the protective effect of the patent granted for a specific active ingredient in order to declare that patent to be the basic patent for all combinations of active ingredients in which the patented active ingredient was to be used.

73. On a literal interpretation of Articles 1 to 3 of Regulation No 469/2009, the fact therefore remains that, in the case of medicinal products in which the combination of active ingredients is only partially patented, in the absence of a basic patent within the meaning of Article 1(c) of the regulation, no supplementary protection certificates may be granted.

14 — See, in that regard, Case C-392/97 *Farmitalia* [1999] ECR I-5553.

15 — In this context, it should be recalled that the European Union legal order does not, in principle, aim to define concepts on the basis of one or more national legal systems unless there is express provision to that effect; see Case C-314/06 *Société Pipeline Méditerranée et Rhône* [2007] ECR I-12273, paragraph 21; Case C-103/01 *Commission* v *Germany* [2003] ECR I-5369, paragraph 33; and Case C-296/95 *EMU Tabac and Others* [1998] ECR I-1605, paragraph 30.

16 — The Court has already warned against the risks of differences in the protection conferred by certificates in the European Union in Case C-350/95 *Spain* v *Council* [1995] ECR I-1985, paragraph 36, and pointed out in that regard that differences in the protection given in the European Union to one and the same medicine would give rise to a fragmentation of the market, whereby the medicine would still be protected in some national markets but no longer protected in others. Such differences in protection would mean that the marketing conditions for the medicines would vary from one Member State to another. The Court last confirmed that assessment in Case C-482/07 *AHP Manufacturing* [2009] ECR I-7295, paragraph 35, in which it pointed out that a heterogeneous development of the protection conferred by certificates in the individual Member States would be likely to create obstacles to the free movement of medicinal products within the European Union and thus directly affect the establishment and the functioning of the internal market.

2. Teleological interpretation of Regulation No 469/2009

74. It follows from my above observations that, as a general rule, on a literal interpretation of Regulation No 469/2009, there can be no question of a supplementary protection certificate being granted for a multi-disease vaccine in which the combination of active ingredients is only partly patented. I shall now examine below first whether such a conclusion is compatible with the aims of Regulation No 469/2009. Since, in my view, the answer to that must be in the negative, I shall then complement the literal interpretation of Articles 1 to 3 of Regulation No 469/2009 with a teleological interpretation.

(a) Necessity of a teleological interpretation of Articles 1 to 3 of Regulation No 469/2009

75. The aim of the supplementary protection certificate for medicinal products is essentially to extend the term of patent protection for active ingredients used in medicinal products.

76. The standard term of patent protection is 20 years, calculated from the date of application for registration of the invention. If an authorisation to place medicinal products on the market in accordance with Directive 2001/83 or Directive 2001/82 is granted following the filing of an application to have the patent registered, manufacturers of medicinal products [17] will be unable commercially to exploit their position of exclusivity in relation to the patented active ingredients of that medicinal product during the period which elapses between the application to have the patent registered and the authorisation to place the medicinal product concerned on the market. Since, in the view of the European Union legislature, that would make the period of effective protection under the patent insufficient to cover the investment in research and to generate the resources needed to maintain a high level of research, [18] Regulation No 469/2009 grants those manufacturers the possibility to extend their rights to exclusivity in the patented active ingredients of a medicinal product by applying for a supplementary protection certificate to cover a period not exceeding 15 years from the time at which the medicinal product concerned first obtains authorisation to be placed on the market within the European Union. [19]

77. Those rules are intended to achieve a balance between the various interests at stake in the pharmaceutical sector. Those interests include, on the one hand, the interests of the

17 — Although the proprietor of the basic patent for an active ingredient or the holder of the supplementary protection certificate does not necessarily have to be the holder of the marketing authorisation for the medicinal product, I am proceeding, for the sake of clarity, in my legal assessment of the questions referred, on the assumption that the manufacturer of the medicinal product is the proprietor of the basic patent and holds the marketing authorisation and has also applied for the supplementary protection certificate.

18 — See recital 4 in the preamble to Regulation No 469/2009.

19 — See Article 13 of Regulation No 469/2009 and recital 9 in the preamble thereto.

undertakings and institutions, some of which pursue very cost-intensive research in the pharmaceutical sector and therefore favour an extension of the term of protection for their inventions in order to be able to recoup the investment costs. On the other hand, there are the interests of the producers of generic medicines who, as a consequence of the extension of the term of protection of the active ingredients under patent protection, are precluded from producing and marketing generic medicines. It is also relevant in this connection that, in general, the marketing of generic medicinal products has the effect of lowering the prices of the relevant medicinal products. Against that background, the interests of patients lie between the interests of the undertakings and institutions conducting research and those of the producers of generic medicines. That is because patients have an interest, on the one hand, in the development of new active ingredients for medicinal products, but, on the other, they also have an interest in those products then being offered for sale as cheaply as possible. The same applies to State public health systems in general which, in addition, have a particular interest in preventing old active ingredients from being brought onto the market in slightly modified form under the protection of certificates but without genuine innovation and thereby artificially driving up expenditure in the health sector.

78. Against the background of that complex situation as regards interests, Regulation No 469/2009 sought to achieve a balanced solution taking due account of the interests of all parties. In view of the complexity of that balance of interests, [20] it is necessary to proceed with great caution when making a teleological interpretation of the individual provisions of the regulation.

79. Nevertheless, it is in my view clear that the result of the literal interpretation of Articles 1 to 3 of Regulation No 469/2009, according to which, in the case of medicinal products with multiple active ingredients only part of which is the subject-matter of a patent, no supplementary protection certificates can be granted, is not compatible with the objectives of Regulation No 469/2009.

80. If no supplementary protection certificates could be granted in respect of medicinal products with multiple active ingredients only part of which is the subject-matter of a patent, that would actually have the result that, in all spheres in which the manufacturers of medicinal products found themselves obliged, for legal or practical reasons, to place patented active ingredients on the market in combination with other active ingredients in one medicinal product, an extension of the term of protection of the patented active ingredients in accordance with the requirements of Regulation No 469/2009 would not be possible.

20 — See also, in that regard, recital 10 in the preamble to Regulation No 469/2009.

81. The fact that such a result would not be compatible with the objectives of Regulation No 469/2009 can be unequivocally substantiated by the example of the development of active ingredients for vaccines with which we are concerned in this case.

82. The importance of vaccines for public health is difficult to overestimate. It is reflected inter alia in the observations of the European Commission's Directorate-General for Health and Consumers on the Commission's vaccination strategy. That directorate-general points out that vaccination offers people immunity to diseases and is unquestionably one of the most cost-effective public health measures available. [21] It also stresses that the Commission has supported the introduction of vaccines against cervical cancer, and the vaccines Gardasil and Cervarix, which are at issue in *Georgetown University and Others*, are expressly mentioned. [22]

83. In their written observations, Georgetown University, University of Rochester and Loyola University of Chicago [23] and Medeva [24] have all pointed out that national health authorities as well as patients have a particular interest in the development of multi-disease vaccines. The use of multi-disease vaccines makes it possible, in particular, to provide infants and young children with fast and complete protection by vaccination against a multitude of diseases by means of only a few vaccinations. That in turn means that vaccination schedules are better adhered to, inconvenience for patients is kept to a minimum and delays in the achievement of comprehensive protection provided by vaccination are avoided. Accordingly, vaccines are in many cases placed on the market only as multi-disease vaccines.

84. To support those arguments, those parties refer, on the one hand, to *WHO Fact Sheet No 288 (2005) – Immunisation against diseases of public importance*, [25] which, under the heading 'Types of vaccines', points out that vaccines are frequently administered as combinations of antigens. In that context, Medeva further stresses that it has produced no vaccine containing only FHA and pertactin. [26]

85. That argument put forward by the undertakings from the pharmaceutical research sector which are represented in the main proceedings is supported by several World Health Organisation publications. In

21 — http://ec.europa.eu/health/vaccination/policy/index_en.htm.

22 — http://ec.europa.eu/health/vaccination/hpv/index_en.htm.

23 — Written observations, point 20.

24 — Written observations, point 74 et seq.

25 — Attached as Annex 4 to the written observations of Georgetown University, University of Rochester and Loyola University of Chicago and as Annex 19 to the written observations of Medeva.

26 — Written observations, point 74.

its article 'Six common misconceptions about immunisation', the World Health Organisation points out, for example, that research is under way to find out how to combine more antigens in a single vaccine injection. The advantage of complete multi-disease vaccines lies in the fact that infants receive extensive protection by being vaccinated as early as possible. The reduction in the number of vaccinations also saves parents time and money and makes the vaccinations less traumatic for the child. [27]

86. In that context, the referring court has also pointed out in *Medeva* that vaccine manufacturers are forced by countries' purchasing policies to produce large combinations of vaccines wherever possible. In the view of that court, the market is thus dictated by the State which insists that vaccines be combined where possible. In such circumstances, there may not be a market for patented vaccines which are provided on their own. [28]

87. Those observations prove that manufacturers of medicinal products may have a legitimate interest in marketing multi-disease vaccines. In my view, it would therefore run counter to the aims of Regulation No 469/2009 if the balance of interests achieved in that regulation, according to which manufacturers of medicinal products should be able to enjoy their position of exclusivity for an overall maximum of 15 years from the time the medicinal product in question first obtains authorisation to be placed on the market in the European Union, were to be upset by the fact that patented active ingredients are placed on the market in combination with other active ingredients in one medicinal product.

88. The literal interpretation of Articles 1 to 3 of Regulation No 469/2009 must therefore be complemented by a teleological interpretation which ensures that the rules on supplementary protection certificates contained in those provisions can also be fully effective in respect of medicinal products in which the combination of active ingredients is only partly the subject-matter of a patent. [29]

(b) The product within the meaning of Article 1(b) of Regulation No 469/2009

89. In the light of my above observations, it appears to me to be necessary to interpret the definition of 'product' in Article 1(b) of Regulation No 469/2009 teleologically to the

27 — http://www.who.int/immunization_safety/aefi/immunization_misconceptions/en/index6.html# (last update: 11 December 2010).

28 — Order for reference in *Medeva*, paragraphs 27 and 28.

29 — The relevance of teleological interpretation in the context of the interpretation of Regulation No 469/2009 is confirmed by the Court in settled case-law. Thus, the Court, emphasising the objectives of Regulation No 1768/92, has already ruled in *Farmitalia*, cited above in footnote 14, paragraph 17 et seq., in favour of a broad interpretation of Article 3(b) of the regulation.

effect that the product within the meaning of the regulation includes not only 'the' active ingredient or 'the' combination of active ingredients, but also 'an' active ingredient or 'a' combination of active ingredients of a medicinal product.

90. Such an interpretation also brings within the scope of Regulation No 469/2009 medicinal products in which the combination of active ingredients is only partly the subject-matter of a patent. It in fact allows an SPC application to designate the part of the combination of active ingredients which forms the subject-matter of a patent as the product within the meaning of Article 1(b). That patent can then automatically be classified as the basic patent within the meaning of Article 1(c) of that regulation, so that on that basis the conditions for obtaining the supplementary protection certificate as laid down in Article 3 of the regulation can be examined.

(c) The product within the meaning of Article 3(a) of Regulation No 469/2009

91. Although the widening of the concept of product within the meaning of Article 1(b) of Regulation No 469/2009 to include 'an' active ingredient or 'a' combination of active ingredients in principle brings within the scope of that regulation medicinal products in which the combination of active ingredients is only partially the subject-matter of a patent, it must be ensured that such a teleological interpretation does not go beyond the aim pursued by it of achieving the balance of interests envisaged by the European Union legislature.

92. In that context, there is a danger, in particular, that an interpretation of Article 1(b) of Regulation No 469/2009 to the effect that both 'the' combination of active ingredients and part of the combination of active ingredients of a medicinal product may be classified as the 'product' could be exploited in order to undermine the system of limitation of the duration of supplementary protection certificates envisaged by the legislature.

93. Under Article 13(1) of Regulation No 469/2009, the supplementary protection certificate is to take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the European Union reduced by a period of five years. Under Article 13(2), the duration of the certificate may not exceed five years from the date on which it takes effect.

94. Those rules reflect the legislature's decision to grant the proprietor of the patent an

extension of his position of exclusivity by the period by which the duration of the authorisation procedure for the medicinal product exceeds five years, although a maximum limit of five years applies in that regard. Moreover, the uniform starting point for the calculation of the duration of the certificate is the first authorisation to place the product on the market 'in the European Union',[30] so that, in principle, supplementary protection certificates have the same duration in respect of the same products in all the Member States.

95. Where a manufacturer of medicinal products thus succeeds in placing a medicinal product with a patented active ingredient on the market within five years from the date of application for the patent, any protection conferred by a certificate is out of the question; however, he enjoys – based on a standard patent term of 20 years – patent protection for at least 15 years. Where, on the other hand, a manufacturer of medicinal products needs 10 years or more from the date of application for the patent in order to obtain the first authorisation to place the product on the market in the European Union, he is entitled to the maximum protection of five years under a certificate.

96. If both the combination of active ingredients of a medicinal product and a patented active ingredient or combination of active ingredients contained in it could in future be classified as a product within the meaning of Article 1(b) of Regulation No 469/2009, there would be a risk that a manufacturer of medicinal products could develop a number of medicinal products with different combinations of active ingredients on the basis of one patented active ingredient or combination of active ingredients and place those products on the market with a time lag in some cases, for the purpose of optimising the protection under the certificate.

97. An optimised duration – from the point of view of the manufacturer of medicinal products – of protection under the patent and the certificate could, for example, be achieved by ensuring that a first medicinal product with a patented active ingredient is placed on the market as quickly as possible in order to exploit the already existing patent protection commercially. Where the procedure for obtaining an authorisation to place the product on the market has taken longer than five years, the manufacturer of medicinal products could at the same time apply for a supplementary protection certificate and declare the complete combination of active ingredients as the product. He could then attempt to substantiate the protection under patent law for that product, required under Article 3(a)

30 — It is not only authorisations granted in the individual Member States of the European Union that are relevant for consideration as the first authorisation to place a product on the market in the European Union; authorisations granted in the EEA States Iceland, Norway and Liechtenstein are also relevant in that respect; see, in that regard, Kellner, H., 'Salz in der Suppe oder Sand im Getriebe? Anmerkungen zu Schutzzertifikaten', GRUR, 1999, p. 805, at p. 808. Furthermore, an authorisation to place a medicinal product on the market issued by the Swiss authorities and automatically recognised by the Principality of Liechtenstein under that State's legislation is also to be regarded as a first authorisation to place a product on the market in the EEA within the meaning of Article 13 of Regulation No 469/2009, as it is to be read for the purposes of the application of the EEA Agreement; see to that effect Joined Cases C-207/03 and C-252/03 *Novartis and Others* [2005] ECR I-3209.

of Regulation No 469/2009, by reference to the protective effect of the basic patent for the patented active ingredient included in the combination of active ingredients. [31] Subsequently, the manufacturer of medicinal products could place such products with slightly differing combinations of active ingredients, also including the patented active ingredient, on the market and, according to the same logic, apply for new supplementary protection certificates for them, which could then have a duration of up to five years.

98. In order to prevent such an undermining of the system of limitation of the duration of the protection conferred by a certificate provided for in Regulation No 469/2009, Article 3(a) must be interpreted as meaning that the product within the meaning of that provision is the same as the product which forms the subject-matter of the basic patent within the meaning of Article 1(c).

99. That definition of the product within the meaning of Article 3(a) of Regulation No 469/2009 implies, on the one hand, that, in the context of a judicial application of Article 3(a), it must essentially be determined whether a product which forms the subject-matter of the basic patent is before the court. That determination must in principle be made according to the rules governing the basic patent. If the answer to that question is in the affirmative, the further condition laid down by Article 3(a), namely that that product must be protected by a basic patent in force, is, as a rule, satisfied by that fact alone. That is because, although the latter question must also be answered according to the rules governing the basic patent, [32] it must be assumed that a product which, according to the rules governing the basic patent, is the subject-matter of the basic patent, will also be protected by the latter.

100. Having particular regard to Article 3(c) of Regulation No 469/2009, according to which only one supplementary protection certificate per product may be granted in the Member State in which the application is submitted, that interpretation of Article 3(a) has the effect, on the other hand, that, for each active ingredient or combination of active ingredients which is the subject-matter of a patent, only one supplementary protection certificate for the extension of that patent's term of protection may be granted, regardless of the number of combinations of active ingredients in which the patented active ingredient or combination of active ingredients has been

31 — See also, in that regard, point 68 of this Opinion.

32 — See, in this context, *Farmitalia*, cited above in footnote 14.

used. [33] This makes it impossible for manufacturers of medicinal products to optimise the term of protection under the patent and certificate in relation to an active ingredient by placing the patented active ingredient on the market in a number of combinations of active ingredients as different medicinal products, with a time lag in some cases.

101. Interpreting Article 3(a) of Regulation No 469/2009 to the effect that the product within the meaning of that provision is the same as the product which forms the subject-matter of the basic patent means that a manufacturer of medicinal products who holds a patent for an active ingredient or combination of active ingredients is free to decide how he will place that patented active ingredient or combination of active ingredients on the market: in one medicinal product with only that active ingredient or that combination of active ingredients, in one medicinal product in combination with other active ingredients, or in a number of medicinal products with differing combinations of active ingredients. For each of those medicinal products, the patented active ingredient or combination of active ingredients must be classified as the product protected by a basic patent in force within the meaning of Article 3(a). Under Article 3(c) of the regulation, however, only one supplementary protection certificate may be applied for in respect of that product, regardless of in how many different combinations of active ingredients the patented active ingredient or combination of active ingredients is placed on the market as a medicinal product.

102. Having particular regard to the account of the facts in *Georgetown University and Others*, the special case in which a patent relates to several active ingredients and also to one or more combinations of those active ingredients should not go unmentioned at this point. In such a case, each of those active ingredients and each combination of active ingredients which is used in a medicinal product can be classified as a product within the meaning of Article 1(b) of Regulation No 469/2009. Moreover, the patent belonging to the manufacturer of medicinal products is to be classified as the basic patent within the meaning of Article 1(c) of Regulation No 469/2009 in relation to each of those active ingredients and each combination of active ingredients. Nevertheless, there can be no question of applying for supplementary protection certificates on the basis of that

33 — Where an active ingredient is protected by a number of basic patents in force, which may belong to a number of patent proprietors, each of those patents may of course be designated for the purpose of the procedure for the grant of a certificate; however, only one certificate may be granted for each basic patent; see Case C-181/95 *Biogen* [1997] ECR I-357, paragraph 28. In *AHP Manufacturing*, cited above in footnote 16, the Court confirmed, moreover, that the rule in Article 3(c) of Regulation No 1768/92 does not preclude the grant of a supplementary protection certificate in favour of the proprietor of a basic patent for a product even where, at the date of his SPC application, one or more certificates have already been granted to one or more proprietors of one or more other basic patents.

basic patent in relation to each of those active ingredients and combinations of active ingredients used in a medicinal product. That is because, according to the Court's case-law, only one supplementary protection certificate may be granted for each basic patent. [34]

If a supplementary protection certificate could be applied for in respect of each of those active ingredients and each combination of active ingredients, the term of patent and certificate protection in relation to individual active ingredients could subsequently be optimised by placing the individual active ingredients and combinations of those active ingredients on the market in different medicinal products with time lags. [35]

103. It follows that the proprietor of a patent relating to a number of active ingredients and also to one or more combinations of those active ingredients must decide in respect of which active ingredient or combination of active ingredients he is going to apply for a supplementary protection certificate on the basis of the basic patent. The grant of a first supplementary protection certificate in respect of one active ingredient or combination of active ingredients in reliance on that patent then precludes the grant of further supplementary protection certificates in reliance on the same basic patent.

105. On the other hand, in my view, that interpretation would normally also afford manufacturers of medicinal products the possibility of obtaining appropriate certificate protection by relating their SPC application to the central active ingredient or combination of active ingredients contained in the various medicinal products to be developed.

104. On the one hand, that interpretation of Regulation No 469/2009 avoids a situation in which the system of limitation of the duration of protection conferred by a certificate, provided for in the regulation, is undermined by the claims in the patent application being formulated for the purpose of optimising the duration of protection in the sense that they cover both one or more individual active ingredients and a number of combinations of those individual active ingredients.

106. The extent, scope and content of the protection conferred by a certificate are laid down in Articles 4 and 5 of Regulation No 469/2009. Under Article 4 of Regulation No 469/2009, within the limits of the protection conferred by the basic patent, the protection conferred by a certificate extends 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.

34 — *Biogen*, cited above in footnote 33, paragraph 28.

35 — See, in that regard, points 97 and 98 of this Opinion.

Article 5 provides that, subject to Article 4, the certificate is to confer the same rights as conferred by the basic patent and to be subject to the same limitations and the same obligations.

107. It follows from both those provisions that the protection conferred by a certificate is always protection for a specified purpose: the extent of protection and protective effect of the supplementary protection certificate are restricted to those uses of the product as a medicinal product for which a marketing authorisation exists. [36]

108. Where a supplementary protection certificate is granted for an active ingredient or combination of active ingredients of a medicinal product, the protective effect of that certificate therefore extends, within the limits of the protection conferred by the basic patent, to all uses of the product in subsequent medicinal products for which marketing is authorised before the expiry of the certificate. In so far as the basic patent for the certificate-protected active ingredient or combination of active ingredients offers the patent proprietor protection against unauthorised production and distribution of medicinal products containing that active ingredient or combination of active ingredients, the supplementary protection certificate for that active ingredient or combination of active ingredients therefore also gives protection against unauthorised production and distribution of all subsequent medicinal products which are authorised before the expiry of the certificate and contain that active ingredient or combination of active ingredients.

109. By relating his SPC application to the central active ingredient or combination of active ingredients which is also contained in the medicinal products to be placed on the market in the future, the proprietor of a patent covering a number of active ingredients and also one or more combinations of those active ingredients can therefore ensure that those subsequent medicinal products also enjoy – within the limits of the basic patent and during the term of the supplementary protection certificate – protection against unauthorised production and distribution.

(d) Interim conclusion

110. In the light of the above, a teleological interpretation of Regulation No 469/2009 leads to the conclusion that the definition of product in Article 1(b) of the regulation covers not only 'the' active ingredient or 'the'

36 — See, in that regard, Brändel, C., 'Offene Fragen zum "ergänzenden Schutzzertifikat"', GRUR, 2001, p. 875, at pp. 876 and 877.; Hacker, F., PatG – Anhang zu § 16a, in Patentgesetz (founder: Busse, R.), Berlin, 2003, 6th edition, paragraphs 56 to 67.

combination of active ingredients, but also 'an' active ingredient or 'a' combination of active ingredients of a medicinal product. Moreover, Article 3(a) of the regulation is to be interpreted to the effect that the product within the meaning of that provision must be the same as the product which forms the subject-matter of the basic patent within the meaning of Article 1(c) of the regulation.

3. Answers to Questions 1 to 5 in *Medeva*

111. In the light of my above observations, Questions 1 to 5 in *Medeva* are to be answered as follows.

112. In order to answer the first question, as to how and on the basis of what criteria Article 3(a) of Regulation No 469/2009 is to be interpreted and applied, it is necessary to start from the principle that a product within the meaning of Article 3(a) is to be understood as a product which forms the subject-matter of a basic patent within the meaning of Article 1(c) of the regulation. Whether a product forms the subject-matter of a basic patent within the meaning of Article 1(c) and whether that product is protected by a basic patent in force in accordance with the requirement of Article 3(a) are determined, in principle, according to the rules governing the basic patent. However, the definition of a basic patent laid down in Article 1(c) of the regulation precludes combinations of active ingredients which are not the subject-matter of a basic patent, but nevertheless enjoy patent protection due to the presence of a patented active ingredient, from being characterised as a product within the meaning of Article 3(a).

113. Against that background, the *first* question must answered as follows: the condition for the classification of an active ingredient or combination of active ingredients of a medicinal product as a product within the meaning of Article 3(a) of Regulation No 469/2009 is that that active ingredient or combination of active ingredients forms the subject-matter of a basic patent within the meaning of Article 1(c) of that regulation. Whether an active ingredient or combination of active ingredients of a medicinal product forms the subject-matter of a basic patent within the meaning of Article 1(c) and whether that active ingredient or combination of active ingredients is protected by a basic patent in force in accordance with the requirement of Article 3(a) are determined, in principle, according to the rules governing the basic patent. However, the definition of the basic patent laid down in Article 1(c) of the regulation precludes use of the protective effect of the basic patent from being invoked as a criterion for the purpose of answering the question whether an active ingredient or combination

of active ingredients of a medicinal product forms the subject-matter of a basic patent.

114. That interpretation of Article 3(a) of Regulation No 469/2009 applies both to medicinal products with only one active ingredient and to medicinal products with multiple active ingredients.

115. Against that background, the *second* and *third* questions are to be answered to the effect that, in the context of the assessment of an SPC application relating to a medicinal product with multiple active ingredients or to a multi-disease vaccine, there are no further or different criteria for determining whether a product within the meaning of Article 3(a) of Regulation No 469/2009 exists and whether that product is protected by a basic patent in force.

116. On the basis of those premisses, the *fourth* and *fifth* questions are to be answered to the effect that the questions whether a multi-disease vaccine can be classified as a product within the meaning of Article 3(a) of Regulation No 469/2009 and whether that product is protected by a basic patent in force where only one of its active ingredients or each of its active ingredients against one of the diseases is protected by a basic patent in force, in principle, must be answered according to the rules governing the basic patent. However, the protective effect of the basic patent must not be used as a criterion for the purpose of answering the question whether a product within the meaning of Article 3(a) of the regulation exists.

B — *Sixth question referred in Medeva and sole question referred in Georgetown University and Others*

117. By the sixth question in *Medeva* and the (identically worded) sole question in *Georgetown University and Others*, the referring courts wish to know whether Article 3(b) of Regulation No 469/2009 precludes the grant of a supplementary protection certificate for a patented active ingredient or combination of active ingredients where that active ingredient or combination of active ingredients is combined with one or more other active ingredients in a medicinal product, so that the marketing authorisation in accordance with Directive 2001/83 or Directive 2001/82 relates to a medicinal product in which the patented active ingredient or combination of active ingredients has been combined with other active ingredients.

118. My above observations on the teleological interpretation of Regulation No 469/2009 have led me to the conclusion that the regulation is also intended to cover

medicinal products in which the combination of active ingredients is not patented in its entirety but nevertheless includes a patented active ingredient or combination of active ingredients.

119. For the purposes of the interpretation of Article 3(b) of Regulation No 469/2009, it follows from the foregoing that a valid marketing authorisation within the meaning of that provision may also exist where that authorisation under Directive 2001/83 or Directive 2001/82 relates to a medicinal product which also contains, together with the patented active ingredient or combination of active ingredients, one or more other active ingredients.

120. However, it should be pointed out in that connection that Article 3(b) of Regulation No 469/2009 must be read in conjunction with Article 3(d) and Article 7(1) of the regulation. Under Article 3(d), the authorisation referred to in point (b) of that provision is the first authorisation to place the product on the market as a medicinal product. Article 7 of the regulation provides, moreover, that the SPC application must be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted, or, where the authorisation to place the product on the market is granted before the basic patent is granted, within six months of the date on which the patent is granted. [37]

121. It thus follows from the combined operation of those provisions that a manufacturer of medicinal products who places an active ingredient which is the subject-matter of a basic patent on the market in combination with other active ingredients in the form of a number of medicinal products with differing combinations of active ingredients must lodge the SPC application for the patented active ingredient within six months of the date on which the first authorisation to place the first medicinal product with the patented active ingredient on the market is granted in the Member State for which the application is made. [38]

122. That analysis is confirmed inter alia by the order of the Court in *Yissum*, [39] in which the Court dealt with the interpretation of Regulation No 1768/92 in a case in which a patented active ingredient was placed on the market in a number of medicinal products and the supplementary protection certificate was not applied for with reference to the first medicinal product authorised in the Member

37 — Those time-limits are designed to respect, first, the interests of the patent proprietor and, second, those of third parties wishing to know as early as possible whether or not the product in question will be protected by an SPC (*AHP Manufacturing*, cited above in footnote 16, paragraph 28).

38 — With regard to that combined operation of Articles 7(1) and 3(b) and (d) of Regulation No 469/2009, see Case C-66/09 *Kirin Amgen* [2010] ECR I-7943, paragraph 36, and Case C-127/00 *Hässle* [2003] ECR I-14781, paragraph 26.

39 — Case C-202/05 [2007] ECR I-2839.

State in which the application was made, which contained the patented active ingredient. In the main proceedings, the applicant had tried to justify its reliance on the medicinal product authorised later by a reference to the differing therapeutic uses of the patented active ingredient in the various medicinal products. [40] That line of argument, which could lead to a circumvention of the rule in Article 3(d) of the regulation, was rejected by the Court on the ground that the concept of 'product' within the meaning of Article 1(b) of the regulation does not include the therapeutic use of an active ingredient protected by a basic patent. [41]

123. The rule that, where there are several medicinal products with the same patented active ingredient, the supplementary protection certificate must be applied for on the basis of the first authorisation to place on the market the medicinal product which was authorised as the first medicinal product with that active ingredient in the Member State in which the application is submitted also makes sense within the overall scheme of Regulation No 469/2009. Because the supplementary protection certificate relates to the active ingredient or combination of active ingredients which is the subject-matter of the basic patent, the grant of a supplementary protection certificate on the basis of the first medicinal product containing that active ingredient or combination of active ingredients leads to the result that all later medicinal products in which the active ingredient or combination of active ingredients under certificate protection is used are also protected against production and distribution by third parties within the limits of the protection conferred by the basic patent, in accordance with the requirements of Articles 4 and 5 of Regulation No 469/2009. [42]

124. In the light of the above, the sixth question referred in *Medeva* and the sole question referred in *Georgetown University and Others* must be answered to the effect that a valid authorisation to place the product on the market as a medicinal product within the meaning of Article 3(b) of Regulation No 469/2009 exists for a single active ingredient or combination of active ingredients where that active ingredient or combination of active ingredients is contained together with one or more other active ingredients in a medicinal product which was the subject of a valid marketing authorisation granted in accordance with Directive 2001/83 or Directive 2001/82.

40 — The active ingredient in question had been placed on the market in three different medicinal products: as an aqueous solution for intravenous injection, as soft gelatine capsules for oral administration and as an ointment.

41 — Ibid., paragraph 18.

42 — See, in that regard, point 105 et seq. of this Opinion.

## VII — Conclusion

125. In the light of the foregoing considerations, I propose that the Court answer the questions referred for a preliminary ruling as follows:

'A — *Questions 1 to 5 of the Court of Appeal (England and Wales) (Civil Division) (Case C-322/10)*

(1) The condition for the classification of an active ingredient or combination of active ingredients of a medicinal product as a product within the meaning of Article 3(a) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products is that that active ingredient or combination of active ingredients forms the subject-matter of a basic patent within the meaning of Article 1(c) of that regulation. Whether an active ingredient or combination of active ingredients of a medicinal product forms the subject-matter of a basic patent within the meaning of Article 1(c) and whether that active ingredient or combination of active ingredients is protected by a basic patent in force in accordance with the requirement of Article 3(a) are determined, in principle, according to the rules governing the basic patent. However, the definition of the basic patent laid down in Article 1(c) of the regulation precludes use of the protective effect of the basic patent from being invoked as a criterion for the purpose of answering the question whether an active ingredient or combination of active ingredients of a medicinal product forms the subject-matter of a basic patent.

(2) In the context of the assessment of a supplementary protection certificate application relating to a medicinal product with multiple active ingredients or to a multi-disease vaccine, there are no further or different criteria for determining whether a product within the meaning of Article 3(a) of Regulation No 469/2009 exists and whether that product is protected by a basic patent in force.

(3) The questions whether a multi-disease vaccine can be classified as a product within the meaning of Article 3(a) of Regulation No 469/2009 and whether that product is protected by a basic patent in force where only one of its active ingredients or each of its active ingredients against one of the diseases is protected by a basic patent in force must, in principle, be answered according to the rules governing the basic patent. However, the protective effect of the basic patent must not be used as a criterion for the purpose of answering the question whether a product within the meaning of Article 3(a) of the regulation exists.

B — *Sixth question of the Court of Appeal (England and Wales) (Civil Division) (Case C-322/10) and sole question of the High Court of Justice of England and Wales Chancery Division (Patents Court) (Case C-422/10)*

(4) A valid authorisation to place the product on the market as a medicinal product within the meaning of Article 3(b) of Regulation No 469/2009 exists for a single active ingredient or combination of active ingredients where that active ingredient or combination of active ingredients is contained together with one or more other active ingredients in a medicinal product which was the subject of a valid marketing authorisation granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC.'