Utilising TRIPs flexibilities on competition law to ensure a sustainable supply of affordable essential medicines: a focus on South Africa

Jonathan Berger
Senior Researcher
AIDS Law Project

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Produced with the support of the ICTSD-UNCTAD Project on IPRs and Sustainable Development, the paper was co-authored by:

- **Trudi Hartzenberg**
  - Executive Director
  - tralac
- **Tenu Avafia**
  - IP Policy Advisor
  - UNDP
- **Jonathan Berger**
  - Senior Researcher
  - AIDS Law Project
Overview of presentation

• Using competition law in South Africa
  – Why use competition law?
    • Setting the South African context
    • Medicines access and the Competition Act 89 of 1998
  – Case studies
    • Hazel Tau vs. GlaxoSmithKline (GSK) and Boehringer Ingelheim
    • Treatment Action Campaign (TAC) and the Southern African HIV Clinicians’ Society vs. Bristol-Myers Squibb (BMS)
  – Strengthening the Competition Act

• Lessons for SADC from South Africa
  – What, if anything, can SADC countries learn from SA?
The South African context

• **Access concerns**
  – Excessive pricing and sustainability of supply

• **Leadership**
  – No government-issued licences under Patents Act
  – Chilling effect of TRIPs+ licensing provisions
    • Failure to implement *Doha Declaration*
    • No licences issued by courts on any patented products

• **Constitutional framework**
  – Socio-economic rights protections
  – Positive state obligations
  – Interpretation of all legislation
Medicines access and the
Competition Act 89 of 1998

• **Standing**
  – Initiating a complaint (section 49B)
    • “Any person may … submit a complaint against an alleged prohibited practice”
  – Interim relief (section 49C)
    • Complainant may apply if at risk of “serious or irreparable damage”
  – Participation in Competition Tribunal hearings (section 53)
    • Complainant, if interest is not adequately represented by others
    • Any other person with a material interest, provided interest not adequately represented by others

• **Sustainability of supply and pricing concerns**
  – Restrictive horizontal and vertical practices (sections 4 & 5)
  – Abuse of dominance (section 8)
    • Excessive pricing (section 8(a))
    • Access to an essential facility/exclusionary acts (sections 8(b) – (d))
Case studies

• **Hazel Tau vs. GSK and Boehringer Ingelheim**
  – Focus on three essential ARVs: AZT, 3TC and NVP
  – Patent-protected
  – No generic competition
  – Excessive private sector prices

• **BMS’s Amphotericin B (Fungizone®)**
  – Gold standard for cryptococcal meningitis
  – Off-patent
  – No generic competition
  – Excessive public and private sector prices
• GSK and BI alleged to have “engaged in excessive pricing of ARVs to the detriment of consumers”

• Conduct was alleged to be –
  – Directly responsible
  – For the premature, predictable and avoidable deaths
  – Of people living with HIV/AIDS

• In contravention of section 8(a) of the Competition Act, 89 of 1998
  – As interpreted in light of the Constitution
What had to be proven?

• Charging a price for a good or service which –
  – Bears no reasonable relation to the economic value of that good or service; and
  – Is higher than this value

• What makes up the economic value?
  – Manufacturing costs
  – R&D costs (where applicable)
  – Licensing costs (where applicable)
  – Reasonable profits

• Reasonable relation
  – Relationship between price and access
  – Within context of constitutionally guaranteed rights
Resolution by settlement

• **Matter settled in December 2003**
  – Avoided Competition Tribunal public hearing
  – Separate settlement agreements
    • Tau et al and two groups of companies
    • Competition Commission and companies
  – Complex legal issues remain unresolved

• **Implementation of settlement**
  – Excessive pricing complaint, but licensing solution
  – Reasonable terms and conditions
    • Public and private sectors
    • Imports and/or local production of products (including FDCs)
    • Exports of locally produced ARVs to sub-Saharan Africa
    • 5% royalty maximum (including for FDCs)
<table>
<thead>
<tr>
<th>Particulars of ARV medicine</th>
<th>Price of patented product at time complaint lodged (in private sector)</th>
<th>Price of cheapest available generic equivalent today (in private sector)</th>
<th>Percentage drop</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZT 300mg (30 days’ supply)</td>
<td>R663.48</td>
<td>R228.91</td>
<td>65.5%</td>
</tr>
<tr>
<td>AZT solution (200ml)</td>
<td>R157.46</td>
<td>R66.78</td>
<td>57.6%</td>
</tr>
<tr>
<td>Lamivudine 150mg (30 days’ supply)</td>
<td>R729.60</td>
<td>R85.50</td>
<td>88.3%</td>
</tr>
<tr>
<td>Lamivudine solution (240ml)</td>
<td>R267.90</td>
<td>R62.88</td>
<td>76.5%</td>
</tr>
<tr>
<td>AZT/lamivudine 300mg/150mg (30 days’ supply)</td>
<td>R912.00</td>
<td>R296.38</td>
<td>67.5%</td>
</tr>
<tr>
<td>Nevirapine 200mg (30 days’ supply)</td>
<td>R410.40</td>
<td>R159.60</td>
<td>61.1%</td>
</tr>
</tbody>
</table>
Amphotericin B

• **Need for access**
  – Cryptococcal meningitis has 25 – 40% mortality rate in people living with HIV/AIDS
  – Limited use in public sector primarily as result of price
  – Private sector price even higher

• **Legal action**
  – Threat of excessive pricing action
  – Request for justification of pricing policy
  – Matter settled after series of letters
    • Private/public divide overcome
    • Price reduction of between 80% and 85%
Strengthening the Competition Act

• **Overcoming the complex set of hurdles**
  – Amend statute to clarify its application to IP
  – Commission to make use of section 79(1) powers → guidelines on policy approach to competition/IP interface

• **Resource allocation**
  – Commission to facilitate complainants’ role

• **Express recognition of compulsory licensing**
  – Unclear when – if at all – it is an appropriate form of relief

• **Coherency in medicines regulation**
  – Needs to “speak” to Medicines Act and Patents Act
Lessons for SADC from South Africa?

• Recognition of challenges in SADC countries
  – Lack of appropriate competition laws?
  – Lack of capacity for “Rolls Royce” competition authority?

• Context supporting the use of competition law
  – Competition law within a constitutional framework
  – Well-resourced and mobilised civil society

• Not “either/or” but “and”
  – GARPP/TAC Treatment Project application for a compulsory licence in terms of section 56 of Patents Act
  – TAC/ALP pressure on state to issue licences (section 4)
  – Nevertheless, back to Competition Commission
    • TAC vs. MSD and Abbott Laboratories – forthcoming in 2007
The AIDS Law Project, a section 21 company and a registered law clinic, is formally associated with the School of Law at the University of the Witwatersrand, Johannesburg.

AIDS Law Project
Braamfontein Centre
23 Jorissen Street
Braamfontein JOHANNESBURG
P O Box 32361
Braamfontein 2017
SOUTH AFRICA

+27(0)11 356 4100 (tel)
+27(0)11 356 4112 (direct)
+27(0)11 339 4311 (fax)
+27(0)83 419 5779 (cell)

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