JUDGMENT OF THE COURT
16 March 2004 *

In Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01,

REFERENCES to the Court under Article 234 EC by the Oberlandesgericht Düsseldorf (Germany) and by the Bundesgerichtshof (Germany) for preliminary rulings in the proceedings pending before those courts between

AOK Bundesverband,

Bundesverband der Betriebskrankenkassen (BKK),

Bundesverband der Innungskrankenkassen,

Bundesverband der landwirtschaftlichen Krankenkassen,

Verband der Angestelltenkrankenkassen eV,

* Language of the case: German.

Verband der Arbeiter-Ersatzkassen,

Bundesknappschaft,

See-Krankenkasse

and

Ichthyol-Gesellschaft Cordes, Hermani & Co. (C-264/01),

Mundipharma GmbH (C-306/01),

Gödecke GmbH (C-354/01),

Intersan, Institut für pharmazeutische und klinische Forschung GmbH (C-355/01),

on the interpretation of Articles 81 EC, 82 EC and 86 EC,

THE COURT,

composed of: V. Skouris, President, P. Jann, C.W.A. Timmermans, C. Gulmann, J.N. Cunha Rodrigues and A. Rosas (Presidents of Chambers), J.-P. Puissochet, R. Schintgen, F. Macken, N. Colneric and S. von Bahr (Rapporteur), Judges,

Advocate General: F.G. Jacobs,
Registrar: H.A. Rühl, Principal Administrator,

after considering the written observations submitted on behalf of:

— the AOK Bundesverband, the Bundesverband der Betriebskrankenkassen (BKK), the Bundesverband der Innungskrankenkassen, the Bundesverband der landwirtschaftlichen Krankenkassen, the Verband der Angestelltenkrankenkassen eV, the Verband der Arbeiter-Ersatzkassen, the Bundesknappschaft and the See-Krankenkasse, by C. Quack, Rechtsanwalt (C-264/01 and C-306/01), and A. von Winterfeld, Rechtsanwalt (C-354/01 and C-355/01),

— Ichthyol-Gesellschaft Cordes, Hermani & Co. and Mundipharma GmbH, by U. Doepner, Rechtsanwalt,

— Gödecke GmbH and Intersan, Institut für pharmazeutische und klinische Forschung GmbH, by U. Reese, Rechtsanwalt,

— the Commission of the European Communities, by W. Wils and S. Rating, acting as Agents,

having regard to the Report for the hearing,

after hearing the oral observations of the AOK Bundesverband, the Bundesverband der Betriebskrankenkassen (BKK), the Bundesverband der Innungskrankenkassen, the Bundesverband der landwirtschaftlichen Krankenkassen, the Verband der Angestelltenkrankenkassen eV, the Verband der Arbeiter-Ersatzkassen, the Bundesknappschaft and the See-Krankenkasse, represented by C. Quack (C-264/01 and C-306/01) and A. von Winterfeld (C-354/01 and C-355/01); Ichthyol-Gesellschaft Cordes, Hermani & Co. and Mundipharma GmbH, represented by U. Doepner; Gödecke GmbH and Intersan, Institut für pharmazeutische und klinische Forschung GmbH, represented by U. Reese; the German Government, represented by W.-D. Plessing, acting as Agent; and the Commission, represented by S. Rating, at the hearing on 14 January 2003,

after hearing the Opinion of the Advocate General at the sitting on 22 May 2003,

gives the following

Judgment

1 The Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf) and the Bundesgerichtshof (Federal Court of Justice) have referred to the Court for a preliminary ruling pursuant to Article 234 EC a number of questions on the

interpretation of Articles 81 EC, 82 EC and 86 EC. The Oberlandesgericht Düsseldorf has referred four questions, by two orders of 18 May 2001 and 11 July 2001, received at the Court on 5 July 2001 and 6 August 2001 respectively. The Bundesgerichtshof has referred three questions, by two orders of 3 July 2001, received at the Court on 20 September 2001.

2 Those questions were raised in a number of actions between the AOK Bundesverband, the Bundesverband der Betriebskrankenkassen (BKK), the Bundesverband der Innungskrankenkassen, the Bundesverband der landwirtschaftlichen Krankenkassen, the Verband der Angestelltenkrankenkassen eV, the Verband der Arbeiter-Ersatzkassen, the Bundesknappschaft and the See-Krankenkasse (hereinafter 'the fund associations') and pharmaceutical companies producing medicinal products, namely Ichthyol-Gesellschaft Cordes, Hermani & Co. (Case C-264/01), Mundipharma GmbH (Case C-306/01), Gödecke GmbH (Case C-354/01) and Intersan, Institut für pharmazeutische und klinische Forschung GmbH (Case C-355/01) (hereinafter 'the pharmaceutical companies'), concerning the determination of fixed maximum amounts payable by sickness funds towards the cost of medicinal products and treatment materials.

Factual and legal context

Economic and social context

3 It is apparent from the orders for reference of the Bundesgerichtshof that, according to Federal Government findings, the costs of the German statutory health insurance scheme have increased appreciably faster than the incomes used as the basis for calculation of contributions, and therefore much more rapidly than the resources of that scheme. Such an increase is stated to be due to a lack of competition between suppliers in the health-care sector, insufficient awareness among insured persons of the cost of treatment and medicinal products, and the

inability of sickness funds to influence the choice made between medicinal products whose cost is borne under the scheme. The German legislature therefore adopted a series of measures designed to fill these gaps, one of the measures being the determination of fixed maximum amounts payable by those funds in respect of the cost of medicinal products (hereinafter 'fixed maximum amounts').

Fixed maximum amounts and the statutory health insurance scheme

4 The principal features of the system for determining fixed maximum amounts, as they appear from the orders for reference, are as follows.

5 The system is connected with the statutory health insurance scheme to which the vast majority of the population belongs. This scheme relies on sickness funds, which are independently managed bodies governed by public law possessing legal personality. The scheme is intended to protect, maintain, restore or improve the health of insured persons.

6 It is in principle obligatory for employees to be insured under the statutory scheme. The exceptions essentially concern, first, employees whose income exceeds a statutorily prescribed level and, second, employees subject to a specific statutory scheme, such as civil servants. People who are not employees may insure themselves on a voluntary basis provided that certain conditions are met. The obligation to be insured enables a mechanism providing for solidarity amongst insured persons to be applied.

7 The benefits provided by the sickness funds are financed through contributions levied in most cases in equal shares on insured persons and their employers. The amount of the contributions is determined principally by the insured person's income and the contribution rate set by each sickness fund.

8 The sickness funds are in competition with regard to contribution rates in order to attract people for whom insurance under the scheme is obligatory and those for whom it is voluntary. It is laid down by statute that insured persons may freely choose their sickness fund as well as their doctor or the hospital in which they have treatment.

9 The scheme is founded on a system of benefits in kind and not on subsequent reimbursement of expenditure incurred by insured persons. The benefits are essentially identical so far as concerns the categories of obligatory treatment and vary solely for complementary optional treatment. With regard to medicinal products, the prescription fees are borne by the patient, but it is the sickness fund which pays the pharmacy for the medicinal products supplied by it, within the limits of the fixed maximum amounts determined in accordance with the law. If the price of the medicinal product is lower than or equal to the fixed maximum amount, the fund pays the price in full. On the other hand, if the price exceeds the fixed maximum amount, the insured person pays the difference between that amount and the sale price for the product.

10 The sickness funds operate in accordance with a solidarity mechanism ('Risikostrukturausgleich') under which an equalisation is effected between sickness funds in order to remedy the financial disparities resulting from differences in the degree of risk insured. Thus, the sickness funds insuring the least costly risks contribute to the financing of those insuring more onerous risks.

11 The sickness funds can be subdivided into a number of categories according to the sectors of activity concerned. They are represented at regional level and at federal level where they are brought together in federal associations. Where there is just one sickness insurance fund in a given sector, it also assumes the functions of national association.

12 By the Gesundheits-Reformgesetz (Law on Health Reform) of 20 December 1988 (BGBl. 1988 I, p. 2477), the legislature introduced a provision, now Paragraph 35 of the Fifth Book of the Sozialgesetzbuch (Code of Social Law) — Gesetzliche Krankenversicherung (Statutory Health Insurance) (hereinafter 'SGB V'), intended to reduce costs in the health sector. This provision lays down the rules applicable to determination of fixed maximum amounts, which may be summarised as follows.

13 In the first stage, the Bundesausschuß für Ärzte und Krankenkassen (Federal Committee of Doctors and Sickness Funds; hereinafter 'the Federal Committee'), an independent body composed of doctors' representatives and representatives of the sickness funds in the statutory health insurance scheme, determine the groups of medicinal products for which fixed maximum amounts must be laid down. Each group of medicinal products consists of preparations containing the same or similar active substances or having a comparable therapeutic effect. When choosing the medicinal products, the Federal Committee must make sure that the therapeutic possibilities for the treatment of illnesses will not be limited and that a sufficient number of alternative treatment solutions will be available to doctors.

14 The groups of medicinal products must as a general rule include preparations of competing manufacturers. Experts designated by the medicinal product manufacturers, scientists and professional bodies representing pharmacists must be given an opportunity to state their views and their observations must be taken into

account before the Federal Committee makes a decision. The Federal Committee must submit its decisions to the Federal Ministry of Health. They enter into force only if the ministry approves them or does not object to them within two months.

15 In the second stage, the fund associations jointly determine the uniform fixed maximum amounts applicable to the medicinal products falling within the categories as defined. Those amounts must ensure an adequate and appropriate supply that is economically viable and of good quality. They must be set using all the economic margins available to the medicinal-product manufacturers, give rise to effective price competition and thus allow the most inexpensive supply possibilities. The fixed maximum amounts are generally determined taking account of the products offered by a number of manufacturers. They must be based on the lowest pharmacy sale prices.

16 Fixed maximum amounts must be reviewed at least once a year and must be adapted at appropriate intervals to changes in the market.

17 If the fund associations do not succeed in determining fixed maximum amounts, the decision is taken at ministerial level.

18 Actions for annulment of decisions determining fixed maximum amounts can challenge only the amounts themselves and not the choice of the groups of medicinal products made by the Federal Committee.

The main proceedings and the questions referred for a preliminary ruling

Cases C-264/01 and C-306/01

19 Cases C-264/01 and C-306/01 concern medium-sized pharmaceutical undertakings which have their seat in Hamburg (Germany): Ichthyol-Gesellschaft Cordes, Hermani & Co. (hereinafter 'Ichthyol') and Mundipharma GmbH (hereinafter 'Mundipharma').

20 Ichthyol manufactures and sells medicinal products containing the active substance ammonium bituminosulphonate, which is used in dermatology and also to treat arthrosis and arthritis. Products manufactured by Ichthyol account for almost 90% of the German market in medicinal products containing ammonium bituminosulphonate. Mundipharma manufactures and sells analgesics containing morphine.

21 In 1998 the fund associations adapted the fixed maximum amounts for certain medicinal products, a decision affecting these two pharmaceutical undertakings.

22 Ichthyol and Mundipharma then brought proceedings against the fund associations for an order that the latter refrain from applying the fixed maximum amounts concerning them and for compensation in respect of the loss suffered.

23 The court at first instance upheld the actions of the two pharmaceutical undertakings on the basis inter alia of Article 81(1) EC. The fund associations brought appeals against those judgments before the Oberlandesgericht Düsseldorf, claiming that the actions should be dismissed.

24 It was in those circumstances that the Oberlandesgericht Düsseldorf decided to stay proceedings and refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Is Article 81(1) EC to be interpreted as meaning that the leading associations of statutory sickness funds of a Member State are to be regarded as associations of undertakings or, where a leading association is also a direct provider of statutory sickness insurance, as undertakings within the meaning of Article 81(1) EC when they jointly determine the applicable level of uniform fixed amounts for medicinal products in the Member State, where such amounts constitute the highest price at which the statutory sickness funds, who are required to provide benefits in kind to insured persons, will purchase and pay for medicinal products and thereby limit their liability to insured persons?

(2) If the answer to the first question is in the affirmative:

(a) are determinations of fixed amounts as described in question 1 above to be regarded as agreements (or decisions) of the leading associations of statutory sickness funds which restrict competition, in particular within the meaning of Article 81(1)(a) EC, and are prohibited by Article 81(1) EC?

(b) is question 2(a) to be answered in the affirmative at least where the object of the regulation concerning fixed amounts is, inter alia, to exploit all reserves of medicinal product manufacturers in terms of economy as regards sale price, and the application of the regulation concerning fixed amounts in the Member State so far has had the effect that, of the finished medicinal product packages offered on the market that fall within the regulation concerning fixed amounts, approximately 93% do not now exceed the amount fixed for them?

(3) If the answer to either or both of the questions in question 2 above is in the affirmative:

Can a system of fixed amounts as described in questions 1 and 2 be exempted from Article 81(1) EC under Article 86(2) EC, first sentence, even though when they determine fixed amounts the leading associations of statutory sickness funds represent the biggest purchasers on the medicinal product market, who when taken together dominate the market, and it would be possible, as a solution to the problem of trying to reduce costs in the health sector, to grant power to determine such fixed amounts to an institution other than a participant in the medicinal product market, in particular to the Federal Government or a Federal Minister?

(4) If the answer to question 3 is also in the affirmative:

(a) what conditions must be set forth and proved by the leading associations of statutory sickness funds so that they may be exempted under Article 86 (2) EC, first sentence, in relation to determinations of fixed amounts or

(b) is the grant of an exemption under Article 86(2) EC, first sentence, precluded in any case by Article 86(2) EC, second sentence, owing to the effects the system of fixed amounts has on trade?'

Cases C-354/01 and C-355/01

25 Case C-354/01 concerns Gödecke GmbH, an undertaking which markets medicinal products containing the active ingredient Diltiazem-HC12 which is included in the list of the Bundesgesundheitsamt (Federal Health Authority) and is contained in a number of medicinal products.

26 Case C-355/01 relates to Intersan, Institut für pharmazeutische und klinische Forschung GmbH, an undertaking which markets medicinal products containing the active ingredient 'ginkgo-biloba dry extract' which is included in the list of the Bundesgesundheitsamt and used in particular in the treatment of deficiencies in performance linked to dementia syndromes.

27 In both of these cases, the fund associations decided on 14 February 1997 to set new fixed maximum amounts for the active substances in question at a level markedly lower than the amounts previously laid down. The following year, after the amounts were again reduced, the two pharmaceutical undertakings concerned each brought an action challenging the decisions of the fund associations.

28 The court at first instance dismissed the actions of the pharmaceutical undertakings concerned which sought principally an injunction prohibiting

application of the fixed maximum amounts and a declaration that the fund associations were liable to pay compensation for the loss resulting from the setting of those amounts. However, the appeal court varied the first-instance judgments and essentially made an order against the fund associations in the terms requested. The fund associations then appealed on a point of law, seeking the complete dismissal of the actions.

29 The Bundesgerichtshof decided to stay proceedings and refer the following questions to the Court for a preliminary ruling:

'(1) Are Articles 81 and 82 EC to be interpreted as precluding national rules under which national leading associations of statutory sickness insurance determine binding maximum amounts for all statutory sickness funds and compensatory sickness funds up to which the funds bear the costs of medicines, where the legislature defines the criteria by which the maximum amounts are to be calculated, providing in particular that the fixed amounts must ensure comprehensive and quality-assured treatment of insured persons as well as an adequate range of therapeutic alternatives, and the determination is subject to comprehensive review by the courts, which may be initiated by both insured persons and affected medicinal product manufacturers?

(2) If question 1 is answered in the affirmative:

Does Article 86(2) EC exempt such a determination from Articles 81 and 82 EC where the purpose of the determination is to safeguard, in the manner provided for in Paragraph 35 of SGB V, a sickness insurance scheme whose existence was endangered by a significant increase in costs?

(3) If question 1 is answered in the affirmative and question 2 in the negative:

Are leading associations such as the defendants liable to claims under Community law for damages and an injunction even where in determining maximum amounts they follow a statutory direction, notwithstanding that national law does not impose any penalty for refusal to assist in the making of such a determination?'

30 By order of the President of the Court of 26 October 2001, Cases C-264/01, C-306/01, C-354/01 and C-355/01 were joined for the purposes of the written procedure, the oral procedure and judgment.

Preliminary observations

31 By their questions, the Bundesgerichtshof and the Oberlandesgericht Düsseldorf essentially ask the Court whether the competition rules laid down by the EC Treaty preclude groups of sickness funds, such as the fund associations, from determining fixed maximum amounts corresponding to the upper limit of the price of medicinal products whose cost is borne by sickness funds. The Bundesgerichtshof also asks whether, if that question is answered in the affirmative, there is a right against those groups to an injunction remedying the situation and to compensation for the loss suffered by reason of the introduction of the fixed maximum amounts.

32 The national courts essentially ask the following four questions:

(1) Are groups of sickness funds, such as the fund associations in question in the main proceedings, to be regarded as undertakings or associations of undertakings within the meaning of Article 81 EC when they determine fixed maximum amounts corresponding to the upper limit of the price of medicinal products whose cost is borne by sickness funds?

(2) If the first question is answered in the affirmative, do those groups infringe Article 81 EC when they adopt decisions intended to determine the amounts?

(3) If the second question is answered in the affirmative, does the derogation provided for in Article 86(2) EC apply to those decisions?

(4) If the Treaty competition rules are infringed, is there a right against such groups to an injunction remedying the situation and to compensation for the loss suffered?

The first question

33 This question concerns the concepts of 'undertaking' or 'association of undertakings' within the meaning of the Treaty competition rules and the related concept of 'economic activity'. It concerns groups of sickness funds, such as the fund associations, and sickness funds themselves.

Observations of the parties

34 The fund associations and the Commission of the European Communities submit that the activities of the sickness funds do not constitute economic activities and that the same is true of the activities of the fund associations. Those entities are therefore not undertakings within the meaning of Article 81 EC.

35 First, the sickness funds fulfil a function which is exclusively social and entirely non-profit-making, consisting in the provision of medical cover to insured persons irrespective of their financial position and their state of health. The object of the fund associations is to ensure continuance of operation of the health system.

36 Second, the sickness funds' operation is founded on a principle of solidarity. This principle rests on the fact that roughly 90% of the population are members, and finds expression in the practice of financial equalisation between the sickness funds. The amount of the contributions paid by insured persons is unrelated to the insured risks and the benefits do not depend on the amount of the contributions.

37 Finally, the State exercises control over the activity of the fund associations. If they were unable to adopt fixed maximum amounts payable in respect of medicinal products, the State would take their place and determine those amounts itself.

38 According to the pharmaceutical companies, on the other hand, the sickness funds and the fund associations are undertakings and associations of undertakings engaging in economic activity.

39 The pharmaceutical companies submit that the sickness funds compete strongly with one another in the following three areas: the amount of the contributions, the benefits offered, and the management and organisation of their services.

40 The amount of the contributions is determined by each fund, all striving to offer the lowest possible contribution rate, particularly by restricting their management costs. Sometimes the difference between the contribution rates of the various sickness funds is considerable. Thus, on 1 January 2002 the highest rate exceeded the lowest by a third.

41 It is true that the benefits are partially laid down by the provisions of SGB V, but the sickness funds retain some freedom of action in the field of optional additional benefits, in particular with regard to rehabilitation, alternative and natural methods of treatment, or preventive measures for certain chronic illnesses, such as diabetes or asthma.

42 The sickness funds also compete with one another with regard to the management and organisation of their operations. Certain funds emphasise for example their presence on the ground by means of a substantial network of offices, while others, by contrast, favour communication by telephone and on the internet.

43 The pharmaceutical companies add that, generally, the sickness funds engage in intense promotional and marketing activity. The number of insured persons who have changed sickness fund over the last three years has varied between 3% and 5% per year. Furthermore, sickness funds may be closed by the supervisory authority when their long-term financial viability is no longer guaranteed.

44 Accordingly, the insurance activity of the sickness funds, including their activity when purchasing medicinal products, is economic in nature.

Findings of the Court

45 In answering this question, it is appropriate to establish first whether bodies such as the sickness funds in the German statutory health insurance scheme are undertakings before examining whether groups representing those bodies, such as the fund associations, must be regarded as associations of undertakings when they determine the fixed maximum amounts.

46 The concept of an undertaking in competition law covers any entity engaged in economic activity, regardless of the legal status of the entity or the way in which it is financed (Case C-41/90 *Höfner and Elser* [1991] ECR I-1979, paragraph 21, and Case C-218/00 *Cisal* [2002] ECR I-691, paragraph 22).

47 In the field of social security, the Court has held that certain bodies entrusted with the management of statutory health insurance and old-age insurance schemes pursue an exclusively social objective and do not engage in economic activity. The Court has found that to be so in the case of sickness funds which merely apply the law and cannot influence the amount of the contributions, the use of assets and the fixing of the level of benefits. Their activity, based on the principle of national solidarity, is entirely non-profit-making and the benefits paid are statutory benefits bearing no relation to the amount of the contributions (Joined Cases C-159/91 and C-160/91 *Poucet and Pistre* [1993] ECR I-637, paragraphs 15 and 18).

48 The fact that the amount of benefits and of contributions was, in the last resort, fixed by the State led the Court to hold, similarly, that a body entrusted by law with a scheme providing insurance against accidents at work and occupational diseases, such as the Istituto nazionale per l'assicurazione contro gli infortuni sul lavoro (the Italian National Institute for Insurance against Accidents at Work), was not an undertaking for the purpose of the Treaty competition rules (see *Cisal*, cited above, paragraphs 43 to 46).

49 On the other hand, other bodies managing statutory social security systems and displaying some of the characteristics referred to in paragraph 47 of the present judgment, namely being non-profit-making and engaging in activity of a social character which is subject to State rules that include solidarity requirements in particular, have been considered to be undertakings engaging in economic activity (see Case C-244/94 *Fédération française des sociétés d'assurance and Others* [1995] ECR I-4013, paragraph 22, and Case C-67/96 *Albany* [1999] ECR I-5751, paragraphs 84 to 87).

50 Thus, in *Fédération française des sociétés d'assurance and Others*, at paragraph 17, the Court held that the body in question managing a supplementary old-age insurance scheme engaged in an economic activity in competition with life assurance companies and that the persons concerned could opt for the solution which guaranteed the better investment. In paragraphs 81 and 84 of *Albany*, concerning a supplementary pension fund based on a system of compulsory affiliation and applying a solidarity mechanism for determination of the amount of contributions and the level of benefits, the Court noted however that the fund itself determined the amount of the contributions and benefits and operated in accordance with the principle of capitalisation. It deduced therefrom that such a fund engaged in an economic activity in competition with insurance companies.

51 Sickness funds in the German statutory health insurance scheme, like the bodies at issue in *Poucet and Pistre*, cited above, are involved in the management of the

social security system. In this regard they fulfil an exclusively social function, which is founded on the principle of national solidarity and is entirely non-profit-making.

52 It is to be noted in particular that the sickness funds are compelled by law to offer to their members essentially identical obligatory benefits which do not depend on the amount of the contributions. The funds therefore have no possibility of influence over those benefits.

53 In its orders for reference, the Bundesgerichtshof states in this regard that the sickness funds are joined together in a type of community founded on the basis of solidarity ('Solidargemeinschaft') which enables an equalisation of costs and risks between them. In accordance with Paragraph 265 et seq. of SGB V, an equalisation is thus effected between the sickness funds whose health expenditure is lowest and those which insure costly risks and whose expenditure connected with those risks is highest.

54 The sickness funds are therefore not in competition with one another or with private institutions as regards grant of the obligatory statutory benefits in respect of treatment or medicinal products which constitutes their main function.

55 It follows from those characteristics that the sickness funds are similar to the bodies at issue in *Poucet and Pistre* and *Cisal* and that their activity must be regarded as being non-economic in nature.

56 The latitude available to the sickness funds when setting the contribution rate and their freedom to engage in some competition with one another in order to attract members does not call this analysis into question. As is apparent from the observations submitted to the Court, the legislature introduced an element of competition with regard to contributions in order to encourage the sickness funds to operate in accordance with principles of sound management, that is to say in the most effective and least costly manner possible, in the interests of the proper functioning of the German social security system. Pursuit of that objective does not in any way change the nature of the sickness funds' activity.

57 Since the activities of bodies such as the sickness funds are not economic in nature, those bodies do not constitute undertakings within the meaning of Articles 81 EC and 82 EC.

58 However, the possibility remains that, besides their functions of an exclusively social nature within the framework of management of the German social security system, the sickness funds and the entities that represent them, namely the fund associations, engage in operations which have a purpose that is not social and is economic in nature. In that case the decisions which they would be led to adopt could perhaps be regarded as decisions of undertakings or of associations of undertakings.

59 It must therefore be examined whether determination of the fixed maximum amounts by the fund associations is linked to the sickness funds' functions of an exclusively social nature or whether it falls outside that framework and constitutes an activity of an economic nature.

60 In the submission of the pharmaceutical companies, the fund associations adopt decisions of associations of undertakings, of an economic nature, when they determine the fixed maximum amounts.

61 However, as is apparent from the documents before the Court, when the fund associations determine the fixed maximum amounts they merely perform an obligation which is imposed upon them by Paragraph 35 of SGB V in order to ensure continuance of operation of the German social security system. That paragraph also lays down in detail the applicable procedure for determining the amounts and specifies that the fund associations must observe certain requirements as to quality and profitability. SGB V also provides that if the fund associations do not succeed in determining fixed maximum amounts, the competent minister must then decide them.

62 Thus, only the precise level of the fixed maximum amounts is not dictated by legislation, but decided by the fund associations having regard to the criteria laid down by the legislature. Furthermore, while the fund associations have a certain discretion in this regard, the discretion relates to the maximum amount paid by the sickness funds in respect of medicinal products which is an area where the latter do not compete.

63 It follows that, in determining those fixed maximum amounts, the fund associations do not pursue a specific interest separable from the exclusively social objective of the sickness funds. On the contrary, in making such a determination, the fund associations perform an obligation which is integrally connected with the activity of the sickness funds within the framework of the German statutory health insurance scheme.

64 It must accordingly be found that, in determining the fixed maximum amounts, the fund associations merely perform a task for management of the German social security system which is imposed upon them by legislation and that they do not act as undertakings engaging in economic activity.

65 The answer to the first question must therefore be that groups of sickness funds, such as the fund associations, do not constitute undertakings or associations of undertakings within the meaning of Article 81 EC when they determine fixed maximum amounts corresponding to the upper limit of the price of medicinal products whose cost is borne by sickness funds.

66 In view of the answer given to the first question, there is no need to answer the other questions asked by the national courts.

Costs

67 The costs incurred by the German Government and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the actions pending before the national courts, the decision on costs is a matter for those courts.

On those grounds,

THE COURT,

in answer to the questions referred to it by the Oberlandesgericht Düsseldorf by orders of 18 May 2001 and 11 July 2001 and the Bundesgerichtshof by orders of 3 July 2001, hereby rules:

Groups of sickness funds, such as the AOK Bundesverband, the Bundesverband der Betriebskrankenkassen (BKK), the Bundesverband der Innungskrankenkassen, the Bundesverband der landwirtschaftlichen Krankenkassen, the Verband der Angestelltenkrankenkassen eV, the Verband der Arbeiter-Ersatzkassen, the Bundesknappschaft and the See-Krankenkasse, do not constitute undertakings or associations of undertakings within the meaning of Article 81 EC when they determine fixed maximum amounts corresponding to the upper limit of the price of medicinal products whose cost is borne by sickness funds.

Skouris Jann Timmermans

Gulmann Cunha Rodrigues Rosas

Puissochet Schintgen Macken

Colneric von Bahr

Delivered in open court in Luxembourg on 16 March 2004.

R. Grass V. Skouris

Registrar President