



EGA Position Paper

TRIPS Article 39.3 Does not require Data Exclusivity Provisions

A critical issue for access to medicines

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The EGA represents over 400 companies in Europe
dedicated to the production and supply of affordable generic medicines.

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TRIPS Article 39.3 does not require Data Exclusivity Provisions: A critical issue for access to medicines

1. Summary

Article 39.3¹ obliges WTO Member States to protect clinical data made for registration purposes against "acts of unfair competition". Certain pharmaceutical companies are now claiming that Article 39.3 requires the introduction of "data exclusivity" provisions as operated in the EU or USA.

However, "exclusivity" and "protection from acts of unfair competition" are not the same and should not be confused.

Data exclusivity² prevents the regulatory authority from making reference to the original clinical data for a set period, during which no authorisation of generic medicines may take place. Data exclusivity, therefore, provides a form of market exclusivity. However, what Article 39.3 requires is a form of data protection so as to prevent unfair commercial use of the data by third parties. The intention of the Article 39.3 is not to create a form of market protection.

The reason that certain companies are seeking an interpretation of Article 39.3 as meaning "data exclusivity" is to gain market protection for pharmaceutical products that are not covered by product patents. Such an interpretation would of course create a major barrier to access to medicines in many countries. Moreover, since Article 39 has no time limitation, the effect of such an interpretation would be to provide an unlimited market protection against generic applications for an un-patented product. This is clearly not the intention of TRIPS.

The interpretation that Article 39.3 requires data exclusivity is clearly beyond the agreed terms of TRIPS. It also undermines the basic objective of the Agreement as outlined in Article 7, i.e. to seek the enforcement of intellectual property "in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

In addition, arguments have been made that data exclusivity laws preventing the exclusivity periods from extending beyond the period of a patent (as are operated in 3 EU Member States) are incompatible with TRIPS. However, since Article 39.3 does not relate to data exclusivity, there is in effect no impact of TRIPS on such laws. This is important for several Accession countries, which are seeking to introduce such linkage laws upon accession to the EU.



2. The Purpose of TRIPS Article 39.3 - preventing unfair competition

Article 39.3 cannot be viewed in isolation from the whole of TRIPS Article 39 which is devoted to effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention.

In order to understand the nature of TRIPS Article 39.3, the difference between the "repression of unfair competition" and other forms of intellectual property protection should be understood. This difference is made clear by WIPO when it states:

*"Industrial property deals principally with the protection of inventions, marks (trademarks and service marks) and industrial designs, and the repression of unfair competition. The three subjects first mentioned have certain features in common inasmuch as protection is granted for inventions, marks and industrial designs in the form of exclusive rights of exploitation. The repression of unfair competition is not concerned with exclusive rights, but is directed against acts of competition contrary to honest practices in industrial or commercial matters, for example, in relation to undisclosed information (trade secrets)."*³

A clear definition of unfair competition, and the examples of unfair competition, is provided by WIPO.⁴

"The repression of unfair competition is directed against acts or practices, in the course of trade or business, that are contrary to honest practices, including, in particular:

- *Acts which may cause confusion with the products or services, or the industrial or commercial activities, of an enterprise;*
- *False allegations which may discredit the products or services, or the industrial or commercial activities, of an enterprise;*
- *Indications or allegations which may mislead the public, in particular as to the manufacturing process of a product or as to the quality, quantity or other characteristics of products or services;*
- *Acts in respect of unlawful acquisition, disclosure or use of trade secrets;*
- *Acts causing a dilution or other damage to the distinctive power of another's mark or taking undue advantage of the goodwill or reputation of another's enterprise."*



3. Article 39.3 - confidentiality of data in relation to generic applications

Clearly, no parts of Article 39, including Article 39.3, create a "property" in information nor create "exclusive rights" of any kind, as is the case with EU and US data exclusivity laws. What Article 39.3 requires is that the data submitted is either protected against disclosure or protected against "unfair commercial use".

The last paragraph of Article 39.3 is quite clear: *"In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use"*.

Consequently, Article 39.3 cannot prevent a regulatory authority from using/relying on the data of a registered product in order to assess and register other "similar" products - so long as this information is not disclosed to the third party e.g. a generic manufacturer.

The difference between "data exclusivity" and "data protection" can in fact be seen in the regulatory practices of the EU. The EU operates 6 or 10-year data exclusivity periods during which the regulatory authority may not rely on the originator's data. However, after expiry of this period, during which no generic applications are assessed, commercially sensitive data still remains undisclosed to third parties.

The differences are also well argued by the Hungarian Patent Office. Mihály Ficsor, Head of Legal and International Department states that:

*"It has to be taken into account that the whole Article [Article 39] is devoted to effective protection against unfair competition as provided in Article 10bis of the Paris Convention. Therefore Article 39.3 of the TRIPS Agreement cannot be interpreted in such a way as to mean that Members are required to establish a special legal regime for the protection of undisclosed tests or other data submitted for the regulatory approval of pharmaceutical products. This is clearly only an option open to Members. Nevertheless, Members are no less free to choose other means of ensuring that such data be protected against unfair commercial use. Those means may include the application of general rules against unfair competition, in particular those protecting trade secrets (undisclosed information). This interpretation is further justified by the reference Article 39.1 of the TRIPS Agreement makes to Article 10bis of the Paris Convention. Hungary has opted for a solution of this kind by relying on Article 4 of the Hungarian Competition Act (ACT NO LVII of 1996 on the Prohibition of Unfair Market Practices and the Restriction of Competition). The provisions the Article comply, in full, with all the requirements following from Article 39 of the TRIPS Agreement."*⁵



The point is also stressed by Professor Carlos Correa of the University of Buenos Aires, who has assisted the WHO in the area of health perspectives on TRIPS Agreement. Professor Correa wrote in 1999:

"The protection conferred to data submitted for the marketing approval of the product (in accordance with Article 39.3) of the TRIPS Agreement has been another problematic issue in some countries. The Agreement does not oblige to recognize any kind of exclusivity on data submitted for approval, since the protection should be granted under the discipline of "unfair competition"... Once data on a new drug have been submitted, their use by a national health authority to study and approve a subsequent application on the basis of similarity, does not entail a violation of the confidentiality obligation under the Agreement".⁶

Moreover, it must be stressed that clinical information which is often claimed to be protected under both art. 39.3 and data exclusivity does not in fact meet the basic conditions indicated in Article 39. It is important to note that Article 39.2 sets the conditions/criteria to qualify/define certain information as "undisclosed information". Point (a) clearly states that confidential information "is secret in the sense that it is not ... generally known or readily accessible to persons ... " However, the information and data about the pharmaceutical and therapeutic property of certain pharmaceutical products are widely published; thus they represent part of "public knowledge". Therefore, it cannot be claimed that when a generic producer shows that their product is bioequivalent to the originator, he has used "undisclosed information". To the contrary, generic producers only use the generally known information and do not use the protected information of the originator.

4. Previous statements by the European Commission and holders of pharmaceutical patents show that Article 39.3 is not Data Exclusivity

It is important to note that documentation from the Transatlantic Business Dialogue held in Berlin at the end of 1999 also shows that Article 39.3 does not mean data exclusivity.

The European Commission position paper on Intellectual Property under the heading "Data Protection" (note not "Data Exclusivity") states that:

"The TRIPS Agreement requires countries to protect such data against unfair commercial use" (emphasis added).

Significantly during these discussions the European and US originator pharmaceutical industry are cited as calling for:



"a common position" between the EU and the USA that "TRIPS Article 39.3. means non-reliance by governments on the originator's data for a fixed time i.e. 10 years".

Similarly, The international Federation of Pharmaceutical Manufacturers Associations (IFPMA) in its own paper "Industry Objectives for the WTO Millennium Round of October 1999" states that

"Should the TRIPS agreement be discussed in this Round, the industry would propose that the text be clarified and strengthened in several ways:

A Ten Year Right of Data Exclusivity should be instituted for the propriety and costly business information, such as the data files compiled by the pharmaceutical companies for application for drug regulatory approval."

In other words, the EU and US originator industry itself recognizes that Article 39.3 does not at present provide for data exclusivity and are asking for TRIPS to be changed. The European Commission indicated during the TABD that it supports the overall recommendation of the originator industry to enhance the protection of undisclosed test and other data and indicated that it was prepared to raise this issue in the future Millennium Round, i.e. that it would constitute part of new negotiations under TRIPS.

5. EU Accession and Data Exclusivity

Countries seeking EU accession will of course be required to introduce data exclusivity through the adoption of Council Directive 65/65/EEC as amended by Directive 87/21/EEC.

However, as is well known, there is no harmonised data protection period and Member States operate one of three periods:

- 10 year data exclusivity period
- 6 year data exclusivity period
- 6 year data exclusivity which does not extend beyond patent protection⁷

It should be stressed that EU data exclusivity only covers the first authorization of a medicinal product and cannot be given for additional indications, strengths or dosages.⁸

These provisions only need to be effective as from date of accession of a new Member.



6. Linking Data Exclusivity to Patent Life is compatible with TRIPS since Article 39.3 is not Data Exclusivity

Finally, arguments have also been raised that linking data exclusivity to patent life - as is provided for under EU law - is in breach of TRIPS since they are two separate rights and one right should not be used to limit another. However, linking data exclusivity to patents is possible under TRIPS because, as this paper has demonstrated, data exclusivity itself is not provided for in TRIPS. Moreover, the linkage does not limit the rights of the patent but only the length of the data exclusivity period. Consequently, the three EU countries, which operate the linkage (i.e. Greece, Portugal and Spain), and the Accession countries in Europe, which have indicated their intention to have this link upon EU accession, are completely in line with their TRIPS obligations.

7. Conclusion

It is clear that TRIPS Article 39.3 does not require the implementation of EU/US type data exclusivity provisions for pharmaceutical products. The purposes of seeking to interpret Article 39.3 as meaning "data exclusivity" - as opposed to meaning protecting data against "unfair competition" - is an attempt to extend "exclusive marketing rights" to pharmaceutical products which are not in fact covered by product patents in TRIPS. The proposed interpretation is therefore beyond the agreed terms of TRIPS and would, if applied in many countries, have a major negative impact on access to health and the development of local generic pharmaceutical companies. In addition Article 39.3, because it does not relate to data exclusivity, does not impact on existing EU law, which allows EU Member States to prevent data exclusivity from going beyond the patent period.

¹ The full text of Article 39 is as follows:

Article 39

1. *In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.*

2. *Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices¹ so long as such information:*

(a) *is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;*

(b) *Has commercial value because it is secret; and*



(c) *has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.*

3. *Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use*

² Under EU law data exclusivity is granted to cover the information submitted for the first authorisation of a medicinal product based on a full dossier i.e. the Chemical, Pharmaceutical and Biological Documentation, Toxicological and Pharmacological Tests and Clinical Documentation required for the approval of a new medicinal product. Additional protection is not granted for any new data relating to any subsequent variations such as changes in indications, dosages, and strengths.

³ See WIPO Website <http://www.wipo.org>

⁴ See WIPO Website <http://www.wipo.org>

⁵ Extract from a paper presented at the International Conference on Pharmaceutical Patents and Intellectual Property in EU Accession Countries, Budapest, and 14-15 October 1999. Importantly, Dr. Ficsor goes on to say that:

Furthermore the current Hungarian practice in this regard is also in line with paragraph 4 of Article VI of the US-Hungary Agreement on Intellectual Property and its protocol concerning regulatory approval of products. Paragraph 4 of that Protocol reflects the Parties' agreement that the following procedure is in conformity with the provisions of paragraph 4 of Article VI of the Agreement, (which are substantially identical to those conditions in Article 39.3 of the TRIPS Agreement): "When applying for an application for marketing approval of a generic product, the applicant (the second submitter) can prove the equivalence of its own product, while referring to the original document if needed. When deciding on the approval of the second application, the competent authority bases its decision on the examination of the documentation attached to this application. During the procedure the authority in question does not reveal any information in any form on the documentation of the original product."

⁶ Recent Developments in Intellectual Property Law on Pharmaceuticals. Dr. Carlos M. Correa, University of Buenos Aires, May 1999.

⁷ The data exclusivity periods of EU Member States are as follows:

10 years B, D, F, I, NL, S, UK

6 years A, DK, FIN, IRL, LUX

6 years not beyond patent E, GR, PT

⁸ It should be noted that data exclusivity is 5 years in Australia, New Zealand and the USA. In the USA certain innovative indications may be granted 3 years.