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South Africa
Enforcement of Pharmaceutical Patents
and
the New Draft IP Policy

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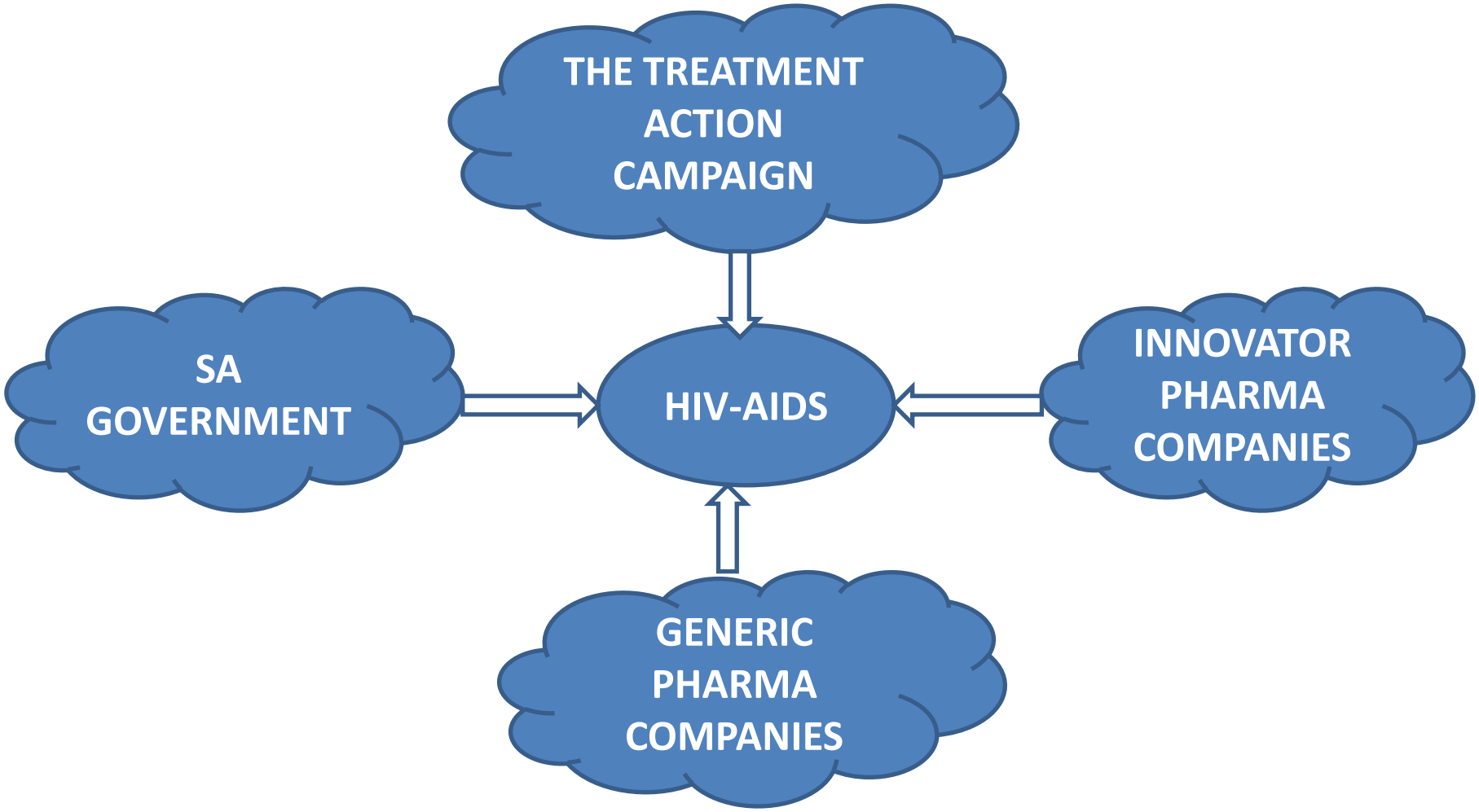
OVERVIEW | Enforcement of Pharmaceutical Patents

- The Role Players
- Compulsory Licensing Provisions
- Section 15C of Medicines Act
- The Taxotere Case
- The Way Forward

THE ROLE PLAYERS



COMPULSORY LICENSING PROVISIONS

Abuse of rights if:

- the demand for the patented article in SA is not being met to an adequate extent and on reasonable terms
- licence refused on reasonable terms and trade or industry, or establishment of any new trade or industry is being prejudiced, and it is in the public interest that licences should be granted
- Demand met by importation but price charged by patentee (or licensee) excessive in comparison to other countries where the patented product manufactured.

SECTION 15C OF THE MEDICINES ACT

Minister may prescribe conditions for supply of more affordable medicines in certain circumstances so as to protect the health of public and in particular may:

- "Notwithstanding anything to the contrary contained in the Patents Act .... determine that the rights with regard to any medicine under a patent ....shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine"

SECTION 15C OF THE MEDICINES ACT - cont.

- Widely publicised dispute between Pharma companies and SA Government in early 2000's

- Settlement that SA Government would not implement without regard to TRIPS obligations (Article 8 and 31)

SECTION 15C OF THE MEDICINES ACT – cont.

The broad outcomes:

- Competition law inquiry resulted in licences being agreed to ("forced") for certain HIV Drugs.
- Commercial reality overtook legal events

THE TAXOTERE CASE

TAC INTERVENED (*amicus*) AT SUPREME COURT HEARING

- Right to access to medicines enshrined in Constitution
- Preliminary injunction should not prevent supply of cheaper medicines for critical "life saving" drugs
- Public interest – *eBay Inc vs. Merck Exchange LLC*

WHERE ARE WE NOW?

- Compulsory licence provisions in Patents Act are dormant
- 15(3C) of Medicines Act not enforced/used
- Historical and future pressures continue to enhance supply
- Public interest now a factor in preliminary injunction applications

THE FUTURE

- Patent Examination System

OVERVIEW | New Draft IP Policy

- Setting the scene
- IP Policy – pharma
- IP Policy:
  - Patentable Subject Matter
  - Substantive Examination
  - Access
- Conclusion

Setting the Scene | General Comments

"..Innovation cannot take place in isolation from concerns about access, and access has to be seen in the broader context of the need for innovation and effective regulation."

"..Access is not a static equation – an integral feature of appropriate access strategies must be a recognition of the value of targeted and appropriate innovation, both for major new breakthroughs and for adaptations to, and improvements in, existing technologies.

- (Promoting Access to Medical Technologies and Innovation, Intersections between public health, intellectual property and trade, WTO, WIPO, WHO 2013 ("PAMTI"), p30 and 35 respectively)

Setting the Scene | General Comments

IP:

- **"provide incentives and creations that benefit society at large…"**

- **"…directly and negatively/positively impacts on access to healthcare … and access to medicines/drugs…"**

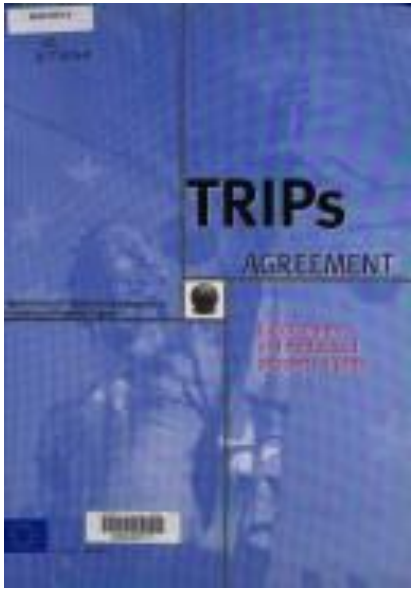
- **"…must not contradict public health policies and the two should be balanced… "**
  - (Draft National Policy on Intellectual Property of South Africa GG 36816 of 4 September 2013, p 23, 24 and 39)

IP Policy | General Objectives Relevant to Pharmaceutical Sector

Objectives:

- To addresses emerging issues relating to IP … **such as public health**
- To **improve access** (other sectors and local innovation)
- To **promote research, development and innovation**
- To improve **national compliance with international treaties** (TRIPS?)
- To **engender confidence and attract investment**
- To alignment with developing countries
- To reject the Roadmap on PCT as it may lead to policy **compromise** and introduce TRIPS Plus requirements
- "weak" patents stifles access to public health

Patents | The Basics



- **No extensions of this term** (20 years)
- Market authorisation required (3 to 5 years delay)
- **Lapse** of SA patents: year 8 +/- only 40% maintained, 20% by year 15 and less than 10% in the last year
- WHO list of essential medicines, 95% of the medicines were patented and now **less than 1.4% remain**

IP Policy | .....

- Patentable Subject Matter
  - Incremental innovation?
  - Different industries ?
- Prosecution of Patent Applications
  - Invalid or partially valid patent not enforceable
  - Revocation on various grounds available at any time by any person
  - Substantive search and examination
  - Pre and post grant oppositions
  - Costs and resources vs real benefits
  - Interim protection, presumptions on validity, enforceability of partially valid patents vs abuse of opposition proceedings

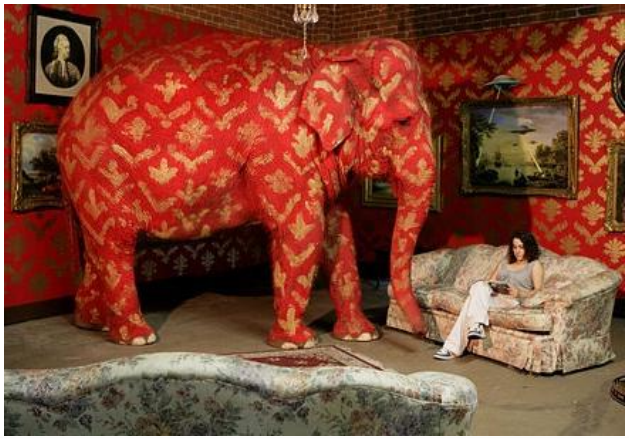
IP Policy | .....cont.

- Access - by way of compulsory licenses
  - Abuse of patent rights
  - Court determined conditions
  - TRIPS Art 8 and 31 - terms and conditions
  - Local manufacturing and development
- Access – By way of Parallel Importation
  - Local exhaustion unless sold internationally without restrictions
  - For genuine pharmaceutical products under permit
  - Quality and counterfeits
  - Various reasons for costs differences
  - Profit driven

IP Policy | Conclusions

- Constitutionality of parallel importation never pronounced upon
- Legislation introduced for parallel importation – never used
- SA small market – about 1.5% or lower of global pharmaceutical market
- Reticence to launch new and/or improved products
- Interdependence: No new products = 0 access = 0 generics

- <u>Elephant in the room:</u>
  Infrastructure, hospital costs, patient compliance and support, manufacturing?



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Thank You

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