Court of Justice EU, 21 June 2018, Pfizer v Orifarm

PATENT LAW – SPCs

Holder of an SPC issued in another Member State than the new Member States is authorised by the Specific Mechanisms to oppose the parallel importation of a medicinal product where the legal systems of those States did not yet provide for such a possibility at the time when the application for a basic patent was filed,

- **with the result that it was impossible for the holder to obtain an equivalent patent and SPC.**

57 In the light of the foregoing considerations, the answer to the first and second questions is that the Specific Mechanisms must be interpreted as authorising the holder of an SPC issued in a Member State other than the new Member States to oppose the parallel importation of a medicinal product from the new Member States in a situation where the legal systems of those States provided for the possibility of obtaining equivalent protection at the time when the application for the basic patent was published and/or the application for an SPC in the importing Member State was filed, but did not yet provide for such a possibility at the time when the application for a basic patent was filed, with the result that it was impossible for the patent holder to obtain an equivalent patent and SPC in the exporting States.

Specific mechanisms apply to the extension provided for in Article 36(1) of the Regulation on medicinal products for paediatric use.

- **Having regard to the foregoing, the answer to the third and fourth questions is that the Specific Mechanisms must be interpreted as applying to the extension provided for in Article 36(1) of Regulation No 1901/2006.**

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Court of Justice EU, 21 June 2018, Pfizer v Orifarm
(M. Ilešič, A. Rosas, C. Toader (Rapporteur), A. Prechal and E. Jarašiūnas)
JUDGMENT OF THE COURT (Second Chamber)
21 June 2018 (*)
(Reference for a preliminary ruling — Intellectual and industrial property — Patent law — Acts of Accession to the European Union of 2003, 2005 and 2012 — Specific Mechanism — Whether applicable to parallel imports — Regulation (EC) No 469/2009 — Product protected by a supplementary protection certificate in a Member State and marketed by the holder of the basic patent in another Member State — Exhaustion of intellectual and industrial property rights — No basic patent in the new Member States — Regulation (EC) No 1901/2006 — Extension of the protection period)
In Case C‑681/16,
REQUEST for a preliminary ruling under Article 267 TFEU from the Landgericht Düsseldorf (Regional Court, Düsseldorf, Germany), made by decision of 15 December 2016, received at the Court on 27 December 2016, in the proceedings
Pfizer Ireland Pharmaceuticals, Operations Support Group
v
Orifarm GmbH,
THE COURT (Second Chamber),
composed of M. Ilešič, President of the Chamber, A. Rosas, C. Toader (Rapporteur), A. Prechal and E. Jarašiūnas, Judges,
Advocate General: E. Tanchev,
Registrar: K. Malacek, Administrator,
having regard to the written procedure and further to the hearing on 15 November 2017,
after considering the observations submitted on behalf of:
– Pfizer Ireland Pharmaceuticals, Operations Support Group, by J. Feldges and B. Kramer, Rechtsanwälte, and by M. Struys, avocat,
– Orifarm GmbH, by A. Rosenfeld, A. Okonek, and L. Manthey, Rechtsanwälte,
– the European Commission, by T. Scharf and J. Samnadda, acting as Agents,
after hearing the Opinion of the Advocate General at the sitting on 7 February 2018,
gives the following
Judgment
1. This request for a preliminary ruling concerns the interpretation of the Specific Mechanisms laid down in Chapter 2 of Annex IV to the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (OJ 2003 L 236, p. 33, and corrigendum OJ 2004 L 126, p. 2; ‘the Act of Accession of 2003’), in Chapter 1 of Annex V to the Act concerning the conditions of accession of the Republic of Bulgaria and Romania and the adjustments to the Treaties on which the European Union is founded (OJ 2005 L 157, p. 203; ‘the Act of Accession of 2005’), and in Chapter 1 of Annex IV to the Act concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community (OJ 2012 L 112, p. 21; ‘the Act of Accession of 2012’), and the

interpretation 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 (OJ 2009 L 152, p. 1; 'the SPC Regulation') and of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ 2006 L 378, p. 1).

2. The request has been made in proceedings between Pfizer Ireland Pharmaceuticals, Operations Support Group and Orifarm GmbH concerning parallel imports into Germany of the medicinal product 'Enbrel' from new Member States.

Legal context

The Act of Accession of 2003

3. Chapter 2 of Annex IV to the Act of Accession of 2003, entitled 'Company law', provides:

'Specific Mechanism

With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia or Slovakia, the holder, or his beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.

Any person intending to import or market a pharmaceutical product covered by the above paragraph in a Member State where the product enjoys patent or supplementary protection shall demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given to the holder or beneficiary of such protection.'

The Act of Accession of 2005

4. Chapter 1 of Annex V to the Act of Accession of 2005, entitled '*Company law*', is worded as follows:

'Specific Mechanism

With regard to Bulgaria or Romania, the holder, or his beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.

Any person intending to import or market a pharmaceutical product covered by the above paragraph in a Member State where the product enjoys patent or supplementary protection shall demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given to the holder or beneficiary of such protection.'

The Act of Accession of 2012

5. Chapter 1 of Annex IV to the Act of Accession of 2012, entitled '*Intellectual property law*', states:

'Specific Mechanism

With regard to Croatia, the holder, or the holder's beneficiary, of a patent or Supplementary Protection Certificate (SPC) for a medicinal product filed in a Member State at the time when such protection could not be obtained in Croatia for that product, may rely on the rights granted by that patent or SPC in order to prevent the import and marketing of that product in the Member State or Member States where the product in question enjoys patent or SPC protection, even if this product was put on the market in Croatia for the first time by the holder or with the holder's consent.

Any person intending to import or market a medicinal product covered by the first paragraph in a Member State where the product enjoys patent or SPC protection shall demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given to the holder or beneficiary of such protection.'

Regulation No 1901/2006

6. Recitals 4, 26 and 27 of Regulation No 1901/2006 are worded as follows:

'(4) This Regulation aims to facilitate the development and accessibility of medicinal products for use in the paediatric population, to ensure that medicinal products used to treat the paediatric population are subject to ethical research of high quality and are appropriately authorised for use in the paediatric population, and to improve the information available on the use of medicinal products in the various paediatric populations. These objectives should be achieved without subjecting the paediatric population to unnecessary clinical trials and without delaying the authorisation of medicinal products for other age populations.

...

(26) For products falling within the scope of the requirement to submit paediatric data, if all the measures included in the agreed paediatric investigation plan are complied with, if the product is authorised in all Member States and if relevant information on the results of studies is included in product information, a reward should be granted in the form of a 6-month extension of the [SPC] created by Council Regu47lation (EEC) No 1768/92 [of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1)]. ...

(27) An application for an extension of the duration of the certificate pursuant to this Regulation should only be admissible where a certificate is granted pursuant to Regulation [No 1768/92].'

7. Article 36(1) of Regulation No 1901/2006 states:
'Where an application under Article 7 or 8 includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or [SPC] shall be entitled to a six-month extension of the period referred to in Articles 13(1) and 13(2) of Regulation [No 1768/92].'

The SPC Regulation

8. Recitals 2, 4, 5, 6, 8 and 10 of the SPC regulation read as follows:
'(2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.
...
(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.
...
(8) Therefore, the provision of [an SPC] 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.
...
(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.'

9. Article 1 of the SPC Regulation, entitled *'Definitions'*, states:
'For the purposes of this Regulation, the following definitions shall apply:
(a) "medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings ...;
(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 [SPC];
...'

10. Article 3 of the SPC Regulation, entitled 'Conditions for obtaining a certificate', is worded as follows:
'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 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)] ...;
(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.'

11. Article 4 of that regulation, entitled 'Subject matter of protection', provides:
'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.'

12. Article 5 of the SPC Regulation reads as follows:
'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.'

13. Article 6 of the SPC Regulation, headed 'Entitlement to the certificate', provides that the SPC is to be granted to the holder of the basic patent or his successor in title.

14. Paragraphs 1, 3, 4 and 5 of Article 7 of the regulation, entitled *'Application for a certificate'*, provide as follows:
'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.
...
3. The application for an extension of the duration may be made when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements of Article 8(1)(d) or Article 8(2), respectively, are fulfilled.
4. The application for an extension of the duration of a certificate already granted shall be lodged not later than two years before the expiry of the certificate.
5. Notwithstanding paragraph 4, for five years following the entry into force of Regulation [No 1901/2006], the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate.'

15. Under Article 13 of the regulation, entitled *'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.

3. The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of Regulation [No 1901/2006] applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.

...'

16. According to the correlation table in Annex II to that regulation, the provisions of Article 13(1), (2) and (3) of Regulation No 1768/92 correspond to those of Article 13(1), (2) and (3) of the SPC Regulation.

The dispute in the main proceedings and the questions referred for a preliminary ruling

17. The applicant in the main proceedings, Pfizer Ireland Pharmaceuticals, Operations Support Group, established in Ireland, is a pharmaceutical company of the Pfizer Group, to which Pfizer Pharma GmbH, a sister company of the applicant in the main proceedings, established in Germany, also belongs.

18. According to the statement made by the applicant in the main proceedings during the hearing before the Court, the Pfizer Group purchased the pharmaceutical company Wyeth Pharma and its assets in October 2009, including, inter alia, the SPC, the grant of which that company had applied for on 26 June 2003 on the basis of European patent No 0 939 121 ('the SPC at issue') and the authorisation to place the medicinal product Enbrel on the market ('the marketing authorisation'). Enbrel is manufactured by the applicant in the main proceedings in Germany and is marketed in several other countries for the treatment of arthritis. The SPC at issue covered the protein etanercept, an active ingredient of that medicinal product.

19. AHP Manufacturing BV held the basic patent at issue in the main proceedings, which had been applied for on 31 August 1990 by the pharmaceutical company Roche on the basis of the Swiss priorities of 12 September 1989, 8 March 1990 and 20 April 1990. That application was published on 1 September 1991.

20. The first marketing authorisation for the medicinal product Enbrel was granted to Wyeth Pharma on 1 February 2000 for Switzerland, which also had effect for the European Union.

21. On 11 January 2006, the Deutsches Patent- und Markenamt (German Patent and Trade Mark Office) granted the SPC at issue for Germany.

22. Following the expiry of the basic patent at issue in the main proceedings, on 31 August 2010, the SPC at issue entered into force on 1 September 2010, for a period expiring on 1 February 2015.

23. By decision of the German Patent and Trade Mark Office of 15 October 2012, the duration of the SPC at issue was extended until 1 August 2015 under the combined provisions of the SPC Regulation and Regulation No 1901/2006.

24. The defendant in the main proceedings, established in Germany, is an undertaking in the Danish group Orifarm, operating as a parallel importer of medicinal products.

25. It is apparent from the file before the Court that the defendant in the main proceedings informed Pfizer Pharma in November 2012 of its intention to carry out parallel imports from Estonia and Latvia mainly and — from February 2015 — from Bulgaria, the Czech Republic, Hungary, Poland, Romania, Slovakia and Slovenia. By a considerable amount of written correspondence with the defendant in the main proceedings between 2012 and 2015, Pfizer Pharma repeatedly opposed those imports.

26. In April 2015, it came to the attention of Pfizer Pharma that packages of the medicinal product Enbrel, which had been manufactured for Poland, Slovenia, Lithuania and Croatia, and all of which identified the defendant in the main proceedings as a parallel importer, were available on the German market.

27. Given that the Specific Mechanisms laid down in the Acts of Accession of 2003, 2005 and 2012 ('the Specific Mechanisms') prevent parallel imports of the products concerned into Germany, the applicant in the main proceedings brought an action on 1 June 2015 before the Landgericht Düsseldorf (Regional Court, Düsseldorf, Germany) for infringement of the SPC at issue and for its extension.

28. It seeks, in the first place, an injunction prohibiting the importation, possession, offering for sale and placing on the market of the medicinal product Enbrel. The information before the Court shows that the applicant in the main proceedings withdrew, after 1 August 2015, the first head of claim following the expiry of the SPC at issue. It seeks, in the second place, orders requiring the disclosure of information about those activities for the period from 1 September 2010 to 1 August 2015, including the submission of copies of invoices, and the recall and destruction of the imported products, and, in the third place, a declaration of a right to damages.

29. The applicant in the main proceedings is of the opinion that the date on which the levels of protection should be compared, for the purpose of examining the applicability of the Specific Mechanisms, is the date on which the application for the basic patent was filed in the importing Member State. It also argues that the concept of 'extension' of the SPC must be understood as meaning that it is included in the concept of an *'SPC'* for the purposes of the Specific Mechanisms, even though Regulation No 1901/2006, which governs that extension, was not in force at the time when the Acts of Accession of 2003 and 2005 were concluded.

30. For its part, the defendant in the main proceedings argues before the referring court that the Specific Mechanisms are inapplicable on the ground that, on the date of the filing of the application for the SPC at issue, equivalent protection should have been obtained in the new Member States in question. In that regard, it

submits that the basic patent and the SPC must be considered separately.

31. It is apparent from the order for reference that it is common ground between the parties that, on the date on which the application for the basic patent was filed, namely 31 August 1990, it was impossible to obtain equivalent protection for the product at issue in the main proceedings in all of the new Member States in question and that, on the date on which the application for the SPC at issue was filed, namely 26 June 2003, it was possible to obtain protection of that product by means of an SPC in all those States, with the exception of Croatia.

32. In that regard, the referring court considers, in the light of the **judgment of 15 January 2015, Forsgren** (C‑631/13, EU:C:2015:13), that the basic patent and the SPC are protection rights that are both independent and closely connected and points out that the possibility of obtaining protection by means of an SPC in the new Member States in question at the time when the application for the SPC at issue for Germany was filed must be examined in the light of the fact that the product at issue in the main proceedings could not be protected in those States at the time when the application for the basic patent at issue in the main proceedings was filed.

33. According to the referring court, the contention that the basic patent is a necessary condition for the subsequent grant of an SPC is an argument in favour of taking into account the date on which the application for the basic patent was filed. It does, however, acknowledge that such an interpretation could result in a disproportionate restriction of the principle of exhaustion and of the free movement of goods.

34. As the referring court is also uncertain as to whether the Specific Mechanisms cover the SPC extension — if the question is answered in the affirmative, the defendant in the main proceedings would not be able to rely on the exhaustion of rights for the period from 1 February to 1 August 2015 — that court observes that the wording of the Acts of Accession merely distinguishes the basic patent from the SPC and does not refer to Regulation No 1901/2006. According to the referring court, the fact that the purpose of the SPC and that of its extension are identical nonetheless supports that affirmative answer. It notes, however, that that reasoning is opposed by the need to interpret the Specific Mechanisms narrowly, as well as the regard to be had to the hierarchy of norms, inasmuch as a secondary legislative act, in the present case Regulation No 1901/2006, would broaden — in some cases ex post facto — the scope of primary legislative acts, namely the Acts of Accession of 2003, 2005 and 2012 laying down the Specific Mechanisms.

35. In those circumstances, the Landgericht Düsseldorf (Regional Court, Düsseldorf) decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

‘(1) Can the holder of [an SPC] that was issued to it for [Germany] rely on the Specific Mechanism to prevent the importation of products into [Germany] from the Accession States the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria, Romania and Croatia […] if the [SPC] was applied for in [Germany] at a time at which the laws for obtaining such [an SPC] already existed in the respective Accession States but could not be applied for by, or issued to, the holder of the […] certificate issued for [Germany] because the basic patent required for the issuing of the [SPC] did not exist in the Accession State?

(2) Does it make any difference to the answer to the first question if it was merely at the time of the filing of the application for the basic patent issued for [Germany] that such protection through a basic patent could not be obtained in the Accession State but, by the time of publication of the application on which the basic patent issued for the Federal Republic of Germany was based, it could be so obtained?

(3) Can the holder of [an SPC] that was issued to it for [Germany] rely on the Specific Mechanism to prevent the importation of products into [Germany] from the Accession States the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria, Romania and Croatia if those products are imported after the expiry of the term of the [SPC] stipulated in the original decision to grant the patent but before the expiry of the six-month extension of the term of the [SPC] that was granted to it on the basis of Regulation [No 1901/2006]?

(4) Does it make any difference to the answer to the third question, in the case of Croatia, that, on account of the accession of Croatia in 2013, the Specific Mechanism did not come into force until after the entry into force of Regulation [No 1901/2006] — unlike in the other Member States which acceded prior to 26 January 2007, namely the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria and Romania?’

Consideration of the questions referred

The first and second questions

36. By the first and second questions, which it is appropriate to examine together, the referring court asks, in essence, whether the Specific Mechanisms must be interpreted as authorising the holder of an SPC issued in a Member State other than the new Member States to oppose the parallel importation of a medicinal product from those new Member States in a situation where the legal systems of those States provided for the possibility of obtaining equivalent protection at the time when the application for the basic patent was published and/or the application for an SPC in the importing Member State was filed, but did not yet provide for such a possibility at the time at which the application for a basic patent was filed, with the result that it was impossible for the patent holder to obtain an equivalent patent and an SPC in the exporting States.

37. More specifically, by those questions, the referring court seeks to determine the precise date in respect of which the level of protection in the importing Member State and the level of protection in the exporting States

should be compared for the purpose of applying the Specific Mechanisms.

38. By virtue of a general rule contained in Article 2 of the Acts of Accession of 2003, 2005 and 2012, the provisions of the original Treaties and the acts adopted by the institutions prior to the accession of the new Member States are binding on those States, from the date of their accession, and apply in those States under the conditions laid down in those Treaties and acts. It follows that, from the time of accession, the provisions of the Treaties relating to the free movement of goods and the principles deriving therefrom by virtue of the Court's case-law apply to trade between the new Member States and the other EU Member States.

39. As the Court has consistently held, the holder of an intellectual or industrial property right protected by the legislation of a Member State cannot rely upon that legislation to prevent the importation of a product which has been lawfully marketed in another Member State by the holder himself or with his consent (see, inter alia, **judgments of 14 July 1981, Merck,** 187/80, EU:C:1981:180, paragraph 12, and of **12 February 2015, Merck Canada and Merck Sharp & Dohme**, C‑539/13, EU:C:2015:87, paragraph 24).

40. However, as is the case in the Act concerning the conditions of accession of the Kingdom of Spain and the Portuguese Republic and the adjustments to the Treaties (OJ 1985 L 302, p. 23), the Acts of Accession of 2003, 2005 and 2012 lay down, as observed by the Advocate General in **point 47** of his Opinion, specific mechanisms that seek to achieve a balance between the free movement of goods and the effective protection of intellectual and industrial property rights granted under a basic patent. For that purpose, those mechanisms enable the holder of the basic patent to rely on his exclusive rights against importers in situations in which those rights would otherwise be exhausted under the Court's case-law. Those mechanisms therefore seek to prevent a situation in which full application of internal market principles after the accession of the new Member States would expose the holder of the basic patent to parallel imports from those States without having been able to protect his invention in those States and, as a result, without having received adequate compensation.

41. The Specific Mechanisms thus derogate from the free movement of goods. However, the Court has consistently held that provisions in an Act of Accession which permit exceptions to or derogations from rules laid down by the Treaties must be interpreted strictly (see, inter alia, **judgments of 5 December 1996, Merck and Beecham,** C‑267/95 and C‑268/95, EU:C:1996:468, paragraph 23, and of **12 February 2015, Merck Canada and Merck Sharp & Dohme**, C‑539/13, EU:C:2015:87, paragraph 25 and the case-law cited).

42. In the present case, although the wording of the provisions of Chapter 2 of Annex IV to the Act of Accession of 2003, of Chapter 1 of Annex V to the Act of Accession of 2005 and of Chapter 1 of Annex IV to the Act of Accession of 2012 is somewhat ambiguous, it is nonetheless the case that the phrase 'protection could not be obtained', used in those provisions, establishes a negative condition relating to the equivalence of the levels of protection to be compared. It follows that the application of the Specific Mechanisms to parallel imports depends on there being no such equivalent protection.

43. As regards the exact date on which the level of protection in the importing Member State and that in the exporting States must be compared, it follows from the use of the word 'filed' in the provisions cited in **paragraph 42 of this judgment** that that date is the date on which the application for protection was lodged.

44. In that regard, it must be pointed out that, although the original German version of the Acts of Accession of 2003 and 2005 used the word *'eingetragen'* (registered) instead of *'beantragt'* (filed), that version was rectified, in 2004 and 2011, by means of the second procès-verbal of rectification to the Treaty of Accession 2003 (OJ 2004 L 126, p. 2) and the procès-verbal of rectification to the Treaty of Accession 2005 (OJ 2011 L 347, p. 62) respectively. The Act of Accession of 2012 used the term *'beantragt'* from the outset.

45. In the present case, the basic patent at issue in the main proceedings was filed in Germany on 31 August 1990, at a time when equivalent protection was not yet provided for in the legislation of the 11 exporting States which would join the European Union in 2004, 2007 and 2013. For example, patent protection was introduced in Czechoslovakia only in November 1990, in Romania and Slovenia in 1992, in Poland and Latvia in 1993, and in Lithuania, Hungary and Estonia in 1994.

46. As observed by the referring court, the SPC at issue was, for its part, applied for in Germany on 26 June 2003, a date at which the legal systems of the exporting States already provided for the possibility of obtaining equivalent protection.

47. In those circumstances, the question is whether the date to be taken into account in order to compare the levels of protection in the importing Member State and the exporting States must be the date on which the application for the SPC was filed or the date on which the application for the basic patent was filed.

48. In order to answer that question, the purpose of the SPC must be taken into account.

49. In that regard, it should be recalled that the Court has consistently held that the SPC is designed simply to re-establish a sufficient period of effective protection of the basic patent by permitting the holder to enjoy an additional period of exclusivity on the expiry of that patent, which is intended to compensate, at least in part, for the delay to the commercial exploitation of his invention by reason of the time which has elapsed between the date on which the application for the patent was filed and the date on which the first marketing authorisation in the European Union was granted (judgment of 12 December 2013, Eli Lilly and

Company, C‑493/12, EU:C:2013:835, paragraph 41 and the case-law cited).

50. In order for an SPC to be granted, however, the cumulative conditions set out in Article 3 of the SPC Regulation must be fulfilled. That provision provides, in essence, that an SPC can be granted only if, at the date of the application, the product is protected by a basic patent in force and has not already been the subject of an SPC. In addition, that product must have been granted a marketing authorisation as a medicinal product which is still valid, in accordance with Directive 2001/83 or Directive 2001/82, as appropriate; and, lastly, that marketing authorisation must be the first in relation to that product as a medicinal product (judgment of 15 January 2015, Forsgren, C‑631/13, EU:C:2015:13, paragraph 32).

51. It follows from the considerations in **paragraphs 49** and **50** of this judgment that there is an unbreakable connection between the existence of an SPC and that of a basic patent, since, if there is no basic patent, a product cannot be protected by an SPC.

52. That finding is supported by the wording of several provisions of the SPC Regulation. Thus, Article 6 of that regulation provides that the SPC is to be granted to the holder of the basic patent or his successor in title. Article 13(1) of that regulation provides that the CCP 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 filed and the date of the first marketing authorisation in the European Union, reduced by a period of five years.

53. What is more, under Article 5 of the SPC Regulation, an SPC confers, upon the expiry of the basic patent, the same rights as were conferred by the patent in relation to the product in question, within the limits of the protection conferred by the patent, set out in Article 4 of that regulation. Accordingly, if, during the period in which the basic patent was valid, the patent holder could oppose, on the basis of the patent, all use or certain uses of his product in the form of a medicinal product consisting of such a product or containing it, the SPC granted in respect of that product would confer on the holder the same rights for all uses of the product, as a medicinal product, which were authorised before the expiry of the SPC (see, to that effect, order of 9 February 2012, Novartis, C‑574/11, not published, EU:C:2012:68, paragraph 18 and the case-law cited).

54. Consequently, although the legal systems of the exporting States already provided for the possibility of obtaining equivalent protection at the time when the SPC at issue was applied for, that possibility was in fact hypothetical, since a basic patent in each of those States is a necessary condition for effectively obtaining an SPC.

55. It is common ground that, at the time when the application for the basic patent at issue in the main proceedings in Germany was filed, on 31 August 1990, it was impossible for the patent holder to apply for equivalent protection in the exporting States, as the possibility of such protection was not introduced by those States until a later date.

56. In addition, if a later date than that on which the application for the basic patent was filed were to be considered decisive for comparing the level of protection in the importing State and that in the exporting States, this would jeopardise the balance, which the Specific Mechanisms seek to establish, between the effective protection of the rights granted by a basic patent or an SPC and the free movement of goods under the FEU Treaty, by imposing, in particular, an obligation on the patent holder continually to monitor the laws of any potential Accession State and even by according different treatment to patent holders who filed patent applications on the same day, depending on the length of the marketing authorisation procedure, over which patent holders have, as a general rule, no influence. Moreover, as observed by the Commission, in many cases the filing of a patent application in exporting States upon the entry into force of equivalent protection in those States would be bound to fail for want of novelty of the invention at that time.

57. In the light of the foregoing considerations, the answer to the first and second questions is that the Specific Mechanisms must be interpreted as authorising the holder of an SPC issued in a Member State other than the new Member States to oppose the parallel importation of a medicinal product from the new Member States in a situation where the legal systems of those States provided for the possibility of obtaining equivalent protection at the time when the application for the basic patent was published and/or the application for an SPC in the importing Member State was filed, but did not yet provide for such a possibility at the time when the application for a basic patent was filed, with the result that it was impossible for the patent holder to obtain an equivalent patent and SPC in the exporting States.

The third and fourth questions

58. By its third and fourth questions, which it is appropriate to examine together, the referring court asks, in essence, whether the Specific Mechanisms must be interpreted as applying to the extension provided for in Article 36(1) of Regulation No 1901/2006, although that extension is not expressly provided for in those mechanisms.

59. At the outset, it should be borne in mind that Article 36(1) of Regulation No 1901/2006 governs the SPC extension. According to recital 26 of that regulation, such an extension represents a reward for products falling within the scope of the requirement to submit paediatric data, if all the measures included in the agreed paediatric investigation plan are complied with, if the product is authorised in all Member States and if relevant information on the results of studies is included in product information.

60. Article 36(1) of Regulation No 1901/2006 provides that, where an application under Article 7 or 8 of the regulation includes the results of all studies conducted in compliance with an agreed paediatric investigation

plan, the holder of the basic patent or SPC is entitled to a six-month extension of the period referred to in Articles 13(1) and 13(2) of Regulation No 1768/92.

61. Regulation No 1768/92, which has been amended on several occasions, was codified, then repealed and replaced by the SPC Regulation. Article 22 of that regulation states that references to the repealed regulation are to be construed as references to the SPC Regulation.

62. Article 13(1) of the SPC Regulation provides that the SPC 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 filed and the date of the first market authorisation in the European Union, reduced by a period of five years. Article 13(2) of that regulation provides that the duration of the SPC cannot exceed five years from the date on which it takes effect.

63. It should also be noted that Article 13(3), inter alia, of the SPC Regulation also refers to Regulation No 1901/2006 and provides that the periods laid down in paragraphs 1 and 2 of Article 13 are to be extended by six months in the case where Article 36 of Regulation No 1901/2006 applies.

64. It follows that, according to a systematic interpretation of the provisions of the SPC Regulation, the SPC extension is not provided for in Regulation No 1901/2006 alone, but is also referred to in the SPC Regulation.

65. In addition, it should be noted that Article 36(1) of Regulation No 1901/2006 does not alter the substance of the SPC, but merely provides for its extension. That SPC extension is merely ancillary to the SPC itself, which is confirmed by the reference to it in Article 13 of the SPC Regulation, entitled *'Duration of the certificate'*.

66. The ancillary nature of an SPC extension in relation to the SPC itself is also apparent from the comparison of their respective subject matters and purposes.

67. Thus, it is apparent from recitals 2, 4, 5 and 6 of the SPC Regulation that the continuing improvement in public health through research is the main concern of the EU legislature. In the same vein, Regulation No 1901/2006 aims, according to recital 4 thereof, to facilitate the development and accessibility of medicinal products for use in the paediatric population and to ensure that medicinal products used to treat the paediatric population are subject to ethical research of high quality. The objective of Regulation No 1901/2006, like that of the SPC Regulation, is the improvement in public health, and the protection of a particularly vulnerable population in particular.

68. In those circumstances, it cannot be inferred from the fact, raised by the defendant in the main proceedings during the written and oral parts of the procedure before the Court, that the provisions establishing the Specific Mechanisms do not expressly mention the SPC extension and that Regulation No 1901/2006 was not part of the EU acquis at the time when the Acts of Accession of 2003 and 2005 were concluded, that that extension does not come within the scope of those mechanisms.

69. As observed in paragraphs 65 to 74 of the present judgment, it is apparent from the scheme of the SPC Regulation and of Regulation No 1901/2006, the objective of the paediatric extension — comparable to that of the SPC — and the close connection between the SPC and its possible extension that the extension must be included within the scope of those mechanisms.

70. Lastly, the fact that the Specific Mechanism provided for in the Act of Accession of 2012 expressly mentions only the basic patent and the SPC, as do the Acts of Accession of 2003 and 2005, even though Regulation No 1901/2006 had already entered into force when the Republic of Croatia joined the European Union, does not warrant the adoption of a different interpretation in relation to parallel imports originating from that Member State. Apart from the fact that that circumstance appears to be explicable on historical grounds, the intrinsic complementarity of the SPC and its extension can justify the choice of the EU legislature not to include the SPC extension in the text of the Specific Mechanisms.

71. Moreover, as observed by the Advocate General in **point 83** of his Opinion, if a new Member State were treated differently to the others, parallel imports could come in through that Accession State; as a result there would be a hole in EU patent protection which could ultimately render ineffective the protection created by the Specific Mechanisms of the other Acts of Accession.

72. As for the economic argument raised by the defendant in the main proceedings that parallel imports are desirable under EU law, as they lead to a fall in prices in the importing Member State, suffice it to note that such an argument can have no bearing on the appropriate interpretation of the Specific Mechanisms that, as recalled in **paragraph 40 of this judgment**, were established by the Acts of Accession of 2003, 2005 and 2012 with a view to achieving a balance between the free movement of goods and the efficient protection of intellectual and industrial property rights granted by a basic patent.

73. Having regard to the foregoing, the answer to the third and fourth questions is that the Specific Mechanisms must be interpreted as applying to the extension provided for in Article 36(1) of Regulation No 1901/2006.

Costs

74. Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Second Chamber) hereby rules:

1. The Specific Mechanisms laid down in Chapter 2 of Annex IV to the Act concerning the conditions of accession of the Czech Republic, the Republic of

Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded, in Chapter 1 of Annex V to the Act concerning the conditions of accession of the Republic of Bulgaria and Romania and the adjustments to the Treaties on which the European Union is founded, and in Chapter 1 of Annex IV to the Act concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community, must be interpreted as authorising the holder of a supplementary protection certificate issued in a Member State other than the new Member States referred to in those Acts of Accession to oppose the parallel importation of a medicinal product from those new Member States in a situation where the legal systems of those States provided for the possibility of obtaining equivalent protection at the time when the application for the basic patent was published and/or the application for a supplementary protection certificate in the importing Member State was filed, but did not yet provide for such a possibility at the time when the application for a basic patent was filed, with the result that it was impossible for the patent holder to obtain an equivalent patent and a supplementary protection certificate in the exporting States.

2. The Specific Mechanisms laid down in Chapter 2 of Annex IV to the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded, in Chapter 1 of Annex V to the Act concerning the conditions of accession of the Republic of Bulgaria and Romania and the adjustments to the Treaties on which the European Union is founded, and in Chapter 1 of Annex IV to the Act concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community, must be interpreted as applying to the extension provided for in Article 36(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004.

Opinion Advocate General Tanchev

OPINION OF ADVOCATE GENERAL TANCHEV

delivered on 7 February 2018(1)

Case C‑681/16

Pfizer Ireland Pharmaceuticals, Operations Support Group

v

Orifarm GmbH

(Request for a preliminary ruling from the Landgericht Düsseldorf (Regional Court, Düsseldorf, Germany))

(Preliminary ruling — Accession of new Member States — Acts of Accession — Specific Mechanism — Patent law — Medicine protected by a supplementary protection certificate — Regulation No 469/2009 — Paediatric prolongation of the protection — Regulation No 1901/2006 — Product protected in an old Member State and marketed in a new Member State without protection by the holder of the patent— Parallel imports — Exhaustion of intellectual property rights)

1. This request for a preliminary ruling from the Landgericht Düsseldorf (Regional Court, Düsseldorf, Germany) deals with parallel imports of medicine from new Member States into Germany. When comparable patent protection for pharmaceutical products was not available in those States, the Acts of Accession provide for an exception to the free movement of goods. The scope of that exception is at issue here.

2. In the main proceedings, the holder of a 'supplementary protection certificate for medicinal products' ('SPC') in Germany sought an injunction prohibiting such parallel imports from Bulgaria, Croatia, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, and Slovenia ('the new Member States concerned'), and consequently seeks remedies. The referring court therefore asks for an interpretation of the exception clauses, known as the 'Specific Mechanism', that are contained in these Member States' Acts of Accession of 2003, 2005 and 2012.

I. Legal framework

A. Acts of Accession to the European Union

3. Sentence 1 of Annex IV No 2 to the Act of Accession 2003 (2) states in the first paragraph:

'SPECIFIC MECHANISM With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia or Slovakia, the holder, or his beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.'

4. Sentence 1 of Annex V No 1 to the Act of Accession 2005 (3) in the first paragraph provides:

'SPECIFIC MECHANISM With regard to Bulgaria or Romania, the holder, or his beneficiary, of a patent or supplementary protection certificate for a

pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent protection or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.'

5. Sentence 1 of Annex IV No 1 first paragraph to the Act of Accession 2012 (4) is worded as follows:

'SPECIFIC MECHANISM With regard to Croatia, the holder, or the holder's beneficiary, of a patent or Supplementary Protection Certificate (SPC) for a medicinal product filed in a Member State at the time when such protection could not be obtained in Croatia for that product, may rely on the rights granted by that patent or SPC in order to prevent the import and marketing of that product in the Member State or Member States where the product in question enjoys patent or SPC protection, even if this product was put on the market in Croatia for the first time by the holder or with the holder's consent.'

B. Regulation No 469/2009 on the SPC

6. Article 3 of Regulation No 469/2009 (5) reads as follows:

'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;

…'

7. Article 7(1) of Regulation No 469/2009 states:

'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.'

8. Article 13(1) to (3) of Regulation No 469/2009 reads:

'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.

3. The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of Regulation No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.'

C. Regulation No 1901/2006 on the paediatric extension

9. The first subparagraph of Article 36(1) of Regulation No 1901/2006 (6)states:

'Where an application under Article 7 or 8 includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Articles 13(1) and 13(2) of Regulation (EEC) No 1768/92.'

II. The facts in the main proceedings and the questions referred for a preliminary ruling

10. Pfizer Ireland Pharmaceuticals, Operations Support Group, the plaintiff in the main proceedings, is an Irish-based pharmaceutical company in the Pfizer Group, and was the registered holder of an SPC (7) protecting the protein Etanercept. (8) Etanercept is an active substance of the drug Enbrel® that the plaintiff produces and markets in Germany and many other countries and is authorised for the treatment of arthritis in adults and in children. (9)

11. Orifarm GmbH, the defendant in the main proceedings, is a company in the Danish Orifarm Group and operates as a so-called parallel importer of medical products into Germany from countries with lower price levels.

12. An SPC grants a supplementary protection for a medicinal product that was protected by a basic patent and extends the rights under that patent for a certain period after its expiry. (10) The plaintiff's SPC was issued on the basis of a European basic patent (11)that had effect for the Federal Republic of Germany.

13. This patent had been filed on 31 August 1990 by the pharmaceutical company Roche, (12) which had developed the product and which was also able to utilise Swiss priorities of 12 September 1989, 8 March 1990 and 20 April 1990.

14. On 31 August 1990, none of the 11 new Member States concerned, which would join the EU in 2004, 2007 and 2013, provided for comparable rules for the protection of pharmaceutical products or specific therapeutic indications.

15. On 1 February 2000, the pharmaceutical company Wyeth Pharma, obtained an authorisation for Enbrel®, which allowed the marketing of that product. This authorisation was first issued in Switzerland and was also valid for the European Community.

16. On 26 June 2003, Wyeth Pharma applied for an SPC that was issued on 11 January 2006. (13) In 2009, the plaintiff acquired Wyeth Pharma, with all its assets, including the SPC. (14)

17. Upon expiration of the basic patent on 1 September 2010, the SPC entered into effect for a period which lasted until 1 February 2015.

18. In view of the authorisation of Enbrel® for the paediatric population and as a reward for the research undertaken for this population, on 15 October 2012, the German Patent and Trade Mark Office granted to the plaintiff a 'paediatric extension' of the SPC (15) by which the protection was extended for another six months and thus expired only on 1 August 2015.

19. Since 2012, the defendant had informed the plaintiff of its intention to carry out parallel imports from Estonia and Latvia and - from February 2015 - also from Bulgaria, the Czech Republic, Hungary, Poland, Rumania, Slovakia and Slovenia. The plaintiff repeatedly objected to this and an ongoing correspondence ensued.
20. In April 2015, the plaintiff finally discovered that packages of Enbrel®, which had been produced for Poland, Slovenia and Lithuania (for which an identical packaging is used) and also packages that had been produced for Croatia, all of which identified the defendant as the parallel importer, were available on the German market.
21. Therefore, on 1 June 2015, the plaintiff filed suit with the referring court, the Landgericht Düsseldorf (Regional Court, Düsseldorf), for infringement of its SPC, also taking into account its paediatric extension. The plaintiff requested (i) an injunction prohibiting the import, possession, offering for sale and placing on the market of Enbrel®, (16) and (ii) orders to disclose information about these activities for the period of 1 September 2010 to 1 August 2015, including the submission of copies of invoices, and to recall and destroy the products, and (iii) a declaration of a right to damages.
22. In the context of these proceedings, the defendant argues that it had lawfully acquired Enbrel® in the new Member States concerned and invokes the free movement of goods within the European Union. It refers to its defence of exhaustion. According to the principle of Community exhaustion, the exclusive rights granted by a patent or an SPC cannot be invoked for those products protected by the patent that are marketed in another Member State in a legal manner by the patent holder himself or with his consent, even if the product is imported from a Member State where it is not patentable. (17)
23. The plaintiff, however, pleads an exception to these principles, and it finds that exception in the Acts of Accession of the new Member States concerned. In fact, it submits, that the Acts of Accession of 2003, 2005 and 2012, under the term of *'Specific Mechanism'*, have codified a rule according to which the holder of a patent or SPC may, under certain conditions, rely on its rights to prevent the import of medicinal products from the new Member States concerned.
24. The principal condition for this Specific Mechanism to apply is that equivalent protection was not obtainable in these new Member States at the time when the patent or SPC was filed in the State of import. However, as it constitutes an exception to free movement of goods within the European Union, the Specific Mechanism needs to be interpreted narrowly. (18) That is why the referring court asks the Court to clarify the scope of application of the Specific Mechanism in the present case where an SPC as such was available in the Accession State at the relevant time but the requisite basic patent did not exist (first question) and whether it makes a difference if the basic patent could have been obtained in the Accession State by the time of publication of the German patent application (second question). With its third and fourth questions, the Landgericht Düsseldorf (Regional Court, Düsseldorf) queries whether and to what extent the Specific Mechanism applies to the paediatric extension, which is not expressly mentioned in the wording of the Acts of Accession.
25. It is in that context, that the Landgericht Düsseldorf (Regional Court, Düsseldorf) decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling:
'(1) Can the holder of a supplementary protection certificate that was issued to it for the Federal Republic of Germany rely on the Specific Mechanism to prevent the importation of products into the Federal Republic of Germany from the Accession States the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria, Romania and Croatia (Annex IV to the Act of Accession 2003; Part I of Annex V to the Act of Accession 2005; Annex IV to the Act of Accession 2012) if the supplementary protection certificate was applied for in the Federal Republic of Germany at a time at which the laws for obtaining such a supplementary protection certificate already existed in the respective Accession States but could not be applied for by, or issued to, the holder of the supplementary protection certificate issued for the Federal Republic of Germany because the basic patent required for the issuing of the supplementary protection certificate did not exist in the Accession State?
(2) Does it make any difference to the answer to Question 1 if it was merely at the time of the filing of the application for the basic patent issued for the Federal Republic of Germany that such protection through a basic patent could not be obtained in the Accession State but, by the time of publication of the application on which the basic patent issued for the Federal Republic of Germany was based, it could be so obtained?
(3) Can the holder of a supplementary protection certificate that was issued to it for the Federal Republic of Germany rely on the Specific Mechanism to prevent the importation of products into the Federal Republic of Germany from the Accession States the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria, Romania and Croatia if those products are imported after the expiry of the term of the supplementary protection certificate stipulated in the original decision to grant the patent but before the expiry of the six-month extension of the term of the supplementary protection certificate that was granted to it on the basis of Regulation No 1901/2006?
(4) Does it make any difference to the answer to Question 3, in the case of Croatia, that, on account of the accession of Croatia in 2013, the Specific Mechanism did not come into force until after the entry into force of Regulation No 1901/2006 – unlike in the other Member States which acceded prior to 26 January 2007, namely the Czech Republic, Estonia,

Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria and Romania?'

26. Written observations have been submitted to the Court by both parties to the main proceedings and the European Commission, all of whom presented oral argument at the hearing on 15 November 2017.

III. Assessment

27. I have come to the conclusion that the Specific Mechanism of the Acts of Accession applies to circumstances like the ones in the main proceedings, so that the plaintiff, as a holder of a German SPC with a paediatric extension, has the right, for the entire term of his protection, i.e. until 1 August 2015, to prevent the import into Germany of medicinal products marketed by him or with his consent in Bulgaria, Croatia, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, and Slovenia.

28. Along with the Commission and the plaintiff, I therefore propose answering the first and third questions in the affirmative and the second and fourth in the negative. My view is in line with the opinion of the referring court which indicates its preference with regard to the first two questions. The defendant's dissenting reasoning as to the first and third question is not convincing to me.

A. First question

29. By its first question, the referring court asks whether a situation such as that in the main proceedings where the plaintiff invokes his SPC to prevent parallel imports from new Member States falls within the scope of application of the Specific Mechanism, although at the time when he filed for the SPC in Germany, i.e. on 26 June 2003, laws for obtaining an SPC already existed in all of the respective Accession States except for Croatia. The answer to this is, in my opinion, '*yes*'.

1. Obtainability of an SPC in the Accession States

30. According to the wording, which in this regard is identical (19) in all three Acts of Accession relevant to the present case, the Specific Mechanism is applicable if '*… a Supplementary Protection Certificate (SPC) for a medicinal product [was] filed in a Member State at the time when such protection could not be obtained in [the Accession State] for that product*'.

31. This wording leaves no doubt that the concrete possibility of protection of the individual product in the Accession State is at issue. The Specific Mechanism does not content itself with the general availability of abstract rules providing for SPC protection in the Accession State, but rather looks at the particular situation and requires that 'for that product' such protection could not have been obtained in the Accession State.

32. In the situation at hand this was the case because, even though the laws of the Accession States concerned provided for an SPC, such a certificate can never be obtained without a basic patent and a basic patent did not exist in any of these States. Under these circumstances, one of the preconditions of an SPC could not be fulfilled and therefore SPC protection could not be obtained there.

33. The grant of an SPC requires fulfilment of four cumulative conditions, one of which is that a basic patent is in force at the date of the application for the SPC. (20)

34. Several aspects of the Regulation on the SPC indicate that the basic patent is the essential element of an SPC and that without a basic patent an SPC is just not conceivable: according to the regulation on the SPC, only a '*product protected by a patent in the territory of a Member State … may … be the subject of a certificate*'. (21) Also, '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'. (22) Finally without a basic patent, one would not even be able to determine the period of validity of the SPC, as '*the certificate shall take effect at the end of the lawful term of the basic patent*'. (23)

35. Consequently, an SPC cannot exist without a basic patent.

36. That patent must have been in force at the date of application for the SPC. (24)

37. Furthermore, the basic patent must have been valid in the country where the SPC is sought. This can be concluded from the fact that the SPC can only be granted by an authority of the Member State which granted the basic patent. (25) Thus, the plaintiff in the present case was not able to obtain an SPC with effect for an Accession State on the basis of its basic patent valid in Germany.

38. To summarise, '*such protection*', namely SPC protection, for 'that product' (Enbrel®) 'could', for lack of a basic patent, in fact 'not [have be]en obtained' in the new Member States concerned. Therefore, the preconditions of the Specific Mechanism, according to its wording, seem to be fulfilled. Nevertheless, I think that for the Specific Mechanism to apply, an additional requirement needs to be satisfied.

2. Obtainability of a basic patent in the Accession States as a precondition

39. The simple fact that a patent to which the SPC can be attached did not exist in these States cannot, in my view, suffice for allowing a far-reaching exception such as the one provided for by the Specific Mechanism.

40. Rather, I consider that the lack of a basic patent should be accepted as a valid reason for holding that the SPC '*could not be obtained*' only upon the condition that the basic patent itself could not have been obtained in that State.

41. This means that in a situation where, at the time, the holder of the German patent had simply not made the effort of seeking patent protection in the relevant Accession States, although that protection would have been available, he cannot rely on the Specific Mechanism.

42. It appears to me that such a restriction is necessary for the following reasons.

(a) Narrow interpretation of the Specific Mechanism

43. So far as concerns the protected products, the Specific Mechanism suspends the free movement of

goods for a transitional period and constitutes an express derogation from the principle of exhaustion.
44. According to the principle of Union-wide exhaustion, which is applicable in all Member States, the exclusive rights granted by a patent or an SPC cannot be invoked for products protected by the patent that are marketed in another Member State in a legal manner by the patent holder himself or with his consent, (26) even if the product is imported from a Member State where it is not patentable. (27)
45. As the Specific Mechanism, which provides for the possibility of preventing the import of the product from some of the EU Member States into others, establishes a derogation from that principle, the Court has held that it is to be construed narrowly. (28)
46. Taking into account the fact that the Specific Mechanism is also an exception to the free movement of goods, codified in the FEU Treaty, the Court has further clarified that a restrictive interpretation of provisions in an Act of Accession must limit the restriction to what is absolutely necessary to attain the objective pursued. (29)

(b) Purpose of the Specific Mechanism

47. Firstly, the Specific Mechanism seeks to achieve a balance between effective protection of patent or SPC rights and the free movement of goods. (30) For that purpose the Specific Mechanism enables the patent owner to rely on his exclusive rights against importers in situations in which these rights would otherwise be exhausted under the Court's case-law. (31) This is deemed justified for a limited period during which an interim regime takes into account the special situation created by an accession of new Member States: typically, the level of patent protection in Accession States has, prior to the accession, been lower than the protection prevalent in the old Member States, especially with respect to patents for pharmaceutical products. (32) The Specific Mechanism's aim is to prevent a situation where full application of internal market principles after the accession would lead to a situation in which the patent owner would be exposed to parallel imports from new Member States without having been able to protect his invention there and, as a result, without having received adequate compensation. (33)
48. Secondly, the interim regime created by the Specific Mechanism mitigates the harsh effect of an uncushioned, complete merger of the economies of the Accession States with the old Member States in the sensitive domain of the supply of pharmaceutical products. The lack of patent protection in the Accession States in the situation of separated markets leads to the price level being lower there. Free movement of goods would inevitably lead to a certain rise in price because of the additional demand created by parallel exports to the old Member States. This would produce a negative effect as to the accessibility of medicine in the new Member States. The Specific Mechanism therefore also contributes to a temporary preservation of the lower price level, for the benefit of public health in these States.
49. In view of the first purpose mentioned above, the restriction of the Specific Mechanism to situations where the lack of protection in the new Member State is not imputable either to the holder of the SPC or to the holder of the basic patent makes sense. This is because that is the only situation which the Specific Mechanism seeks to remedy, namely where the SPC holder or the respective holder of the basic patent is unable to protect his invention in the new Member State. If, conversely, the holder of the German basic patent had just refrained from protecting, or not taken care to protect his right in the Accession State, a lack of adequate compensation is imputable to him or his successor. As the Specific Mechanism is explicitly limited to cases where protection 'could not be obtained', there is no reason to apply that mechanism to cases where the unobtainability of the protection sought (the SPC) is due to the lack of a requisite basic protection which was, in itself, in fact obtainable but which the respective holder failed to apply for. This would constitute an expansion of the protection granted by the Specific Mechanism and be contrary to the abovementioned obligation to give it a narrow interpretation.
50. The abovementioned second purpose makes it necessary to consider the possible consequences that might occur if it were to be held that the SPC was unobtainable regardless of the reasons for which the basic patent did not exist. If the basic patent did not exist in the Accession Member State because the holder of the basic patent never asked for patent protection in that Accession Member State, although he could have done so, he himself will not be able to invoke the Specific Mechanism for his patent and thereby prevent parallel imports into the old Member State. Nevertheless, after the expiry of the term of the basic patent, the holder of the SPC could then invoke the Specific Mechanism in the old Member State for his SPC, if the SPC had to be considered unobtainable simply for lack of the basic patent. The effect of this would be that right after the accession, during the lawful term of the basic patent in the old Member State, free trade would take place, whereas, a while later, during the lawful term of the SPC in the old Member State, free movement of goods would be prevented.
51. This goes against the interim nature of the Specific Mechanism, which is designed to apply upon accession and not at a later time. It also corrupts the transitional nature of the Specific Mechanism, which aims to gradually adapt the circumstances to the new situation of a common market.
52. In such a scenario, the second purpose (34) could not be achieved. Once exports to the old Member States take place, the price level in the new Member States will inevitably rise and this is irreversible. Preventing imports only from the beginning of the SPC term onwards cannot restore the situation that existed before the accession.
53. The ensuing difference in treatment of the SPC and the patent would be incoherent and no reason for this

can be seen. This would not be compatible with the nature of the SPC as deriving from the basic patent.

3. Conclusion

54. To summarise, for an SPC valid in an old Member State to enable its holder to prevent imports from the new Member States under the Specific Mechanisms of 2003, 2005 and 2012, ultimately a two-step analysis is necessary: if at the time of filing an SPC in the old Member State, (1) the new Member State provides for SPC protection but (2) a basic patent to which the SPC could be attached at the date of application for the SPC could not have been obtained in that new Member State, the holder can prevent importation into the old Member State.

B. Second question

55. In view of the answer given to the first question, for SPC protection it is decisive whether or not a basic patent could have been obtained in the acceding Member State.

56. As none of the Member States at issue had equivalent patent protection at the time when the patent holder had filed his patent in Germany on 31 August 1990, but some of these States introduced patent protection for pharmaceutical products a few months or years after this date, the question arises whether the patent protection, required according to my answer given to the first question, must have already been available at the time of filing the patent in Germany or whether legislation introduced at a later time could be considered sufficient. (35) Naturally, the relevant date could not be after the date of publication of the German patent application (36) because, for want of novelty, from that moment on, a patent application could no longer succeed, also not in an Accession State.

1. Scope of protection of the patent holder in a situation of accession

57. In the present context, the patent is not required for patent protection but for the indirect effect it has, as a basic patent, of enabling SPC protection. Therefore, the protection could in fact be established any time before the application for the SPC was filed.

58. Nevertheless, I am of the opinion that the relevant date should be that of filing the application for the patent in the old Member State and not a period extended until the publication of that application.

59. It may well be that the introduction of new patent legislation would enable the patent holder to go back to the Accession State and apply for a patent there. Taking this into account would however result in imposing a burden of observation on the patent holder: he would have to monitor, until the moment of publication, whether new laws have come into force.

60. In my view, there is no reason to increase his duties beyond what the Act of Accession explicitly demands. It is true that the scope of the Specific Mechanism has to be kept narrow, (37) and that could arguably entail narrowing it down even further by increasing the burden on the SPC holder if he is to fall under that exception.

61. It should be noted, however, that the privilege granted by the Act of Accession in the Specific Mechanism in fact gives less protection to a holder of patent in an old Member State than what the Specific Mechanism aims to do. It aims to make up for the loss of adequate compensation that may ensue as a result of a combination of the free movement of goods and the principle of Union-wide exhaustion as a consequence of the accession of a country that was a third State at a relevant time. (38)

62. The instrument with which the Specific Mechanism tries to remedy that situation is imperfect, however. It does not take into account the fact that the accession of a new Member State is hardly foreseeable for an inventor. One could imagine that if the inventor refrained from seeking patent protection in 1990 for a small country, which, as a hypothesis, had a weak economy and a low standard of living, the inventor, in such an example, might well have considered not going through the trouble of seeking protection in that country, even though protection might have been available; on the other hand, with the knowledge that this State would eventually accede to the European Union, he might have envisaged the later occurrence of parallel imports based on free movement of goods in combination with Union-wide exhaustion, and his strategic business decision whether to file in that State at the time might well have been different. The Acts of Accession do not take into account the risk inherent in this prognosis, even though an inventor's legitimate expectations seem to be involved here.

63. Thus, as the holder of patent protection still bears that portion of the risk ('risk of accession of a former third State') on his own, I do not see any reason why — as to the other portion of the risk ('risk of availability of patent protection in the former third State') that the Acts of Accession aim to mitigate for him — the threshold should be raised and why he should bear any burden in the present context that is additional to what the Specific Mechanism expressly expects him to do in order to safeguard his rights.

64. What the Act of Accession expects him to do, however, is to file a patent in the Accession State at the time when the patent was 'filed' in the old Member State.

2. Date of filing in the old Member State

65. Although that last statement is clear from the wording of the Specific Mechanism in its English version ('… a patent … for a medicinal product filed in a Member State at the time when …'), (39) I would still like to briefly address the wording at issue, since the original German version of some of the Acts of Accession used by the requesting court did not employ the term 'filed' but 'registered'. If the decisive time was the date of registration rather than the date of filing, this may suggest that changes in the legislation of the new Member States entering into force after the filing of the application in the old Member State but before the patent was registered there could be relevant and give rise to an obligation of the patent holder to make use of these new laws. Under this hypothesis, a failure to use that opportunity would exclude the patent holder's reliance on the Specific Mechanism.

66. In fact, the original German version of the Acts of Accession of 2003 and 2005 used the term 'eingetragen' (registered) instead of 'beantragt' (filed). Nonetheless, this was considered a mistake and officially corrected, in 2004 and 2011, by proceedings ordering the rectification of these Acts. (40) The Act of Accession 2012 used the term 'beantragt' from the very beginning.
67. Looking at the entirety of language versions, also taking into account their rectifications, one can observe that with regard to the Act of Accession 2003, 20 out of 21, (41) with regard to the Act of Accession 2005, 22 out of 23 (42) and, with regard to the Act of Accession 2012, 23 out of 24 (43) language versions employ the term 'filed'. In the end only the Czech version of the Acts of 2003 and 2005 employed the term 'registered', but used 'filed' in the Act of 2012, whereas the Spanish version employed 'filed' in the Acts of 2003 and 2005, but for the Act of 2012 used 'registered'. Whenever the term was corrected by proceedings of rectification this was done by replacing 'registered' by 'filed' and never the opposite way. This is even true for the proceedings of rectification concerning the Spanish version of 2003, where 'registrado' was replaced by 'presentado'. (44) Therefore the return of the Spanish version of the Accession Act of 2012 to 'registrado' is clearly an isolated exception to the overall trend and a deviation from the otherwise uniform preference for the term 'filed'.
68. I am aware of the fact that all language versions of a legal act of the EU are equally authentic and that the majority version cannot simply prevail over the others. In the present case, however, in addition to the abovementioned evolution in the terminology quite clearly converging on the term 'filed', there are strong substantive arguments in favour of the majority version. Under the established case-law of the Court, in the event of difference in language versions, the provision in question must be interpreted by reference not to a particular language version, but to the purpose and general scheme of the rules of which it forms part. (45)
69. Two arguments militate in favour of holding the date of filing rather than the date of registration in the old Member State decisive in the context of the Specific Mechanism: firstly, if a patent holder wants to apply for protection in another State, he has to do so before publication of the application in the first State, because from that time on, as a general rule, protection will not be granted any more for lack of novelty of the invention, unless a priority can be invoked. Both events, however, can occur before the time of registration. That is why referring to the date of registration in the old Member State is not suitable to define the time by which protection has to be available in the Accession State.
70. Secondly, the purpose of the Specific Mechanism corroborates the wording used in the majority of language versions of the three Acts of Accession. As has been mentioned, the purpose does not require raising the threshold for the patentee who wants to benefit from the Specific Mechanism. (46) It is thus sufficient that he take the decision to apply for a patent in the Accession State when he deals with the matter in the old Member State, i.e. at the time when he files there. Any extension of the diligence required of him would place an undue burden on him and compromise the compensation he is meant to have for the consequences of the accession of a State to the EU, which was potentially unforeseeable for him at the time when he sought protection for his invention.

3. Conclusion

71. In view of the foregoing considerations, I come to the conclusion that the relevant time for the availability of patent protection in the Accession States, in the context of the question of the availability of SPC protection, is the date of filing of the basic patent in the old Member State. Therefore, I propose to answer the second question in the negative: it does not make a difference if in some Accession States a basic patent could have been obtained by the time of the publication of the patent holder's German application, if it was not obtainable at the date of filing of that application.

C. Third question

72. According to the defendant, the paediatric extension of the plaintiff's SPC does not fall within the scope of application of the Specific Mechanism.
73. I do not share that view. The defendant's arguments are not persuasive.
74. Firstly, the defendant argues that – unlike the patent and the SPC – the paediatric extension is not explicitly mentioned in the Specific Mechanism.
75. In order for the paediatric extension to fall within the scope of application of the Specific Mechanism, the Contracting States did not need to expressly mention it because, by its nature, it is not another protection right besides a patent and an SPC, but rather a simple extension of the protection term of an SPC. (47) This extension serves as a reward for having done ethically responsible studies as to the use of the relevant medicine for the paediatric population in conformity with European norms. (48) The ancillary nature of the paediatric extension is also confirmed by its mention in Article 13(3) of Regulation No 469/2009 on the SPC, which is entitled 'duration of the certificate'.
76. Secondly, the defendant submits that the Specific Mechanism could not be applied to the paediatric extension because Regulation No 1901/2006 was not part of the acquis communautaire when the Acts of Accession of 2003 and 2005 were concluded. In its view, the Specific Mechanism cannot apply to EU secondary law that came into existence only after the Act of Accession concerned.
77. Article 8 of the Act of Accession of 2003 and Article 7(2) of the Act of Accession of 2005, however, provide, with identical wording, that 'Acts adopted by the institutions to which the transitional provisions laid down in this Act relate shall retain their status in law; in particular, the procedures for amending those acts shall continue to apply'.
78. This shows that the Acts of Accession in no way preserve the acquis communautaire. Instead, the articles

cited above evince the Contracting Parties' awareness of the possibility of changes of secondary law referred to in these Treaties. (49)

79. Moreover, as regards the defendant's concerns as to the hierarchy of norms, it should be mentioned that the Court has held that, even when a rule is explicitly fixed in the Act of Accession itself, it can still be amended by secondary law afterwards. (50)

80. Also, I see no problem of retroactivity or legitimate expectations in the case at hand: according to settled case-law of the Court, new rules apply, as a matter of principle, immediately to the future effects of a situation which arose under the old rule. (51) The principle of legitimate expectations cannot be extended to the point of generally preventing a new rule from applying to the future effects of situations which arose under the earlier rule. (52) This applies especially in a field such as the common organisation of the markets, the purpose of which necessarily involves constant adjustment to the variations of the economic situations in the various sectors. (53)

81. This leads me to the conclusion that the paediatric extension falls within the scope of application of the Specific Mechanism, because it is a mere extension of the duration of an SPC and it is necessary to accept the modification that it brings about to the acquis communautaire in force when the Acts of Accession were concluded.

D. Fourth question

82. As to the Act of Accession of 2012 concerning the accession of Croatia, the answer to the third question should not be any different.

83. If one Accession Member State was treated differently than the others, parallel imports could come in through that State; as a result there would be a hole in EU patent protection which could ultimately negate the protection created by the Specific Mechanisms of the other Acts of Accession.

84. I see no reason to treat the situation of Croatia upon its accession to the EU differently than the one upon accession of the other new Member States concerned.

85. Even though Regulation No 1901/2006 providing for the possibility of a paediatric extension had already come into effect at the time of accession of Croatia, there was no reason for the Treaty to explicitly mention that possibility, because it is, as has been said above, not a proper protection right like the patent or the SPC, but a mere extension modifying the duration of such a right.

IV. Conclusion

86. In light of the foregoing, I propose that the Court answer the questions referred by the Landgericht Düsseldorf (Regional Court, Düsseldorf, Germany) to the following effect:

(1) The holder of a supplementary protection certificate that was issued to it for the Federal Republic of Germany can rely on the Specific Mechanism to prevent the importation of products into the Federal Republic of Germany from the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria, Romania and Croatia (Annex IV to the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded; Part I of Annex V to the Act concerning the conditions of accession of the Republic of Bulgaria and Romania and the adjustments to the Treaties on which the European Union is founded; Annex IV to the Act concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community) if the supplementary protection certificate was applied for in the Federal Republic of Germany at a time at which the laws for obtaining such a supplementary protection certificate already existed in the respective Accession States but could not be applied for by, or issued to, the holder of the supplementary protection certificate issued for the Federal Republic of Germany because the basic patent required for the issuing of the supplementary protection certificate did not exist in the abovementioned Accession State.

(2) It does not make any difference to the answer to Question 1 if it was merely at the time of the filing of the application for the basic patent issued for the Federal Republic of Germany that such protection through a basic patent could not be obtained in the Accession State but, by the time of publication of the application on which the basic patent issued for the Federal Republic of Germany was based, it could be so obtained.

(3) The holder of a supplementary protection certificate that was issued to it for the Federal Republic of Germany can rely on the Specific Mechanism to prevent the importation of products into the Federal Republic of Germany from the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria, Romania and Croatia if those products are imported after the expiry of the term of the supplementary protection certificate stipulated in the original decision to grant the patent but before the expiry of the six-month extension of the term of the supplementary protection certificate that was granted to it on the basis of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004.

(4) It does not make any difference to the answer to Question 3, in the case of Croatia, that, on account of the accession of Croatia in 2013, the Specific Mechanism did not come into force until after the entry into force of Regulation No 1901/2006 on 26 January 2007 – unlike in the other Member States which acceded prior to 26 January 2007, namely the Czech

Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia, Slovakia, Bulgaria and Romania.

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1. Original language: English.
2. Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded ('Act of Accession 2003', OJ 2003 L 236, p. 797).
3. Act concerning the conditions of accession of the Republic of Bulgaria and Romania and the adjustments to the Treaties on which the European Union is founded ('Act of Accession 2005', OJ 2005 L 157, p. 268).
4. Act concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community ('Act of Accession 2012', OJ 2012 L 112, p. 60).
5. 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 (Codified version) (OJ 2009 L 152, p. 1).
6. Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ 2006 L 378, p. 1).
7. By the number DE 103 99 023.
8. Etanercept is a TNF-binding protein, produced by way of genetic engineering. It serves as a TNF α-blocker (tumor necrosis factor alpha blocker).
9. Enbrel® is authorised for the treatment of rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis, and psoriasis in adults, as well as for the treatment of juvenile idiopathic arthritis and severe psoriasis in children and adolescents.
10. See Articles 2 to 5 of Regulation No 469/2009.
11. By the number EP 0939121, the German docket number being DE 590 10 933.
12. The patent applicant's name was given by the plaintiff's representative in the oral hearing, see minutes of the hearing, p. 20.
13. On the basis of a rectification decision of the German Patent and Trade Mark Office of 31 March 2006.
14. According to the plaintiff's representative's statement in the oral hearing, see minutes of the oral hearing, pp. 19 to 21.
15. Such an extension is granted under Article 36 of Regulation No 1901/2006 to give a reward and incentive for studies conducted to meet the specific therapeutic needs of the paediatric population.
16. In the main proceedings, the plaintiff, after 1 August 2015, modified this first claim into a claim for declaration of termination of the substantive dispute.
17. Judgment of 12 February 2015, Merck Canada and Merck Sharp & Dohme, C‑539/13, EU:C:2015:87, paragraph 24.
18. Judgments of 12 February 2015, Merck Canada and Merck Sharp & Dohme, C‑539/13, EU:C:2015:87, paragraph 25, and of 5 December 1996, Merck and Beecham, C‑267/95 and C‑268/95, EU:C:1996:468, paragraph 23.
19. In some language versions, there are differences which are not relevant in the context of the first question, see below point 65 et seq.
20. See judgment of 15 January 2015, Forsgren, C‑631/13, EU:C:2015:13, paragraph 32, which summarises the four conditions set out in Article 3 of Regulation No 469/2009 as follows: 'That provision provides, in essence, that an SPC can be granted only if, at the date of the application, the product is protected by a basic patent in force and has not already been the subject of a certificate. In addition, that product must have been granted a marketing authorisation as a medicinal product which is still valid …; and, lastly, that authorisation must be the first in relation to that product as a medicinal product.' Under the original version of the SPC, Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1), the seminal role of an existing patent protection was already clear, as Articles 2, 4 to 6 have not been changed in that respect.
21. Article 2 of Regulation No 469/2009.
22. Article 5 of Regulation No 469/2009.
23. Article 13(1) of Regulation No 469/2009.
24. Article 3 of Regulation No 469/2009.
25. Article 10(1) combined with Article 9(1) of Regulation No 469/2009.
26. See judgment of 31 October 1974, Centrafarm and de Peijper, 15/74, EU:C:1974:114, paragraphs 10 and 11; affirmed by the Court in the judgment of 12 February 2015, Merck Canada and Merck Sharp & Dohme, C‑539/13, EU:C:2015:87, paragraph 24.
27. Judgment of 12 February 2015, Merck Canada and Merck Sharp & Dohme, C‑539/13, EU:C:2015:87, paragraph 24; see also judgment of 31 October 1974, Centrafarm and de Peijper, 15/74, EU:C:1974:114, paragraph 10, and as to exhaustion with regard to the specific marketed products, but concerning trademarks, judgment of 3 June 2010, Coty Prestige Lancaster Group, C‑127/09, EU:C:2010:313, paragraph 31 and the case-law cited there.
28. Judgments of 12 February 2015, Merck Canada and Merck Sharp & Dohme,C‑539/13, EU:C:2015:87, paragraph 25, and of 5 December 1996, Merck and Beecham, C-267/95 and C‑268/95, EU:C:1996:468, paragraph 23.
29. Judgments of 12 February 2015, Merck Canada and Merck Sharp & Dohme, C‑539/13, EU:C:2015:87, paragraph 25, and of 28 April 2009, Apostolides, C‑

420/07, EU:C:2009:271, paragraph 35 and the case-law cited.
30. Judgment of 12 February 2015, Merck Canada and Merck Sharp & Dohme, C‑539/13, EU:C:2015:87, paragraph 25, and Opinion of Advocate General Jääskinen in the same case (EU:C:2014:2322, point 18).
31. Opinion of Advocate General Jääskinen in Merck Canada and Merck Sharp & Dohme (C‑539/13, EU:C:2014:2322, point 18).
32. Opinion of Advocate General Jääskinen in Merck Canada and Merck Sharp & Dohme (C‑539/13, EU:C:2014:2322, point 17), referring in footnote 9 to the origin (treaties such as EPC and TRIPS as indirect agents) of an advanced harmonisation of patent protection within the EU despite the fact that there is no substantive EU legislation on patents.
33. Opinion of Advocate General Jääskinen in Merck Canada and Merck Sharp & Dohme (C‑ 539/13, EU:C:2014:2322, point 17).
34. See above point 48.
35. Some of the acceding Member States concerned introduced patent protection for pharmaceutical products shortly after the present filing date of 31 August 1990. As Olivier Lemaire, 'Parallel trade of pharmaceutical products within the enlarged European Union', in: European Intellectual Property Review 2005, E.I.P.R. 2005, 27 (2), 43-52, p. 43 et seq. points out, providing further references, such protection was available in November 1990 in the (then still undivided) Czech Republic and Slovakia, in 1992 in Slovenia, in 1993 in Poland and Latvia and in 1994 in Lithuania, Hungary and Estonia.
36. According to the defendant's statement in the main proceedings the publication of this application took place on 1 September 1999.
37. See above point 43 et seq.
38. See above point 47.
39. My emphasis.
40. See Second Procès-Verbal of rectification to the Treaty of Accession 2003 (OJ 2004 L 126, p. 4) as well as Procès-Verbal of rectification to the Treaty of Accession 2005 (OJ 2011 L 347, p. 62). As to both Acts of Accession the German term 'eingetragen' has been modified to 'beantragt'. The Procès-Verbal of rectification of 2004 also corrected the following language versions: the Danish was modified from 'registreret'to 'indgivet', the Dutch version from 'geregistreerd' to 'aangevraagd', the French version from 'enregistré' to 'déposé', the Greek from 'καταχωρηθεί' to'κατατεθεί', the Portuguese from 'registrado' to 'pedido' and the Spanish from 'registrado' to 'presentado'. The Procès-Verbal of rectification of 2011 corrected, besides the German one, four other language versions that, in the Act of Accession 2005, at the outset had failed to use 'filed': The Dutch version was modified from 'geregistreerd' to 'aangevraagd', the Greek from 'καταχωρηθεί' to 'κατατεθεί', the Maltese from 'reġistrat' to 'depożitat' and the Romanian from 'înregistrat' to 'depusă'.
41. The Danish version employs 'indgivet', the Dutch 'aangevraagd', the English 'filed', the Estonian 'taotletud', the Finnish 'hakenut', the French 'déposé', the German 'beantragt', the Greek 'κατατεθεί', the Hungarian 'a bejelentést tették', the Irish 'arna chomhdú', the Italian 'presentato', the Latvian 'saņemšanai pieteikums', the Lithuanian 'paraiška paduota', the Maltese 'ppreżentat', the Polish 'zgłoszone', the Portuguese 'pedido', the Slovak 'predmetom prihlášky', the Slovenian 'je prijavljen', the Spanish 'presentado' and the Swedish 'lämnades in' which in all cases can be translated as 'filed' or 'submitted' or 'applied for', whereas the Czech version employs 'přihlášených', meaning 'registered'.
42. See the language versions enumerated in footnote 41 and additionally the Bulgarian version, which employs 'подадена заявка', and the Romanian version which employs 'depusă', whereas the Czech version still employs 'přihlášených' ('registered').
43. See footnotes 41 and 42. The Croatian version uses 'je prijava podnesena', meaning 'filed', whereas the Spanish version now employs 'registrado' ('registered').
44. See Second Procès-Verbal of rectification to the Treaty of 2003, OJ 2004 L 126, p. 4.
45. See judgment of 21 September 2016, Commission v Spain, C‑140/15 P, EU:C:2016:708, paragraph 80.
46. See above point 63.
47. See Article 36 of Regulation No 1901/2006.
48. See Article 36 of Regulation No 1901/2006 and recital 26.
49. Moreover, as the protection period of the pertaining right is extended by no more than six months, the interim character of the Specific Mechanism as a transitional provision is maintained. Patent protection usually being 20 years and SPC protection of up to 5 years, the 6 months extension at issue here does not change the nature of the period in a categorical way.
50. See judgment of 20 September 1988, Spain v Council, 203/86, EU:C:1988:420, paragraph 20.
51. See judgments of 14 April 1970, Brock, 68/69, EU:C:1970:24, paragraph 7, and of 10 July 1986, Licata v ESC, 270/84, EU:C:1986:304, paragraph 31.
52. See judgments of 14 January 1987, Germany v Commission, 278/84, EU:C:1987:2, paragraph 36; of 22 February 1990, Busseni, C‑221/88, EU:C:1990:84, paragraph 35; of 29 June 1999, Butterfly Music, C‑60/98, EU:C:1999:333, paragraph 25; and of 11 December 2008, Commission v Freistaat Sachsen, C‑334/07 P, EU:C:2008:709, paragraph 43.
53. See judgment of 20 September 1988, Spain v Council, 203/86, EU:C:1988:420, paragraph 19 and case-law cited, as to the agricultural sector (milk quota).