

COMPETITIVENESS AND DATA PROTECTION

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Introduction

1. What is the link?

The predominant policy of the EU is currently and for the years to come up to 2010 the Lisbon agenda. That is mainly, but not only, about competitiveness. European competitiveness becomes thus the driving European policy, although in the complex context of sustainability. If competitiveness is the goal, one of the keys to attain this goal is innovation: *“In advanced economies such as that of the EU, innovation is the principal determinant of productivity growth. In turn, competition and tax policy play a crucial role in determining innovation especially in the context of rapidly changing technology. By obtaining more output from given inputs, productivity growth can also make a significant contribution to ensuring that economic growth is increasingly environmentally sustainable”*¹. In its turn innovation depends on research and development (R&D): *“In advanced economies such as the EU, knowledge, including R&D, is a key driver of productivity growth. The EU invests about a third less in R&D*

¹ SEC (2005) 192, Brussels, 3.2.2005, Central Policy area 6 in **LISBON ACTION PLAN INCORPORATING EU LISBON PROGRAMME AND RECOMMENDATIONS FOR ACTIONS TO MEMBER STATES FOR INCLUSION IN THEIR NATIONAL LISBON PROGRAMMES**. Companion document to the Communication to the Spring European Council 2005 {COM (2005) 24}

than the USA – this is largely due to less private sector R&D. Annually the USA spends about €80 billion more on business R&D than the EU. More favourable framework conditions for both public and private R&D and better co-ordination across Member States and with the EU level could contribute to ensuring faster progress towards the target of 3% of GDP for R&D expenditure. In fact a strong competitive pressure provides powerful incentives for companies to continuously engage in innovation and R&D². If R&D is a prerequisite for innovation and if the latter is key to competitiveness the assumption is that Data Protection (meaning here protection of proprietary, business data and not personal data) is a stimulus for R&D for the very reason that thanks to the protection of data R&D companies get the necessary and indispensable guarantee that their expenditure will be compensated by the profits from the results of their R&D activities during the protected period. However, it is worth noting that in both above references the common denominator is the significance of competition policy in boosting R&D and, subsequently, innovation. Nonetheless, competition and data protection are by definition not compatible.

2. About data protection

- a. Data Protection in a regulatory environment is essentially different from other intellectual property or patent approaches. Intellectual property protection for patents concerns the protection of ideas, inventions, etc. that may be commercially exploited by the originator. An invention or idea can attract protection only once, and for a fixed period of time, after which the exclusive rights to it expire.

In a regulatory environment, the marketable item is a product, for which normal patent rights and other intellectual property rights apply. The main difference with Data Protection is that the regulator (national or other public authorities) requires the generation and submission of scientific or other data, before market access is granted as well as during the marketing of a product, whenever new regulatory requirements are adopted. Without prejudice to the existing patent and other intellectual property rights, the idea behind is that the initial and continued requirement for investing in knowledge requires commercial protection in order to prevent unfair competition. However, the antilog could be that data protection does not refer to any invention or innovation. Protected data are not the result of R&D. Their origin was not the intention to invent a new product. Simply, the reason for money being spent on Data Protection is to cope with regulatory safeguards pertaining to health and environmental considerations. In the era of corporate social responsibility every company should have the moral and legal obligation to prove the safety of its products. In fact Data Protection is not about R&D or innovation, but about testing new products prior to their introduction to the market. Certainly this is costly and it would be unfair from the competition point of view if others would be entitled to refer to these tests for their own benefit. But from the moment they

² SEC (2005) 192, see note 1, Central Policy area 5

would be willing to share the costs there should in principle not be any legal or moral impediment to them marketing products for which the same tests could serve as sufficient reference. Several arguments would militate in favour of that: reduction of costs, spare of human and other resources, thus increased competitiveness, better and more competition, hence better prices in the interest of consumers and, above all, transparency and the subsequent restoration of lost consumer confidence, thereby favouring overall competitiveness.

b. COUNCIL DIRECTIVE of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC) (*Official Journal L 230* , 19/08/1991 P. 0001 – 0032) (the Directive) provides in its article 13³ for the protection of the data required by member states

³ COUNCIL DIRECTIVE of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC)

Data requirements, data protection and confidentiality

Article 13

1. Without prejudice to Article 10, Member States shall require that applicants for authorization of a plant protection product submit with their application:

- (a) a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex III; and,
- (b) for each active substance in the plant protection product, a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex II.

2. By way of derogation from paragraph 1, and without prejudice to the provisions of paragraphs 3 and 4, applicants shall be exempted from supplying the information required under paragraph 1 (b) except for that identifying the active substance if the active substance is already listed in Annex I, taking into account the conditions of inclusion in Annex I, and does not differ significantly in degree of purity and nature of impurities, from the composition registered in the dossier accompanying the original application.

3. In granting authorizations, Member States shall not make use of the information referred to in Annex II for the benefit of other applicants:

- (a) unless the applicant has agreed with the first applicant that use may be made of such information; or

(b)

for a period of 10 years from first inclusion in Annex I of an active substance not on the market two years after the date of notification of this Directive; or

(c)

for periods not exceeding 10 years from the date of the decision in each Member State and provided for in existing national rules, concerning an active substance on the market two years after the date of notification of this Directive; and

(d)

for a period of five years from the date of a decision, following receipt of further information necessary for first inclusion in Annex I, which has been taken either to vary the conditions for, or to maintain, the inclusion of an active substance in Annex I, unless the five-year period expires before the period provided for in paragraphs 3 (b) and (c), in which case the period of five years shall be extended so as to expire on the same date as those periods.

4. In granting authorizations, Member States shall not make use of the information referred to in Annex III to the benefit of other applicants:

- (a) unless the applicant has agreed with the first applicant that use may be made of such information; or

(b)

for a period of 10 years from first authorization of the plant protection product in any Member State, where authorization follows the inclusion in Annex I of any active substance contained in the product; or

(c)

for periods not exceeding 10 years and provided for in existing national rules after the first authorization of the plant protection product in each Member State, where that

to be submitted by applicants for authorization of a plant protection product (PPP)/active substance with their applications, while article 14⁴ provides for the confidential treatment of

authorization precedes inclusion in Annex I of any active substance contained in the product.

5. Member States, on examination of an application for authorization, shall inform the Commission of instances where they consider an active substance to be listed in Annex I, which has been produced by a person or manufacturing process other than those specified in the dossier on the basis of which the active substance was first included in Annex I. They shall transmit to it all data regarding the identity and impurities of the active substance.

6. By way of derogation from paragraph 1, for active substances already on the market two years after notification of this Directive, Member States may, with due regard for the provisions of the Treaty, continue to apply previous national rules concerning data requirements as long as such substances are not included in Annex I.

7. Notwithstanding paragraph 1, and without prejudice to Article 10, where the active substance is listed in Annex I:

(a) applicants for authorization of plant protection products shall, before carrying out experiments involving vertebrate animals, enquire of the competent authority of the Member State to which they intend making application:

- whether the plant protection product for which an application is to be made is the same as a plant protection product for which authorization has been granted, and
- as to the name and address of the holder or holders of the authorization or authorizations.

The enquiry shall be supported by evidence that the prospective applicant intends to apply for authorization on his own behalf and that the other information specified in paragraph 1 is available;

(b) the competent authority of the Member State, if satisfied that the applicant intends to apply, shall provide the name and address of the holder or holders of previous relevant authorizations and shall at the time inform the holders of the authorizations of the name and address of the applicant.

The holder or holders of previous authorizations and the applicant shall take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals.

Where data is requested with a view to inclusion in Annex I of an active substance already on the market two years after notification of this Directive, the competent authorities of the Member State shall encourage data holders to cooperate in the provision of the requested data, with a view to limiting the duplication of testing on vertebrate animals.

If, nevertheless, the applicant and holders of previous authorizations of the same product can still not reach an agreement on the sharing of data, Member States may introduce national measures obliging the applicant and holders of previous authorizations located within their territory to share the data with a view to avoiding duplicative testing on vertebrate animals and determine both the procedure for utilizing information, and the reasonable balance of the interests of the parties concerned.

⁴ Article 14

Member States and the Commission shall, without prejudice to Council Directive 90/313/EEC of 7 June 1990 on the freedom of access to information on the environment (6), ensure that information submitted by applicants involving industrial and commercial secrets is treated as confidential if the applicant wishing to have an active substance included in Annex I or the applicant for authorization of a plant protection product so requests, and if the Member State or the Commission accepts that the applicant's request is warranted.

Confidentiality shall not apply to:

- the names and content of the active substance or substances and the name of the plant protection product,
- the name of other substances which are regarded as dangerous under Directives 67/548/EEC and 78/631/EEC,
- physico-chemical data concerning the active substance and plant protection product,
- any ways of rendering the active substance or plant protection product harmless,
- a summary of the results of the tests to establish the substance's or product's efficacy and harmlessness to humans, animals, plants and the environment,

information submitted by applicants that involves industrial and commercial secrets. In this way the Directive distinguishes between the former –they are granted limited but automatic protection, both in time, as well as their disclosure is concerned, in the sense that “*Member States shall not **make use of the information ... for the benefit of other applicants***” – and the latter -they are granted unlimited but conditional (“*if the Member State or the Commission accepts that the applicant’s request is warranted*”) protection. In this regard, it has to be noted that there is a grey/overlapping area between the two, since an applicant can reasonably invoke the former as industrial and/or commercial secrets. Moreover, it is worth of pointing out that the Directive does not refer to any specific legal basis in relation to articles 13 and 14 except in two recitals; the first ⁵ pleads for an exception from the prohibition of use of submitted data when it comes to the protection of vertebrate animals used for experimental and other scientific purposes; the second ⁶ establishes the availability among member states on request of the particulars and scientific documentation submitted in connection with applications for authorization of PPP.

In view of the foregoing an evaluation of the data protection will first be attempted (A); the compatibility of the Directive with Treaty provisions will follow(B); there is equally need for clarification of notions such as the access to file and the rights of defence, as well as business secrecy and confidentiality (C) versus transparency, before a conclusion (D) is drawn as far as the reason of being of the system on Data Protection and its relationship to similar notions, such as intellectual property under the patent system are concerned.

- recommended methods and precautions to reduce handling, storage, transport, fire or other hazards,
 - methods of analysis referred to in Articles 4 (1) (c) and (d) and 5 (1),
 - methods of disposal of the product and of its packaging,
 - decontamination procedures to be followed in the case of accidental spillage or leakage,
 - first aid and medical treatment to be given in the case of injury to persons.
 If the applicant subsequently discloses previously confidential information, he shall be required to inform the competent authority accordingly.

⁵ “Whereas resources devoted to the conduct of tests on vertebrate animals should not be dissipated as a result of the differences in the laws of the Member States and whereas considerations of public interest and Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (4) militate against needless repetition of tests on animals;”

⁶ “Whereas it is in the interests of free movement of plant products as well as of plant protection products that authorization granted by one Member State, and tests carried out with a view to authorization, should be recognized by other Member States, unless certain agricultural, plant health and environmental (including climatic) conditions relevant to the use of the products concerned are not comparable in the regions concerned; whereas to this end there is a need to harmonize the methods of experimentation and control applied by the Member States for the purpose of granting authorization;
 Whereas it is therefore desirable that a system for the mutual supply of information should be established and that Member States should make available to each other on request the particulars and scientific documentation submitted in connection with applications for authorization of plant protection products;”

A. The pathology of the data protection system

The original Directive 91/414 introduced a harmonised system of Data Protection, resembling mainly the systems already existing and implemented in the Member States. The system follows a simple but logical system: when data are requested, either when a new product is introduced in the market, or when the dossiers for existing products need to be “upgraded” in order to comply with the latest regulatory requirements, all authorisation holders alike are obliged to generate and submit the same data, unless they agree on sharing the cost of data-generation and submission, and become “co-owners” of the data. The exception is in some countries the generation and submission of data with vertebrate animals where, in order to avoid unnecessary duplication of animal tests, data holders can be obliged to give access to their data (after agreement on a compensation for the cost, if necessary under arbitration). Except in the case of animal tests, the fixed period is established during which only the owner of the data has access to these data, in order to support his authorisations.

However, the system as presented is showing major problems in its implementation: in the first place because the text of the Directive leaves too much room for interpretation. Secondly, because the “Data Protection Guidance Document” presents ambiguous explanations of the text of the Directive. One key factor that contributes to the confusion is the fact that the transition from pre-existing national systems towards a harmonised system was not well thought through. The Directive has created a system whereby the majority of data must be submitted at EU level, but Data Protection must be implemented at national authorisation level. The EU submissions result in an Annex I inclusion, which in itself does not allow market access, and can therefore not be considered as “proprietary”. The national authorisations rely both on the data submitted at EU level and data subsequently submitted at national level. Especially for existing substances/products it has become extremely complicated to establish whether or not such data have already exhausted their period of Data Protection. Data may have been already used in one Member State but not in another and may have different remaining periods of Data Protection under national legislation. The Rapporteur Member State has no insight into the previous use of data in other Member States, and the subsequent Annex I inclusion only presents a list of “studies for which Data Protection has been claimed”. Interpretation on the previous use of data and their remaining right on Data Protection remains a topic of discussion, and is interpreted differently in the different Member States.

B. Legal basis in the Treaty establishing the European Community (TEC)

According to article 284 TEC *“The Commission may, within the limits and under conditions laid down by the Council in accordance with the provisions of this Treaty, collect any information and carry out any checks required for the performance of the tasks entrusted to it”*. This article applies particularly to the Commission -and not to other Institutions- and its scope is the collection of information and the conduction of checks for the performance of its tasks. However, when these tasks, i.e. tasks with a community dimension like the authorization of PPP under the Directive, are entrusted to the member states, the national administrations are in this case acting as extensions of the Commission and, thus, they are covered by article 284 TEC. From this point of view it constitutes the legal basis of article 13 of the Directive although it is not mentioned at all in its preamble. As the Court of Justice of the European Communities (CJEC) has confirmed, article 284 TEC can as such be the legal basis for an action by the Council (CJEC C-426/93, Germany v. Council, R. 1995, I-3723, 16). This is also the case with Regulation 17 ⁷in the competition field; although it regulates the investigation rights of the Commission, it does not refer to article 284 TEC. Subsequently, despite the non reference, article 284 TEC constitutes anyway the legitimacy of *“the conditions laid down by the Council”* in the Directive.

However, article 284 TEC does not grant unlimited discretion in the collection of information and the carriage out of checks. On the contrary, since it is bound to go hand in hand with its counterweight, i.e. article 287 TEC: *“The members of the institutions of the Community, the members of the committees, and the officials and other servants of Community shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components”*. Needless to clarify that national officials are also covered by this obligation directly (*“the members of the committees”* who are mostly national civil servants is an additional indication⁸) and not only by national legislation. According to the CJEC the obligation of professional secrecy extends beyond the cases in which the public authorities are exercising their duties and/or rights and covers also the cases of voluntary disclosure of information on the condition of confidentiality⁹. More particularly, in the case of undertakings, Regulation 17 provides in article 20 (2) that *“...the Commission and the competent authorities of the Member States, their officials and other servants shall not disclose information acquired by them as a result of application of this Regulation and of the kind covered by the obligation of professional secrecy”*. Furthermore, the CJEC has judged that information given by undertakings to the Commission at its request, which is not published, can not be used as means of proof by the member states when they apply national

⁷ JO 1962, 13/204 OJ 1959-62, 87, as am. By Reg. 1216/1999, OJ 1999 L/148/5

⁸ N.Mackel, in *“Commentaire article par article des Traités UE et CE”* sous la direction de Ph. Léger, Helbing & Lichtenhan, Dalloz, Bruylant, 2000, p.1852

⁹ CJEC C-145/83, Adams v. Commission, 7.11.1985, Rec. p. 3539, 34

or community competition rules¹⁰. Finally, although the article 287 TEC does not foresee any sanction, the infringement of the professional secrecy obligation can give rise to a damages claim according to article 288 (2) TEC¹¹; also, the Regulation 259/68 on the Statutes of EC officials¹² foresees the imposition of disciplinary measures (art. 86) in the case of non respect of professional secrecy (art. 17)¹³; more specifically, the lack of discretion by the members of the Commission may way, according to articles 213 and 216 TEC, to their dismissal.

All in all, the respect of professional secrecy is a rule of constitutional character; the obvious reason of this status is the key role of the respect of this obligation for the effective implementation of competition rules; any secondary legislation –derived community law- has to be in conformity with article 287 TEC; the same applies to national legislation due to the primacy of community law. Besides, when it comes to undertakings and business secrets, the obligation of professional secrecy becomes even stronger, since it is then combined with major objectives of the TEC, such as the functioning of a free market under undistorted competition conditions, getting, thus, upgraded to the level of a general principle of community law¹⁴.

C. Access to file-Business Secrecy and Confidentiality

As already pointed out, next to the TEC, in the competition field Regulation 17 requires the Commission and the competent authorities of the member states to comply with their obligation of professional secrecy (article 20)¹⁵. The obligation to protect business secrets is only mentioned in article 19 (3) and article 21 (2)¹⁶. “However, the latter Articles are merely examples of a general principle of Community law to protect confidential information”¹⁷.

¹⁰ CJEC C-67/91, *Asociacion Espagnola de Banca Privada*, R. 1992, I-4785

¹¹ CJEC 145/83, *Adams v. Commission*, R. 1985, 3539

¹² OJ L 56, 4.3.1968

¹³ 15th Report on Competition Policy (1985), points 50-51

¹⁴ See, among others: Ch. Bolze, *Régime communautaire de l'entreprise*, RTDcom., 1996.383; N.M. Hunnings, *The Stanley Adams affair or the Biter Bit*, CMLRev., 1987, 65; J. Swaw, *The use of information in competition proceedings*, ELRev., 1993, 154

¹⁵ Article 20

Professional secrecy

1. Information acquired as a result of the application of Articles 11, 12, 13 and 14 shall be used only for the purpose of the relevant request or investigation.

2. Without prejudice to the provisions of Articles 19 and 21, the Commission and the competent authorities of the Member States, their officials and other servants shall not disclose information acquired by them as a result of the application of this Regulation and of the kind covered by the obligation of professional secrecy.

3. The provisions of paragraphs 1 and 2 shall not prevent publication of general information or surveys which do not contain information of undertakings

¹⁶ Article 19

Hearing of the parties and of third persons

1. Before taking decisions as provided for in Articles 2, 3, 6, 7, 8, 15 and 16, the Commission shall give the undertakings or associations of undertakings concerned the opportunity of being heard on the matters to which the Commission has taken objection.

2. If the Commission or the competent authorities of the Member States consider it necessary, they may also hear other natural or legal persons. Applications to be heard on

In fact, as it comes out from the rich case-law of the CJEC in competition cases:

- a) The Commission's procedures are administrative. Nonetheless, the CJEC has stressed that "necessity to have regard to **the rights of the defense** is a fundamental principle of Community law which the Commission must observe in administrative procedures which may lead to the imposition of penalties under the rules of competition laid down in the Treaty"¹⁸. Failure to observe the rights of defense may lead to the annulment of the decision¹⁹.
- b) The most fundamental aspect of the rights of defense is **the right to be heard** (see, Reg. 17, art. 19 par. 1). The CJEC has held that observance of the right to be heard requires: "*...that the undertaking concerned must have been afforded the opportunity, during the administrative procedure, to make known its views on the truth and relevance of the facts and circumstances alleged and on the documents used by the Commission to support its claim that there has been an infringement of the Treaty*"²⁰.
- c) **Access to the file** is complementary to the right to be heard, not only because it enables a defendant to comment on the documents relied on by the Commission but because it encompasses the right to see exculpatory documents that may assist the defense in making its case on an equal footing with the Commission's case against it. Failure to give proper access therefore infringes the rights of the defense and is a

the part of such persons shall, where they show a sufficient interest, be granted.

3. Where the Commission intends to give negative clearance pursuant to Article 2 or take a decision in application of Article 85 (3) of the Treaty, it shall publish a summary of the relevant application or notification and invite all interested third parties to submit their observations within a time limit which it shall fix being not less than one month.

Publication shall have regard to the legitimate interest of undertakings in the protection of their business secrets.

Article 21

Publication of decisions

1. The Commission shall publish the decisions which it takes pursuant to Articles 2, 3, 6, 7 and 8.

2. The publication shall state the names of the parties and the main content of the decision; it shall have regard to the legitimate interest of undertakings in the protection of their business secrets.

¹⁷ Marc Brealey, "Business secrecy and confidentiality" in Procedural Aspects of EC Competition Law, edited by The Rt. Hon. The Lord Slynn of Hadley and Spyros A. Pappas, EPPA 1995, p. 68

¹⁸ CJEC 322/81, Michelin v. Commission, 1983, ECR 3461

¹⁹ Belamy & Child, European Community Law of Competition, Sweet & Maxwell 5th ed 2001, §§ 12-121

²⁰ CJEC 100/80, Musique Diffusion Française v. Commission, 1983, ECR 1825

ground for annulment of the Commission's decision²¹. In the Soda Ash cases²² the CFI referred to the right of access to the file in the context of "the general principle of equality of arms" and held that it was irrelevant that the Commission had considered the documents to see whether they were exculpatory; the Commission should have given the undertakings the opportunity to examine the documents and make their own appraisal.

Until 1991, as a matter of law, the defendant had no right to have the full file made available to him. In 1997, the Commission published a Notice²³ on the access to the file that draws a distinction between "communicable" and "non-communicable" documents. The latter fall into the following categories:

- Internal Commission documents
- **Business secrets.** Business secrets are "information of which not only disclosure to the public but also mere transmission to a person other than the one that provided the information may seriously harm the latter's interests"²⁴. In this way the Commission has to reconcile the protection of business secrets with the principle of access to the file and the public interest in having the infringement of the competition rules terminated. To this end the Commission assesses (i) the relevance of the information to determining whether or not an infringement has been committed; (ii) its probative value; (iii) whether it is indispensable; (iv) the degree of sensitivity involved (to what extent disclosure would harm the interests of the firm; and (v) the seriousness of the infringement. In *Postbank v. Commission*, the CFI held that if business secrets are transmitted to third parties, the Commission "must make such transmission subject to an appropriate procedure intended to safeguard the legitimate interests of the undertakings concerned in not having their business secrets disclosed".
- Other confidential documents: Even if information is not a business secret, it may nonetheless be confidential to the undertaking concerned. The Commission may also have obtained information or documents from undertakings on condition that they remain confidential²⁵. In principle, such documents will be made available if they are either inculpatory or exculpatory²⁶.

²¹ CJEC 24/62, *Germany v. Commission*, 1963, ECR 63, 69; T-24/93, *Compagnie Maritime Belge Transports v. Commission*, 1996, ECR II-1201

²² Case T-30/91, *Solvay v. Commission*, 1984, ECR 883; T-36/91, *ICI v. Commission*, 1995, ECR II-1775 and 1847

²³ OJ 1997 C23/3

²⁴ Case T-353/94 *Postbank v. Commission*, 1996, ECR II-921

²⁵ CJEC 310/93P *BPB v. Commission*, 1995, ECR I-865

²⁶ *Bellamy & Child*, supra n. 16, § 12-047

d) On the basis of existing statements of the CJEC and the CFI the legal position as regards access to documents on the file might be described in the following series of propositions²⁷:

- The Commission, the competent authorities of the member states and their officials and servants, by virtue of article 20 (2) of Regulation 17, **must not disclose information** “of the kind covered by the obligation of professional secrecy”²⁸. This provision has to be read with article 287 TEC; **The concept of “professional secrecy” covers both the confidential information and business secrets**; “business secrets” are “*information of which not only disclosure to the public but also mere transmission to a person other than the one that provided the information may seriously harm the latter’s interests*”²⁹, but the scope of “confidential information” remains indeterminate³⁰. Subsequently, the obligation of professional secrecy includes, but extends beyond, the protection of “business secrets”³¹.
- If it is necessary for **the proper conduct of the investigation**, i.e. for the proper exercise of the right to be heard, the Commission may communicate to another party to the proceedings information or documents, other than business secrets, of the kind covered by professional secrecy³².
- **Reconciling the obligation of professional secrecy with the right to be heard** the Commission is obliged to give the undertakings concerned access to all documents used by the Commission to support its claim that there has been a breach of the competition rules³³.
- This does not however mean that the Commission is obliged to show the undertakings concerned all the documents which are in its possession³⁴.
- Except when the Commission relies on them as proof of the objections being made against the undertakings concerned, the Commission **should not**

²⁷ Christopher Kerse, “Access to file”, in Procedural Aspects of EC Competition Law, supra n. 14, p. 57

²⁸ Interpretative letters of the Commission to the US authorities (OJ 1995 L95/45) and to the Canadian Government (OJ 1999 L175/59)

²⁹ see Postbank supra n.22

³⁰ Commission in Cartoonboard, OJ 1994, L243/1: The obligation of professional secrecy extends to all information obtained from the undertakings under Reg. 17 “except that which is so trivial that is not worthy of consideration.

³¹ Ballamy & Child, supra n. 16, § 12-059

³² CJEC 53/85, AKZO v. Commission, 1986, ECR 1965

³³ CJEC 85/76, Hoffman-La Roche & Co. AG v. Commission, 1979, ECR 461

disclose documents which contain business secrets or are otherwise subject to rules of confidentiality whose purpose is to protect other undertakings or individuals³⁵. However, even when the Commission relies on confidential documents, it is not entitled to disclose the entirety of a document containing business secrets but only public versions of it, i.e. after elimination of the sensitive information³⁶. Thus, the Commission must not disclose the business secrets of one undertaking to another save in accordance with a procedure that safeguards the legitimate interest of undertakings in the non-disclosure of their business secrets; in particular, the undertaking concerned must be given an opportunity to state its views, and in particular to indicate the nature of the damage that that disclosure could cause to it³⁷; in addition to that, before making any disclosure the Commission must give the undertaking adversely affected an opportunity to challenge the proposed disclosure before the Court³⁸.

- The Commission must make available **exculpatory documents**³⁹.
- The Commission does not have to make available **internal working documents** and certain other procedural steps such as the report of the Hearing Officer or the opinion of the Advisory Committee⁴⁰.
- A failure to disclose a document will only vitiate a decision if and to the extent that it is a document on which reliance is necessary as proof of the offense or is otherwise one whose failure to disclose would materially prejudice the decision-making process or rights of defense⁴¹.
- **Professional secrets** can be disclosed “in so far as it is necessary to do so for the proper conduct of the investigation”⁴². Thus the obligation of professional secrecy is subject to right of third parties to be heard.

e) On the contrary, there is a general principle of Community law that a complainant “may not in any circumstances be given access to documents containing **business**

³⁴ CJEC 56 & 58/64, *Constern and Grundig v. Commission*, 1966, ECR 299

³⁵ Case T-7/89, *S.A.Hercules NV v. Commission*, 1992

³⁶ Art. 21 (2) of Reg. 17 requires the Commission to respect business secrets and the Commission’s published decisions omit business secrets.

³⁷ *Postbank*, supra n. 22

³⁸ *AKZO*, supra 30

³⁹ *Hercules*, supra n. 33

⁴⁰ *Hercules*, supra n. 33; CJEC 100-103/80, *Pioneer Musique Diffusion Française and Others v. Commission*, 1983, ECR 1825

⁴¹ CJEC 107/82, *AEG-Telefunken v. Commission*, 1983, ECR 3151

⁴² CJEC 53/85, *AKZO v. Commission*, 1986, ECR 1965

secrets⁴³. In other words, the Commission should not disclose business secrets to a complainant. It is also a general principle of Community law that the Commission should not disclose to the defendant business secrets communicated to the Commission by a complainant or a third party. The corollary is that the Commission cannot rely as against the defendant on the information that has been provided to it, but not disclosed to the defendant⁴⁴. Also, the Commission cannot rely on confidential information in any appeal proceedings if this has not been disclosed to the defendant. In contrast, the Commission can rely on confidential information communicated to it by the defendant in order to reject a complaint⁴⁵. **Thus, in relation to business secrets, the obligation of professional secrecy takes precedence over the right of third parties to be heard.** As the CJEC stated⁴⁶ *“The Commission cannot rely on the provisions of Article 19 and 20 of that regulation (17) to justify passing on the information to third parties who are making complaints. Article 19 (2) gives the latter a right to be heard and not a right to receive confidential information”*.

D. Conclusion

In the discussions on solutions for the Data Protection issue several suggestions have been made, many of them ignoring the real cause of the problems in implementation, and exclusively focusing on the periods of protection, or the rules for previous use of the data. Some of the more specific suggestions frequently heard are the following:

a. The age of the data

A suggestion has been made to radically change the key-parameter for the right to exclusive use of data: instead of the previous use of data/studies for regulatory purposes, the age of the study becomes the key-factor. Depending on how specific parameters are set, this approach might provide a pragmatic solution that favours neither data-owners nor second parties wishing to have access to such proprietary data. The argument that the exclusive use of data is justified because they have been generated and submitted in order to comply with regulatory requirements can be considered to be covered by this approach: if studies are

⁴³ AKZO, supra n. 30

⁴⁴ CJEC 107/82, AEG v. Commission, 1983, ECR 3151

⁴⁵ As the Commission stated in BAT and Reynolds (C-142 and 156/1987, ECR 4487, “...the companies which are the object of the investigation and the companies which have submitted an application under Article 3 of Regulation 17/62, having shown that they have a legitimate interest in seeking an end to the alleged infringement, are not in the same procedural situation and the latter cannot invoke the right to a fair hearing as defined in the cases relied on”.

older than a certain age (longer for first submission than for later “upgrading” of a dossier) it can be assumed that they have been generated for another purpose, and therefore do not constitute an investment made for the continued marketing of the product. The approach solves the key obstacle for implementation of a feasible Data Protection: it can be centrally decided which data are eligible for Data Protection, and fixed periods for such protection can be established and implemented. Also lists of protected data can be made available at an early stage in the review process, allowing generic producers to negotiate access with data owners, or to generate their own data in time for post Annex I review. Depending on the age criteria chosen, some studies that are currently eligible for Data Protection will lose their protection, and *vice versa*. Such a novel basis for protection does require specific transition measures.

If the current basis for protection (previous use of data) is to be maintained, it requires a thorough administration of each submitted and used study, in each of the Member States. At EU level, the only parameter that needs to be established for each study is whether or not it concerns “necessary data”. Subsequently, in the (re-) authorisation stage, each Member State will have to establish whether or not the necessary data have been previously used as the basis for a regulatory decision, prior to Annex I inclusion. This approach does not require specific transition measures.

b. Forced Data Compensation

It has been suggested that the discussions on Data Protection can be solved by introducing forced data-sharing. This principle had already been introduced at Member State level in order to avoid the unnecessary duplication of animal-testing. As such, forced data-sharing is a generally accepted principle⁴⁷, although industry opposes that the ownership of regulatory data does not prevent others to generate similar data and use them for regulatory purposes. However, the reasons to try and reduce duplication of studies, and the submission of multiple studies seem to be sustainable arguments:

⁴⁶ CJEC 209-215 and 218/78, FEDETAB v. Commission, 1980, ECR 3125

⁴⁷ See the *Ruckelshaus v. Monsanto Co.* case relates to the protection of data submitted for the registration of an agrochemical product. Though a subsequent applicant was obliged to compensate for the use of Monsanto’s original data, Monsanto argued that such use undermined its reasonable “investment backed expectations” and was unconstitutional. A basic argument of the plaintiff was that the possibility given to a competitor of using the data against payment of compensation nullified its “reasonable investment-backed expectation”. However, the Supreme Court described the extensive practice of relying on data submitted by the first applicant in the United States, and rejected Monsanto’s complaint. The Supreme Court considered that Monsanto could not have had a reasonable, investment-backed expectation that the Environmental Protection Agency (EPA) would keep the data confidential beyond the limits prescribed in the amended statute itself. Monsanto was on notice of the manner in which EPA was authorized to use and disclose any data turned over to it by an applicant for registration.

- To avoid unnecessary duplication of animal tests (vertebrate animals). This is more or less/virtually undisputed.
- To facilitate the evaluation-process by Regulatory Authorities: however, this is contradicted by the provision in the Directive that a fee can be requested from applicants, representative of the real cost of evaluation. Therefore, when studies are repeated by more than one applicant, the cost of additional evaluation is covered by the fees.

c. Solutions?

Prior to any proposal, a number of things need to be well understood and separated:

1. What are the criteria that decide if a study is protected?
2. How long is a study protected?
3. What are the criteria that oblige a Member State to verify if an application for a new authorisation can rely on a complete data-set, or to verify if existing authorisations do still rely on such data-set?

If one sticks to the logic of the ongoing discussion, the key elements for a functioning and fair Data Protection system could be the following:

- Decide at EU level (Annex I inclusion) which data are necessary, and which of those data are protected. Age of studies, rather than their previous use, is a workable and fair solution: if studies are older than a certain age, it can be safely assumed that they were not generated in the first place to comply with the regulatory requirements for which they are submitted.
- After Annex I inclusion, introduce a rapid verification system to force Member States to check existing authorisations for their access to necessary data. If no such access can be demonstrated by the authorisation-holder, and no data to cover missing protected necessary data can be provided at Member State level, authorisations should be revoked.
- For Annex I renewal, a data call-in system should be established, by which a Rapporteur Member State proposes a list of necessary data for Annex I renewal; such proposal is to be confirmed by the Standing Committee, and published. Thus, all interested parties have equal opportunities to safeguard their continued marketing and where possible to form Taskforces for the generation of data. Also,

there will be no discussion later in the process with regard to completeness of the submitted renewal data-package.

- Any new Data Protection system should contain transitional measures that allow introduction as early as possible. The current system is unworkable to such an extent that any new system must and can be introduced in the current review process. Especially because most of the problems with regard to Data Protection concern existing substances, and because the implementation of Data Protection does not take place until after Annex I inclusion, there is no reason to delay introduction of a better functioning system. In fact, consideration should be given to the option of introducing a new system for Data Protection prior to the revision of the Directive.

d. A different approach

It has been shown that Data Protection does not refer to cases of patentability but rather to the so called undisclosed information. It has also been shown that undisclosed information is protected when it comes to business secrets, confidential documents and to the obligation of professional secrecy. Besides, at present, the balance is clearly in favor of the protection of confidential information both before the Commission and the Courts. **Under no circumstances can business secrets be disclosed.** The absolute nature of the protection of all confidential information appears from the judgments in *Stanley Adams v. Commission* and *BPB & British Gypsum v. Commission*⁴⁸. As a consequence, since the protection of confidential information is absolute, the Commission does not have any discretion to disclose such information in the public interest (e.g. where the information is essential to found a case)⁴⁹.

The obvious reasons for which the CJEC and the CFI gave to the protection of business secrets such an **absolute character**, despite the lack of clarity in the secondary Community law, is based on the one hand to the article 287 TEC, but merely, I would say, on the very *raison d'être* of the European Community according to the preamble of the TEC, i.e. "the constant improvement of the living and working conditions" of the peoples of the member states, the essential objective of the European construction, that in its turn is based on "a system ensuring that competition in the internal market is not distorted" (article 3 (1g) TEC).

⁴⁸ 1993, 5 CMLR 32 at par. 29-35

Thus, if there is to be a **counterweight**, it must lie in the definition of what is confidential and secret; the narrower the definition, the less likely that the balance is tipped too much in favor of protecting confidential information. However, as explained above, the criteria for determining what constitutes a business secret have not yet been defined in full. Relevant criteria are those in the AKZO and the BAT & Reynolds judgments, as well as in the anti-dumping procedures⁵⁰. In their light the term “business secret” must be construed in its **broader sense**: according to AKZO, Regulation 17 requires the Commission to have regard to the legitimate interest of firms in the protection of their business secrets.

All of that is reflected in the most recent secondary legislation enshrined in the Merger Regulation⁵¹: while article 17 provides for the obligation of professional secrecy, in paragraph 3 of article 18 “Hearing of the parties and of third persons” it is stipulated that “...*The rights of defence shall be fully respected in the proceedings. Access to the file shall be open at least to the parties directly involved, subject to the legitimate interest of undertakings in the protection of their business secrets*”. In this way precedence is clearly given to the protection of business secrets.

Finally, it should also be borne in mind that the TRIPS Agreement Article 39.2 protects undisclosed information -- trade secrets or know-how. To this end, undisclosed information requires: one, commercial value (no need for a form of property) and, second, reasonable steps to keep it secret. The TRIPS Agreement also addresses undisclosed test data and other data whose submission is required by governments as a condition of approving the marketing of pharmaceutical or agricultural chemical products, which use new chemical entities.

In such a situation the Member government concerned must protect the data against disclosure and unfair commercial use. Member governments must protect such data,

- except where necessary to protect the public,
- unless steps are taken to ensure that the data are protected against unfair commercial use.

All in all, “...policy makers have always had to strike a **tricky balance**. A balance between creating incentives for innovation through private rights *and* serving society’s interest in the dissemination of knowledge through the limitation of these private rights. As intellectual property is a privatisation, albeit temporary, of knowledge in order to reward innovation, the

⁴⁹ Marc Brealey, supra n. 15, p. 71; see also above p. 7 under “business secrets”

⁵⁰ Order of the Court of 30.3.1982, 1982 in Case 236/81, Celanese v. Commission and Council, 1982, ECR 1183

⁵¹ Reg. 4064/89, as amended by Reg. 1310/97, OJ 1997 L180/1, corr. By OJ 1998 L40/17

whole debate is indeed to get this balance right....More concretely, there are two challenges in my view: delivering global public goods and responding to the demands of development. While some people consider that patents on pharmaceuticals prevent access for all to the newest and most effective treatments, others point to the fact that, without patents, it is unlikely that any treatment would have been developed at all. On one hand, we have a moral obligation to provide health care, on the other hand, we have to encourage innovation in the pharmaceutical sector....So what am I trying to demonstrate through all these examples? That without global rules, we cannot expect often contradictory objectives to coexist and deliver an optimal result for society. And that these global rules must be established in a world where societal choices, political values, in other words what I often refer to as collective preferences, largely differ....

The TRIPs agreement is, in my view, a first component of an emerging system of global governance in the field of knowledge and technology, alongside other institutions dealing with development, trade, IP and technology transfer. However, there is still a large gulf between the stated objective of TRIPs, *i.e.* a world where everybody can benefit from innovation and knowledge, and the reality on the ground. Without well-developed global governance, a global regime of IPR will remain difficult to implement to the benefit of all⁵².

Taking into account the analysis above, the conclusion cannot be different than the following one: to the extent that the undisclosed information pertains to business secrets the limited protection of regulatory data for PPP under the Directive and in particular the time limits in the protection granted by article 13 do not seem to be compatible with the TEC and the relevant case-law of the Courts. In fact, numerous reasons militate to the qualification of some of these regulatory data as business secrets besides the fact that the extraordinary costs for their production are also a determinant consideration: they reflect a business strategy and a special know-how exclusive to the applicant company; under this angle regulatory data may constitute "business secrets". As such, they should benefit from absolute protection as this is the case for all other business secrets. Consequently, data for PPP, either required by public authorities or voluntarily submitted, should be treated, if so requested and evidenced by the applicant company, as a business secret. The same applies even when regulatory studies with vertebrate animals are required. The logic of competition does not allow watering down its foundations –one of which is the

⁵² Extracts from SPEECH/04/327 Pascal Lamy, former EU Trade Commissioner "The TRIPs agreement 10 years on", International Conference on the 10th Anniversary of the WTO TRIPs Agreement Brussels, 23 June 2004, Intellectual property has become a global political issue

protection of business secrets- on the basis of whatever other “reasonable” considerations. Besides, the constitutional legitimacy of the business secrets protection means that the latter prevails over any other legitimate objectives which are not, however, based on the TEC. In this case, all subsidiary and subsequent problems from the implementation of the Directive, like the differentiation between data for Annex II and data for Annex III, or the extent of the prolongation in case of continuation etc would automatically be resolved (or by-passed) and the system, as a whole, would become simpler and more effective thanks to its clarity and firmness. Nonetheless, this not being the case with the Directive and since it has not yet been challenged before the Courts, its amendment offers an opportunity to redress wrong assumptions. To this end the basis of the debate and the direction of the consultation with the Commission should radically change **from an evolutionary to a revolutionary approach**. Instead of trying to find an unsatisfactory compromise between the main notifiers and generic companies agreeable to the Commission and later on to the EP and Council, it is opportune to draw the line there where it is drawn by the TEC and the jurisprudence of the Courts. At the same time, industry could and should take the initiative of tabling a Code of Conduct/Deontology dealing with all ethical issues, such as the studies with vertebrates animals. For instance, already the Directive in force contains an incentive for an auto-regulation when providing for the possibility of an agreement with the first applicant that use of the data is made by other applicants; it could become the backbone philosophy of the Code when it comes to other questions, like the studies with vertebrate animals. Besides, the Code should develop a reliable system for the checking of its implementation and the imposition of penalties. In this way a regulatory tool would be coupled with an auto-regulation and both could coexist, complementing each other or, more correct, the Code could match with the Directive in a coherent and simplified manner.

In any event, the new approach cannot and should not overlook the global nature of the issue, as well as civil society’s recent role in the new European Governance concept. In fact, when addressing the question of Data Protection in plant protection products there are two prevailing, yet conflicting, considerations:

- i. Transparency, as enshrined in article 255 of the Treaty establishing the European Community (TEC) and further detailed by Regulation 1049/2001.
- ii. Data protection with the view of ensuring fair competition and stimulate research with the view of strengthening European competitiveness.

Ø In fact Regulation 1049/2001, although merely regarding public access to documents it recognizes the obligation, as acknowledged by the CJEC, to protect business secrets without time limit. According to article 4 §§ 2, 4, 6 and 7 “2. The institutions shall **refuse access** to a document where disclosure would undermine the protection of:
- **commercial interests** of a natural or legal person, including **intellectual property** ...4. As regards third-party documents, the institution shall **consult the third party** with a view to assessing whether an exception in paragraph 1 or 2 is applicable, unless it is clear that the document shall or shall not be disclosed...6. If **only parts** of the requested document are covered by any of the exceptions, the remaining parts of the document shall be released.
7. The exceptions as laid down in paragraphs 1 to 3 shall only apply for the **period** during which protection is **justified** on the basis of the content of the document. The exceptions may apply for a maximum period of **30 years**. In the case of documents covered by the exceptions relating to privacy or commercial interests and in the case of sensitive documents, the exceptions may, if necessary, continue to apply **after this period.**”

The principles deriving from this Regulation are as follows: Access to commercial interests (including intellectual property) is not allowed for a reasonable period to be determined in consultation with the owner of the data, which can be extended beyond the maximum period of 30 years.

Ø The most recent translation of these principles into legislation is Regulation 1831/2003. According to article 18 “Confidentiality,
1. **The applicant** may indicate which information submitted under this Regulation he wishes to be treated **as confidential** on the ground that its disclosure might significantly harm his **competitive** position. Verifiable reasons must be given in such cases.
2. The Commission shall determine, after consultation with the applicant, which information other than that specified in paragraph 3 should be kept confidential and shall inform the applicant of its decision.
3. The following information shall not be considered confidential:
(a) name and composition of the feed additive and, where appropriate, indication of the production strain;
(b) physico-chemical and biological characteristics of the feed additive;
(c) the conclusions of the study results on effects of the feed additive on human and animal health and on the environment;
(d) the conclusions of the study results on effects of the feed additive on the

characteristics of animal products and its nutritional properties;

(e) methods for detection and identification of the feed additive and, where applicable, monitoring requirements and a summary of the results of the monitoring.

4. Notwithstanding paragraph 2, the Authority shall, on request, supply the Commission and Member States with all information in its possession, including any identified as confidential pursuant to paragraph 2.

5. The Authority shall apply the principles of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (20) when handling applications for access to documents held by the Authority.

6. The Member States, the Commission and the Authority shall keep confidential all the information identified as confidential under paragraph 2 except where it is appropriate for such information to be made public in order to protect **human health, animal health or the environment**. Member States shall handle applications for access to documents received under this Regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.

7. If an applicant withdraws or has withdrawn an application, the Member States, the Commission and the Authority shall respect the confidentiality of commercial and industrial information, **including research and development information**, as well as information on which the Commission and the applicant disagree as to its confidentiality". Next to this provision, article 20 deals more specifically with data protection: "1. The **scientific data** and other information in the application dossier required under Article 7 may not be used for the benefit of another applicant for a period of **10 years** from the date of authorisation, unless the other applicant has agreed with the previous applicant that such data and information may be used.

2. In order to stimulate efforts to obtain authorisations for minor species for additives whose use is authorised for other species, the 10-year data protection period shall be extended by one year for each minor species for which a use extension authorisation is granted.

3. The applicant and the previous applicant shall take all necessary steps to **reach agreement** on sharing the use of information, in order not to repeat toxicological tests on vertebrates. If, however, no such agreement is reached on sharing the information, **the Commission may decide to disclose information necessary to avoid repeating toxicological tests on vertebrates, while ensuring a reasonable balance between the interests of the parties concerned**.

4. On the expiry of the 10-year period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the Authority for the benefit of another applicant".

Conclusion: The existing legislative literature is plenty of inconsistencies as far as the existence in parallel of patentability according to the intellectual property system, business secrets and confidential documents and finally Data Protection are concerned; the complexity is even bigger if one considers the coexistence of national, European and International (WTO) regulations. In the case of Data Protection a simplification could lead to the distinction between business secrets and the other data part of which could be qualified as intellectual property (formulation recipe, manufacturing process etc.); the remaining, that cannot be qualified either as business secrets or intellectual property, could be protected for a reasonable period in order to protect the fair functioning of the market while public access should be allowed since it comes to health and safety. The above regulation might inspire the amendment of Directive 91/414. Scientific information can be referred to only after a protection period of 10 years except the data requiring toxicological tests on vertebrates on the condition that an agreement is reached between the parties, as well as except each time there is contribution to the costs by every company wishing to make reference to the data. The calculation of the contribution should reflect the real costs, as well as the investment risk, and could be auto-regulated. This latter procedure might be generalised for all scientific data while the Commission would remain the final judge. In this way, commercial interests would be covered by the TEC protection and for all remaining data the system would remain flexible in such a way as to lead to a disclosure only if the owner gets satisfaction by the interested party or, if not, having the possibility to argue why (on grounds of economic and business reasons) protection should be granted for a reasonable period which could vary depending on the circumstances, but which could never be longer than 10 years.