Compete as a First Mover: Innovation in Generics

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AHMTEC – Topic 12

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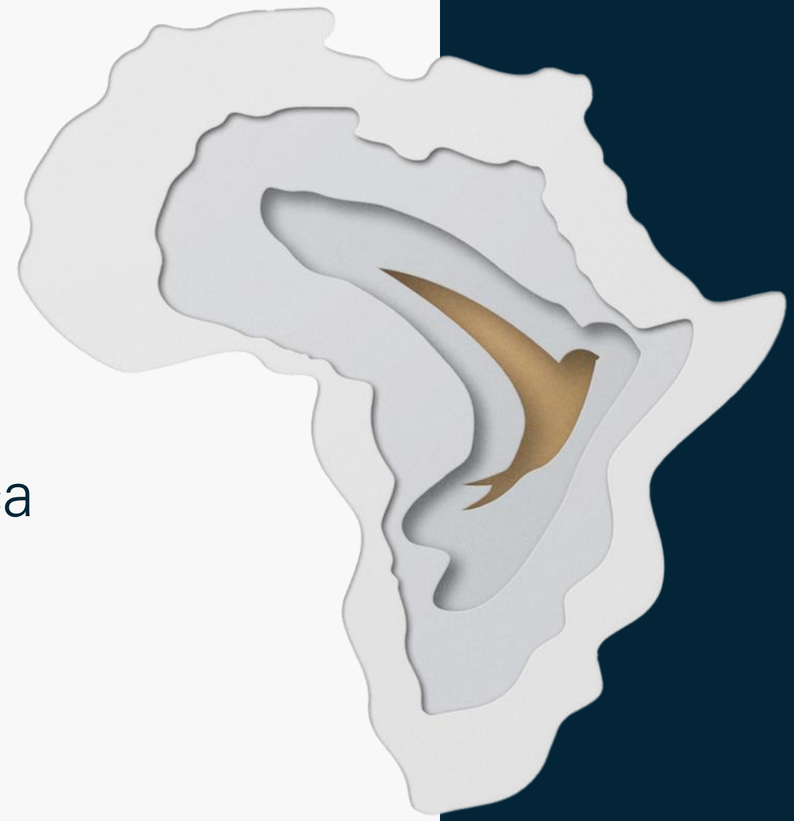
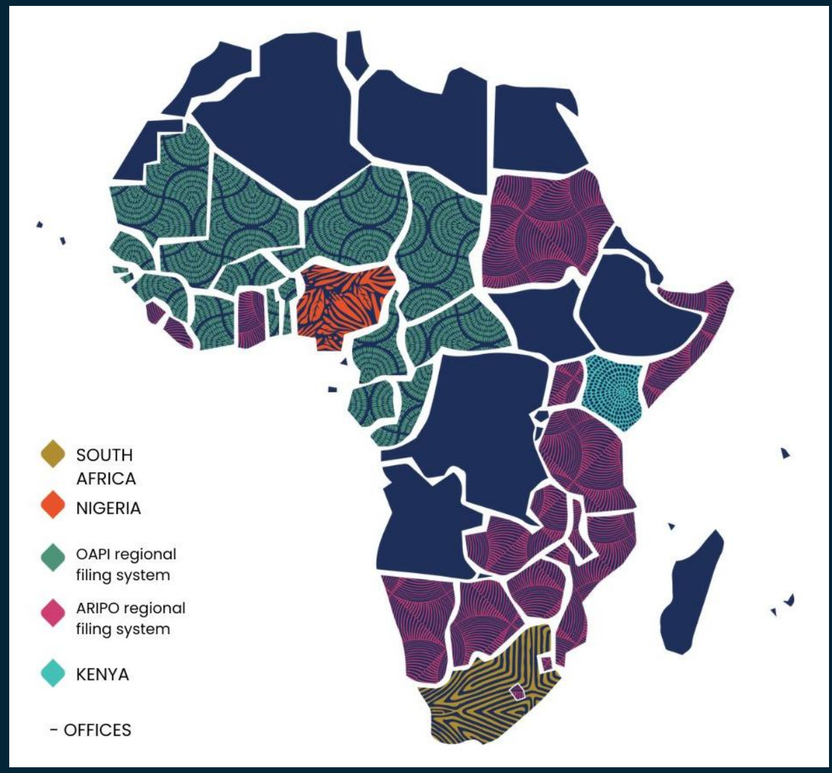


Disclaimer:

Africa has 54 recognised countries. Each has its own legal system. While there are commonalties in IP regimes, there are also country specific nuances that are important. It is beyond the scope of this presentation to provide an "African pharmaceutical IP solution".

Our focus is to rather provide an overview of approaches to dealing with patents.



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Licensing Strategies for Pre-Expiry Launch

Two approaches:

1. Voluntary
2. Compulsory

Voluntary Licences

- A compelling business case must be made
- Usually, patentees do not want to negotiate with generics (or be seen to be doing so)
- Requires tech transfer – can be "old" tech (neither green nor efficient)
- Closely bound to originator and its technology and process
  - Stifles innovation
  - Difficult to move
  - Entrenches "stale" technology in a fresh landscape

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Compulsory Licensing

Two types:

1. Abuse of rights
2. Dependent patents

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Abuse of Rights

These are typically applied for through a judicial or quasi-judicial process in circumstances where:

1. The patented medicine is not being supplied to meet demand; or
2. Where pricing is exorbitant

Difficulties:

1. It can be simple for the patentee to step up supply;
2. Pricing is normally globally controlled so it becomes difficult to show it as excessive in a specific country;
3. The licence typically falls away if the “abuse” ceases.

What can be done:

1. Lobby local governments to change requirements (being aware of TRIPS)
2. Run a test case to try have exorbitant pricing be defined as manufacturing costs plus country-specific premium set at GDP (or similar)

Dependent Patents

(If you take one thing away from this presentation…)

Completely under-utilised

Can typically obtain a compulsory licence where one cannot work one's own patent without infringing a previous patent. *For example: I cannot work my formulation patent without infringing a compound patent*

What do we need:

1. Active research into improving drugs:
    a. Manufacturing process
        i. Cheaper
        ii. More environmentally friendly
        iii. Safer
    b. Formulations
    c. Specific packaging?

2. Much of this is inherent in the development process
    a. Monitor closely
    b. Protect where possible
    c. Incentivise teams to innovate

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Dependent Patents

Difficulties:

Will one still be able to file ANDA?
May need more than a frivolous improvement

Advantages:

Helps turn focus from copy to innovate
Long-term culture shift with benefits
Possible medium-term gains with pre-expiry entries
Leapfrog existing technology

Thank you

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