CATHERINE ASHTON
MEMBER OF THE EUROPEAN COMMISSION

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Dr Tido von Schoen-Angerer
Mrs Kris Torgeson
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Dear Dr von Schoen-Angerer, Mrs Torgeson,

Thank you for your letter of 12 February 2009 where you raise the recent detainment of generic medicines by the Dutch customs authorities.

Let us first underline that access to medicines is and remains one of the main priorities for the EU in order to support health policies in developing countries. This support involves both creating the right regulatory framework and EU funded projects and programmes.

The EU has therefore implemented various legal provisions to facilitate access to medicines. It has reaffirmed its attachment to the Doha Declaration on the TRIPS agreement and Public Health by implementing the waiver decision on compulsory licensing into Community legislation and by accepting (in November 2007) the Protocol amending the TRIPS Agreement, ahead of most WTO Members including most DCs.

In addition to this, the EU has also adopted a regulation on tiered-pricing which encourages European producers to significantly increase supplies of medicines at lower prices to developing countries.

In terms of funded projects, the EU has taken the initiative to launch a number of projects and programmes in developing countries from research to production, to procurement and to delivery, including quality control. That is the case, for example, of the EU Africa Clinical Trial Partnership with a financing frame of 800 million Euros and the contribution of the European Commission to the Global Fund for AIDS, Tuberculosis and Malaria of 672 million Euros since 2002.

Regarding the detainment of generic medicines by Dutch customs authorities, we understand your concerns as to the inter-relationship between measures to detect IPR infringements and the need to ensure trade in generic medicines to developing countries. However, let us first point out that the EU Member States Customs Authorities are fully entitled, including from the point of view of international law, to inspect goods in transit suspected to infringe IP rights so that, if need be, they can take measures to stop the traffic of potentially dangerous products, such as for example fake medicines.

Especially in the case of counterfeit medicines, which is a problem that mainly concerns developing countries, the EU considers it a duty to also prevent – to the extent possible – any adverse effects trade in such products could have on vulnerable populations in third countries. As a matter of fact, it is likely that EU customs actions on goods in transit have saved lives in final destination countries. In 2007, out of the 76 million counterfeit and pirated goods intercepted by the European customs, 40% were in transit. And the EU is not isolated in having adopted customs procedure for goods in transit. Notably other WTO-members apply border measures for goods in transit suspected to infringe intellectual property rights.

This being said, we fully concur with you that actions against counterfeit should not be at the expense of legitimate trade in generic medicines. However, in the case mentioned in your letter, the pharmaceutical products in question have not been seized or removed from trade by the customs authorities, but only temporarily detained, and then returned to their owner. Nothing in EU customs law would have prevented the owner of these goods to ship them further to their intended destination once they had been released by the customs authorities.

The EU is fully committed to ensuring the fluidity of trade in generic medicines to developing countries and fully subscribes to this objective. Let us therefore reassure you that the Commission will monitor the situation and remain attentive to any possible application of EU legislation that may lead to undue hampering of the legitimate trade in generic medicines or to the creation of legal barriers to prevent movement of drugs to developing countries. We will look further into this particular case in The Netherlands, and into any other case that may be reported, and see whether any conclusions should be drawn from such cases.

As you may be aware, the Commission has recently been invited by the Council to examine existing customs legislation, with a view to improving action against counterfeit products which are a danger to consumers[1]. The review, covering the basic legislation to protect intellectual property rights, is on-going and contributions from stakeholders are welcomed. One of the issues that must be taken into account concerns the need to ensure that our framework does not hinder the legitimate trade in (generic) medicines. We would therefore invite you to submit to us any contribution you would wish to make.

As regards the other questions raised in your letter, and in particular the EU's policy in terms of customs legislation and IPR enforcement including in the context of Free Trade Agreements, we refer to the annex to this letter which sets out in detail our approach to these issues.

Finally, our services are available to discuss these issues further, if needed.

Yours sincerely,

Catherine Ashton

László Kovács

[1] Council Resolution of 25 September 2008 on a comprehensive European anti-counterfeiting and anti-piracy plan (2008/C 253/01).

ANNEX

Compatibility of the EU customs legislation on IPR enforcement with TRIPS

The purpose of the enforcement of EU legislation on intellectual property rights (IPR) at the EU's borders is both to protect the legitimate interests of manufacturers and right holders, as well as the health, safety and expectations of consumers. The work of Customs has an incidence on consumers within the EU and elsewhere.

Customs in the EU have stopped several consignments of infringing IPR pharmaceutical products in transit to other countries. As an example, Belgian customs recently stopped a consignment of 600,000 anti-malaria pills coming from India and destined for Togo. In this case, customs were alerted by suspect packaging. Whilst the policy concerning access to medicines for all is not at all questioned, surely all stakeholders have an obligation to protect vulnerable populations from unscrupulous and potential life-threatening practices.

EU legislation (Council Regulation 1383/2003) provides for customs to detain goods suspected of infringing certain intellectual property rights, including patents, even when goods are in transit. Under the customs legislation, customs do not decide whether goods are infringing IPR. The general procedure is to detain goods, where there is a suspicion that there is an infringement and contact the right holder. It is then up to the right holder to pursue the matter through a court, under national provisions.

It is accepted that such a procedure may potentially cause a delay but the role of customs in IPR border enforcement is recognised by the WTO, as well as the World Customs Organisation. Regulation 1383/2003 contains strict time limits within which court proceedings must be initiated. The procedure is fully in accordance with the relevant TRIPS provisions, in particular Article 55, which sets out the time-limit of 10 working days for suspending the release of the goods, as well as the possible extension of a further 10 working days.

Additionally, if goods are detained on the basis of an unsubstantiated complaint the owner of the products may seek legal redress. Indeed, Regulation 1383/2003 is fully in line with WTO/TRIPS requirements, in terms of scope and coverage of customs intervention. TRIPS foresees that border enforcement measures may apply not only to imports of goods infringing any intellectual property right (including patents), but also to goods introduced into the customs territory or leaving that territory (including export, goods placed under a suspensive regime, goods placed in a free zone or free warehouse and goods in the process of being re-exported).

With regard to the shipments of medicines from India, the Dutch customs authorities *temporarily* detained the drugs in question whilst in transit, following requests by companies which had patent rights over the medicines in question in the Netherlands. In the specific case highlighted in the media, the goods were finally released after the right holder and the owner of the goods came to an agreement not to pursue the case. There is no reason to suggest that customs in the Netherlands acted outside the framework of the provisions outlined above. We would also underline that there is a clear distinction between the procedures for temporarily customs detention, as described above, and the seizure of goods. The latter requires a court decision and is not a decision taken by the custom services.

FTA policy as regards IPR enforcement

You have requested information about the content of the negotiation texts for a number of bilateral agreements, either under negotiation or concluded. For those agreements already concluded you will find the relevant information on the following link on the web site of DG Trade:

http://trade.ec.europa.eu/doclib/docs/2006/december/tradoc_111588.pdf

It is worth noting that, with the exception of the agreement with Cariforum, none of these agreements contains any specific provision on border measures. Even so the scope of the customs provisions with Cariforum does not include patents.

As for other agreements currently being negotiated, we cannot disclose the detailed content of these provisions since the negotiation texts are of a confidential nature and any disclosure would undermine our international economic relations with relevant negotiation partners.

However, the objective of an IPR section in our bilateral agreements is to ensure an adequate and effective level of protection of intellectual, industrial and commercial property rights and other rights covered by TRIPS in line with international standards, whilst reducing distortions and impediments to bilateral trade and fostering investment and economic development.

The approach proposed by the Commission regarding the IPR section in the bilateral agreements, is to clarify and complement the TRIPS where TRIPS is unclear, is not sufficiently detailed or simply has been overtaken by IP developments elsewhere. The Customs procedure in place in the EU has proven to be effective, balanced and with sufficient in-built guarantees to avoid abuse by bad-faith complainants. Therefore, the Commission is considering introducing similar provisions in the new generation of bilateral trade agreements. In any event, it should also be noted that that these agreements should also include provisions that stress and reinforce the letter and the spirit of the Doha Declaration on the TRIPS Agreement and Public Health.