Opportunities and Challenges in Africa Protection and Enforcement of Trade Marks and Anti-Counterfeiting Strategies

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Agenda

- Scope of presentation
- Africa and its legal systems
- IP Protection – searching and filing
- Anti Counterfeiting
- Enforcement
- Conclusions
How big is Africa?

- World’s second largest continent
- Covers about 1/5 of the earth’s land area
- Almost 60 territories
- Population of over 1 billion people
- Fastest growing region in the world (ahead of East Asia in 8 of the past 10 years according to The Economist)
Legal systems in Africa

- Based on or heavily influenced by former colonising powers – Great Britain, France and Portugal
- Most French and Portuguese former colonies have civil law legal systems based on the Napoleonic code
- Former English colonies have a common law legal system
- South Africa has a mixed Roman-Dutch/common law regime as a result of it first being colonised by the Dutch then the British, which then spread to Namibia, Botswana, Zimbabwe, Lesotho and Swaziland
IP developments in Africa

- Recognition that IP laws need to be updated
- Burundi, Djibouti, Ethiopia, Gambia, Ghana, Kenya, Mauritius, Rwanda, Uganda, Zanzibar – new laws
- Kenya, Malawi, Namibia, Nigeria, Uganda, Zambia and South Africa – new laws in progress
- Sudan and South Sudan?
Trade mark filing, prosecution, opposition and cancellation

- Searches across Africa are highly recommended although can be challenging due to different standards of record-keeping at each registry.
- In some countries e.g. Nigeria the value of searches is somewhat dubious.
- Searches are compulsory in Uganda
- Search and prosecution time frame in each country depends on:
  - type of system
  - whether examination is involved
  - resources at each registry
  - each registry’s capacity to handle volume
- All countries with a registration system have an opposition or cancellation procedure
The good....
....and the not so good!
## East Africa

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- **Somalia**
  - non operational since 1991
  - no sign of any change
- **Tanzania** Political union between mainland Tanzania and Zanzibar
SOUTHERN AFRICA
## Southern Africa

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- Malawi and Zambia no service mark protection
- Burundi no renewals i.e. unlimited term
ARIPO

• African Regional Intellectual Property Organisation
• Beneficial in theory
• Coverage of Botswana, Lesotho, Liberia, Malawi, Namibia, Swaziland, Tanzania, Uganda and Zimbabwe
• Presently in two states where rights are definitely enforceable (Botswana and Zimbabwe)
• Tanzania?
French West Africa
French West Africa

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- **OAPI**
  - Benin, Burkina-Faso, Cameroon, Central African Republic, Chad, Comoros, Republic of Congo, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Ivory Coast, Mali, Mauritania, Niger, Senegal and Togo
  - One central registry, no national registries
  - Works very well
  - The **Comoros** joined OAPI on 25 May 2013 and indications are that the Democratic Republic of Congo may also be considering joining OAPI
English West Africa
## English West Africa

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- **Sierra Leone** no service mark protection; local classification
- **Gambia** registration delays
- **Liberia** opposition possible in theory but not in practice
Anti Counterfeiting in Sub-Saharan Africa
What is a Counterfeit Medicine?

WHO definition:
“…one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging”.

World Health Organization
Doesn’t include Expired Product
Doesn’t include “Look-a-likes”
Definitely Does Not Include Generics

• Generics can themselves be the victim of counterfeiting
• We should focus on trade mark rights rather than patent rights when discussing border measures
• Access to medicines campaigners claim Pharma companies use counterfeit and customs legislation to impede generic medicines
• This has contributed to failure of legislation and/or treaties e.g. Kenyan AC Act and ACTA
Africa: Where Have Counterfeit GSK Products Been Found?
GSK’s Anti-Counterfeiting Objectives

- Protect Public Health
- Prevent Manufacture or Distribution
- Prosecute Counterfeiters
- Protect GSK’s Reputation
Challenges

- Counterfeiting is a clandestine activity- impossible to accurately quantify
- Counterfeiters become increasingly sophisticated.
- Corruption- lack of funds in correct places
- Lack of legal framework to prevent counterfeiting.
- Lack of judicial awareness/appetite.
- Lack of punishment- in some countries can accept fine instead of prison (or prison sentences are short)
Regulatory Challenges

- Many pharma companies do not have local offices and are reliant on distributors.
- Some African countries still have no regulatory approval system in place or regulatory law e.g. Burkina Faso.
- Some countries don’t have effective IP rights.
- Resource challenges around enforcement.
- Regulatory restrictions mean communicating effectively with patients can be difficult.
Relationship with Customs: Challenges

- Customs reporting lines (to Minister of Finance) Limited taxes on pharmaceuticals
- Sharing of information between Customs internationally and within Africa
- EU cessation on stopping in transit shipments
Relationship with Customs: Solutions

- World Customs Organisation
  - Regional Operations with multiple countries
    e.g. Vice Grips 2 – Togo
IPM enables rights holder’s to input details such as:

- Previous counterfeit cases,
- known counterfeiters and routes,
- trade mark rights
- images of genuine and counterfeit product
- Region specific information
Relationship with Customs: Solutions

- Top level information
  - Shipping documents
  - Consignment outer packaging
  - Shipping Routes
  - Customs brokers
Relationship with Police: Challenges & Solutions

- Lack of interest or resource
- Corruption

Interpol

- Various pharma companies are supporting an Interpol project targeting counterfeit medicines
- Conferences and linked operations are being organised
Variations of Counterfeit & Genuine

ZENNTEL 400mg
albendazole
Boîte de 1 comprimé pelliculé

ZENNTEL 400mg
albendazole
comprìmo pelliculé

ZENNTEL 400mg
film-coated tablet
albendazole

ZENTEL albendazole
Each tablet contains 200 mg albendazole
treatment for common worms

One dose
2 tablets
جرعة واحدة

NAFDAC REG. No.:04-2400
Is it All About Nigeria?

- Prominent voice on global stage
- Even product not destined for Nigeria often bears a NAFDAC registration number
Challenges of Analysis: Nigeria – “fruity” antibiotics

- metronidazol + rhaponticin and astringen
- amoxicillin + clavulanic acid
Packaging: Anti-Counterfeiting Tools

Purpose
- Detect
- Deter
- Defend

Packaging Design Options
- Serialisation
- Overt features
- Covert features with revealing aid
- Covert features

Increasing confidence pack is real
Overt Features

- Must be difficult to copy
- Must not be able to be re-used
- Deterrent rather than obstacle to counterfeits
- Often more expensive than covert options
- Counterfeiters quickly catch on…
Verification Techniques and Tools: Why mobile in Africa?

Source: IMF 2009

- 37% Mobile penetration
- 25% Electricity penetration

6.7% Internet penetration

3.9% of the world’s Internet users are African

27% of Africa’s Internet users reside in South Africa
What is delivered to the Customer?

1. Customer buys labelled product from Vendor

2. Customer Texts Hidden Code to SMS Service

3. SMS Service Responds if Code Recognised

4. If issue contact SMS Help Line

Service free to customer

OK
Original Ampiclox cap 500mg
NRN:04-2401
GlaxoSmithKline: Do more, feel better, live longer
Problem? Call 08039012929
NAFDAC & GSK Pharm. Nig. Ltd
SMS by Sproxil
What Else is Being Done?

- IFPMA – video/survey/UN report
- OECD – survey on counterfeit levels
- WHO – independent survey on counterfeits
- Medicrime – Guinea currently the only SSA signatory
- EFPIA – lobbying on goods in transit & Medicrime
Other Considerations
Donated/ Cost Price Product

• What happens when product is cheap/ free and its distribution is outside your control?
• Packaging can be less sophisticated – often doesn’t have overt/covert features
• Sometimes packaging doesn’t bear a trade mark you can use to enforce
• Enforcement opportunity may be limited by contract
Bribery & Corruption

- Many SSA countries have a low Transparency International Corruption Index rating
- Increased focus in pharma industry on FCPA and UK Bribery Act
- Regulatory and police authorities in many countries are under resourced and genuinely cannot carry out raid action

Credit: Pharmaceutical Security Institute
Sanctions Issues

- Can you enforce in Sudan, Zimbabwe or the Ivory Coast?
- All three countries are the subject of EU sanctions which affect “designated persons” from those countries.
- Important to check prior to engaging local counsel, investigators etc.
Enforcement
Enforcement of trade mark rights
TM infringement – English Law Countries

• A registered trade mark is a prerequisite for an infringement action
• An infringement is generally:
  – Unauthorised use of an identical mark or mark so nearly resembling it as to be likely to deceive or cause confusion;
  – In the course of trade;
  – On the same or similar goods / services.
• Burden of proof on the plaintiff
• Relief includes:
  • Interdict / interim injunction;
  • Permanent injunction;
  • Damages (actual quantified damages);
  • Reasonable royalty (in SA).
TM infringement – English law countries

- Action is brought before the High Court or Commercial Court;
- Usually preceded by a letter of demand;
- Advantage is that the process is driven by the Plaintiff and that Judges usually of high calibre;
- Disadvantage is cost; inconvenience to witnesses; time taken to complete proceedings.
SOUTH AFRICA
Counterfeit Enforcement in South Africa

- Comprehensive TRIPS-compliant legislation
- Provides for comprehensive criminal and civil remedies and procedures in order to protect against counterfeiting
- The Counterfeit Goods Act - relatively low threshold for availability of relief and reduces potential liability of the police or customs officers
- Very effective legislation
- No monetary value/bond required, only an indemnity required before Customs recordal can be approved
- If action is taken without justification, the affected party can institute an action for damages
- The scope of the Act can be divided into two general scenarios: border remedies and open market enforcement
Enforcement in Kenya

- The Anti-counterfeit Act (13/2008) combats the prolific trade in counterfeit goods in Kenya.
- Some of the key features of the Act:
  - Enables owners of various IP rights to take action against counterfeiting and provides for streamlined and effective enforcement measures.
  - Brings Kenya substantially into compliance with certain provisions of the Agreement on trade-related aspects of IP rights, to which it is a party.
  - Makes provision for inspectors to search and enter premises with a view to seizing counterfeit goods.
  - CHALLENGE: The Act was the subject of judicial review on the basis of access to medicines claiming that present wording would mean generics could be stopped.
Enforcement in Kenya

Enforcement can be carried out by various appointed officials including:

- police officers,
- authorised customs officers and
- inspectors appointed under other relevant legislation

- Before any enforcement official will take action, the IP rights holder must sign an indemnity form indemnifying the officials from any liability for damages
- An inspector may arrest, without a warrant, any person he suspects has committed an offence
Anti Counterfeiting Agency (ACA) - Kenya

- Established under Section 3 of the Anti-Counterfeit Act No. 13 of 2008
- Entered into operation June 2010
- Targeting around 380 staff by end of 2013
- Governed by mixture of ministries and existing bodies such as PPB & Customs as well as input from KAM (Kenyan Association of Manufacturers)
- Lacks funding and facilities
NIGERIA
Counterfeit Enforcement in Nigeria

- A very difficult and uncertain jurisdiction with no specific anti-counterfeiting laws
- Court action is only recommended where importers and sellers of infringing goods are established companies at a fixed address
- No customs watch notices
- Historically = statutory infringement action brought in the Federal High Court
- The Merchandise Marks Act empowers police to conduct raids for search and seizure of counterfeit goods – difficult in practice
- Many of the informal markets are too dangerous to take action in
- NAFDAC are primarily responsible for medicines enforcement
- The formation of a Federal Task Force against counterfeits is currently underway as a collaboration between NAFDAC, Police, Customs, - seeking funding from industry
Mauritius

- Mauritius is one of the few countries to actively enforce against parallel imports:
  - via a customs recordal
  - once product has entered the country.
- Ralph Lauren case
  - POLO
  - POLO by Ralph Lauren
TM infringement – French law countries

- A registered trade mark is a prerequisite for an infringement action.
- An infringement is generally:
  - Unauthorised use of an identical mark or mark so nearly resembling it as to be likely to deceive or cause confusion;
  - In the course of trade;
  - On the same or similar goods / services.
- Burden of proof on the plaintiff.
- Relief includes:
  - Seizure and forfeiture of infringing goods;
  - Permanent order preventing repeat infringements;
  - Damages.
TM infringement – French law countries

- Inquisitorial system – quite time consuming;
- Postponements common;
- Action initiated by the filing of a complaint with the Court who appoint a Hussier to conduct preliminary enquiries and serve the summons;
- Assuming the action is defended it can take years to reach judgment;
- Generally less costly than English law countries;
- Generally no need for the Plaintiff to appear in person as a witness.
All roads lead to China....

- As a developing continent Africa is reliant on foreign infrastructure investment
- Growth in China to Africa direct cargo flights
- Regular direct links between cases in Africa and China
- African nationals regularly involved in Chinese counterfeit factories (but often not punished)
- Majority of GSK raids and arrests are in China but often indirectly link to Africa
Conclusions

• The sleeping lion is awakening
• Challenges often seem daunting but the rewards can be worthwhile
• Do the benefits outweigh the risks for the pharma industry?
• Questions?