Use of Compulsory Licenses
Selected National Experiences

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Outline

• Brief overview over Art. 30/31

• National Examples of Use of Compulsory Licenses
  – Brazil
  – Thailand
  – Zimbabwe
  – Mozambique

• Brief overview Paragraph 6
  – Rwanda’s experience
Compulsory Licenses: Art 31

- Government grant of licence to 3rd party to use patent without consent of patent holder
- Governments have right to determine grounds for compulsory licence (reaffirmed in Doha Declaration)
- Examples for granting compulsory license include:
  - failed negotiations to obtain a license on reasonable terms,
  - public interest,
  - national emergencies,
  - failure to exploit or insufficiency of working
  - to remedy anti competitive practices (Article 40)
  - to establish pharmaceutical industrial base or in line with trade/industrial policy objectives
Conditions for getting a CL

• **Need to show prior negotiations** to obtain license under reasonable terms from the patent holder failed

  **Except** when CL issued in cases of

  a) national emergency
  b) situation of extreme urgency including public health crises
  c) Remedy anti-competitive practices

• Payment of “adequate remuneration”

• CL has to be “predominantly for the supply of the domestic market” Article 31 (f)
Government Use Orders

Article 31 of TRIPS

• Government utilization of compulsory licenses
• "Public non-commercial use"
• Government right (govt. agency, dept. or contractor) to use patent in the public interest without the consent of the patent holder
• Fast-track approach
• No need for prior negotiation with patent holder
• Payment of “Adequate Remuneration” to patent holder
Brazil
Brazilian Context

- Since 1996 Brazil free provision of ARVs
- One centralized procurement agency – MoH
- Government run generic manufacturing capacity
- 1996 Brazil becomes TRIPS compliant
- Strong role of national health authorities in IP policy
  - ANVISA gives prior consent to granting of pharmaceutical product and process patents
  - Health sector participates in the Inter-ministerial Group of Intellectual Property
  - Health sector present at international IP negotiations
Brazil’s Use of CLs

• Between 2001-2006 repeated threats of compulsory licenses
• Threat in combination with strong local generics industry main strategy to lower prices for ARVs
• Brazil subject to substantial bilateral pressure
  • Since 2000: Priority Watch List / Special Watch List
  • 2001: USTR files complaint in WTO Dispute Settlement Body for ‘local working’ requirement – later withdrawn due to public pressure

Price reductions:

- Efavirenz – 73%
- Tenofovir 56%
- Lopinavir 56%,
- Nefinavir 74%
From threat to implementation
Efavirenz 2007

<table>
<thead>
<tr>
<th></th>
<th>Brazil</th>
<th>Thailand</th>
<th>UNICEF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per pill</td>
<td>US 1.59</td>
<td>US 0.65</td>
<td>US 0.45</td>
</tr>
<tr>
<td>Per patient / yr</td>
<td>US 580</td>
<td>US 245</td>
<td>US 166</td>
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- Brazil attempted to negotiate from March 2006 to April 2007 for price reductions (matching Thailand), but Merck offer: $ 1.10 per pill
- Brazil issued compulsory license for efavirenz to be imported at US 0.46 per pill
Impact of Price Negotiations
Source: Juliana Vallini, ANVISA, Brazil

EFAVIRENZ (EFZ)
PREÇO E PACIENTES EM USO
BRASIL, 1999 a 2007*

NOTAS:
* Dados referentes a julho/2007.
* Média entre o preço unitário AUROBINDO/UNICEF (US$ 0,4662) e RANBAXY/OPAS (US$ 0,4460).
  - De 1999 a 2002, aquisição da apresentação cápsula de 200mg.
  - A partir de maio/2003, aquisição da apresentação comprimido de 600mg.
  - Para efeito de comparação, de 1999 a 2002, os preços unitários do EFZ 200mg foram obtidos a partir da multiplicação do preço do EFZ 600mg por 3.
Brazil: Average cost of ARVs per patient per year

Source: MOH – STD/HIV-AIDS National Program. Brazil / UNDP
Thailand
Timeline Thai Compulsory License
(Source: Ministry of Public Health and the National Health Security Office 2007)

• 1992: Introduction of product patent protection
• 2000: Introduction of universal health coverage
• 2003: commitment to provide ARVs for all
• 2005: Thailand sets up Ad Hoc Working Group on price negotiations of patented drugs
• 2006: GUL on efavirenz to import (0.5%)
• 2007: GULs on LPV/r and clopidogrel to import (0.5%)
• 2008: GULs on letrozole, docetaxel, elortinib, (imatinimb)
**Price Reductions From 2007 - 2012**

*Source: Thai Ministry of Health*

<table>
<thead>
<tr>
<th>Patients per year</th>
<th>Millions USD Without GUL</th>
<th>Millions USD With GUL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efavirenz</td>
<td>113</td>
<td>36</td>
</tr>
<tr>
<td>LPV+RTV</td>
<td>77</td>
<td>21</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>22</td>
<td>14</td>
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<tr>
<td>Letrozole</td>
<td>92</td>
<td>40</td>
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<tr>
<td>Docetaxel</td>
<td>48</td>
<td>17</td>
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<tr>
<td>Erlotinib</td>
<td>7</td>
<td>0</td>
</tr>
</tbody>
</table>

**Patients**
- 200,000
- 50,000
- 300,000
- 4,900
- 2,000
- 4,600
Predicted Impact Access to Efavirenz

Source: Thai Ministry of Public Health

Figure 2.2 Increase in number of patients with access to EFV following grant of government use license (GUL)
Predicted Impact Access Docetaxel
Source: Thai Ministry of Health

Figure 2.6 Increase in number of patients with access to docetaxel to treat breast and lung cancers following grant of government use license (GUL)
Economic Repercussions and FDI
Source: Ministry of Health, Thailand

• Fear of repercussions often considered key obstacle to use of TRIPS flexibilities
• 2007: on Foreign Priority Watch List due to “lack of transparency and due process”
• US withdraws 3 export products from GSP status (US$ 980 export value):
  – gold jewelery;
  – polyethylene terephthalate in primary forms
  – flat screen colour television sets
• No impact on overall FDI visible – FDI to US still increasing
• Export under GSP largely the same over last 10 years, relative share is going down
• Export of three products to US reduced by US$ 388 million, but increased to rest of world by US$ 521 million
• No impact on Thai Stock Exchange
Mozambique
Legislative Framework

- Mozambique’s Patent Law allows for compulsory licenses:
  - Failure to obtain a license on reasonable terms
  - Cases of emergency or extreme urgency
  - Obligation to demonstrate that negotiations have failed
    - Apart from situation of emergency
    - Need to give adequate remuneration
    - Predominantly for domestic supply
Mozambique compulsory licensing experience

• May 2004: Ministry of Industry and Commerce issues CL
  • States that at end of 2002, more than 1.5 million HIV/AIDS patients in Mozambique
  • CL mentioned the flexibilities conferred by Doha Declaration
  • Failure to obtain ARVs at affordable prices
  • Focused on triple combination of lamivudine, stavudine and nevirapine

• CL granted to Pharco Moz. Ltd to produce 3TC, D4T and NVP
• Total amount of royalties set at 2% total turnover
• Duration of compulsory license linked to the “national emergency” created by HIV/AIDS pandemic A31(c)
• Price of APIs meant local production uneconomically viable
• Original product was not patented in country
→ highlights need for data on patent status
Zimbabwe
Legislative Framework

According to Section 35(1) of Zimbabwean Patents Act:

35. (1) During any period of emergency the powers exercisable in relation to an invention by a department of the State or a person authorized by the Minister under section thirty-four shall include the power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient – [...] 

- for the maintenance of supplies and services essential to the life of the community; or
- for securing a sufficiency of supplies and services essential to the well-being of the community [...]

Issuing of GULs

- 2002: Minister of Justice declares a period of emergency due to HIV/AIDS pandemic valid for 6 months

- 2003: period of emergency extended by 5 years (- 31 December 2008)

- GUL issued to either import or make ARVs

- Local production of antiretrovirals though the generic company Varichem Pharmaceuticals (Private) Limited

- According to MSF lowered the price of AZT/3TC from US$30 per month to less than US$15 a month
Paragraph 6 / 30 August Mechanism
Paragraph 6 of Doha Declaration

• Recognize problem of countries without insufficient or no manufacturing capacity in making use of CLs
• 30 August 2003 adoption of Mechanism:
  – waives 31(f) for exporting country
  – 31(h) waived for importing country
  – countries with manufacturing capacity can make and export pharmaceutical products under patent protection to countries with public health needs
• Conditions for use:
  – Importing member must notify TRIPS Council (except LDCs) and demonstrate that it has insufficient manufacturing capacity
  – Indicate that it has or intends to issue CL
  – Export members must notify TC of terms of export license (destination, quantity, duration, etc)
  – Products must be specially labeled
• Further exemption for RTAs
Jean Chretien Pledge to Africa

- September 2003 Canada announces intention to implement August 30th Decision
- Bill C-9 (JCPA) passed in May 2004: permits granting of ‘export only’ CLs to countries with inadequate or no pharmaceutical capabilities
- May 2004 MSF commits to make use of JCPA
- Meeting with Health Canada to identify key drugs
- December 2004 Apotex agrees to produce triple combination ARV combination of zidovudine / lamivudine / nevirapine
Rwanda’s Use of 30 August Mechanism

- Rwanda Centre for Treatment and Research on AIDS manages to convince government to make use of mechanism
- Document IP/N/9/RWA/1 on 19 July 2007 expresses intention to import 260,000 doses of AZT, 3TC & NVP from Apotex
- LDC status precludes notification as importing country
- Sept 2007: Apotex obtained CL to export
- May 08: Apotex announces price of US$0.195 per tablet
- Cheapest previous source was India at US$0.246 per tablet
- Oct. 08: shipment arrives in Kigali
- Apotex publically stated that it would be hard pressed to repeat the endeavor
Stated reasons for delay

• Generic company needs to negotiate for VL first
• Anti diversion measures so complex it kills incentive of company to produce
• Notification requirements to provide information and proof too burdensome (except LDCs)
• Case by case approach does not reflect need requirements
• Too many hurdles do not allow for expeditious and fast mechanism needed
“When we order medicines normally, all we need to do is type up a form, send it to the supplier and pay the bill - then we receive the shipment. With this system we have to persuade a government to notify the WTO, find a company willing to produce, push to get a drug on the list of eligible medicines, wait for voluntary license negotiations to be completed, wait for the compulsory license application to be made, and then granted ....

For a disease that kills 8,000 people a day, not only is this is not a solution, it's unacceptable”

Dr. Felipe de la Vega, MSF
Conclusions

• CLs powerful tool for reducing prices / increasing access to medicines
  • Price negotiations mechanism – nationally and beyond
  • For national production
  • Importation of products not under patent in producer country
  • To some extent for importation of products under patent protection (RTAs?)

• CLs common tool for limiting the impact of certain patents
  • US most frequent user – mostly for anti trust / competition issues
  • Other examples: Italy, UK, Germany, France, China, Indonesia, Malaysia, Eritrea, Ghana, Guinea, Swaziland, Argentina, Peru, Dominican Republic
  • Even companies try to issue compulsory licenses: Abbott bid to manufacture / sell Hepatitis C virus genotyping kits patented by Innogenetics Inc (2006)
Conclusions

• CL recommended as a tool to reduce medicine prices by:
  • UK CIPR report of 2002
  • CIPIH Report of 2006
  • Several WHO Resolutions
  • UNDP Human Development Reports of 2001 and 2005

• Important to have enabling legislative provisions e.g.
  • Providing for expedient negotiation process
  • Not being too restrictive in limiting applications for CL

• Reality of possible trade repercussions
  • Likely to be bigger in larger developing countries
  • Power of civil society and public outcries
  • The more use of CLs the lesser the repercussions

• BUT pre grant flexibilities should always be first option ...
Thank you!

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