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



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# Overview of presentation

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- **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)

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- **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)

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- **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)

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- **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

# Identifying the “rules” (4)

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- **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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# Rules, competition policy and access

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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

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- **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

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- **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

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- **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

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- **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

# *Tau v GSK and Boehringer Ingelheim*

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- **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

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- **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

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
<b>AZT 300mg (30 days' supply)</b>	<b>R663.48</b>	<b>R161.25</b>	<b>75.7%</b>
<b>AZT solution (200ml)</b>	<b>R157.46</b>	<b>R64.41</b>	<b>59.1%</b>
<b>Lamivudine 150mg (30 days' supply)</b>	<b>R729.60</b>	<b>R44.40</b>	<b>93.9%</b>
<b>Lamivudine solution (240ml)</b>	<b>R267.90</b>	<b>R75.81</b>	<b>71.8%</b>
<b>AZT/lamivudine 300mg/150mg (30 days' supply)</b>	<b>R912.00</b>	<b>R250.80</b>	<b>72.5%</b>
<b>Nevirapine 200mg (30 days' supply)</b>	<b>R410.40</b>	<b>R171.00</b>	<b>58.3%</b>

# *TAC v MSD and Merck*

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- **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

# Essence of legal argument

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- **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

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- **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% @  $\pm$  39% off; 30% @  $\pm$  35% off)
  - *Aurobindo v Chairperson, State Tender Board*
  - Greater competition for and scrutiny of 2010 ARV tender

# Lessons learnt from cases

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- **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

# Contact details

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