

# Seizing Drugs in Transit

Bryan Mercurio  
Faculty of Law  
Chinese University  
of Hong Kong

# The facts

- Dec 2008, Dutch customs officials delayed 500 kg of losartan potassium docked in Rotterdam while in transit on route from India to Brazil
- Shipment is delayed for suspected patent infringement or counterfeiting
- Drug is neither in the country of export or in the country of final destination, but is patented in the EU
- Drug was not subject to a compulsory licence

# The aftermath

- Brazilian Ambassador Roberto Azevedo
  - “The protection of intellectual property cannot supersede the protection of more fundamental values, such as the protection of life and the right to promote public health...The decision to impede the transit of a cargo of generic medicines – which was not headed for the Dutch market – is unacceptable and sets a dangerous precedent”

# The aftermath

- Joint statement by Brazil's Foreign Minister Celso Amorim and Health Minister Jose Gomes Temporao:
  - “The Brazilian Government considers that the decision by the Dutch authorities to detain an input which is strategic to public health in a developing country, and exported in conformity with the existing international norms, represents a grave drawback in the treatment of the issue of the universal access to medicines...[The Dutch decision to seize the drugs was] distorted use of the international intellectual property system, supposedly upheld by European Union legislation, and contrary to the spirit and provisions of the Doha Declaration on TRIPs and Public Health.”

# The law

- Border Measures Regulation, Council Regulation (EC) 1383/2003
  - EU uniform procedures for customs action against infringing goods
  - Allows customs to temporarily detain any suspected of infringing IPRs

# The law

- EU Ambassador Eckart Guth
  - EU regulation “has absolutely no intention to hamper any legitimate trade in generic medicines or to create legal barriers to prevent movement of drugs to developing countries, nor have our measures had this effect...We are absolutely committed to all the efforts that are being made to facilitate access to medicines.”

# The Complaint

- TRIPS Agreement Articles 41, 51-60
- Doha Declaration on the TRIPS Agreement and Public Health (2001)
- GATT Article V

# TRIPS: general provision

- TRIPS Art.1.1, second sentence
  - “Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.”



## TRIPS : Section 4: special requirements related to border measures

- Article 51, first sentence
  - Members must adopt procedures “to enable a right holder, who has valid grounds for suspecting that the importation of *counterfeit trademark or pirated copyright goods* may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods.”

## TRIPS : Section 4: special requirements related to border measures

- Article 51, FN 13
  - There is no obligation to apply such procedures ... to goods in transit.

## TRIPS : Section 4: special requirements related to border measures

- Article 51, second sentence
  - Permits Members to extend border measures to ‘goods which involve other infringements of intellectual property rights, *provided that the requirements of this Section are met.*

# TRIPS : Section 4: special requirements related to border measures

- Article 52
  - rights holders are required to submit ‘adequate evidence’
  - that ‘under the laws of the country of importation’
  - there is ‘*prima facie* an [IP] infringement’
  - supply a sufficiently detailed description of the goods to make them readily recognizable by the customs authorities


## TRIPS : Section 4: special requirements related to border measures

- Remedies (art 59)
  - Competent authorities have authority to order the destruction or disposal of infringing goods in accordance with the principles set out in Article 46.

# Legality: TRIPS

- EC Border Measures are a ‘twin-expansion’ of the IP protection mandated as minimum standard under Arts 51-60
  - (1) goods involving IP infringements other than trademark counterfeits or copyright piracy; and
  - (2) to goods in transit.

- Constraints on border measures
  - TRIPS Art 52, first sentence: Right holders initiating the procedures under Article 51 “shall be required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is *prima facie* an infringement of the right holder’s intellectual property right”.

- 
- Which is ‘the country of importation’?
    - Country of final destination; or
    - EC Member State through which these goods transit



- How does the Supreme Court of India define the term?
  - Import means *'bringing into India from outside India', that it is not limited to importation for commerce only but includes importation for transit across the country.*"  
(para 39)

- Is there an opening for a ‘contextual’ based argument?
  - ‘the word “import” ... cannot bear the narrow interpretation sought to be placed upon it to limit it to import for commerce. It must be interpreted in a sense which will fit the Copyright Act into the setting of the international conventions.’ (para 29)

## • European Court of Justice

### • *Polo / Lauren* (2000)

- Predecessor to BMR “expressly designed to apply to goods passing through Community territory from a non-member country destined for another non-member country”

### • *Class International* (2005)

- Owner can oppose the offering for sale or sale of such goods even when this is done while the goods are still under the external transit procedure if there is a risk of diversion of the goods to the European market

### • *Montex Holdings Ltd. v. Diesel SpA*<sup>57</sup> (2006)


- No infringement by virtue of goods merely passing through a member state if the goods are not in free circulation

- *Nokia Corporation v Her Majesty's Commissioners of Revenue & Customs*
  - "49. ... First, infringement of registered trade mark requires goods to be placed on the market and that goods in transit and subject to suspensive customs procedures do not, without more, satisfy this requirement. ...
  - 50. Second, the position is different if the goods in the transit procedure are subject to the act of a third party which necessarily entails their being put on the market ("the *Montex* exception"). But the burden of establishing this rests on the trade mark proprietor.
  - 51. Third, a mere risk that the goods may be diverted is not sufficient to justify a conclusion that the goods have been or will be put on the market.
  - 52. Fourth, the Counterfeit Goods Regulation has not introduced a new criterion for the purposes of ascertaining the existence of an infringement of a registered trade mark or to determine whether there is a use of the mark which is liable to be prohibited.
  - 80. ... I recognise that this result is not satisfactory. I can only hope it provokes a review of the adequacy of the measures available to combat the international trade in fake goods by preventing their transshipment through Member States."



## ● Options

- ‘Country of Importation’ is deemed to be final importation
- ‘Country of Importation’ is deemed to be the country of transit, and consistent with TRIPS
- ‘Country of Importation’ is deemed to be the country of transit, and inconsistent with TRIPS

- 
- Purely textual interpretation
    - TRIPS ‘ceilings’
      - TRIPS always limits border measures to the countries of origin and country of destination

## TRIPS : Section 4: special requirements related to border measures

- Security or Equivalent Assurance (Art.53(1))
  - “competent authorities shall have the authority to require an applicant to provide a security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse.”

# Vienna Convention on the Law of Treaties

- Vienna Convention on the Law of Treaties (art 31)
  - in good faith
  - in accordance with the ordinary meaning to be given to the terms of the treaty
  - in their context
  - in the light of its object and purpose.



# Context: general provisions

- Objectives and Principles of the TRIPS
  - Article 7
  - Article 8

# Context: general provisions

- TRIPS Article 41
  - Any intellectual property enforcement measures should ‘be applied in such a manner as to avoid the creation of barriers to legitimate trade...’
  - Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.

# Context: Doha Declaration

- Doha Dec. on TRIPS and Public Health (para 4)
  - ‘the [TRIPS] 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.’

# Context: World Health Assembly

- WHA61.21
  - Member states should “take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights”

# Context: European Parliament

- European Parliament Resolution of 12 July 2007 on the TRIPS Agreement and Access to Medicines
  - “Stresses that access to affordable pharmaceutical products in poor developing countries and LDCs is essential to attain the proposed EU development goals and would contribute to poverty reduction, increase human security, and promote human rights and sustainable development;” and
  - “Believes that EU policy should aim at maximizing the availability of pharmaceutical products at affordable prices in the developing world”.

# Context: Can it be discriminatorily applied?

- Using 'context' to justify interpretation
  - Doha Declaration on TRIPS and Public Health as an 'interpretation'
  - TRIPS Article 27 vs. 'health'

# Vienna Convention on the Law of Treaties: Object and Purpose

- What is the 'object' and 'purpose'?


# Consequence

- Free Trade Agreements
  - Most FTAs contain WTO/TRIPS adherence and consistency clauses



# GATT Article V

- Article V(2)
  - “There shall be freedom of transit through the territory of each Member, via the routes most convenient for international transit, for traffic in transit to or from the territory of other Members. No distinction shall be made which is based on the flag of vessels, the place of origin, departure, entry, exit or destination, or on any circumstances relating to the ownership of goods, of vessels or of other means of transport.”
- Article V(3)
  - “shall not be subject to any unnecessary delays or restrictions.”

- 
- On the other hand...
    - Articles V(3): *'...except in cases of failure to comply with applicable customs laws and regulations'*

- 
- Exception under Article XX(d)
    - (1) designed to ‘secure compliance’ with laws or regulations that are not themselves inconsistent with some provision of the *GATT 1994*; and is
    - (2) ‘necessary’ to secure such compliance.



- ‘Necessary’

- Does not necessarily mean ‘indispensable’, but instead certain factors should be ‘weighed and balanced’ in order to determine if a measure is ‘necessary’.
- The relevant factors include:
  - (1) importance of the interests or values involved;
  - (2) contribution of the measure to the goal;
  - (3) trade-restrictiveness; and
  - (4) whether there are any less trade restrictive alternative measures available.



- *The Chapeau*

- Not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade

# Conclusion

- Sensitive case
  - Unexplored area of TRIPS
  - Treaty interpretation
  - Intersection between TRIPS and the GATT
  - Access/right to medicine