Court of Justice EU, 18 July 2013, Daiichi Sankyo and Sanofi Aventis v DEMO

PATENT LAW - TRIPs

Article 27 of the TRIPs Agreement falls within the field of the common commercial policy

- **to regard the rules on patentable subject-matter in Article 27 of the TRIPs Agreement as falling within the field of the common commercial policy rather than the field of the internal market correctly reflects the fact that the context of those rules is the liberalisation of international trade, not the harmonisation of the laws of the Member States of the European Union.**

That argument does not take sufficient account of the objective of the TRIPs Agreement in general and Part II of the agreement in particular.

The primary objective of the TRIPs Agreement is to strengthen and harmonise the protection of intellectual property on a worldwide scale (Case C-89/99 Schieving-Nijstad and Others [2001] ECR I-5851, paragraph 36). As follows from its preamble, the TRIPs Agreement has the objective of reducing distortions of international trade by ensuring, in the territory of each member of the WTO, the effective and adequate protection of intellectual property rights. Part II of the agreement contributes to attaining that objective by setting out, for each of the principal categories of intellectual property rights, rules which must be applied by every member of the WTO.

Admittedly, it remains altogether open to the European Union, after the entry into force of the FEU Treaty, to legislate on the subject of intellectual property rights by virtue of competence relating to the field of the internal market. However, acts adopted on that basis and intended to have validity specifically for the European Union will have to comply with the rules concerning the availability, scope and use of intellectual property rights in the TRIPs Agreement, as those rules are still, as previously, intended to standardise certain rules on the subject at world level and thereby to facilitate international trade.

Article 27 of the TRIPs Agreement concerns patentability, not the protection conferred

- **that Article 27 of the TRIPs Agreement concerns patentability, not the protection conferred by a patent. The question of the protection conferred by a patent is governed in particular by Article 28 of the agreement, 'Rights Conferred', Article 30, 'Exceptions to Rights Conferred', and Article 33, 'Term of Protection'.**

Pharmaceutical process patent does not, by reason of rules set out in Articles 27 and 70 TRIPs, have to be regarded from the entry into force of the agreement as covering the invention of pharmaceutical product

- **the answer to Question 3 is that a patent obtained following an application claiming the invention both of the process of manufacture of a pharmaceutical product and of the pharmaceutical product as such, but granted solely in relation to the process of manufacture, does not, by reason of the rules set out in Articles 27 and 70 of the TRIPs Agreement, have to be regarded from the entry into force of that agreement as covering the invention of that pharmaceutical product.**

Case Note – Dick van Engelen

Source: **curia.europa.eu**

Court of Justice EU, 18 July 2013

(V. Skouris, K. Lenaerts, A. Tizzano, M. Ilešič, L. Bay Larsen, T. von Danwitz, A. Rosas and E. Jarašiūnas, U. Lõhmus, J.-C. Bonichot, A. Arabadjiev, A. Prechal and C.G. Fernlund,)

JUDGMENT OF THE COURT (Grand Chamber)

18 July 2013 (*)

"Common commercial policy – Article 207 TFEU – Commercial aspects of intellectual property – Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) – Article 27 – Patentable subject-matter – Article 70 – Protection of existing subject-matter"

In Case C-414/11,

REQUEST for a preliminary ruling under Article 267 TFEU

from the Polimeles Protodikio Athinon (Greece), made by decision of 21 July 2011, received at the Court on 8 August 2011, in the proceedings

Daiichi Sankyo Co. Ltd,

Sanofi-Aventis Deutschland GmbH

v

DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon,

THE COURT (Grand Chamber)

composed of V. Skouris, President, K. Lenaerts, Vice-President, A. Tizzano, M. Ilešič (Rapporteur), L. Bay Larsen, T. von Danwitz, A. Rosas and E. Jarašiūnas, Presidents of Chambers, U. Lõhmus, J.-C. Bonichot, A. Arabadjiev, A. Prechal and C.G. Fernlund, Judges,

Advocate General: P. Cruz Villalón,

Registrar: K. Malacek, Administrator,

having regard to the written procedure and further to the hearing on 5 June 2012,

after considering the observations submitted on behalf of:
– Daiichi Sankyo Co. Ltd, by E. Metaxakis and K. Kilimiris, dikigori, and L. Van den Hende, advocaat,
– DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon, by E. Mikhalopoulou and G. Kotroni, dikigori,
– the Greek Government, by K. Paraskevopoulou, Z. Khatzipavlou, V. Kiriazopoulos and A. Zakhilas, acting as Agents,
– the German Government, by T. Henze and J. Kemper, acting as Agents,
– the French Government, by G. de Bergues, S. Menez and A. Adam, acting as Agents,
– the Italian Government, by G. Palmieri, acting as Agent, and S. Fiorentino, avvocato dello Stato,
– the Netherlands Government, by C. Wissels, acting as Agent,
– the Portuguese Government, by L. Inez Fernandes and A.P. Antunes, acting as Agents,
– the Finnish Government, by J. Heliskoski, acting as Agent,
– the Swedish Government, by A. Falk, acting as Agent,
– the United Kingdom Government, by A. Robinson, acting as Agent, and T. Mitcheson, Barrister,
– the European Commission, by C. Hermes and I. Zervas, acting as Agents,
after hearing **the Opinion of the Advocate General** at the sitting on 31 January 2013, gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Articles 27 and 70 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ('the TRIPs Agreement'), constituting Annex 1C to the Agreement establishing the World Trade Organisation (WTO), signed at Marrakesh on 15 April 1994 and approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ 1994 L 336, p. 1) ('the WTO Agreement').

2 The request has been made in proceedings between Daiichi Sankyo Co. Ltd ('Daiichi Sankyo') and Sanofi-Aventis Deutschland GmbH ('Sanofi-Aventis') and DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon ('DEMO') concerning the marketing by DEMO of a generic medicinal product whose active ingredient is a substance allegedly protected by patent rights of Daiichi Sankyo.

Legal context

The TRIPs Agreement

3 The preamble to the TRIPs Agreement states that it is intended to 'reduce distortions and impediments to international trade' and declares in that context 'the need to promote effective and adequate protection of intellectual property rights'.

4 In Section 5, 'Patents', of Part II of the TRIPs Agreement, 'Standards concerning the availability, scope and use of intellectual property rights', Article 27, 'Patentable Subject Matter', provides:

'1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application ... Subject to […] paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

[…]'

5 In Part VII of the TRIPs Agreement, 'Institutional arrangements; final provisions', Article 70, 'Protection of Existing Subject Matter', provides:

'1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.

2. Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement.

[…]

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application;

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement,

for those of these applications that meet the criteria for protection referred to in subparagraph (b).
[…]'

6 Part VI of the TRIPs Agreement, to which Article 70 refers, comprises Articles 65 to 67 of the agreement. Article 65(1) provides that 'no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement'.

The European Patent Convention

7 The Convention on the Grant of European Patents, signed in Munich on 5 October 1973, which entered into force on 7 October 1977, in the version in force at the time when the patent at issue in the main proceedings was obtained ('the EPC'), governs certain aspects of patents within the European States which have acceded to the convention. Its objectives include standardisation of the rules relating to the term of a patent, the concept of invention and the requirements for patentability.

8 Article 167 of the EPC, 'Reservations', provided:

'[…]
(2) Each Contracting State may reserve the right to provide that:
(a) European patents, in so far as they confer protection on chemical, pharmaceutical or food products, as such, shall, in accordance with the provisions applicable to national patents, be ineffective or revocable; this reservation shall not affect protection conferred by the patent in so far as it involves a process of manufacture or use of a chemical product or a process of manufacture of a pharmaceutical or food product;
[…]
(3) Any reservation made by a Contracting State shall have effect for a period of not more than ten years from the entry into force of this Convention. However, where a Contracting State has made any of the reservations referred to in paragraph 2(a) and (b), the Administrative Council may, in respect of such State, extend the period by not more than five years […]
[…]
(5) Any reservation made in accordance with paragraph 2(a), (b) or (c) shall apply to European patents granted on European patent applications filed during the period in which the reservation has effect. The effect of the reservation shall continue for the term of the patent.
(6) Without prejudice to paragraphs 4 and 5, any reservation shall cease to have effect on expiry of the period referred to in paragraph 3, first sentence, or, if the period is extended, on expiry of the extended period.'

Regulation (EEC) No 1768/92

9 Article 2 of 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) provided:

'Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure … may, under the terms and conditions provided for in this Regulation, be the subject of a [supplementary protection] certificate [(SPC)].'

10 Article 1 of Regulation No 1768/92 specified that the terms 'medicinal product' and 'product' referred to 'any substance or combination of substances presented for treating or preventing disease' and 'the active ingredient or combination of active ingredients of a medicinal product' respectively.

11 In accordance with Article 4 of that regulation, *'[w]ithin the limits of the protection conferred by the basic patent, the protection conferred by [an SPC] 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 [SPC]'.*

Article 5 of the regulation stated that *'[s]ubject to the provisions of Article 4, the [SPC] shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations'.*

12 The term 'basic patent' meant, in accordance with Article 1 of that regulation, *'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'.*

13 Article 13 of that regulation provided:

'1. The [SPC] 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 [SPC] may not exceed five years from the date on which it takes effect.'

14 Regulation No 1768/92 was repealed and replaced by 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), which entered into force on 6 July 2009. The provisions of Regulation No 1768/92 cited above were repeated in substance in Regulation No 469/2009.

Greek patent law

15 The Hellenic Republic ratified the EPC in 1986, subject to a reservation within the meaning of Article 167(2)(a) of the convention for pharmaceutical products. In accordance with Article 167(3), the reservation expired on 7 October 1992.

16 The TRIPs Agreement was ratified by the Hellenic Republic with effect from 9 February 1995.

17 The field of patents is further governed in Greece by Law No 1733/1987 on technology transfer, inventions, technological innovation and the establishment of an

atomic energy commission, which entered into force on 22 April 1987.

18 Article 5 of Law No 1733/1987 provides that a patentable invention may be a product, a process or an industrial application, and Article 7 of that law states that it is for the applicant for the patent to indicate, by means of claims, which of those is the subject-matter of the protection sought.

19 Article 11 of Law No 1733/1987 provides that the term of the protection conferred by a patent is 20 years and commences on the day after the filing of the patent application.

20 In accordance with Article 25(3) of Law No 1733/1987, '[a]s long as the reservation made by Greece under Article 167(2)[(a) of the EPC] remains in force, the [Organismos Viomikhanikis Idioktisias (Industrial Property Office)] shall not grant patents for pharmaceutical products'.

21 Pursuant to that law as interpreted by the Greek courts, that office was thus prohibited from granting national patents for pharmaceutical products, and only the grant of patents protecting the invention of a process of manufacture of a pharmaceutical product was authorised.

22 It was, moreover, also impossible for European and national patents to be granted for pharmaceutical products in the period between the entry into force of the EPC for the Hellenic Republic and the entry into force of Law No 1733/1987. In accordance with the primacy of international agreements over domestic laws under Article 28 of the Constitution, the scope of Law No 2527/1920 on patents, which was the predecessor of Law No 1733/1987, was interpreted, with respect to that period, as limited by the reservation made under the EPC.

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

23 Daiichi Sankyo was the holder in Greece of a national patent granted on 21 October 1986 relating to the chemical compound levofloxacin hemihydrate. That compound is used as an active ingredient in antibiotic treatments.

24 The application for that patent had been filed on 20 June 1986 and contained a claim for protection both for levofloxacin hemihydrate as such and for its process of manufacture.

25 The protection conferred by that patent, which was due to expire on 20 June 2006, was extended by an SPC pursuant to Regulation No 1768/92. In accordance with Article 13 of that regulation, the term of validity of that SPC could not exceed five years. Daiichi Sankyo therefore ceased to benefit from the patent in question in 2011.

26 Levofloxacin hemihydrate appears as the active ingredient in an original medicinal product called Tavanic. That medicinal product is distributed in Greece by Sanofi-Aventis, which holds a licence there, granted by Daiichi Sankyo, for the marketing of original pharmaceutical products whose active ingredient is levofloxacin hemihydrate. The authorisation to place Tavanic on the market was granted by the competent Greek authorities on 17 February 1999.

27 On 22 September 2008 and 22 July 2009 those authorities granted DEMO authorisations to place on the market generic medicinal products with the active ingredient levofloxacin hemihydrate. DEMO made preparations to market such a product under the name Talerin.

28 On 23 September 2009 Daiichi Sankyo and Sanofi-Aventis brought proceedings against DEMO before the Polimeles Protodikio Athinon (Court of First Instance, Athens), seeking inter alia the cessation of all marketing by DEMO of Talerin or any other medicinal product with the active ingredient levofloxacin hemihydrate, payment of a penalty payment per package of such a medicinal product, authorisation to seize and destroy any product infringing the patent in question in the possession of DEMO or a third party, and access to data relating to the manufacture and sale of Talerin or any other generic medicinal product with the same active ingredient.

29 That court explains that the outcome of the dispute pending before it depends on whether Daiichi Sankyo's SPC extended solely to a process of manufacture of the active ingredient levofloxacin hemihydrate or also to that active ingredient as such. In the case of protection of the 'product' within the meaning of Regulation No 1768/92, it would be sufficient for Daiichi Sankyo to prove that Tavanic and Talerin have the same active ingredient, in order to obtain a ruling that DEMO infringed its patent rights. If, on the other hand, the protection conferred by the SPC extended only to the process of manufacture, the fact that Tavanic and Talerin have the same active ingredient would only raise the presumption that the generic medicinal product was manufactured on the basis of the process protected by the SPC. In that case, it would be sufficient for DEMO to rebut that presumption by showing that that medicinal product was manufactured by a different process.

30 The referring court observes that, because pharmaceutical products were not patentable in Greece until 7 October 1992, Daiichi Sankyo's patent, applied for on 20 June 1986 and granted on 21 October 1986, originally did not protect the active ingredient levofloxacin hemihydrate as such. The court does not, however, exclude the possibility that the patentability of pharmaceutical products imposed by Article 27 of the TRIPs Agreement has the effect, having regard to the rules set out in Article 70 of that agreement, that since the entry into force of the TRIPs Agreement Daiichi Sankyo's patent rights extend to that active ingredient. It says that the Greek courts disagree as to the scope of those provisions of the TRIPs Agreement.

31 The referring court is uncertain, moreover, whether it is for that court or for the Court of Justice to interpret Article 27 of the TRIPs Agreement. It considers that that issue of jurisdiction is linked to the question whether that provision falls within a field for which the Member States continue to have primary competence.

32 In those circumstances, the Polimeles Protodikio Athinon decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'1. Does Article 27 of the TRIPs Agreement setting out the framework for patent protection fall within a field for which the Member States continue to have primary competence and, if so, can the Member States themselves accord direct effect to that provision, and can the national court apply it directly subject to the requirements laid down by national law?

2. Under Article 27 of the TRIPs Agreement, are chemical and pharmaceutical products patentable subject-matter provided that they satisfy the requirements for the grant of patents and, if so, what is the scope of their protection?

3. Under Articles 27 and 70 of the TRIPs Agreement, do patents covered by the reservation in Article 167(2) of the [EPC] which were granted before 7 February 1992, that is to say, before the above agreement entered into force, and concerned the invention of pharmaceutical products, but which, because of the aforementioned reservation, were granted solely to protect their production process, fall within the protection for all patents pursuant to the provisions of the TRIPs Agreement and, if so, what is the extent and content of that protection, that is to say, have the pharmaceutical products themselves also been protected since the above agreement entered into force, or does protection continue to apply to their production process only, or must a distinction be made based on the content of the application for grant of a patent, that is to say, as to whether, by describing the invention and the relevant claims, protection was sought at the outset for the product or the production process or both?'

33 By letter of 20 June 2012, received at the Court after the close of the written and oral procedures, Sanofi-Aventis and DEMO stated that, following the conclusion of an out-of-court settlement, Sanofi-Aventis had withdrawn from the action by Daiichi Sankyo against DEMO. In that letter they noted that the withdrawal had no effect on the mutual rights and claims of Daiichi Sankyo and DEMO.

Consideration of the questions referred

Admissibility

34 DEMO claims in its written observations that the request for a preliminary ruling is devoid of purpose, since Daiichi Sankyo's basic patent and SPC have expired.

35 According to settled case-law, the Court may refuse to rule on a question referred for a preliminary ruling by a national court only where it is quite obvious that the interpretation of European Union law that is sought bears no relation to the actual facts of the main action or its purpose, where the problem is hypothetical, or where the Court does not have before it the factual or legal material necessary to give a useful answer to the questions submitted to it (see, inter alia, Case C-379/98 PreussenElektra [2012] ECR I-2099, paragraph 39; Joined Cases C-94/04 and C-202/04 **Cipolla and Others [2006] ECR I-11421, paragraph 25**; and Case C-180/11 Bericap Záródástechnikai [2012] ECR I-0000, paragraph 58).

36 In the present case, the referring court seeks, by its second and third questions, an interpretation of Articles 27 and 70 of the TRIPs Agreement, which in its view is necessary for examining Daiichi Sankyo's assertions concerning the alleged infringement of its patent rights by DEMO.

37 Contrary to DEMO's contention, it is not obvious that the purpose of the main proceedings has ceased to exist and that the interpretation sought thus bears no relation to the actual facts or purpose of the main proceedings.

38 There is nothing in the order for reference, which was made shortly before the expiry of the SPC held by Daiichi Sankyo, to suggest that the dispute would become devoid of purpose following that expiry. On the contrary, it appears that some of the claims brought by Daiichi Sankyo could still purposefully be upheld by the referring court if it were to find that DEMO had encroached on the protection conferred by the SPC. That is the case, in particular, with the claim for access to data relating to the manufacture and sale of Talerin and the application for seizure and destruction of packages of Talerin, some of which could have been manufactured and put on sale before the expiry of the SPC and still be in the possession of DEMO or third parties.

39 In those circumstances, the request for a preliminary ruling must be held to be admissible.

Question 1

40 By its first question, the referring court asks essentially whether Article 27 of the TRIPs Agreement falls within a field for which the Member States have primary competence and, if so, whether the national courts may accord that provision direct effect subject to the conditions laid down by national law.

41 The TRIPs Agreement was concluded by the Community and its Member States by virtue of shared competence (**Joined Cases C-300/98 and C-392/98 Dior and Others** [2000] ECR I-11307, paragraph 33, and **Case C-431/05 Merck Genéricos – Produtos Farmacêuticos [2007] ECR I-7001**, paragraph 33). In those circumstances, the parties to the main proceedings and the governments which have submitted observations argue that, in order to answer the first question, it must be examined whether, at the present stage of development of the law, the European Union has exercised its powers in the field of patents, or, more precisely, of patentability.

42 They rely on the case-law on mixed agreements which states that, to establish the dividing line between the obligations which the European Union assumes and those which remain the responsibility of the Member States, it must be determined whether, in the field covered by the relevant article of the agreement in question, the European Union has exercised its powers and adopted provisions to implement the obligations which derive from it (Case C-240/09 Lesoochranárske zoskupenie [2011] ECR I-1255, paragraphs 31 and 32 and the case-law cited).

43 The European Commission, by contrast, submits that that case-law is no longer relevant for the TRIPs Agreement, since it applies only to agreements which fall within the shared competence of the European Union and the Member States, not to those for which the European Union has sole competence. The Commission argues that the TRIPs Agreement as a whole relates to 'commercial aspects of intellectual property' within the meaning of Article 207(1) TFEU. Consequently, that agreement in its entirety now falls within the field of the common commercial policy.

44 This argument of the Commission, which was moreover specifically the subject of the oral procedure before the Court, should be examined first. During that procedure, the governments which took part in the proceedings replied to that argument by submitting that the majority of the rules in the TRIPs Agreement, such as those on patentability in Article 27, concern international trade only indirectly, and do not therefore fall within the field of the common commercial policy. The subject of patentability is covered by shared competence in the field of the internal market.

Preliminary considerations

45 In accordance with Article 207(1) TFEU, '[t]he common commercial policy shall be based on uniform principles, particularly with regard to changes in tariff rates, the conclusion of tariff and trade agreements relating to trade in goods and services, and the commercial aspects of intellectual property, foreign direct investment, the achievement of uniformity in measures of liberalisation, export policy and measures to protect trade … The common commercial policy shall be conducted in the context of the principles and objectives of the Union's external action.'

46 That provision, which entered into force on 1 December 2009, differs noticeably from the provisions it essentially replaced, in particular those in Article 133(1), (5), first subparagraph, (6), second subparagraph, and (7) EC.

47 It differs even more from the provision that was in force when the TRIPs Agreement was concluded, namely Article 113 of the EC Treaty (subsequently, after amendment, Article 133 EC). Paragraph 1 of that article stated that '[t]he common commercial policy shall be based on uniform principles, particularly in regard to changes in tariff rates, the conclusion of tariff and trade agreements, the achievement of uniformity in measures of liberalisation, export policy and measures to protect trade'. Commercial aspects of intellectual property were mentioned neither in that paragraph nor in any other paragraph of Article 113.

48 In view of that significant development of primary law, the question of the distribution of the competences of the European Union and the Member States must be examined on the basis of the Treaty now in force (see, by analogy, Opinion 1/08 [2009] ECR I-11129, paragraph 116). Consequently, neither Opinion 1/94 ([1994] ECR I-5267), in which the Court established in relation to Article 113 of the EC Treaty which provisions of the TRIPs Agreement fell within the common commercial policy and hence the exclusive competence of the Community, nor the judgment in **Merck Genéricos – Produtos Farmacêuticos**, defining, at a date when Article 133 EC was in force, the dividing line between the obligations under the TRIPs Agreement assumed by the European Union and those remaining the responsibility of the Member States, is material for determining to what extent the TRIPs Agreement, as from the entry into force of the FEU Treaty, falls within the exclusive competence of the European Union in matters of the common commercial policy. The concept of 'commercial aspects of intellectual property'

49 In accordance with Article 207(1) TFEU, the common commercial policy, which under Article 3(1)(e) TFEU falls within the exclusive competence of the European Union, relates inter alia to 'the commercial aspects of intellectual property'.

50 As follows from that provision, in particular the second sentence which states that the common commercial policy is within the context of 'the Union's external action', that policy relates to trade with non-member countries, not to trade in the internal market.

51 It is also common ground that the mere fact that an act of the European Union, such as an agreement concluded by it, is liable to have implications for international trade is not enough for it to be concluded that the act must be classified as falling within the common commercial policy. On the other hand, a European Union act falls within the common commercial policy if it relates specifically to international trade in that it is essentially intended to promote, facilitate or govern trade and has direct and immediate effects on trade (Opinion 2/00 [2001] ECR I-9713, paragraph 40; Case C-347/03 Regione autonoma Friuli- Venezia Giulia and ERSA [2005] ECR I-3785, paragraph 75; and Case C-411/06 Commission v Parliament and Council [2009] ECR I-7585, paragraph 71).

52 It follows that, of the rules adopted by the European Union in the field of intellectual property, only those with a specific link to international trade are capable of falling within the concept of 'commercial aspects of intellectual property' in Article 207(1) TFEU and hence the field of the common commercial policy.

53 That is the case of the rules in the TRIPs Agreement. Although those rules do not relate to the details, as regards customs or otherwise, of operations of international trade as such, they have a specific link with international trade. The TRIPs Agreement is an integral part of the WTO system and is one of the principal multilateral agreements on which that system is based.

54 The specific character of the link with international trade is illustrated in particular by the fact that the Understanding on Rules and Procedures governing the settlement of disputes, which forms Annex 2 to the WTO Agreement and applies to the TRIPs Agreement, authorises under Article 22(3) the cross-suspension of concessions between that agreement and the other principal multilateral agreements of which the WTO Agreement consists.

55 Moreover, when providing in Article 207(1) TFEU that the 'commercial aspects of intellectual property' are now fully part of the common commercial policy, the authors of the FEU Treaty could not have been unaware that the terms thus used in that provision correspond almost literally to the very title of the TRIPs Agreement.
56 The existence of a specific link between the TRIPs Agreement and international trade justifying the conclusion that the agreement falls within the field of the common commercial policy is not rebutted by the argument of the governments which took part in the oral proceedings that at least the provisions of Part II of the TRIPs Agreement, concerning the availability, scope and use of intellectual property rights, which include Article 27 of the agreement, fall within the field of the internal market, by virtue in particular of Articles 114 TFEU and 118 TFEU.
57 That argument does not take sufficient account of the objective of the TRIPs Agreement in general and Part II of the agreement in particular.
58 The primary objective of the TRIPs Agreement is to strengthen and harmonise the protection of intellectual property on a worldwide scale (Case C-89/99 Schieving-Nijstad and Others [2001] ECR I-5851, paragraph 36). As follows from its preamble, the TRIPs Agreement has the objective of reducing distortions of international trade by ensuring, in the territory of each member of the WTO, the effective and adequate protection of intellectual property rights. Part II of the agreement contributes to attaining that objective by setting out, for each of the principal categories of intellectual property rights, rules which must be applied by every member of the WTO.
59 Admittedly, it remains altogether open to the European Union, after the entry into force of the FEU Treaty, to legislate on the subject of intellectual property rights by virtue of competence relating to the field of the internal market. However, acts adopted on that basis and intended to have validity specifically for the European Union will have to comply with the rules concerning the availability, scope and use of intellectual property rights in the TRIPs Agreement, as those rules are still, as previously, intended to standardise certain rules on the subject at world level and thereby to facilitate international trade.
60 Consequently, as the Commission observes, to regard the rules on patentable subject-matter in Article 27 of the TRIPs Agreement as falling within the field of the common commercial policy rather than the field of the internal market correctly reflects the fact that the context of those rules is the liberalisation of international trade, not the harmonisation of the laws of the Member States of the European Union.
61 In the light of the above considerations, the answer to the first part of Question 1 is that Article 27 of the TRIPs Agreement falls within the field of the common commercial policy.
62 Having regard to the answer to the first part of that question, there is no need to consider the second part of the question.

Question 2
63 By its second question, the referring court asks essentially whether the invention of a pharmaceutical product such as the active chemical compound of a medicinal product is patentable subject-matter within the meaning of Article 27 of the TRIPs Agreement and, if so, what is the scope of the protection conferred by a patent for such a product.
64 DEMO did not specifically adopt a position on this issue. Daiichi Sankyo, the governments which submitted written observations, and the Commission all consider that it follows from the actual wording of the TRIPs Agreement that inventions of pharmaceutical products are patentable.
65 This argument must be accepted. Article 27(1) of the TRIPs Agreement provides that any invention, whether a product or a process, which is new, involves an inventive step and is capable of industrial application is patentable, provided only that it belongs to a field of technology.
66 As regards that condition, it is clear that pharmacology is regarded by the contracting parties to the TRIPs Agreement as a field of technology within the meaning of Article 27. That follows in particular, as the Italian Government and the Commission have observed, from Article 70(8) of the TRIPs Agreement, a transitional provision dealing with the situation in which 'a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical … products commensurate with its obligations under Article 27' which provides that, in that situation, the WTO member in question must at least provide, as from that date, 'a means by which applications for patents for such inventions can be filed'. As follows from the wording of that provision, Article 27 of the TRIPs Agreement includes the obligation to make inventions of pharmaceutical products patentable.
67 Nor, moreover, is that conclusion called into question in any way by paragraphs 2 and 3 of Article 27. Article 27(2) allows members of the WTO to exclude from patentability inventions the prevention of whose commercial exploitation is necessary for overriding reasons of the public interest, while Article 27(3) allows them to exclude from patentability certain products and processes, among which are 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals'. Those derogations provided for by Article 27(2) and (3) cannot, without depriving Articles 27(1) and 70(8) of the TRIPs Agreement of effectiveness, be interpreted as laying down a general exclusion for inventions of pharmaceutical products.
68 In the light of the foregoing, the answer to the first part of Question 2 is that Article 27 of the TRIPs Agreement must be interpreted as meaning that the invention of a pharmaceutical product such as the active chemical compound of a medicinal product is, in the absence of a derogation in accordance with Article 27(2) or (3), capable of being the subject-matter of a patent, under the conditions set out in Article 27(1).

69 In so far as Question 2 relates also to the scope of the protection conferred by a patent for a pharmaceutical product, it suffices to observe, in the context of the present request for a preliminary ruling, that Article 27 of the TRIPs Agreement concerns patentability, not the protection conferred by a patent. The question of the protection conferred by a patent is governed in particular by Article 28 of the agreement, 'Rights Conferred', Article 30, 'Exceptions to Rights Conferred', and Article 33, 'Term of Protection'. As it does not appear from the order for reference that an interpretation of those other provisions would be of use for resolving the dispute in the main proceedings, there is no need to answer the second part of Question 2.

Question 3

70 By its third question, the referring court seeks essentially to know whether a patent obtained following an application claiming the invention both of the process of manufacture of a pharmaceutical product and of the pharmaceutical product as such, but granted solely in relation to the process of manufacture, must none the less, by reason of the rules set out in Articles 27 and 70 of the TRIPs Agreement, be regarded, as from the date of entry into force of that agreement, as covering the invention of that pharmaceutical product.

71 DEMO, the Greek, Portuguese and United Kingdom Governments, and the Commission consider that the question should be answered in the negative. Daiichi Sankyo and the Italian Government take the contrary view, basing their arguments on Article 70(2) and Article 70 (8) of the TRIPs Agreement respectively.

72 It must be stated at the outset that the answer to Question 3 cannot, in the context of the present request for a preliminary ruling, be based on Article 70(8) of the TRIPs Agreement. 73 It is common ground that the Hellenic Republic recognised the patentability of pharmaceutical products from 8 October 1992, in other words well before the entry into force of the TRIPs Agreement. Furthermore, there is nothing in the documents submitted to the Court to suggest that the compatibility of the conditions of that patentability with those stated in Article 27 of the TRIPs Agreement is challenged. It must therefore be considered that the legal situation of the Hellenic Republic was never that referred to in Article 70(8) in which 'a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical … products commensurate with its obligations under Article 27'.

74 As regards, next, the rule in Article 70(2) of the TRIPs Agreement, which states that the agreement 'gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question', it must be examined whether, in circumstances such as those of the main proceedings, that rule affects the interpretation of Regulation No 1768/92.

75 It must be recalled that the object of the dispute in the main proceedings is to determine whether the SPC held by Daiichi Sankyo from 2006 to 2011, in other words, in the period during which DEMO was preparing to market medicinal products containing the pharmaceutical product levofloxacin hemihydrate, covered the invention of that pharmaceutical product or only the invention of the process of manufacture of that product.

76 In accordance with Articles 4 and 5 of Regulation No 1768/92, the protection conferred by the SPC was subject to the same limitations as those affecting the protection conferred by the basic patent.

77 As the basic patent was granted in 1986, the first part of its term overlapped the last part of the term of validity of the reservation made by the Hellenic Republic in accordance with Article 167(2) of the EPC. While that reservation did not formally apply to Daiichi Sankyo's patent, that being a national patent, not a European one, it none the less follows from the information supplied by the referring court, summarised in paragraphs 20 and 21 above, that, in accordance with Law No 1733/1987, that reservation was applied by analogy to national patents.

78 Although this is for the referring court to verify, it appears from that information that the statement in Article 167(5) of the EPC that '[t]he effect of the reservation [mentioned in paragraph 2] shall continue for the term of the patent' was, for its part, also applicable by analogy to national patents, with the consequence that Daiichi Sankyo's national patent and the SPC deriving from that patent were of no effect as regards the invention of the pharmaceutical product, notwithstanding the patentability of pharmaceutical products from 8 October 1992.

79 As DEMO and the United Kingdom Government in particular have observed, regardless of the precise scope to be given to the rule in Article 70(2) of the TRIPs Agreement and the balance to be struck between that rule and the rule in Article 70(1) which states that the TRIPs Agreement 'does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question', it cannot be considered that the protection of existing subject-matter referred to in Article 70 of the TRIPs Agreement can consist in attributing to a patent effects which it does not have and never has had.

80 It follows, admittedly, from Article 70(2) read in conjunction with Article 65(1) of the TRIPs Agreement that every member of the WTO is, from the entry into force of the WTO Agreement, or at the latest one year after that date, required to fulfill all the obligations arising from the TRIPs Agreement in respect of existing subject-matter (**Case C-245/02 Anheuser-Busch [2004] ECR I-10989, paragraph 49**). That existing subject-matter includes inventions protected by a patent on that date in the territory of the WTO member concerned (see, to that effect, the Report of the WTO Appellate Body, issued on 18 September 2000, Canada – Term of Patent Protection (AB-2000-7), WT/DS170/AB/R, paragraphs 65 and 66).

81 However, to classify the invention of the product levofloxacin hemihydrate as protected by virtue of Daiichi Sankyo's patent on the date of application for the Hellenic Republic of the TRIPs Agreement, when

that invention was precisely not protected under the rules which governed that patent until then, would be possible only if that agreement were interpreted as requiring the members of the WTO to convert claimed inventions to protected inventions, on the occasion and solely because of the entry into force of the agreement. Such an obligation cannot, however, be derived from the TRIPs agreement, and would go beyond the ordinary meaning of the words 'existing subject-matter'.

82 Nor does a reading of Articles 27 and 70 of the TRIPs Agreement in conjunction lead to a different conclusion. It is true that, as follows from the examination of Question 2, Article 27 of the TRIPs Agreement obliges members of the WTO to make it possible to obtain patents for inventions of pharmaceutical products. That obligation cannot, however, be understood as meaning that members of the WTO which, in a period anterior to the date of that agreement's entry into force, excluded protection of inventions of pharmaceutical products claimed in patents granted for inventions of processes of manufacture of those products must, from that date, regard those patents as covering those inventions of pharmaceutical products.

83 In the light of the foregoing, the answer to Question 3 is that a patent obtained following an application claiming the invention both of the process of manufacture of a pharmaceutical product and of the pharmaceutical product as such, but granted solely in relation to the process of manufacture, does not, by reason of the rules set out in Articles 27 and 70 of the TRIPs Agreement, have to be regarded from the entry into force of that agreement as covering the invention of that pharmaceutical product.

Costs

84 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 (Grand Chamber) hereby rules:

1. Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, constituting Annex 1C to the Agreement establishing the World Trade Organisation (WTO), signed at Marrakesh on 15 April 1994 and approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986- 1994), falls within the field of the common commercial policy.

2. Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights must be interpreted as meaning that the invention of a pharmaceutical product such as the active chemical compound of a medicinal product is, in the absence of a derogation in accordance with Article 27(2) or (3), capable of being the subject-matter of a patent, under the conditions set out in Article 27(1).

3. A patent obtained following an application claiming the invention both of the process of manufacture of a pharmaceutical product and of the pharmaceutical product as such, but granted solely in relation to the process of manufacture, does not, by reason of the rules set out in Articles 27 and 70 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, have to be regarded from the entry into force of that agreement as covering the invention of that pharmaceutical product.

* Language of the case: Greek.

OPINION OF ADVOCATE GENERAL CRUZ VILLALÓN

presented on 31 January 2013 (2)

Case C‑414/11

Daiichi Sankyo Co. Ltd

Sanofi-Aventis Deutschland GmbH

v

DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon

[Reference for a preliminary ruling from the Polimeles Protodikio Athinon (Greece)]

"TRIPs Agreement – Interpretation as to whether it has direct effect – Competence of the European Union or the Member States – Patent for medicinal products – Pharmaceutical products and production processes – Article 207(1) TFEU – 'Commercial aspects of intellectual property' – Judgment in Merck Genéricos"

1. In the context of national proceedings concerning issues relating to the patentability of pharmaceutical products and arising as a result of the entry into force of the Agreement on Trade-Related Aspects of Intellectual Property Rights ('the TRIPs Agreement'), (3) the Court of Justice has the opportunity to rule on the scope of the exclusive competence of the European Union in matters relating to the common commercial policy (Article 3(1)(e) TFEU), now that that policy includes, pursuant to Article 207(1) TFEU, 'the commercial aspects of intellectual property'.

2. I consider that the central question raised by this case is whether the above expression, in that it is now a matter within the exclusive competence of the European Union, presently applies in a way which is different from that in which it previously applied, in the context of Article 133 TFEU.

3. In much more specific terms, the issue which arises is whether or not the rule laid down in Merck Genéricos, (4) according to which the Member States remain 'principally competent' in matters governed by the TRIPs Agreement, is valid.

4. The remaining questions referred are raised solely in the event that it is concluded that the Merck Genéricos rule is no longer valid. In so far as I consider that those questions are clearly less problematic, I shall focus my analysis on the first question.

5. Since I am aware of the extraordinary interpretative difficulty that this question raises, as will be seen, I

shall ultimately propose that the Court's answer to the Polymeles Protodikeio Athinon should be that the matters governed by Article 27 of the TRIPs Agreement ('patentable subject-matter'), as European Union law now stands, have not fallen within the scope of the 'commercial aspects of intellectual property' within the meaning of Article 207(1) TFEU, with resulting consequences concerning jurisdiction to interpret that provision.

6. In the alternative, and in the event that the Court reaches the conclusion that, ultimately, it is now for the Court to interpret Article 27 of the TRIPs Agreement, I shall propose that the Court, in accordance with its settled case-law, reinforced in this case by the nature of the obligation contained in that provision, should rule that that provision does not have direct effect.

7. Even so, and in the event that the Court should accept the reasons for changing its case-law, I shall still propose that the Court should rule that a patent on a production process for a pharmaceutical product does not in addition acquire the nature of a pharmaceutical product patent by the mere fact that at the time of filing the production patent, when a prohibition on patenting pharmaceutical products was in force, the application also covered the product patent itself.

8. Finally, whatever the interpretation provided by the Court and as regards the temporal effect of its ruling, I shall suggest that that interpretation, in view of the particular features of the case, should have no effect in situations which are the outcome of a final court judgment.

I – Legislative framework

A – The TRIPs Agreement

9. Article 27 of the TRIPs Agreement, under the heading 'Patentable Subject-matter', provides:

'1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. ...'.

10. For its part, and under the heading 'Protection of Existing Subject-matter', Article 70 of the TRIPs Agreement provides:

'1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.

2. Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject-matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. [...]

[...]

6. Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorisation of the right holder where authorisation for such use was granted by the government before the date this Agreement became known.

7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application;

and (c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

[...]'

B – National legislation

11. The Hellenic Republic ratified the Convention on the Grant of European Patents ('the EPC') in 1986, making a reservation, for the purposes of Article 167(2)(a) of the EPC, in relation to pharmaceutical products. Pursuant to Article 167(3) of the EPC, that reservation expired on 7 October 1992.

12. In 1995 the Hellenic Republic also ratified the TRIPs Agreement.

13. The field of patents is also governed in Greece by Law No 1733/1987 on technology transfer, inventions, technological innovation and the establishment of an atomic energy commission, which entered into force on 22 April 1987.
14. Article 5 of Law No 1733/1987 provides that products, processes and industrial applications are patentable, and under Article 7 of that law it is for the applicant to state which of those is the subject-matter of the protection sought.
15. In accordance with Article 11 of Law No 1733/1987, the term of a patent is 20 years and commences on the day after the filing of the patent application.
16. Article 25(3) of Law No 1733/1987 provided that, while the reservation made by Greece under Article 167(2)(a) of the EPC was in force, European patents would not be granted for pharmaceutical products.
17. The Greek courts have interpreted Law No 1733/1987 to the effect that it prohibited the granting of national patents for pharmaceutical products and allowed patents to be granted only to protect the invention of a production process for a pharmaceutical product. That restriction already existed under Law No 2527/1920, which preceded Law No 1733/1987, and ended on 7 October 1992.

II – Facts

18. Daiichi Sankyo Co. Ltd. ('Daiichi Sankyo') is a company based in Tokyo (Japan) which has held a national patent granted in Greece on 21 October 1986 relating to the chemical compound 'levofloxacin hemihydrate', which is used as an active ingredient in antibiotic treatments. The patent application, filed on 20 June 1986, sought protection for both the compound itself and its production process.
19. The patent, which expired on 20 June 2006, was extended by a supplementary protection certificate ('SPC') pursuant to Regulation No 1768/92. Under Article 13 of that regulation, the validity of the SPC could not exceed five years, with the result that the protection accorded to Daiichi Sankyo ended in 2011.
20. 'Levofloxacin hemihydrate' is used as the active ingredient in an original medicinal product called 'TAVANIC'; the German company Sanofi-Aventis Deutschland GmbH ('Sanofi-Aventis') has marketing authorisation to distribute that medicinal product in Greece. That authorisation, which covers original pharmaceutical products containing the active ingredient 'levofloxacin hemihydrate', was granted by the competent Greek authorities on 17 February 1999.
21. On 22 September 2008 and 22 July 2009, those authorities granted the Greek pharmaceutical company DEMO AVEE Farmakon ('DEMO') authorisation to place on the market generic pharmaceutical products containing the active ingredient 'levofloxacin hemihydrate'. DEMO marketed such products under the name 'TALERIN'.
22. On 23 September 2009 Daiichi Sankyo and Sanofi-Aventis brought an action against DEMO before the referring court, seeking the cessation of all marketing by DEMO of the product TALERIN or any other product containing the active ingredient 'levofloxacin hemihydrate' until the date of expiry of the SPC.

III – Questions referred

23. In the course of the proceedings brought by Daiichi Sankyo and Sanofi-Aventis, the Polymeles Protodikeio Athinon referred the following questions:

'(l) Does Article 27 of the TRIPS Agreement setting out the framework for patent protection fall within a field for which the Member States continue to have primary competence and, if so, can the Member States themselves accord direct effect to that provision, and can the national court apply it directly subject to the requirements laid down by national law?

(2) Under Article 27 of the TRIPS Agreement are chemical and pharmaceutical products patentable subject-matter provided that they satisfy the requirements for the grant of patents and, if so, what is the scope of their protection?

(3) Under Articles 27 and 70 of the TRIPS Agreement, do patents covered by the reservation in Article 167(2) of the 1973 Munich Convention which were granted before 7 February 1992, that is to say, before the above agreement entered into force, and concerned the invention of pharmaceutical products, but which, because of the aforementioned reservation, were granted solely to protect their production process, fall within the protection for all patents pursuant to the provisions of the TRIPS Agreement and, if so, what is the extent and content of that protection, that is to say, have the pharmaceutical products themselves also been protected since the above agreement entered into force or does protection continue to apply to their production process only or must a distinction be made based on the content of the application for grant of a patent, that is to say, as to whether, by describing the invention and the relevant claims, protection was sought at the outset for the product or the production process or both?'

24. The referring court explains that the resolution of the dispute brought before it depends on whether Daiichi Sankyo's patent covers only the production process for the active ingredient 'levofloxacin hemihydrate' (the 'production process for the pharmaceutical product') or also covers active ingredient itself (the 'pharmaceutical product'). In the second case, it would be sufficient for the plaintiffs in the main proceedings to establish that TAVANIC and TALERIN have the same active ingredient. If, on the other hand, the protected subject-matter is the procedure, the fact that both pharmaceutical products have the same active ingredient would only raise the presumption that the generic product was manufactured using the process protected by the patent, and DEMO could rebut that presumption if it showed that its product was manufactured using a different process.
25. The Polymeles Protodikeio Athinon notes that pharmaceutical products were not patentable in Greece before 7 October 1992, so that the patent granted to Daiichi Sankyo in 1986 did not initially protect the active ingredient 'levofloxacin hemihydrate' as such. In its view, however, this does not preclude the possibility that the patentability of pharmaceutical products

imposed by Article 27 of the TRIPs Agreement means that the active ingredient in dispute has been protected by Daiichi Sankyo's patent since the entry into force of that agreement, an issue on which there is disagreement between the Greek courts.

IV – The procedure before the Court of Justice

26. The request for a preliminary ruling was received by the Court Registry on 8 August 2011.

27. Written observations were submitted by Daiichi Sankyo and DEMO, and also by the United Kingdom, Greek, Italian and Portuguese Governments and the Commission.

28. At the hearing, held on 5 June 2012, written observations were presented by the attending representatives of Daiichi Sankyo, the German, United Kingdom, Finnish, Greek, Netherlands, Portuguese, Spanish and Swedish Governments and the Commission. In the notice of the hearing, the parties had been invited to comment on the Commission's statement in its written observations which is referred to in point 30 of this Opinion.

V – Arguments

29. Although it did not raise a plea of admissibility, DEMO claims that the main proceedings have become devoid of purpose, since both the patent and the SPC have expired.

30. In relation to the first question raised, all the parties, except the Commission, argued in their written observations that Article 27 of the TRIPs Agreement relates to a field in which the Member States continue to have primary competence, so that whether it has direct application depends on the outcome in each case under the relevant national law. That view, based on the rule established in Merck Genéricos, (5) is not shared by the Commission, which argues that the basis of that rule has changed with the entry into force of the TFEU, Article 207 of which refers to 'the commercial aspects of intellectual property' (the very subject-matter of the TRIPs Agreement) as one of the elements on which the common commercial policy is based. That would mean that the European Union now has a competence which it lacked at the time of the Merck Genéricos ruling and, accordingly, that it is for the European Union to determine whether or not Article 27 of the TRIPs Agreement has direct effect. According to the Commission, that is a question which must be answered in the negative, in the light of the case-law of the Court of Justice concerning the WTO Agreement.

31. The parties having been requested to comment on that issue at the hearing, Daiichi Sankyo and the German, United Kingdom, Finnish, Greek, Netherlands, Portuguese and Swedish Governments opposed the position adopted by the Commission. Essentially, all the Governments concurred that, beyond its title, the TRIPs Agreement has a subject-matter which is broader than 'the commercial aspects of intellectual property' as referred to in Article 207 TFEU. Accordingly, they take the view that it is necessary to examine on a case-by-case basis the subject-matter dealt with in each of its provisions, since the subject-matter of Articles 27 and 70 of the TRIPs Agreement relates to substantive patent law rather than the commercial aspects of intellectual property. In their view, therefore, the situation in terms of legislation and competence has not altered from that which obtained at the time of Merck Genéricos, so the rule which was applied then should also be applied now. The Commission, for its part, argued that since the Lisbon Treaty the European Union has had exclusive competence in relation to the subject-matter of the TRIPs Agreement.

32. With regard to the second question, Daiichi Sankyo and the United Kingdom, Greek, Italian and Portuguese Governments argue that it unambiguously follows from the wording of Article 27 of the TRIPs Agreement that, subject to the exceptions provided for in that provision, a pharmaceutical product as such may be patentable. The Commission, for its part, argues that, if that provision is held to be applicable, the Court should rule that pharmaceutical and chemical products are patentable if they fulfil the general conditions for the grant of a patent and that those products enjoy the extended protection which is set out in Article 28 of the TRIPs Agreement.

33. Finally, in relation to the last question, Daiichi Sankyo argues that it follows from a combined reading of Articles 27(1) and 70(2) of the TRIPs Agreement that patents existing at the time of the entry into force of that agreement protect, from that date, pharmaceutical products for which protection was sought in the applications for such patents. For their part, DEMO and the Greek Government consider that both provisions must be interpreted as meaning that a patent existing prior to the entry into force of the TRIPs Agreement is governed by the rules of that agreement from its entry into force, but that the agreement does not cover a pharmaceutical product which was never protected. The Italian Government argues that patents relating to pharmaceutical products and granted before 7 February 1992 but which, on account of the reservation referred to in Article 167(2) of the EPC, were granted only to protect their production process, enjoy, following the entry into force of that agreement, the protection – for the products and the processes – provided for all patents under the TRIPs Agreement. To that effect, the Italian Government argues that it will be necessary to examine in each case the content of the relevant application. The Portuguese Government submits that the protection conferred by a patent is determined by the content of its application, and that, apart from in the case of Article 70(7) of the TRIPs Agreement, it is not possible to seek an a posteriori extension of the protection initially sought. Accordingly, a patent on a process granted prior to the TRIPs Agreement cannot afterwards become a product patent, and any claim of a product patent while the reservation under Article 167(2)(a) of the EPC was in force is inadmissible. The United Kingdom Government argues that, in view of the lack of substantive legislation of the European Union in that regard, the Court of Justice lacks jurisdiction to interpret, from the point of view of substantive law,

Article 27 of the TRIPs Agreement. In the alternative, it argues that, in the circumstances of the case, Article 70 of the TRIPs Agreement does not allow the patent to be extended to the product as such. Finally, the Commission considers that, since the TRIPs Agreement does not have direct effect, its entry into force has not had the effect of automatically extending to products the protection granted to processes.

VI – Assessment

A – Preliminary remarks

1. Meaning and scope of the questions referred

34. The Polymeles Protodikeio Athinon asks the Court of Justice, first, whether Article 27 of the TRIPs Agreement *'fall[s] within a field for which the Member States continue to have primary competence'*. In the event that it does, the national court then asks whether or not the Member States can accord direct effect to that provision. For their part, the second and third questions relate specifically to the interpretation of the content and the effects of Articles 27 and 70 of the TRIPs Agreement, so that by raising them the referring court proceeds on the assumption that the answer to the first question will be in the negative; that is to say that Article 27 of the TRIPs Agreement falls within a field for which competence now lies not with the Member States but with the European Union.

35. In my view, the three questions raise three very specific issues. First, there is the issue of the effect of Article 207 TFEU on the interpretative jurisdiction of the Court of Justice with respect to the TRIPs Agreement. The national court refers to that issue when asking whether Article 27 of the TRIPs Agreement falls within a field for which competence now lies not with the Member States but with the European Union. As has been stated in point 31 above, the Commission's arguments in that respect led the Court to request that the parties express their views at the hearing on the effect of the new Article 207 TFEU with regard to jurisdiction to interpret the TRIPs Agreement.

36. Secondly, I am of the opinion that the question concerning the possibility that chemical and pharmaceutical products are patentable under Article 27 of the TRIPs Agreement should be reformulated. The reason is that, as the parties pointed out, it is a question which, as worded, raises no difficulties. However, the question implicitly contains a more significant issue, namely the issue of the direct effect of the WTO Agreements. More precisely, as we shall see, the use of the term 'direct effect' once again raises, in fact, the issue of whether the WTO Agreements 'may be relied upon' in European Union law.

37. Thirdly and finally, and a question directly relating to the matter at issue in the main proceedings, the Court is asked whether, as a direct result of the TRIPs Agreement, a person should be regarded as having also acquired a product patent where, at the material time, he applied for a manufacturing patent and a pharmaceutical product patent but only obtained the manufacturing patent because the then applicable legislation allowed nothing more. The question is, ultimately, what is meant by 'subject-matter existing at the time of entry into force of the TRIPs Agreement' for the purposes of Article 70(2) of that agreement?

2. The relevance of the questions referred

38. Without expressly raising a plea of admissibility against this request for a preliminary ruling, DEMO pointed out that, since both Daiichi Sankyo's patent and the SPC have expired, the main proceedings have, in its view, become devoid of purpose, so that, whatever the response of the Court, it will not substantially affect the decision finally taken by the referring court.

39. This may be countered by the fact that, as stated in the order for reference, the national legislation provides for the possibility that, where a patent infringement has been established, the patent holder may claim compensation for the damage suffered. That fact alone would be sufficient to consider that this question is not irrelevant, since the answer to the questions raised by the Greek court must allow it at least to determine whether there has been a patent infringement capable of forming the basis of a claim for damages. Accordingly, the Court must give a ruling not only on an ongoing infringement, but also on an infringement which, though it may have been committed in the past, caused damage for which the injured party may seek reparation using a right which continues to exist beyond the expiry of the legal title which entitled him, as against third parties, to rely on the protection conferred by patent law.

B – First question: the interpretative jurisdiction of the Court of Justice in relation to the TRIPs Agreement following the Lisbon Treaty

40. As I have already had occasion to point out, what is, in essence, in dispute in these proceedings is the extent to which the matters governed by the TRIPs agreement – and therefore the interpretation of the relevant law – now fall within the exclusive competence for commercial policy in so far as they constitute 'commercial aspects of intellectual property' (Article 207(1) TFEU). Put succinctly, according to the Commission, those matters fall entirely, almost by definition, within the scope of that article. According to the Member States, on the contrary, only a separate examination of the content of the various components of the agreement will make it possible to determine whether they should be classified as 'commercial aspects': in any event, according to the Member States, both Article 27 ('protected subject-matter') and as a consequence Article 70 ('existing subject-matter') of the TRIPs Agreement would be excluded from that classification.

41. It is undisputed that, at the time of the entry into force of the Lisbon Treaty, jurisdiction to interpret the TRIPs Agreement, whether that of the Court of Justice or that of the national courts, was determined on the basis of whether the specific subject-matter at issue fell within the European Union's sphere of competence or the Member States' area of competence. (6) That rule, established in the Court's case-law since Hermès, (7) and continuously upheld until Merck Genéricos, has meant that the complexity of the system of distribution

of competences prevailing between the European Union and the Member States has necessarily been carried over into the area of jurisdiction. (8)

42. Addressing that issue directly, the Court recently ruled, in paragraph 34 of Merck Genéricos, that Article 33 of the TRIPs Agreement – and the same could have been said with regard to many other articles thereof – 'forms part of a sphere in which, at this point in the development of [European Union] law, the Member States remain principally competent'. (9) Moreover, it need hardly be stated that the present problem arises not because European Union law on intellectual property has, through harmonisation, changed significantly compared to the situation obtaining when that judgment was delivered, which is not the case, but as a result of the change established by the Treaty of Lisbon in relation to the treatment of the 'commercial aspects of intellectual property'.

43. The problem having thus been set out, it must be stated that, in particular at the time of the oral hearing and as I have just pointed out, two opposing positions have emerged: the Commission's position, on the one hand ('the single dissenting voice', according to the representative of the Portuguese Republic at the hearing), and the position of the Member States appearing in these proceedings, on the other.

44. Expressed very succinctly, the Member States' approach is that the Lisbon Treaty has in no way changed the existing status of intellectual property as a shared competence, now as an element contained in Article 4(2)(a) TFEU ('internal market'), a harmonised subject-matter to a greater or lesser degree (Article 114 TFEU), which is now covered by additional provisions, including, in particular, one which establishes a unified patent (Article 118 TFEU).

45. In that context, Article 207(1) TFEU raises to the status of an exclusive competence, forming part of the common commercial policy, the commercial aspects of intellectual property, which are understood as being an entirely determinable part of the rules governing that subject-matter, which in any event does not include the contents of Article 27 of the TRIPs Agreement. The shared competence of the Member States in that regard remains, moreover, expressly guaranteed by Article 207(6) TFEU, which contains an express prohibition on harmonisation where not permitted by the Treaty.

46. For its part, the Commission's approach is that the wording of Article 207(1) TFEU constitutes a reference, implicit but no less clear, to the subject-matter governed by the TRIPs Agreement: such a striking parallelism between the wording of Article 207 TFEU and the title of the agreement practically leads to that conclusion. Essentially, its argument is simply that it is impossible to imagine that the European Union legislature had any intention other than that of raising to the status of exclusive competence of the European Union an area of substantive law, the 'commercial aspects of industrial property', which was provided for in a very different way by Article 133 EC. (10) Accordingly, what the TRIPs Agreement covers – and, it should be added, what it may cover – 'is' ipso facto a 'commercial aspect of intellectual property' within the meaning of Article 207(1) TFEU. Moreover, the Commission does not seem to see in that approach any particular problem as regards the nature of the shared competence for intellectual property as such.

47. It must here be pointed out that, generally speaking, the Commission's approach has independent support in the legal literature, which, moreover, often uses the same argument, that is to say that it is obvious. (11)

48. I think that, before undertaking an analysis of each of the those conflicting positions, it is appropriate to recall, if only in a very basic way, first, what constitutes intellectual property law and, secondly, what the TRIPs Agreement governs or contains, or simply 'is'.

49. Starting with the first issue, and as the Court ruled in Opinion 1/94, (12) '[i]ntellectual property rights enable those holding them to prevent third parties from carrying out certain acts. The power to prohibit the use of a trade mark, the manufacture of a product, the copying of a design or the reproduction of a book, a disc or a videocassette inevitably has effects on trade. Intellectual property rights are moreover specifically designed to produce such effects' (point 57).

50. However, it is necessary at this point to note that the law governing that intellectual property is not confined to those effects, but, by necessity, also includes its legislative organisation in the form of rights recognised and guaranteed by the legal system. In other words, the economic effect of a legal provision is preceded, as a separate reality, by the establishment of the provision itself and the determination of its status. (13)

51. With regard to the second issue, that is to say what the TRIPs Agreement 'is', it must be agreed that the TRIPs Agreement is an international agreement which lays down minimum requirements concerning intellectual property law. As may be readily acknowledged, the signatories to the agreement established a number of agreed essential elements in the field of law of intellectual property. In that regard, many of its provisions are essential components of any intellectual property legislation, national or otherwise. (14)

52. Of course, the TRIPs Agreement clearly also contains a number of provisions expressly relating to the trade in goods. The Member States cited some of them at the oral hearing. What must be emphasised is that those provisions constitute neither the core nor the most relevant part of the TRIPs Agreement. In any event, the latter provisions raise no difficulties. It is unlikely that the European Union will be challenged concerning its exclusive competence under the common commercial policy to agree such provisions, and it is not necessary for Article 207(1) TFEU to make any in that regard.

53. The problem lies in the substantive, or even 'undeniably' substantive, provisions of any intellectual property law which such treaties almost inevitably contain: in the case of the TRIPs Agreement, it must be

agreed that such provisions constitute its core and, it ought almost be said, its 'essence'.
54. In that regard, I think it is now possible to point out that, at least to some degree and to some extent, that type of provision explains precisely why Article 207(1) TFEU contains the wording which is at issue here. As I have just noted, no reform of primary law is needed to justify the European Union's competence to subscribe to general provisions relating to external trade.
55. Having set out the relevant positions and the issues they raise, I shall now put forward my own analysis. In that regard, and from the outset, my assessment is that the Member States and the Commission are both correct.
56. The Member States are correct in that the argument of the Commission is, as a nominalist argument, clearly unsatisfactory. Certainly, the minimal textual differences between the wording of Article 207(1) TFEU and the name of the agreement cannot invalidate the Commission's approach, (15) but only invalidate the force of that approach.
57. Furthermore, that argument is not sufficiently strong to address the consequences of the approach. In the first place, in so far as it means that the scope of an exclusive competence of the European Union would be determined by the present or prospective content of a particular international agreement, or by others having a similar content, that argument would have to be opposed almost on principle.
58. I think it should be beyond dispute that the concept of 'commercial aspects of intellectual property' within the meaning of Article 207 (1) TFEU must be an autonomous concept of European Union law and that the Court must be independently responsible for its interpretation, instead of its meaning being determined, in a more or less stable or consistent way, by the agreements to which the European Union is a party (whether the TRIPs Agreement or other similar ones). The difficulty which developing that concept undeniably raises is a separate matter: that task will from the outset require the abandonment of any abstract or ex ante definition. Instead, the concept must be developed gradually, as I shall attempt to propose in this case.
59. Secondly, the Commission's argument is insufficient in that it effectively disregards what a systematic interpretation of the rule makes immediately apparent: intellectual property is a shared competence and must remain so, not only under the provisions of primary law, as is the case, but also, of course, as regards its interpretation.
60. Furthermore, it is clear that the comprehensive and immediate inclusion of the field governed by the TRIPs Agreement in the concept
of 'commercial aspects' tends to bring the core of industrial property law within the European Union's exclusive competence, allowing it to effect a type of 'indirect' harmonisation or even 'to deactivate' the shared competence. Moreover, subject to what is set out below, understanding the provision as an exclusive 'external' competence, capable of existing alongside a shared 'internal' competence, leads only to a dead end.
61. By confining the analysis in so far as possible, that is to say to the content of Article 27 of the TRIPs Agreement, it is clear that that provision, concerning the definition of the protected subject-matter, and also the following one, concerning the 'rights conferred', form a core part of any substantive rules on intellectual property, the effect and content of which must above all be defined and specified. Regulating 'patentable subject-matter', as does Article 27 of the TRIPs Agreement, is, in my view, to deal with an aspect of intellectual property which is directly concerned with establishing legal rules governing the rights in that special property which a legal system recognises and guarantees. If that is a 'commercial aspect' and an exclusive competence, this certainly has an effect on the shared competence of the Member States. (16)
62. The Member States are correct, then, in arguing that not all of the matters covered by the TRIPs Agreement, and in particular the contents of Article 27 thereof, are the exclusive competence of the European Union. In that regard, it is difficult not to provide the answer that, in essence, the rule in Merck Genéricos continues to be valid.
63. However, the Commission is also correct or, in any event, is not incorrect. Of course, the argument that something 'is obvious' is always somewhat unsatisfactory. However, the very fact that an institution such as the Commission, supported by the legal literature and using terms of rhetoric, argues that its approach seems 'obvious' must have some weight.
64. In my effort to see the 'obvious', I must start by recognising that that peculiar expression 'commercial aspects' would not have entered primary law had an international agreement entitled the 'TRIPs' Agreement not existed for over a decade. In other words, the link between the wording of Article 207(1) TFEU and the wording of the TRIPs Agreement is very powerful as an idea.
65. It must also be recognised that in departing from the safe ground of 'reference', that is to say reference to the TRIPs Agreement, the interpretative difficulties are formidable. Although it has been accepted that the concept of 'commercial aspects' must necessarily extend beyond the scope of specifically commercial provisions and fall within the scope of substantive provisions, eliminating from them the most essential ones will be difficult, because they are the ones which are most important. In an international agreement laying down minimum requirements on the identity and nature of intellectual property, the issues which are necessarily addressed will not be collateral issues. In that regard, there can be no better example than the TRIPs Agreement.
66. In view of the foregoing, the effectiveness of the wording reproduced would strongly support the idea that some substantive rules of intellectual property included in such agreements are based on the wording of the article in question. In short, Article 207(1) TFEU must add something to what was there previously.

Furthermore, I think that that 'something' relates to the substantive provisions of intellectual property law which may, none the less, occasionally assume a 'strategic' position, on account of their impact on trade.
67. From that perspective also, it would be impossible to exclude matters such as those governed by Article 27 of the TRIPs Agreement (protected subject-matter) from the scope of Article 207(1) TFEU without to some extent undermining the effectiveness of the provision.
68. The paradoxes of the situation which arises will now be summarised. The significance to international trade of a particular substantive provision is not in itself capable of justifying the European Union's exclusive competence to determine the rules governing it. Functionality cannot be put forward as the single or even main criterion. It must be weighed against a systematic interpretation. Furthermore, a systematic interpretation immediately indicates that the matter in question cannot be solely determined by Article 207(1) TFEU. The systematic interpretation rule clearly requires a 'topographic' or even 'compartmentalised' interpretation of the wording of Article 207(1) TFEU: at least a part of intellectual property law must be 'resistant' to the sway of its commercial aspects.
69. However, a 'topographical' or 'compartmentalised' interpretation would disproportionately undermine the effectiveness of the change in primary law brought about by Article 207(1) TFEU. In the same way as a 'functional' interpretation which immediately and without further precautions made reference in each case to the provisions of the TRIPs Agreement and similar agreements would simply destroy, at least potentially, the shared nature which intellectual property undoubtedly retains, thereby also depriving it of its inherent effectiveness.
70. In short, the functional approach and the systematic approach seem to result in an irreconcilable contradiction. One approach seems to require that competence relating to essential elements of intellectual property law lies with the European Union and the other approach that it lies with the Member States.
71. Having set out all the foregoing considerations, I consider that, as has been noted, the fact that the Commission is also correct cannot lead me to conclude that, with the entry into force of the Lisbon Treaty, the Court now has jurisdiction to interpret a provision such as Article 27 of the TRIPs Agreement and that there is therefore a need to refine the rule that the national courts have primary jurisdiction to interpret that agreement. However, in order to draw this conclusion, it is necessary to find a way out of the dilemma.
72. I am of the view that that dilemma can be resolved only through an analysis based on the respective consequences, in terms of effectiveness in each case, which arise when opting for either of the opposing approaches. In other words, it is necessary to provide the best possible interpretation of the legislative provisions on which each of those approaches is based.
73. Having been thus set out, that interpretive task must be limited in two dimensions: the spatial and the temporal. The first is easy to explain: it means that the correspondence rule must not be applied to the scope of the wording of Article 207(1) TFEU or to the TRIPs Agreement as a whole. To that effect, I would refer to my preceding statements. The question refers to Article 27 of the TRIPs Agreement.
74. More explanation is required for the temporal limitation, which obviously can mean only that the relevant time is the present. It is true that Article 207(1) TFEU contains a competence which is 'external' in nature, in particular if it is examined in the light of the form of its previous version, that in Article 133 EC, and the caveat concerning competences in Article 207(6) TFEU is taken into account. However, this cannot lead us to think that the answer may be found through an approach in which the European Union's external competence could entirely coexist with the Member States' internal competence. Rather, I consider that, in the absence of instruments defining the scope of each competence, that coexistence is conceptually unviable, in any event in the long term.
75. It is a separate matter whether this is possible at the present time, that is to say, in the initial stages of that new exclusive competence. I consider that it is possible to argue that the European Union's exclusive external competence calls for the prominent role of the Member States' shared external competence to be somewhat 'eclipsed' or lost. However, that cannot take place by abruptly favouring the former over the latter.
76. Still with a view to effectiveness, the effectiveness of Article 207 TFEU is likely to be undermined less at present by a decision ruling that a provision such as Article 27 of the TRIPs Agreement remains in the sphere of competence of the Member States than it would be by the contrary decision. The European Union currently has a broad remit in the field of harmonisation and the creation of a unified title. The Member States, on the other hand, have only a shared competence. At present, there are therefore good reasons to avoid the general and immediate development of an interpretation of Article 207(1) TFEU linked to the content of international agreements such as the TRIPs Agreement. In that regard, to cite just one situation, the general and immediate 'expulsion' of the Member State from the negotiations for such agreements does not seem viable.
77. However, I also consider that it is necessary to ensure from the outset that the wording of Article 207(1) TFEU has some degree of effectiveness. In other words, it is very obvious that it is necessary to reject any interpretation which renders practically nugatory the change to primary law brought about by that provision.
78. That means, in the first place, that, having stated that intellectual property continues to be a share competence, this must be interpreted so as to facilitate in so far as possible the exercise by the European Union of its exclusive competence for commercial aspects. That would preclude an interpretation of 'commercial aspects' which is excessively influenced by the maxim that the exception proves the rule. In

other words, it is necessary to avoid an overly strict interpretation of 'commercial aspects'.

79. In the second place, I consider that a means for achieving the effectiveness of Article 207(1) TFEU could lie in its interpretation as an implicit rule directed towards the progressive harmonisation of intellectual property matters. The justification for the wording of Article 207 (1) TFEU would also be strengthened by effective progress in the field of harmonisation.

80. As a final consideration in my approach, I do not consider that 'shortcuts' are appropriate in this context, even if they paradoxically take the form of 'detours'. It is necessary to recognise that, in the past, difficulties have been encountered in harmonising patent law within the European Union. Furthermore, it can readily be understood that, in response to such difficulties, it has been possible to view the European Union's new exclusive competence as an indirect instrument for attaining the desired harmonisation of patent law. However, if there is anything that is unambiguous in the wording of Article 207(1) TFEU it is the statement that the European Union's exclusive competence relates to the 'commercial aspects of intellectual property' and not simply to 'intellectual property'. It is not in dispute that there remains an area of 'intellectual property' which goes beyond its 'commercial aspects', and the European Union has available several instruments for harmonisation in that area. Article 207(1) TFEU is not one of them, however.

81. In conclusion, I consider that, in particular as European Union law now stands, Article 27 of the TRIPs Agreement does not regulate subject-matter which falls within the commercial aspects of intellectual property within the meaning of Article 207(1) TFEU, and accordingly, with regard to its interpretation, the case-law of the Court which links the scope of the Court's jurisdiction to interpret provisions set out in international treaties to the substantive competence for the subject-matter in question continues to be valid.

82. Notwithstanding the above, and in the event that the Court should draw a different conclusion, I shall, in the alternative, now consider the question relating to the effectiveness of that provision.

C – Second question: the possible 'direct effect' of Article 27 of the TRIPs Agreement

83. By raising the question of whether the Member States may accord 'direct effect' to Article 27 of the TRIPs Agreement, the referring court is effectively asking whether the national court may apply that provision of the agreement. In fact, in the final part of its first question, it uses the expression 'apply it directly'.

84. I am of the view that it is questionable whether the order for reference is correct in using the expression 'direct effect', despite its widespread use. I concur in that regard with Advocate General Maduro in his Opinion in FIAMM and Others v Council and Commission (17) that the distance between the 'direct effect' of treaties and the 'direct effect' of European Union law is so great, 'in both concept and scope', that it would be advisable 'to use different terms to describe them in future in order to avoid any unfortunate confusion, and hence to speak only of the possibility of relying on international agreements'. (18)

85. In my opinion, the question at issue here relates primarily to the possibility of relying on the TRIPs Agreement before the courts, which entails taking into account the settled case-law of the Court concerning the possibility of relying on the WTO Agreements. (19)

86. That case-law, the source of which dates back to International Fruit Company, (20) has been reiterated on numerous occasions and in relation to a wide range of WTO instruments. (21)

87. It is true that this approach continues to have weaknesses, as has been pointed out in some of the legal literature (which criticises what it regards as a weak conception of the principle of legality, or the political nature of the reciprocity argument, or, finally, the lack of legal protection which it entails for individuals). (22) Nevertheless, the arguments of those who criticise the Court's approach also warrant several objections, as shown by the voices less hostile to the case-law (which object that its critics fail both to explain the democratic basis for the WTO rules and to specify the level of legal regulation which has been achieved in international trade law, and justify the reciprocity argument in terms of a true constitutional principle or point out that the direct effect rule is meaningful only in the context of the creation of a common market). (23)

88. In either case, that rule, as Advocate General Maduro explained in his Opinion in FIAMM, (24) only accords direct effect where the international rule in question fulfils a dual condition: 'the terms, nature and general scheme of the agreement do not prevent it being relied upon and … the provisions relied upon appear, in the light of both the object and purpose of the agreement and of its context, to be unconditional and sufficiently precise, in other words contain a clear and precise obligation which is not subject, in its implementation or effects, to the adoption of any subsequent measure'. (25)

89. In my view, Article 27 and, since it is connected, Article 70 of the TRIPs Agreement are not 'unconditional and sufficiently precise', that is they do not contain 'a clear and precise obligation' not subject 'in its implementation or effects, to the adoption of any subsequent measure'.

90. That is demonstrated, in my view, by the experience of the national courts which have addressed the issue of the direct applicability of the TRIPs Agreement.

91. Until now, the national courts have had jurisdiction to rule on the possible direct effect of the TRIPs Agreement in so far as it relates to the patentability of medicinal products and the possible extension to medicinal products of patents covering their manufacturing processes. Naturally, the practice followed by those courts may now be most useful to the Court in determining a rule on the solution which

should be adopted in that regard at European Union level.
92. There are no court rulings on this matter in those Member States which recognised the patentability of medicinal products prior to the 1980s. (26) That is also true in those Member States whose patent legislation is very recent. (27) Accordingly, the relevant judicial practice is to be found only in those countries which, having had patent legislation prior to the European Patent Convention (1973) and the TRIPs Agreement (1994), did not allow the patenting of medicinal products at the time of the entry into force of those international provisions. That is perfectly logical, since Article 70 of the TRIPs Agreement specifically affects the situation in the latter Member States.
93. The courts of three Member States (Slovenia, Finland and Portugal) have ruled that Article 70 of the TRIPs Agreement is not applicable, on the ground that the content of the provision is not sufficiently precise.
94. The courts of Austria, Spain and Greece (Member States which at the material time adopted the reservation set out in Article 167 of the Munich Convention) have given rulings on the applicability of Article 70 of the TRIPs Agreement to existing patents on processes for the manufacture of medicinal products which when they were granted could not, under national law, have covered the medicinal product itself.
95. In the case of Spain, the Audiencia Provincial de Madrid (2006) and the Juzgado Mercantil No 3 de Barcelona (2007) have ruled that the TRIPs Agreement applies both to patent applications pending at the time of its entry into force and to existing patents. The Tribunal Supremo confirmed that interpretation (2011), adding that the TRIPs Agreement has abrogated the effects of the reservation made under the Munich Agreement.
96. The Audiencia Provincial de Madrid also ruled that Article 70(7) of the TRIPs Agreement (amendment of pending applications) has direct effect . (28)
97. As regards the Austrian experience, the Supreme Court (2008) accorded direct effect to the TRIPs Agreement, ruling that the protection conferred by Article 70 of the agreement is the protection provided for by Austrian law. Applying its national rules, it concluded that the patents granted for processes could not be extended to medicinal products before those products were patentable in Austria.
98. In the case of Greece, it should be noted that two positions have been upheld by the Regional Court of Athens, which in 2009 ruled that the TRIPs Agreement is retroactive, with the result that all medicinal product patent applications are valid retroactively from 9 February 1995 for a period of 20 years from the date of filing. However, in 2011 it reviewed that position and stated that retroactivity required the existence valid title in force from the outset.
99. The solutions adopted in the Member States are therefore far from uniform, which places the Court in a position to adopt a solution in accordance with its own criteria.
100. In my view, the competence accorded to the European Union to rule on the effect of Articles 27 and 70 of the TRIPs Agreement can only mean, by definition, that it must be concluded that under no circumstances may that effect be direct. There are two reasons for this.
101. The first reason is inherent in European Union law as it now stands. The second reason stems from the actual content of Article 27 of the TRIPs Agreement itself.
102. As regards the first reason, it is sufficient to point out that Article 27 of the TRIPs Agreement establishes principles and rules concerning ‘patentability’ which are clearly directed at the public authority responsible for substantive patent law. It is not necessary here to consider which public authority that ought to be: suffice to say that it must have legislative powers.
103. In my view, Article 27 of the TRIPs Agreement actually constitutes a requirement placed upon the legislature competent in patent matters, imposing upon it the obligation to establish a patent system which, in principle, and in so far as is relevant here, provides for the ‘patentability’ of medicinal products. If the legislature having primary substantive competence continues to be the national one, the European Union could, where appropriate, derive from that requirement, by contrary inference, only a right for individuals to whom the Member States grant patents for medicinal products, provided that those Member States have not opted to exclude the ‘patentability’ of some inventions for reasons of ordre public, morality, the protection of life, health or the environment (Article 27(2)). If, however, the European Union now has the competence in question, that requirement is addressed to its institutions. (29)
104. In conclusion, I am of the opinion that Article 27 of the TRIPs Agreement, in conjunction with Article 70 of that agreement, does not have direct effect, in that it is not a provision that can be relied on directly by individuals either against the public authorities or, as in this case, against other individuals.
105. Nevertheless, and in the event that the Court should draw a different conclusion, I shall now turn to the third of the issues raised by the referring court.

D – Third question: the interpretation of ‘subject-matter existing at the time of entry into force of the TRIPs Agreement’ for the purposes of Article 70(2) of that agreement

106. Above all, it must not be forgotten that a product patent and a patent on a process are separate entities, subject to different conditions. I note that there has been some attempt to argue that the existing ‘subject-matter’ in the case of a patent for a process also covers, in some way, the product itself. It suffices to point out that they have different protection. Under Article 28(1) of the TRIPs Agreement, the ‘product’ patent is more advantageous to its holder, since it allows him to prevent competitors from the acts of ‘making, using, offering for sale, selling, or importing’. On the other hand, a patent on a ‘process’ does not prevent

competitors from manufacturing the same product through a different process. (30)

107. In any event, that question may primarily be answered in conjunction with the considerations set out above concerning the need for legislative development.

108. What is ultimately at issue in the main proceedings is whether, pursuant to Article 27, in conjunction with Article 70, of the TRIPs Agreement, the entry into force of that agreement allows a patent granted for a process when it was not possible to patent a pharmaceutical product to be extended to that product once the prohibition which prevented this no longer exists, where, in spite of that prohibition, the product patent was also applied for at the material time.

109. In that regard, it is necessary to take into account that in the case of Greece, the impossibility of patenting medicinal products derived solely from the reservation under Article 167 of the Munich Agreement, the expiry of which led to the possibility of again applying the national legislation which made it possible to patent medicinal products before the reservation was entered into. Once the reservation expired on 7 October 1992, nothing prevented the filing of an application for a medicinal product patent, and there was no need to rely on the mechanism provided for in Article 70(8) of the TRIPs Agreement.

110. That provision actually provides that '[w]here a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall ... provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed [...]'.

111. Upon the entry into force of the TRIPs Agreement in Greece it was not necessary to provide 'a means by which applications for patents for [medicinal products could] be filed', since, as I have noted, once the effects of the reservation under Article 167 of the Munich Convention had expired, the ordinary patent rules in force in Greece prior to that reservation applied in their entirety, and those rules did not exclude the 'patentability' of medicinal products.

112. However, I am of the view that it follows from Article 70(8) of the TRIPs Agreement that that agreement is based on the principle that in every case it is necessary to file an express application for a patent. That application must be processed through the channel laid down by paragraph 8 or through the normal channel for patents where the national legislation does not require the extension of the ordinary rules to medicinal products, which is precisely the case with Greece.

113. Therefore, I consider that the TRIPs Agreement does not, under any circumstances, provide for the type of 'automatic extension' of a patent on a process to a patent on a pharmaceutical product claimed by Daiichi Sankyo. Nor does it allow for the 'deferred granting' of a patent for a medicinal product which was applied for at a time when it could not be granted. In short, for reasons which I consider fundamental to safety in a field as sensitive as that of the patenting and resulting marketing of medicinal products, the TRIPs agreement must be interpreted as meaning that a patent for a pharmaceutical product can be granted only following a specific examination and control procedure which must be initiated by an express application.

114. In conclusion, in the event that the Court considers that it has jurisdiction to interpret Article 27 of the TRIPs Agreement – and, since it is connected, Article 70 of that agreement – and that the above provision is directly applicable, I propose that the Court rule that the mere entry into force of that agreement does not have the effect that persons acquire a patent on the product itself where they held patents on the production of that pharmaceutical product at the material time under a law which did not allow patents on pharmaceutical products themselves, even in cases where at the time of applying for the patent on the process those persons applied for a patent on the product itself.

VII – Temporal effects

115. My analysis in the alternative of the interpretation which the Court should give to the TRIPs Agreement must take into account the temporal effects of the Court's judgment, whatever its answer to the third question.

116. The first point to be noted is that there is, in any event, a lower limit: the date of entry into force of the Lisbon Treaty.

117. In my view, it is clear that the Court's decision could relate to the effect of the provision only from 1 December 2009, that is to say after the entry into force of the Lisbon Treaty, Articles 3 and 207 of which confer on the European Union the competence under which the Court has jurisdiction to give such a ruling.

118. Until that time, after all, in accordance with the rule established by the Court itself, the Member States had exclusive jurisdiction to determine whether or not provisions such as Article 27 of the TRIPs Agreement could be directly effective in their national law.

119. The change brought about by the new distribution of powers established in the Lisbon Treaty means that the Member States no longer have the power to resolve this question. Nevertheless, it is clear that, if only on account of the possible consequences, the Court's ruling should in no way undermine the effects produced prior to that date in the national legal systems as a result of the solution adopted in this matter by their courts.

120. The decision taken by the Court therefore cannot have any effect on legal situations established within the substantive scope of Article 27 of the TRIPs Agreement prior to 1 December 2009.

121. However, this may not be sufficient: the diversity and enormous quantity of litigation, largely resolved, justifies taking into account very basic considerations of legal certainty. In my view, given the uncertainty that has, with good reason, existed until now concerning the magnitude of the change brought about by the Lisbon Treaty in that field – as evidenced by this

very reference for a preliminary ruling and the dispute between the parties on this issue – the Court's decision on the effect, whether direct or indirect, of Article 27 of the TRIPs Agreement should apply only from the date of publication of the judgment setting out that decision and bringing these proceedings to a close. In any case, it is necessary to ensure the inviolability of judgments which have the force of res judicata on the date of publication of the Court's judgment bringing these proceedings to a close. In my opinion, there are in this case 'overriding considerations of legal certainty', which, according to the case-law of the Court, justify the exercise of 'discretion' on its part in order to preserve the finality of judgments delivered prior to a ruling which, as would be the case in the present dispute, changes the present legislative framework in a radical and, to some extent, surprising way. (31)

VIII – Conclusion

122. In the light of the foregoing observations, I suggest that the Court should answer the question referred as follows:

A – Primarily

'1) Article 27 of the TRIPs Agreement, which defines the scope of patent protection, falls within a field for which the Member States remain principally competent.

2) Accordingly, it is not necessary to give any ruling on the remaining questions raised by the Polymeles Protodikeio Athinon.'

B – In the alternative

In the event that the Court should consider that Article 27 of the TRIPs Agreement falls within a field for which the European Union is principally competent, and therefore that it is for the Court itself to declare whether or not that provision has direct effect:

'Article 27 of the TRIPs Agreement does not have direct effect.'

C – In the further alternative

In the event that the Court considers that Article 27 of the TRIPs Agreement – and, since it is connected, Article 70 of that agreement – is directly applicable:

'*The mere entry into force of the TRIPs Agreement does not have the effect that persons acquire a patent on the product itself where they held patents on the production of a pharmaceutical product under a law which did not allow patents on pharmaceutical products, even in cases where at the time of applying for the patent on the process those persons applied for a patent on the pharmaceutical product.'*

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2 – Original language: Spanish.

3 – Annex 1C to the Agreement establishing the World Trade Organisation (WTO Agreement), signed in Marrakesh on 15 April 1994 and approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ 1994 L 336, p. 1).

4 – Case C-431/05 [2007] ECR I-7001.

5 – Cited in point 3 above.

6 – .Merck Genéricos, paragraphs 46 and 47.

7 – Case C-53/96 [1998] ECR I-3603.

8 – In the words of Piet Eeckhout, EU External Relations Law, 2nd ed., Oxford University Press, Oxford, 2011, p. 279, '[i]f competence is the criterion for jurisdiction, the latter will be the hostage of the complexity of the former'.

9 – Emphasis added.

10 – As compared to the former Article 133 EC (post Nice), Article 207 TFEU differs by specifically including 'the commercial aspects of intellectual property' among the subject-matters in respect of which '[t]he common commercial policy shall be based on uniform principles', whereas Article 133(5) EC, simply provided that Paragraphs 1 to 4 were also to apply 'to the negotiation and conclusion of agreements in the fields of trade in services and the commercial aspects of intellectual property, in so far as those agreements [we] re not covered by the said paragraphs', the first of which required that the common commercial policy was to be based on uniform principles. Article 113 EC therefore already covered, in that field and as a matter of principle, the external dimension of the commercial aspects of intellectual property. Article 207 TFEU simply includes them in a direct and comprehensive manner, beyond the mere external dimension. In line with this, Advocate General Kokott considered, in point 63 of her Opinion in Case C-13/07 Commission v Council, that pursuant to Article 133(5) EC the Community had not acquired 'exclusive competence … in the field of trade in services and the commercial aspects of intellectual property', but rather that 'that step [was] completed only in the Treaty of Lisbon: Article 207(1) TFEU henceforward expressly places the "new" fields of commercial policy on the same footing as the conventional fields, and the common commercial policy as a whole is expressly assigned to the exclusive competence of the Union (Article 3(1)(e) TFEU)'. This does not mean, however, that Article 207 TFEU has conferred on the European Union exclusive competence for intellectual property law.

11 –See, inter alia, Eeckhout, P, EU External Relations Law, cited above, p. 285; Dimopoulos, A., 'The Common Commercial Policy after Lisbon: Establishing parallelism between internal and external economic relations?', in Croatian Yearbook of European Law and Policy, vol. 4 (2008), pp. 108 and 109; Hahn, M., 'Art. 207', in: Callies, C and Ruffert, M., EUV/AEUV, 4th ed., C. H. Beck, Munich, 2011, marginal note 2 and 16.

12 – Opinion 1/94 [1994] ECR I-5267.

13 – Evidence of the extent to which property (in particular intellectual property) is closely intertwined with trade – or, if it is preferred, its 'commercial aspects' may be regarded as decisive to the concept of it – can in fact be found in the TRIPs Agreement itself. As is clear from the internal history of its drafting, the contracting parties did not have the same understanding of the scope of the expression 'trade-related aspects', since while the developing States advocated a strict

interpretation (focusing, so to speak, purely on 'trade' matters), the developed States argued that it was necessary to have a broader, more comprehensive concept of the very field of intellectual property, based on the idea that the insufficient protection of property inevitably harms trade. See, for example, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Meeting of 25 March 1987, MTN.GNG/NG11/1, paragraph 6 et seq. Meeting of the Negotiating Group of 10 June 1987, MTN.GNG/NG11/2, paragraphs 4 and 5. Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Suggestion by the United States for Achieving the Negotiating Objective, MTN.GNG/NG11/W/14. In a way, as we shall see, both positions eventually prevailed: the first, by giving the agreement its title; the second, by determining its content. The negotiation process for the TRIPs Agreement and the inclusion of intellectual property in the GATT forum are described in H. P. Hestermeyer, Human Rights and the WTO, Oxford, OUP, 2007, pp. 33 to 48.

14 – It should be recalled that, as stated in Opinion 1/94, point 58, the primary objective of the TRIPs Agreement is 'to strengthen and harmonise the protection of intellectual property on a worldwide scale', and that its conclusion, in so far as it 'lays down rules in fields in which there are no Community harmonisation measures … would make it possible at the same time to achieve harmonisation within the Community and thereby to contribute to the establishment and functioning of the common market'.

15 – It is certainly true that the wording of the title of the agreement ('on trade-related aspects of intellectual property rights') and the wording of Article 207(1) TFEU ('commercial aspects of intellectual property') are not identical. In that regard, see Krajewski, M., 'The Reform of the Common Commercial Policy', in: Biondi, A., Eeckhout, P., Ripley, S., EU Law After Lisbon, Oxford University Press, Oxford, 2012, p. 301.

16 – 'Patentability' is a quality relating to the conditions which a product or process must satisfy for the purpose of constituting the subject -matter of a protected right. The establishment and regulation of such conditions are legislative actions which clearly fall within the scope of substantive or material patent law, that is to say, within a field relating to the 'establishment' of patents as legal realities which may be commercially exploited and are, therefore, capable within that framework of producing (commercial) effects, the regulation of which is provided for in many, but not all, of the provisions of the TRIPs Agreement.

17 – Joined Cases C-120/06 P and C-121/06 P [2008] ECR I-6513.

18 – Opinion in Joined Cases C-120/06 P and C-121/06 P, point 31.

19 – It is appropriate to recall the Court's traditional refusal to confer direct effect (the possibility of relying) on the rules of the WTO (both those in the treaties agreed within that organisation and the decisions of its bodies). That refusal is based on the flexible nature of the WTO system, which deprives it of a legal system which is sufficiently sophisticated to benefit from direct effect under European Union law. Both the GATT and subsequently the WTO constitute a political commitment subject to the maintenance of a balance between the parties, which is achieved through diplomatic negotiations. For a general analysis of this line of case-law, see Blázquez Navarro, I, Integración europea y diferencias comerciales en la OMC, Marcial Pons, Madrid, 2007, p. 357 et seq.

20 – Joined Cases 21/72 to 24/72 [1972] ECR 1219.

21 – So much so that questions referred for a preliminary ruling on the issue have been resolved by way of orders under the former Article 104 of the Rules of Procedure. See, for example, the Order in Case C-307/99 OGT Fruchthandelsgesellschaft [2001] ECR I-3159.

22 – See, inter alia, S. Griller, 'Judicial Enforceability of WTO Law in European Union', Journal of International Economic Law, 3(3) 2000; J.-V. Louis, 'Some Reflections on the Implementation of WTO Rules in the European Community Legal Order', in M. Bronckers and R. Quick (eds.), New Directions in International Economic Law: Essays in Honour of John H. Jackson, The Hague, London, Boston, Kluwer Law International, 2000.

23 – For example, A. von Bogdandy, 'Legal Effects of World Trade Organisation Decisions within European Union Law: A Contribution to the Theory of the Legal Acts of International Organisations and the Action for Damages Under Article 288(2) EC', in Journal of World Trade, 39 (19) 2005.

24 – Opinion cited in point 84 above, points 27 to 41.

25 – Opinion in Joined Cases C-120/06 P and C-121/06 P, point 27, citing, inter alia, the judgments in Case 17/81 Pabst & Richard [1982] ECR 1331, paragraph 27, and Case 104/81 Kupferberg [1982] ECR 3641, paragraphs 22 and 23.

26 – Germany, Belgium, Denmark, France, Italy, Luxembourg, Malta, Netherlands, United Kingdom and Sweden.

27 –Bulgaria, Slovakia, Estonia, Latvia, Lithuania, Czech Republic and Romania.

28 –Following the judgment of the Audiencia Provincial (Ratiopharm), the European Patent Office issued two notices (4 and 7/2007) in which it stated that: a) it is for the Spanish courts to decide whether the transitional arrangements of the TRIPs Agreement are directly applicable in Spain; b) Article 70(7) of the agreement applies, by definition, only to pending applications; c) Article 70(1) and (3) of the agreement clearly establish that the agreement does not have retroactive effect, and; d) Article 123 of the Munich Convention excludes the possibility that the protection of the agreement can be obtained after a patent has been granted and during the opposition period. According to the Office, a patent application filed before the expiry of the reservation made by Spain may be extended, while it is pending, to obtain the protection provided for by the TRIPs Agreement and,

in particular, by Article 27(1) thereof. For its part, the WTO considers that Article 70 of the agreement is not retroactive, but applies to existing patents (those which stem from acts completed prior to the entry into force of the agreement).

29 – The situation becomes the same as that which led Advocate General Ruiz-Jarabo Colomer to conclude in Merck Genéricos that Article 33 of the TRIPs Agreement did not have direct effect.

30 – See C. M. Correa, Trade Related Aspects of Intellectual Property Rights, Oxford, OUP, 2007.

31 – To that effect, see the judgment in Case C-409/06 Winner Wetten [2010] ECR I-8015, paragraph 67. It is similarly appropriate to cite the Opinion of Advocate General Jacobs in Case C-475/03 Banca Popolare di Cremona [2006] ECR I-9373.