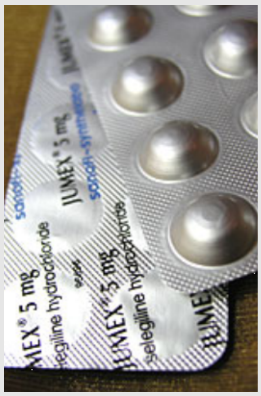
European Court of Justice, 1 April 2004, Kohlpharma



FREE MOVEMENT – PHARMACEUTICAL LAW

Common origin

- **Articles 28 EC et 30 EC preclude the applithe applica-tion being rejected solely on the ground that the two medicinal products do not have a common origin.**

The question referred for a preliminary ruling must therefore be understood as asking essentially whether, if the assessment carried out on the safety and efficacy of the medicinal product which is already authorised can be applied to the second product without any risk to the protection of public health, Articles 28 EC and 30 EC preclude the competent authorities from refusing to grant marketing authorisation to the second medicinal product with reference to the first one solely on the ground that the two medicinal products do not have a common origin.

Application for marketing authorisation under a simplified procedure

- **When an active ingredient is sold to two different manufacturers established in two Member States, the applicant for marketing authorisation for the second medicinal product may, for the purpose of assessing its safety and efficacy, demonstrate by means of available or accessible information that the medicinal product to be imported does not differ significantly from the medicinal product which is already authorised**

In circumstances such as those in the main proceedings, which are characterised by the fact that an active ingredient is sold to two different manufacturers estab-lished in two Member States, the applicant for marketing authorisation for the second medicinal product may, for the purpose of assessing its safety and efficacy, demonstrate by means of available or accessi-ble information that the medicinal product to be imported does not differ significantly from the medicinal product which is already authorised.

When, in particular in the case of an importer, the applicant does not have access to all the necessary information but provides data that make it at least plausible that the two medicinal products do not differ significantly for the purpose of assessing their safety and efficacy, the competent authorities must act in such a way that their decision as to whether to extend to the second medicinal product the marketing authorisation granted to the first one is taken on the basis of the fullest information possible, including information which is available to them or which they could have obtained through cooperation with the health authorities in other Member States.

Source: **curia.europa.eu**

European Court of Justice, 1 April 2004
(C. Gulmann, J.N. Cunha Rodrigues, J.-P. Puissochet, R. Schintgen and F. Macken)
JUDGMENT OF THE COURT (Sixth Chamber)
1 April 2004 (1)
(Free movement of goods – Medicinal products – Importation – Application for marketing authorisation under a simplified procedure – Common origin)
In Case C-112/02,
REFERENCE to the Court under Article 234 EC by the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Germany) for a preliminary ruling in the proceedings pending before that court between
Kohlpharma GmbH
and
Bundesrepublik Deutschland,
on the interpretation of Community law, in particular Articles 28 EC and 30 EC,
THE COURT (Sixth Chamber),
composed of: C. Gulmann (Rapporteur), acting for the President of the Sixth Chamber, J.N. Cunha Rodrigues, J.-P. Puissochet, R. Schintgen and F. Macken, Judges,
Advocate General: A. Tizzano,
gistrar: H.A. Rühl, Principal Administrator,
after considering the written observations submitted on behalf of:
–
Kohlpharma GmbH, by W.A. Rehmann, Rechtsanwalt,
–
the Commission of the European Communities, by H. Støvlbæk and S. Fries, acting as Agents,
having regard to the Report for the Hearing,
after hearing the oral observations of Kohlpharma GmbH, represented by W.A. Rehmann; of the Bundesinstitut für Arzneimittel und Medizinprodukte, represented by M. Wagner and A. von Hagen, acting as Agents; and of the Commission, represented by H. Støvlbæk and S. Fries, at the hearing on 13 March 2003,
after hearing the **Opinion of the Advocate General** at the sitting on 11 September 2003,
gives the following
Judgment
1 By order of 14 March 2002, received at the Court on 27 March 2002, the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Higher Administrative Court of North Rhine-Westphalia) referred to the Court for a preliminary ruling under Article 234 EC a ques-

tion on the interpretation of Community law, in particular Articles 28 EC and 30 EC.

2 That question has arisen in proceedings between Kohlpharma GmbH ('Kohlpharma') and the Federal Republic of Germany concerning marketing authorisation for a medicinal product imported from Italy.

Main proceedings

3 The company Chiesi Farmaceutici SpA (hereinafter 'Chiesi') produces and markets the medicinal product Jumex in Italy under a marketing authorisation which it was granted in that country. That medicinal product is manufactured from the active ingredient selegiline hydrochloride. The company Orion Pharma GmbH (hereinafter 'Orion') produces and markets the medicinal product Movergan in Germany under a marketing authorisation issued to it in that country. Movergan is manufactured using the same active ingredient as that in Jumex.

4 The active ingredient used by Chiesi and Orion is supplied by the undertaking Chinoin Pharmaceutical and Chemical Works Co. Ltd (hereinafter 'Chinoin'), established in Hungary. While Chiesi has a licensing agreement with Chinoin, Orion receives its supplies, either directly or through Finland, under a supply agreement between Chinoin and Orion Corp. Finland.

5 Kohlpharma applied to the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Medicinal Products, hereinafter 'the Bundesinstitut') for marketing authorisation for the medicinal product Jumex, for the purpose of importing it into Germany. It referred to the medicinal product Movergan, which is already authorised in Germany, and requested that the marketing authorisation for that medicinal product be extended to Jumex.

6 The Bundesinstitut rejected that application, citing the judgment in Case C-201/94 Smith & Nephewand Primecrown [1996] ECR I-5819. That judgment, the Bundesinstitut argued, establishes that the extension to an imported medicinal product of a marketing authorisation already issued to another medicinal product in the State of importation is subject to the condition that the two medicinal products have a common origin, that is, that their manufacturers are part of the same group of undertakings or, at the very least, that they produce those medicinal products under agreements with the same licensor.

7 Kohlpharma appealed against that rejection decision to the Oberverwaltungsgericht, arguing that the medicinal product to be imported and that already authorised in the Member State of importation could not be required to have a common origin. In the case-law relating to parallel imports, it submitted, the Court did not establish the condition of identity of origin as a binding principle but merely took it into account, since the conditions of identity of products and of origin were in fact both satisfied in the cases which had been referred to it for a preliminary ruling.

8 In those circumstances, the Oberverwaltungsgericht für das Land Nordrhein-Westfalen decided, by order of 14 March 2002, to stay proceedings and to refer the following question to the Court for a preliminary ruling:

'Is it justified under Article 30 EC or other Community law for the competent German authority to obstruct the parallel import of a medicinal product by refusing marketing authorisation under the simplied procedure, contrary to Article 28 EC, although, on the one hand, it accepts that the medicinal product to be imported (Jumex), authorised for Chiesi Farmaceutici SpA in Italy, is as regards the medically active ingredient (selegiline hydrochloride) identical to the medicinal product (Movergan) produced by the German authorisation holder Orion Pharma GmbH, the medically active ingredient of which is delivered to the Italian firm by the manufacturer, located in Hungary, on the basis of a licensing agreement, but is delivered to the German firm only on the basis of a supply agreement with Orion Corp. Finland, either directly or via Finland, if, on the other hand, that authority does not demonstrate in detail as regards either the medically active ingredient or the excipients, which it considers to differ in the present case both qualitatively and quantitatively, that the two medicinal products are not identical, and in particular are not manufacturered according to the same forumulation and using the same active ingredient or that they have different therapeutic effects?'

Question referred for a preliminary ruling

9 It must first be pointed out that:

–

the main proceedings concern two medicinal products produced in Italy and Germany, respectively, by different manufacturers which obtained marketing authorisations in Italy and Germany, respectively, in accordance with the rules and procedures laid down in Community legisation, namely, at present, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), which states that marketing authorisation will be granted only if, after verification of the particulars and documents relating to the efficacy and safety of the medicinal product at issue, it appears that the product is not harmful in normal conditions of use and that its therapeutic effect has been demonstrated (see Articles 8 to 11 of Directive 2001/83);

–

the manufacturer of the medicinal product Jumex has not submitted an application for marketing authorisation in Germany;

–

the two medicinal products at issue are manufactured using the same active ingredient supplied by the same undertaking.

10 Next, it must be recalled that:

–

in those circumstances, Kohlpharma submitted an application for marketing authorisation for the medicinal product Jumex, which it wishes to market in Germany, and claimed that the marketing authorisation already granted to the medicinal product Movergan should be extended to the medicinal product Jumex, inasmuch as

those two medicinal products are in its view essentially identical;

–

the competent authorities refused to grant that application, since they took the view that it was not possible to extend the marketing authorisation for the medicinal product Movergan to the medicinal product Jumex, since the two medicinal products did not have a common origin.

11 In that context, in order to give a useful answer to the question referred for a preliminary ruling, the Court can take as a basis the premiss that, for the purposes of assessing their safety and efficacy, the two medicinal products do not differ significantly.

12 The question referred for a preliminary ruling must therefore be understood as asking essentially whether, if the assessment carried out on the safety and efficacy of the medicinal product which is already authorised can be applied to the second product without any risk to the protection of public health, Articles 28 EC and 30 EC preclude the competent authorities from refusing to grant marketing authorisation to the second medicinal product with reference to the first one solely on the ground that the two medicinal products do not have a common origin.

13 The refusal to issue a marketing authorisation for a medicinal product imported from another Member State, in which that product was issued a marketing authorisation, constitutes a restriction on the free movement of goods between Member States. Such a restriction is contrary to Article 28 EC unless it is warranted by imperative needs, in particular the protection of public health.

14 It is for the competent national authorities, before they issue a marketing authorisation, to ensure that the primary objective of the Community legislation, namely the safeguarding of public health, is fully complied with. Nevertheless, the principle of proportionality requires that, in order to protect the free movement of goods, the legislation in question be applied within the limit of what is necessary in order to achieve the aim of protecting health that is legitimately being pursued (see, to that effect, **Case C-172/00 Ferring [2002] ECR I-6891**, paragraph 34).

15 Once it has been established that the safety and efficacy assessment carried out for the medicinal product which is already authorised can, without any risk to the protection of public health, be used in respect of the medicinal product for which marketing authorisation is sought, the restriction on the free movement of goods between Member States which results from the refusal to issue a marketing authorisation to the second medicinal product cannot be justified on grounds of protecting public health if that refusal is based solely on the fact that the two medicinal products do not have the same origin.

16 In a situation such as that in the main proceedings, the problem confronting the competent authorities as regards marketing authorisations for medicinal products is whether, as is claimed by the applicant for a marketing authorisation, the safety and efficacy assessment carried out for the medicinal product which has already been authorised can indeed be applied to the application for a marketing authorisation for the second medicinal product without any risk to the protection of public health.

17 In that regard, a common origin of the two medicinal products may constitute an important element in establishing that such is the case.

18 Nevertheless, the absence of a common origin for the two medicinal products does not in itself constitute a ground for refusing a marketing autorisation to the second medicinal product.

19 In circumstances such as those in the main proceedings, which are characterised by the fact that an active ingredient is sold to two different manufacturers established in two Member States, the applicant for marketing authorisation for the second medicinal product may, for the purpose of assessing its safety and efficacy, demonstrate by means of available or accessible information that the medicinal product to be imported does not differ significantly from the medicinal product which is already authorised.

20 When, in particular in the case of an importer, the applicant does not have access to all the necessary information but provides data that make it at least plausible that the two medicinal products do not differ significantly for the purpose of assessing their safety and efficacy, the competent authorities must act in such a way that their decision as to whether to extend to the second medicinal product the marketing authorisation granted to the first one is taken on the basis of the fullest information possible, including information which is available to them or which they could have obtained through cooperation with the health authorities in other Member States.

21 The answer to the question must therefore be that, in the case where

–

an application for a marketing authorisation for a medicinal product is submitted with reference to a medicinal product that has already been authorised,

–

the medicinal product which is the subject of the application is imported from a Member State in which it has obtained a marketing authorisation,

–

the thethe assessment of safety and efficacy carried out for the medicinal product which is already authorised can be used in the application for a marketing authorisation for the second medicinal product without any risk to public health,

Articles 28 EC et 30 EC preclude the applithe application being rejected solely on the ground that the two medicinal products do not have a common origin.

Costs

22 The costs incurred by the Commission, which has submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,
THE COURT (Sixth Chamber),
in answer to the question referred to it by the Oberverwaltungsgericht für das Land Nordrhein-Westfalen by order of 14 March 2002, hereby rules:
In the case where
–
an application for a marketing authorisation for a medicinal product is submitted with reference to a medicinal product that has already been authorised,
–
the medicinal product which is the subject of the application is imported from a Member State in which it has obtained a marketing authorisation,
–
the assessment of safety and efficacy carried out for the medicinal product which is already authorised can be used in the application for a marketing authorisation for the second medicinal product without any risk to public health,

---

OPINION OF ADVOCATE GENERAL TIZZANO

delivered on 11 September 2003 (1)
Case C-112/02
Kohlpharma GmbH
v
Bundesrepublik Deutschland
(Reference for a preliminary ruling from the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Germany))
(Articles 28 EC and 30 EC – Medicinal products – Marketing authorisation – Parallel imports)

1. By order of 14 March 2002, the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Higher Administrative Court of North Rhine-Westphalia), Germany (hereinafter 'the Oberverwaltungsgericht'), referred a question to the Court for a preliminary ruling regarding the interpretation of Articles 28 EC and 30 EC, pursuant to Article 234 EC. The national court refers in particular to the situation where a proprietary medicinal product imported from a Member State in which it is covered by a marketing authorisation is manufactured on the basis of the same active ingredient as that used to manufacture a proprietary medicinal product which is covered by a marketing authorisation in the Member State of importation. In those circumstances, the Oberverwaltungsgericht asks whether the competent authority of the latter State may refuse to extend to the imported proprietary medicinal product the marketing authorisation granted for the other proprietary medicinal product on the sole ground that the two proprietary medicinal products do not have a common origin, or whether, under Articles 28 EC and 30 EC, that authority may refuse that marketing authorisation only if, after appropriate testing, there are reasonable doubts that those proprietary medicinal products have different therapeutic effects or do not offer the same guarantees of harmlessness to health.

I – Relevant legislation

2. It is common knowledge that Article 28 EC prohibits quantitative restrictions on imports between Member States and all measures having equivalent effect. However, under Article 30 EC, such restrictions are permitted where they are justified on grounds of the protection of health and life of humans and where they do not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

3. Article 3 of Directive 65/65/EEC (2) (hereinafter 'Directive 65/65') provides that no proprietary medicinal product may be placed on the market in a Member State unless a marketing authorisation has been issued by the competent authority of that State.

4. Article 4 of that directive sets out in detail the procedure, documents and particulars necessary for a marketing authorisation to be granted.

5. Directive 65/65 was subsequently repealed and replaced by Directive 2001/83/EEC (3) (hereinafter 'Directive 2001/83').

6. Article 6(1) of Directive 2001/83, like Article 3 of Directive 65/65, provides that no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that State or a centralised marketing authorisation has been issued in accordance with the conditions laid down by Regulation (EEC) No 2309/93. (4)

7. Like Article 4 of Directive 65/65, Articles 8 to 11 of Directive 2001/83 set out the procedure, documents and particulars necessary for a marketing authorisation to be granted.

8. Article 10(1) of Directive 2001/83 provides, in particular, that, derogating from Article 8(3)(i) of that same directive, a person applying for a marketing authorisation 'shall not be required to provide the results of toxicological and pharmacological tests or the results of clinical trials if he can demonstrate that the medicinal product is essentially similar to a medicinal product which has been authorised within the Community, in accordance with Community provisions in force, for not less than six years and is marketed in the Member State for which the application is made '.

II – Facts and the question referred for a preliminary ruling

9. Chiesi Farmaceutici S.p.A. (hereinafter 'Chiesi') sells in Italy the medicinal product 'Jumex', manufactured using the same active ingredient, 'selegiline hydrochloride', used to manufacture 'Movergan', a medicinal product marketed in Germany by the German company Orion Pharma GmbH (hereinafter 'Orion'). In both cases, the medically active ingredient comes from the same undertaking: the Hungarian company Chinoin. However, while Orion obtains that active ingredient (directly or through the Finnish company Orion Corp.) by virtue of a mere supply agreement with Chinoin, Chiesi obtains that same substance under a licensing agreement with Chinoin.

10. Since the abovementioned medicinal products contain exactly the same active ingredient, Kohlpharma GmbH (hereinafter 'Kohlpharma'), which wishes to import 'Jumex' into Germany, asked the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Medicinal Products; hereinafter 'the Bundesinstitut') to extend to that product the marketing authorisation which it had already granted for 'Movergan' with regard to the territory of the Federal Republic of Germany.

11. However, the Bundesinstitut rejected that request, citing the judgment in Smith & Nephew and Primecrown, (5) which I shall come back to at greater length below. In its view, it follows from that judgment that a condition for extending to an imported proprietary medicinal product a marketing authorisation already granted for another proprietary medicinal product in the State of importation is that the two proprietary medicinal products must have a common origin, or that the manufacturers of those proprietary medicinal products should be part of the same group of undertakings or, at least, manufacture those products pursuant to agreements concluded with the same licensor. That, it argued, was not the situation in the case before it, since Chiesi and Orion were not part of the same group of undertakings and only the former was linked to Chinoin by a licensing agreement.

12. Kohlpharma appealed against that decision to the Oberverwaltungsgericht, claiming that the requirement of common origin is not a prerequisite for extending to a proprietary medicinal product imported from a Member State a marketing authorisation already granted in the State of importation for an – essentially identical – proprietary medicinal product.

13. The Oberverwaltungsgericht took the view that it was not clear whether, in the circumstances of this case, the Bundesinstitut could refuse to extend to Jumex the marketing authorisation that covers 'Movergan' in the Federal Republic of Germany. It therefore stayed the proceedings and referred the following question to the Court for a preliminary ruling:

14. 'Is it justified under Article 30 EC or other Community law for the competent German authority to obstruct the parallel import of a medicinal product by refusing marketing authorisation under the simplified procedure, contrary to Article 28 EC, although, on the one hand, it accepts that the medicinal product to be imported (Jumex), authorised for Chiesi Farmaceutici S.p.A. in Italy, is as regards the medically active ingredient (selegiline hydrochloride) identical to the medicinal product (Movergan) produced by the German authorisation holder Orion Pharma GmbH, the medically active ingredient of which is delivered to the Italian firm by the manufacturer, located in Hungary, on the basis of a licensing agreement, but is delivered to the German firm only on the basis of a supply agreement with Orion Corp. Finland, either directly or via Finland, if, on the other hand, that authority does not demonstrate in detail as regards either the medically active ingredient or the excipients, which it considers to differ in the present case both qualitatively and quantitatively, that the two medicinal products are not identical, and in particular are not manufactured according to the same formulation and using the same active ingredient or that they have different therapeutic effects?'

III – Proceedings before the Court

15. Kohlpharma and the Commission have submitted written observations to the Court. Those parties to the proceedings and the German Government attended the hearing on 13 March 2003.

IV – Legal analysis

16. By the question it has referred for a preliminary ruling, the national court is essentially asking the Court whether, if a proprietary medicinal product imported from a Member State, where it is covered by a marketing authorisation, is manufactured on the basis of the same active ingredient used to manufacture a proprietary medicinal product which is covered by a marketing authorisation in the Member State of importation, the competent authority of the latter State may refuse to extend to the first product the marketing authorisation that covers the second product on the sole ground that those proprietary medicinal products do not have a common origin.

A – Relevant case-law of the Court

17. Both the national court, in the statement of reasons in its order for reference, and the interested parties, in the main proceedings and in the observations submitted to the Court, made extensive reference to the relevant case-law of the Court. I therefore consider it appropriate to begin by summarising that case-law.

18. The judgments in Smith & Nephew and Primecrown and Rhône-Poulenc Rorer and May & Baker, (6) in particular, play a central role for the purposes of the present case. In both cases the Court was asked to rule on the conditions laid down by Community law for the granting of a marketing authorisation in the context of parallel imports of medicinal products.

19. In Smith & Nephew and Primecrown, the national court had asked the Court to clarify under what conditions a proprietary medicinal product, which is covered by a marketing authorisation issued under Directive 65/65 in one Member State, may be covered in another Member State by the marketing authorisation granted in the latter State for another proprietary medicinal product.

20. The Court stated, first of all, that, since the primary purpose of Directive 65/65 is 'to ensure that, when a proprietary medicinal product is marketed, public health is safeguarded by means which cannot hinder

the development of the pharmaceutical industry or trade in medicinal products within the Community', the production of all the documents and all the information required by that directive as a pre-condition to the granting of a marketing authorisation is justified, for the purposes of safeguarding public health, 'only in regard to proprietary medicinal products which are being put on the market for the first time' (paragraphs 19 and 20 of the judgment in Smith & Nephew and Primecrown).

21. The Court held that 'a proprietary medicinal product covered by a marketing authorisation in one Member State which is being imported into another Member State as a parallel import of a product already covered by a marketing authorisation in that other Member State' could not be regarded as being placed on the market for the first time (paragraph 21 of the judgment in Smith & Nephew and Primecrown).

22. The Court then observed that it had already held in its judgment in De Peijper (7) that the competent authorities of a Member State may not require an importer of a medicinal product lawfully marketed in another Member State to produce all the particulars necessary for the purposes of checking that that medicinal product is effective and not harmful, if those authorities possess those particulars in respect of a medicinal product which is 'in every respect the same' as the imported medicinal product 'or whose differences [as compared with the latter] have no therapeutic effect' (paragraph 22 of the judgment in Smith & Nephew and Primecrown).

23. The Court therefore pointed out that, although 'the proprietary medicinal products at issue [in De Peijper] had been manufactured by the same group of companies and therefore had a common origin', the principles asserted in that judgment are applicable also to a situation 'in which independent companies produce proprietary medicinal products, which have a common origin by virtue of the fact that they are manufactured pursuant to agreements concluded with the same licensor' (paragraphs 24 and 25 of the judgment in Smith & Nephew and Primecrown).

24. Nevertheless, the Court added, '[t]he competent authority in the Member State of importation must verify that the two proprietary medicinal products, if not identical in all respects, have at least been manufactured according to the same formulation, using the same active ingredient, and that they also have the same therapeutic effects' (paragraph 26 of the judgment in Smith & Nephew and Primecrown).

25. If – the Court concluded – following 'its examination, the competent authority of the Member State of importation finds that all the abovementioned criteria are satisfied, the proprietary medicinal product to be imported must be regarded as having already been placed on the market in the Member State of importation and, consequently, must be entitled to benefit from the marketing authorisation issued for the proprietary medicinal product already on the market, unless there are countervailing considerations relating to the effective protection of the life and health of humans' (paragraph 29 of the judgment in Smith & Nephew and Primecrown).

26. However, '[i]f the competent national authority concludes that the proprietary medicinal product to be imported does not satisfy all the abovementioned criteria and cannot therefore be regarded as having already been placed on the market in the Member State of importation, it cannot issue the new marketing authorisation required for the marketing of the product to be imported unless the conditions listed in Directive 65/65, as amended by Directive 87/21, are fulfilled' (paragraph 30 of the judgment in Smith & Nephew and Primecrown).

27. Lastly, as regards the judgment in Rhône-Poulenc Rorer and May & Baker, I note, in so far as it is relevant to the present case, that, after having stated – by reference to paragraphs 25 and 26 of the judgment in Smith & Nephew and Primecrown – that, 'in order to ascertain whether imports of a medicinal product constitute parallel imports, the competent authority in the Member State of importation must [inter alia] verify that the two medicinal products have a common origin '(paragraph 28), the Court noted that in that case the existence of that factor was common ground (paragraph 29).

28. The considerations of the national court and the arguments of the parties, which I shall deal with in turn, should therefore be assessed in the light of the case-law which has just been cited above.

B – Considerations of the national court

29. The Oberverwaltungsgericht doubts whether, in circumstances such as those in this case, the competent authority can refuse to extend, for the benefit of a medicinal product imported from a Member State, the marketing authorisation granted for another medicinal product in the State of importation solely because there is no licensing agreement between the manufacturer of the latter product and the supplier of the active ingredient and it cannot therefore be established that those medicinal products have a 'common origin'. Indeed, it is not clear to the national court why that extension may be granted, as the Bundesinstitut claims, only where the two medicinal products are manufactured by independent undertakings on the basis of licensing agreements with the same licensor, but not where those independent undertakings manufacture the medicinal products on the basis of a supply agreement for the active ingredient with the same undertaking.

30. In those circumstances – according to the Oberverwaltungsgericht, which refers to paragraph 26 of the judgment in Smith & Nephew and Primecrown (see point 24 above) and to the Opinion of Advocate General Geelhoed in Case C-172/00 (8) – the competent national authority must verify, however, if necessary, in consultation with the competent authorities of the Member State of exportation, whether the imported medicinal product and the product already marketed in the State of importation, although not identical in all respects, are nevertheless manufactured on the basis of the same formulation and using the same active ingredients, and have the same therapeutic effects. The

national court maintains that where that authority establishes the existence of those factors, it must authorise the marketing of the product; where it does not, it must in any case explain the reasons for refusing the authorisation.

C – Summary of the parties' arguments

31. Kohlpharma first claims that the criterion of common origin, referred to in the judgments in Smith & Nephew and Primecrown and Rhône-Poulenc Rorer and May & Baker, does not constitute a prerequisite for extending to an imported medicinal product a marketing authorisation already granted for another medicinal product in the State of importation.

32. In fact, in Kohlpharma's view, the reason why those judgments refer to the common origin of the imported medicinal product and the product already authorised in the State of importation is that there was a common origin in both cases and, therefore, the Court mentioned it merely as an additional argument.

33. Kohlpharma takes the view that that is the only tenable interpretation in the light of the Court's case-law. If common origin were considered to be a separate and essential condition, a medicinal product which was identical to, but did not have the same origin as, a medicinal product covered by a marketing authorisation in the State of importation could be imported only after it had been subjected to a full new assessment by the competent authority. However, since that authority already has all the data on that medicinal product, Kohlpharma claims that such an assessment is not justified, under Article 30 EC, on grounds of the protection of health and life of humans. (9)

34. In any event, according to Kohlpharma, the concept of common origin, within the meaning of the judgment in Smith & Nephew and Primecrown, should include the situation where, as in this case, two undertakings, which are independent of each other, manufacture a medicinal product on the basis of an active ingredient obtained from the same supplier.

35. Kohlpharma continues by submitting that if the possibility of 'Movergan' and 'Jumex' having a common origin is ruled out solely because there is a supply agreement between the Chinoin company and the Orion group rather than a licensing agreement, pharmaceutical undertakings would have at their disposal an easy means of partitioning national markets. They would have only to replace licensing agreements concerning the manufacture and marketing of their own medicinal products with mere supply agreements.

36. Kohlpharma goes on to point out that the facts of this case do not differ substantially from those in Smith & Nephew and Primecrown. It notes that, admittedly, in this case, it is only the active ingredient, on the basis of which 'Movergan' and 'Jumex' are manufactured, which has a common origin. Nevertheless, in Smith & Nephew and Primecrown also, the licensor of the two medicinal products in question had stated that it supplied only the active ingredient to the manufacturer of one of those products and, consequently, it could not ensure that the two medicinal products were identical. (10)

37. The Commission agrees with Kohlpharma that it is necessary to include cases such as the present within the concept of common origin. What really matters is that the two proprietary medicinal products are essentially identical and that any differences are not significant in terms of the products' safety and efficacy for human health.

38. Lastly, the German Government, which intervened only at the hearing, took the view, referring to the abovementioned judgments in De Peijper and Smith & Nephew and Primecrown and, in particular, paragraphs 24 and 25 of the latter judgment (see point 23 above), that the common origin of the imported medicinal product and the product already authorised in the State of importation constitutes an essential requirement if the former is to be covered by the marketing authorisation granted for the latter. That requirement must be understood as meaning that those medicinal products must be manufactured by undertakings which are part of the same group or by undertakings linked by a licensing agreement with the same licensor.

D – Assessment

1. Introduction

39. Before addressing the substance of the question referred, I must first note that Directive 65/65 was repealed, as were the directives which amended it and other directives on medicinal products for human use, by Directive 2001/83.

40. The latter directive, far from amending the substance of the repealed directives, codified them, in the interests of clarity and rationality, by assembling them in a single text. (11) In confirmation of that, Article 128 of Directive 2001/83 provides that '[r]eferences to the repealed Directives shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex III'.

41. Consequently, in the light of the foregoing, the principles established by the case-law of the Court with regard to Directive 65/65 must now be understood as referring, mutatis mutandis, to Directive 2001/83. For those reasons, I shall refer below exclusively to the latter directive.

42. That having been established, it is apparent from the considerations of the Oberverwaltungsgericht and from the observations of the parties to the proceedings that, by the question referred for a preliminary ruling, the Court is essentially being asked to clarify two issues concerning parallel imports of medicinal products.

43. The first is whether the competent authority of a Member State may refuse to extend to a proprietary medicinal product imported from another Member State a marketing authorisation already granted in the first State for a proprietary medicinal product solely because those proprietary medicinal products do not have a common origin.

44. The second – discussed principally and at length at the hearing – is whether the parallel importer is required to provide the competent authority of the State of importation with proof that those proprietary medicinal products are essentially identical, or whether he may simply provide evidence to that effect, in the light

of which that authority is bound to carry out appropriate investigations before being able to adopt any decision.

45. Although those issues are closely connected, in the interests of setting them out clearly, I shall address them separately.

2. Common origin

46. As regards this issue, I note once again that, under Article 6(1) of Directive 2001/83, no proprietary medicinal product may be placed on the market of a Member State unless it is covered by a marketing authorisation issued by the competent authority of that State in accordance with the conditions laid down by that directive.

47. However, as is apparent from the Court's case-law, that condition does not necessarily apply to parallel imports of medicinal products between Member States. (12) Indeed, in such cases, the imported proprietary medicinal product may under specific conditions be permitted to benefit in the Member State of importation from the marketing authorisation already granted in that State for another proprietary medicinal product (see point 25 above).

48. That said, however, it remains to be clarified – and this is the crux of the matter – what those conditions are and what their scope is.

49. I note straight away that the parties to the proceedings and the national court appear to have no doubts as regards two of those conditions.

50. The first is that the proprietary medicinal product, which is the subject of parallel importation, must already be covered by a marketing authorisation issued by the competent authorities of the Member State of origin (see also point 21 above).

51. The second is that that proprietary medicinal product, if not identical in all respects to a proprietary medicinal product already authorised in the Member State of importation, should be so similar to the latter that it can be considered to be essentially identical (see also points 24 and 25 above). That is the case, in particular, when those proprietary medicinal products contain, qualitatively and quantitatively, the same active ingredients, have the same pharmaceutical form, (13) are bioequivalents, (14) and do not appear, in the light of scientific knowledge, to differ as regards their safety and efficacy. (15)

52. While Kohlpharma and the Commission consider that those factors are in themselves sufficient to classify the importation of medicinal products as a parallel import falling outside the scope of Directive 2001/83, the German Government maintains that a further condition must be fulfilled. According to that Government, as has been noted, the imported proprietary medicinal product and the product marketed in the Member State of importation must also have a 'common origin', that is to say they must be manufactured by companies which are part of the same group of undertakings or by independent companies but on the basis of agreements with the same licensor.

53. In support of its argument, the German Government relies chiefly on the abovementioned case-law of the Court, which, in its view, establishes precisely that condition.

54. I do not share that view. It is certainly true that, in Smith & Nephew and Primecrown, the Court pointed out that the imported proprietary medicinal product and the reference product in the State of importation had a common origin (see point 23 above).

55. That does not mean, however, as Kohlpharma has rightly observed, that the Court considered that factor to be decisive for the purposes of establishing whether the import was a parallel import falling outside the scope of Directive 2001/83.

56. Indeed, on closer examination, it is apparent that, in that judgment, the Court referred to the common origin of the medicinal products above all because that factor was present both in the case it was examining and in the case that resulted in the judgment in De Peijper. This made it simpler for the Court to hold that the principles set out in De Peijper could be extended to Smith & Nephew and Primecrown (see point 23 above).

57. Secondly, the Court referred to that factor because the common origin of the imported medicinal product and of the 'national' product is at any rate a reliable indication that the two products are essentially identical, a fact which the parallel importer may rely on before the competent authority of the Member State of importation in order to avoid application of Directive 2001/83 (see point 82 below).

58. However, the fact that common origin does not constitute an essential requirement for the purposes of the present case is, in my view, also apparent from the very wording of the judgment in Smith & Nephew and Primecrown. In paragraphs 21 to 24 of that judgment, after stating that 'the provisions of Directive [2001/83] concerning the procedure for issue of marketing authorisations cannot apply' to a case such as that examined in De Peijper, where the proprietary medicinal product which was the subject of a parallel import 'was in every respect the same' (16) as the reference proprietary medicinal product in the State of importation (paragraphs 21 to 23), the Court added that '[m]oreover, the proprietary medicinal products at issue in that judgment had been manufactured by the same group of companies and therefore had a common origin' (17) (paragraph 24).

59. It seems to me that that wording, in particular the use of the word 'moreover', supports the view that common origin is a factor which, while certainly being important, is none the less supplementary and additional to the – decisive – factor of the identical or essentially identical nature of the products.

60. In my view, similar considerations apply also in relation to paragraph 28 of the judgment in Rhône-Poulenc Rorer and May & Baker already cited (see point 27 above), which could equally be interpreted as proving that the Court considers the decisive condition to be the common origin of the imported medicinal product and the product already marketed in the State of importation.

61. In actual fact, it seems to me that that passage has a different meaning. In it, as Kohlpharma has observed, the Court merely refers to Smith & Nephew and Primecrown in order to be able to state immediately afterwards (in paragraph 29) that some of the factors which led to that judgment were also present in the case at issue. The Court thus avoided having to examine the consequences which would have arisen were some of those factors not present, including specifically the common origin of the medicinal products in question.

62. For the reasons set out above, I do not, therefore, consider that the Court's case-law lays down the condition at issue, unequivocally and unambiguously, and, consequently, that condition cannot conclusively be relied on in support of the German Government's view.

63. However, in my opinion, there are arguments which counter that view and which can be inferred from the exact same case-law of the Court to which considerable reference is made here.

64. As already mentioned, that case-law places considerable emphasis on the fact that the primary purpose of Directive 2001/83 is 'to ensure that, when a proprietary medicinal product is marketed, public health is safeguarded by means which cannot hinder the development of the pharmaceutical industry or trade in medicinal products within the Community'. (18)

65. Therefore, what is above all clear from that case-law is that the principal aim of the relevant Community legislation is to safeguard public health. Indeed, that is why the production of all the documents and all the information necessary for the granting of a marketing authorisation is justified 'only in regard to proprietary medicinal products which are being put on the market for the first time' (paragraphs 19 and 20 of the judgment in Smith & Nephew and Primecrown), just as parallel imported proprietary medicinal products may be placed on the market in a Member State without being subject to the requirements laid down by that legislation only where those products do not pose any risk to human health and life (see points 23 and 24 above).

66. However, if the main criterion must be the protection of public health, I do not believe that common origin can play a decisive role in this case.

67. On the one hand, in my view, the fact that a proprietary medicinal product has already been authorised in the Member State of exportation and, above all, that it is identical or essentially identical, as defined above (see point 51), to a proprietary medicinal product which is itself also authorised in the Member State of importation, can be considered quite sufficient to rule out the possibility that the placing on the market of the Member State of importation entails a risk for public health.

68. On the other hand, even if the imported proprietary medicinal product and the product authorised in the State of importation have a 'common origin', in my view, that is not in itself sufficient to rule out the possibility of risks for public health. Indeed, it is conceivable that, even though they have a common origin, the imported proprietary medicinal product and the product authorised in the Member State of importation may be manufactured using different substances or different processes and that, therefore, the first may differ from the second not only in terms of its therapeutic properties but also in terms of safety for human health.

69. I would add that, in my opinion, the other requirement highlighted by the Court's case-law, that is to say the requirement not to hinder 'the development of the pharmaceutical industry or trade in medicinal products within the Community' (see point 20 above), is also better safeguarded by the premiss which does not require the condition of common origin. Further, more generally, that premiss is clearly more consistent with the principles of the free movement of goods, as well as with the second and third recitals in the preamble to Directive 2001/83, which specifically enunciate those principles. (19)

70. Since the conditions laid down by Directive 2001/83 for the granting of a marketing authorisation represent potential obstacles to the free movement of medicinal products between Member States, within the meaning of Article 28 EC, such obstacles can be justified under Article 30 EC only in so far as they are intended to safeguard public health.

71. However, since public health can be considered to be safeguarded where the two conditions referred to above are fulfilled (see points 50 and 51 above), the requirement that the additional condition of common origin be fulfilled would constitute an unjustified restriction on the free movement of the products in question.

72. Consequently, it seems to me that the conclusion can be drawn, with regard to this case, that the fact that the two proprietary medicinal products in question have been manufactured on the basis of a licensing agreement or a supply agreement with the same undertaking cannot be regarded as crucial when it comes to placing on the market the medicinal product which is the subject of a parallel import into the Federal Republic of Germany.

73. In the light of the foregoing considerations, I therefore propose that the question referred for a preliminary ruling should be answered to the effect that Article 28 EC precludes a national authority from obstructing the parallel importation of a proprietary medicinal product which is covered by a marketing authorisation in the Member State of exportation and which, although it is not identical to a proprietary medicinal product authorised in the Member State of importation and does not have a common origin with that product, contains, qualitatively and quantitatively, the same active ingredients, has the same pharmaceutical form, is bioequivalent and does not appear, in the light of scientific knowledge, to present significant differences as regards safety and efficacy.

3. The burden of proof

74. That having been established, it remains to be clarified, in relation to the discussion which took place at the hearing in this connection, whether it is for the importer to provide the proof that the products in question are essentially identical, or whether, where there is sufficient evidence in that regard, it is for the compe-

tent authority of the State of importation to carry out any investigations necessary before it can adopt a decision on the application for the marketing authorisation to be extended to the imported proprietary medicinal product.

75. Kohlpharma favours the latter theory. It is of the opinion that the judgments in De Peijper and Smith & Nephew and Primecrown indicate that the authority of the State of importation can refuse to allow the imported medicinal product to be covered by the marketing authorisation already granted for the other product only if, using all the means at its disposal and, if necessary, in consultation with the competent authorities of the State of exportation, it ascertains – or at least cannot rule out the possibility – that the two medicinal products do not have the same therapeutic effects or are not equally harmless for human health.

76. The Commission and the German Government, however, contend that in principle it is incumbent on the importer to prove to the competent authority that all the conditions for allowing a medicinal product imported from a Member State to be covered, in the Member State of importation, by the marketing authorisation already granted for another medicinal product have been fulfilled. More specifically, if, as in this case, the imported medicinal product and the product already authorised in the State of importation contain different excipients, the importer is subject to a burden of proof similar to that incumbent on manufacturers – such as, for example, manufacturers of generic medicinal products – wishing to rely on the procedure laid down in Article 10 of Directive 2001/83, that is to say the duty to prove by means of bioavailability studies that the medicinal products which they intend to place on the market are bioequivalent to medicinal products already on that market.

77. Moreover, according to the Commission, the slighter the degree of common origin between two medicinal products, that is to say the weaker the link between the holders of the marketing authorisations issued for those medicinal products in the two Member States, the greater should be the burden on the importer to prove that those medicinal products are so similar that, in the event of the importation of one of those products into one or other of those States, the application of Directive 2001/83 would not be justified.

78. For my part, I should first point out that the alleged similarity between a parallel importer and a manufacturer of generic medicinal products seems to me to be questionable. The former simply purchases a medicinal product, which, given that it is on the market in the Member State of origin, is already covered by a marketing authorisation granted by the competent authority of that State, in order to place it on the market of another Member State where an identical, or essentially identical, proprietary medicinal product is marketed at a higher price. As a mere importer, he does not usually have all the data concerning the efficacy and safety of the imported medicinal product, but that data has presumably already been supplied to the competent authority of the State of exportation by the holder of the marketing authorisation in that State.

79. In principle, however, a manufacturer of generic medicinal products places on the market of one or more Member States medicinal products which are not yet covered by a marketing authorisation in any Member State, and, consequently, he alone possesses information on their safety and efficacy. It therefore seems clear to me that such a manufacturer should be required to fulfil all the conditions laid down by Directive 2001/83 where he seeks to avail himself of the abridged procedure provided for by Article 10 of that directive. (20)

80. In my view, however, that same obligation can be placed on a parallel importer only within the limits which I shall attempt to define below.

81. Firstly, it should be borne in mind that considerable evidence with regard to the lack of significant differences, in terms of safety and efficacy, between the imported proprietary medicinal product and the reference product in the State of importation can be found in the package leaflets of those proprietary medicinal products. Under Article 59 of Directive 2001/83, those leaflets should include: a full statement of the active substances and excipients of the medicinal product expressed qualitatively, a statement of its active substances expressed quantitatively, the pharmaceutical form, the therapeutic indications, the information necessary for taking it (contra-indications, precautions for use and special warnings), the dosage, the method and frequency of administration and the undesirable effects.

82. Secondly, in addition to that evidence, the parallel importer can, if necessary, provide other useful information to the competent authority. He can, for example, demonstrate that the proprietary medicinal products in question are sold under the same name in the two States concerned, or that they have a common origin in that they are manufactured by undertakings belonging to the same group or on the basis of licensing agreements with the same licensor, or that, as in this case, their active ingredient is identical and is obtained from the same undertaking.

83. In other words, the parallel importer must provide, on request, all useful information in his possession or accessible to him. However, in my view, any additional information necessary to establish the safety and efficacy of the imported proprietary medicinal product should be sought first and foremost by the competent authority of the Member State of importation using, as Kohlpharma points out, all the means at its disposal and, in particular, in consultation with the competent authority of the Member State of exportation. (21)

84. In this connection, I note that, according to the Court's case-law: 'even if it were absolutely necessary to require the parallel importer to prove this conformity, there would in any case be no justification under Article [30 EC] for compelling him to do so with the help of documents to which he does not have access, when the administration, or as the case may be, the

court, finds that the evidence can be produced by other means'. (22)

85. That is true also because, again according to the Court, 'simple cooperation between the authorities of the Member States would enable them to obtain the necessary substantiating documents on a reciprocal basis' regarding the safety and efficacy of the imported medicinal product. (23)

86. In those circumstances, therefore, and in the light also of the principles of the free movement of goods, it is my view that, if there is reliable evidence to show that there are no significant differences between a proprietary medicinal product imported from a Member State, where it is covered by a marketing authorisation, and a proprietary medicinal product which is covered by a marketing authorisation in the Member State of importation, the competent authority of the latter State may not refuse an application to extend to the former proprietary medicinal product the marketing authorisation granted for the latter simply by raising possible doubts as to the efficacy and safety of the imported proprietary medicinal product.

87. If it has such doubts, that authority must first of all avail itself of all means at its disposal to seek to obtain additional information, consulting in particular the competent authority of the Member State of exportation.

88. If, having carried out the appropriate investigations, doubts persist as to the safety and efficacy of the proprietary medicinal product in question, only then can that authority require the importer to provide proof capable of dispelling those doubts and thus avoiding the marketing of the imported proprietary medicinal product being made subject to the conditions laid down by Directive 2001/83.

89. In the light of the foregoing considerations, I therefore propose that the answer to the national court should be that where, despite information provided by the importer, serious doubts persist as to the lack of significant differences between a proprietary medicinal product imported from a Member State, in which it is lawfully marketed under a marketing authorisation issued by the competent authority of that State, and a proprietary medicinal product placed on the market in the Member State of importation, the competent authority of the latter State can require that the imported proprietary medicinal product be placed on the market subject to full compliance with the conditions laid down by Directive 2001/83 only after it has itself carried out all the appropriate investigations, including consultation with the competent authorities of the Member State of exportation.

V – Conclusion

90. In the light of the foregoing considerations, I therefore propose that the Court reply to the question raised by the Oberverwaltungsgericht as follows:

(1) Article 28 EC precludes a national authority from obstructing the parallel importation of a proprietary medicinal product which is covered by a marketing authorisation in the Member State of exportation and which, although it is not identical to a proprietary medicinal product authorised in the Member State of importation and does not have a common origin with that product, contains, qualitatively and quantitatively, the same active ingredients, has the same pharmaceutical form, is bioequivalent and does not appear, in the light of scientific knowledge, to present significant differences as regards safety and efficacy.

(2) Where, despite information provided by the importer, serious doubts persist as to the lack of significant differences between a proprietary medicinal product imported from a Member State, in which it is lawfully marketed under a marketing authorisation issued by the competent authority of that State, and a proprietary medicinal product placed on the market in the Member State of importation, the competent authority of the latter State can require that the imported proprietary medicinal product be placed on the market subject to full compliance with the conditions laid down by Directive 2001/83 only after it has itself carried out all the appropriate investigations, including consultation with the competent authorities of the Member State of exportation.

---

1 – Original language: Italian.

2 – Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20).

3 – Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67). See in particular Article 128 of that directive.

4 – Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1).

5 – Case C-201/94 Smith & Nephew and Primecrown [1996] ECR I -5819.

6 – Case C-94/98 Rhône-Poulenc Rorer and May & Baker [1999] ECR I-8789.

7 – Case 104/75 De Peijper [1976] ECR 613.

8 – Opinion of Advocate General Geelhoed in Case C-172/00 Ferring Arzneimittel [2002] ECR I -6891, points 37 to 40.

9 – In support of that argument, Kohlpharma refers to the Opinion of Advocate General Geelhoed in Case C-172/00 Ferring Arzneimittel, cited above, points 37 to 40.

10 – See the judgment in Smith & Nephew and Primecrown, cited above, paragraphs 11 and 14.

11 – See the first recital in the preamble to Directive 2001/83.

12 – See the judgment in Smith & Nephew and Primecrown, paragraphs 19 and 20, cited above in points 20 and 21. To the same effect, see the Opinion of 12 December 2003 delivered by Advocate General

Jacobs in Case C -15/01 Paranova Läkemedel [2003]
ECR I-4175, paragraph 6, where there are further references.
13 – The pharmaceutical form of a medicinal product means the form in which it is presented (capsules, drops to be taken orally in solution, injections and so on) and the form in which it is administered (orally, rectally, nasally, cutaneously and so on). On this subject, see point 37 of the Opinion of Advocate General Ruiz-Jarabo Colomer in Case C-368/96 Generics (UK) and Others [1998] ECR I-7967.
14 – '[T]wo medicinal products are bioequivalents if they are pharmaceutical equivalents or alternatives and if their bioavailabilities (rate and extent) after administration in the same molar dose are similar to such a degree that their effects, with respect to both efficacy and safety, will be essentially the same' (judgment in Generics, cited above, paragraph 31).
15 – See, in this regard, the judgment in Generics, cited above, paragraph 36.
16 – Emphasis added.
17 – Emphasis added.
18 – Judgment in Smith & Nephew and Primecrown, cited above, paragraph 19. To the same effect, see judgment in Generics, cited above, paragraph 22.
19 – Those recitals state: '[t]he essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health … by means which will not hinder [the free movement of] medicinal products within the Community'.
20 – If, however, a manufacturer of generic medicinal products intends to place on the market of a Member State a medicinal product for which he has already obtained a marketing authorisation in another Member State, he may avail himself of the procedure on the mutual recognition of marketing authorisations provided for by Chapter 4 of Directive 2001/83.
21 –
I am thinking, for example, of any bioavailability studies that might have been submitted to that authority. Section E [under Part 4] of Annex I to Directive 2001/83 provides that '[t]he assessment of bioavailability must be undertaken in all cases where it is necessary, e.g. where the therapeutic dose is near the toxic dose or where the previous tests have revealed anomalies which may be related to pharmacodynamic properties, such as variable absorption'.
22 –
Judgment in De Peijper, cited above, paragraph 29.
23 –
Judgment in Smith & Nephew and Primecrown, cited above, paragraph 28.