

TRIPS Council 8-9 June 2009

Agenda item M – Other Business

Madam Chair,

My delegation would like to thank India and Brazil for their statements which give me once again the opportunity to further explain and clarify the EU position on this issue.

First of all let me confirm that the EU remains fully committed to ensuring access to affordable medicines in developing countries. At our meeting in March, my delegation enumerated a number of initiatives the EU has already taken in this respect and I would like to refer to our previous statement on this point.

We agree that customs action against counterfeit and sub-standard medicines should not be at the expense of legitimate trade, including that on generic medicines. That's why, in order to limit the delays that customs controls may potentially cause, the EU Customs Regulation 1383/2003 contains strict time-limits within which court proceedings – if any – must be initiated. Moreover, if goods are detained on the basis of an unsubstantiated complaint, the owner of the product may seek legal redress.

We take this issue very seriously. Since our meeting in March my delegation has been active in this matter and has met many stakeholders.

In particular, my delegation welcomes the statement made by the EU pharmaceutical industry in which the latter has clearly clarified that transiting generic medicines, even if infringing patents in Europe, should not be detained if they are generic medicines in the country of origin and destination. This is an important statement. Since any patent-related customs actions must, in any event, be supported by right holder action, this statement should allow generic medicines to transit through the EU.

My delegation has also raised the awareness among the EU Member States, informed the European Parliament and engaged in dialogues with the civil society. Moreover, the Customs

Authorities of the EU Member States have been invited to pay particular attention when controlling generic medicines in transit in order to avoid actions that would delay or cause unnecessary disruption to the trade in generic medicines. Last but not least, we are in permanent contact with the WTO Members concerned.

As to the case in the Frankfurt Airport that was mentioned by India and Brazil, the only case in 2009 raised to our attention, we have looked into the matter. It appears that the customs procedures set out in the EC Customs Regulation have been respected. On 5 May, the German Customs controlled a shipment of antibiotics from India and destined for Vanuatu of about 25,000€. The Customs acted on the basis of a prior request for action lodged by the right holder. This shipment was suspected to infringe a trademark, not a patent. Therefore, it did not involve the issue of generics, which is a patent matter in the present context. On 7 May, the Customs informed the right holder on the interception. The right holder received this information from the Customs on 12 May. On 20 May, the right holder informed the Customs that there was no trademark infringement and the goods could be released. On 26 May, the Customs informed the declarant that the goods were released for further destination. On 28 May, the declarant, after having fulfilled the customs formalities, actually transported the goods towards their destination.

As you can see, this case was solved quite swiftly within the EC Customs Regulation rules and procedures. It is also important to note that, amongst the numerous customs actions undertaken in EC on a daily basis, no further case has been reported to us since the issue was first raised in the WTO last March, and indeed since the beginning of the year.

With regard to the 17 cases mentioned by India and Brazil, which all refer to 2008 actions, we are looking further into all details but I can ensure that we will pay particular attention to this issue. It seems that these cases include old cases that have already been discussed in March. They also include shipments that seem to be destined for EU Member States and cannot therefore be considered in transit in the EU territory.

Having said that, my delegation maintains that it is important to continue to allow the Customs Authorities to control goods in transit and ensure that measures can be taken against global trade in counterfeit products, and in particular fake medicines whose effects mainly hit developing countries. And to respond to what has been said I want to insist that we do not

make any confusion between generic medicines, which are legitimate quality products, and fake medicines, which are too often sub-standard products aiming at confusing the consumer about its quality.

Indeed, many dangerous goods, such as fake medicines, are shipped to developing countries, often via European ports and airports. In 2007, out of 76 million counterfeit and pirated goods stopped by the European customs, 40% were goods in transit.

EU customs statistics for 2007 have revealed a significant increase – compared to 2006 – in trade of fake medicines (+51%). Although customs controls of this kind of goods are often difficult, their role is crucial to prevent the flow of fake medicines in transit from reaching the populations of EU and other countries, in particular developing countries.

It is likely that EU customs action have saved lives in final destination countries – often developing countries. As an example, Belgian Customs recently stopped a consignment of 600,000 fake and sub-standard anti-malaria pills coming from India and destined for Togo.

Moreover, often fake medicines flow follow very complex and sophisticated routes, transiting through several territories, before reaching their final destination which is not necessarily the one mentioned in the customs documents. That's why it is important for the EU Customs to control such shipments, also given the risk of re-entering the EU territory.

I would also like to react to the assertion that the EU Customs Regulation would violate WTO disciplines.

Let me reaffirm that the EU does not intend to hamper trade in generic medicines or to create legal barriers to prevent movements of medicines to developing countries.

EU Customs Regulation provides for customs to detain goods suspected of infringing certain IP rights, including patents, even when goods are in transit. Under EU legislation, customs do not make a final decision on whether goods are infringing IPR. The general procedure is to temporarily detain goods, where there is a suspicion that there is an infringement and to 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 detention on grounds of suspicion of IPR infringement may cause some delay but the role of customs in IPR border enforcement is recognised by the WTO, as well as the World Customs Organisation. EU Customs Regulation 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.

Moreover, let me repeat that if goods are detained on the basis of an unsubstantiated complaint the owner of the products can claim compensation. Indeed, the Customs Regulation 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 IPR, including patents, but also to goods introduced into the customs territory or leaving that territory, including transit.

And the EU is not alone in allowing for customs enforcement action on goods in transit when they infringe intellectual property rights. Notably, other WTO Members apply border measures for goods in transit suspected of infringement of intellectual property rights.

Finally, regarding the principle of territoriality let me reassure you that the EU Customs Regulation has no extra-territorial effect.

To conclude, I would like to confirm that the EU will continue monitoring the situation and remain attentive to any possible application of EU legislation that could lead to undue hampering of legitimate trade, including that of generic medicines, or to the creation of legal barriers to prevent movements of medicines to developing countries. We will continue to maintain close contacts with the interested parties and Members concerned.
