PATENT INFRINGEMENTS, LEGITIMATE TRADE AND ACCESS TO ESSENTIAL MEDICINES

The Territorial Reach of Border Measures under EU Law, TRIPS and ACTA

Henning Große Ruse - Khan

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Seizures of Generics in Transit

- Starting 2008, customs in EU Mbs seized, delayed and returned shipments of generics transiting EU ports on account of suspected patent infringements in the transit country.
- The shipments originated in India and were destined to developing countries such as Brazil, Venezuela, Colombia, Peru or Nigeria.
- The drugs at issue are protected in the EU transit country, but not in the countries of origin or destination.
- In 19 cases, Dutch customs seized transiting generics
- At least 1 seizure involves generics used by UNITAID for HIV/AIDS treatment in Africa
- In all cases, customs in EU Mbs acted pursuant to the EU Regulation 1383/2003 on border measures (BMR)
Facts of the Case

- Transfer of generic pharmaceuticals from India (CoO) to various CoDs
  - No patent protection in CoO and CoD

- Transit of products through European Union, i.e. The Netherlands
  - Patent protection by third party in CoT

- Seizure of products in Rotterdam by Dutch border control on patentee’s request
  - Delay in port / returned to CoD

CoO = Country of Origin; CoD = Country of Destination; CoT = Country of Transit
# Overview of Generic Drug Seizure Cases

<table>
<thead>
<tr>
<th>Date</th>
<th>Generic Product Name</th>
<th>Patentee</th>
<th>Country of Origin</th>
<th>Country of Destination</th>
<th>Country of Transit</th>
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</thead>
<tbody>
<tr>
<td>10/2008</td>
<td>Clopidogrel</td>
<td>Sanofi-Aventis</td>
<td>India</td>
<td>Colombia</td>
<td>The Netherlands</td>
</tr>
<tr>
<td>11/2008</td>
<td>Abacavir</td>
<td>GlaxoSmitkline</td>
<td>India</td>
<td>Nigeria (via UNITAID)</td>
<td>The Netherlands</td>
</tr>
<tr>
<td>11/2008</td>
<td>Olanzapine</td>
<td>Eli Lilly</td>
<td>India</td>
<td>Peru</td>
<td>The Netherlands</td>
</tr>
<tr>
<td>11/2008</td>
<td>Rivastigmine</td>
<td>Novartis</td>
<td>India</td>
<td>Peru</td>
<td>The Netherlands</td>
</tr>
<tr>
<td>12/2008</td>
<td>Losartan</td>
<td>Merck&amp;Co. / MSD</td>
<td>India</td>
<td>Brazil</td>
<td>The Netherlands</td>
</tr>
</tbody>
</table>

Source: India WTO Dispute Consultation with EU and The Netherlands
WTO Complaints by India and Brazil

- In May 2010, India and Brazil initiated WTO dispute settlement proceedings against the EU and the Netherlands by requesting consultations over the seizures of generic medicines in transit (WT/DS408 & DS409)

- Apart from alleging inconsistency with several GATT provisions, both India and Brazil argue that the EU and Dutch measures (as such and as applied) violate the TRIPS Agreement (e.g. Artt. 1:1, 41:1, 52, 53:1&2)

- At stake is not the failure to meet minimum standards, but the TRIPS-plus character of the measures

- For the first time in WTO dispute settlement, TRIPS is used as a benchmark for constraining additional (‘TRIPS-plus’) IP protection

- The complaints hence reinforce a ceilings-approach
The Principle of Territoriality

Territoriality of IP Protection

- IP rights are granted by national law and limited to the territory of the granting state
- **Rationale**: historic grant of privileges, state sovereignty, ‘comity’ (non interference)
- ‘Bundle of national rights’ – potentially differing on subject matter; conditions for, scope of & limitations to IP protection

**Expressions of territoriality:**
- Principle of independence of patents, [Art.4bis (1) PC]
- *Lex loci protectionis* as applicable IP law, see [Art.5 (2) BC]
International IP Enforcement

**IP Enforcement Provisions** in TRIPS

1. General Obligations
2. Civil and Administrative Procedures and Remedies
3. Provisional Measures
4. **Special Requirements Related to Border Measures**
5. Criminal Procedures
International IP Enforcement

TRIPS IP Enforcement Rationale

Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements.

These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse. (Art.41:1, TRIPS Preamble)
Border Measures under the EU BMR

Subject Matter and Scope

- This Regulation sets out the conditions for action by the customs authorities when goods are suspected of infringing an intellectual property right (Art. 1:1 BMR)
- BMR covers goods being imported, exported and those in transit (Art. 1:2, recital 3,4 BMR)
- For the purposes of this Regulation, "goods infringing an intellectual property right" means: (…)
  - (c) goods which, in the Member State in which the application for customs action is made, infringe:
    - (i) a patent under that Member State’s law (Art. 2:1 BMR)

→Whether generics in transit fall under the BMR depends on the scope of patent protection in the transit country!

P: Does the BMR establish a ‘Manufacturing Fiction’?
Border Measures under TRIPS

Subject Matter and Scope

- Importation of counterfeit trademark goods and pirated copyright goods, Art.51 TRIPS

- **counterfeit trademark goods**: goods (incl. packaging) bearing an identical trademark to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark (fn.14 to Art.51)

- **pirated copyright goods**: copies made without authorisation in the country of production directly or indirectly from an article if making that copy would constitute copyright- or related right infringement under the law of the country of importation (fn.14 to Art.51)
Border Measures under the ACTA Draft

Background on ACTA

- Secret Negotiations for a new IP Enforcement Treaty outside WIPO, WTO since 2006
- Current Negotiating Parties are: US, EU, Japan, South Korea, Mexico, New Zealand, Switzerland, Canada, Australia, Singapore, Morocco
- Almost complete absence of transparency, but increasing leaks of draft texts
- Public released Draft in April 2010
Border Measures under the ACTA Draft

The **Six Chapters** in the ACTA Draft

- Initial Provisions and Definitions
- Legal Framework for Enforcement of IPR
  - General Obligations
  - Civil Enforcement
  - **Border Measures**
  - Criminal Enforcement
  - Technological IP Enforcement in the Digital Environment
- International Cooperation
- Enforcement Practices
- Institutional Arrangements
- Final Provisions
Border Measures under the ACTA Draft

Provisions with Relevance for Seizure Cases

- Article 2.X:1-3 of the ACTA Draft (Scope of Border Measures)
- Implications of Footnotes 21, 22 and Art.1.3:2 (Confusingly Similar TMs, Non-infringing goods)
- Applications by Right Holders under Art.2.6 (Scope and Substance)
- Implications of Footnotes 23 and 24 to Art.2.6 (Definition of Transit, Exceptional Release)
- *Ex Officio* Actions under Art.2.7 (Scope and Substance)
- Enforcement in the Country of Destination as Alternative under Art.2.X
Border Measures under the ACTA Draft

Subject Matter and Scope, Art.2.X ACTA

1. This section sets out the conditions for action by the competent authorities when goods are suspected of infringing intellectual property rights, within the meaning of this agreement, when they are imported, exported, in-transit or in other situations where the goods are under customs supervision.

2. For the purposes of this section, “goods infringing an intellectual property right” means goods infringing any of the intellectual property rights covered by TRIPS (…)

3. [Parties shall provide for the provisions related to border measures to be applied [at least] in cases of trade mark counterfeiting and copyright piracy. [Parties may provide for such provisions to be applied in other cases of infringement of intellectual property rights.]]

P: Patents covered? Press releases now deny this…
Border Measures under the ACTA Draft

Scope of **TM Infringements** under ACTA

[22 The provisions of this section shall also apply to confusingly similar trademark goods [which means any goods, including packaging, bearing without authorization a trademark that is similar to the trademark validly registered in respect of such or similar goods where there exists a likelihood of confusion on the part of the public between the trademark borne and the trademark validly registered, and that thereby infringes the rights of the owner of the trademark in question under the law of the country in which the procedures set out in this Section are invoked.]

→ Potential impact on transiting generics?
→ Danger of seizures based on alleged TM infringements?
Border Measures under the ACTA Draft

Implications of Footnotes 21 and Art.1.3:2

- It is understood that this Agreement does not create any obligation on a Party to apply measures where a right in intellectual property is not protected under the laws and regulations of that Party. (Art.1.3:2)

- Even if ACTA will cover transits, seizure dependant on whether the scope of substantive IP protection in the transit country actually covers the mere transit as an infringing act

  → But even under narrow scope of substantive IP protection, (temporary) detentions (to determine infringement) may occur which create barriers to international trade
Border Measures under the ACTA Draft

Options for Exceptional Release under Fn.24

- [Where the competent authorities suspend the release of suspected counterfeit trademark or pirated copyright goods, the authorities shall not permit the goods to be released into free circulation, exported, or subject to other customs procedures, except in exceptional circumstances.] (Fn.24)

- Ability to function as public health safeguard which allows the release of generics in transit?

- Narrow interpretation of exceptional circumstances or integrative approach taking Art.V GATT, Art.12 ICESCR into account (see Art.31:3 c) VCLT)?

→ No solution which offers a comprehensive safeguard against seizures of generics
Border Measures under the ACTA Draft

Enforcement in the **Country of Destination**

- [As an alternative to procedures in Article 2.6.1 and 2.7.1 relating to export or in-transit shipments, each Party shall provide that where shipments are exported from that Party, or shipments are in-transit through that Party, it shall cooperate to provide all available information to the destination Party, upon request of the destination Party, to enable effective enforcement against shipments of infringing goods.] (Art.2.X)

- An **alternative** to seizures in the transit country?
  - Limited to transits destined to another ACTA party
  - subject to “request of the destination Party”

→No *a priori* exclusion of transit seizures and hence insufficient safeguard for international trade
TRIPS Ceilings on TRIPS-plus Border Measures?

→ Does TRIPS Impose Limits on TRIPS-plus Border Measures?

- **Art.1:1** TRIPS allows additional IP protection provided that it does not “contravene” TRIPS norms

- **Art.51 2nd sentence** TRIPS permits WTO Members to extend border measures to goods involving other IP infringements “provided that the requirements of this Section are met.”

- **China – IP Enforcement**, Panel Report, para. 7.223: “The second sentence includes an express condition that applies where Members provide border measures for other infringements of intellectual property rights, namely "provided that the requirements of this Section are met".”
TRIPS Ceilings on TRIPS-plus Border Measures?

EC – Generics in Transit, Art.41 TRIPS

- IP enforcement procedures “shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse” (Art.41:1)

- Seizures and temporary detentions of transiting goods as barriers to legitimate trade?

- Legitimacy arguably dependent on IP infringing nature of goods – to be judged under the law of the importing country or the transit country?

→ Art.52 as well as Fn.14 to Art.51 TRIPS define IP infringement on the basis of the law of the country of importation… arguably should legality in the importing country determine the legitimacy under Art.41:1…
TRIPS Ceilings on TRIPS-plus Border Measures?

EC – Generics in Transit, Art.52 TRIPS

- EC Regulation 1383/2003 extends border measures to goods in transit; other IP infringements
- Even in transit cases, IP infringements are judged on the basis of IP laws of the transit country
- Under TRIPS, EC measures must comply with requirements of Artt.51-60 (Art.51 2nd sen.)
- Art.52 demands adequate evidence for a prima facie IP infringement – based on the “law of the country of importation” (see also fn.14 to Art.51 TRIPS)

→ Is a Transit Country a “country of importation”?
TRIPS Ceilings on TRIPS-plus Border Measures?

Interpreting ‘country of importation’

- Ordinary meaning and context:
  - **Origin**: *importare*, translated as ‘to bring in’
  - **Dictionary**: “bring (goods or services) into a country from abroad”
  - **Relevant Context** supporting a limited scope:
    - fn.13 to Art.51 (distinguishing imports and goods in transit);
    - Art.41:1 TRIPS (obligation to apply IP enforcement measures “as to avoid the creation of barriers to legitimate trade”)
    - Art.V GATT: (demanding “freedom of transit”)

- **TRIPS objectives and principles**:
  - IP enforcement conducive to social/economic welfare;
  - Public health supportive interpretation (Doha Decl)
TRIPS Ceilings on TRIPS-plus Border Measures?

Transit Seizures and the “Para.6 Mechanism”

- 30 August 2003 **Waiver** of Art.31 f) TRIPS to allow WTO Members to **export essential drugs** to countries with a lack of manufacturing capacity in the pharmaceutical sector

- Supply of essential drugs to countries without sufficient capacity **relies on international trade in- and free transit of** the drugs produced under a compulsory license in the exporting country

- Seizing / detaining drugs in transit based on potential IP (patent, TM) infringements in the transit country threatens also the effectiveness of the para.6 mechanism: **BMR does not foresee any safeguards** which would **exempt such drug shipments a priori from its scope**…
GATT ‘Ceilings’ on TRIPS-plus Border Measures?

Freedom of Transit, Art.V GATT

- “There shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties” (Art.V:2)

- (...) “except in cases of failure to comply with applicable customs laws and regulations, such traffic coming from or going to the territory of other contracting parties shall not be subject to any unnecessary delays or restrictions” (Art.V:3)

- “Subject to the requirement that such measures are not applied in a manner which would constitute (...) a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent (...) measures necessary to secure compliance with laws or regulations (...) relating to (...) the protection of patents” (Art.XX d)
GATT ‘Ceilings’ on TRIPS-plus Border Measures?

Relation between GATT and TRIPS in WTO Law

In case the seizures are found inconsistent with either GATT or TRIPS, but not with the respective other WTO Agreement, can consistency with on body of WTO law justify an inconsistency with another?

“there is no hierarchy between the TRIPS Agreement and GATT 1994, which appear in separate annexes to the WTO Agreement. The ordinary meaning of the texts of the TRIPS Agreement and GATT 1994, as well as Article II:2 of the WTO Agreement, taken together, indicates that obligations under the TRIPS Agreement and GATT 1994 can co-exist and that one does not override the other.” (...)

“Further, a "harmonious interpretation" does not require an interpretation of one that shadows the contours of the other. It is well established that the covered agreements apply cumulatively and that consistency with one does not necessarily imply consistency with them all.” (EC – GIs Panel Report, para.207)
TRIPS ‘Ceilings’ on TRIPS-plus Border Measures?

ACTA TRIPS-plus Norms in conflict with TRIPS?

**Art.1:1 TRIPS**: Right to introduce additional IP protection “provided that such protection does not contravene the provisions of this Agreement.”

- **Art.41:1 TRIPS** (IP enforcement shall not create barriers to legitimate trade)
- **Art.52 TRIPS** (border measures must be based on IP infringements in the country of importation)
- ‘**Paragraph 6 Mechanism**’ to export drugs produced under CL to countries with insufficient manufacturing capacity

→ Potential for conflict increases when TRIPS balancing objectives (Art.7) and public interest principles (Art.8) are guiding TRIPS interpretation (see Art.31:1 VCLT, para.5 a) Doha Declaration)
TRIPS ‘Ceilings’ on TRIPS-plus Border Measures?

Conflict Resolution Tools under Int. Law

- Principle of harmonious interpretation and systemic integration: Mutual consistent interpretation possible?
- Definition of Conflict: Directly incompatible obligations or (also) prevention to exercise treaty rights?

→ Overriding TRIPS flexibilities unlikely to conflict/’contravene’ TRIPS...

- Relevant Conflict Resolution Norms in TRIPS, ACTA, IL:
  - Art.1:1 TRIPS: ACTA may not ‘contravene’ TRIPS ceilings
  - Art.1:1 ACTA: No derogation from inter partes int. obligations – hence no overriding TRIPS ceilings
  - Art.30:2 VCLT: Due to Art.1:1 ACTA, TRIPS prevails
  - Art.41 VCLT: ACTA as inter-Se Agreement may not prevent the exercise of TRIPS flexibilities by other WTO Members
Conclusions

- The impact of IP enforcement on goods in transit and international trade depends on
  - the scope and subject matter of the (procedural) border measures
  - the scope of substantive IP protection in the law of the country where the border measures are invoked

- Based on the WTO/GATT free trade context, TRIPS contains binding safeguards against IP enforcement functioning as trade barrier

- These safeguards can function as limits (ceilings) to additional IP protection in
  - national laws of WTO Members
  - international (inter-se) treaties amongst WTO Members
Thank you for your attention!

Any comments and questions to
henning.gr-khan@ip.mpg.de