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 fulfil 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.

[Signatures]

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* Language of the case: Greek.