

**ELSA MOOT COURT COMPETITION (EMC<sup>2</sup>) ON WTO LAW  
2006-2007**

**THE CASE**

***Factoril – Compulsory Licensing of Pharmaceutical Patent***

by

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1. **Distria** is a developing country WTO Member. On 5 January 2005, Distria notifies the Council for TRIPS that it intends to use, as an importer, the General Council's decision of 30 August 2003 on the 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (the Decision), but only in a national emergency.
2. On 5 January 2006, the previously unknown Amblo Virus is discovered in certain house pets in Distria as well as **Listria**, a least developed country that hopes to commence WTO accession negotiations in the next few years.
3. Tests show that the Amblo Virus may be transmitted to humans through contact with animal fur, with fatal results within days. Scientists are not yet certain whether the Amblo Virus can be transferred from one human to another. Nevertheless, the governments of Distria and Listria consider that the Amblo Virus threatens the population of both countries, and potentially the world.
4. **Costo** is a developed country WTO Member. Costo Inc is a company incorporated in Costo that holds a pharmaceutical patent in Costo and most other countries for the drug M63, which is thought to allow people infected with the Amblo Virus to survive without symptoms for up to 15 years after infection.
5. On 1 February 2006, Distria notifies the Council for TRIPS that:
  - a) it needs an estimated 5 million units of M63 to combat the Amblo Virus;
  - b) it has some manufacturing capacity in the pharmaceutical sector, but it has examined this capacity and determined that it is insufficient to meet its M63 needs; and
  - c) it has granted a non-renewable compulsory licence of Costo Inc's M63 patent in Distria (**Licence A**) to Distria Inc (a company incorporated in Distria) for 12 months to import up to 5 million units of M63 into Distria in accordance with Article 31 of the TRIPS Agreement and the Decision.

6. Distria does not explain to the Council for TRIPS how it determined that it had insufficient manufacturing capacity.
7. Licence A does not require Distria Inc to pay any royalties to Costo Inc.
8. **Factoril** is a developing country WTO Member that entered a bilateral free trade agreement with Costo in 2000 (FTA). On 20 February 2006, Factoril notifies the Council for TRIPS that it is granting a non-renewable compulsory licence of Costo Inc's M63 patent in Factoril (**Licence B**) to Factoril Inc (a company incorporated in Factoril) for 12 months to manufacture and export to Distria up to 5 million units of M63, distinguished by their pink colour (M63 ordinarily being green). The notification also includes the other details that the Decision requires, namely the address of Factoril Inc and the address of the website to be established pursuant to Licence B.
9. Licence B requires Factoril Inc to establish a website setting out the information specified by the Decision and to pay Costo Inc royalties at the rate of 3% of the amount paid by the importer for the M63 that Factoril Inc supplies.
10. Factoril Inc has not made any efforts to obtain a voluntary licence from Costo Inc on reasonable terms in order to fulfil Distria's M63 needs; nor does Licence B require Factoril Inc to do so.
11. Pursuant to Licence B, Factoril Inc enters a contract to export to Distria Inc 5 million units of pink M63 over 12 months. The price is 30% of what Distria Inc would have to pay to Costo Inc if it imported directly from Costo Inc. Given the distinctive colour of the imported M63, the urgent need for M63 within Distria, and Distria's limited resources, Distria decides that it need not take any additional steps to prevent re-exportation of the imported M63.
12. Factoril also grants to Factoril Inc a non-renewable compulsory licence of Costo Inc's M63 patent in Factoril (**Licence C**) for 12 months to manufacture and export to Listria up to 1 million units of pink M63. Licence C requires Factoril Inc to pay Costo Inc royalties at the rate of 1.5% of the amount paid by the importer for the M63 that Factoril Inc supplies. Listria has no established patent system and therefore M63 is not protected by patent in Listria. Factoril does not notify the Council for TRIPS of Licence C.
13. Pursuant to Licence C, Factoril Inc enters a contract to export to Lister Inc (a company incorporated in Listria) 1 million units of pink M63 over 12 months. The price is 15% of what Lister Inc would have to pay to Costo Inc if it imported directly from Costo Inc. Lister Inc also imports several hundred units of pink M63 from various companies in Distria.

14. Article 5 of the FTA between Costo and Factoril allows either party to issue a compulsory licence for a pharmaceutical patent only to respond to a national emergency and only to supply the domestic market. Article 20 specifies that if one party considers that the other party has violated its FTA obligations it may refer the dispute to the FTA tribunal. Article 21 provides that, notwithstanding Article 20, where the circumstances giving rise to such a dispute may also involve a WTO violation, the complaining party must elect whether to bring the dispute before the FTA tribunal or a WTO panel; it cannot pursue remedies under both systems (either simultaneously or in succession).
15. In March 2006, before the FTA tribunal, Costo argues that Factoril has violated Article 5 of the FTA by issuing Licences B and C. The tribunal finds in favour of Factoril, on the basis that Article 5 must be interpreted in the light of the Decision. Costo disputes this interpretation, but the FTA provides no avenue of appeal.
16. On 15 July 2006, following consultations between Costo and Factoril that fail to resolve the dispute, Costo requests the establishment of a panel at a meeting of the WTO Dispute Settlement Body (DSB). No Member objects to the establishment of a panel at that meeting, and the DSB therefore establishes the panel. Distria reserves its rights as a third party in the panel proceedings.
17. Before the panel, Costo claims that Factoril has acted inconsistently with its WTO obligations because:
  - a) Licence B is inconsistent with paragraphs 1(b), 2(a)(ii), and 4 of the Decision and Articles 28.1(a), 31(b), and 31(f) of the TRIPS Agreement; and
  - b) Licence C is inconsistent with Article 28.1(a) of the TRIPS Agreement and does not fall within Article 30 or 31 of the TRIPS Agreement or the Decision.
18. Factoril maintains that the panel lacks jurisdiction to hear Costo's claims, in view of the FTA terms and tribunal decision. It also contends that Licences B and C are consistent with the TRIPS Agreement and the Decision, taking into account Articles 7-8 of the TRIPS Agreement and the circumstances surrounding the Decision.

**Indicative references:**

*Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),  
Articles 7-8, 28, 30-31*

*Marrakesh Agreement Establishing the World Trade Organization (WTO Agreement),  
Articles IX-X*

*Vienna Convention on the Law of Treaties (VCLT), Articles 30-32*

*Canada – Pharmaceutical Patents (WT/DS114)*

*EC – Chicken Cuts (WT/DS269, WT/DS286)*

*Mexico – Taxes on Soft Drinks (WT/DS308)*

*US – Gambling (WT/DS285)*

Ministerial Conference, ‘Declaration on the TRIPS Agreement and Public Health  
Adopted on 14 November 2001’, WT/MIN(01)/DEC/2.

General Council, ‘Minutes of Meeting Held in the Centre William Rappard on 25, 26  
and 30 August 2003’, WT/GC/M/82.

Council for Trade-Related Aspects of Intellectual Property Rights, ‘Minutes of  
Meeting Held in the Centre William Rappard on 28 August 2003’,  
IP/C/M/41.

General Council, ‘Implementation of Paragraph 6 of the Doha Declaration on the  
TRIPS Agreement and Public Health: Decision of 30 August 2003’, WT/L/540.

General Council, ‘Amendment of the TRIPS Agreement: Decision of 6 December  
2005’, WT/L/641.