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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- **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

Tau v GSK and BI

- **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)

Price reductions

Particulars of ARV medicine	Price of patented product at time complaint lodged (in private sector)	Price of cheapest available generic equivalent today (in private sector)	Percentage drop
AZT 300mg (30 days' supply)	R663.48	R228.91	**65.5%**
AZT solution (200ml)	R157.46	R66.78	**57.6%**
Lamivudine 150mg (30 days' supply)	R729.60	R85.50	**88.3%**
Lamivudine solution (240ml)	R267.90	R62.88	**76.5%**
AZT/lamivudine 300mg/150mg (30 days' supply)	R912.00	R296.38	**67.5%**
Nevirapine 200mg (30 days' supply)	R410.40	R159.60	**61.1%**

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)