A Trade Agreement Creating Barriers to International Trade?

ACTA Border Enforcement and Generic Drugs in Transit

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Outline

- Introduction: ACTA Creating Trade Barriers?
- Seizures of Generics in Transit
- WTO Complaints by India and Brazil
- Relevant ACTA Provisions on Border Measures
- Conclusions
Introduction: ACTA Creating Trade Barriers?

Distinct Views on IP Enforcement & Trade

- Increasing **trade in ‘counterfeits’** and fake goods destroys markets for the originals and deceives consumers; **lack of adequate IP enforcement** in markets abroad is key **obstacle to international trade** in IP protected goods (IP exporting countries)

  ➔ ACTA as a remedy to restore fair global competition and **facilitate trade in ‘legitimate’ goods**

- As goods from emerging economies are becoming increasingly competitive with those of developed country producers, new international IP enforcement rules are viewed as ‘**non-tariff’ barriers to trade** for exports from developing countries (DCs)

  ➔ ACTA as ‘**protectionist**’; its trade restrictive effects contrary to the main principle of trade liberalization in the WTO
Introduction: ACTA Creating Trade Barriers?

IP Enforcement Rationale in TRIPS

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)
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 generics through EU ports, e.g. Rotterdam (The Netherlands)
  - Patent protection for third party in CoT

- Seizure of generics by customs on patentee’s request
  - Delay in port / returned to CoD / destruction of goods?

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>
</tr>
</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>GlaxoSmithKline</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
ACTA Provisions on Border Measures

Background on ACTA

- Secret Negotiations for a new IP Enforcement Treaty outside WIPO, WTO since 2006
- Negotiating Parties: Australia, Canada, the EU and its Member States, Japan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland, US
- Almost complete absence of transparency, but increasing leaks of draft texts
- Public released Final Text of 3/12/2010
ACTA Provisions on Border Measures

The Six Chapters in ACTA

- Initial Provisions and General Definitions
- Legal Framework for Enforcement of IPR
  - General Obligations: Art.6
  - Civil Enforcement: Artt.7-12
  - Border Measures: Artt.13-22
  - Criminal Enforcement: Artt.23-26
  - Enforcement of IPRs in the Digital Environment: Art.27
- Enforcement Practices
- International Cooperation
- Institutional Arrangements
- Final Provisions
ACTA Provisions on Border Measures

Does ACTA mandate seizure of generics?

**Scope** of ACTA Border Measures:
- Patent Infringements, Fn.6 to Art.13
- In-Transit Goods, Art.16:2
- Other Forms of IP Infringements, Art.13

**Applicable Law** and Determination of **Infringement**
- The Applicable Law in IP Border Enforcement Cases, Art.17:1
- Determination of Infringement, Art.19 & 3:2

**ACTA Safeguards** for Public Health and against Trade Barriers
- Interpretation Based on Articles 7 and 8 TRIPS, Art.2:3
- Obligation to Avoid the Creation of Barriers to Legitimate Trade, Art.6:1
ACTA Provisions on Border Measures

Subject Matter and Scope of BM

- “The Parties agree that patents and protection of undisclosed information do not fall within the scope of this Section.” (Fn.6 to Art.13)

- “A Party may adopt or maintain procedures with respect to suspect in-transit goods” (Art.16:2)

- “Each Party shall ensure that enforcement procedures are available under its law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement” (Art.6:1) … in Art.5 (h) defined as any IP right covered by TRIPS

→ Ordinary TM infringements in principle covered by ACTA border measures – impact on trade in generics?
ACTA Provisions on Border Measures

Option to exclude ordinary TM Infringements?

■ “In providing, as appropriate, and consistent with its domestic system of intellectual property rights protection and without prejudice to the requirements of the TRIPS Agreement, for effective border enforcement of intellectual property rights, a Party should do so in a manner that does not discriminate unjustifiably between intellectual property rights and that avoids the creation of barriers to legitimate trade.” (Art.13)

→ Good faith reasons (public health, access to medicines, freedom of transit) can justify treating ordinary TM infringements different from TM ‘counterfeits’

→ Border measures should not create barriers to legitimate trade… (?)
ACTA Provisions on Border Measures

Applicable Law & Determining IP Infringements

■ “Each Party shall provide that its competent authorities require a right holder (...) to provide adequate evidence to satisfy the competent authorities that, under the law of the Party providing the procedures, there is prima facie an infringement of the right holder's intellectual property right” (Art.17)

→ Where goods are seized in transit, the law of transit Country decisive for determining infringement

■ “This Agreement does not create any obligation on a Party to apply measures where a right in intellectual property is not protected under its laws and regulations.” (Art.3:2)

→ IP enforcement measures depend on existence of substantive IP infringements: If mere transit does not amount to infringement, goods will be released...
ACTA Provisions on Border Measures

Safeguards for Public Health & Free Trade

■ “The objectives and principles set forth in Part I of the TRIPS Agreement, in particular in Articles 7 and 8, shall apply, mutatis mutandis, to this Agreement.” (Art.2:3 – ‘Nature and Scope of Obligations’)

■ Recognizing the principles set forth in the Doha Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, at the Fourth WTO Ministerial Conference (ACTA Preamble)

■ “[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.6:1 – ‘General Obligations’)

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

- **IP Enforcement** has strong links to **Int. Trade**; its role and impact is subject to opposing views.
- ACTA does not mandate seizure of **generics in transit**
- If countries however extend **border measures against goods in transit**, they have to rely on several safeguards for public health and free trade to avoid such seizures.
- ACTA **safeguards and ‘checks and balances’** are often ambiguous and of general nature – they demand for a responsible interpretation and implementation in order to function as balance to the concrete and precise rules on IP enforcement in ACTA.
- This **imbalance** raises serious concerns: Especially if ACTA is ‘transplanted’ into the laws of developing countries.
Thank you for your attention!

Any comments and questions to

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for details see

http://ssrn.com/abstract=1706567