

WTO TRIPS Council: India questions the United States on eBay v. MercExchange precedent as alternative to Paragraph 6 mechanism

Date: 26 October 2011

Source: KEOnline.org

Link: <http://keionline.org/node/1299>

On 25 October 2011, the WTO TRIPS Council held its annual review of the Paragraph 6 System. The following are extracts from the intervention of India. Note that under "Any alternatives to the use of Paragraph 6 System to achieve the objective of access to medicines" India asked the United States to shed light on state practice in the US following the US Supreme Court's eBay versus MercExchange ruling (<http://keionline.org/content/view/174/1>). When the WTO secretariat publishes its summary of the October 2011 TRIPS Council proceedings, it would be important to examine the United States' response to India's request to provide clarification on how the compulsory licenses and court ordered royalties for medical technologies that followed the eBay precedent "are not bound by the restrictions on exports under a compulsory license granted under Article 31 of the TRIPS". In his closing remarks, the representative of India stated, "In fact we feel that these cases and practices in the US can shed light in addressing the present problem of providing access to public health without the complicated mechanism of Para 6."

India's question to the United States

My question is to the delegation of the United States. The question is aimed at accessing the State practices on the application of TRIPS Articles 30, 31 and 44 which may be of importance to our current discussion. My question relates to the application of Article 44 of the TRIPS agreement where the court decides about the injunction when a patent has been infringed.....Secondly we note that in the case of Edwards Lifesciences vs CoreValve, a compulsory licence was granted for manufacturing a medical device for manufacture in the United States and meant exclusively for the export market.

We understand that there have been several such cases in the United States following the landmark Supreme Court judgment in eBay vs MercExchange in the issuance of all compulsory licences. We would request the US delegation to explain to the Members how these cases are not bound by the restrictions on exports under a compulsory license granted under Article 31 of the TRIPS. In fact we feel that these cases and practices in the US

can shed light in addressing the present problem of providing access to public health without the complicated mechanism of Para 6.

India's intervention for discussion under the annual review of the Paragraph 6 System

I) My delegation appreciates the role of the Government of Canada who took the initiative to implement the Para 6 Mechanism and supply the much needed AIDS drugs to Rwanda under its CAMR programme. It was however unfortunate that the actual delivery of the drugs took almost 3 years and we do not know if the patients who needed them really got the drugs in time. The TRIPS Council has been reviewing the Para 6 Mechanism for the last several years and till now we have not been able to get any convincing reply for our basic questions.

The esteemed delegate from Canada mentioned about the private Member's bill 393 which lapsed last summer on account of the dissolution of the House of Parliament. We understand that there has been a constructive debate on this issue and several amendments were suggested to make the system work better. Can the delegation of Canada highlight these issues to the benefit of all the Members? This experience would be useful when we review the mechanism.

Let me now turn to the specific agenda item i.e. "Any alternatives to the use of Paragraph 6 System to achieve the objective of access to medicines"

The TRIPS agreement handles the delicate balance between the exclusive right of the patent holder and the public interest....Articles 30 and 31 do provide such a mechanism. Article 30 is a substantive exception, detailing three criteria for any exception to exclusivity. Article 31, in contrast, is primarily procedural in nature, detailing a list of requirements for a limitation to exclusivity. Taken together, the Articles appear to define the universe of allowed unauthorized use under TRIPS. Similarly Article 44 of the TRIPS agreement does provide some flexibility as far as the State's right to provide permanent injunction is concerned.

My question is to the delegation of the United States. The question is aimed at accessing the State practices on the application of TRIPS Articles 30, 31 and 44 which may be of importance to our current discussion. My question relates to the application of Article 44 of the TRIPS agreement where the court decides about the injunction when a patent has been infringed.

This is a recent case between eBay, which owns and operates an Internet website that allows buyers and sellers to do transaction in goods and MercExchange. MercExchange alleged that eBay had violated some of its patents and requested the Court to provide permanent injunction. However in this case the US Supreme Court

pronounced a landmark judgement which could be relevant to us. In this judgement the Supreme Court held that principles of equity required that the plaintiff in infringement cases satisfy a four-factor test before a court may issue a permanent injunction:

- (1) that it has suffered an irreparable injury;
- (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury;
- (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and
- (4) that the public interest would not be disserved by a permanent injunction.

Secondly we note that in the case of *Edwards Lifesciences vs CoreValve*, a compulsory licence was granted for manufacturing a medical device for manufacture in the United States and meant exclusively for the export market.

We understand that there have been several such cases in the United States following the landmark Supreme Court judgment in *eBay vs MercExchange* in the issuance of all compulsory licences. We would request the US delegation to explain to the Members how these cases are not bound by the restrictions on exports under a compulsory license granted under Article 31 of the TRIPS. In fact we feel that these cases and practices in the US can shed light in addressing the present problem of providing access to public health without the complicated mechanism of Para 6.

Keywords: WTO / TRIPS / India / Paragraph 6 / Mechanism