JUDGMENT OF THE COURT (Grand Chamber)

11 September 2007 *

In Case C-431/05,

REFERENCE for a preliminary ruling under Article 234 EC from the Supremo Tribunal de Justiça (Portugal), made by decision of 3 November 2005, received at the Court on 5 December 2005, in the proceedings

Merck Genéricos — Produtos Farmacêuticos L^da^

v

Merck & Co. Inc.,

Merck Sharp & Dohme L^da^,

THE COURT (Grand Chamber),

composed of V. Skouris, President, P. Jann, C. W. A. Timmermans (Rapporteur), A. Rosas, K. Lenaerts, P. Kūris, E. Juhász and J. Klučka, Presidents of Chambers, K. Schiemann, G. Arestis, U. Lõhmus, E. Levits and A. Ó Caoimh, Judges,

* Language of the case: Portuguese.

Advocate General: D. Ruiz-Jarabo Colomer,
Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 28 November 2006,

after considering the observations submitted on behalf of:

— Merck Genéricos — Produtos Farmacêuticos L^{da}, by F. Bívar Weinholtz, advogado,

— Merck & Co., Inc. and Merck Sharp & Dohme, L^{da}, by R. Subiotto, Solicitor, and by R. Polónio de Sampaio, advogado,

— the Portuguese Government, by L. Fernandes and J. Negrão, acting as Agents,

— the French Government, by G. de Bergues and M^{me} R. Loosli-Surrans, acting as Agents,

— the United Kingdom Government, by V. Jackson, acting as Agent, assisted by A. Dashwood, Barrister,

— the Commission of the European Communities, by B. Martenczuk and M. Afonso, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 23 January 2007,

gives the following

Judgment

1 The question referred for a preliminary ruling concerns the interpretation of Article 33 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 ('the WTO'), signed at Marrakesh on 15 April 1994 and approved by Council Decision 94/800/EC 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 That question was raised in proceedings between Merck Genéricos — Produtos Farmacêuticos L^{da} ('Merck Genéricos') and Merck & Co. Inc. (M & Co.) and Merck Sharp & Dohme L^{da} ('MSL') concerning the alleged violation by Merck Genéricos of a patent held by M & Co. in Portugal.

Legal context

The WTO and TRIPs Agreements

3 The WTO Agreement and the TRIPs Agreement which forms an integral part thereof entered into force on 1 January 1995. However, according to Article 65(1) of the TRIPs Agreement, the members of the WTO were not obliged to apply its provisions before the expiry of a general period of one year from the entry into force of that agreement, that is to say, before 1 January 1996.

4 Article 33 of the TRIPs Agreement, headed 'Term of Protection' and contained in Section 5 on patents in Part II of the agreement, dealing with standards concerning the availability, scope and use of intellectual property rights, provides:

'The term of protection available shall not end before the expiration of a period of 20 years counted from the filing date.'

National law

5 Article 7 of the Industrial Property Code (Código da Propriedade Industrial), approved by Decree No 30.679 of 24 August 1940 ('the 1940 Industrial Property Code'), provided that patents were to fall into the public domain at the end of a period of 15 years from the date of their issue.

6 A new Industrial Property Code, approved by Decree-Law No 16/95 of 24 January 1995 ('the 1995 Industrial Property Code'), entered into force on 1 June 1995.

7 Article 94 of that code provided that patents should be valid for a period of 20 years from the date on which the application was filed.

8 None the less, Article 3 of that code contained the following transitional provision:

'Patents in respect of which applications were filed before the entry into force of this Decree-Law shall remain valid for the period of validity conferred on them by Article 7 of the [1940] Industrial Property Code.'

9 Article 3 was subsequently repealed, without retrospective effect, by Article 2 of Decree-Law No 141/96 of 23 August 1996, which entered into force on 12 September 1996.

10 Under Article 1 of that Decree-Law:

'Patents in respect of which applications were filed before the entry into force of Decree-Law No 16/95 of 24 January 1995 and valid on 1 January 1996 or issued after that date shall be covered by the provisions of Article 94 of the [1995] Industrial Property Code.'

11 The Intellectual Property Code now in force was approved by Decree-Law No 36/2003 of 5 March 2003. Article 99 of that Code provides:

'Term

A patent shall be valid for a term of 20 years from the date on which the corresponding application was filed.'

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

12 The facts of the case in the main proceedings, as they appear from the file submitted to the Court, may be summarised as follows.

13 M & Co. is the holder of Portuguese patent No 70 542, the application in respect of which was filed on 4 December 1979 and which was issued on 8 April 1981. This patent, entitled 'Process for the preparation of amino-acid derivatives as hypertensives', concerns a process for preparing a pharmaceutical compound containing the active substance Enalapril. The resulting pharmaceutical product has been marketed since 1 January 1985 under the trade mark RENITEC. MSL has been granted the right to exploit that patent, including powers to defend it.

14 In 1996 Merck Genéricos placed on the market a pharmaceutical product under the trade mark ENALAPRIL MERCK, which it sells at prices appreciably lower than those for the product under the trade mark RENITEC and which it has claimed, when promoting its use by doctors, to be the same product as Renitec.

15 M & Co. and MSL have brought an action against Merck Genéricos, seeking an order that the latter should refrain from importing, marketing in Portugal or exporting the product at issue under the trade mark ENALAPRIL MERCK or under any other commercial description without the express and formal authorisation of M & Co. and MSL, and seeking compensation for the material and non-material damage caused by the defendant's unlawful conduct.

16 In its defence, Merck Genéricos argued, inter alia, that the period of protection of patent No 70 542 had reached its term, given that the period of 15 years provided for by Article 7 of the 1940 Industrial Property Code, applicable pursuant to the transitional rules introduced by Article 3 of Decree-Law No 16/95, had expired on 9 April 1996.

17 M & Co. and MSL countered that, by virtue of Article 33 of the TRIPs Agreement, the patent in question had not expired until 4 December 1999.

18 M & Co. and MSL were unsuccessful at first instance. On appeal, however, the Tribunal da Relação (Court of Appeal), Lisbon, ordered Merck Genéricos to indemnify M & Co. and MSL for the damage done to patent No 70 542, on the ground that, pursuant to Article 33 of the TRIPs Agreement, which has direct effect, that patent expired not on 9 April 1996 but on 9 April 2001.

19 Merck Genéricos has appealed against that judgment to the Supremo Tribunal de Justiça (Supreme Court of Justice), claiming in particular that Article 33 of the TRIPs Agreement is without direct effect.

20 The referring court states that the 1995 Industrial Property Code, especially Article 94 thereof fixing the minimum term of a patent's validity at 20 years, cannot be applied to the case in the main proceedings.

21 Consequently, pursuant to Article 7 of the 1940 Industrial Property Code it must be found that the patent at issue in the main proceedings expired on 8 April 1996.

22 Nevertheless, according to that court, if Article 33 of the TRIPs Agreement, providing that the minimum term of protection of patents is 20 years, were applicable, the outcome of the dispute would be different, for M & Co. and MSL would be entitled to claim protection for the patent at issue in the main proceedings.

23 In this respect, the Supremo Tribunal de Justiça states that in accordance with the principles of Portuguese law governing the interpretation of international agreements, Article 33 of the TRIPs Agreement has direct effect inasmuch as it may be relied on by one individual in proceedings against another.

24 The national court recalls, in addition, that with regard to the interpretation of the provisions of the TRIPs Agreement in the field of trade marks, the Court of Justice has already declared that it has jurisdiction when those provisions apply to situations governed by both domestic and Community law (Case C-53/96 *Hermès* [1998] ECR I-3603, and Joined Cases C-300/98 and C-392/98 *Dior and Others* [2000] ECR I-11307).

25 In this connection the national court observes that in the field of patents the Community legislature has adopted the following provisions:

— Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (JO 1992 L 182, p. 1);

— Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (OJ 1994 L 227, p. 1), a field explicitly referred to in Article 27(3)(b) of the TRIPs Agreement,

— Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (JO 1998 L 213, p. 13).

26 The national court therefore considers that the Court of Justice also has jurisdiction to interpret the provisions of the TRIPs Agreement relating to patents, in particular Article 33 thereof.

27 It accepts, however, that that point of view is open to challenge for, unlike the Community rules on trade marks, the acts of Community law in the sphere of patents relate only to certain limited areas.

28 The Supremo Tribunal de Justiça accordingly decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Does the Court of Justice have jurisdiction to interpret Article 33 of the TRIPs Agreement?

(2) If the first question is answered in the affirmative, must national courts apply that article, on their own initiative or at the request of one of the parties, in proceedings pending before them?'

Concerning the questions referred for a preliminary ruling

29 By its two questions, which may be examined together, the referring court asks, in substance, whether it is contrary to Community law for Article 33 of the TRIPs Agreement to be applied directly by a national court in proceedings before it.

30 A preliminary point to be made is that Article 300(7) EC provides that 'agreements concluded under the conditions set out in this Article shall be binding on the institutions of the Community and on Member States'.

31 The WTO Agreement, of which the TRIPs Agreement forms part, has been signed by the Community and subsequently approved by Decision 94/800. Therefore, according to settled case-law, the provisions of that convention now form an integral part of the Community legal order (see, inter alia, Case C-344/04 *IATA and ELFAA* [2006] ECR I-403, paragraph 36, and Case C-459/03 *Commission* v *Ireland* [2006] ECR I-4635, paragraph 82). Within the framework of that legal order the Court has jurisdiction to give preliminary rulings concerning the interpretation of that agreement (see, inter alia, Case 181/73 *Haegeman* v *Belgium* [1974] ECR 449, paragraphs 4 to 6, and Case 12/86 *Demirel* [1987] ECR 3719, paragraph 7).

32 The WTO Agreement was concluded by the Community and all its Member States on the basis of joint competence and, as the Court has earlier remarked in *Hermès*, paragraph 24, without any allocation between them of their respective obligations towards the other contracting parties.

33 It follows that, the TRIPs Agreement having been concluded by the Community and its Member States by virtue of joint competence, the Court, hearing a case brought before it in accordance with the provisions of the EC Treaty, in particular Article 234 EC, has jurisdiction to define the obligations which the Community has thereby assumed and, for that purpose, to interpret the provisions of the TRIPs Agreement (see, to that effect, *Dior and Others*, paragraph 33).

34 In addition, as the Court has previously held, when the field is one in which the Community has not yet legislated and which consequently falls within the competence of the Member States, the protection of intellectual property rights and measures taken for that purpose by the judicial authorities do not fall within the scope of Community law, so that the latter neither requires nor forbids the legal order of a Member State to accord to individuals the right to rely directly on a rule laid down in the TRIPs Agreement or to oblige the courts to apply that rule of their own motion (*Dior and Others*, paragraph 48).

35 On the other hand, if it should be found that there are Community rules in the sphere in question, Community law will apply, which will mean that it is necessary, as far as may be possible, to supply an interpretation in keeping with the TRIPs Agreement (see, to that effect, *Dior and Others*, paragraph 47), although no direct effect may be given to the provision of that agreement at issue (*Dior and Others*, paragraph 44).

36 In order to answer the question which of the two hypotheses set out in the two paragraphs above is concerned, in relation to the relevant sphere covering the

provision of the TRIPs Agreement at issue in the main proceedings, it is necessary to examine the matter of the sharing of competence between the Community and its Member States.

37 That last question calls for a uniform reply at Community level that the Court alone is capable of supplying.

38 There is, therefore, some Community interest in considering the Court as having jurisdiction to interpret Article 33 of the TRIPs Agreement in order to ascertain, as the national court has asked it to, whether it is contrary to Community law for that provision to be given direct effect.

39 Having regard to the principles noted in paragraphs 34 and 35 above, it is now appropriate to examine whether, in the particular sphere into which Article 33 of the TRIPs Agreement falls, that is to say, that of patents, there is any Community legislation.

40 As Community law now stands, there is none.

41 Indeed, of the Community acts cited by the national court, only Directive 98/44 concerns the field of patents itself. However, it is only a specific isolated case in that field which is regulated by the directive, namely, the patentability of biotechnological inventions which is, moreover, quite distinct from the object of Article 33 of the TRIPs Agreement.

42 Regulation No 2100/94 sets up a system for the Community protection of plant varieties which, as the Advocate General has observed in point 48 of his Opinion, cannot be placed on the same footing as the system of patents, as the Commission of the European Communities has acknowledged. Thus, Article 19 of that regulation provides for a term of protection of 25 years, even of 30 years, from the grant of protection.

43 Lastly, with regard to Regulation No 1768/92, to which may be added Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (OJ 1996 L 198, p. 30), it is to be borne in mind that the purpose of that certificate is to compensate for the long period which, for the products concerned, elapses between the filing of a patent application and the granting of authorisation to place the products on the market by providing, in certain circumstances, for a supplementary period of patent protection (see, so far as Regulation No 1768/92 is concerned, Joined Cases C-207/03 and C-252/03 *Novartis and Others* [2005] ECR I-3209, paragraph 2).

44 The supplementary certificate does not affect the domestic, and therefore perhaps different, extent of the protection conferred by the patent or, more specifically, the term as such of the patent, which is still governed by the domestic law under which it was obtained.

45 That is made clear by Article 5 of those two regulations, which states that 'the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations', and by Article 13(1) of those regulations, which provides that '[t]he certificate shall take effect at the end of the lawful term of the basic patent'.

46 The fact is that the Community has not yet exercised its powers in the sphere of patents or that, at the very least, at internal level, that exercise has not to date been of sufficient importance to lead to the conclusion that, as matters now stand, that sphere falls within the scope of Community law.

47 Having regard to the principle recalled in paragraph 34 above, it must be concluded that, since Article 33 of the TRIPs Agreement forms part of a sphere in which, at this point in the development of Community law, the Member States remain principally competent, they may choose whether or not to give direct effect to that provision.

48 In those circumstances, the reply to be given to the questions referred must be that, as Community legislation in the sphere of patents now stands, it is not contrary to Community law for Article 33 of the TRIPs Agreement to be directly applied by a national court subject to the conditions provided for by national law.

Costs

49 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:

As Community legislation in the sphere of patents now stands, it is not contrary to Community law for Article 33 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, constituting Annex 1C to the Agreement establishing the World Trade Organisation, signed at Marrakesh

on 15 April 1994 and approved by Council Decision 94/800/EC 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), to be directly applied by a national court subject to the conditions provided for by national law.

[Signatures]