



No time to wait: taking legal action to increase access to HIV medicines

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Overview of presentation



- **South African context**
 - Access concerns
 - Political context
 - Constitutional framework
- **Case studies**
 - *Hazel Tau vs. GSK and Boehringer Ingelheim*
 - BMS's Amphotericin B (Fungizone[®])
- **Concluding thoughts**



South African context



- **Access concerns**
 - Excessive pricing
 - Sustainability of supply
- **Political context**
 - Government inaction
 - Civil society leadership
- **Constitutional framework**
 - Socio-economic rights protections
 - Positive state obligations
 - Interpretation of all legislation

- ***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 = balancing of rights**



Resolution by settlement



- **Matter settled in December 2003**
 - Avoided Competition Tribunal public hearing
 - 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%



Concluding thoughts



- **Civil society took the lead**
 - No government-issued licences under Patents Act
 - Not even threats of issuing licences
 - State willing to let civil society do its “dirty work”
 - Chilling effect of TRIPs+ compulsory licensing provisions
 - Failure to implement *Doha Declaration*
 - No licences issued by courts on any patented products
 - No applications for licences by generic manufacturers of ARVs
- **Need for regulatory reform**
 - Express licensing remedy for excessive pricing
 - Implement the *Doha Declaration*



Go to www.AIDStruth.org for accurate information on HIV/AIDS and to learn about how AIDS denialists twist the truth and peddle lies.