KAREL DE GUCHT
MEMBER OF THE EUROPEAN COMMISSION

Brussels, 160511
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Dear Commissioner, Andris,

Thank you for your letter of 18 April 2011, highlighting two issues which are indeed raising important questions both from a trade policy as well as from a development point of view, namely access to medicines in the context of the EU-India FTA, and the relationship between IPR and development policies more generally.

1. EU-India FTA

As regards the EU-India FTA I fully agree that we must ensure the Commission's position in this negotiation is in line with the commitment I have given in public that nothing in this agreement should undermine India's capacity to produce and export essential medicines for domestic use or other developing countries in need. And I would like to reassure you that I remain fully attached to this commitment.

With respect to the overall level of ambition on IPR, there is agreement with India that this is to be determined by both sides' legislative frameworks, i.e. that the FTA will reflect and consolidate both sides' legislative developments.

As regards data exclusivity in particular, you know that India's legislation at present does not provide for data exclusivity. A domestic debate is ongoing whether to introduce data exclusivity in India, but given the sensitivity surrounding this issue it appears unlikely that India will have introduced such system by the time of concluding the FTA. This means that in the context of this FTA, we will only ask India that any data exclusivity regime to be introduced by India should be applied in a non-discriminatory manner and satisfy the requirements of the TRIPS Agreement, so that European producers will also benefit from it.

Having said this, we continue to believe that access to medicines and protection of test data can and should coexist constructively through instruments such as compulsory licences or exceptions for public health needs. Further dialogue by all interested stakeholders should help to develop a common understanding on this matter. And we would certainly welcome any views from DG DEVCO as to how these two objectives can be achieved in a complementary manner.

Commissioner Andris Piebalgs
BERL 11/363

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As regards your proposal for a more formal process involving your and other services to discuss such issues, this is actually already addressed to a large extent in the context of the preparation of our Communication on a revised IPR strategy vis-à-vis third countries (further commented below), namely through the setting-up of a broad inter-service group in which DG DEVCO is also participating, and which already held two meetings. Even after the adoption of our Communication, my services will continue to hold regular meetings with other services concerned, in order (1) to discuss any relevant IPR issue having an international dimension which may arise, (2) to create consensus across the Commission where needed, and (3) to promote proactive exchange of information about new initiatives, so as to enhance their coherence.

2. *Relations between IPR and development policies*

Regarding the broader links between IPR and development, please rest assured that this is an issue which will be explicitly addressed in the Communication intended to be adopted by the Commission by the end of the year regarding a revised strategy for the protection and enforcement of IP rights in third countries. It should also be briefly referred to in the Communication being prepared on trade and development.

I fully agree with you that a careful balance needs to be found between the interests of (EU) right holders and those of developing countries and their people, while properly differentiating between different categories of developing countries (emerging, LDCs, etc.).

I also agree that, in addition to encouraging developing countries to strengthen their IPR legislation and enforcement mechanisms, there is a need to set up operational initiatives – e.g. regarding technical assistance and technology transfer – able to help these countries build capacity and develop skills conducive to an effective implementation of IPR policies. A large number of such operational initiatives[1] are currently being conducted by various DGs, including DG DEVCO and DG ENTR (not to mention Member States), and I look forward to collaborating with you in order to promote coherence and consistency in this field. The role of international institutions such as WIPO should certainly be considered in this perspective, although the crisis which WIPO had to face in recent years has been somewhat detrimental to its effectiveness.

I am aware that the UK has called for an extension of the TRIPs waivers for LDCs (2013/2016). A possible extension of these waivers merits some reflection and may have some benefits, but we believe that it is too early for the Commission to openly take a position at this moment in time, considering in particular the on-going DDA negotiations. Moreover, I am not in favour of a one-sided statement at the LDC-IV, or any other conference, as this would entail no benefits for the EU/Commission, other than the announcement in itself.

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[1] many of which are listed in our annual submission to the WTO (http://trade.ec.europa.eu/doclib/docs/2010/april/tradoc_146038.pdf); another submission specifically focuses on technology transfer to LDCs (http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146121.pdf)

Nevertheless, this is clearly an issue which we shall continue to analyse, and which we should further discuss with e.g. DG DEVCO. Furthermore, the Commission could perhaps address this question in its Communication on a revised strategy for the protection and enforcement of IP rights in third countries which should be adopted by end of the year, and which we are currently working on.

Finally, I confirm that we have never opposed and shall never oppose the use of TRIPs flexibilities by any developing country. Regarding the EU-India FTA, in particular, we have proposed an explicit reference to the Doha Declaration on the TRIPs Agreement and Public Health, *to clarify that the flexibilities granted by the TRIPs Agreement, especially as regards patents on medicines, will not be affected by the FTA.*

Yours sincerely,

Karel De Gucht