Using competition law to increase access to medicines: *Tau v GSK* and *TAC v MSD*

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Overview of presentation

- Identifying relevant “competition rules”
  - Articles 1.1, 8, 31(c) and (k), and 40 of TRIPS

- Rules, competition policy and access
  - General comments
  - Abuse of dominance
    - Excessive pricing
    - Refusals to license

- Using competition law in South Africa
  - Understanding South Africa’s competition law framework
  - *Tau v GSK and Boehringer Ingelheim*
  - *TAC v MSD and Merck*
Identifying the “rules” (1)

- Article 1.1: freedom to determine “appropriate method of implementing the provisions of ... [TRIPs] within ... own legal system and practice”
  - Form of legislation
    - Single IP statute, including dealing with anti-competitive practices
    - Separate legislation for patents, copyright, competition law ...
    - Abuse of exclusive rights in patent and/or competition law
  - Institutional framework
    - Specialist regulatory authority
    - Utilise ordinary court system
    - Hybrid system
  - Extent/nature of state involvement
    - Forum/mechanism for third party dispute settlement
    - Active enforcement of competition law and policy
Identifying the “rules” (2)

• Article 8.1: recognises possible need to adopt certain measures in the public interest
  – Regardless of conduct of exclusive rights holder
  – Depends on role ascribed to competition policy
    • In SA: development of economy; advancement of welfare
    • Strengthening of domestic manufacturing capacity where necessary to ensure sustainability of supply

• Article 8.2: recognises possible need to prevent abuse of rights in IP/other problematic conduct
  – To deal with three areas of problematic conduct
    • Abuse of exclusive rights
    • Unreasonable restraint of trade
    • Adversely affect international transfer of technology
Identifying the “rules” (3)

• Articles 31(c) and (k)
  – Recognise egregious nature of anti-competitive practices involving patents
    • 31(c): limits use of compulsory licensing w.r.t. semi-conductor technology to “public non-commercial use” or to remedy an anti-competitive practice
    • 31(k): exemption from certain requirements if license issued to remedy an anti-competitive practice
      – No prior negotiations
      – No limitations on exports
      – No possibility of termination of licences
  – Definition of anti-competitive
    • Not a blank cheque
    • But wide room for country-specific definitions
• Article 40
  – Rights holders generally are free to determine:
    • Whom to license
    • Under what conditions to license
  – Provided:
    • None of the terms and conditions of the licences (or manner of their implementation)
    • Constitutes an abuse of rights
    • Having an “adverse effect on competition”
  – Abuse of rights?
    • Use of exclusive rights
    • In anti-competitive way
    • That affects trade negatively
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• Exercise of rights cannot in and of itself provide a basis for using competition law tools
  – Freedom to determine grounds for licensing (*Doha*) ≠ overly broad definition of “anti-competitive”
  – When no abusive or problematic conduct, invoke government-use and other standard instruments: competition policy is an inappropriate vehicle where conduct not problematic (or potentially problematic)

• Focus on abuse of dominance
  – Preliminary comments
  – Excessive pricing
  – Refusals to license
Preliminary comments

• Patents do not necessarily confer dominance
  – But in certain circumstances, existence is sufficient
  – Need for guidelines on how patents contribute to / result in dominance

• Need to get the definitions right
  – Market definition
  – Extent of market share for deemed dominance

• Focus on unfair advantage of dominance
  – More than mere assertion of exclusive rights
    • Higher prices than those of generic competitors not enough
    • Simple refusals to license not enough
Excessive pricing

• **Context specific**
  – May vary from country to country
    – Human development index
    – Constitutional context
  – Taking unfair advantage of market exclusivity
    – To extract unjustifiable benefit
    – Not necessary for creating or maintaining incentives to innovate

• **Value of pricing investigation**
  – Openness and accountability
  – Justification of pricing models
  – Easy to tap into public sentiment
  – Strengthen hand in negotiations for licences
Refusals to license

• Refusal to license not in and of itself abusive
  – Essence of the right to exclude
  – Case-by-case analysis

• No developed country consensus
  – EU: unlawful where prevents market entry of innovative product for which there is consumer demand if –
    • Not objectively justifiable
    • Excludes competition in a “secondary market”
  – US: freedom to choose whether to license

• How to frame?
  – Essential facilities doctrine vs. exclusionary conduct
  • Refusal to deal not objectively justifiable?
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South Africa’s framework

- **Competition Authority**
  - Competition Commission
  - Competition Tribunal
  - Competition Appeal Court
  - Other courts (SCA and Constitutional Court)

- **Standing requirements**
  - Anyone may lodge a complaint
    - Need legal representation to make a substantive complaint
    - Limited capacity of the Competition Commission
  - “Interested” parties may intervene in Competition Tribunal
  - Competition Commission solicits civil society input
    - Aspen / GSK merger
• 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 death of adults and children with HIV/AIDS

• In contravention of –
  – Section 8(a) of the Competition Act, 89 of 1998
    • Part of the abuse of dominance provisions
  – As interpreted in light of the Constitution
    • Definition of excessive price – no “reasonable relation” between the price charged and the “economic value” of the product
Resolution by settlement

• **Matter settled in December 2003**
  – Avoided potentially embarrassing public hearing
  – Separate settlement agreements
    • Tau et al and two groups of companies
    • Competition Commission and companies (later declared invalid)
  – 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), with exports of latter to all of sub-Saharan Africa
    • 5% royalty maximum (including for FDCs)
## Price reductions

<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>R161.25</td>
<td>75.7%</td>
</tr>
<tr>
<td>AZT solution (200ml)</td>
<td>R157.46</td>
<td>R64.41</td>
<td>59.1%</td>
</tr>
<tr>
<td>Lamivudine 150mg (30 days’ supply)</td>
<td>R729.60</td>
<td>R44.40</td>
<td>93.9%</td>
</tr>
<tr>
<td>Lamivudine solution (240ml)</td>
<td>R267.90</td>
<td>R75.81</td>
<td>71.8%</td>
</tr>
<tr>
<td>AZT/lamivudine 300mg/150mg (30 days’ supply)</td>
<td>R912.00</td>
<td>R250.80</td>
<td>72.5%</td>
</tr>
<tr>
<td>Nevirapine 200mg (30 days’ supply)</td>
<td>R410.40</td>
<td>R171.00</td>
<td>58.3%</td>
</tr>
</tbody>
</table>
TAC v MSD and Merck

• Began discussions with MSD in May 2002
  – No licences had been issued at this point
  – Simultaneously began discussions with other companies

• Discussions and correspondence through 2007
  – Series of letters in 2002 and 2004/2005
  – Letter of demand sent in May 2007

• MSD’s history of inching along
  – Licensed Thembalami in November 2004
  – Aspen Pharmacare became sole licensee in July 2005
  – Adcock Ingram became second licensee in August 2007
  – Price of drug reduced when generic prices dropped
• Refusal to license *per se* is not anti-competitive

• Approach to abuse of dominance provisions
  – Interpret within context of Act, constitutional rights recognised in South Africa, and international law
  – Balance between effect of and reason for exclusion

• Sufficient reason, *in the circumstances*, to compel MSD to license?
  – Prevented market entry of cheaper and new combinations (FDCs and co-packs) of existing drugs
  – Placed sustainability of supply at risk
Outcome of the complaint

• Additional licences granted
  – Cipla-Medpro, Aurobindo and Sonke (Ranbaxy)

• Terms of all licensing agreements amended
  – Permission for combinations not unreasonably withheld
  – Contribution in lieu of royalty no longer required

• State procurement of generic efavirenz
  – 4-plus-1 600mg products registered for 2008 ARV tender
  – Split award (70% @ ± 39% off; 30% @ ± 35% off)
  – Aurobindo v Chairperson, State Tender Board
  – Greater competition for and scrutiny of 2010 ARV tender
Lessons learnt from cases

• **Successes**
  – Practical outcome
    • Multiple licensees = price reductions
  – Confirmed approach to private sector
    • Mere threat of legal action insufficient, but rational response to filing of strong case

• **Challenges**
  – Unsustainable approach
    • Limited focus on particular drug(s) with unique facts
    • Commission has limited capacity to investigate
  – Unlikely to result in jurisprudence
    • Companies always likely to settle in face of strong case
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