OPINION OF ADVOCATE GENERAL TIZZANO
delivered on 2 October 2003 [1]

1. By an order of 12 July 2001 the Landgericht (Regional Court) Frankfurt am Main (Germany) (the Landgericht) referred to the Court for a preliminary ruling three questions concerning the interpretation of Article 82 EC. [2] In summary the German court is asking whether in the circumstances set out an undertaking commits an abuse of a dominant position where it does not permit (for valuable consideration) its competitors to use a database over which it claims copyright.

Facts and procedure

Facts underlying the dispute in the main proceedings

2. The dispute in the main proceedings is between IMS Health GmbH & Co. KG (IMS) and NDC Health GmbH & Co. KG (NDC) which in August 2000 took over Pharma Intranet Information AG (PII).

3. Both parties to the proceedings are engaged in the collection, processing and interpretation of data concerning regional sales of pharmaceutical products in Germany. For present purposes, it is important to point out that the studies produced by those companies are structured on the basis of a geographical criterion under which the data on the sales of medicines are grouped together in a series of areas into which Germany is subdivided.

1 — Original language: Italian.

2 — That article provides: 'Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States.
Such abuse may, in particular, consist in:
(a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
(b) limiting production, markets or technical development to the prejudice of consumers;
(c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
(d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.'

4. It is apparent from the order for reference that for the purpose of its market reports IMS in the 1970s initially subdivided Germany into 418 segments which were predominantly determined by the political boundaries of the urban and provincial districts. Since that structure was not sufficiently accurate for the drug manufacturers concerned, the federal territory was subdivided in 1989 into 1000 segments to take account, inter alia, of diverse market conditions and marketing structures. Following introduction of the five-digit postcode system on 1 June 1993 market segmentation was again reworked and a structure based on 1845 segments was developed. Since January 2000 IMS has been delivering its market reports on the basis of a subdivision of German territory into 1860 segments or a further subdivision derived from it into 2847 segments (hereinafter, respectively the '1860 brick structure' and the '2847 brick structure').

5. Those structures came into existence in response to various factors, such as the political boundaries of the municipalities and postcode areas. Detailed demarcation of segment boundaries is determined by other factors such as for example whether an urban or rural district is involved, communications and geographical concentration of pharmacies and doctors' practices.

6. In order to involve the pharmaceutical industry in the determination of its own structures, IMS some years ago established a working group known as the RPM working group ('Regionaler Pharmazeutischer Markt' — regional pharmaceutical market). This working group which is convened twice a year comprises firms in the pharmaceutical industry which are customers of IMS. They make suggestions for improving and optimising market segmentation in light of their particular requirements. According to IMS the working group (whose proposals have been considered only in exceptional cases) in regard to fewer than 10% of the segments is essentially a marketing instrument for tying customers to its products. Conversely, according to NDC, the working group played an important role in determining individual segments.

7. The 1860 and 2847 brick structures were not used by IMS only for market reports sold to the pharmaceutical companies but were also distributed free of charge to pharmacy accounting centres and associations of health insurance schemes. Consequently, according to the matters mentioned by the referring court, those structures became a normal standard for the compilation of regional evaluations of the German pharmaceutical market. The pharmaceutical industry has adjusted its marketing and electronic data retrieval systems in line with them.

8. PII, founded by a former director of IMS, initially drew up its reports on the basis of a segmentation of German territory into 2201 areas. It emerged from contacts with potential customers that data pro-

cessed in that form would be difficult to market because it did not follow the structures with which the pharmaceutical undertakings had brought themselves into line. Accordingly, PII went over to working with 1860 and 3000 brick structures which were very close to those used by IMS. [3]

Previous judgments of the national courts

9. In order to prevent the use of those structures, regarded as infringing its copyright, IMS brought proceedings before the Landgericht, seeking adoption of urgent measures to restrain such use. In granting that application on 27 October 2000, the German court issued an interim injunction restraining PII from using the 3000 brick structure and any other structure derived from the IMS 1860 brick structure. On 19 June 2001 the appeal by PII against that injunction was dismissed by a judgment of the Oberlandesgericht (Higher Regional Court), Frankfurt am Main. Consequently, it now has the force of *res judicata*. Following acquisition of PII by NDC, an analogous injunction by way of order was obtained in the same terms against NDC. That order was confirmed on 12 July 2001 by a judgment of the referring court but, on the date of the order for reference herein, it had not acquired the force of *res judicata*.

10. In those proceedings the national court viewed the IMS structures as data banks (or parts thereof) which are protected by the German copyright law. Without expressing a view on the involvement of the RPM working group in the development of such structures, they considered IMS none the less to be a joint owner of copyright and entitled as such to prevent unauthorised use of the structures.

The interim decision of the European Commission and the orders of the Presidents of the Court of First Instance and of the Court of Justice

11. As emphasised by the national court, during the course of those proceedings the use of IMS's structures also formed the subject-matter of competition proceedings before the European Commission.

12. Faced with the imminent adoption by the Landgericht of the first interim injunction, NDC requested IMS to grant to it for valuable consideration a licence to use its

3 — The 1860 brick structure included only 30 bricks which were different from the corresponding structure used by IMS, whilst the 3000 brick structure was based on the IMS 2847 brick structure with a further subdivision of around 150 bricks.

structure over 1860 areas. In response to the refusal by IMS to grant it such a licence NDC lodged a complaint of abuse of a dominant position with the Commission, at the same time requesting it to adopt urgent measures.

13. The Commission upheld NDC's request and on 3 July 2001 adopted on an interim basis in line with the decision in *Camera Care* [4] Decision 2002/165/EC 'on a proceeding under Article 82 of the EC Treaty'. [5] By that decision the Commission (i) required IMS 'to grant a licence without delay to all undertakings currently present on the market for German regional sales data services, on request and on a non-discriminatory basis, for the use of the 1860-brick structure, in order to permit the use of and sales by such undertakings of regional sales data formatted according to this structure' (Art. 1); (ii) provided for the manner in which royalties were to be determined (Art. 2) and (iii) laid down the penalty for non-compliance to be imposed on IMS (Art. 30).

14. In the part of the decision concerning the *fumus boni juris* and thus the prima facie infringement of Article 82 EC by IMS the Commission considered that IMS held a dominant position on the market for German regional sales data services (the whole German territory and a substantial part of the common market). [6]

15. On that premiss, in order to assess whether the refusal by IMS to grant a licence in respect of its structure constituted an abuse of a dominant position, the Commission considered that it had to 'examine whether the 1860-brick or compatible structure [was] indispensable to compete on the relevant market, that is to say whether there [was] a realistic possibility for undertakings wishing to offer regional sales data services in Germany to employ — instead of the 1860-brick or a compatible structure — another structure which would not infringe IMS's copyright'. [7] Moreover, 'the answer to this question depend[ed] on whether there [was] a real possibility for customers of regional sales data of buying data formatted in another structure.' [8]

16. On the basis of its investigations and in particular in light of information received from a number of pharmaceutical companies questioned by it the Commission reached an affirmative determination on that question.

4 — Order of the Court in Case 792/79 R *Camera Care* v *Commission* [1980] ECR 119.

5 — OJ 2002 L 59, p. 18.

6 — Paragraphs 45 to 62.

7 — Paragraph 71.

8 — Paragraph 72.

17. In that connection it highlighted a series of factors tying customers (the pharmaceutical companies) to IMS's 1860 brick structure, in particular the matters set out below:

— the 'working group played an extensive role in designing' the 1860 brick structure. 'The pharmaceutical industry in Germany invested considerable resources in ensuring that the brick structure fully met their requirements'. This in part explains their 'dependence, built up over a long period, on this structure, the extremely high disincentives they have to switch to a new one, and so the impossibility for a regional sales data service formatted in another structure to be able to compete'. [9]

— 'the 1860-brick structure functions as an industry standard', in part because of the role played by the firms in this industry in its creation. The 'pharmaceutical companies have become "locked in"' to 'this standard such that to switch away from it to buy sales data formatted in a non-compatible structure, whilst theoretically possible, would be an unviable economic proposition'. [10]

— 'Data for different time periods therefore need to be comparable, and data in any new structure would have to be converted to the 1860 structure (or vice versa) to ensure such comparability, at considerable cost.' [11]

— 'If regional sales data were supplied in a structure which was not compatible with the 1860 structure, this would necessitate significant changes in the territories allocated to sales representatives by their pharmaceutical companies' with consequential 'loss of relationships between doctors and sales representatives' which would be the 'inevitable result of a change to a brick structure which was incompatible with the 1860-brick structure and would act as a important disincentive for certain pharmaceutical companies to make such a change.' [12]

9 — Ibid.

10 — Paragraphs 86 and 92.

11 — Paragraph 93.

12 — Paragraph 114. With reference to the relationship between doctors and sales representatives the Commission observed in particular that 'the pharmaceutical companies attach great importance to the relationship between a doctor and a sales representative, which is one of the few means to promote a drug.' (paragraph 113).

— The sales territory, defined as the aggregation of a number of bricks, may be 'indicated in the working contract between the company and the sales representative, in which case a change of structure would require a modification of the working contract. This procedure would be another disincentive to switch brick structure'. [13]

— 'The costs of modifying internal applications which are at present wholly dependent on the 1860-brick structure are significant and represent a significant disincentive to switching brick structures.' [14]

18. The Commission went on to highlight the 'technical and legal constraints' which [might] make it unreasonably difficult for other undertakings to create another structure in which regional data sales services could be formatted and marketed in Germany'. [15] In that connection it observed that 'most of the parameters used in building the structure are in the public domain and fixed (postcode areas, location of pharmacies and doctors, sociodemographic data, topology, territory able to be covered by sales representatives in a day, and so on), as noted above. The choice of boundaries between bricks depends greatly on these objective parameters, and so limits the choices available to would-be structure creators'. [16]

19. The Commission also pointed to other factors rendering unlikely the development of an alternative structure on the part of competitors of IMS, stressing in particular legal uncertainty around selling data in a new structure, [17] unsuccessful past attempts to create new structures [18] and the impossibility of obtaining pointers as to the development of new structures from the experience of other countries. [19]

20. On the basis of all the abovementioned matters the Commission therefore considered that the 1860-brick or compatible structure was indispensable to compete on the relevant market. Taking the view that there were no objective grounds for refusal

13 — Paragraph 115.

14 — Paragraph 122.

15 — Paragraph 124.

16 — Paragraph 131. The Commission went on to state more specifically that 'the clear importance of using postcode areas limits the choices available to potential designers of new brick structures' (paragraph 132); that 'there are strong arguments for the necessity for brick structures to respect the boundaries of the 440 German Kreise' (paragraph 137), and that 'there is a probability that German data protection laws do impose certain constraints on the construction of a second structure in Germany' (paragraph 142).

17 — Paragraphs 143 to 145.

18 — Paragraphs 146 to 152.

19 — Paragraphs 153 to 166.

of a licence [20] the Commission accordingly held that such refusal constituted a prima facie abuse of a dominant position.

21. Replying to the arguments put forward by IMS that, in accordance with the relevant Community case-law, 'IMS is entitled to refuse licences of its copyright to competitors for the market to which copyright relates', [21] the Commission emphasised that 'the fact that the cases considered by the European Court of Justice and Court of First Instance to which IMS refers involved two markets does not preclude the possibility that a refusal to license an intellectual property right can be contrary to Article 82.' [22] In order to establish an infringement of that provision in the present case, the Commission specifically deemed the following matters to be sufficient: (i) 'use of the 1860-brick structure is an indispensable input to allow undertakings to compete in the market for regional sales data services in Germany'; (ii) there is 'an important distinction between the product, which is regional sales data services, and the brick structure in which data used to create these services is formatted'; (iii) in 'the specific and exceptional circumstances in which the 1860-brick structure was developed and copyright was asserted and found to subsist, the work in question for the technical, legal and economic constraints referred to above is incapable of being replicated by means of a non-infringing parallel creation'. [23] Again with reference to the Community case-law 'there [was] no requirement for a refusal to supply to prevent the emergence of a new product in order to be abusive'. [24]

22. By applications lodged on 6 August 2001 IMS applied to the Court of First Instance for annulment under Article 230 EC of the Commission Decision and for suspension of operation under Article 243 EC. By order of 26 October 2001 the President of the Court of First Instance granted the application for interim suspension. [25] For present purposes it should be emphasised that in the part of the order concerning whether there was a prima facie case the Court considered well founded (or at least not manifestly unfounded) the arguments by IMS according to which the Commission had departed from Community case-law in holding that the refusal to grant a licence entailed an infringement of Article 82 EC even where it did not prevent 'the appearance of a new product on a market separate from that on which the undertaking in question is dominant.' [26]

20 — Paragraphs 167 to 174.
21 — Paragraph 182.
22 — Paragraph 184.
23 — Paragraph 184.
24 — Paragraph 180.
25 — Case T-184/01 R *IMS Health* v *Commission* [2001] ECR II-3193.
26 — Paragraph 105.

23. The appeal by NDC against that order was dismissed by the President of the Court by order of 11 April 2002. [27]

Main proceedings and questions referred

24. As stated in the order for reference, IMS is pursuing its claim in the main proceedings that NDC be denied use of the 1860-brick structure or any derivative thereof. However, the Landgericht considers that the right to injunctive relief which is in principle guaranteed in favour of IMS by national copyright law cannot apply in the present case if the refusal by IMS to enter into a licence agreement with NDC on reasonable terms were to be held to constitute abusive conduct within the meaning of Article 82 EC.

25. On that point the referring court adopts the conclusions arrived at by the Commission in regard to the definition of relevant market and the dominant position occupied by IMS. [28] However, in order to establish whether the refusal by IMS to grant a licence constitutes an abuse of a dominant position, the Landgericht seeks a ruling by the Court on the following questions:

'1. Is Article 82 EC to be interpreted as meaning that there is abusive conduct by an undertaking with a dominant position on the market where it refuses to grant a licence agreement for the use of a data bank protected by copyright to an undertaking which seeks access to the same geographical and actual market if the participants on the other side of the market, that is to say potential clients, reject any product which does not make use of the data bank protected by copyright because their set-up relies on products manufactured on the basis of that data bank?

2. Is the extent to which an undertaking with a dominant position on the market has involved persons from the other side of the market in the development of the data bank protected by copyright relevant to the question of abusive conduct by that undertaking?

3. Is the material outlay (in particular in regard to costs) in which clients who have hitherto been supplied with the product of the undertaking having a dominant market position would be involved if they were in future to go over to purchasing the product of a competing undertaking which does not

27 — Case C-418/01 P(R) *NDC Health* v *IMS Health and Commission* [2002] ECR I-3401.

28 — The Landgericht refers specifically to paragraphs 45 to 55, 59 and 60 of the Commission Decision.

make use of the data bank protected by copyright relevant to the question of abusive conduct by an undertaking with a dominant position on the market?'

Procedure before the Court and the proceedings pending before the Court of First Instance

26. In the proceedings thus brought before the Court observations were submitted by the parties to the main proceedings and by the Commission. Those parties also presented oral argument at the hearing on 6 March 2003.

27. In the case brought by IMS before the Court of First Instance for annulment of the Commission Decision proceedings were suspended by order dated 26 September 2002 pending delivery of judgment by the Court in the present case.

Legal analysis

Preliminary

28. As has been seen, the questions referred form part of a complex series of matters which have already involved in various regards the Commission and the Presidents of the Court of First Instance and of the Court of Justice. Thus, in order to seek to give a useful reply to the national court, in the light also of the Commission Decision and the interim orders adopted by the Community Courts, I consider it appropriate to make some preliminary remarks concerning the scope of the questions and the problems essentially raised by them.

29. I would begin by observing that the first question appears to be based on two hypotheses: (a) the use of a specific brick structure protected by copyright is *essential* to the marketing of studies on regional sales of medicines in a given country and thus to the ability to operate on the relevant market, inasmuch as the potential clients (the pharmaceutical companies) *refuse to accept any study not carried out on the basis of that structure*;[29] (b) the undertaking owning the copyright of the structure in question holds a dominant position on the market for data services relating to regional sales of medicines in the country concerned. On the basis of those premisses, the national court seeks to ascertain whether Article 82 EC must be interpreted as meaning that, in such a situation, the undertaking owning the copyright is abusing its dominant position by refusing to grant (for valuable consideration) a licence

29 — The ground for such refusal which does not seem to be challenged by the question under examination seems to be attributable to organisational problems on the part of pharmaceutical undertakings.

for the use of its structure to persons seeking to use it in order to operate *on the same market* (geographical and product-based) in which the owner occupies the dominant position and asserts its right to that structure.

30. In other words, by its first question the national court is essentially seeking to ascertain whether, in a situation of the type described above, the refusal to grant a licence may constitute an abuse of a dominant position even if there is no restriction or elimination of competition on a market distinct from that in which the owner of the copyright exploits his right and holds a dominant position but is merely preventing potential competitors from operating on the same market as the dominant undertaking.

31. Moreover, it has already been pointed out that, with specific reference to that aspect, IMS had criticised the Commission's approach, arguing that it was 'entitled to refuse to grant a licence over its own copyright to competitors operating on the market concerned by the copyright itself'. [30] It is specifically on this aspect that, as has been seen, the President of the Court of First Instance dwelt when he held to be prima facie well founded (or at least not manifestly unfounded) the arguments of IMS alleging that the Commission had erroneously adjudged that the refusal to grant a licence constituted an infringement of Article 82 EC even if it did not prevent 'the emergence of a new product in a market not connected with that in which the undertaking concerned was dominant'. [31]

32. The two subsequent questions read in the light of the Commission Decision and the interim orders seem instead to concentrate on one of the matters underlying the first question since they seek essentially to clarify when a specific brick structure is to be deemed *indispensable* for the marketing of studies on regional sales of medicines in a given country. More specifically, the national court seeks to ascertain whether the following factors are material to such assessment: (i) the level of participation of the representatives of the pharmaceutical companies in the development of the structure protected by copyright; (ii) the lengths (particularly, in terms of cost) to which the pharmaceutical companies should be required to go in order to acquire studies carried out on the basis of a structure differing from the one protected by copyright.

33. Having thus clarified the scope of the questions, I will immediately turn to an examination of them, starting with the first

30 — Paragraph 182 of the Commission Decision.

31 — Paragraph 105 of the order of the President.

and then considering the second and third together. Once that examination has been concluded, it will finally be appropriate to make a few brief observations on the problems relating to the simultaneous application of Article 82 EC by the national court and the Commission.

First question

Arguments of the parties

34. With reference to the first question IMS begins by stressing that the power of exclusive enjoyment of an intellectual property right and thus the owner's power to refuse to others a licence to use it constitutes an essential element of that right. For that reason, as has been elucidated in the case-law, the mere refusal to grant a licence, even if it is by an undertaking having a dominant position, cannot of itself be determinative of abusive conduct within the meaning of Article 82 EC. That provision can be infringed only if the refusal to grant the licence is accompanied by a further element constituting abusive conduct. [32] Any other interpretation of the provision whereby a refusal to grant a licence could be declared per se abusive would moreover have very serious and undesirable consequences for the market economy inasmuch as it would deprive the owners of an intellectual property right of the due recompense for their creative endeavour and would act as a disincentive to investments in innovation and research.

35. IMS goes on to observe that in a case such as that under examination the refusal to grant a licence would also not be capable of constituting an abuse of a dominant position under the essential facility doctrine on which the Commission Decision is essentially based. According to that doctrine the dominant undertaking must offer on an (upstream) market the goods or services which are indispensable for competing with it on a second (downstream) market: in that situation, by unjustly denying access to its goods or services the dominant undertaking would be abusively restricting competition on the downstream market. [33] Thus, the essential facility doctrine cannot require the dominant undertaking to share with other operators an intellectual property right solely in order to

32 — In that connection IMS cites Case 238/87 *Volvo* [1988] ECR 6211 and Case 53/87 *Renault* [1988] ECR 6039 and Joined Cases C-241/91 P and C-242/91 P *RTE and ITP* v *Commission* [1995] ECR I-743, paragraph 49, hereinafter the '*Magill*' judgment.

33 — According to IMS all the judgments of the Community Courts and the Commission decisions concerning the refusal to grant a contract and essential facilities are to that effect. In that connection it makes specific reference to the judgments of the Court in Joined Cases 6/73 and 7/73 *Commercial Solvents* [1974] ECR 223; Case 311/84 *Télémarketing* [1985] ECR 3261; Case C-18/88 *GB-Inno-BM* [1991] ECR I-5941; *Magill*; Case C-7/97 *Bronner* [1998] ECR I-7791; Case T-504/93 *Ladbroke* [1997] ECR II-923; and Commission Decision of 14 January 1998 concerning a procedure under Article 86 of the EC Treaty (Case IV/34.801 FAG — Flughafen Frankfurt Main AG (OJ 1998 L 72, p. 30)).

allow the latter to compete with it more effectively on the same market on which it is exploiting its right.

36. IMS stresses, moreover, that in the present case no reliance may be placed on the *Magill* judgment in order to maintain that the refusal to grant a licence constitutes an abuse of a dominant position. In that judgment the Court confirmed that a refusal to grant a licence may constitute an abuse only in exceptional cases where (i) it prevents the appearance of a new product not offered by the dominant undertaking which owns the intellectual property right and for which there is a potential demand; (ii) it is unjustified; (iii) it has the effect of reserving a derivative market to the dominant undertaking. In the present case the first and third conditions are not satisfied inasmuch as NDC is not seeking to introduce a new product on a derivative market but wishes to avail itself of the structure developed by IMS in order to supply on the same market a product almost identical to that developed by that company.

37. In the view of IMS, finally, to interpret Article 82 EC as meaning that the refusal of a dominant undertaking to grant a licence in itself constitutes an abuse would be an infringement (a) of the right of property protected by the European Convention on Human Rights; (b) of the international obligations of the Community under the WTO agreement on aspects of intellectual property rights relating to trade and the Bern Convention on the protection of literary and artistic works.

38. NDC's pleas and submissions are plainly to the contrary.

39. In particular that company maintains that the facts of the present case are analogous in a number of respects with the *Magill* case in which the Court held that the refusal by the owner of the copyright to grant a licence constituted an abuse. As in that case,

— the intangible asset protected by copyright is not the result of great creative effort and considerable investment (in the present case the structure is based to a large extent on the borders of the German postal codes and was brought into existence thanks to the decisive contribution of the pharmaceutical industry):

— the asset is made available to persons who are not in competition with the owner of the copyright (in the present case, for example, cartography services).

— the product offered by the undertaking seeking the licence is in many respects better than that produced by the owner of the copyright (in the present case there is a wider spectrum of data, online access is offered and the significative value of the data is greater and they are presented in a more customer-friendly manner.

— the monopoly situation in regard to the upstream activity (in this case the brick structure) would be extended to downstream activity (marketing of studies on regional sales of medicines).

40. The solution proposed by it is also supported, in NDC's view, by the fact that it does not intend merely to reproduce the data collected by IMS but wishes autonomously to collect and process the data on regional sales in order then to transpose them into a product of its own. Moreover, NDC stresses that in the present case the intangible asset protected by the copyright constitutes a sectoral standard which, on the basis of the assessments by the Commission in its guidelines on the applicability of Article 81 of the EC Treaty to horizontal cooperation agreements, [34] should be as accessible as possible.

41. Finally, NDC observes that for refusal to grant a licence to constitute an abuse it is not necessary for there to be two separate markets (upstream and downstream). [35] As may be inferred from the *Magill* judgment, for the application of Article 82 EC it is sufficient that the dominant undertaking on a given market holds a monopoly on information necessary for competing with it. The fact that such information is not offered on the market by the dominant undertaking is immaterial.

42. For its part the Commission maintains that for the refusal by a dominant undertaking to allow its competitors access to an essential facility to be deemed an abuse it is not necessary for that facility to be in a market different from that in which the competitors seek to operate. To that end it is sufficient for the infrastructure to be located in an upstream production stage and for it to constitute a clearly separable input for the production of given upstream goods or services.

43. More specifically, according to the Commission, for a given product or service to be deemed to be infrastructure or an essential input, it must be distinguishable from the downstream goods or services and between it and the downstream product or

34 — OJ 2001 C 3, p. 2.

35 — in that regard NDC emphasises in particular that at paragraph 47 of the *Magill* judgment the Court did not assess whether in the present case two markets could technically be distinguished.

service 'added value' must be created. That approach based on the distinction between various stages of production rather than on the existence of separate markets is confirmed by the Court's analysis in the *Magill* and *Bronner* judgments and by the Court of First Instance in the *Ladbroke* judgment.

44. The mere fact that input essential for the production of the downstream goods or service is not independently marketed by the dominant undertaking does not operate to exclude the unjustified refusal of access to that input from constituting abusive conduct. In that case as well refusal of access imposes a significant restriction of competition in the market for the downstream goods or service in breach of Article 82 EC. The restriction would be still more serious if the essential input were not in fact marketed given that the undertakings concerned in the production of the downstream goods or service could not secure that input indirectly by having recourse to third parties who had acquired it from the dominant undertaking.

45. That reasoning, the Commission adds, holds good also where the essential input is constituted by an intangible asset protected by copyright. If in fact that intangible asset is distinguishable from the downstream goods or service for the production of which it were essential, the refusal to grant a licence by the dominant undertaking owning the copyright would go beyond the essential function of that right because it would reserve to the undertaking the market in the downstream goods or service. In that regard, the Commission goes on to stress that copyright is a property right like any other with which it has in common the power of the owner to have exclusive rights of disposition over the (tangible or intangible) asset which forms the subject-matter thereof but also the obligations flowing from competition law.

Appraisal

46. The question under examination, as has been seen, raises an important and delicate problem of interpretation of Article 82 EC concerning the obligation on a dominant undertaking to grant (for valuable consideration) to its competitors the right to use an intangible asset protected by copyright where that is essential for operating on the same market in which that undertaking is exploiting its right and occupying a dominant position.

(a) Relevant case-law

47. For the purposes of examining that question I believe that it is first necessary to recall the judgments of the Court concerning the possibility that a refusal to enter into

contractual relations may be deemed to constitute an abuse of a dominant position in which (or at least in some of which) it is possible to discern an application of the essential facility doctrine, to which the parties have on several occasions referred. [36]

48. In that connection I shall begin by recalling the *Commercial Solvents* judgment in which those problems were dealt with by reference to an interruption of the supply of raw materials. Upholding the Commission Decision impugned in that case, the Court clarified that 'an undertaking which has a dominant position in the market in raw materials and which, with the object of reserving such raw material for manufacturing its own derivatives, refuses to supply a customer, which is itself a manufacturer of these derivatives, and therefore risks eliminating all competition on the part of this customer, is abusing its dominant position within the meaning of Article 86'. [37]

49. In the *Telemarketing* judgment the Court subsequently had occasion to specify that that reasoning 'also applies to the case of an undertaking holding a dominant position on the market in a service which is indispensable for the activities of another undertaking on another market.' [38] In that case the Community judicature held that it was contrary to Article 86 of the EC Treaty (now Article 82 EC) for a dominant undertaking on the telediffusion market to refuse without objective justification to allow television space to independent telemarketing undertakings thereby reserving to an associated company operations in that sphere, with the risk that that entails of eliminating all competition on that market. In regard to those facts the Court specifically affirmed the principle that 'an abuse within the meaning of Article 86 is committed where, without any objective necessity, an undertaking holding a dominant position on a particular market reserves to itself an ancillary activity which might be carried out by another undertaking as part of its activities on a neighbouring but separate market, with the possibility of eliminating all competition from such undertaking.' [39]

50. With specific reference to intellectual property rights, the *Volvo* case must be considered next. In that case the Court was essentially asked whether that motor manufacturer was abusing its dominant position on the (presumptive) market for original spare parts by not granting to third parties a licence for the manufacture of such spare parts. In reply to that question the Court stated that 'the right of the proprietor of a protected design to prevent third parties from manufacturing and selling or importing, without its consent, products incorporating the design constitutes the very subject-matter of his exclusive right. It follows that

36 — With reference to that doctrine and its application in the United States and in Europe see in particular Opinion of Advocate General Jacobs in the *Bronner* case, cited above, paragraphs 45 to 53.

37 — Paragraph 25 of the judgment cited.

38 — Paragraph 26 of the judgment cited.

39 — Ibid. The same principle has been reaffirmed in a partly different context in the *GB-Inno-BM* judgment, paragraph 8.

an obligation imposed upon the proprietor of a protected design to grant to third parties, even in return for a reasonable royalty, a licence for the supply of products incorporating the design would lead to the proprietor thereof being deprived of the substance of his exclusive right, and that a refusal to grant such a licence cannot in itself constitute an abuse of a dominant position.'[40] However, the Court added that 'the exercise of an exclusive right by the proprietor of a registered design in respect of car body panels may be prohibited by Article 86 if it involves, on the part of an undertaking holding a dominant position, certain abusive conduct such as the arbitrary refusal to supply spare parts to independent repairers, the fixing of prices for spare parts at an unfair level or a decision no longer to produce spare parts for a particular model even though many cars of that model are still in circulation, provided that such conduct is liable to affect trade between Member States.'[41]

51. Giving judgment on an appeal from two judgments of the Court of First Instance in the well-known *Magill* case the Court had the opportunity of returning to the question of a refusal to grant a licence for the use of an intellectual property right. In the judgments appealed against the Court of First Instance had upheld a decision in which the Commission had adjudged that certain television broadcasters had abused the dominant position held by them on the market for their television programme listings, by invoking their copyright over such listings in order to prevent third parties from publishing complete weekly guides to the programmes of the various broadcasters.

52. In that connection the Court primarily emphasised that it followed from the judgment in *Volvo* that, although a refusal to grant a licence in respect of an intellectual property right cannot in itself constitute an abuse of a dominant position, 'exercise of an exclusive right by the proprietor may, in exceptional circumstances, involve abusive conduct.'[42] In that case, in the Court's view, the circumstances were such as to constitute abusive conduct on the part of the appellant broadcasters since:

— first, 'the appellants — who were, by force of circumstances, the only sources of the basic information on programme scheduling which is the indispensable raw material for compiling a weekly television guide — gave viewers wishing to obtain information on the choice of programmes for the week ahead no choice but to buy the weekly guides for each station and draw from each of them the information they needed to make comparisons. The refusal to provide basic informa-

40 — *Volvo* judgment, paragraph 8.

41 — Paragraph 9. The Court ruled essentially to the same effect in the *Renault* judgment, cited above.

42 — Paragraph 50.

tion by relying on national copyright provisions thus prevented the appearance of a new product, a comprehensive weekly guide to television programmes, which the appellants did not offer and for which there was a potential consumer demand. Such refusal constituted an abuse under heading (b) of the second paragraph of Article 86 of the Treaty.' [43]

— Secondly, 'there was no justification for such refusal either in the activity of television broadcasting or in that of publishing television magazines.' [44]

— Thirdly, 'the appellants, by their conduct, reserved to themselves the secondary market of weekly television guides by excluding all competition in that market ... since they denied access to the basic information which is the raw material indispensable for the compilation of such a guide.' [45]

53. Finally, the Court had the opportunity of examining the problem of the refusal to grant a licence in the well-known *Bronner* judgment. In that case the Court, positing the existence of an autonomous market for nationwide home-delivery schemes, was required, inter alia, to assess 'whether the refusal by the owner of the only nationwide home-delivery scheme in the territory of a Member State, which uses that scheme to distribute its own daily newspapers, to allow the publisher of a rival daily newspaper access to it constitutes an abuse of a dominant position within the meaning of Article 86 of the Treaty, on the ground that such refusal deprives that competitor of a means of distribution judged essential for the sale of its newspaper.' [46]

54. After recalling the *Magill* judgment, the Court observed that 'even if that case-law on the exercise of an intellectual property right were applicable to the exercise of any property right whatever', it would still be necessary in order to plead the existence of an abuse within the meaning of Article 86 of the Treaty, not only for 'the refusal of the service comprised in home delivery to be likely to eliminate all competition in the daily newspaper market on the part of the person requesting the service and [for] such refusal to be incapable of being objectively justified, but also for the service in itself to be indispensable to carrying on that person's business, inasmuch as there [was] no actual or potential substitute in existence for that home-delivery scheme.' [47]

43 — Paragraphs 53 and 54.
44 — Paragraph 53.
45 — Paragraph 56.
46 — Paragraph 37.
47 — Paragraph 41.

(b) Inferences

55. It may be inferred from the foregoing brief examination of the case-law that, as IMS has highlighted, in all the cases in which it has acknowledged that the refusal to supply or make available certain (tangible or intangible) goods or services might constitute an abuse of a dominant position, the Court has distinguished between a market for such goods or services (upstream) and a derivative market (downstream) in which they are utilised as inputs for the production of other goods or services. The infringements of Article 82 established or presumed in those cases in fact concerned vertically integrated undertakings which (at least hypothetically) by refusing to grant a licence abused their dominant position on an upstream market in order to restrict or eliminate competition on a downstream market.

56. As has been rightly pointed out by NDC and the Commission, however, in order to identify an (upstream) market for inputs the Court has not deemed it necessary that the latter be autonomously marketed by the dominant undertaking. In *Magill* the Court in fact identified a market for television listings even where they were not marketed independently by the television broadcasters but merely offered free of charge to certain newspapers. Then, in the *Bronner* judgment the Court acknowledged the existence of a market in the nationwide home-delivery scheme for daily newspapers even where the undertaking holding a monopoly in such a (hypothetical) market did not independently sell the home-delivery scheme. [48]

57. Thus, in applying the case-law cited on the refusal to grant a licence I consider it to be sufficient that it is *possible to identify* a market in upstream inputs, even where the market is a 'potential' one only, in the sense that operating within it is a monopoly undertaking which decides not to market independently the inputs in question (notwithstanding that there is an actual demand for them) but to assert exclusive rights over a downstream market by restricting or eliminating all competition on that market.

58. To take a classic example of the essential facility doctrine it is instructive to consider the case where access to a port is indispensable in order to be able to provide maritime transport services in a given geographical market. For the purposes of such a case it may be assumed that the owner of the port uses that infrastructure on an exclusive basis in order to secure a monopoly over the market for maritime transport services refusing without any

48 — In identifying the relevant market the Court does not seem to have taken into consideration the fact that the owner of the delivery scheme provided a series of services to an independent publisher including home delivery of one of its daily newspapers. In that case the home-delivery scheme was not sold independently but formed part of a 'package' including the printing and sale in kiosks of the daily newspaper in question.

objective justification to provide the necessary port services to arm's-length undertakings which make a request in that regard. I consider that in such a case the case-law on the refusal to grant a licence must apply irrespective of the fact that the port services are not offered on the market. That fact does not preclude the possibility of identifying a market in port services requested by the maritime transport undertakings given that there is an actual demand for such services and there are no obstacles of a technical nature to the marketing thereof. In terms of the case-law on the refusal to grant a licence it may therefore be held that, by denying without justification access to the port infrastructure, the owner of that infrastructure would be abusing its dominant (monopoly) position on the market for port services inasmuch as by its conduct it would be eliminating any competition on the secondary market for maritime transport services.

59. Since it has therefore been established that in order to be able to identify a market for upstream inputs it is not necessary for them to be marketed independently by the undertaking controlling them, it seems plain to me that such a market may by definition be always identified where: (a) the inputs in question are essential (since they cannot be substituted or duplicated) to operating on a given market; (b) there is an actual demand for them on the part of undertakings seeking to operate on the market for which those inputs are essential.

60. If I now turn to examine in light of the foregoing the case canvassed in the first question it must be recognised that in the present case the case-law on the refusal to grant a licence cannot not be applied owing to the sole fact that the undertaking seeking the licence to use the brick structure intends to operate on the same market as the owner of the copyright. In view of the fact that that question proceeds on the assumption that the brick structure for which the licence was sought is essential to the marketing of the studies on regional sales of medicines in a given country, it is not hard to identify an upstream market for access to the brick structure (monopolised by the owner of the copyright) and a secondary downstream market for the sale of the studies.

61. That said, I must none the less add that the judgments of the Court on the refusal to grant a licence over an intellectual property right lead me to believe that, in order for an unjustified refusal to be deemed abusive, it is not sufficient that the intangible asset forming the subject-matter of the intellectual property right be essential for operating on a market and that therefore, by virtue of that refusal, the owner of the copyright may eliminate all competition on the secondary market.

62. Even where those circumstances obtain, in weighing the balance between the interest in protection of the intellectual property right and the economic freedom of its owner, on the one hand, and the interest in protection of free competition, on the other, the balance may in my view come down in favour of the latter interest only if the refusal to grant the licence prevents the development of the secondary market to the detriment of consumers. More specifically, I consider that the refusal to grant a licence may be deemed abusive only if the requesting undertaking does not wish to limit itself essentially to duplicating the goods or services already offered on the secondary market by the owner of the intellectual property right but intends to produce goods or services of a different nature which, although in competition with those of the owner of the right, answer specific consumer requirements not satisfied by existing goods or services.

63. That was in my view clearly held in the *Magill* judgment in which, as has been seen, the Court held an unjustified refusal to grant a licence to be abusive, inasmuch as (a) 'it prevented the appearance of a new product, a comprehensive weekly guide to television programmes, which the appellants did not offer and for which there was a potential consumer demand'; and (b) by way of that refusal the appellants [had] 'reserved to themselves the secondary market of weekly television guides by excluding all competition in that market'. [49]

64. In that case the Court thus found it an abuse to refuse to grant a licence in view of the fact that the undertaking seeking the grant of a licence wished to place on the market a weekly television guide different from those produced by the owners of the copyright (inasmuch as it would not list the programmes of a single broadcaster but would provide a conspectus) in order to satisfy a specific consumer need. In that way, the emergence of a 'new' product was being prevented which would have been in competition with products marketed by copyright owners in the general market for weekly television guides.

65. Yet it is perhaps possible also to construe the *Volvo* judgment in this way. In that case the Court stated that 'a refusal to grant ... a licence cannot in itself constitute an abuse of a dominant position'. [50] Even though in that case a registered design in respect of car body panels could be regarded as an essential input for operating on the (presumptive) market for original spare parts, it may be considered that the Court did not deem the refusal to

49 — Paragraph 56.

50 — Paragraph 8.

grant a licence abusive owing to the fact that the undertaking seeking the licence wished to do no more than duplicate the products of the owner of the registered design, and thus produce original Volvo spare parts.

66. In light of all the foregoing considerations I therefore consider that the reply to the first question should be that Article 82 EC must be interpreted as meaning that the refusal to grant a licence for the use of an intangible asset protected by copyright entails an abuse of a dominant position within the meaning of that provision where (a) there are no objective justifications for such refusal; (b) use of the intangible asset is essential for operating on a secondary market with the consequence that by way of such refusal the owner of the right would ultimately eliminate all competition on that market. However, that is subject to the condition that the undertaking seeking the licence does not wish to limit itself essentially to duplicating the goods or services already offered on the secondary market by the owner of the intellectual property right but intends to produce goods or services of a different nature which, although in competition with those of the owner of the right, answer specific consumer requirements not satisfied by existing goods or services.

Second and third questions

67. As has been said, by its second and third questions the national court seeks essentially to ascertain when a specific brick structure protected by copyright must be deemed indispensable for the marketing of studies on regional sales of medicines in a given country. More specifically, the national court seeks to ascertain whether the following factors are material to such assessment: (i) the level of participation of the representatives of the pharmaceutical companies in the development of the structure protected by copyright; (ii) the lengths (particularly, in terms of cost) to which the pharmaceutical companies would have to go in order to acquire studies carried out on the basis of a structure differing from that protected by copyright.

Parties' arguments

68. With reference to the problems raised by the questions under examination, IMS observes in general terms that client preferences cannot justify classification of the 1860 brick structure as an essential facility. In order to assess whether a brick structure is essential to the marketing of the studies on regional sales of medicines, reference may not be made to the subjective preparedness of customers to accept studies

carried out on the basis of another structure. In that connection the decisive factor is whether it is objectively possible for a competitor of comparable dimensions to develop an alternative structure.

69. In regard to the role played by the pharmaceutical companies in the development of the brick structure, IMS observes that a contribution by customers to the creation of products or services more and more in keeping with their requirements is entirely normal. In that context the imposition of a requirement to grant a licence has negative consequences inasmuch as it would incite the undertakings to forgo any contact with customers in regard to the development of their products.

70. As to the costs of adjustment to be borne by customers in order to be able to use studies carried out on the basis of other structures, IMS observes finally that the fact that the customers must incur expenditure in order to opt for a different product is entirely normal and cannot be relevant in establishing whether a refusal to grant a licence entails an abuse of a dominant position.

71. Conversely, NDC observes that industry practices or customer expectations are relevant in establishing whether an infrastructure constitutes an essential facility, given that in certain circumstances they can mean that access to an infrastructure is essential where it normally would not be.

72. NDC goes on to emphasise that, in line with the *Bronner* judgment, access to a predetermined infrastructure may be deemed essential where the creation of an alternative infrastructure would not be economically viable. In the present case the costs of adjustment which would have to be borne by the pharmaceutical companies in order go over to another brick structure would be so great that the introduction of a competing structure not only would not be profitable but would indeed be economically unviable.

73. For its part the Commission points out that its decision indicates numerous matters in support of the contention that the IMS 1860 brick structure is indispensable for the marketing of studies on regional sales of medicines in Germany. The matters mentioned by the national court are thus only some of those which must be taken into consideration for the purposes of that assessment.

74. That stated, the Commission stresses that the major involvement of customers in the development of the IMS brick structure has contributed to creating a relationship of

dependency by the pharmaceutical companies on that structure. In its view, that degree of regular and intense collaboration by customers aimed at the creation of a common structure for the provision of a series of compatible services displays the characteristics of a process leading to the establishment of a *de facto* standard.

75. The Commission goes on to observe that in order to establish whether an infrastructure is essential, it must be assessed whether a competitor of analogous dimensions could create a valid alternative. For the purposes of that assessment, it would however be useful for there to be an attentive examination of the relevant factors on the demand side and in particular of the adjustment efforts to be carried out by customers in order to go over to another infrastructure. An analysis of the situation from the point of view of both supply and demand would in particular be opportune in order to establish whether the creation of an alternative infrastructure is economically viable.

76. Referring to the assessments carried out in its decision, the Commission highlights the obstacles which in the present case discourage the pharmaceutical companies from moving to a brick structure incompatible with that of IMS and the extraordinary efforts, not only of a financial nature, which that would entail.

Assessment

77. For an analysis of the question under examination, it is appropriate to start with the *Bronner* judgment in which the Court provided certain useful indications in order to establish when a (tangible or intangible) asset or a service may be deemed to be essential for operating on a given market.

78. In that case the Court specifically ruled out that the only system of home delivery existing nationwide in a Member State was essential for the sale of daily newspapers, emphasising on the one hand that 'it is undisputed that other methods of distributing daily newspapers, such as by post and through sale in shops and at kiosks, even though they may be less advantageous for the distribution of certain newspapers, exist and are used by the publishers of those daily newspapers.' Nor, moreover, were there 'any technical, legal or even economic obstacles capable of making it impossible, or even unreasonably difficult, for any other publisher of daily newspapers to establish, alone or in cooperation with other publishers, its own nationwide home-delivery scheme and use it to distribute its own daily newspapers.' [51]

51 — Paragraphs 43 to 44.

79. The Court further ruled that 'in order to demonstrate that the creation of such a system is not a realistic potential alternative and that access to the existing system is therefore indispensable, it is not enough to argue that it is not economically viable by reason of the small circulation of the daily newspaper or newspapers to be distributed. For such access to be capable of being regarded as indispensable, it would be necessary at the very least to establish ... that it is not economically viable to create a second home-delivery scheme for the distribution of daily newspapers with a circulation comparable to that of the daily newspapers distributed by the existing scheme'. [52]

80. It is therefore clear from that judgment that, in order to establish whether an 'input' is essential for operating on a given market, it must be assessed whether (a) there are substitute inputs, which may be used to operate (more or less effectively) on the market in question; (b) there are obstacles of a technical, legislative or financial nature which may make it impossible or unreasonably difficult for any undertaking seeking to operate on that market to create other inputs possibly in conjunction with other operators. For there to be obstacles of a financial nature to the creation of alternative inputs, it must at least be the case, the Court held, that their creation is not economically viable for production on a scale comparable to that of the owner of existing inputs.

81. In the case under examination, as has been stated, it is necessary to establish the relevance for the purposes of that assessment of: (i) the level of participation of the pharmaceutical undertakings in the development of the structure protected by copyright; (ii) the effort (particularly in terms of cost) to be made by the pharmaceutical undertakings in order to be able to acquire studies based on a structure other than the one protected by copyright.

82. In my view those aspects must be examined jointly inasmuch as they both manifest themselves ultimately as financial obstacles to the creation of an alternative structure.

83. In fact, according to the submissions of NDC and the Commission, the intense involvement of the pharmaceutical undertakings in the development of the IMS structure, although not an absolute technical or legal impediment to a move to an alternative structure, is one of the causes of the dependency of the pharmaceutical companies on the existing structure. But if it is so, the involvement of the pharmaceu-

52 — Paragraphs 45 to 46.

tical industries in the development of the IMS structure simply explains why those industries have to make exceptional efforts in order to be able to go over to acquiring studies carried out on the basis of a different structure.

84. However, it is clear that if the pharmaceutical industries had to make exceptional (organisational and financial) efforts in order to go over to another structure, that would render the creation of such a structure by a competitor of IMS more onerous or, depending on one's viewpoint, less profitable. To persuade potential customers to acquire studies carried out on the basis of the alternative structure the competitor of IMS would have to offer them particularly favourable terms with the risk that the investments made would not be amortised.

85. It must therefore be deduced that the level of participation of the pharmaceutical undertakings in the development of the structure protected by copyright and the effort to be made by the pharmaceutical undertakings in order to be able to acquire studies based on a structure other than the one protected by copyright are elements to be taken into account in establishing whether or not there are obstacles of a technical, legislative or financial nature which may make it impossible or extraordinary difficult for any other undertaking seeking to operate on that market to create such an alternative structure possibly in conjunction with other operators.

86. In light of the foregoing I therefore consider that the reply to the second and third questions should be that the level of participation of the pharmaceutical undertakings in the development of the structure protected by copyright and the effort to be made by the pharmaceutical undertakings in order to be able to acquire studies based on a structure other than the one protected by copyright are matters to be taken into account in establishing whether the latter structure is essential for the marketing of studies on regional sales of medicines.

Simultaneous application of Article 82 EC by the national courts and the Commission

87. As indicated, before concluding I would like to devote certain summary considerations to the problems arising in the present case with reference to the application in this context of Article 82 EC by the national courts and the Commission. Those problems arise inasmuch as the judgment to be delivered by the Court in the present case, although indicating the manner in which Article 82 EC is to be interpreted in regard to the questions

formulated by the national court, will presumably leave to the latter a certain margin of appreciation in order to establish whether the refusal by IMS to grant a licence constitutes an abuse of a dominant position. In theory the national court could give a ruling in conflict with the Commission Decision which established that such refusal was prima facie contrary to Article 82 EC.

88. In such a situation it seems to me opportune to point out that the Court has already had occasion to clarify that 'when national courts rule on agreements or practices which are already the subject of a Commission decision [under Article 81 or Article 82 EC] they cannot take decisions running counter to that of the Commission.' [53] That prohibition, which is founded on the duty of cooperation enshrined in Article 10 EC and the binding force of decisions adopted by the Commission pursuant to Articles 81 or 82 EC, [54] must in my view also apply whenever that institution has ruled on an interim basis, inasmuch as the interim nature of a decision certainly does not detract from its binding force or from the abovementioned duty of cooperation. As the Court has, moreover, clarified, the prohibition on adopting decisions in breach of Commission decisions applies even where the operation of such decisions is suspended on an interim basis by an order of the President of the Court of First Instance. [55]

89. Plainly, if the national court, within the context of the margin of appreciation which will presumably be left to it by the Court, were to have any doubts on the validity of the Commission decision, it could in that connection raise a new question for a preliminary ruling. [56] Where it deems it opportune, the national court may also stay its proceedings pending final judgment by the Court of First Instance on the Commission's interim decision or await its definitive decision, [57] possibly having first consulted the Commission. As emphasised by the Court, where proceedings are stayed, the national court must examine whether it is necessary to order interim measures in order to safeguard the interests of the parties pending final judgment. [58]

53 — Case C-344/98 *Masterfoods* [2000] ECR I-11369, paragraph 52.

54 — Paragraphs 49 and 50.

55 — Paragraph 53.

56 — Paragraph 57.

57 — Paragraph 57.

58 — Paragraph 58.

Conclusion

90. In light of the foregoing considerations I therefore propose that the Court should reply to the Landgericht in the following terms:

(1) Article 82 EC should be interpreted as meaning that the refusal to grant a licence for the use of an intangible asset protected by copyright entails an abuse of a dominant position within the meaning of that provision where (a) there are no objective justifications for such refusal; (b) use of the intangible asset is essential for operating on a secondary market with the consequence that by way of such refusal the owner of the right would ultimately eliminate all competition on that market. However, that is subject to the condition that the undertaking seeking the licence does not wish to limit itself essentially to duplicating the goods or services already offered on the secondary market by the owner of the intellectual property right but intends to produce goods or services of a different nature which, although in competition with those of the owner of the right, answer specific consumer requirements not satisfied by existing goods or services.

(2) The level of participation of the pharmaceutical undertakings in the development of the structure protected by copyright and the effort to be made by the pharmaceutical undertakings in order to be able to acquire studies based on a structure other than that protected by copyright are matters to be taken into account in establishing whether the latter structure is essential for the marketing of studies on regional sales of medicines.