THE EUROPEAN OMBUDSMAN

P. NIKIFOROS DIAMANDOUROS

S2009-103197

Dr Peter C. Gøtzsche
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The Nordic Cochrane Centre, Dept. 3343
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DANEMARK

Strasbourg, 21-04-2009

Complaint 2560/2007/BEH

Dear Dr Gøtzsche and Mr Jørgensen,

On 27 February 2009, EMEA sent its reply to my friendly solution proposal which I forwarded to you for your information on 10 March 2009. Considering that further inquiries were necessary in your case, on 10 March 2009 I asked EMEA for further clarification in relation to certain issues. EMEA sent its reply on 7 April 2009.

Please find enclosed EMEA's replies to my friendly solution proposal as well as my request for further clarification.

If you wish to make any observations on EMEA's replies, please send them to me before 31 May 2009.

Please note that if I do not receive any observations from you, I may close the case with a decision based on the information that you have already provided and the submissions received from EMEA.

Yours sincerely,

P. Nikiforos DIAMANDOUROS

Annex: 2

The European Ombudsman
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2560/2007/BEH

European Medicines Agency
Executive Director

London, 7 April 2009
Doc. Ref.: EMEA/213195/2009

Mr. P. Nikiforos DIAMANDOUROS
The European Ombudsman
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Re: Complaint 2560/2007/BEH

Dear Mr. Diamandouros,

Thank you for your letter dated 10 March 2009 where, *inter alia*, you requested the EMEA to clarify the relevance of Article 39 (1) and (3) of the TRIPs agreement, which reads as follows:

1. "In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* 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."

3. "Members, when requiring, as a condition of approving the marketing of pharmaceutical (...) products which 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."

As already outlined in our first reply to the European Ombudsman, Article 39 of the TRIPs is the only provision enforceable in the EU legal system, and therefore also binding for the EMEA (being the European Communities part of the TRIPS), which expressly foresees a specific legal obligation to protect undisclosed data in the framework of the procedure for the approval of medicinal products.

In its communication on "*The relationship between the provisions of the TRIPs agreement and access to medicines*", submitted by the European Communities and their Members States to the TRIPs Council on 12 June 2001 (IP/C/W/280), the EC highlights that: "The view ctaken by the EC and their Member States is that the Agreement does contain an obligation to protect test data against 'unfair commercial use'" (document attached for your convenience).

For this reason, it is the EMEA view that the concerned provision has to be deemed as *lex specialis* in respect to Article 3 (2) (a) of the EMEA rules for implementation of Regulation 1049/2001. This Article only foresees a general exception to the principle of transparency whenever the disclosure of a document would undermine the protection of commercial interests, without specifying the framework of applicability.

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The EMEA made reference to article 39 of TRIPS as an additional legal basis applicable to the Agency in the framework of access o documents requests. This provision is indeed applicable to the case at stake, given the content of the request of the applicant and the nature of the information contained in the relevant documents

On the other hand, as indicated by the Ombudsman, the EMEA, on the basis of the example given by the EIB could have the possibility of granting a private access to the documents.

The EMEA, has taken into careful consideration the suggestions made by the Ombudsman and would like to clarify the following aspects.

Transparency is a public right and so it is regarded by Regulation (EC) 1049/2001. According to the interpretation of the Regulation, once a document is released to a single applicant, it is considered of public domain. As known, Regulation (EC) 1049/2001 foresees that, as a general principle, the Institutions and bodies of the EU should grant access to the documents they hold and that, only in some fixed limited cases (foreseen by article 4), they have the legitimate right to refuse access. The legislation does not foresee a third option of a so called "private access" and therefore granting a private access to some documents would imply entering, every time, into a confidentiality undertaking with the requesters and creating unequal treatment conditions towards different categories of applicants. In view of the fact that this possibility is not indicated by Regulation (EC) 1049/2001 and that considering the number of requests addressed to the Agency, entering a confidentiality agreement with every applicant, would imply a big effort in term of human resources and workload, the EMEA is not considering the proposed solution as a viable one.

Moreover, it has to be noted that the documents requested by the complainants not only contain commercially confidential information but also substantial amounts of personal data of the person involved in the clinical trials, hence the need for reduction of the concerned document in case of possible disclosure, which in the present case comprises more than 500 volumes of documentation (approximately 300-400 pages per volume) corresponding to 29 studies. As extensively described in our letter dated 28 February 2009, the redaction of the document, would involve long and complex work which would cause the Agency a disproportionate effort in terms of time and resources, that would be inevitably devoted to this exercise and would divert attention from the core business activities as foreseen by Article 57 Regulation (EC) 726/2004.

I trust the Ombudsman would consider the position of the Agency as in compliance with the obligation set by the applicable rules on access to documents.

Yours sincerely,

Thomas Lönngren
Executive Director

Annex:

EC communication on "*The relationship between the provisions of the TRIPs agreement and access to medicines*", submitted by the European Communities and their Members States to the TRIPs Council on 20 June 2001 (IP/C/W/280),

WORLD TRADE ORGANIZATION

IP/C/W/280
12 June 2001

(01-2903)

Council for Trade-Related Aspects of Intellectual Property Rights

Original: English

COMMUNICATION FROM THE EUROPEAN COMMUNITIES AND THEIR MEMBER STATES

The following communication, dated 11 June 2001, has been received from the European Communities and their member States with the request that it be circulated to Members.

THE RELATIONSHIP BETWEEN THE PROVISIONS OF THE TRIPS AGREEMENT AND ACCESS TO MEDICINES

BACKGROUND

1. At the last session of the TRIPS Council (2-5 April 2001), the Africa Group proposed that one day be set aside at the June session to clarify the interpretation and/or application of certain provisions of the TRIPS Agreement. The discussion is intended to examine the relationship between intellectual property and access to medicines and will seek to bring clarity regarding the interpretation and the application of the provisions of the Agreement which provide scope for Members to address public health concerns. The European Communities (EC) and their member States, together with most other delegations, welcomed and supported this initiative. It is an important development, since it will be the first time that the TRIPS Council discusses intellectual property issues in the context of public health.

2. In view of the urgent need to fight communicable diseases, the EC and their member States have already taken a number of initiatives in the area of access to affordable medicines for developing countries. On 14 May 2001, the Council of Ministers endorsed the Commission's comprehensive Programme for Action targeted at the combating of the major communicable diseases. The Council's Resolution focuses on three main goals: maximising the impact of existing interventions, increasing the affordability of key pharmaceuticals, and increasing investment in research and development of specific global public goods.

3. The main objective of EC development policy, as set out in COM (2000) 212 of 26 April 2000, is to foster sustainable development with a view to eradicating poverty in developing countries and to integrating them into the world economy. It is now clear that certain strategic interventions, if implemented effectively, have the potential to reduce disease and suffering and promote prosperity, thereby contributing to a more secure world for all. However, major communicable diseases, such as HIV/AIDS, malaria and tuberculosis, continue to act as a brake on human development.

4. For this reason, the European Commission adopted, in September 2000, a new policy framework set out in its Communication entitled 'Accelerated action targeted at major communicable diseases within the context of poverty reduction' (COM (2000) 585 of 20 September 2000). This was

followed up by a 'High-level Round Table' held in Brussels on 28 September 2000[1], and by a Resolution of the Council on 10 November 2000 (Doc 13127/00, Annex II), which called on the Commission to draw up an action plan.

5. The Commission proceeded to develop a Programme for Action on accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction over the next five years. The Programme for Action (COM (2001) 96 was adopted by the Commission on 21 February 2001 (see website http://www.cc.cec:8082/comm/development/sector/social/health_en.htm).

6. The EC and their member States recognise that the lack of affordable pharmaceuticals is a serious problem in many developing countries and especially for the poorest people.

RELEVANCE OF INTELLECTUAL PROPERTY

7. The EC and their member States consider that intellectual property rights provide an essential stimulus for creativity and innovation. These rights need to be adequately protected in order to encourage, for example, investment in research and development of new medicines, and particularly those targeted at the major communicable diseases.

8. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which emerged from the Uruguay Round negotiations has, however, sometimes been criticised as limiting policy options in relation to public health concerns. In the view of the EC and their member States, the Agreement's objectives, principles and purpose (set out in **Articles 7** and **8**), special transitional arrangements and other provisions give these countries a sufficiently wide margin of discretion in implementing it. This margin enables them to set up an intellectual property regime that meets their policy needs and is capable of responding to public health concerns. The EC and their member States have declared their willingness - most notably in the Programme for Action - to promote discussions, within the WTO, WIPO and WHO, to address the link between the Agreement and public health protection issues.

This Communication summarises the views of the EC and their member States on some of the relevant provisions of the Agreement.

COMPULSORY LICENSING

9. In a number of areas, the TRIPS Agreement can be seen as allowing Members a certain degree of discretion in the manner in which they implement it. Compulsory licensing (or 'other use without the authorisation of the right holder') is one such area.

10. Since **Article 31** of the Agreement does not specify the grounds on which compulsory licences may be granted, a number of reasons, *inter alia* those of public health, may legitimately be cited. The Article simply lays down certain procedural safeguards which have to be respected on those occasions when such licences are issued: for example, it is required that a voluntary licence be requested before a compulsory one is issued, and that the patent-holder be paid adequate remuneration. It is important to note, though, that the requirement to first try and obtain a voluntary licence can be waived in the following cases: i) in a national emergency, or other circumstances of extreme urgency; ii) where the subject matter of the patent is required for public non-commercial use.

[1] The Round Table was convened by the European Commission under the aegis of the French Presidency of the European Union, and was co-sponsored by WHO and UNAIDS. The proceedings may be consulted at http://europa.eu.int/comm/development/sector/social/health_en.htm

11. However, some have claimed that Article 31 is hedged around with too many procedural restrictions for it to be of use to developing countries who might wish to resort to compulsory licensing in order to obtain access to patented medicines at affordable prices.

The EC and their member States consider that procedural safeguards are important to guarantee legal security. Article 31 nevertheless leaves some flexibility in cases of national emergency and other circumstances of extreme urgency, or when the subject matter of the patent is required for public non-commercial use. Although Article 31 does not itself contain tailor-made solutions to any specific problem raised in the debate on access to health, it does leave WTO Members the freedom to determine the grounds for granting compulsory licences, provided the terms of the Article, and of other provisions of the Agreement, are met, and it allows for swift action in case of emergency or extreme urgency.

12. The lack of any explicit reference to public health is said to make countries wary of using the Article for fear of provoking expensive litigation. This has led to calls for a declaration, or perhaps a recommendation to the General Council, to clarify what phrases such as 'national emergency' and 'public non-commercial use' can be interpreted as referring to. As for the level of HIV/AIDS infection reported in some developing countries, there would appear to be very good reasons for describing it as a 'national emergency' or as a 'circumstance of extreme urgency'.

The view of the EC and their member States is that the absence of any explicit reference to public health in Article 31 does not prevent WTO Members from invoking public health concerns. Article 7 ('Objectives') refers to 'social and economic welfare' as an objective of the Agreement while Article 8 ('Principles') allows Members to take measures necessary to protect public health, provided such measures are consistent with the provisions of the Agreement. Although Articles 7 and 8 were not drafted as general exception clauses, they are important for interpreting other provisions of the Agreement, including where measures are taken by Members to meet health objectives.

13. Article 31 has been further criticised for requiring that goods manufactured under a compulsory licence be 'predominantly for the supply of the domestic market of the Member authorising such use.' This provision is sometimes said to prevent a small country that has no production facilities of its own from obtaining cheap medicines from abroad under a compulsory licence. This is an important argument as the Agreement does not appear to offer any legal certainty on the issue. What can be said is that a WTO Member is free to grant a compulsory licence for the importation of goods which are under patent in its own territory, as long as the imported goods have been produced in a country where they are not patented, or where the term of protection has expired. However, the EC and their member States also point to another possible interpretation of the Agreement (see DG Trade website http://www.cc.cec:8082/comm/trade/pdf/med_lic.pdf) that would allow a Member to issue a compulsory licence to a manufacturer in another country, provided the government of that other country recognised the licence (which it would not be obliged to do under the Agreement), and provided that all the goods manufactured under the licence were exported to the country granting the licence. It should be noted, however, that it is far from certain whether such a 'permissive' reading of the Agreement would stand scrutiny by a panel or the Appellate Body.

The EC and their member States are ready to discuss this matter in order to reach consensus on this issue among all WTO Members.

EXCEPTIONS TO PATENT RIGHTS

14. Article 30 of the TRIPS Agreement ("Exceptions to Rights Conferred") also leaves a certain degree of discretion to WTO Members as regards its implementation. It allows for limited exceptions to the exclusive rights conferred by a patent, provided they are: 1) limited; 2) not unreasonable; and 3) do not prejudice the legitimate interests of the patent holder or of third parties.

The EC and their member States consider that Article 30 amounts to a recognition that the patent rights contained in Article 28 ('Rights Conferred') may need to be adjusted in certain circumstances. The provisions of Article 30 should be fully respected, and be read in the light of Articles 7 and 8 (referred to above). They should not be interpreted as allowing for any substantial or unjustified curtailment of patent rights. However, the EC and their member States are not opposed in principle to exceptions being made, for example, for purposes of research, provided of course that such exceptions are non-discriminatory.

PROTECTION OF UNDISCLOSED INFORMATION

15. Further clarification of Article 39.3 could also be useful in the context of the debate on access to drugs. This provision obliges WTO Members to protect undisclosed test or other data against unfair commercial use, when those WTO Members require submission of such data, the origination of which involves considerable efforts, as a condition of approving the marketing of pharmaceutical products.

Indeed, a new medicine normally has to go through a series of safety tests before it is granted marketing approval. The question then arises as to whether the resulting test data can be relied on by the regulatory authority years later when reviewing an application for marketing approval for a generic version of the medicine, thus avoiding the need for the applicant to submit new data and speeding up commercialisation of the generic medicine in, for example, developing countries.

The view taken by the EC and their member States is that the Agreement does contain an obligation to protect test data against 'unfair commercial use', and that the most effective method of doing so is to deny the regulatory authorities the possibility of relying on such data for a reasonable period of time. Furthermore, data protection should be available whether or not the product subject to regulatory approval is protected by patent or not, since data protection is quite a different issue from patent protection.

16. Concern has been expressed in some quarters that such an interpretation could render compulsory licensing ineffective, because it would oblige the licensee to produce its own test data in order to obtain a separate marketing approval, thereby delaying the arrival of the goods on the market.

The EC and their member States consider, though, that Article 39.3 neither obliges Members to have marketing approval procedures, nor does it prescribe what those procedures should be. The provision should certainly not be interpreted in such a way as to weaken or nullify Members' rights under other Articles of the Agreement, such as the 'fast track' procedure in case of emergency foreseen under Article 31(b), which is a recognition of the need, in certain circumstances, for compulsory licences to be given immediate effect.

CONCLUSION

17. The TRIPS Agreement represents a delicate balance between the interests of right-holders and consumers. The EC and their member States stand ready to contribute constructively to any debate concerning the interpretation of its provisions.

18. Moreover, the spiralling health crisis in the developing world has underlined the need for rapid action. The TRIPS Agreement has increasingly come under fire for allegedly standing in the way of developing countries' efforts to implement an effective public health policy. The EC and their member States take such criticisms seriously and stand ready to engage in a positive manner in the discussion, leading where necessary to clarification, of certain of the Agreement's provisions. This paper has focussed on Articles 7, 8, 30, 31 and 39, but Members may wish to discuss other provisions they consider to be relevant. The EC and their member States are also ready to discuss to what extent technical assistance can take into account health concerns.

19. Improving health at the same time as combating poverty requires a mix of complementary social, economic and health policies and practices. Health gains largely depend on using available resources in productive and efficient ways, as shown by the great strides made by some middle and low-income countries. Intellectual property rights play a role with regard to access to medicines. However, the TRIPS Agreement cannot be held responsible for the health crisis in developing countries, while it must not stand in the way for action to combat the crisis. The EC and their member States will continue to constructively and positively take part in the expanding global effort to develop a coherent and effective response to the health problems of the developing world.

Extremely

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