

KAREL DE GUCHT

MEMBER OF THE EUROPEAN COMMISSION

Brussels, 25. 05. 2010  
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Dear Mr. von Schoen-Angerer,

Thank you for your letter of 6 April 2010 expressing your concerns about the possible effects that intellectual property provisions likely to be proposed in the FTA negotiations with India may have on access to medicines.

First of all, let me reiterate that the Commission is fully committed to ensuring that people in the world's poorest countries can access affordable medicines. I hope that the following explanations can reassure you of our unwavering commitment to this.

I would like to be very clear that nothing in this agreement will prevent India from using compulsory licensing for manufacture and export of life-saving medicines to other developing countries in need.

To this effect, the Commission has already proposed a legally binding reference to the Doha Declaration on the TRIPs Agreement and Public Health stating furthermore that "nothing in this Agreement shall be construed as to impair the capacity of the Parties to promote access to medicines".

I would also like to clearly confirm that the agreement will not interfere with the trade of generic medicines in transit. I am sure you are aware of the ongoing revision of Regulation 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights. In this context, the Commission is ready to propose any modifications to the Regulation that may be necessary to clarify the procedures relating to generic medicines in transit to ensure that they are not unnecessarily affected when merely transiting the EU. This will also be reflected in the IPR chapter to be agreed with India.

In addition, your letter also refers to two other issues, data exclusivity and patent term extension. It is clear that on the one hand, an adequate protection on intellectual property in India is crucial to incite innovative industry for the development of new medicines and to enable EU generic companies to compete with Indian companies on a level-playing field. On the other hand, intellectual property protection must take into account interests related to public health protection.

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Patent term extension refers to a mechanism that exists in certain countries including the EU to compensate drug innovators for long delays, during patent life, for obtaining marketing approval. As a result of these delays, the product is often available in the market only several years after the patent application has been filed. Such measure may be appropriate in the EU where a patent can effectively be protected up to 15 years from the time the medicinal product receives marketing authorization – but not necessarily in a country like India. The issue of patent term extension was suggested for discussion in the negotiations. If our bilateral discussions confirm that the processing of marketing approval applications in India is not a major concern, then the EU would not pursue the issue of supplementary protection any longer. Preliminary information indicates indeed that market authorizations in India are handled in an expeditious manner.

Data exclusivity takes into account the fact that the development and marketing of a new medicine requires the originator to conduct extensive research and testing, which are very costly and often take more than 10 years to complete. The negotiations are still ongoing on this issue, but let me be very clear that we are ready to show the necessary flexibility here, and fully take into account the specificities of the Indian legal system, the policy developments on this issue within India, its developing country status and the role it plays with regard to production of essential generics for the developing world.

In case of public health needs, we would of course not object to exceptions to data exclusivity whereby the authorities would be allowed to base the authorisation to a second applicant on data provided by the first applicant, if this is necessary in view of ensuring access to medicines.

In conclusion, I think your concerns about access to medicines for people in the world's poorest countries are certainly legitimate but perhaps not fully founded with regard to the reality of the negotiations with India. The IPR chapter of the FTA with India is still under negotiation. Certain elements have been put on the table for discussion and the Commission together with India is looking into these elements in order to reach a final outcome which will satisfy both sides. Promoting access to medicines is an essential pillar of the Commission's policy on IPR and I assure you that it is also fully taken into account in the negotiations with India.

Yours sincerely,



Karel De Gucht