

**TRAINING COURSE:
INTELLECTUAL PROPERTY RIGHTS
AND
PHARMACEUTICAL PRODUCTS AND PROCEDURES**

**PANEL DISCUSSION:
ASSESSING/ADDRESSING CONTENTIOUS ISSUES**

Saturday 14 February 2009 at 11:30 – 12:30

CASE STUDY 1: SEIZURE OF GENERIC PRODUCTS

1. **CASE STUDY FACTS:**

Dutch customs authorities recently seized, in Rotterdam harbour, a shipment of a generic drug GX manufactured in India and in transit to Brazil. The original drug OX was not under patent in India nor in Brazil, but was covered by a patent in the Netherlands.

The customs authorities acted on an application by the owner of the Dutch patent covering the original drug OX. The original drug OX was not under patent in either India or Brazil, so that manufacture of GX in India, and sales of GX in Brazil would not constitute an infringement of patent rights in those countries.

Commentators on the seizure believe that the seizure may have contravened provisions or at least the spirit of the WTO/TRIPS Agreement.

Questions

1.1 Does TRIPS have provisions requiring countries to put in place laws to deal with the importation of infringing or counterfeit goods?

Refer: TRIPS Articles 51 - 60

- 1.2 Does SA have legislation to enable a patent owner to request Customs Authorities or any other authority to seize infringing goods being imported into SA?

Refer: Counterfeit Goods Act no. 37 of 1997.

- 1.3 Should it make a difference to the legality of the seizure that the shipment of drugs was only in transit, ie was only passing through the Netherlands not intended for distribution and was in the Netherlands.

Refer: AM Moolla Group Ltd and others v The Gap Inc and others 2005 (2) SA 412 (SCA).

- 1.4 Does it make a different to the legality of the seizure that the generic drug GX would not constitute an infringement in the country of origin (India) nor in the country of destination (Brazil), but would be an infringement in the Netherlands?

Refer: TRIPS Article 28; TRIPS Article 52

- 1.5 Would the importation of the generic drug GX into the Netherlands constitute parallel importation?

Refer: TRIPS Article 6

- 1.6 How should the Doha Declaration of the WTO Ministerial meeting of August 2001 be interpreted and/or be applied to the circumstances of the seizure?

Refer WT/MIN(01)/DEC/2 - 20 November 2001 (Doha Declaration)

"We recognise the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

We recognise that intellectual property protection is important for the development of new medicines. We also recognise the concerns about its effects on prices.

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”

- 1.7 How should the preamble to the TRIPS Agreement be interpreted and/or applied to the circumstances of the seizure?

Refer: TRIPS Preamble:

“Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.”