

## European Court of Justice, 11 September 2007, Merck



### PATENT LAW

#### Minimal duration of patent –TRIPs

##### Jurisdiction of the Court – interpretation TRIPs

- Court competent to interpret TRIPs Agreement

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.

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).

- Court competent to determine if Community has previously legislated in a certain area, which will either lead to the competence of Member States, or not

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).

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).

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.

##### No Community legislation for patents

- Current Community law does not provide in Community legislation for patents

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.

As Community law now stands, there is none. (...)

##### Discretion national law Member States

- Member States competent to directly apply Article 33 of the TRIPs Agreement, subject to national conditions

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.

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.

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.

Source: [ECLI:EU:C:2007:496](#)

### European Court of Justice, 11 September 2007

(V. Skouris, 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. Löhmus, E. Levits and A. Ó Caoimh)  
JUDGMENT OF THE COURT (Grand Chamber)  
11 September 2007 (\*)

*(Agreement establishing the World Trade Organisation – Article 33 of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs) – Patents – Minimum term of protection – Legislation of a Member State providing for a lesser term – Article 234 EC– Jurisdiction of the Court – Direct effect)*

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 Ld<sup>a</sup>*

v

Merck & Co. Inc.,  
Merck Sharp & Dohme Lda,  
THE COURT (Grand Chamber),  
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 Lda,  
by F. Bivar Weinholtz, advogado,  
– Merck & Co., Inc. and Merck Sharp & Dohme,  
Lda, 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  
Mme 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 Agree-  
ment on Trade-Related Aspects of Intellectual Property  
Rights ('the TRIPs Agreement'), constituting Annex  
1C to the Agreement establishing the World Trade Or-  
ganisation ('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 Lda  
(‘Merck Genéricos’) and Merck & Co. Inc. (M & Co.)  
and Merck Sharp & Dohme Lda (‘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 en-  
try 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 pa-  
tents in Part II of the agreement, dealing with standards  
concerning the availability, scope and use of intellectu-  
al 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 Prop-  
erty 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 be-  
fore 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 ret-  
rospective 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 be-  
fore 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 Ar-  
ticle 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 ques- tions 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 summarized 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 con-  
taining the active substance Enalapril. The resulting  
pharmaceutical product has been marketed since 1 Jan-  
uary 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 ENAL-  
APRIL 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 lat-

ter 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 authorization 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 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.

**Opinion of Advocate General Ruiz-Jarabo Colomer  
I – Introduction**

1. It has been written of mixed agreements that they inevitably cause complication, because they help to establish a political situation which does so too. (2) The questions referred for a preliminary ruling by the Supremo Tribunal de Justiça (Portuguese Supreme Court of Justice) insist on putting their finger on the spot of that of that complexity, paradoxically with two straightforward questions, which are easy to read and understand but have the emotional charge of potential disagreements, which arise because they are unavoidable.

2. The context of the referral is familiar: the TRIPs Agreement, one of the conventions concluded in 1994 within the framework of the World Trade Organisation. (3) Although, once again, the dispute concerns the jurisdiction of the Court of Justice to interpret a specific provision and whether the provision has direct effect, this case differs from the previous cases in that the referral relates not to trade mark law but to patent law.

3. It is therefore necessary to analyse in depth the progress made in the former of those fields, so as to ascertain whether it may be applied as it stands, whether it requires substantial modification or even whether it needs complete revision. In any event, it is necessary to point out the important practical effects of this case-law which has changed the way in which Community foreign policy is implemented, avoiding in particular negotiations for mixed agreements. (4)

**II – Legal framework**

**A – The TRIPs Agreement**

4. With the aim of effecting a partial harmonisation of intellectual property rights by reason of their incidental impact on international trade, the TRIPs Agreement contains a series of provisions applicable to the various kinds of intellectual property. I shall go on to mention those which affect patents and serve to clarify this matter.

5. Thus, Article 33 of that Agreement, contained in Part II, Section 5, on standards concerning the scope and use of intellectual property rights, under the heading ‘Term of Protection’, states as follows:

‘The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.’

6. Also, within Part VII of the Annex, which concerns the institutional arrangements and final provisions, Article 70, entitled ‘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 [...], 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 [...]

[...]

**B – The national law**

7. Patent law in Portugal was formerly contained in Law 30.679, of 24 August 1940, which in that year approved the Industrial Property Code (‘the 1940 Code’). Article 7 provided that those intangible rights were to fall into the public domain at the end of a term of 15 years from the grant of the patent.

8. Law 16/95 adopted a new legislative text, which has been in force since 1 June 1995 (‘the 1995 Code’), Article 94 of which provides that a patent is valid for 20 years from the date on which the application was filed.

9. However, in order to remedy situations of transitional law, Article 3 of the 1995 Code was worded as follows:

‘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) Code.’

10. Article 3 of the 1995 Code was subsequently repealed, without retrospective effect, by Article 2 of Decree-Law No 141/96 of 23 August 1996, which has been in force since 12 September 1996. Under Article 1 of this national 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 Article 94 of the (1995) Code [...].’

11. Article 94 increased the term of protection of those intangible property rights by five years.

12. On 5 March 2003 the current Intellectual Property Code was adopted by Decree-Law 36/2003, Article 99 of which provides:

‘Term

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

**III – Facts living rise to the dispute**

13. Merck & Co. Inc. (‘Merck’) is the holder of invention patent N° 70 542, issued on 8 April 1981, with priority as from 11 December 1978, entitled ‘process for the preparation of derivatives of amino acids as hypertensives’, in order to develop the chemical

compound 'Enalapril' and manufacture 'Maleate of Enalapril'. The pharmaceutical composition at issue has been marketed since 1 January 1985 under the trade mark 'Renitec'.

14. Merck Sharp & Dohme Lda. ('MSL') obtained a licence to exploit that patent in order to use, sell or in any way dispose of Renitec products in Portugal, together with powers to defend that patent.

15. In 1996 Merck Genéricos-Produtos Farmacêuticos Lda. ('Merck Genéricos') placed a product on the market under the trade mark Enalapril Merck at prices substantially lower than those of Renitec and promoted its use by doctors, stating that it was the same product.

16. Merck and MSL brought proceedings against Merck Genéricos seeking an order that the latter should refrain from using, directly or indirectly (importing, manufacturing, preparing, handling, packaging or selling), either in Portugal or for export, the pharmaceutical product Enalapril Merck, even under another commercial description, which contains the active substances 'Enalapril' or 'Maleate of Enalapril', without their express and formal authorisation. They also claimed compensation for material and non-material damage in the amount of ESC 32 500 000.

17. In its defence, Merck Genéricos argued that patent No 70 542 had reverted to the public domain on 8 April 1996, on the expiry of the term of 15 years provided for by Article 7 of the 1940 Code pursuant to the transitional provisions established by Article 3 of the 1995 Code.

18. MSL maintained, on the basis of Article 33 TRIPs, that the patent had not become invalid until 4 December 1999.

19. The action was dismissed at first instance

20. At second instance, the Tribunal da Relação (Court of Appeal), Lisbon, upheld the appellants' claim and ordered Merck Genéricos to pay compensation for the damage caused by the infringement of patent N° 70 542 on the ground that, in accordance with Article 33 of the TRIPs Agreement, which has direct effect, the patent had not expired on 9 April 1996, as the respondent to that appeal maintained, but five years later.

21. Merck Genéricos brought an appeal against that judgment before the Supremo Tribunal de Justiça, denying that Article 33 had direct effect.

22. The Portuguese supreme court observes that, although Article 94 of the 1995 Code had extended the validity of patents to 20 years, that provision was not applicable to this case because patent No 70 542 had expired on 8 April 1996, at the end of the 15-year period laid down by Article 7 of the 1940 Code. Thus, application of Article 33 of the TRIPs Agreement, which grants patents a minimum duration of 20 years, would lead to a finding in favour of MSL.

23. The Supremo Tribunal considers that, in accordance with the principles governing the interpretation in Portugal of international agreements, Article 33 of the TRIPs Agreement has direct effect and can be relied on in proceedings by one individual against another individual.

24. However, being uncertain as to the extrapolation to the field of patents of the Community case-law on the TRIPs Agreement in respect of trade marks, as regards both the substance and the interpretative jurisdiction of the Court of Justice, the national court has stayed proceedings and referred the following questions for a preliminary ruling pursuant to Article 234 EC:

'1 Does the Court of Justice of the European Communities 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?

#### **IV – The proceedings before the Court of Justice**

25. The order for reference was lodged at the Registry of the Court of Justice on 5 December 2005.

26. Written observations were submitted, within the period laid down in Article 23 of the Statute of the Court of Justice, by Merck and MSL jointly, Merck Genéricos, the Portuguese Government, the French Government and the Commission.

27. At the hearing, held on 28 November 2006, the representatives of the parties in the main proceedings, and the representatives of the French Government, the United Kingdom and the Commission respectively, presented oral argument.

#### **V – Analysis of the questions referred for a preliminary ruling**

##### **A – Approach**

28. By its first question, the national court wishes to know whether the Court of Justice has jurisdiction to comment on the TRIPs Agreement and, in particular, Article 33 thereof.

29. In their observations Merck and MSL maintain that, in accordance with settled case-law, (5) that question is not objectively required in order to settle the dispute in the main action, but they do not seem to call in question its admissibility, since they suggest only that it should be disregarded.

30. That point of view could be shared, but only in part, since it is not essential to deal with the question as such, not however for the reasons put forward by those companies, but because the Court of Justice has to consider of its own motion whether it has jurisdiction in cases concerning mixed international agreements.

31. Furthermore, as will be seen later in the examination of the Community case-law, the Supremo Tribunal would have jurisdiction if the Court of Justice were to decline it.

32. Therefore, the analysis of the first question raised is not undertaken with the aim of satisfying the curiosity of the national court, but in answer to an invitation to the Court of Justice to consider its jurisdiction of its own motion.

##### **B – The jurisdiction of the Court of Justice to interpret the TRIPs Agreement**

33. The competence of the Court of Justice to give rulings on mixed international treaties, namely, those which concern the powers shared by the Communities

and the Member States, has already been considered, the case-law being copious. However, successive developments, far from offering a smooth passage, have constructed a long and winding path, whose complex route demands certain adjustments in order to help its confused users find their way.

### **1. The reply according to the case-law of the Court of Justice**

#### **a) Origins**

34. The journey begins with *Haegeman*, (6) confirmed by *Demirel*; (7) since then those mixed agreements have formed part of the interpretative jurisdiction of the Court of Justice, regarded as acts approved by Community institutions; (8) mixed agreements are also included, by reason of parallelism with the Community powers, as a reflection of the fundamental Community-law principle of conferred powers, laid down in Article 5 EC and alluded to Article 220 EC. (9)

35. The judgment in *Demirel* (10) stated that these agreements have the same status in the legal order of the Union as purely Community agreements, the spheres concerned being attributed to the Community. (11) Admittedly, the judgment referred to the EEC-Turkey Association Agreement, (12) which it held came fully within the scope of the EC Treaty; that does not, however, invalidate the general nature of the foregoing statement. (13)

36. Turning to the substance of the case, it is to be pointed out that the Court of Justice has been asked to interpret the TRIPs Agreement on several occasions. However, Opinion 1/94, (14) given at the request of the Commission with the aim of defining the scope of the powers of the European Community to conclude all the parts of the Agreement establishing the World Trade Organisation ('the WTO'), must not be disregarded. Nevertheless, that text did not deal with the powers of the Court of Justice.

37. Accordingly, when examining whether those powers were exclusive or shared, the Opinion took the *AETR* judgment (15) as its basis for considering the acts of secondary legislation of the Community institutions which might be affected by the participation of the Member States in the TRIPs Agreement. The Opinion pointed out that harmonisation of the intellectual property rights covered by Annex C of the WTO Agreement was as yet incomplete, noting that there was no Community legislation in force relating to patents, the area concerned in the main proceedings. (16)

38. So, the case-law started off by suggesting the existence of Community legislation as a determining factor for establishing the jurisdiction of the Court of Justice to interpret mixed international agreements.

#### **b) Rulings on the TRIPs Agreement**

39. Later, *Hermès* (17) confirmed that approach; Article 99 of the Regulation on the Community trade mark, (18) in force one month before the Final Act and the WTO Agreement were signed, (19) was used to deduce from the competence of the Community, thanks to the unitary character of industrial property, that it afforded judicial protection within the meaning of Article

50 of the TRIPs Agreement, the Court of Justice declaring that it had jurisdiction to interpret that provision.. (20)

40. The case was criticised on the ground that the dispute which gave rise to the reference for a preliminary ruling in *Hermès* related to a Benelux rather than a Community trade mark and that, in any event, Article 99 of Regulation No 40/94 refers to national law, (21) but the Court of Justice confirmed that ruling in the judgment in *Dior*, (22) in paragraph 39 of which it extended its jurisdiction to interpret Article 50 of the TRIPs Agreement to cover not only trade marks but all other intellectual property rights.

41. Its fundamental argument was that, as a procedural provision to be applied in the same way in all situations falling within its scope, capable of applying both to situations covered by national law and to situations covered by Community law, the duty to cooperate in good faith (laid down in Article 10 EC) requires the judicial bodies of the Member States and the Community, for practical and legal reasons, to give a uniform interpretation of Article 50 of the TRIPs Agreement (23)

42. This was the origin of the need for that uniform interpretation as a corollary to the duty to cooperate in good faith, one of the main recommendations made by Advocate General Tesauro in his opinion in *Hermès*, which was not followed in the judgment, in order to establish the jurisdiction of the Court of Justice in respect of mixed agreements such as the TRIPs Agreement, (24) a view I shall consider in more detail below.

43. However, instead of elevating that need to the category of 'fundamental requirement', as Advocate General Tesauro suggested, which would lend it authority as the only guarantor of the correct interpretation of mixed agreements concluded by the Community, the Court of Justice merely inferred from that argument that it had jurisdiction to examine Article 50 of the TRIPs Agreement, as it had already done in the judgment in *Hermès*, although without mentioning that premise. We may wonder about the scope of the referral to Article 10 EC in *Dior*, if the Court then followed the same line of argument as in *Hermès*, (25) basing its jurisdiction to examine mixed international agreements on the European legislation in force.

#### **c) Modulation**

44. The case-law supported this line of thought in *Commission v Ireland*, (26) a judgment on adherence to the Berne Convention (27) concerning intellectual property which, in an action for failure to fulfil obligations, reveals the use of an identical methodology to define Community powers; the judgment in *Etang de Berre* (28) and the more recent judgment in *Fábrica de MOX* (29) also follow in the wake of *Hermès*, establishing the powers of the Court of Justice on the basis of the existence of Community legislation.

45. However, the judgment in *Etang de Berre* added a slight nuance by stating that the fact that a specific field covered in large measure by Community legislation has not yet been the subject of Union legislation, is

not capable of calling into question the finding that it also falls within the scope of Community competence. (30) The judgment in *Fábrica de MOX* refers expressly to the previous judgment, (31) thus reiterating the important reservation introduced into the syllogism from which the Court's interpretative jurisdiction may be inferred.

46. If, therefore, the current case-law is to be used to assess whether the Court of Justice has jurisdiction to examine mixed agreements and, particularly, the TRIPs Agreement in respect of patents, it would be necessary to examine any Community legislation on that branch of industrial property, without losing sight of the aforementioned 'flexibility clause' of the judgment in *Etang de Berre*.

#### **d) Application to the present case**

47. The list of Community measures supplied by the Commission in its observations would thus acquire relevance; it includes Regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products; (32) Regulation (EC) No 2100/94 on Community plant variety rights; (33) Regulation (EC) No 1610/96 concerning the creation of a supplementary protection certificate for plant protection products; (34) Directive 98/44/EC on the legal protection of biotechnological inventions; (35) the Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems; (36) the Proposal for a Council Regulation on the Community patent; (37) as well as the Proposal for a Council Decision conferring jurisdiction on the Court of Justice in disputes relating to the Community patent; (38) and the Proposal for a Council Decision establishing the Community Patent Court and concerning appeals before the Court of First Instance. (39)

48. Unlike trade marks, a field in which both Directive 89/104/EEC (40) and Regulation No 40/94 on the Community trade mark have been adopted, the European legislation on patents is far from offering such a clear response to the question whether the Court of Justice has jurisdiction to examine the TRIPs Agreement. Of the list of measures in the previous paragraph, some, such as that relating to plant varieties, cannot even be placed on the same footing as patents, as the Commission itself concedes. Others, on the other hand, have fallen at the preparatory stage and have not been adopted.

49. In fact, harmonising legislation is wanting, and the creation of a Community patent has met with insuperable resistance in the Council. At this stage, the *Hermès* case-law, as altered by the judgment in *Etang de Berre*, which calls for applicable legislation, collapses, although uncertainty immediately arises concerning the parameters that would make it possible to ascertain the level of legislative activity sufficient to establish the competence of the Community and therefore of the Court of Justice.

50. In these preliminary ruling proceedings there is no dispute concerning the exercise of the powers con-

ferred on the Community, either those granted to it by Article 95 EC, in respect also of the various kinds of intangible property rights in connection with the internal market, or those which revert to it by way of Article 308 EC, for example, in order to obtain the Community patent, a project which did not come to fruition. It should be stressed in this connection how involved and complicated for the Community is the use of its powers.

51. Thus, the Convention on the Grant of European Patents 1973 ('The Munich Convention'), to which the Member States have acceded in succession, conceived a pan-European instrument coexisting with national instruments. The proposal for a Regulation on the Community patent sought symbiosis between the Community and inter-State systems, an undertaking which requires the adoption of the Regulation on the Community patent, due account to be taken of the Munich Convention and the status of the European Patent Office, the accession of the Community to the Munich Convention, and coordination of the corresponding development of the Regulation and the Convention. Furthermore, the Munich Convention does not authorise the Office to carry out those functions, so it must be revised. (41)

52. It is difficult to decide whether, in the circumstances, it would be iniquitous to punish the Community for not having crowned its plans with success, especially in a procedure subject to the rule of unanimity. (42) Perhaps the author was right who wrote, in respect of mixed agreements, that when competence becomes the yardstick for determining jurisdiction, it converts it into a hostage of its complexity. (43) With the gradual increase in shared competence in the many and varied fields which are 'communitised', it is predicted that an avalanche of questions will fall on the Court of Justice, requiring it to rule on its own jurisdiction in the matter, and it will not always be able to avoid examining the relevant Community legislation.

53. In short, applying the case-law literally, it may be said that the Court of Justice does not have jurisdiction on account of the absence of Community provisions, but also, as the Commission implies, that it does have jurisdiction, if intellectual property is regarded as a single sector, made up of trade marks, designs and the other kinds of rights with which the TRIPs Agreement is concerned, and in which Community legislation is lacking, concerning, for example, the duration of the protection granted under invention patents, which, because of the judgment in *Etang de Berre*, is not an obstacle to the interpretative power of the Court of Justice.

#### **2. Alternative proposal**

54. In the light of the problems with the aforementioned case-law, in which the Court of Justice has itself become embroiled, I prefer to support a thesis which makes it possible to overcome such a firmly entrenched position and to undertake a task of reorganisation in the interests of the Community, maintaining that the Court

of Justice has unlimited jurisdiction to interpret the TRIPs Agreement for the following reasons:

55. First, more attention should be given than has hitherto been the case to the inclusion of the WTO Agreements as part of international law, in which agreements are ratified with the intention of complying with them in good faith. It should also be pointed out that GATT has undergone a change, in which its original 'contractual' nature has weakened and it has virtually become a 'constitutional' framework for world trade owing to its full alignment with the standards of the international treaties in accordance with the Vienna Convention on the Law of Treaties of 23 May 1969. (44) It is therefore expedient to use the judgments in *Haegemann and Demirel* as the starting point in relation to mixed agreements, so as to consider them as part of the Community legal order.

56. Secondly, the agreements concluded by the Community and the Member States jointly reveal their common objective and bind them *vis-à-vis* the third countries which are party to those agreements; the principle of good faith laid down in Article 10 EC requires the Member States to cooperate not only in the process of negotiation and conclusion of those agreements, but also in their implementation; (45) this must be read in conjunction with the duty to achieve the effectiveness of Community law not only in the legislative sphere but also in the executive and judicial spheres. (46)

57. Thirdly, the best way of guaranteeing observance of international agreements with third parties and of achieving the necessary harmony in the interpretation of mixed agreements is to ensure that they are interpreted uniformly, a view reinforced by the fact that the provisions of the Agreement may be interconnected, as Advocate General Tesauro suggested; (47) in this connection, the only body capable of carrying out that task is the Court of Justice, always with the invaluable help of the national courts by means of the preliminary ruling mechanism under Article 234 EC. Furthermore, this awareness of the need for harmony in the interpretation of Community law was made clear in Opinion 1/94, relating to the Agreement creating the European Economic Area, which lent weight to the argument that the power to interpret Community law, which is the guarantee of its coherence, should not be dispersed. (48)

58. Fourthly, that the Court of Justice may consider that it has the power to examine mixed agreements, in particular the TRIPs Agreement, does not imply transference to the Community of national legislative powers, nor of those which revert to the Member States because the Community institutions fail to exercise them. On the contrary, if there were uniform interpretation, binding on everybody, even in the fields in which there is as yet no Community legislation, the Member States could more easily comply with the provisions of Article 10 EC, making use of those powers.

59. Fifthly and lastly, the situation caused by the current case-law concerning mixed agreements is surprising, since to deny the Court of Justice jurisdiction to examine an agreement of that kind, ratified by the

Community, until legislation has been adopted in respect of specific matters is as illogical as prohibiting a national court from interpreting a framework law until the authorities to whom the legislative power has been delegated have exercised it.

60. So, the Court of Justice ought to be aware of the deficiencies in its case-law and try to resolve the constant unease regarding its power to examine mixed agreements, by daring to change course and to assume its responsibility, in order both to reformulate its case-law and adapt it to the fundamental principles of international law, and to invest it with the legal certainty required by institutions at intra-Community level. The judgment in *Dior* has already taken a step in that direction by including the reference to Article 10 EC in its statement of reasons, but it erred in not giving it the scope which I suggest.

61. In the light of all the foregoing, I venture to suggest that the Court of Justice declare that it has jurisdiction to interpret the TRIPs Agreement and, accordingly, Article 33 thereof.

#### **C – The direct effect of Article 33 of the TRIPs Agreement**

62. If, in the musical score of the legal problems linked to the Community's foreign relations, the interpretation of mixed agreements has become the *ritornelle*, direct effect is the vocal part inseparably linked to it, so that one is never present without the other. The simile is not gratuitous since, as will be seen below, the arguments in the Community case-law disclose the concomitant existence of several methodologies.

63. The wording of the question referred by the Supremo Tribunal de Justiça is ambiguous and seems to refer both to direct effect and to the possibility that the parties in cases pending before the national courts may rely on of the provisions of the WTO Agreements, but the order for reference and the observations submitted in these preliminary ruling proceedings stress the immediate and direct applicability of Article 33 of the TRIPs Agreement.

64. I shall therefore start with the premisses on which the Court of Justice's case-law is based in order to deduce the appropriate reply, and adapt it in the light of certain thoughts.

#### **1. The answer according to the case-law of the Court of Justice**

##### **a) From *Hermès* to *Van Parys***

65. The judgment in *Demirel* regarded a provision in an agreement concluded by the Community with non-member countries as being directly applicable when, regard being had to its wording and the purpose and nature of the agreement itself, the provision contained a clear and precise obligation which was not subject, in its implementation, to the adoption of any subsequent measure. (49)

66. Although the judgment in *Hermès* makes no reference to that aspect, Advocate General Tesauro is inclined to accept that the WTO Agreements have direct effect, on the basis that the misgivings of the Court of Justice regarding GATT had been overcome by the

agreement which succeeded it. (50) However, he explains that the TRIPs Agreement may be relied on by individuals 'where the relevant law so permits', which brings to mind the quotation from the judgment in Demirel, reproduced in the previous point, since 'what is important [...] is to decide whether the provision in question lends itself to application and this is the case whenever it requires no further act to enable it to produce its effects. (51)

67. The Court of Justice expressed its views in Portugal v Consejo, (52) the facts of which were unconnected with the TRIPs Agreement, since the applicants challenged the validity of two treaties, one with India and the other with Pakistan, concerning access to the textiles market alleging that contested decision relating to the signing of those treaties (53) was unlawful because it constituted a breach of certain rules and fundamental principles of the WTO.

68. The judgment has attracted extensive comment from academic writers, mostly very critical; (54) so as not to prolong this opinion, I shall set it out briefly. Thus, the Court of Justice, although it acknowledged that the WTO agreements differ significantly from the provisions of GATT 1947, in particular by reason of the strengthening of the system of safeguards and the mechanism for resolving disputes, (55) stressed the negotiating role of the States, and inferred that to recognise the direct effect of that Treaty would have the consequence of depriving the legislative or executive organs of the contracting parties of the possibility afforded by Article 22 of the Memorandum of Understanding of entering negotiated arrangements even on a temporary basis. (56)

69. The Court of Justice added that the purpose of the WTO Agreements does not determine the appropriate legal means of ensuring that they are applied in good faith in the legal orders of the contracting parties, (57) so that the provisions of those agreements are not to be used in the review of the legality of measures adopted by the institutions of the Union. (58)

70. It referred, however, to two situations in which it has given direct effect to the GATT rules, namely, when the Community intended to implement an obligation assumed in the context of the WTO (Fediol), (59) or where the Community measure refers expressly to the WTO Agreements (Nakajima), (60) cases in which it is for the Court to review the legality of the Community measure in question in the light of the WTO rules, which contain the only two exceptions to the general rule, as is evident from the judgment in Van Parys. (61)

71. In the latter judgment, the denial of direct effect to the WTO rules is absolute in tone, since the Court of Justice held that it was not possible to plead before a court of a Member State that Community legislation was incompatible with the WTO rules, even if the Dispute Settlement Body (62) had stated that that legislation was incompatible with those rules. (63) It might have infringed the principle of *pacta sunt servanda*, contained in Article 26 of the Vienna Convention on the Law of Treaties, (64) by disregarding the decisions of a body whose competence was accepted by the

Community when it signed the WTO agreements; however, the judgment in Van Parys is in addition surprising because the Court of Justice has always tried to ensure compliance with its judgments at every national level, administrative, legislative or judicial.

#### **b) The consequences of the judgment in Dior**

72. Unlike the judgment in Hermès, the judgment in Dior did not evade the questions from the Netherlands courts regarding the immediate legal effect of the TRIPs Agreement. It did not, however, settle them in the manner suggested by Advocate General Tesauro in Hermès, but persisted with the division of powers between the Member States and the Community.

73. On the basis of Article 14 of the judgment in Demirel, and after pointing out that individuals cannot rely on the WTO rules before national courts (Portugal v Council), it distinguished the fields governed by European law from those in which the Community has not yet exercised its powers. (65) In respect of the former, it reiterated the obligation to interpret the TRIPs Agreement in the light of its wording and purpose; (66) in respect of the latter, it considered that, since they were not governed by the law of the Union, that law 'neither requires nor forbids that the legal order of a Member State should accord to individuals the right to rely directly on the rule laid down by Article 50(6) of TRIPs'.

74. In short, according to this case-law, competence, whether Community or national, to apply the specific provision and to decide who is to determine whether it may be relied on, acquires a new meaning. Applying that idea to the present case, it may appropriately be observed that, if Article 33 of the TRIPs Agreement were to fall within the Community domain, jurisdiction to make that assessment would belong to the Court of Justice and, if it were to fall within the scope of national powers, then jurisdiction would belong to the judicial bodies of the Member States. (67)

75. As occurred with the first question, I am likewise not persuaded by this practice of the Court of Justice of distinguishing the respective powers of the Community and the countries of which it is composed, because it again makes it necessary to consider whether the Union has exercised its powers sufficiently; the lack of predictability for the institutional actors and the excessively prominent role of the Court of Justice resurface, resolving the dispute in terms of the division of powers. But, above all, the unity and consistency of the interpretation of Community law, including the international treaties in which the Member States participate with the Community, are jeopardised, which seems to indicate the need for a different methodology.

#### **2. Alternative proposal**

76. The governing theme of my argument is simpler; it unites the need to fulfil the Union's international obligations in accordance with the principle of good faith, which must always govern the conduct of the Member States, but also that of the organisations which operate within the world order, and the interpretation of the agreements which they conclude, (68) in accordance

with Articles 26 and 31 of the Vienna Convention on the Law of Treaties, mentioned above.

77. I believe I am not wrong to include the judgment in *Demirel* in this philosophy, when, in paragraph 14, it provided that the direct applicability of agreements concluded by the Community depended on the wording, purpose and nature of the agreement itself, and on its containing a clear and precise obligation. It is those two successive criteria that must be set up as the guide to the examination of direct effect, rather than the case-law referred to.

78. However, while the views expressed in the judgment in *Portugal v Council*, most recently confirmed in the judgment in *Van Parys*, persist, I can glimpse no chance of abandoning the dualistic system by which, on an uncertain legal basis, the Court of Justice has transformed the implementation in the Community of the *ius gentium*, and of the WTO agreements, into a means of evading its obligations. (69) Consequently, a provision of that kind will never have direct effect in the European Union, except in the situations contemplated in the judgments in *Fediol* and *Nakajima*, mentioned above.

79. As the arguments of the Court of Justice belong rather to the political than the legal sphere, (70) it is pointless to examine the dispute in depth and to trust that the criticisms of academic lawyers will overcome the resistance to accepting Advocate General Saggio's view that a provision in an agreement can as a rule, by virtue of its clear, precise and unconditional terms, constitute a criterion of legality of Community acts, and that individuals are entitled to rely on it before the national courts only if it is implicit in the general context of the agreement that its provisions may be invoked before the courts. (71)

80. All that remains is for me to make two more points in relation to this dispute, which appears to be resolved by settled case-law.

81. First, if the real reason for which the Court of Justice refuses to acknowledge the direct effect of the WTO agreements is that it does not wish to interfere with the powers of the Community political institutions to act within the margin for negotiation granted to them in the *Dispute Settlement Understanding*, (72) that applies only to fields in which compromise is genuinely possible.

82. Although the *Memorandum of Understanding* includes the *TRIPs Agreement* among the matters to which it applies, the nature of the legislation it seeks to harmonise, intellectual and industrial property rights, does not sit comfortably alongside the mechanism for settling disputes, since, by definition, those rights belong to individuals, not to the Member States. (73)

83. The essence of this Annex to the *WTO Agreement* is far removed from that of the *General Agreement*, on which the Court of Justice based its arguments in the judgment in *Portugal v Council*; it is difficult to put – without incongruities – minimum standards of protection, such as the duration of the patents, on the same footing as rules which, for example, require the reduction or withdrawal of customs tariffs

in order to facilitate the access of products to the market. I doubt whether those different kinds of rules offer the same flexibility for achieving a compromise. More attention must therefore be paid to the provision that is interpreted, when ascertaining whether it may be evaded by negotiation.

84. Secondly, the importance which the approach of the Court of Justice accords the *WTO system* for settling disputes is disproportionate, because it puts the option of relinquishing the responsibilities assumed under the *WTO Agreement* before its binding value as a multilateral international treaty.

85. It is true that that agreement does not provide a remedy like the action for failure to fulfil obligations pursuant to Article 226 EC, still less like the coercive measures pursuant to Article 228 EC, but that lack does not permit the terms of the transnational agreement to be turned upside down, giving the method for settling disputes the function of a legal subterfuge and of an alternative to the obligation to comply with international law in good faith. It may not be given that priority, distorting what ought to be an exception. Furthermore, a negotiated result is always of a provisional nature, (74) and must tend towards observance of the agreement, (75) which supports the arguments of those who emphasise the singularity of the mechanism for settling disputes.

86. Also, although Article IX of the *WTO Agreement* grants exclusive authority to the Ministerial Conference and the General Council to adopt interpretations of the Agreement and of the *Multilateral Trade Agreements*, the decision to adopt an interpretation must be taken by a majority of three quarters of the Members. In view of the large number of parties in the *WTO*, it is difficult to obtain that majority, so I do not share the view that that power conferred by Article IX tempers the judicial nature of the dispute settling procedure, (76) because to date that power has never been used. (77)

87. The above considerations make it possible to overcome the first obstacle, relating to the essence and context of the agreement to be analysed. Therefore, it remains only to interpret Article 33 of the *TRIPs Agreement* in order to decide whether it is immediately enforceable.

88. However, as I suspect that the proposal set out in the light of the case-law under the first heading of Part V-C(1) of this opinion will not be of interest to the national court, which in reality seeks interpretative guidelines to help it discern whether the provision at issue has direct effect, it would be appropriate to examine it under a third heading which, from a methodological point of view, must be regarded as common to the other two. Logic dictates that this should be so, since the two paths converge at the point at which the direct applicability of the rule entails its close examination.

### **3. Examination of Article 33 of the TRIPs Agreement**

89. Several of the observations submitted in these preliminary ruling proceedings have indicated, on the

basis of too superficial a reading of the provision in question, that it is clear.

90. I do not share that view. Article 33 of the TRIPs Agreement contains two premises: first, the minimum duration of the protection for patents, which it fixes at 20 years; secondly, the maximum, which it leaves to the discretion of the national legislature.

91. The wording is not clear and so has been misinterpreted. The correct meaning of the provision is that it is intended as requiring the signatory States to adapt their legislation on patents to the first premiss, providing for those industrial property rights to be protected for at least 20 years from the date of application. On the other hand, the second premise of the provision grants them discretion to fix the maximum duration.

92. It would be possible to assert that the first premiss has an 'asymmetrical' direct effect in cases like this, when the infringement arises from having maintained the protection for intangible rights of that kind below that temporal limit, once the provisional period granted by the TRIPs Agreement itself has expired. It seems indisputable that the obligation of the Member States fulfils all the conditions for its direct applicability. Thus, those affected by the failure to legislate are entitled to invoke the contested provision against the State in default. This sanction is supported by the developments of the Court of Justice regarding the vertical direct effect of directives.

93. Greater doubts arise in the recognition of horizontal direct effect, because of the lack of a maximum limit. The end of the period of protection for those special rights affects not only their holder but, in particular, third parties and the public domain, which in this respect represents the general interest. Competitors and also the appropriate registration authority have to know when protection of that patent comes to an end in the national legal order.

94. If the legislature does not exercise that power, it is impossible to pinpoint, merely from the wording of Article 33, the precise moment at which the term of the lawfully granted monopoly ends. In particular, to decide that it is sufficient to take the minimum option of 20 years would amount to assuming a power belonging to the legislature and it could not be raised against third parties.

95. Consequently, Article 33 of the TRIPs Agreement, because it is subject to the power of the national legislature to fix the exact duration of the protection granted to patents in its own legal order, does not have direct effect.

96. It should be added, finally, that Article 70 of the TRIPs Agreement, concerning 'Protection of Existing Subject Matter', cited in support of the argument that Article 33 has direct effect, is intended to guarantee for rights already in existence when the TRIPs Agreement came into effect the same protection as for those rights granted pursuant to the legislation adopted by the signatory States in order to implement the Agreement. It is a question, therefore, of extending the new protection to old patents, and consequently has nothing to do with the direct effect of its provisions.

## VI – Conclusion

97. In the light of all the foregoing, I propose that the Court of Justice give the following reply to the questions referred for a preliminary ruling by the Supremo Tribunal de Justiça:

'Being subject to subsequent measures taken by the national legislature to fix the exact duration of the protection granted to patents, Article 33 of the TRIPs Agreement does not have direct effect and therefore cannot be invoked before the national courts vis-à-vis other individuals.'

---

1 – Original language: Spanish.

2 – Dashwood, A., 'Why continue to have mixed agreements at all?', in Bourgeois, H.J., Dewost, J.L. and Gaiffe, M.A., (Editors) *La Communauté européenne et les accords mixtes: quelles perspectives?*, Collège d'Europe, Bruges, 1997, p. 98.

3 – Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) – Annex 1C of the Agreement establishing the World Trade Organisation, approved on behalf of the Community 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 TRIPs Agreement is to be found on p. 213).

4 – Rosas, A., 'The European Union and mixed agreements' in Dashwood, A. and Hillion, Ch., *The General Law of E.C. External Relations*, Sweet & Maxwell, London, 2000, p. 216 et seq.

5 – Case C-18/93 *Corsica Ferries* [1994] ECR I-1783, paragraph 14; Case C-96/94 *Centro Servizi Spediporto* [1995] ECR I-2883, paragraph 45; Case C-266/96 *Corsica Ferries France* [1998] ECR I-3949, paragraph 27; and Case C-291/96 *Grado and Bashir* [1997] ECR I-5531, paragraph 2.

6 – Case 181/73 *Haegeman* [1974] ECR 449.

7 – Case 12/86 *Demirel* [1987] ECR 3719, paragraph 7.

8 – Paragraphs 4 to 6 of the judgment in *Haegeman*, cited above.

9 – Wegener, B., 'Artikel 220', in Callies, Ch. and Ruffert, M., *Kommentar zu EU-Vertrag und EG-Vertrag*, Ed. Luchterhand, 2nd ed. revised and extended, Neuwied and Kriftel, 2002, p. 1991, point 17.

10 – Paragraph 9.

11 – Confirmed by inter alia Case C-13/00 *Commission v Ireland* [2002] ECR I-2943, paragraph 14.

12 – The Agreement establishing an Association between the European Economic Community and Turkey, signed at Ankara on 12 September 1963 and concluded on behalf of the Community by a decision of the Council of 23 December 1963 (OJ 1964, p. 3687).

13 – Case-law stated in Case 104/81 *Kupferberg* [1982] ECR 3641, paragraph 13.

14 – Opinion pursuant to Article 228(6) of the EC Treaty (now, following amendment, Article 300 EC), (Opinion 1/94, ECR I-5267).

15 – Case 22/70 *Commission v Council* [1971] ECR 263.

- 16 – Paragraph 103 of Opinion 1/94.
- 17 – Case C-53/96 *Hermès* [1998] ECR I-3603.
- 18 – Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark (OJ 1994 L 11, p. 1).
- 19 – *Hermès*, cited above, paragraph 25.
- 20 – *Hermès*, paragraphs 26 to 29.
- 21 – This was stated by Advocate General Jacobs in the opinion he delivered in Case C-89/99 *Schieving-Nijstad and Others* [2001] ECR I-5851, point 40. Also, Heliskoski, J., ‘The jurisdiction of the European Court of Justice to give preliminary rulings on the interpretation of mixed agreements’, in *Nordic Journal of International Law*, vol. 69, N° 4/2000, p. 402 et seq.; also Cebada Romero, A., *La Organización Mundial del Comercio y la Unión Europea*, Ed. La Ley, Madrid, 2002, p. 358.
- 22 – Joined Cases C-300/98 and C-392/99 *Dior and Others* ECR I-11307.
- 23 – *Dior and Others*, paragraph 37.
- 24 – Opinion delivered on 13 November 1997 (ECR 1998, I-3603).
- 25 – Eeckhout, P., *External relations of the European Union – Legal and constitutional foundations*, Oxford University Press, Oxford, 2004, p. 242.
- 26 – Case C-13/00 *Commission v Ireland* [2002] ECR I-2943, specifically paragraphs 15 to 20.
- 27 – The Berne Convention for the Protection of Literary and Artistic Works (Paris Act of 24 July 1971).
- 28 – Case C-239/03 *Commission v France* [2004] ECR I-9325.
- 29 – Case C-459/03 *Commission v Ireland* [2006] ECR I-0000.
- 30 – *Etang de Berre*, cited above, paragraphs 29 and 30. That case concerned discharges of fresh water and alluvia into the marine environment, which had not yet been the subject of Community provisions, although they were covered by copious harmonised environmental legislation.
- 31 – Paragraph 95 of that judgment.
- 32 – Council Regulation of 18 June 1992 (OJ 1992 L 182, p. 1).
- 33 – Council Regulation of 27 July 1994 (OJ 1994 L 227, p. 1).
- 34 – Regulation of the European Parliament and of the Council of 23 July 1996 (OJ 1996 L 198, p. 30).
- 35 – Directive of the European Parliament and of the Council of 6 July 1998 (OJ 1998 L 213, p. 13).
- 36 – COM (2004) 737 final and SEC (2004) 1348.
- 37 – COM (2000) 412 final (OJ 2000 C 337 E, p. 278).
- 38 – COM (2003) 827 final.
- 39 – COM (2003) 828 final.
- 40 – First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks (OJ 1989 L 40, p. 1).
- 41 – Point 2.3 of the proposal for a Regulation on the Community patent, cited above.
- 42 – The legal basis for the Proposal for a Regulation on the Community patent is Article 308 EC, which requires unanimity in the Council. At the hearing, the Commission, when asked why the Proposal had been unsuccessful in the Council, referred to the rules on the use of languages as the main obstacle to its being approved.
- 43 – Eeckhout, P., *op. cit.*, p. 237.
- 44 – Pescatore, P. ‘Opinion 1/94 on “conclusion” of the WTO Agreement: is there an escape from a programmed disaster?’, in *Common Market Law Review*, Vol. 36, 1999, p. 400.
- 45 – Opinion 1/94, cited above, paragraph 108.
- 46 – Kahl, W. ‘Artikel 10’, in Callies, Ch. and Ruffert, M., *op. cit.*, p. 451 et seq.
- 47 – Points 20 and 21 of his opinion, cited above, in *Hermès*.
- 48 – Opinion issued, pursuant to the second subparagraph of Article 228(1) of the EEC Treaty, on 14 December 1991 (Opinion 1/91 ECR I-6079), paragraphs 43 to 45.
- 49 – Demirel, paragraph 14.
- 50 – Opinion in *Hermès*, point 30, second paragraph.
- 51 – *Ibidem*, point 37, emphasis added.
- 52 – Case C-149/96 *Portugal v Council* [1999] ECR I-8395, paragraphs 42 to 47.
- 53 – Council Decision 96/386/EC of 26 February 1996 concerning the conclusion of Memoranda of Understanding between the European Community and the Islamic Republic of Pakistan and between the European Community and the Republic of India on arrangements in the area of market access for textile products (OJ 1996 L 153, p. 47).
- 54 – Perfectly summarised in Cebada Romero, A., *op. cit.*, p. 467 et seq.
- 55 – Memorandum of Understanding on Rules and Procedures Governing the Settlement of Disputes (Annex 2 to the WTO Agreements).
- 56 – *Portugal v Council*, cited above, paragraphs 36 to 40.
- 57 – Paragraph 41 of the judgment cited in the previous footnote.
- 58 – *Portugal v Council*, paragraph 47.
- 59 – Case 70/87 *Fediol v Commission* [1989] ECR 1781, paragraphs 19 to 22.
- 60 – Case C-69/89 *Nakajima v Council* [1991] ECR I-2069, paragraph 31.
- 61 – Case C-377/02 *Van Parys* [2005] ECR I-1465, paragraphs 39 and 40.
- 62 – Established in Article 2(1) of the aforementioned Memorandum of Understanding.
- 63 – *Van Parys*, paragraph 54.
- 64 – Laget-Annamayer, A., ‘Le Statut des accords OMC dans l’ordre juridique communautaire: en attendant la consécration de l’invocabilité’, in *Revue trimestrielle de droit européen*, 42 (2), April/June 2006, p. 281 et seq.
- 65 – *Dior*, paragraphs 47 and 48.
- 66 – In accordance with the judgment in *Hermès*, paragraph 28.
- 67 – Also the judgment in *Schieving-Nijstad and Others*, cited above, paragraphs 51 to 55.
- 68 – Dupuy, P. M., *Droit international public*, Dalloz, 4th ed., Paris, 1998, p. 284.

69 – Pescatore, P., ‘Free World Trade and the European Union’, in Pérez van Kappel, A. and Heusel, W., (coordinators) Free World Trade and the European Union – The reconciliation of Interest and the Review of the Understanding on Dispute Settlement in the Framework of the World Trade Organisation, Academy of European Law, vol. 28, Tréveris, 2000, p. 12.

70 – Laget-Annamayer, A., op. cit., p. 287; also Cebada Romero, A., op. cit., p. 490.71 – Opinion in Portugal v Council, cited above, point 18.

72 – Eeckhout, P., op. cit., p. 306.

73 – Fourth paragraph of the statement of reasons of the TRIPs Agreement.

74 – Article 22(1) of the Memorandum of Understanding.

75 – This is inferred from Article 3(7) of the Memorandum of Understanding, according to which ‘[...] A solution mutually acceptable to the parties to a dispute and consistent with the covered agreements is clearly to be preferred. [...]’; emphasis added.

76 – Timmermans, C.W.A., ‘L’Uruguay Round: sa mise en oeuvre par la Communauté européenne’, in Revue du Marché Unique Européen, N° 4/1994, p. 178.

77 – According to verbal information provided by the Legal Department of the WTO.