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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 03~~\*~~.07.2001  
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**COMMISSION DECISION**

**of 3 July 2001**

**relating to a proceeding pursuant to Article 82 of the EC Treaty**

**(Case COMP D3/38.044 – NDC Health/IMS HEALTH: Interim measures)  
(Only the English text is authentic)**

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation No 17 of 6 February 1962, first Regulation implementing Articles 85 and 86 of the Treaty<sup>1</sup>, as last amended by Regulation (EC) No 1216/1999 of 10 June 1999<sup>2</sup>, and in particular Articles 3 and 16 thereof,

Having regard to the Commission Decision of 8 March 2001 to initiate proceedings in this case,

Having given the firm concerned the opportunity to make known its views on the objections raised by the Commission in accordance with Article 19 of Regulation No 1 and Article 2 of Commission Regulation (EC) No 2842/98 of 22 December 1998 on the hearing of the parties in certain proceedings under Articles 85 and 86 of the EC Treaty,<sup>3</sup>

Having given Advisory Committee on Restrictive Practices and Dominant Positions the opportunity to deliver an opinion on 19 June 2001.

Whereas:

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<sup>1</sup> OJ L3, 21.2.1962, p. 204/62.

<sup>2</sup> OJ L 148, 15.6.1999, p. 5.

<sup>3</sup> OJ L 354, 30.12.1998 p. 18.

## **I. THE FACTS**

### **1. THE NATURE OF THE PRESENT DECISION**

1. This Decision provides for interim measures pending a final decision on the application made under Article 3 of Regulation No 17 by National Data Corporation Health Information Services (NDC) of Atlanta, United States of America, alleging that an infringement of Article 82 of the EC Treaty had been committed by IMS HEALTH Incorporated (IMS) of Westport, United States of America.

### **2. THE UNDERTAKINGS**

2. The companies referred to below are all involved in tracking sales in the pharmaceutical industry and in the healthcare products sector. They supply pharmaceutical firms with data on the sales performance of pharmaceutical products recorded by pharmacies and on doctors' prescriptions.

#### **IMS**

3. **Intercontinental Marketing Services Health Inc (IMS)**, a US company, is the world's number one supplier of information to the pharmaceutical and healthcare industry. IMS HEALTH describes itself as "*the world's leading provider of information solutions to the pharmaceutical and healthcare industries*".

IMS is active in 100 countries. IMS' turnover was USD 1.4 billion in 2000 with an increase of 1.9% compared to 1999. The healthcare activity revenue increased 9.1% to USD 1.1 billion in 2000 from USD 1 billion in 1999. Operating income for this activity was higher by 3.7% in 2000, USD 344 315.

IMS's European headquarters are located in London. IMS' German subsidiary is IMS GmbH & Co. OHG located in Frankfurt am Main.

#### **NDC**

4. **National Data Corporation Health Information Services (NDC)**, also a US company, supplies database services mainly in the United States, specialising in the pharmaceutical sector. Like IMS, NDC also offers an information service in various countries aimed at the pharmaceutical and healthcare sector. In 1998, NDC entered the EU market via two acquisitions in the UK, specifically having acquired Hadley Hutt and John Richardson Computers. In June 2000 NDC concluded an agreement for the purchase of PI Pharmaintranet ("PI"), thereby giving NDC an operational platform in the German market under the name of NDC Health GmbH. PI was established by a former IMS employee, Mr Roland Lederer in February 1999. Following an internal restructuring in January 2001, National Data Corporation's health and banking services have been separated into NDC Health and Global Payment Systems. NDC Health had a worldwide turnover of USD 289.3 million in 2000.

### 3. THE COMPLAINT AND APPLICATION FOR INTERIM MEASURES

5. NDC lodged a complaint on 19 December 2000 requesting the Commission to:
  - initiate a procedure to establish the existence of an infringement of Article 82; and
  - grant interim measures.
6. NDC considers that IMS is abusing its dominant position by refusing to grant it a licence to use the “1860 brick structure”, a segmentation of Germany into 1860 geographical areas, used to report sales information. Without this licence NDC claims it cannot provide regional sales reports based on this structure for Germany (hereinafter “regional sales data services”), the largest pharmaceutical market of the EU, and is also prevented from making contracts for multi-jurisdictional coverage because it would be unable to provide German reports. Furthermore, NDC claims that the German Court has strengthened IMS’ dominant position through its interim judgements which prohibited PI from using the the 1860, 2847 or 3000 brick structures or any other brick structure derived from the 1860 brick structure on the basis that they constitute a personal intellectual creation belonging to IMS. For violation of this order NDC may be fined a maximum of 500,000DM. and that IMS’ procedure represents vexatious litigation. The latter two points are not related to this Decision and will not be examined further.
7. The interim measures requested by NDC are an *order compelling IMS to grant NDC a license to the 1860 structure and all of its derivatives, upon non-discriminatory, commercially reasonable terms, with such license to be extinguished (and royalties to be reimbursed to NDC) as and when NDC is able to prove that IMS does not own a copyright in any of said structures.*

### 4. THE INVESTIGATION

8. The complaint was sent to IMS on 20 December 2000. Two requests for information under Article 11 of Regulation 17 were sent to IMS on 20 December 2000 and 19 January 2001. IMS commented on the complaint in its letter of 12 January 2001 and replied to the requests for information by letters of 15 and 26 January and 7 March.
9. Requests for information to pharmaceutical companies under Article 11 were initially made to a sample of 20 firms, amongst whom were 17 of the 20 largest pharmaceutical companies in Germany and 9 members of the Working Group (see paragraph 76 et seq.). Meetings took place with 8 pharmaceutical companies. Further requests pursuant to Article 11 were made to other information providers such as NDC, AzyX, Cégédim and Suomen LääkeData Oy (SLD).
10. On 9 March 2001 the Commission sent a Statement of Objections to IMS HEALTH. IMS replied by letter dated 2 April 2001 and requested an oral hearing, which took place on 6 April 2001. The Commission sent a further request for information on 3 May to which IMS replied on 14 May. IMS also provided the Commission with 4 supplementary memoranda dated 18 April, 15 May, 16 May and 5 June. In its written response dated 2 April 2001, during the oral hearing and in subsequent submissions, IMS commented on the Statement of Objections and put forward a number of counter-arguments, which are responded to in the appropriate section of the legal assessment.

11. In order to clarify further certain assertions raised by IMS in its written and oral replies to the Statement of Objections, requests for information were sent to the original 20 companies and to a further 90 pharmaceutical companies (110 in total). 85 replied, of which 11 did not buy regional sales reports. Further contacts also took place with information providers such as NDC, AzyX, Cégédim, Farmastat, SLD and GESDAT, the data marketing facility of three German wholesalers. This new information was communicated to IMS on 22 May and 7 June 2001 for their comments. IMS responded by letter of 14 June. A meeting took place between IMS and the Commission services on 18 June 2001.

## **5. THE FACTS**

### **5.1 Regional data services**

12. Pharmaceutical companies use regional data services to build their sales territories, to develop and implement incentive schemes for their sales representatives and to gain knowledge of market developments (market shares of their products, comparison with previous time periods etc.).
13. Regional sales reports are based on data delivered by pharmaceutical wholesalers to report providers, such as IMS, NDC and AzyX<sup>4</sup>. These data represent the purchases of the individual pharmacies from the wholesalers<sup>5</sup>. It is assumed that these purchases are a good proxy<sup>6</sup> for pharmacy sales and therefore for doctor's prescriptions. Wholesalers commonly have data supply agreements with providers of regional sales reports, whereby wholesalers provide data on sales to an aggregation of pharmacies within geographic segments to the report providers. Providers of regional sales reports require from wholesalers the data broken down in a predefined structure (the input structure). IMS licences this structure to the wholesalers only for the reporting of their data and not for other uses. This input structure differs between providers: IMS' structure has 2847 segments, NDC's originally had 3000, though this was replaced by a 3942 (ex 3944) segment structure, and the AzyX structure has 2881 segments.
14. This input segmentation structure is a grid superimposed on a country map, grouping communities of doctors, pharmacies and patients and contains among others the following data: postal codes of the German post office, information of Federal Statistical Office (political boundaries, number of residents), distribution of physicians and pharmacies, mapping materials (topographic and street maps) and information about the regional organisation of the physicians' billing associations. The purpose of the segmentation is to allow reporting of sales data broken down into a small, useful geographic area, called a 'brick', while avoiding the identification of sales to individual pharmacies. The latter is necessary for data privacy protection<sup>7</sup> purposes. In Germany data privacy protection rules require that at least three pharmacies be aggregated. In order to keep the structure stable at least four or five

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<sup>4</sup> The Group AzyX is composed by Pharma Groupe SA, holding company set up in February 1999 under Luxembourg Law and 5 national subsidiaries: AzyX Belgium, AzyX Deutschland GmbH Geopharma Information Services, AzyX servicios de Geomarketing Farmaceutico Lda, AzyX Polska Geopharma Information services Sp.z.o.o. (all set up in 1999) which is active on the same markets as IMS and NDC.

<sup>5</sup> There are 16 wholesalers in Germany. On average 3 wholesalers serve each pharmacy.

<sup>6</sup> Only 15% is purchased by the pharmacies directly from the manufacturers and not through wholesalers

<sup>7</sup> Federal Data Protection Act (Bundesdatenschutzgesetz) as most recently amended on 23 May 2001

pharmacies are necessary in each segment. There are around 21,500 pharmacies and 287,000 doctors in Germany.

15. The process of producing regional data services begins with receipt of the data from the wholesalers to the service provider according to the latter's input structure. The data are then checked and formatted in the brick structure, on which many analyses are carried out. This brick structure, which is used to provide regional sales data services to pharmaceutical companies, may differ from the input structure. The final end products, i. e. the regional sales reports offered by the 3 providers in the German market differ markedly. For example, the "RPM" sales reports of IMS and the "RPI" product of NDC are different, though the incoming data is similar. According to customers, RPI provides for a more complete coverage of some parts of Germany and provides more detail on types of information, such as re-imported products and products returned to wholesalers.
16. In the course of the Commission's investigation, AzyX explained how its regional data service products differ from those of its competitors. First, different criteria are used to classify pharmaceutical products into so-called ATCs (anatomical therapeutic classes). Both World Health Organisation and European Pharmaceutical Market Research Association (EphMRA) classifications are used, the WHO criteria being more scientifically oriented and the EphMRA criteria more marketing oriented. Clients might define different competitive markets using different classifications. AzyX can build competitive markets based on which molecules are active in a certain product, which can lead to a different views of what the market is: for example, since the same active molecules in aspirin can also be used to prevent cardiac infarction at a different dosage, manufacturers are interested to know which other painkillers could because of their active molecules also be positioned in the cardiological market by simply changing the dosage. Also, some data providers show 'returns' i.e. the quantities of a product which are sold and then later taken back by the pharmaceutical company. This helps measure a sales representatives' true performance. There are also a variety of analysis tools associated with different data providers.

## 5.2 Brick structures

17. In many countries regional sales data are provided in a predefined segmentation known as a "brick structure", mainly so to create segments with equal sales potential, and to comply with data protection law (which stems from Directive 95/46/EC<sup>8</sup>). For the pharmaceutical manufacturers, the brick structure in which regional sales data are being reported is very important because they have organised their sales forces and the way the sales personnel are rewarded according to this structure. The territory of a salesperson is composed of a number of bricks of the brick structure. A number of companies define the sales territory of a sales representative as an aggregation of several 1860-bricks in that representative's working contract. The remuneration of sales representatives is based on movements in drugs' market shares and growth rates per brick.
18. The data, formatted according to the brick structure, forms the basis for regional market reports which are delivered in printed form, on CD-ROM or online. The

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<sup>8</sup> OJ L 281 of 23.11.95, p.31

pharmaceutical companies then process the data internally or transfer it to other service providers in order for it to be analysed.

19. The 1860 brick structure, which is the subject of the refusal to licence disputed here, is formed by allocating a number of postcode areas to a particular brick. This brick is then identified by a 7-digit number. The first five of the seven digits are public numbers that represent political borders - the first two digits represent the Bundesland, the next digit represents the Regierungsbezirkskennziffer (political border) and the next two stand for Landkreis or Stadtkreis (metropolitan area). The last two digits are a running number which differentiates the bricks within a particular Landkreis or Stadtkreis. Both IMS and NDC use seven digits to differentiate the bricks/segments of their respective structures. NDC's running numbers (the last two digits) are different from those of IMS.
20. In February 1999, PI (before being taken over by NDC in 2000) began operations in Germany in competition with IMS. PI entered the market with a brick structure of 2201 segments, but this structure was rejected by potential customers who claimed that the data was not usable unless it could be presented within the format of Germany's industry standard of 1860 segments. A few months later, PI therefore introduced RPI 3000 ('Regional PharmaInformation), regional sales reports based on a 3000 segment structure, which could be aggregated to 2847 and 1860 segments. Using this structure PI offered a product which was attractive to pharmaceutical companies and thereby contracted with a number of customers in a short period of time. After the judgement which prohibited it from using the 1860 brick structure and derivatives NDC (ex PI) introduced a regional sales data product based on a 3942-segment structure.
21. In October 1999 AzyX entered the market for regional sales data with its product, ARD ('AzyX Regionale Daten'), which was able to be flexible as far as the brick structure is concerned, i.e. it was able to deliver the data according to a customised structure. Potential customers nevertheless asked for the 1860 brick structure. After the judgement enjoining AzyX from using the 1860 brick structure and derivatives, AzyX launched a regional sales data product which used a new structure with 2881 segments.

### **5.3 Evolution of the 1860 brick structure**

22. The first brick structure used in Germany was devised in 1969 and had 329 brick segments, representing the basic districts and non-district cities of the then West Germany. This was later sub-divided into structures containing first 418 and later 922 segments. In 1991 selected cities were subdivided into areas, creating a structure with 1086 bricks. In 1992, following German reunification, 244 bricks were added, corresponding precisely to administrative units in the former East Germany. In 1993, following the introduction of the 5-digit postcode system in Germany, 119 cities were restructured to create the 1845 structure. Minor changes were made to this structure in 1995 and 1998, leading to the current 1860 structure. A regional sales data service formatted in this structure, the RPM 1860 ('Regional Pharmaceutical Market' reports giving information on sales for the 1,860 territories in Germany) was launched in January 2000.
23. Each successive structure in the series was formed by the subdivision of original segments into several units and/or the process of taking into account changes in German administrative system, and the inclusion of the former East Germany. Each



structure became the new industry standard and would be adopted by the pharmaceutical industry as a whole, with very few exceptions, although the companies themselves were under no compulsion to do so.

#### **5.4 Other users of the 1860 brick structure**

24. Today, in Germany, the 1860 brick structure is also used by companies in other markets either directly to provide other sorts of data in this format or indirectly to analyse the regional sales data for the pharmaceutical manufacturers.
25. A number of companies providing geographical and other data services such as Globalmaps, Bacher, Macon, Easycom and Lutum Tappert deliver their maps or data (population, households, revenues, purchasing power and age classes) according to the 1860 structure. Other marketing and mailing companies provide their services according to the 1860 structure.
26. Software providers and market research companies such as GfK, DHM<sup>9</sup>, GFD<sup>10</sup>, IDV<sup>11</sup>, ISS ais, Regware, IfAp and P&P<sup>12</sup> receive information from companies such as IMS, then analyse these data, providing market shares analysis, trends over time etc. and other value added services. Some of them also use the 1860 structure in the specific software designed for the sales representatives, such as an Electronic Territorial Management System.

#### **5.5 The copyright issue**

27. *[Deleted business secret]*
28. On 26 May 2000, IMS filed a lawsuit in the Frankfurt District Court (*Landgericht*) against PI, alleging a breach of IMS' copyright in the 1860 brick structure as well as unfair competition. A judgement was entered in this proceeding on 12 October 2000, which prohibited PI and Roland Lederer, its founder, from employing the 1860 brick structure and imposed a potential fine in an amount up to 500,000 DM for violating this order. On 27 October 2000, a preliminary injunction from the Frankfurt District Court, which resulted in a confirming judgement on 16 November effectively prohibited PI from employing the brick structures containing 2847 or 3000 segments, or any other brick structure derived from the 1860 brick structure, as well as imposing a potential fine of up to 500,000 DM for the violation of this order. On 19 June 2001 PI's appeal against the 27 October and 16 November injunctions was turned down by the Frankfurt Court.
29. On 22 December 2000, IMS filed two separate actions for copyright infringement against AzyX and NDC in the Frankfurt District Court. On 28 December 2000, the Court gave preliminary injunction enjoining AzyX and NDC from using the 1860 and 2847 brick structures or derivatives thereof. *[Deleted business secret]* The Court in its judgement limited the injunction to 2847 and 1860 segments and any other number of segments so far as it constitutes a derivative from RPM 1860.
30. On 20 November 2000, NDC appealed the two October judgments of the Frankfurt District Court. AzyX also appealed the 28 December judgement.

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<sup>9</sup> DHM: Dr. Haase Managementsysteme.

<sup>10</sup> GFD : Gesellschaft für Datenverarbeitung mbH.

<sup>11</sup> IDV – Bodenheim

<sup>12</sup> P&P : P&P Software u. Consulting GmbH.

31. On 15 February 2001, the 28 December preliminary injunction to AzyX was confirmed by the Frankfurt Court. AzyX lodged an appeal against this judgement before the higher court.

## **5.6 The request for a licence and the refusal**

32. On 26 October 2000, NDC's Vice President of International Business Development, faxed a letter to Dr Wolfgang Hartmann, the head of IMS Germany, requesting a licence to use the 1860 brick structure, pending resolution of the copyright claim by IMS. The stated deadline for the start of negotiations was 1 November 2000. This deadline was based on impending contracts that NDC would have been unable to fulfil if it did not have access to the 1860 brick structure. This letter was followed up by efforts to reach Dr Hartmann by telephone and email. *[Deleted business secret]* This is likely to be the case for around 3 years.
33. On 12 December 2000, NDC's Vice President sent a separate letter to the Chief Executive Officer of IMS HEALTH, requesting that IMS begin licence negotiations by 15 December. *[Deleted business secret]*
34. According to NDC, IMS is taking positive measures to discourage wholesalers from providing data to IMS's competitors in the 1860 brick structure or any associated structure, effectively threatening copyright infringement actions against the wholesalers if they fail to comply. Similarly, IMS is now warning pharmaceutical manufacturers that they risk infringing IMS' copyright if they accept regional sales reports from any third party in an 1860 brick structure or any derivative one.
35. On 23 April 2001, AzyX requested from IMS a licence to use the 1860 brick structure. *[Deleted business secret]*

## II. LEGAL ASSESSMENT

36. The Commission assumes for the purpose of these proceedings and according to German law that the 1860-brick structure is covered by a copyright. This legal assessment will not consider questions of copyright law either with regard to the specific subject matter of the right or the national measures which the German court employs to enforce copyright legislation. The Commission notes that the Frankfurt Court considered that the 1860 brick structure is a database, and that copyright protection for databases is harmonised under Directive 96/9/EC<sup>13</sup>.

### 6. CONDITIONS FOR ORDERING INTERIM MEASURES

37. The Court of Justice held in the case *Camera Care*<sup>14</sup> (paragraph 18), that the Commission may “*take protective measures to the extent to which they might appear indispensable in order to avoid the exercise of the power to make decisions given by Article 3 from becoming ineffectual or even illusory because of the action of certain undertakings*”.

38. On the conditions to be met for the granting of interim measures, the Court of Justice also made clear in the judgment *Ford*<sup>15</sup> ( paragraph 19) confirmed in the CFI’s judgment in *Peugeot*<sup>16</sup>, that “*the provisional measures which the Commission may adopt on a temporary basis must come within the framework of the final decision which may be adopted by the Commission*”. The Court added in the judgment *La Cinq* (paragraph 28) as follows:

*“[P]rotective measures may be granted only where the practices of certain undertakings are prima facie such as to constitute a breach of the Community rules on competition in respect of which a penalty could be imposed by a decision of the Commission. Furthermore, such measures are to be taken only in cases of proven urgency, in order to prevent the occurrence of a situation likely to cause serious and irreparable damage to the party applying for their adoption or intolerable damage to the public interest.”*<sup>17</sup>

39. On the *prima facie* infringement, the CFI held in the *Peugeot* case cited that the test of *prima facie* infringement required showing the “*probable existence*” of an infringement. The CFI made clear in the same judgment (paragraph 61), that the requirement of a finding of a *prima facie* infringement *cannot be placed on the same footing as the requirement of certainty that a final decision must satisfy*.

40. On the risk of serious and irreparable harm establishing the urgent need to grant interim measures, the CFI held in the *Peugeot* judgment (paragraph 80) that it was necessary to show that there was “*damage which could no longer be remedied by the decision to be adopted by the Commission upon the conclusion of the administrative procedure.*”

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<sup>13</sup> OJ L 077 of 27.03.96, p.20

<sup>14</sup> Case No 792/79 R, *Camera Care v. Commission* [1980] ECR 119.

<sup>15</sup> Joined Cases 228 and 229/82 *Ford v Commission* [1984] ECR 1129

<sup>16</sup> Case T-23/90 *Peugeot v. Commission* [1991] ECR II-653

<sup>17</sup> Case T-44/90 [1992] ECR II-1.

41. It is therefore not necessary for the Commission to make a definitive finding that an infringement has occurred. However, before it will grant interim measures in a case such as the present the Commission, to be consistent with the jurisprudence, must be satisfied that:
- there is a reasonably strong prima facie case establishing an infringement,
  - there is a likelihood of serious and irreparable harm to the applicants unless measures are ordered,
  - there is an urgent need for protective measures.
42. Any measures the Commission takes must be of a temporary and conservatory nature and restricted to what is required in the given situation. The Commission must also have regard to the legitimate interests of the undertaking which is the subject of the interim measures. The interim measures may not go beyond the framework of the Commission's powers to order the termination of an infringement in the final decision.

### **Application of these principles to the present case**

#### **7. PRIMA FACIE CASE OF INFRINGEMENT OF ARTICLE 82**

43. At this stage and for the reasons mentioned above the Commission does not have to make a final determination on all points at issue in this case. The question here is whether legal and factual elements exist showing a reasonably strong prima facie case.
44. Article 82 states that *any abuse by one or more undertakings of a dominant position shall be incompatible with the common market insofar as it may affect trade between Member States*. In this case the point at issue is whether IMS' refusal to licence the 1860 brick structure amounts to an abuse of any dominant position.

#### **7.1 The relevant market**

45. In order to determine whether an undertaking is dominant it is necessary first to identify the relevant market, i.e. the area of competition in which the market power of the allegedly dominant undertaking (and of any actual or potential competitors) is to be judged.
46. In principle, the product market comprises all products that consumers regard as being reasonably substitutable by dint of their characteristics, price or intended use.<sup>18</sup>
47. The information in question is very specific and would only be useful to pharmaceutical companies, since it tracks sales of medicines. In a memorandum of 7 March IMS defined two main sources of data and four types of services, as follows:

Data collected from retail pharmacists

(a) National prescription data services provide information on prescriptions dispensed at national level, measuring the broad movement of pharmaceutical products out of pharmacies and into the hands of patients. These data are collected

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<sup>18</sup> Case 27/76 United Brands v Commission [1978] ECR 207.

from samples of pharmacies that are analysed regionally and then projected to national level.

(b) Regional prescription data services measure the number of prescriptions dispensed by pharmacies in a given area. They are used by the marketing and sales departments of pharmaceutical companies to determine which products to promote or to improve promotional effectiveness.

Data from pharmaceutical wholesalers

(c) National distribution services provide an analysis of sales of pharmaceutical products to pharmacies by wholesalers and manufacturers at a national level. These data are used by market research departments to plan national product strategies, determine which drugs to research and develop, to set prices, position them in the market and benchmark company performance against other pharmaceutical companies.

(d) regional distribution services provide an analysis of sales of pharmaceutical products to pharmacies by wholesalers and manufacturers with a higher degree of territorial disaggregation than national data. Regional data are used primarily by pharmaceutical manufacturers to monitor the performance of their sales representatives and determine their remuneration.

48. The four services are different both in terms of the way the data are collected and of the uses to which the data are put. In the memorandum of 7 March referred to above, IMS states that: *data collected from one source cannot be used to meet a different customer demand.*
49. For each of the four above-mentioned services the German data is a separate product that is not substitutable for data of another country, because the data relates to the sales or the prescriptions of medicines at national or regional level or relates to the sales territories which are limited to the territory of a single Member State.
50. Furthermore in the case of regional sales data services, it is the subsidiaries that make the decision and subscribe to the services in question without reference to the headquarters, as the replies from the pharmaceutical companies show. This is so because the pharmaceutical companies use these services mainly to measure the sales performance of their sales representatives who are allocated a small geographical area inside a specific country.
51. For these reasons, the relevant product market in this case is the market for German regional sales data services.
52. As regards the geographical market, the CFI in its judgment in *Ladbroke*<sup>19</sup> (paragraph 102) recalled that *the geographical market can be defined as the territory in which all the traders concerned are exposed to objective conditions of competition which are similar or sufficiently homogeneous.*
53. From the replies to the requests for information and the meetings with the pharmaceutical companies, it appears that demand for the regional data is confined to the relevant country. AstraZeneca headquarters stated that *the central business support functions of AstraZeneca UK limited buy sales data at a country level.*

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<sup>19</sup> Case T-504/93 Tiercé Ladbroke SA v Commission. [1997] ECR page II-923

*AstraZeneca's subsidiaries companies in the relevant markets buy regional sales data for their own market research purposes. Roche Basel also explains that at corporate level the need for that detailed structure is not obvious. NDC considered that from the demand point of view, German pharmaceutical manufacturers have shown that they are unwilling to purchase regional sales reports from anyone not established in Germany.*

54. The data in question relate to fundamental aspects which differ from one Member State to another, such as the name of the drug, the packaging, the product code, the therapeutic category and the method of reimbursement. As a result of differences between countries in how pharmaceutical products are sold at retail level, the packaging, language and safety requirements, what the medicines on offer are trademarked as, consumers' expectations and habits and so on, pharmaceutical markets tend to be national, with many features specific to those markets. This means it is essential for the sales data providers themselves to have a subsidiary in each country to sell and support their services and to know well the market they are supplying data on. Trust is very important in this sector and a local presence is indispensable in order to offer informatics support, technical assistance and to have the contacts with customers but also with wholesalers for the collection of raw data. The value-added process requires a lot of controls and checks on the raw data which have to be done locally.
55. Therefore the relevant geographic market is considered to be Germany.
56. In conclusion, the relevant market is German regional sales data services.

## **7.2 Dominant position**

57. The Court of Justice has defined a dominant position as *a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers.*<sup>20</sup>
58. IMS is in a quasi-monopoly situation. Based on 2000 sales, the market shares of the 3 providers are: IMS – *[Deleted business secret]*; NDC (PI) - *[Deleted business secret]*; AzyX – *[Deleted business secret]*. Prior to the entry of NDC and AzyX, there was no competition in this market.
59. Amongst the criteria for evaluating the dominance, high market shares were mentioned by the Court in its judgment AKZO<sup>21</sup> as decisive: *with regard to market shares, the Court has held that very large shares are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position. That is the situation where there is a market share of 50% such as that found to exist in this case.* In *CMB v. Commission*, the CFI further stated (at paragraph 76) that *"a dominant position may be the outcome of a number of factors which, considered separately, would not necessarily be determinative. However, in the absence of*

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<sup>20</sup> Case 85/76 Hoffmann-La Roche [1979] ECR 461.

<sup>21</sup> Case C-62/86 AKZO Chemie BV v Commission of the European Communities - ECR 1991 page I-3359.

*exceptional circumstances, extremely large market shares are in themselves evidence of the existence of a dominant position".<sup>22</sup>*

60. Germany, as a Member State, and indeed the one with the largest market for regional sales data services in Europe, may be regarded as a substantial part of the common market as regards the relevant market. This follows from consideration of, for example, the *Suiker Unie*<sup>23</sup> case (paragraph 375), in which the Belgium and Luxembourg market for sugar was considered to be a substantial part of the common market, or *BP v Commission*<sup>24</sup>, where the Advocate-General indicated that Luxembourg would be likely to be considered such a substantial part. In the *Bronner*<sup>25</sup> judgment, the Court also stressed that “*the case-law indicates that the territory of a Member State over which a dominant position extends is capable of constituting a substantial part of the common market*”.
61. *[Deleted business secret]*
62. However, for the above reasons, the Commission considers that IMS is dominant on the relevant market.

### **7.3 Abuse of a dominant position**

63. In its complaint, NDC, referring to what is known as the “essential facilities” doctrine, considers that IMS is obliged to license the 1860 brick structure since it is a prerequisite for effective competition on the regional sales data services market. According to that doctrine a company which has a dominant position in the provision of facilities which are essential for the supply of goods or services abuses its dominant position where, without objective justification, it refuses access to those facilities. As stated by the Advocate General in his Opinion on the *Bronner* case: *thus in certain cases a dominant undertaking must not merely refrain from anti-competitive action but must actively promote competition by allowing potential competitors access to the facilities which it has developed.*
64. Neither the ECJ nor CFI has as yet explicitly referred in its case law to the essential facilities doctrine. Nevertheless it has ruled in a number of cases concerning refusal from an undertaking in a dominant position to supply goods or services. In two early cases the Court stated that the cutting off of supplies to an existing customer could constitute an abuse. In the *Commercial Solvents*<sup>26</sup> judgement (paragraph 25), it held that an undertaking in a dominant position as regards production of a raw material could not cease supplying an existing customer who manufactured derivatives of the raw material simply because it had decided to start manufacturing the derivative itself and wished to eliminate its former customer from the market.

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<sup>22</sup> Cases T-24/93, T-25/93, T-26/93 and T-28/93 *Compagnie Maritime Belge Transports and Others v Commission* [1996] ECR II-1201.

<sup>23</sup> Cases 40-48, 50, 54-56, 111, 113-114/73 *Coöperatieve Vereniging Suiker Unie and others v Commission* [1975] ECR 1663

<sup>24</sup> Case 77/77 *BP v Commission* ECR 1998 page 1513.

<sup>25</sup> Case C-7/97 *Oscar Bronner GmbH & Co KG. v Mediaprint Zeitungs-und Zeitschriftenverlag GmbH & Co KG*. ECR 1998 page I-7791

<sup>26</sup> Case 6/73 and 7/73 *Istituto Chemioterapico Italiano and Commercial solvents* ECR 1974 page 223

65. Similarly, in the *United Brands*<sup>27</sup> judgment (paragraph 182), the Court held that an undertaking in a dominant position for the purpose of marketing a product - which cashes in on the reputation of a brand name known to and valued by customers - cannot stop supplying a long standing customer who abides by regular commercial practice, if the orders placed by that customer are in no way out of the ordinary.
66. In two further cases involving goods or services covered by intellectual property rights, the Court considered whether refusal to supply constituted an abuse. In the *Volvo*<sup>28</sup> judgment (paragraphs 8-9), the Court held that “*it was not an abuse of a dominant position for a car manufacturer holding the registered designs for body panels for its cars to refuse to license others to supply replacement panels necessary for the repair of the cars. (...) It must however be noted 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.*”
67. In the *Magill* judgement<sup>29</sup> (paragraphs 49, 50 and 54) cited above, the ECJ declared that *refusal to grant a licence, even if it is the act of an undertaking holding a dominant position, cannot in itself constitute abuse of a dominant position. However, the exercise of an exclusive right by a proprietor may, in exceptional circumstances, involve abusive conduct and the appellants' refusal to provide basic information 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 constitutes an abuse under heading (b) of the second paragraph of Article 86 of the Treaty.* The Court therefore recognised that in exceptional circumstances the exercise of an exclusive right deriving from an intellectual copyright may be abusive even in the absence of abusive additional conduct when, inter alia, it prevents the appearance of a new product.
68. In a subsequent case, *Ladbroke*, cited above (paragraph 131), the CFI stated that *the refusal to supply the applicant could not fall within the prohibition laid down by Article 86 unless it concerned a product or service which was either essential for the exercise of the activity in question, in that there was no real or potential substitute, or was a new product whose introduction might be prevented, despite specific, constant and regular potential demand on the part of consumers.* This judgment makes clear that a refusal to license may constitute an abuse not only when this refusal prevents the introduction of a new product but also when the product or service in question is essential for the exercise of the activity in question.
69. In the *Bronner* judgement (paragraph 41) cited above, the Court said that *therefore, even if that case-law on the exercise of the intellectual property right were applicable to the exercise of any property right whatever, it would still be necessary*

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<sup>27</sup> Case 27/76 *United Brands v Commission* ECR 1978 page 207

<sup>28</sup> Case 238/87 *AB Volvo v Erik Veng (UK) Ltd* ECR 1988 page 6211

<sup>29</sup> Joined cases C-241/91 P and C-242/91 P. *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission*. ECR 1995 page I-0743



*for the Magill judgement to be effectively relied upon in order to plead the existence of an abuse within the meaning of Article 86 of the Treaty in a situation such as that which forms the subject-matter of the first question, not only that the refusal of the service comprised in home delivery be likely to eliminate all competition in the daily newspaper market on the part of the person requesting the service and that such refusal be incapable of being objectively justified, but also that the service in itself be indispensable to carrying on that person's business, inasmuch as there is no actual or potential substitute in existence for that home-delivery scheme. (...) Moreover, it does not appear that there are 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.*

70. Therefore the criteria for the establishment of abuse under Article 82 in cases relating to the exercise of a property right, as further clarified by the Court in *Bronner*, are whether:
- the refusal of access to the facility is likely to eliminate all competition in the relevant market;
  - such refusal is not capable of being objectively justified; and
  - the facility itself is indispensable to carrying on business, inasmuch as there is no actual or potential substitute in existence for that facility.
71. In the present case and following the above reasoning, the Commission is required to assess whether the 1860 brick or compatible structure is indispensable to compete on the relevant market, that is to say whether there is 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' copyright.
72. Clearly the answer to this question depends on whether there is a real possibility for customers of regional sales data to buy data formatted in another structure. To ascertain this, the Commission requested information from first 20, then a further 90 pharmaceutical companies. A total of 85 replies were received.
73. According to IMS the Commission's initial market survey was inadequate and no conclusions should be drawn from it. In all, the 110 requests for information from the Commission have yielded 85 replies. The responding companies represent 56% of total pharmaceutical sales in Germany. The companies which responded to the Commission's inquiry contained a representative survey both of pharmaceutical companies generally and customers of regional sales data services, including almost all of the largest companies and a sample of both small and medium-sized firms.
74. In the present case, the Commission considers that the following facts show clearly that the legal tests set out above have been met.
- 7.3.1 *The 1860 brick structure – Role of the Working Group, function as an industry standard, and economic dependence of the pharmaceutical companies*
- Role of the Working Group

75. The German pharmaceutical industry has a long history of involvement in the shaping of the brick structures that have been used in Germany. A body entitled the RPM *Arbeitskreis* (Working Group) was established in the early 1970s by IMS for this purpose. The Working Group tends to have around 15 members, elected by IMS' customer base as a whole, and involves major pharmaceutical companies such as Bayer, Ciba-Geigy, Aventis (Hoechst), Goedecke (Warner Lambert), Asta Medica, Byk Gulden, Astra Zeneca, Hoffmann-La Roche, Klinge Pharma, Merck, Pfizer and Boehringer Ingelheim. The full Working Group usually meets twice a year, though it has often established subgroups, or workshops, to consider particular issues such as the subdivision of existing bricks to create a more granular structure. Minutes of the Working Group meetings and reports of decisions taken through it were regularly circulated to pharmaceutical companies in Germany.
76. IMS says that the Working Group “...essentially serves as a vehicle for eliciting customer comments and suggestions on a wide range of issues relevant to IMS HEALTH's data services offering in Germany”, and that it presented fully developed new brick structures to certain customers through the Working Group. NDC responds that the brick structures were in fact created by the Working Group.
77. In fact, the Commission's investigation shows that the Working Group played an extensive role in designing the current structure. The origin of the current structure was predominantly in the creation of the 1845 structure in 1993, since this is around 92% similar to the 1860 structure; IMS says that 142 changes were made to the 1845 structure to create the 1860 structure. *[Deleted business secret]*
78. *[Deleted business secret]*
79. Testimony from third parties is explicit on this point. Lilly considered that: “IMS was independently very capable of grouping standard parameters e.g. postal codes, towns, number of pharmacist to define the evolving bricks. However, more specific know-how (e.g. patient travel routes, pool pharmacists, etc.) could only be gained through the knowledge of pharmaceutical sales reps. In my opinion, this was why IMS was very wise to formalise their co-operation with the pharmaceutical industry by sponsoring a work group”. Klinge Pharma agrees with this analysis, and also refers to the IMS letter to customers of 8 October 1993.
80. Krewel Meuselbach stated that “the pharmaceutical industry, or the members of the *Arbeitskreis*, co-developed the 1845 and 1860 RPM structures...The detailed planning and development of the new structure was done in collaboration with the pharmaceutical companies because the field representatives of the pharmaceutical companies had the necessary local knowledge. The IMS employee specifically mentioned that the field representatives of Glaxo Wellcome adjusted certain segments in the Hamburg area...”. IMS' Marketing Director from 1993-5, now working for GESDAT, states that “In these workshops, suggestions of IMS were presented. IMS further provided maps and administrative items. It was, however, the field representatives who always had the final say concerning the exact definition of the individual segments. This can be explained by the fact that the field representatives had the necessary local expertise to develop a reasonable and practical structure”.
81. Merck says that “it is true that IMS had already developed its own suggestions for a segmentation of the federal territory; however, these were, because they were

*developed merely by looking at a map, for the most part not useful to the pharmaceutical industry. ... In order to be able to meaningfully divide the segments, one had to know which physicians prescribed which medicines and to which pharmacies the corresponding patients then went with their prescriptions. ... This knowledge could, however, only have been contributed by the field service representatives... Thus the creation of the new RPM structure without the contribution of the field service representatives would not have been possible at all.”*  
*“The segments were determined, in part, in very time-consuming discussions with massive participation of the industry representatives. In the end, the entire RPM structure was based on a consensus of participating field service representatives of the pharmaceutical industry. Their work results were then adopted by IMS as is.”*

82. Fournier says that *representatives of the pharmaceutical companies, the elected members of the Arbeitskreis, co-developed the 1845 and 1860 RPM structure. Leo Pharma adds that it was fundamentally necessary for IMS to have the detailed, local knowledge of the field service representatives of multiple pharmaceutical concerns as to the geographical details, streams of prescriptions from doctor to pharmacy, proximity of pharmacies to hospital, etc in order to establish the segments in the 1845/1860 structure. Without the contributions of the pharmaceutical concerns, IMS Health would have hardly been able to produce this structure.*
83. It is also clear that the pharmaceutical industry in Germany invested considerable resources in ensuring that the brick structure fully met their requirements. For example, BPI the German Association of pharmaceutical companies said that *the pharmaceutical industry massively participated in the development of the 1860 structure. Even smaller companies or companies not participating in the RPM Arbeitskreis gave their direct or indirect input.* Extensive further documentary evidence and testimonies<sup>30</sup> concerning the time of the creation of the 1845 structure, close forerunner to the 1860 structure, make clear the extensive and crucial role played by the pharmaceutical companies in this task. In part because of this, the 1860-brick structure appears to be the optimum to be achieved and to correspond exactly to the requirements of the pharmaceutical companies. 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.
84. The Working Group has played a significant role at other times too. *[Deleted business secret]*
85. *[Deleted business secret]*
- Function of the 1860 brick structure as an industry standard
86. According to information provided to the Commission, 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. An overwhelming majority of the pharmaceutical companies who replied to the Commission’s information request pursuant to Article 11 of Regulation 17 who purchase regional sales reports (74 companies) consider the 1860 brick structure or compatible brick structures as an industry standard or a

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<sup>30</sup> In particular Essex, Hexal, Lilly, Lundbeck, Schering and Solvay.

“common language”. 9 companies had differing or unclear views<sup>31</sup>. 3 of these 9 considered that the 1860 structure is a de facto industry standard, for the sole reason that it is used by the majority of pharmaceutical companies. 3 of the remaining 6 companies, although stating that they did not consider the 1860 structure to be an industry standard, said that they would nevertheless not switch brick structures in order to receive regional sales data from other service providers. The remaining 3 companies, Robugen, Hermal and Berlin Chemie, are small or medium-sized companies, the former two of which specialise in making specific products: Robugen makes camomile products; Hermal makes creams for skin complaints. These companies make up only 4% of the companies which responded on this particular point. They were also the only 3 firms who said that they would be prepared to accept another brick structure. All other pharmaceutical companies said that either they could not change the current 1860-structure or they could not accept a new structure which would require them to modify their current sales territories.

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<sup>31</sup> Aventis, Robugen, Hermal, Dr Winzer Pharma, Dr Mann, Stada and TAD, Berlin Chemie and Amgen

87. Examples of the statements given to the Commission are as follows: “*the 1860 brick structure is an industry standard because all sorts of pharma data are available from different suppliers on this basis*” (Yamanouchi). “*To our opinion a co-existence of non compatible bricks structures is out of possibility. Only one standard must be available e.g. to avoid immense costs when switching from one provider to another*” (Kreussler). “*The 1860 brick structure is an industrial standard because of the uniqueness of the reporting the proven comparability of the bricks and the long and frequent usage in the industry*” (Schering). “*I cannot imagine that several non compatible structures can co-exist. There must be a standard to compare competitors, and own performance of sales. Different structures would question the validity of the data in the sales reports. Costs would be immense to switch from one provider to another, so competition would not exist*” (Fournier).
88. IMS however, argues that the 1860 brick structure does not bear any of the features of a proper industry standard, that its use is not required by law, and that 30% of German customers do not use it.
89. Whilst the Commission agrees that the 1860 brick structure is not required to be used by law, this structure is a de facto industry standard as mentioned above because the overwhelming majority of surveyed pharmaceutical companies would not change the current 1860-structure or could not accept a new structure which would require them to modify their current sales territory. The 1860 brick structure is a “common” language for communicating information between all players in the pharmaceutical industry, a fact which was confirmed by the industry itself.
90. *[Deleted business secret]*
91. IMS’ claim that around 30% of German customers are not using the industry standard is incorrect, *[Deleted business secret]*
- Economic dependence of the pharmaceutical companies on the 1860 brick structure
92. As the above information shows, the 1860 brick structure, in part because of the role played by the Working Group, has become an industry standard. 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 a unviable economic proposition. According to the information received, the reasons why pharmaceutical companies could not switch to using another brick structure are as follows.
- Comparability and compatibility of data
93. One of the reasons pharmaceutical companies purchase regional sales data is to enable them to record sales of particular drugs vis-à-vis those of their competitors, and hence market shares, and to measure the performance of their sales representatives. Both are vital competitive parameters in the pharmaceutical market, and have to be calculated for different time periods so as to allow comparisons. 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. Marketing campaigns and market research are organised according to the data in this structure. Novo Nordisk considered that

*any data that has to be compared is compiled and collated under the 1860 or 2847 brick structures.*

94. Ensuring data comparability over time when changing between the structures of two different companies presents more problems than did past changes to the prevailing IMS structure. Those changes, as mentioned earlier, usually involved original bricks being sub-divided into smaller ones. In these cases the sum of relevant new smaller bricks could be compared with the original larger one, making comparability very easy. Other changes to the structure tended to be quite small, for example the move from 1845 to 1860 bricks. The fact that the data were from the same company (IMS) also made comparability easier, because the data was formatted in the same way.
95. IMS stated that comparability of data over time and compatibility presents no difficulties since wholesalers keep at least two years' back data; *[Deleted business secret]*
96. As far as the first part of IMS' argument is concerned, it appears that at least some wholesalers keep only 15 to 18 months' back data at pharmacy level, which is the necessary level of detail to allow aggregation according to a completely new structure. GESDAT stated that *for the 3 wholesalers represented by GESDAT, the raw data are stored since 1999 and are destroyed after 15 or 18 months.. However this might be unique and other wholesalers might possibly only store data in the structures already delivered.* The fact that at least 3 of the 16 wholesalers in Germany keep data for only this length of time means that no census of sales data is possible, and back data, if not complete, is close to worthless because pharmaceutical companies require comprehensive data coverage of German pharmaceutical sales and anything else is unacceptable to them.
97. Whilst 2 years' back data is perceived to be the minimum required by pharmaceutical companies (*minimum for back data is a 2 years period (Medac)*), a longer period is needed for specific applications or purposes: *28 months (are needed) for calculating the commission (Wyeth Pharma), 5 years sales (back) data is optimal (Zambon), we at least need last year's data, better last 5 years (Essex Pharma), for general targeting and analysis application, 2-3 years back data is generally enough. However for statistically relevant methods for measuring the impact of spending, etc. 5 years might in some cases be appropriate (Lilly)), depending on the analysis, varying amounts of backdata are required. Usually 2-5 years<sup>32</sup>. (Schaper & Brümmer), market shares development for 36 months [is needed] (Takeda), the data is required for appr. 3 years (MSD), we use backdate for 2 years, if possible also 3 years to show long term developments and calculate capture rates (Novo Nordisk) it would be favourable to have the data for the same period as the product is under promotion by representatives. Therefore the period is currently between 1.5 and 3 years (Bayer), we need comparable backdata for at least 3 years for market research and calculation of incentives<sup>33</sup> (Novartis), we need the backdata at least for the last 3 years (Verla Pharm), for our planning and sales territory development we need 3*

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<sup>32</sup> Original text: *Je nach Auswertung werden unterschiedliche Anzahlen von Jahresdaten benötigt. In der Regel 2-5 Jahre*

<sup>33</sup> Original text: *Wir brauchen vergleichbar Vorjahreszeiträume von minimal 3 Jahren für Marktforschung und Incentiveberechnungen*

*years' backdata*<sup>34</sup> (Pohl Boskamp), *we need backdata for minimum 3 years, we have to see the development of sales in the bricks (Solvay) 3 years will be enough (Galderma).*

98. *Krewel also stated that a change of the structure would, however, have the substantial disadvantage of not allowing a comparison of data to those from previous years. Sales developments could therefore not be tracked anymore. Dermapharm indicated that a change to another structure is financially and time-wise hard to imagine, for such a change would mean the complete restructuring of the entire marketing and field services areas of our company. A further considerable disadvantage would be that a comparison to data of previous years would not be possible any more. But these historical data are absolutely necessary to determine sales developments, evaluation of marketing actions and payment of commissions. Schering said that because of the comparability of the data it is absolutely necessary to have all regional data available in the same geographical structure.*
99. The Commission's investigation in this area therefore shows that pharmaceutical companies often demand older back data than potential new providers of regional data services can provide. This is another important current disincentive for pharmaceutical companies to demand data formatted in a brick structure other than the 1860 structure.
100. There is also the issue of compatibility of regional sales data with other data and other software products. With respect to data, pharmaceutical companies buy data other than that on regional sales in the 1860 structure, such as prescription data, socio-economic information, location of doctors etc. and integrate it with sales data for further analysis. Hence a change in structure would mean changing the format requested for the other information, or converting the data in-house.
101. It is particularly important to have prescription data in a compatible structure, since it is commonly accepted that both forms of data are needed to correct for the measurement problems caused by customers receiving prescriptions in one brick but purchasing drugs in another brick. *[Deleted business secret]* Merck indicated during the oral hearing that *in any case it is absolutely vital that prescription data are delivered in a structure derived from 1860 or compatible to.* DuPont Pharma said that *if not (compatible) no clear performance measurement can be achieved.* Galderma stated that *only with the same structure you can compare the effectiveness and development of your salesmen and the effectiveness of the marketing activities.* Lichtenstein Pharmazeutica indicated that *for the analysis of differences of sales and prescriptions it is necessary to have identical structure for regional sales data and prescription data.* Servier also explained that *the (prescription and sales) data are only of value if they are comparable.* AzyX considered that: *"Both data are used to measure the success of field force work. If they would not be compatible, one of the two could simply not fit the sales territory alignment of the company. Also, one of the main purposes of buying both data, prescription and sales, is to measure the effect of the so-called travelling prescription. This would become impossible if the structures were different."* NDC considered that: *"If prescription and sales structures were not compatible, it would not be possible to measure the relationship of prescriptions*

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<sup>34</sup> Original text: *Wir nutzen für unsere Planungen und Gebietsentwicklungen die Vergangenheitsdaten von 3 Jahren*

*written with the stocking of the product in the pharmacy. In addition it would not be possible to determine where and how many prescriptions travel from one sales territory to another when patients don't fill their prescriptions in the same local [area] as their doctor is located."*

102. *[Deleted business secret]* Moreover IMS states that any third party that developed a different brick structure could offer the same data in its brick structure format. The Commission's investigation shows that in fact around 44% of pharmaceutical companies do purchase such data, which is a significant proportion. One reason for the difference in these two figures might be that IMS is only one of many providers of data formatted in the 1860 brick structure and considers that these data are largely incidental to its principal data services offerings and customers' requirements. In effect, other specialised address or map providers such as Pan Address Direktmarketing, Easy map, or systems like regio graph 5.0 are widely used by pharmaceutical companies for mailing activities or mapping purposes. In this context, Schering stated that *all data like number of doctors, pharmacies, inhabitants by sex, square kilometres of the brick etc has to be in the format of the 1860 structure*. Hoffmann-LaRoche also buys socio-demographic, purchasing power and targeting group selection data and maps from different providers.
103. According to the Commission's investigation, many companies in fact use other sorts of data in this structure, which they consider are essential to allow meaningful analysis of regional sales data reports. Pharmaceutical companies naturally need this data in a format compatible with the 1860 structure. In this respect, BPI, the German Association of pharmaceutical companies indicated that *receiving sales data in a different regional structure would cut us off from any other relevant data which are needed to complement the sales data, and which are all available in the 1860 structure only. Especially for smaller pharmaceutical companies it is impossible to finance all data suppliers to switch to another structure imposed by a new supplier of sales data*. It follows that pharmaceutical companies could only consider switching structures if these other data were also available in this new structure. Whilst it would technically be possible for all this other data to be provided in another format, the costs which would have to be imposed on any pharmaceutical companies which demanded this other data in something other than the industry standard structure would be so high as to put those companies at a clear competitive disadvantage.



104. In terms of software, as explained at paragraph 26 above, third-party software providers also deliver products in the 1860 brick structure amongst which P&P software, IDV, ISS, DHM, GFD, GfK, Easycom. An example of such software is that used to make sales territory alignments, which allows the assignation of postal codes or bricks to a sales representative. The software is pre-loaded with the sales potential and doctor counts for each postal code or brick, and as postal codes or bricks are added or subtracted from a sales territory, the software calculates the cumulative sales and doctor counts for that territory. As Zambon, a pharmaceutical company indicated *all related information (i.e. address data etc) are somewhat linked to this (1860/3000) regional structures* and Zambon would not change brick structure because it *would lose compatibility to the pharma world*. More than half of the companies contacted transfer the regional sales data to marketing analysis or software companies.
105. On this point, IMS argues that the other regional data service providers (AzyX and NDC) would be able to give access to their structures to the software providers in order to develop new software compatible with their brick structures. However, whether this is technically possible is beside the point, for the same reasons as given above with respect to the provision of data in a non-1860 compatible structure. Moreover, pharmaceutical companies departing from the established standard for regional sales data would have to financially support the creation of other software to allow the analysis and use of this data, which again represents an important disincentive to demanding data in a different brick structures.
106. Pharmaceutical companies consider this issue as an important one, as the following comments show. Lilly explained that *the historical 1860 brick structure is used internally by most (if not all) pharmaceutical companies for defining sales rep territories, etc. Moreover, all market research and software vendors who specialise in the pharmaceutical industry have had free access to this standard structure. If the structure differs from company to company, vendors (e.g. software and market research) will have great difficulties to create standard products. This may hinder innovation*. Janssen-Cilag indicated that *all available external data is also based on the 1860 brick structure*.
- Change of sales territories: loss of relationship between the sales representative and the doctors
107. Contrary to other sectors where the orders are taken directly, the sales representative of pharmaceutical products can only recommend the prescription of a product. His/her success at marketing a product is therefore strongly dependent on establishing a good relationship with doctors, and sustaining it for a long period. Evidence suggests that such relationships take a period of time to develop. Novo Nordisk explained the importance of this relationship *“the main reason for keeping the structures as they are is that a change will have negative effects on our customer relationship management. In our business areas, it is very important to foster the relationship to our customers. (...) A lot of customers will be visited by other sales representatives and a lot of well-developed close relationships will be destroyed”*. Pharmacia also stated that *“each restructuring of sales force destroys customers’ relationships with our reps, which means that we would lose a significant number of sales at the end of the day”*. Novartis considered that *the loss of the relationship between sales representatives and prescribing doctors would have a very significant negative effect on sales. Without a relationship that has been developed and nurtured*

*over time, a sales representative will often simply not be heard by busy doctors, particularly those who are already visited several times a day by other sales representatives. Novartis added that it sometimes took several years to develop a relationship that translated into good sales performance.*

108. 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. *[Deleted business secret]* BPI the German Association of pharmaceutical companies stated that *using any other structure would result in a mandatory significant re-alignment.* Essex Pharma GmbH in its reply of 26 January 2001 indicated that *this would change the territorial responsibility of the representatives. The result would be inefficiencies due to organisational reason on the representative's side as well as in administration.* In the same way, Lilly Deutschland noted that *the major cost would be disruption in our sales organisation as our territories are designed using the brick structure.* Essex explained in its reply that *the costs of technically changing the structure are estimated to be minor compared to the financial impact of the major competitive disadvantage described above (changing the territorial responsibility of the representatives).*
109. A study<sup>35</sup> made by I+G, a consultancy company specialised in the pharmaceutical sector based on a sample of practitioners shows that continuous contacts with a sales representative is one of the most important conditions, out of 77 performance parameters tested, for customer retention.
110. IMS consider that the adverse effect of switching on the sales representative and doctor relationship is overstated, mainly for three reasons: first pharmaceutical companies frequently change the structure of their sales force on their own initiative, second even a significant change to a brick structure will only affect relationships at the periphery of each sales representatives' territory and third the closeness of the relationships is exaggerated.
111. On the first aspect, comments received from the request for information gave a different picture. Bastian said that *no modification occurred within the 10 last years, Bayer sales territories are very seldom modified, in general only in case of a bigger restructuring.* AstraZeneca *so far as possible we try to make no changes, Dr Kade the sales territories are changed very seldom.* Moreover, a company acquisition or a launch of a new pharmaceutical product represents a much better justification for losses of sales representative-doctor relationships than a modification resulting from a new brick structure, because of the important underlying business reasons for this move. Schering *said modification in these cases is an investment in the future and follows the strategic business development. Therefore disruptions in doctor sales rep relationship are justifiable and inevitable.* Hoffmann La Roche considered that *in the case of a merger or acquisition a restructuring is inevitable and must be accepted. A restructuring through a change in data provider is hardly acceptable, since apart from the technical modification costs the losses through the destruction of relationships are incalculable*<sup>36</sup>. Lilly said that: *modifying sales territories are only*

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35 Strategic performance benchmarking 1998 for 23 pharmaceutical companies

36 Original text: *Im Falle von Zusammenschluss oder Akquisition ist eine Umstrukturierung unvermeidlich und muss akzeptiert werden. Eine Umstrukturierung durch Wechsel des Datenanbieters ist kaum zu akzeptieren,*

*done if absolutely necessary, Essex we avoid changes to our structure due to the enormous effort involved.*

112. On the second aspect of IMS' argument, it appears likely that it would probably be possible for pharmaceutical companies, especially those with small sales forces whose sales territories are correspondingly large, to add the bricks of a new structure together so as to largely recreate the original territories. IMS says that if a number of large, small and medium-sized companies had switched to the 2201 structure developed by NDC, even the largest of the companies with the smallest sales territories would lose under 3% of doctor – sales rep relationships. NDC has not responded to this argument. *[Deleted business secret]* This is so especially if key specialists or doctors who are very eminent in a particular field are to be covered by a new sales representative.
113. On the third aspect, the pharmaceutical companies attach great importance to the relationship between a doctor and a sales representative, which are one of the few means to promote a drug. According to the law on advertising in the healthcare system<sup>37</sup>, products that are available only on prescription can be advertised solely to doctors, dentists, veterinarians or pharmacists. That explains why the work of the sales reps is so important. BPI the German Association of pharmaceutical companies stated *relationships between medical doctors and reps (...) are the main asset a pharmaceutical company has*. Apogepha for instance explained that *any change of doctor-sales representative relationship is a threat to the business regardless of the reason*, TAD *Changes in brick structure should be reduced to a minimum to avoid disrupting the relationship between doctor and sales rep*, Yamanouchi pharma *the relationship doctor-representative is such an important capital that we try to avoid changes if possible*, Lilly *Maintaining stable relationships between the physician and sales rep are top priority*. Medac *every disruption of the relationship between customers and sales reps has big disadvantages for our company. Therefore we hesitate to modify regional structure if it is possible*.
114. Consequently, the Commission considers that the 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 would act as an important disincentive for certain pharmaceutical companies to make such a change.

– Change of sales territories: modification of the working contracts

115. The sales territory is defined as the aggregation of a number of bricks. This territory 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. Moreover, such changes would be subject to a procedure of “co-determination”. According to German employment law (“*Betriebsverfassungsgesetz*”), the co-determination procedure is compulsory when the working conditions change (Art 87, 98 and 91 of this law). That would mean that the elected workers' council must participate in the decision making process. In case of disagreement, a conciliation council has the last word.

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*da ausser den technischen Umstellungskosten die Verluste durch Wegfall der Beziehungen nicht abzuschätzen sind.*

<sup>37</sup> The *Heilmittelwerbeengesetz*, or Law on Advertising in the Health Care System

116. Many pharmaceutical companies perceive this to be a problem. One indicated that *the brick structure constitutes the basis for negotiations with the company advisor especially regarding assessment and bonus rules for field service employees*. Gsk (GlaxoWellcome SmithKline Beecham) also mentioned the high risk of not reaching agreement with the workers' council if the brick structure were to change. Klinge Pharma considered that if it switched from using the 1860 brick structure to using a novel segmentation, it would experience severe problems with its workers' council, because in the employment contract of sales representatives the place of employment is defined by reference to sales in their territories (which are an aggregate of a number of bricks). Another pharmaceutical company stated that *the territorial structure of our field service is based on 2,847 segments (RPM 3000)*. *If we were not allowed to use this structure anymore due to a change to a competitor, this would have considerable organisational and financial consequences*.
117. IMS stated in its comments that employment law issues and procedures are not determinative. IMS consider that the working contracts typically describe the sales territories in broad geographic terms. IMS is right with respect to certain pharmaceutical companies, where the sales territories in the working contract are defined very broadly with a mention only of a region. But for almost half of the companies who gave information to the Commission on this point, the sales territories are effectively defined as a list of brick codes. Any change of the brick structure would therefore pose for them the problems referred to above.
- Costs of modifying software and applications which use the 1860-brick structure
118. NDC stated that under a change of structure *“Manufacturers would incur the cost of redoing all the analytical work supporting their compensation plan, restructuring their territory alignments, embedding the alternative structure into their sales force automation systems and the extensive training and explanation of the change.”* They further claim that pharmaceutical companies estimate conversion costs at between 200,000 and 400,000 DM. This is corroborated by a number of companies.

119. IMS stated in its comments that there is no clear evidence from customers' responses that the cost of switching to an alternative brick structure form a material barrier. The responses are characterised as inconclusive or unreliable. The Commission is aware that a certain number of pharmaceutical companies were unable to estimate switching costs. Evaluation of additional direct costs appears to be difficult for the companies contacted. Mentioned direct costs vary from 40.000 DM to 1.85 million DM, i.e. around 30% of the annual budget for regional sales data for a large pharmaceutical company. For small and medium size company, the costs represent from 25% to more than 100% of the annual budget for regional sales data.
120. Another pharmaceutical company indicated that *other structures, even if they are acceptable for reasons of confidentiality, entail high investment, both in financial terms and in terms of the work involved.* A further firm said that *a different RPM-structure would have considerable financial and organisational consequences for our company. In addition to the pure costs of the rearrangement for the computer application within the office and the field work and the organisational efforts related thereto, there would be the necessary structural adjustments concerning the existing field service structures...These might cause the loss of grown customer relations, and would surely first have to be arranged with the workers council.* In its reply, MSD Sharp & Dohme stated that *our sale force as well as the entire reporting system and other data available on the market are based on this structure. (...) Specification of costs is not possible. However, both the expenses and timely efforts are extremely high. There would be a need to create a new sales force structure and for a complete internal redesign of data and systems.*
121. Another pharmaceutical manufacturer considered that *"a change of the existing RPM structure, which has been developed by the pharmaceutical industry and which represents the basis of our territorial and therefore field service structure, will involve considerable expenditure and time for [...]. At the same time, a change of the existing RPM and the involved territorial structure would destroy the grown and very developed existing contacts to our customers. This leads to unforeseeable and therefore unacceptable losses for our company."*
122. IMS stated in its comments that the Commission did not properly survey those companies that seem best placed to comment on switching costs: NDC's and AzyX's customers. According to IMS AzyX and NDC have approx. 61 customers and only 28 of these companies were surveyed. In order to have a fair view from customers, the Commission surveyed customers from the 3 services providers. The Commission used a large sample of customers of each provider customer base and does not claim to have surveyed the whole industry. Nevertheless, even according to IMS' figures, the Commission surveyed 46% of AzyX's and NDC's customers, which is sufficient to draw statistically sound conclusions. Therefore the Commission considers that 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.

123. The conclusion of this part of the legal assessment, therefore, is that the role played by the Working Group has contributed significantly to the present situation in which the 1860 brick structure is a de facto industry standard and is acknowledged to be so by almost all pharmaceutical companies. This in turn means that the costs, competitive disadvantages and other problems cited above which pharmaceutical companies would incur if they were to switch from this structure to buy regional sales data services formatted in another structure would be unacceptably high, so creating a very significant obstacle to their doing so.

### 7.3.2 *No likelihood of competitors creating an alternative structure*

124. To investigate further the alleged indispensability of the 1860 brick structure, the Commission considered whether there were technical and legal constraints which at least make it unreasonably difficult for other undertakings to create another structure in which regional data services could be formatted and marketed in Germany.

125. The lack of such constraints was influential in the Court's judgement on *Bronner* (paragraph 44) in coming to the conclusion that access to a newspaper home-delivery scheme was not indispensable to carrying on business:

*"Moreover, it does not appear that there are 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."*

126. IMS argues that the brick structure is not indispensable because the information needed to create a brick structure is publicly available and there are a very large number of potential brick structures which can be created. IMS considers that a new structure could therefore not be a "real or potential substitute" for the 1860 structure within the meaning of the phrase used by the CFI in the *Ladbroke* case (paragraph 131). IMS further argues that the test for an essential facility is whether it is impossible for competitors to duplicate and does not depend on individual, subjective or evolving attitudes of customers.

127. The Commission agrees with IMS that the information needed to construct a brick structure is publicly available, and that without taking into account existing constraints affecting brick structure creation there are in theory many possible structures. However, competitors have no choice but to take into account these constraints if they wish to produce a useful structure. Respecting constraints necessarily means that the possibilities to create a new structure are very limited, for technical (need to use respect postcode boundaries and other objective constraints) and legal reasons (compliance with data protection law, need to avoid infringing IMS' copyright), as will be shown below.

128. *[Deleted business secret]*

129. The Commission cannot agree with IMS' comments on the admissibility of the customers in the finding that the 1860 structure is indispensable. The pharmaceutical companies, as users of data in brick structures, are well placed to know, for example, whether or not the 1860 brick structure functions as an industry standard. They can also comment authoritatively on the likely costs of switching from this structure to

another structure. To give the views of customers no weight in these proceedings would have been to consider the question of whether the structure was indispensable only from the perspective of the possibilities to create any new brick structure, without regard to whether or not it was at all possible to use that structure to compete on the relevant market.<sup>38 39</sup>

#### 7.3.2.1 Lack of options available to potential suppliers of regional sales data services

130. It is important to consider whether, starting from nothing, potential suppliers of regional sales data services could in fact develop alternative structures. Evidence for this perception is provided by the outcome of a meeting of 15 March organised by AzyX, which concluded inter alia that: “*From a legal standpoint, IMS would again attack each structure which could only halfway reconstruct the 1860 structure. For this reason, unless deliberate nonsense was produced, even a new structure could not fulfil the purpose of legal certainty.*”
131. Most of the parameters used in building the structure are in the public domain and fixed (postal code areas, location of pharmacies and doctors, socio-demographic 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. ‘Common sense’ also limits the options available. There are many possible structures which could be created but which would not represent viable segmentations for the presentation of regional sales data, because they could not be usefully employed by customers.
- Administrative boundaries are a significant technical constraint in the creation of a new structure
132. The 1860 structure relies significantly on postcodes. Around 500 of the bricks in the 1860 structure are identical with a single postcode area. For around 1100 further bricks, *there is no other scientific choice as to which postcodes to combine than the one IMS and the RPM workgroup have made (AzyX), and “1100 segments which combine 2 or more postal codes in a way unambiguously defined by the geographic and demographic nature of the area (GESDAT).* The Commission considers that the clear importance of using postal code areas limits the choices available to potential designers of new brick structures.
133. The Commission considers that there are clearly very strong reasons for using postcodes as the basis for a structure. Other data with which pharmaceutical sales data is integrated is provided in this format; it appears the only practical way to allocate doctors and pharmacies to particular bricks; and postcodes also appear to be

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<sup>38</sup> See for example John Temple-Lang in *Defining Legitimate Competition: companies’ duties to supply competitors, and access to essential facilities*, (1994) Fordham Corporate Law Institute at 286: “*The practice of the industry and the expectation of buyers or users may make it essential to have access to a facility that in other circumstances might not be essential.*”

<sup>39</sup> See also the judgement of the CFI in the *Ladbroke* case. The CFI rejected (paragraph 132) the argument put forward by Ladbroke in saying (emphasis added) that *transmission is not indispensable, since it takes place after bets are placed, with the result that its absence does not in itself affect the choices made by bettors and, accordingly, cannot prevent bookmakers from pursuing their business.* It is therefore clear that the CFI took the interests of customers into account in forming its view on the indispensability of transmission of sounds and pictures of horse racing.

the ‘natural’ basis for brick structures, as seen in the decisions of non-European countries to use them as the basis for a structure (see paragraph 153) in the absence of the data protection legislation which exists in the EU.

134. GESDAT said that *some wholesalers are capable of delivering data according to another criterion, others not. The only other criterion which could be used to locate a pharmacy is the address but it is technically more difficult and not reliable as the addresses are written in different ways in different regions of Germany. Also, there is not a unique identification code for a pharmacy, so the wholesaler has to have a straightforward method to allocate a new pharmacy without a need to refer to the provider. The postal code is very useful as it is an obvious and accurate way of allocating a pharmacy to a brick.*

135. AzyX said that: *postcodes are mandatory. If for no other reason, then because wholesalers have postcodes as the only practical criteria that enables them to allocate their sales figures to a territory structure i.e., a structure not respecting postcodes could simply not be handled by most wholesalers, thus no data could be acquired. Using postcodes as building blocks requires to provide wholesalers with a bridge file that specifies which postcode belongs to which brick – and to agree that the sales to each pharmacy in this postcode are allocated to the respective brick.*

*Alternatively, at least in theory, wholesalers could be provided with a file which lists all 21.600 pharmacies and allocates them individually to bricks. In practise, however, this would always fail, because*

*a) even the slightest difference in spelling would make the allocation not work, as the computer system would no longer recognise the pharmacy (such spelling differences are the rule, not the exception wholesalers might even use the name of the pharmacist instead of the name of the pharmacy in their address file, etc, etc)*

*b) any new pharmacy and/or pharmacy changing address would have to be manually allocated, which in practise is impossible to manage.*

136. NDC noted that: *“Any new structure not based on the German postal codes would be completely incompatible with other, publicly available software, such as socio-economic survey data, which are used by pharmaceutical companies in marketing and drug use analyses conducted by the pharmaceutical companies. Thus, a company that chose to use the new structure would be unable to do such analyses and be at a serious competitive disadvantage.”* NDC added that: *“It would be necessary to demonstrate to the [pharmaceutical product] manufacturer why the non-postal code methodology is superior in order to gain their buy in and conversion, which is highly unlikely.”*

137. The Commission also considers that there are strong arguments for the necessity for brick structures to respect the boundaries of the 440 German *Kreise* (counties), as alleged by NDC and AzyX. They referred to the fact that public prescribing and dispensing policies are set on a *Kreis* basis, and so sales data for any brick which crossed a *Kreis* border might not be able to be associated with one prescription and dispensing policy. This means that sales data might not give an accurate picture of the popularity of a drug or the success of a sales representative in marketing it. AzyX added that: *“Kreis boundaries are also mandatory, mainly because a regional structure also needs to meet the territories of doctor associations. Those territories are organised around Kreis boundaries”*. It is noteworthy that German Laender



boundaries, which are also obvious administrative regions to use in the construction of a structure, are made up of *Kreis* boundaries.

- Data protection law imposes further constraints on creation of a second structure

138. NDC argues in its submission that the German data protection law would be violated by the creation of a second brick structure, because it would be possible to compare data in this structure with that in the 2847 and 1860 structures so as to identify information about individual pharmacies. IMS considers that this is only a theoretical possibility, because no party would have a commercial reason to carry out this comparison work, and it would involve disproportionate effort.
139. However, some industry players have a different view. Merck considered that: *The fact that is de facto impossible to come up with a different sales data structure which is still compatible to the prescription data structure has been proven at the occasion of the recent switch from 1845 to 1860 segments. Even though 93% of all segments remained completely untouched, the pharmacy coding centres refused to deliver back data for 1999 on 1860 brick structure. As 1999 data were delivered on 1845 segments, single doctors would have been identifiable.* Similarly, the workshop held on 15 March of various pharmaceutical companies, data providers, wholesalers etc. concluded that: *the coding centres and wholesalers pointed out that they could not deliver in very different structures for data protection reasons, unless the delivery to IMS was stopped (which they could in practise not do for economical and contractual reasons).*
140. IMS further claims, in response to NDC's argument, that there is no evidence that competing brick structures in other EU Member States, where the same data protection rules exist as in Germany, have run into data privacy problems. IMS further argues that NDC's 4000 brick structure in Germany did not run into these data privacy problems.
141. The Commission's investigations suggest however that there is support within the pharmaceutical industry for the view that data protection law does impose real constraints on the construction of a second brick structure. GESDAT says that: *“ As there are around 21000 pharmacies in Germany and around 3000 segments in the input structure, it means that there are 7 pharmacies per segment. If 3 very different brick structures were to co-exist, it would be easy only by deduction to identify the sales of a specific pharmacy. In Germany, a pharmacy is owned by a pharmacist (an individual) who cannot be the owner of another one. It would be then very easy to deduct from the sales of a specific pharmacy the income of the pharmacist in violation of the data privacy protection law. If 3 very different brick structures were to co-exist, each time a pharmacy would close or open, the wholesaler would have to check that there is no violation of the data privacy law. One of the 3 brick structure would have to be amended but which one? Mr Hirth thinks that the same issue would arise with 2 brick structures.*
142. On balance, and in the context of these interim measures proceedings, the Commission considers that there is a probability that German data protection laws do impose certain constraints on the construction of a second structure in Germany. *[Deleted business secret]* Given the limited options available to would-be creators of a new brick structure, this assumption is questionable. IMS also refers to the lack of

analogous problems in other EU countries and with NDC's earlier structure. However, this lack of problems can be explained by the fact that brick structures in other countries are compatible with each other, so that, provided neither structure itself breaches data protection law, combining the data in two structures would not do so either.

#### 7.3.2.2 Legal uncertainty around selling data in a new structure

143. As mentioned above in paragraph 29, the Frankfurt Court judgement of 28 December 2000 gave an injunction preventing the selling of data in both the 2847 and 1860 segments and any other number of segments so far as it constitutes a derivative from RPM 1860. The Court did not define precisely what it would consider to be derivatives, and no clarification is likely for around 3 years. Pharmaceutical companies are aware of this uncertainty, having been warned by IMS not to infringe its copyright, and would be sceptical about the legality of any new structure which competitors of IMS might use to format a new regional sales data service.

144. There is evidence that IMS is likely to exploit this uncertainty by mounting a legal challenge for copyright infringement against any other regional data services product which uses a structure which is similar to the 1860 brick structure, or to any company which receives data in such a structure. According to a recent example, the similarity to the 1860 brick structure would not need to be great in order that IMS would mount such a challenge. AzyX noted as follows:

*"It is to be noted that IMS legally attacked AzyX in Germany on the basis of a delivery to a client Ribosepharm. This client received data in a segmentation with 2793 bricks. AzyX has never before and never after produced data in this segmentation. The segmentation was deliberately constructed to be NOT compatible to 1860 (even though this is almost impossible to avoid if a base structure is – as the AzyX base structure - based on postal codes). The underlying reason AzyX constructed a structure like this was the suspicion that this client would collaborate with IMS. Indeed IMS then received this delivery and attacked AzyX, claiming that even if it was not compatible to 1860 in parts, it was equal enough (because of the postal code base) to be considered derived from 1860. In conclusion, it can be expected that IMS will attack any new structure that is not deliberate nonsense (i.e. any structure which is based on postal codes and which follows common scientific sense)."*

145. It is clear from the above that structures which are similar (where this term is broadly defined) to the 1860 brick structure will be perceived by pharmaceutical companies as being legally questionable and so not marketable. This means that any new brick structure would have to be very significantly different from the 1860 structure in order that it could be perceived as not carrying any legal risk. However, as noted above, a number of objective constraints limit very severely the possibilities to create such a different structure.

#### 7.3.2.3 Attempts to create new structures

146. The experience of AzyX in attempting to create a new brick structure is instructive. It tried two approaches – using university academics and consultants to devise a new structure using scientific principles; and getting AzyX staff to group segments together taking account of 'common-sense' industry rules – the use of postal codes,

administrative regions, doctors' associations areas, health insurance schemes, geographic features, socio-demographic factors etc.

147. The structures resulting from these two approaches were similar to each other and to the 2847 brick structure. In AzyX's view, there were only realistic alternative choices available with respect to the creation of around 100-150 bricks. The remainder was determined by criteria which would have to be adhered to if the structure were to stand a reasonable chance of being attractive to the pharmaceutical industry. This suggests a very low 'margin of creativity' of around 3-5%. According to Merck Sharp Dohme, if one were to create a brick structure which was useful and well suited to the needs of the industry, one would inevitably arrive at a segmentation very similar to the 1860 brick structure. Both NDC and AzyX found after creating their brick structures that only in a small number of cases could these bricks not be aggregated to form the 1860 structure.
148. The fact that both structures had around 3000 segments is also instructive. The granularity of the structure cannot be decided arbitrarily, due to several objective constraints. First, German data protection law requires at least 3 pharmacies to be grouped together, and changes in pharmacy locations means that the minimum needs to be higher – the Working Group agreed on 5. There are approximately 22,000 pharmacies in Germany, so 4,400 bricks is the maximum number available. Second, bricks have to be large enough to address the problem of "travelling prescriptions", where a doctor prescribing a drug is located in a different brick to the pharmacy dispensing it. This situation distorts companies' attempts to measure the effectiveness of their sales force because a sale resulting from the work of the sales representative for brick A will be recorded in brick B and so credited to another representative. In practice it appears that this phenomenon increases markedly if more than 2000 segments are used.
149. On 15 March 2001 AzyX instigated an initiative to find out whether it was possible to develop and establish a new brick structure on the basis of co-operation between all market players: pharmaceutical companies, wholesalers, pharmacy coding centres, software companies who process sales data for the pharmaceutical industry, providers of prescription data, providers of regional sales data services, scientific consultants specialised in regional structure development and lawyers. AzyX describes the outcome as follows:

*"It became clear already during this first kick-off meeting that there is (unfortunately) no way to develop a new industry standard structure.*

*(a) When reviewing the different factors to be taken into account for each reasonable structure (e.g. doctor and pharmacy addresses, administrative borders, sociodemographic data, etc, etc) and the different possible scientific methodologies, it became clear that the result of the development would be quite similar to the IMS structure.*

*(b) When reviewing the areas where differences to the IMS structure were possible without producing nonsense, the pharmaceutical industry pointed out that the choice between these options was already made within the RPM working groups, and that they would not accept other choices against better knowledge now.*

*(c) The coding centres and wholesalers pointed out that they could not deliver in very different structures for data protection reasons, unless the delivery to IMS was stopped (which they could in practise not do for economical and contractual reasons).*

*(d) A base structure with ca. 3000 segments (+/- 300-500) would be the request of the industry. However, with such a fine segmentation, whether equal to the IMS 2847 structure or not, it would be practically impossible to avoid that most of the 1860 structure could be reconstructed by adding segments of the new structure together. The finer (more segments) a base structure would be, the more difficult it would be to avoid compatibility to the 1860 structure."*

150. This meeting was followed by a letter from 17 pharmaceutical companies<sup>40</sup> asking IMS to licence the 1860 brick structure to anyone in the industry who asks for it, in order to allow competition in the market.
151. IMS states that it has developed 3 different structures in Germany over the years and that NDC and AzyX claim to offer or to have developed new brick structures in Germany.
152. The Commission considers that the creation of a new structure by IMS in the past, whether by subdividing existing segments or taking account of changes due to administrative restructuring (e.g. incorporation of the former East Germany, in 1992), is not comparable to the creation of an entirely new structure. The challenges which would be faced by prospective creators of such a new structure were in general not faced by IMS in these situations. Although NDC and AzyX have launched new structures, there continues to be a legal uncertainty, as mentioned previously, around their compatibility with the 1860 brick structure. The Commission considers that there remains significant uncertainty in this area.

#### 7.3.2.4 Brick structures in other countries

153. In countries where there are no data protection law requirements which prohibit reporting data for an individual postal code with only one or two pharmacies- such as the US, Canada and Australia, the postal code areas are used- there is no 'brick structure' as such. In Japan there is no brick structure because doctors dispense drugs directly to their patients and pharmaceutical manufacturers track sales directly from doctor to patient. Brick structures are common in European countries, mainly because of the existence of data protection legislation. In these countries the 'bricks' in the structure are formed by aggregating several postal codes. The brick structure situations in countries where two or more regional sales data service providers are in competition are examined below. *[Deleted business secret]*
154. IMS argues that the two or more brick structure co-exist in a number of countries, and that this enhances competition, and implies that there is no reason why this could not happen in Germany. It cites Portugal, France, Finland, Norway and Poland as examples of such countries.

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<sup>40</sup> Including the following companies: Abbott, Krewel Meuselbach, Bionorica Arzneimittel, Lilly Deutschland, Engelhardt Arzneimittel, Merck, Pohl-Boskamp, Novo Nordisk, Galderma Laboratorium, Schering Deutschland, Hormosan-Kwizda, Solvay Arzneimittel, Klinge

155. It is important to consider whether the situations in these countries do suggest that it would be possible for competitors to develop substitutes for the 1860 brick structure in Germany. First, it is important to note that in France and Norway the several co-existing brick structures appear to be wholly or largely compatible and in the case of the United Kingdom are identical. Furthermore, it is clear that no other market is similar to Germany, in terms of the length of time during which there have been brick structures in the country, the role played by the pharmaceutical industry in these structures, the number of pharmaceutical companies who buy sales data, and the size of the regional pharmaceutical sales data market generally.
156. In Portugal both AzyX and IMS are present on the market for regional sales data services. *[Deleted business secret]*, whilst AzyX had 212 bricks when it entered the market in 1999. In 2001, AzyX has a structure with 324 bricks (called Basic Information Units BIU). Neither IMS nor AzyX has asserted that these structures are incompatible.
157. In France, Cégédim is the only company on the market for regional sales data services. Cégédim is the service provider for the GERS, which is a "groupement d'intérêt économique" created by all the pharmaceutical companies located in France. In 1998 Cégédim changed its structure from one containing 509 bricks to one with 4612 bricks (Agrégats de Points de Vente) which are grouped in 746 bricks (or 'UGA', Unités Géographiques d'Analyses). The 509 structure is still used by a little number of pharmaceutical companies in the transitional period before switching to the 746 structure, so no incompatible brick structures for sales data co-exist in France. *[Deleted business secret]* The APV segmentation applied to this sample raises issues with regard to the French legislation on privacy (Informatique & Libertés) and the French Health Code. *[Deleted business secret]* The two structures although used to provide services on distinct markets (regional sales data and regional prescription data services) are compatible.
158. IMS argue that it is possible for competitors to create their own brick structures and compete effectively, citing the example of France, where, after Cégédim changed its sales data brick structure, 90% of GERS' customers have moved to this new structure.
159. The transition to the 746 brick structure in France and the possibility of creating a new brick structure in Germany are not comparable. Cégédim created the 746 structure in France at the request of the pharmaceutical companies, and it was the subject of a convention between the industry, the wholesalers and the French Government, which needed a new segmentation to create an index of price information for drugs. Therefore the structure Cégédim created has an official status, rather than merely being the creation of a private sector firm. It was also an almost automatic decision for pharmaceutical companies to move to the 746 structure, since they had requested a new structure in the first place. There are only a very few number of companies using the old structure on this transitional period. Therefore this situation contrasts sharply with that in Germany.
160. In Norway, IMS and Farmastat AS are present on the market. *[Deleted business secret]*; Farmastat was formed in 1994 by the pharmaceutical industry association. *[Deleted business secret]* It is now possible since 1 March 2001 to provide information on a per pharmacy basis in Norway, and Farmastat expects to launch a product covering each of the 392 pharmacies in Norway shortly.

161. In Finland, Suomen LääkeData Oy (SLD), which was until very recently 100% owned by the pharmaceutical industry, and IMS, are the providers of regional sales data services. *[Deleted business secret]* SLD entered the market for regional sales data in 1999. SLD's structure was created by subdividing the 24 Finnish healthcare districts, to create 161 regional segments. The decision on the creation of bricks was based on municipal regions, healthcare co-operation areas, the structure of main pharmacies and satellite pharmacies, geographical features and postcodes.
162. The extent to which SLD's structure and that of IMS are compatible is not clear. However, many of the constraints which prevent competitors to IMS in Germany from entering or remaining on the market are in any event not present in Finland. In particular, when SLD entered the market it was much easier for it to attract business from the pharmaceutical industry, since these companies owned 100% of SLD and had a clear interest in it succeeding. *[Deleted business secret]* Also, the market in Finland – which has only around 800 pharmacies, as opposed to around 21,600 in Germany - is much less complex and mature than in Germany, so pharmaceutical companies could not be so 'locked in' to the brick structure as in Germany. The Finnish situation can therefore not serve as a basis for inferences about the German market.
163. In Poland, AzyX is the main competitor to IMS. AzyX has a 646 brick (Basic Information Units) structure *[Deleted business secret]*. The IMS structure cannot be recreated using the AzyX's 646 brick structure. In Poland a new administrative structure was put in place 2 years ago, creating new set of administration regions. *[Deleted business secret]*
164. AzyX and IMS' brick structures are only slightly compatible with each other. The Commission notes, however, the comment of AzyX as follows:
- “It is to be noted, however, that Poland compared to the more mature pharmaceutical markets in western countries is a fast developing market. Pharmaceutical companies are increasing their field forces rapidly (they in average double every 2-3 years), so that frequent fundamental territory re-alignments are needed anyhow. All in all, the market situation in Poland is not at all comparable to the one in mature western markets.”*
165. IMS does not comment on the situation in Poland in any detail. The Commission considers that the differences between Germany and Poland with respect to the maturity of the pharmaceutical market, stability of administrative boundaries and length of time that brick structures have existed indicates that the experience of Poland does not show that it would be possible for competitors to develop substitutes to the 1860 brick structure in Germany
166. In the United Kingdom there were until 1999 two providers of pharmaceutical sales data: IMS and Source Informatics. Source's product, *Source Dispenser* was nevertheless specific as the information provided to clients was restricted to sales data on their own products. Sales of the products covered were analysed by each individual pharmacy or dispensing general practitioner. Source had no real brick structure at that time. *[Deleted business secret]* Following an investigation of the transaction by the MMC, IMS offered, and the UK Competition and Consumer Affairs Minister accepted, undertakings in October 1999 among which was the divestiture of Source Dispenser. NDC was the eventual purchaser of Source

Dispenser in October 2000. The RSA brick structure was part of the sale of Source Dispenser in the form of a perpetual, non-exclusive, royalty-free licence. Therefore, in the United Kingdom, there are two sales data services providers using exactly the same brick structure.

### 7.3.3 *Justification for refusal to licence*

167. It should be recalled that the right of the proprietor of an intellectual property right to prevent third parties from manufacturing and selling or importing, without its consent, products incorporating its right constitutes the very subject-matter of his exclusive right. The ECJ has held in *Volvo* that 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 a licence cannot itself constitute an abuse of a dominant position.
168. However, it is equally clear from the case law that, in exceptional circumstances, a refusal to grant a license may constitute abusive conduct in itself. In this context, the ECJ referred in its *Magill* judgment to the absence of justification for the refusal to grant a licence to an intellectual property right. Likewise, the Court considered in *Bronner* that in order to argue for an abuse of a dominant position it was necessary, inter alia, that “... *such refusal [of the service comprised in home delivery] be incapable of being objectively justified...*”. It is necessary, therefore, to consider whether IMS’ refusal to licence the 1860 brick structure is capable of such justification.
169. In this respect, IMS, invoked the fact that NDC infringed IMS’ copyright, is still contesting the copyright’s validity and did not accept that it was bound by the judgement against PI as justifications for it not entering into licencing discussions with NDC. However, NDC’s conduct can only be seen against the background of IMS’ refusal to licence the 1860 brick structure, which is indispensable to compete with the relevant market. In this context, NDC’s reaction to IMS’ behaviour cannot be an objective justification for not entering into licencing discussions. Moreover, for IMS to grant NDC a licence would not necessarily impact on the question under German law of whether a copyright exists or not, and if so, who owns it. Similarly, these factors cannot amount to an objective justification not to enter into licensing discussions.
170. In its submissions, IMS argues that the Commission’s position in this respect is contrary to EC law, which recognises that licensors may legitimately refuse not to maintain contractual relationships with licensees which contest the licensed rights. IMS refers to Commission Regulation 240/96 on the application of Article 85 (3) (now 81(3) )of the Treaty to certain categories of technology transfer agreements to support its case. Article 1 of this Regulation sets out the criteria for licensing agreements not to fall within Article 85(1) (now 81(1) ). Article 2 says that Article 1 applies notwithstanding in particular various clauses in such licensing agreements, which are not generally restrictive of competition. Clause (15) is:

*“ a reservation by the licensor of the right to terminate the agreement if the licensee contests the secret or substantial nature of the licensed know-how or challenges the*

*validity of licensed patents within the common market belonging to the licensor or undertakings connected with him”.*

171. This paragraph shows only that clauses in licensing agreements which foresee termination if the licensee later contests the licensed rights do not generally infringe Article 81(1). It does not show that interim measures requiring IMS to licence NDC, who does indeed at present contest the licensed rights, would be contrary to Article 81(1), Article 82, or any other aspect of Community law.
172. IMS further argues that NDC offered only a nominal sum for a licence. It is clear that IMS refused, in spite of repeated requests, even to discuss a licence. In a letter to Jeffrey Kanis of NDC of 28 November 2000, IMS did not reject NDC’s request on the basis of the sum offered, but refused entirely to enter into negotiations, stating that *“while the case on the infringement of our copyrights in the RPM data set structures is still pending and the court’s decisions have not become final and unappealable yet, we are not in a position to discuss this matter further.”* If IMS considered that the sum offered by NDC was not enough, it clearly decided against making any counter proposal or suggesting an amount which it considered reasonable.
173. Finally, IMS argues that there are criminal allegations against former senior PI and current NDC officials for theft of information from IMS. In response, NDC says that this allegation is at a preliminary stage (a report to the police), that there is no proceeding in this case, that all those accused strongly deny the allegations, and that no charges have been filed. NDC further mentions that NDC itself has not been accused of any wrongdoing and that the allegations relate to theft of information are not related to the brick structure. The Commission does not consider that this factor represents an objective justification for the refusal to licence. First, IMS has not produced any evidence which shows that there is a criminal investigation or proceeding underway, as opposed to a preliminary inquiry into allegations. Second, the allegation is against an individual and not NDC itself. Third, the individual concerned is no longer an employee of NDC. Even if none of the above factors were present in this case, it is incumbent on IMS to address any perceived harm it has suffered through alleged criminal behaviour through appropriate lawful means, and not by attempting to eliminate competition in the relevant market.
174. As stated above, IMS has recently refused a licence to AzyX also. IMS’ reasons for this refusal are similar to those for refusing NDC except for the criminal allegation element, which is not present in the case of AzyX. The Commission notes that the amount proposed by AzyX is 10 times larger than that offered by NDC and IMS did not make any counter offer or indicate what a reasonable fee should be. In conclusion, the Commission considers that IMS had no objective justification not to licence NDC or AzyX.

#### **7.4 Effect on trade between Member States**

175. Article 82 of the Treaty prohibits any abuse of a dominant position within the common market or in a substantial part of it in so far as it may affect trade between Member States.
176. As the Court of Justice ruled in its judgment in *United Brands* (paragraph 201), *“if the occupier of a dominant position, established in the common market, aims at*



*eliminating a competitor who is also established in the common market, it is immaterial whether this behaviour relates to trade between Member States once it has been shown that such elimination will have repercussions on the patterns of competition in the common market."* The refusal in question aims, among other things, to eliminate NDC and AzyX from the relevant market. If these two companies were eliminated from the market, the structure of competition in the common market would be altered, as no competition would be present on the relevant market.

177. NDC is prohibited from using the 1860 brick structure. According to NDC, it is barred from competing in the provision of regional sales reports. It is clear that IMS's conduct is affecting the survival of the only competitors on the market. In all likelihood this conduct will foreclose the market to potential new entrants and so eliminate all prospect of competition in the future
178. It is assumed that IMS' policy on the 1860 brick structure is to pursue only its competitors on the relevant market for potential copyright infringement. If IMS were to pursue all other users of the 1860 structure (software providers, providers of socio-economic data etc.) for potential breach of copyright, there could be even more widespread competition problems.

## **7.5 Conclusion on abuse under Article 82**

179. The Commission considers that this case meets the requirements for the establishment of abuse under Article 82 as developed in ECJ and CFI jurisprudence, beginning with the *Commercial Solvents* and *Volvo* judgements and taken further in *Magill*, *Ladbroke* and *Bronner*.
180. The Commission considers that there are 'exceptional circumstances' in this case within the meaning of the phrase used by the ECJ in *Magill* (paragraph 50) read in conjunction with the *Ladbroke* and *Bronner* cases. IMS has created, in collaboration with the pharmaceutical industry over a long period of time, a brick structure which has become the de facto industry standard for the presentation of regional data services and which the Frankfurt Court has found is its intellectual property right. IMS is now excluding all competition from the market for regional data services by refusing, without objective justification, to licence this structure to competitors. As clarified in the *Ladbroke* judgement, there is no requirement for a refusal to supply to prevent the emergence of a new product in order to be abusive.
181. It is clear that refusal of access to the 1860 brick structure is likely to eliminate all competition in the relevant market, since without it is not possible to compete on the relevant market. IMS' reasons for its refusal to licence are not capable of being objectively justified. Moreover, use of the 1860 structure is indispensable to carrying on business on the relevant market; there is no actual or potential substitute for it. These exceptional circumstances meet the test set out in *Bronner* for a refusal to supply to be considered an abuse of a dominant position.
182. IMS makes a number of arguments attacking the legal analysis set out in the Statement of Objections. It says that there is no suggestion that IMS has engaged in any abusive conduct or has tried to use its control of intellectual property to monopolise downstream or related markets. IMS is entitled to refuse licences of its copyright to competitors for the market to which copyright relates (cf. the *Volvo*

case). A refusal is only abusive if coupled with additional abusive behaviour, and there is none here.

183. Furthermore, IMS does not consider that the 1860 brick structure is an essential facility, since there is no second related market on which competition is restricted.
184. As regards the first of these two arguments, ECJ and CFI caselaw subsequent to the *Volvo* case makes clear that in exceptional circumstances the refusal to licence an intellectual property right in itself can be considered to be an abuse under Article 82. As described above in paragraphs 75-174, such circumstances exist here. A dominant company has negotiated over a long period with its customer industry so as to produce a structure on which the industry is now very highly dependent, to the extent that they consider it a de facto industry standard, and which a national court has now found is the dominant company's intellectual property. This dominant company now refuses to license this structure to competitors, so that no competing products based on this structure can be produced. On the second argument, the fact that the cases considered by the ECJ and CFI to which IMS refers involved two markets does not preclude the possibility that a refusal to licence an intellectual property right can be contrary to Article 82. In the *Magill* case cited above, the basic information about TV programmes was considered to be an indispensable input to allow an undertaking to compete in a downstream market (that for television listings magazines). The circumstances are similar in this case, in that 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. As explained above in paragraph 15-16, 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. In this case, 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.
185. The finding here is that there is a prima facie case that use of the 1860 brick structure is indispensable to compete on the relevant market. The input which the pharmaceutical companies have made to the structure have contributed greatly to its status as a de facto industry standard and to their current dependence on this structure as a format for the receipt of regional sales data services. It is therefore the case that refusing access to this structure to competitors on the relevant market would exclude all competition from this market, and that therefore IMS' refusal to licence the 1860 brick structure involves abusive conduct.
186. The overall conclusion here is therefore that, on the evidence available at present, there is sufficient prima facie case of behaviour constituting abuse under Article 82 to order interim measures, if the other conditions for ordering such measures are fulfilled.

**8. LIKELIHOOD OF SERIOUS AND IRREPARABLE HARM AND INTOLERABLE DAMAGE TO THE PUBLIC INTEREST; URGENCY**

187. In its judgement in the *La Cinq* case (paragraph 28), the Court established that in addition to the prima facie infringement of the Community rules on competition a second condition had to be fulfilled for it to be possible to order interim measures: *there must be proven urgency requiring the prevention of the occurrence of a situation likely to cause serious and irreparable damage to the party applying for their adoption or intolerable damage to the public interest.*” In this case both aspects are present.
188. On the risk of serious and irreparable harm establishing the urgent need to grant interim measures, the CFI held (in *La Cinq*, at paragraph 4) that it was necessary to show that there was *“damage which could no longer be remedied by the decision to be adopted by the Commission upon the conclusion of the administrative procedure.”*
189. In *La Cinq*, the CFI confirmed that the risk of serious and irreparable damage does not require the risk of cessation of business or insolvency. However, it is clear that where the applicant for interim measures is threatened with going out of business prior to the Commission's taking of a final decision, this in and of itself would demonstrate the urgency of the interim relief sought in order to prevent serious and irreparable damage to the party seeking such relief.
190. On the basis of the evidence obtained there is good reason to suppose that unless NDC is granted a licence to the 1860 brick structure its German operation will go out of business, and that there will be intolerable damage to the public interest.
191. NDC entered the German market in 1999 by making substantial investments to acquire Pharma Intranet AG. It has invested additional a number of millions of DM in the expansion of the German company, and the ongoing costs of running this business are substantial. As a result of IMS’ behaviour, NDC has lost [...] contracts from larger pharmaceutical companies worth around [...] million DM per year and its costs are such that it is currently losing around [...] million DM per year in its German operations. This is an unsustainable financial position. The losses are material to the NDC group as a whole, and will force NDC to withdraw from the German market unless it is able to compete effectively in the very near future.
192. NDC’s only current source of revenue in Germany is derived from the sale of regional sales data services. Such services are the ‘core’ product which a data provider must offer in order to establish itself in the marketplace. NDC currently has a number of contracts for the provision of these services which amount to around [...] million DM for 2001. There is legal uncertainty around the ability of NDC to fulfil those contracts unless it is granted a licence to the 1860 brick structure. *[Deleted business secret]*. The negative impact on NDC of this legal uncertainty is substantial, and is increasing markedly at the present time, making the requirement on IMS to licence NDC urgent. If NDC had to default on these contracts, this would result in serious financial damage as well as the long-lasting damage to its commercial reputation in Germany.
193. Also, NDC’s current customers have indicated that they will all revert to IMS if NDC is unable to provide a product formatted in the 1860 or compatible brick

structure. If it cannot have legally certain access to the 1860 structure, therefore, NDC will lose its current customers. Industry practice is for contracts for the coming calendar year to be negotiated a number of months in advance of the start of that year, so NDC's need for such access is urgent. Moreover, without interim measures, NDC will also have no prospect of attracting new customers for the coming years. It is probable that without interim measures a situation will occur which will cause NDC to cease trading in Germany.

194. There is no prospect of NDC being able to compete on the relevant market by means other than the present Decision in the medium term. The Commission understands that the final verdict on the appeals against the injunctions delivered against NDC in the Frankfurt Court will not be known for around 3 years. Even should these appeals go in its favour, therefore, NDC would not be able to legally employ the 1860 brick structure before around 2004, by which time it is very likely to have ceased trading in Germany. The Commission also notes that, under the present circumstances, it is unlikely that another company will be able for the foreseeable future create a brick structure similar to the 1860 brick structure a priori and successfully publicly claim that this was an original intellectual creation that should be covered by a new copyright.
195. Aside from the serious and irreparable harm to NDC, there is a risk of an intolerable damage to the public interest within the meaning of the *la Cinq* judgement. Since without the 1860 brick structure it is not possible to compete on the market now or in the foreseeable future, there will be, in the absence of interim measures, a serious risk to the continued presence of the other current competitor, AzyX on the market. AzyX is very much smaller than NDC (its worldwide revenue was US\$1.53 million in 2000, compared to US\$289.3 million for NDC), and its European operation (in effect, the entire business) is even more susceptible to going out of business in the absence of interim measures. IMS would then revert to being the sole provider of regional sales data in Germany.
196. An eventual finding in the main decision that IMS had abused its dominant position under Article 82 would be illusory if meanwhile NDC's German subsidiary and other competitors had been put out of business. If that were to happen, not only will IMS be confirmed as the only supplier of regional sales data services in Germany but there is also likely to be complete foreclosure of the relevant market for the foreseeable future.
197. IMS claims that in granting an injunction, the German Courts have already established that IMS' legitimate commercial interests would suffer greater harm than those of the copyright infringers. However, it cannot be the case that the interim judgement of a national court can pre-empt the application of EC competition law.
198. IMS further argues that any harm suffered by NDC is the result of unlawful activity, and so cannot be legitimately relied upon, and that it is not open to NDC to claim that it will suffer harm unless it is able to maintain a customer base that the German Courts have found was unlawfully obtained to begin with. The Commission considers that irrespective of the circumstances, in which NDC operates, it is likely to suffer serious and irreparable harm, because the refusal to grant a licence, as mentioned above, is illegal in itself. NDC therefore urgently requires interim relief.
199. The balance of interests in this case favours the applicant. If, at the end of the full procedure the Commission decides in favour of IMS, IMS will have only have

suffered harm to the extent that it will have had to compete with NDC and AzyX on the relevant market. Moreover, if this were to happen, the situation would be easily reversible, in that IMS would no longer be obliged to grant a licence to other undertakings and would recover any share of the relevant market it had lost. For IMS, granting a licence to the 1860 brick structure will disclose only information which is already in the public domain, and so does not imply an irreversible disclosure of secret information by IMS.

200. IMS' legitimate interests will not be prejudiced by licencing the 1860 brick structure, since it will receive licence fees from any undertaking to whom it grants a licence, in connection with the investments it has made in developing the structure. On the other hand, if interim measures were not granted, there would be a strong possibility that NDC (and AzyX) would cease trading in Germany, and furthermore that all competition on the relevant market would be eliminated.
201. In conclusion, for the reasons set out above, the Commission considers that there is in this case the risk of serious and irreparable harm and intolerable damage to the public interest which establishes the urgent need to grant protective interim measures.

## **9. OTHER ISSUES**

### **9.2 Directive 96/9/EC of 11 March 1996 on the legal protection of databases ("Directive 96/9/EC")**

202. According to decisions of German courts on provisional measures in current proceedings quoted above, IMS has copyright in the 1860 brick structure by virtue of a provision in German copyright law which transposes Directive 96/9/EC.
203. Directive 96/9/EC provides for harmonised protection, both of original databases under copyright, and of non-original databases through a sui generis regime. Any original collections of works and compilations of data or other materials are covered by its copyright part. In addition, the Directive introduces a sui generis regime to protect non-original databases made with substantial investments for a period of 15 years.

204. In its copyright part, the Directive harmonises copyright applicable to the structure (schema) of a database. In line with similar provisions contained in Directive 91/250/EEC on the legal protection of computer programmes, it establishes the level of originality as the eligibility criterion for protection (“the author’s own intellectual creation”). Copyright protection provided by the Directive is accorded to the selection or arrangement of the contents and covers the structure. It does not extend to the contents of a database and applies without prejudice to any rights subsisting in those contents themselves.
205. Under the Directive, exceptions only apply in certain limited circumstances to databases protected by copyright. Article 13 states that the Directive is without prejudice to provisions concerning *inter alia laws on restrictive practices and unfair competition*. Moreover, the application of a Treaty article takes precedence over a Directive, as recently confirmed by the CFI in *Institute of Professional Representatives before the European Patent Office v Commission of the European Communities*.<sup>41</sup>

## 9.2 Consistency of this Decision with the EC’s international obligations

206. IMS claims that the Commission’s position may prejudice its exclusive right and give rise to conflict with the EC’s international obligations because it is not a special case within the meaning of the Berne Convention<sup>42</sup> and the World Trade Organisation’s TRIPS<sup>43</sup> and therefore would unreasonably prejudice IMS HEALTH’s legitimate interests as a copyright owner.
207. The Commission is fully conscious both of the benefits of intellectual property rights and of the need for such rights to be fully subject to the respect of competition laws. It considers that this interim Decision is fully compatible with the Berne Convention and the TRIPS.
208. The TRIPS agreement explicitly obliges Contracting Parties to protect creative databases in Article 10(2). Article 13 also recognises that members may provide for limitations and exceptions to exclusive rights provided that the application of any such exception or limitation meets the conditions of that Article. Exceptions or limitations are to be confined to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interest of the rightholder<sup>44</sup>. The Commission considers that this Decision is compatible with these provisions. The compulsory licence ordered in this Decision constitutes a special case, which is clearly defined and narrow in scope. The Decision does not conflict with the normal exploitation of IMS’ copyright on the 1860 brick structure. IMS’ legitimate interests will not be prejudiced unreasonably, since IMS can demand payment for licences granted pursuant to this Decision and so will not suffer an unreasonable loss of income as a consequence of the Decision.

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<sup>41</sup> See Case T-144/99, paragraph 50 : *Even if that were the case, the principle of the hierarchy of norms precludes this provision in a measure of secondary legislation from permitting a derogation from a Treaty provision.*

<sup>42</sup> Concluded in 1886 for the protection of literary and artistic works and as last revised at Paris in 1971

<sup>43</sup> World Trade Organization’s agreement on Trade Related Aspects of Intellectual Property Rights. Council Decision 94/800/EC of 22 December 1994.

<sup>44</sup> Article 9(2) of the Berne Convention contains very similar wording.

209. In addition, Articles 8 and 40 of TRIPS expressly address the measures that Contracting Parties may take to prevent the abuse of intellectual property rights. Article 8 of TRIPS provides that measures to prevent the abuse of intellectual property rights may be needed, provided that they are "consistent with the provisions of this Agreement". Similarly, Article 40 of TRIPS requires that when Contracting Parties adopt measures aimed at control of abusive intellectual property licensing practices or conditions, they do so "consistently with the other provisions of this Agreement".

### **9.3 Alleged effect on intellectual property right protection**

210. As a general point, IMS argues that the Commission's position would effectively render copyright granted under national law nugatory and so deter investment in intellectual property, since potential investors would not consider that their investments could be recovered.

211. The Commission fully recognises the essential role played by intellectual property rights in promoting innovation and competition. Nevertheless, as IMS admits and as the Court established in the *Magill* judgement (paragraph 50), read in conjunction with the *Ladbroke* and *Bronner* cases, Community law can apply to the exercise of that right in 'exceptional circumstances'. Such exceptional circumstances exist in this case. A dominant company has negotiated over a long period with its customer industry, who are now dependent on it, so as to produce a structure which it subsequently claims is its intellectual property, and refuses to license this structure to competitors so that no competing products based on this structure can be produced. These circumstances, which give rise to an abuse of Article 82, are extremely specific. Under these circumstances, exclusive use of the 1860 brick structure and its derivatives by IMS is a means of monopolising the market for regional data services in Germany.

212. *[Deleted business secret]*

### **9.4 Appropriateness of interim measures**

213. According to IMS it is not possible to impose interim measures in this case, since there is no breach of competition rules in respect of which a penalty could be imposed. IMS argues that there are novel legal principles involved in this case, and that it is Commission practice not to impose fines in such cases. The Commission cannot agree to this proposition. This is a prima facie breach of Article 82 in respect of which a fine could be imposed, pursuant to Article 15 of Regulation 17. This would still be the case even if there were novel legal principles involved in this case which the Commission might take into account in deciding whether or not to impose a fine in a particular case.

### III. THE ORDER

214. The Commission considers that it is justified to make an order which will as far as possible ensure that the applicant is not put out of business, and that no intolerable damage to the public interest occurs, pending the final outcome of the administrative procedure by means of which the applicant complains. In the present case the most urgent need is to maintain the status quo by permitting the other undertakings which, according to the Commission's investigation, are currently present in the relevant market to continue to compete on this market.
215. The Commission therefore intends to require IMS to licence the 1860 brick structure on a non-discriminatory basis to NDC and AzyX. In any agreements in which IMS licences the use of the 1860 brick structure, it is important to ensure that any fee which is charged is reasonable, and that the process does not take an undue amount of time, as this would frustrate the purpose of the order. The order therefore provides for any royalties to be paid for these licences to be determined by mutual agreement between IMS and the party requesting the licence or failing that, by a Decision of the Commission on the basis of a determination by one or more independent experts. The term expert refers to any suitably qualified person. In the event, the expert(s) will be chosen by mutual agreement of IMS and the other party, or if the parties cannot agree, will be appointed by the Commission. The expert(s) should have access to all documents of the parties they might need in order to carry out their task. The expert(s) shall be bound by professional secrecy and not disclose any evidence or documents to third parties except to the Commission. The expert(s) will make the determination on the basis of transparent and objective criteria, and transmit it to the Commission for approval.
216. According to IMS, interim measures are intended only to maintain or restore the status quo, and NDC's application does not meet this criterion, since before IMS' refusal to negotiate a licence NDC had no licence and was illegally infringing IMS' copyright. IMS cites the *Camera Care* judgement of the Court in support of its argument, viz.: "*a further requirement is that these measures must be of a temporary and conservatory nature and restricted to what is required in the given situation.*"
217. This judgement cannot be interpreted to give the meaning desired by IMS. The intention of interim measures is to prevent a situation likely to cause serious and irreparable damage to the applicant party or intolerable damage to the public interest. If such measures were merely to restore a situation which existed before an abuse took place, they would only preserve the ability of IMS to abuse its dominant position, contrary to Article 82. The interim measures granted in this Decision merely maintain NDC's ability to compete on the market, and are no more than what is required in this situation to prevent intolerable damage to the public interest.
218. IMS also argues that the Commission would have to specify how any licence fees were to be calculated and the terms of the licence before taking an interim Decision. As to the method of calculation of licence fees, the Commission considers that allowing the parties to reach a mutual agreement, and failing that, to engage an expert, is entirely appropriate. The Commission will not stipulate in detail the terms of any licence for the 1860 brick structure.
219. The Commission considers that IMS and the undertaking requesting the licence should each bear half the cost of employing the expert(s) referred to above. The



Commission cannot accept IMS' argument that the expert is doing a job which can only lawfully be done by the Commission and so the parties should not be expected to pay for this service.

220. Finally, it is necessary to make provision for periodic penalty payments in the event of any default under the terms of this Decision.

HAS ADOPTED THIS DECISION:

*Article 1*

IMS Health (IMS) is hereby required 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 1860 brick structure, in order to permit the use of and sales by such undertakings of regional sales data formatted according to this structure.

*Article 2*

In any licensing agreements relating to the 1860 brick structure, any royalties to be paid for these licences shall be determined by agreement between IMS and the undertaking requesting the licence ("the parties").

If an agreement has not been reached within two weeks of the date of the request for a licence, appropriate royalties will be determined by one or several independent experts. The expert(s) will be chosen by agreement of the parties within one week of the parties' failure to agree on a licence fee. If an agreement on the identity of the expert(s) has not been reached within this time, the Commission shall appoint an expert or several experts from a list of candidates provided by the parties, or, if appropriate, choose one or several suitably qualified person(s).

The parties will make available to the expert(s) any document which the expert(s) consider necessary or useful to carry out their task. The expert(s) shall be bound by professional secrecy and shall not disclose any evidence or documents to third parties except to the Commission.

The expert(s) will make a determination on the basis of transparent and objective criteria, within two weeks of being chosen to carry out this task. The expert(s) will communicate this determination without delay to the Commission for approval. The Commission's Decision shall be final and take effect immediately.

*Article 3*

A penalty of €1000 per day shall be payable in respect of any period during which IMS fails to comply with the provisions of this Decision.

*Article 4*

The provisions of this Decision shall apply until notification of the decision concluding the proceeding.

*Article 5*

This Decision is addressed to IMS Health of Harewood Avenue, London NW1, United Kingdom.

Done at Stasbourg,

*For the Commission*

*[...]*

*Member of the Commission*