OPINION OF ADVOCATE GENERAL JACOBS

delivered on 7 March 2002 [1]

1. In this case the Court is once again asked for guidance on the circumstances in which a parallel importer may lawfully repackage trade-marked medicaments imported from another Member State.

2. In contrast to the previous cases on repackaging, [2] the present case, which comes by way of a reference from the Landgericht Köln (Regional Court, Cologne), concerns medicaments which were put on the market pursuant to a central marketing authorisation granted under Regulation (EEC) No 2309/93. [3]

The facts and the main proceedings

3. The applicant ('Aventis') is the manufacturer of the insulin product 'Insuman Comb 25 100 IU/ml suspension for injection' ('Insuman') and holds, pursuant to Regulation (EEC) No 2309/93, separate central marketing authorisations for packages containing ten cartridges each containing 3 ml suspension and for packages containing five cartridges each containing 3 ml suspension; it has furthermore been authorised by the holder of the trade mark 'Insuman' to exercise the rights deriving from the trade mark. Aventis markets Insuman in Germany in packages of ten 3-ml cartridges and in France in packages of five 3-ml cartridges.

4. The defendants are parallel importers of medicinal products. They import Insuman in packages of five 3-ml cartridges from France into Germany which they repackage into packages containing ten cartridges presented in the same way as those which Aventis manufactures for Germany.

1 — Original language: English.

2 — Most recently Case C-443/99 *Merck, Sharp & Dohme* and Case C-143/00 *Boehringer Ingelheim and Others*; for an overview of the earlier case-law see my Opinion delivered on 12 July 2001 in those two cases.

3 — 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. Aventis appears to accept that the usual package size in Germany is ten cartridges and that the defendants are accordingly entitled to adapt the imported packages in some way so as to be able to sell Insuman in Germany in units of ten cartridges. It considers however that the defendants could produce 'double packs', namely retail packs consisting of two imported five-cartridge packages not repackaged but overstickered as appropriate. Aventis submits that it is for that reason unnecessary to create new external packaging for units of ten cartridges and that to do so therefore infringes its trade mark rights. It has accordingly sought an order before the Landgericht Köln that the defendants refrain from importing, stocking, offering for sale and marketing the product in new external packaging holding ten cartridges each containing 3 ml suspension.

6. The defendants submitted before the Landgericht Köln that the application should be dismissed, arguing that the repackaging undertaken was 'necessary' within the meaning of the case-law of the Court. Furthermore, the central marketing authorisation related to very specific packages; the creation of a double pack is accordingly excluded.

7. According to the Landgericht Köln, the European Agency for the Evaluation of Medicinal Products ('the EMEA') — the Agency established by Regulation No 2309/93 to provide scientific advice in the context of the authorisation and supervision of medicinal products — is also of the view that a double pack of two five-cartridge packages in not covered by a central marketing authorisation. However the Landgericht Köln notes that the opinion of the EMEA is not legally binding.

8. It appears from the documents before the Court that the EMEA expressed the above view in a letter sent to the first defendant in response to the latter's notification of the proposed parallel import. The EMEA stated in that letter:

'As the proposed shrink-wrapped presentation of 2x5 packs is not specified in the Commission Decision of Insuman,[4] this presentation cannot be accepted for parallel distribution.'

9. The Landgericht Köln adds that, if (in its terms) 'bundling' is none the less permissible, it must be determined whether the rules on the free movement of goods entitle the importer to decide how to repackage or whether bundling is the less intrusive method and for that reason must be chosen by the defendants.

4 — This appears to mean the central marketing authorisation.

10. The Landgericht Köln has accordingly referred the following questions for a preliminary ruling:

'1. Do the provisions governing the central authorisation of medicinal products in the European Union — in particular those of Regulation (EEC) No 2309/93 — preclude the legal possibility of "bundling" (that is to say, the joining together of several packages, each bearing the necessary labelling, in order to form a new retail unit) of packages of medicinal products following importation into one Member State from another Member State, so that "repackaging" of medicinal products (that is to say, the production of new external packaging to which the importer affixes the foreign trademark without the authorisation of the trademark holder) is "necessary" within the meaning of the decision of the European Court of Justice in Case C-232/94 *MPA Pharma* v *Rhône-Poulenc Pharma* [1996] ECR I-3671 and the trademark holder for that reason cannot prohibit such repackaging?

2. In the event that Question 1 should be answered in the negative:

Do the rules on the free movement of goods within the Common Market or other rules of Community law stand in the way of a prohibition which, in cases of the kind referred to in Question 1, is directed against "repackaging" on the ground, derived from national trademark law, that the possibility of creating a double pack, which, moreover, exists *de facto* and *de jure*, constitutes a less intrusive interference with the rights of the trademark holder?'

11. Written observations have been submitted by Aventis, the defendants, the Norwegian Government [5] and the Commission. Aventis, the defendants and the Commission were represented at the hearing.

The relevant Community legislation

12. Since 1 January 1995 it has been possible to obtain centralised Community-wide authorisation for the marketing of medicinal products. Once such an authorisation has been granted, products covered by the authorisation may be marketed in any part of the Community.

5 — Pursuant to Article 20 of the Statute of the Court of Justice of the EC.

13. The procedure for obtaining a Community marketing authorisation is governed by Regulation No 2309/93. [6]

14. Article 6(1) of Regulation No 2309/93 provides:

'An application for authorisation for a medicinal product for human use must be accompanied by the particulars and documents referred to in [Articles 8, 10(1) and 11 of Directive 2001/83]...' [7]

15. Article 8(3) of Directive 2001/83 [8] requires the application for authorisation to be accompanied by listed particulars and documents, submitted in accordance with Annex I. Those particulars and documents include at (j) 'A summary, in accordance with Article 11, of the product characteristics, one or more specimens or mock-ups of the outer packaging and the immediate packaging of the medicinal product, together with a package leaflet.'

16. 'Immediate packaging' is defined as 'The container or other form of packaging immediately in contact with the medicinal product' and 'outer packaging' as 'The packaging into which is placed the immediate packaging'. [9]

17. Article 11 of Directive 2001/83 [10] requires the summary of product characteristics to contain specified information including at 6.4 'nature and contents of the immediate packaging'.

18. Annex I to Directive 2001/83 requires the particulars and documents accompanying an application for marketing authori-

6 — Cited in note 3.

7 — The reference was originally to Articles 4 and 4a of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, OJ, English Special Edition, Second Series 1965-66, p. 20. Directive 65/65, together with numerous other directives on medicinal products, was repealed with effect from 18 December 2001 by 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, Article 128 of which provides that references to the repealed directives are to be construed as references to that directive in accordance with the correlation table in Annex III thereto.

8 — Directive 2001/83 is cited in note 7. Article 8(3) re-enacts the third paragraph of Article 4 of Directive 65/65, cited in note 7, as replaced by Council Directive 83/570/EEC of 26 October 1983 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, OJ 1983 L 332, p. 1. Point 9 under the third paragraph of Article 4 read: 'A summary, in accordance with Article 4a, of the product characteristics, one or more specimens or mock-ups of the sales presentation of the proprietary product, together with a package leaflet where one is to be enclosed'.

9 — Article 1(23) and (24) of Directive 2001/83, re-enacting the definitions in Article 1(2) of Directive 92/27 of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets, OJ 1992 L 113, p. 8.

10 — Re-enacting Article 4a of Directive 65/65, cited in note 7, inserted by Directive 83/570, cited in note 8. The information prescribed by Article 4a included under point 6.4 'nature and contents of container'.

sation to be presented in four parts. Part I, 'Summary of the dossier', includes under 'A. Administrative data':

'The medicinal product which is the subject of the application shall be identified by name and name of the active substance(s), together with the pharmaceutical form, the method of administration, the strength and the final presentation, including packaging'.

19. Part I also includes under 'B. Summary of product characteristics':

'The applicant shall propose a summary of the product characteristics, in accordance with Article 11.

In addition the applicant shall provide samples or mock-ups of the packaging, labels and package leaflets for the medicinal product concerned.'

20. The Committee for Proprietary Medicinal Products [11] is responsible for formulating the opinion of the EMEA concerning the grant of central marketing authorisations. [12] Article 9(3) of Regulation No 2309/93 provides:

'In the event of an opinion in favour of granting the relevant authorisation to place the medicinal product concerned on the market, the following documents shall be annexed to the opinion:

...

(c) the draft text of the labelling and package leaflet proposed by the applicant, presented in accordance with Directive [2001/83/EEC]...'. [13]

21. Article 54 of Directive 2001/83 [14] lists particulars which are to appear on the outer packaging of medicinal products. Those particulars include at (c) 'the phar-

11 — Established by Article 8 of Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, OJ 1975 L 147, p. 13.

12 — Article 5 of Regulation No 2309/93, cited in note 3.

13 — The reference was originally to Council Directive 92/27/EEC, cited in note 9. Directive 92/27 was also repealed with effect from 18 December 2001 by Directive 2001/83, cited in note 7.

14 — Re-enacting Article 2(1) of Directive 92/27, which included identical items under (c) and (l).

maceutical form and the contents by weight, by volume or by number of doses of the product' and at (l) 'the number of the authorisation for placing the medicinal products on the market'.

22. Article 56 of Directive 2001/83 [15] requires the particulars referred to in Article 54 to be 'easily legible, clearly comprehensible and indelible'.

23. Article 58 of Directive 2001/83 [16] provides that the inclusion in the packaging of all medicinal products of a package leaflet is to be obligatory unless all the information required by Articles 59 and 62 is directly conveyed on the outer packaging or on the immediate packaging.

24. Article 59 of Directive 2001/83 [17] lists the information to be included in the package leaflet. That information includes, under '(a) for the identification of the medicinal product':

'the pharmaceutical form and the contents by weight, by volume or by number of doses of the product, in the case of each presentation of the product'. [18]

25. Article 10(1) of Regulation No 2309/93 provides:

'Within 30 days of receipt of the opinion [of the Committee for Proprietary Medicinal Products], the Commission shall prepare a draft of the decision to be taken in respect of the application, taking account of Community law.

In the event of a draft decision which envisages the granting of marketing authorisation, the documents referred to in Article 9(3)(a), (b) and (c) shall be annexed.

...

The draft decision shall be forwarded to the Member States and the applicant.' [19]

15 — Re-enacting Article 4(1) of Directive 92/27.

16 — Re-enacting Article 6 of Directive 92/27.

17 — Re-enacting Article 7(1) of Directive 92/27

18 — Third indent.

19 — The Standing Committee on Medicinal Products for Human Use then delivers its opinion (by qualified majority) on the draft decision. If the decision is approved by the Committee, the Commission adopts it; if not, the Commission submits a proposal to the Council: Article 73 of Regulation No 2309/93.

26. The second paragraph of Article 11 of Regulation No 2309/93 states:

'Authorisation shall... be refused if the particulars and documents provided by the applicant in accordance with Article 6 are incorrect or if the labelling and package leaflets proposed by the applicant are not in accordance with [Directive 2001/83].' [20]

27. Article 12(1) of Regulation No 2309/93 provides:

'... a marketing authorisation which has been granted in accordance with the procedure laid down in this Regulation shall be valid throughout the Community. It shall confer the same rights and obligations in each of the Member States as a marketing authorisation granted by that Member State in accordance with Article 3 of Directive 65/65/EEC.

The authorised medicinal products shall be entered in the *Community Register of Medicinal Products* and shall be given a number which must appear on the packaging.'

20 — The reference was originally to Directive 92/27, cited in note 9.

28. Article 15(3) of Regulation No 2309/93 provides:

'If the person responsible for placing the medicinal product on the market proposes to make any alteration to the information and particulars referred to in Articles 6 and 9, he shall submit an application to the Agency.'

29. Article 51 of the Regulation provides, in so far as is relevant:

'In order to promote the protection of human... health and of consumers of medicinal products throughout the Community... the Agency shall undertake the following tasks within its Committees:

...

(c) the coordination of the supervision... of medicinal products which have been authorised within the Community.'

The first question referred

30. In its first question the Landgericht Köln asks essentially whether, where a medicinal product (in the present case insulin cartridges) is the subject of two separate central marketing authorisations granted pursuant to Regulation No 2309/93 (i) for packages of ten items and (ii) for packages of five items, it is permissible for that product to be marketed in a double pack consisting of two packages of five units.

31. Aventis submits that the question as so formulated should be answered in the affirmative: by virtue of Article 12 of Regulation No 2309/93 a central marketing authorisation is valid throughout the Community and it is therefore not open to the EMEA to impose additional conditions on parallel importers. The authorisation for ten-cartridge packages covers a ten-cartridge retail unit comprising two five-cartridge packages bundled together.

32. The defendants, the Norwegian Government and the Commission submit that the question should be answered in the negative on the basis that each authorisation is limited to the package size to which the application for that authorisation related. The legislation requires the applicant for a central marketing authorisation to submit specific packaging with the application. The authorisation, if granted, relates to packages of the size proposed. Multiple packages are not provided for and are hence not authorised.

33. I concur with that view.

34. It is clear from the legislation that the legislature regards information concerning the proposed packaging of a medicinal product as an important element of an application for a central marketing authorisation. That has historically been a feature of the Community legislation regulating the grant of marketing authorisations: even before the introduction of a central marketing authorisation by Regulation No 2309/93, the legislation seeking to harmonise the conditions for the grant of national authorisations from the outset required applicants to submit information about the proposed packaging of the medicinal product for which they were requesting authorisation. [21]

35. In particular, it is apparent from the legislation that the legislature regards it as important that information concerning the precise quantity of medicinal products in a package for which a central marketing

21 — Article 4 of Directive 65/65, cited in note 7.

authorisation has been granted should be clearly indicated both on the outer packaging and in the package leaflet. Again, the requirement as to outer packaging has a long history, dating back to 1965. [22]

36. The pertinent requirements of the current legislation may be summarised as follows.

37. First, the application must be accompanied by a specimen or mock-up of the outer packaging and the package leaflet required by the legislation. [23] The presentation, including the packaging, must be in final form. [24] The draft text of the proposed labelling and package leaflet is to be annexed both to the opinion of the Committee for Proprietary Medicinal Products in favour of granting the authorisation [25] and to the Commission's draft decision to that effect. [26]

38. Second, the application must be accompanied by a summary of the product characteristics [27] which must specify the contents of the immediate packaging. [28] The outer packaging must show the contents by weight, by volume or by number of doses of the product [29] and the package leaflet must specify the contents by weight, by volume or by number of doses of each presentation of the product. [30]

39. Those requirements reflect what the Court has described as the 'essential objective' of the earlier legislation on national marketing authorisations — many provisions of which are echoed in Regulation No 2309/93 [31] — and what Directive 2001/83 states is the 'essential aim' of any rules governing the production, distribution and use of medicinal products, [32] namely safeguarding public health. [33] The legislature clearly intended by the above provisions that a 'retail unit' — to adopt the terminology of the referring court — of medicinal products should advertise its contents and that the package leaflet for such a 'retail unit' should be tailored to the quantity of medicinal products included therein. Those aims are manifestly in the interests of public health.

22 — Article 13 of Directive 65/65.

23 — Article 6(1) of Regulation No 2309/93 and Article 8(3)(j) of Directive 2001/83; see paragraphs 14 and 15 above.

24 — Article 8(3) of and Annex I to Directive 2001/83; see paragraph 18 above.

25 — Article 9(3) of Regulation No 2309/93; see paragraph 20 above.

26 — Article 10(1) of Regulation No 2309/93; see paragraph 25 above.

27 — Article 6(1) of Regulation No 2309/93 and Article 8(3)(j) of Directive 2001/83; see paragraphs 14 and 15 above.

28 — Article 11 of Directive 2001/83; see paragraph 26 above.

29 — Article 54 of Directive 2001/83; see paragraph 21 above.

30 — Article 59 of Directive 2001/83; see paragraph 24 above.

31 — Cited in footnote 3.

32 — Second recital in the preamble, echoing the first recital in the preamble to Directive 65/65.

33 — Case 227/82 *van Bennekom* [1983] ECR 3883, paragraph 14 of the judgment.

40. The importance of the information which the legislation requires to be shown on the outer packaging and included in the package leaflet is underlined by the facts that (i) a central marketing authorisation is to be refused if the labelling and package leaflets proposed by the applicant are not in accordance with that legislation [34] and (ii) the person responsible for placing the product on the market is required to apply to the Agency if he proposes to make any alteration to that information. [35]

41. Third, the outer packaging must show the number of the central marketing authorisation. [36] Given the points made above, the conclusion appears inescapable that that number must be the number of the authorisation which was sought and granted on the basis of the packaging and package leaflet submitted with the application. That authorisation in my view relates only to the 'retail unit' consisting of packaging of that size and described in that package leaflet.

42. I am accordingly of the view that, where a medicinal product is the subject of two separate central marketing authorisations granted pursuant to Regulation (EEC) No 2309/93 (i) for packages of ten items and (ii) for packages of five items, each of those authorisations relates only to the size of package specified. The product cannot therefore lawfully be marketed in a double pack consisting of two packages of five units.

43. That proposition appears to me, as I have indicated, to follow ineluctably from the scheme, objectives and wording of the legislation. In particular, as the Commission argued at the hearing, there is an obvious risk inherent in the type of 'bundling' envisaged by the referring court that the consumer will be confused and public health thereby jeopardised: there may be inconsistencies in the package leaflets inserted in packages so bundled together since the leaflets will have been designed for — and should specify [37] — the quantities to be marketed in the original packages.

44. Admittedly, the representative of Aventis stated at the hearing that in the present case the package leaflets were identical for packages of four, five or ten Insuman cartridges and there was hence no possible risk of consumer confusion. Even if that is correct however — and it seems puzzling, given that the legislation requires the package leaflet to state the package contents by weight, by volume or by number of doses of the product [38] — circumstances may be envisaged where a conflict between the contents specified in the leaflet and the

34 — Second paragraph of Article 11 of Regulation No 2309/93, set out in paragraph 26 above.

35 — Article 15(3) of Regulation No 2309/93, set out in paragraph 28 above.

36 — Article 54 of Directive 2001/83; see paragraph 21 above.

37 — Article 59 of Directive 2001/83; see paragraph 24 above.

38 — Article 59 of Directive 2001/83; see paragraph 24 above.

contents of the 'retail unit' of bundled packages would be liable to confuse consumers and hence prejudice public health.

45. Aventis relies on Article 12(1) of Regulation No 2309/93, [39] which provides that a central marketing authorisation is to be valid throughout the Community, and submits on that basis that an importer can market a medicinal product which is identical to that for which the authorisation was granted. However, it is clear to me that, for the reasons given above, a central marketing authorisation relates to more than the constituents of the medicinal product concerned, and in particular requires that that product be marketed in packaging of the size submitted with the application.

46. Aventis further submits that the EMEA in its letter [40] required the first defendant to repackage the imported cartridges in packages of ten but that the EMEA has no power to impose any such requirement, which was accordingly unlawful.

47. That letter states that, as the proposed presentation of 2x5 packs is not specified in the central marketing authorisation, it cannot be accepted for parallel distribution.

48. Regulation No 2309/93 requires the Agency to undertake the coordination of the supervision of medicinal products which have been authorised within the Community. [41]

49. In a communication issued in 1998 [42] 'to clarify its position on certain aspects relating to the implementation of the centralised and mutual recognition procedures', [43] the Commission states, under the head 'Parallel distribution of Community authorised medicines':

'Although no further authorisation is required [by parallel importers], the Community (in practice the EMEA) and national authorities... shall be informed that such parallel distribution will take place in order to enable the EMEA to check compliance with the terms of the Community marketing authorisation...'

39 — Set out in paragraph 27 above.

40 — See paragraph 8 above.

41 — Article 51(c), set out in paragraph 29 above.

42 — Commission communication on the Community marketing authorisation procedures for medicinal products, OJ 1998 C 229, p. 4.

43 — Fourth paragraph in the Introduction to the Communication.

50. In 1999 the EMEA issued its 'Procedure for notifications of parallel distribution of centrally authorised medicinal products' 'to provide guidance and assist parallel distributors to fulfil their obligations, without prejudice to the interpretation of Community Directives and Regulations by the European Commission and/or European Court of Justice'. That document refers to the Commission's Communication and notes that 'the EMEA is the Authority designated to check compliance of a product distributed in parallel with the terms of the Community Marketing Authorisation for the concerned centrally authorised medicinal product'. It requires parallel importers of centrally authorised medicinal products to notify the EMEA of proposed imports.

51. There is nothing to suggest that the system described by the Commission goes beyond the role of the EMEA as envisaged by Regulation No 2309/93.

52. It appears that the first defendant accordingly notified the EMEA of its intention to import packages of Insuman from France into Germany and that the EMEA in response expressed its view that bundling two imported packages together was not within the terms of the central marketing authorisation. For the reasons set out above, I concur with the EMEA on that point. I do not consider that, in expressing that view, the EMEA was, as suggested by Aventis, seeking to impose a requirement on the parallel importer and it is therefore not necessary to determine whether it had the power to do so. As the Commission points out, the answer to the first question referred by the Landgericht Köln depends on the correct interpretation of Regulation No 2309/93.

53. I accordingly conclude that the first question — essentially whether Regulation (EEC) No 2309/93 precludes the marketing in double packs of medicinal products imported into one Member State from another Member State — should be answered in the affirmative.

The second question referred

54. The Landgericht Köln has put a second question to the Court 'in the event that question 1 should be answered in the negative'. For the reasons set out above, I consider that question 1 should be answered in the affirmative. However, it seems to me that the second question is none the less relevant for the following reasons.

55. In its second question the referring court asks essentially whether the rules on the free movement of goods or other rules

of Community law preclude a national rule which prohibits repackaging on the ground that creating a double pack constitutes a less intrusive interference with the rights of the trademark holder.

56. That question concerns the trade mark aspects of the defendants' conduct. A parallel importer who repackages trade-marked goods necessarily re-apposes the trade mark, and in so doing *prima facie* infringes the trade mark owner's rights. However, by virtue of the principle of Community-wide exhaustion of rights, first articulated by the Court of Justice and subsequently enshrined in Article 7(1) of the Trade Marks Directive,[44] the trade mark does not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent. By way of exception to that principle, Article 7(2) provides that Article 7(1) 'shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market'.

57. Article 7(2) has been interpreted by the Court to mean that a trade mark owner may not oppose the further marketing of a pharmaceutical product where the importer has repackaged it and reaffixed the trade mark provided that certain conditions are met, namely: (i) reliance on trade mark rights by the owner would contribute to the artificial partitioning of the markets between Member States; (ii) the repackaging cannot affect the original condition of the product inside the packaging; (iii) the new packaging clearly states who repackaged the product and the name of the manufacturer; (iv) the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner; and (v) the importer gives notice to the trade mark owner before the repackaged product is put on sale, and, on demand, supplies him with a specimen thereof. The first condition will be regarded as satisfied where the trade mark owner has put an identical pharmaceutical product on the market in several Member States in various forms of packaging and the repackaging carried out by the importer is necessary in order to market the product in the Member State of importation.[45]

58. The referring court's second question in the present case is concerned with that condition, and in particular with the consequence that a parallel importer of trade-marked products may repackage such products if it is necessary to do so in order to market the product in the State of importation.[46] It appears from the order for reference that 'repackaging' in the

44 — 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.

45 — See Joined Cases C-427/93, C-429/93 and C-436/93 *Bristol-Myers Squibb and Others* [1996] ECR I-3457, operative part of the judgment.

46 — See in particular *Bristol-Myers Squibb*, cited in note 45, and Case C-379/97 *Upjohn* [1999] ECR I-6927; see also my Opinion in *Merck, Sharp & Dohme* and *Boehringer Ingelheim and Others*, cited in note 2.

present case means removing the inner packaging and insulin cartridges from five-unit packages imported from France and putting the contents of two such packages into new ten-unit packages.

59. Aventis, while conceding that the defendants are entitled to adapt the packaging size of the imported products to the German market, considers that that may lawfully be done by over-stickering the imported five-unit packages with a German translation of the requisite information and then putting two such packages together as a double pack.

60. I have explained above why I consider that marketing a double pack of two five-unit packages is not in accordance with either the central marketing authorisation for five-unit packages or that for ten-unit packages. Marketing a newly packaged ten-unit package however will — as all parties appear to accept — be within the terms of the central marketing authorisation for ten-unit packages, provided that the information given on the outer packaging and in the package leaflet is the same (apart from necessary linguistic changes) as that on the basis of which the authorisation was granted.

61. If therefore the only possible 'retail units' in which the Insuman cartridges at issue in the present case could be marketed in Germany were (i) double packs of two five-unit packages and (ii) repackaged ten-unit packages, and if, as I suggest, such double packs are not within the terms of the central marketing authorisation, the defendants would be able to market the imported Insuman only if they repackaged it into ten-unit packages. Such repackaging would accordingly be unequivocally necessary within the meaning of the Court's case-law.

62. As the Commission pointed out at the hearing, those are not, however, the only possible 'retail units': the Insuman cartridges can lawfully be sold in Germany in the five-cartridge packages in which they are imported, subject to necessary linguistic changes. That follows from the fact that five-cartridge packages are the subject of a central marketing authorisation — which is valid throughout the Community.

63. It is not clear however from the documents before the Court whether there is a market in Germany for Insuman in five-cartridge packages. The defendants state in their written observations that the product is marketed in France in a package size which is not marketable in Germany; at the hearing however the defendants' counsel appeared to state that both sizes could be

sold there. If that is the case, the German market is not closed to the defendants if they cannot repackage in ten-unit packages. The Commission concludes from that that such repackaging is not necessary.

64. That conclusion does not however inevitably follow.

65. The Court was recently asked for guidance on the meaning of 'necessary' in the above context in *Merck, Sharp & Dohme* and *Boehringer Ingelheim and Others*.[47] Those cases are still pending before the Court. However in my Opinion delivered on 12 July 2001 I considered the question at some length. After reviewing the case-law I concluded:

'Repackaging is necessary if it is reasonably required to enable the importer to obtain effective access to the market of the importing Member State (or to a significant part of it) and in so far as other, less intrusive, methods of repackaging will not enable him to obtain effective access to that market (or to a significant part of it); for that purpose account must be taken not only of obstacles which exist in law — such as the regulatory requirements of the importing Member State — but also of obstacles which exist in fact, including resistance of consumers, for example to over-stickered boxes, which is such as to affect prescription or dispensing practice.'[48]

66. In the present case therefore the national court must in my view assess whether repackaging in ten-unit packages is reasonably required to enable the defendants to obtain effective access to the German market or whether simply relabelling the imported five-unit packages will enable them to obtain access to that market. The latter will not be the case if marketing the product in five-unit packages encounters such legal or factual obstacles.

67. Even if the national court finds that such repackaging is necessary within the meaning of the Court's case-law, it must be borne in mind that the defendants must comply with the other conditions laid down by the Court in order for the repackaging to be lawful.[49]

47 — Cited in note 2.

48 — See paragraph 118 and operative part of the Opinion.

49 — See paragraph 57 above.

Conclusion

68. I am accordingly of the view that the questions referred by the Landgericht Köln should be answered as follows:

(1) A central marketing authorisation granted pursuant to 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 authorises the marketing of a medicinal product only in the size of packaging specified in the authorisation. Where a medicinal product is the subject of two separate central marketing authorisations granted pursuant to Regulation (EEC) No 2309/93 (i) for packages of ten items and (ii) for packages of five items, the product cannot therefore lawfully be marketed in a 'bundle' of two packages of five units.

(2) Repackaging is necessary if it is reasonably required to enable the importer to obtain effective access to the market of the importing Member State and in so far as other, less intrusive, methods of repackaging will not enable him to obtain effective access to that market; for that purpose account must be taken not only of obstacles which exist in law — such as the regulatory requirements of the importing Member State — but also of obstacles which exist in fact, including resistance of consumers, for example to over-stickered boxes, which is such as to affect prescription or dispensing practice.