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Bridging Innovation and Brand Protection: IP trends in African Pharmaceutical Markets

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Case study:
**The development of the dapivirine
microbicide (PrEP) ring in Africa**

An African case study – user controlled HIV prevention



- Africa’s pharmaceutical landscape is slowly changing from primarily import-dependant to innovative R&D and local clinical evidence generation.
- This can be illustrated by the launch of the Dapivirine Vaginal Ring (“DVR”).
- DVR comprises HIV-prevention technology developed by the International Partnership for Microbicides (IPM).
- DVR features:
 - Novel long-acting drug/device combination.
 - Rings with extended duration (1 month).
 - Multipurpose prevention technologies (HIV prevention and contraception).

An African case study – user controlled HIV prevention (cont.)



- Janssens granted IPM a royalty free, non-exclusive license to develop dapirivine for HIV **prevention** use.
- A need was identified for discreet user-controlled HIV prevention for women in high-prevalence settings like southern Africa.
- It addresses a significant gap in HIV prevention choices for women. In essence, repurposing existing antiretroviral drugs for female controlled prevention.
- Africa-led clinical contribution (South Africa hosted the largest share of clinical trails for DVR Phase III studies).
- Generated pivotal safety, adherence and efficacy evidence.

An African case study – user controlled HIV prevention (cont.)



- It showed Africa's capacity to conduct regulatory-grade clinical research, to support complex, long-acting technologies and how to engage communities through ethics frameworks and collaborative models.
- Thus, Africa seen as a credible partner for global product development (rather than merely a passive recipient of finished goods).
- Aligned to African harmonisation goals: reinforces the importance of AfCFTA's (African Continental Free Trade Area) ambitions and the proposed African Medicines Agency framework.

An African case study – user controlled HIV prevention (cont.)



- What worked in DVR:
 - Flexible IP model – royalty free and tiered licensing to enable access.
 - African-led trials and investment in regional research infrastructure.
 - Strong Regulatory engagement – SAHPRA (South African Health Products Regulatory Authority) / WHO / EMA.
 - Social Value – products positioned with an empowerment narrative (did not merely rely on the data).
 - Local access planning – Aligned clinical R&D with rollout systems early.
 - The transfer of the DVR asset to the Population Council for product introduction and market access.
 - EMA's positive opinion and WHO prequalification were critical enablers.

An African case study – user controlled HIV prevention (cont.)



- Challenges:
 - Fragmented regulatory Systems country-by-country approval.
 - Novel product classification complexities (it is an AVR-based prevention product, vaginal ring drug-device combination and long-acting topical therapy).
 - Gap between approval and implementation (approved by SAHPRA in March 2022 and national implementation only in December 2022).

An African case study – user controlled HIV prevention (cont.)



The development of the DVR shows that African pharma innovation is already happening. With the correct IP models, regulatory partnerships and local involvement, Africa can lead the way in developing, testing, and delivering high-impact health technologies.

Case study provided by Marzelle Haskins: MD Pharma-Ethics (Pty) Ltd.

Overview: Africa market growth, opportunities and IP landscape

Africa is rising: market growth



- World's second largest continent.
- 59 territories including surrounding islands.
- Africa is approximately 3 times the size of the USA.
- Population of over 1 billion people.
- Africa will account for more than half of the global population growth between now and 2050, according to projections from the UN Population Division report (ft.com).
- Nigeria's population is set to double 400m+ by 2050, when it will have overtaken the US as the world's third most inhabited country.



Emerging opportunities



- **Urbanisation** – almost 50% of Africans now live in urban areas. It is also interesting to note that it is estimated that 42% of sub-Saharan Africans are under 15 years old. These children will become the consumers of the future. The median age in the region is 20, compared with 45 in Europe and almost 50 in Japan.
- **Improved governance** – Greater accountability comes hand-in-hand with democracy and the slow strengthening of institutions.
- **Trade, not aid** – Europe is still Africa's largest trading partner, but China's share of trade has exploded in the last decade.
- **The rise of technology** – The number of mobile subscribers in Africa exceeds 650 million, allowing companies greater access to consumers.
- **Infrastructure investment** – Chinese companies are building roads and upgrading railways, ports and airports.

Increased support for patient safety



- **Consumer verification** by way of free text messages to check the authenticity of medicines through encrypted codes placed on packaging of medicines is available in many African countries.
- In **Kenya**, the Pharmacy and Poisons Board has a portal called the **Pharmacy Regulatory Information Management System (PRIMS)** which is an official database where every legal medicine in Kenya is listed. The PRIMS portal is available for consumers to verify medicines. Similar portals or public databases are also available in many other African countries.
- **Regulatory Authorities** in several African countries share information and conduct awareness campaigns of the dangers and risks posed by fake medicines.

The African Continental Free Trade Area (AfCFTA)



- Effective 1 January 2021
- The World Economic Forum describes AfCFTA as the world's largest free trade area in terms of member countries (currently 54 African States), one that will connect over 1.3 billion people.
- AfCFTA's potential lies in the fact that only around 15% of Africa's exports are intra-continental compared to 59% for Asia and 67% for Europe.
- Pharmaceuticals is identified as one of the sectors seen to have the highest potential due to the feasibility of addressing barriers to trade and production in a short time frame, as well as the strong potential for meeting demand locally.

IP landscape in Africa



- The IP landscape in Africa varies dramatically from country to country.
- Substantial efforts have been made to improve IP protection, enforcement and anti-counterfeiting measures.

Do you need a trade mark registration in Africa?



Registration is highly recommended and the safest option

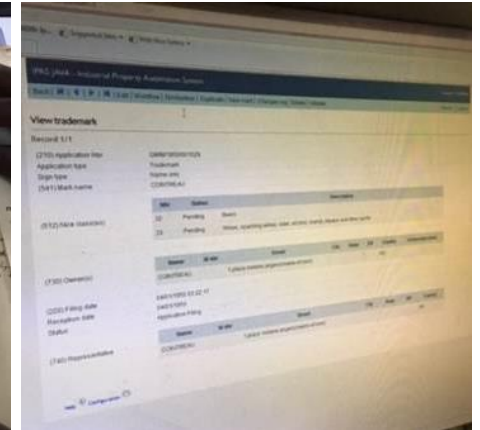
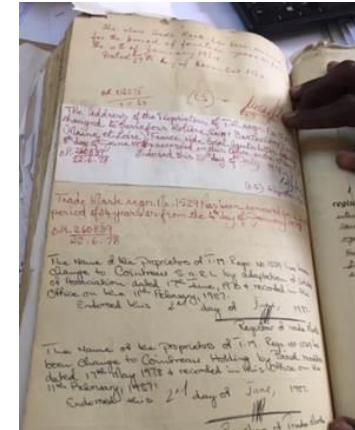
- Rogue entities register unprotected rights in their own name: misappropriation and misuse occur regularly.
- Registrations are *prima facie* evidence of ownership.
- There is a lack of specialised IP Courts across Africa.
- Protection given to unregistered trade marks is very uncertain. Enforcing unregistered trade marks is complex in many countries.
- Difficulties with passing off actions which require more time (cost), evidence and argument.

Trade marks: procedural matters

Searches



- Searching is still done in a distinctly old-fashioned way: agents must submit a request at the Registry.
- Searches are always recommended, but can be challenging:
 - Some countries solely rely on manual records / index cards.
 - In territories that use electronic databases, there is sometimes a reliance on inspecting the physical files due to data migration and maintenance issues.
 - International Registrations are not always included in the official search reports provided by Registries.
- Searches conducted on third party online platforms are based on published trade marks and not live data. Be aware that it can take up to 24 months between filing and publication in some territories.
- Official searches are compulsory in **Uganda**.



Trade mark applications

- The time period from filing to registration varies dramatically across the continent.
- When files are lost sometimes reconstitution is possible but in other circumstances re-filings should be considered, particularly if the Registry now processes new applications more efficiently through the use of electronic records.



Examination



- The level of examination varies significantly from country to country.
- Some Examiners are experienced but others have received very little training.
- In Rwanda there is a specific process manual to try and ensure consistency.
- In other countries Examiners will generally take consistent approaches such as in Kenya or Mauritius.
- In other countries the level of examination may depend on the Examiner, and even then they may issue different decisions on different days!
- We have seen some countries mature in their examination approaches such as Ethiopia which initially would issue poor examination notices but now is generally improved in this area.
- In countries such as Madagascar, the Examiners generally take a very conservative approach so it is a good idea to try and anticipate what might be raised at the outset and persuade them it will not be problematic when filing the application.

Trade marks - regional organisations in Africa

Regional organisations

OAPI

- 17 countries; combined population 100 million.
- ‘First to file’ jurisdiction.
- Centralised system: not necessary or possible to designate individual countries.
- Examination is on absolute grounds - prior marks are not cited.
- Use in one country is sufficient to defend a third party attack on the grounds of non-use.



* In the absence of national legislation to make provision for the accession to ARIPO by these countries, Spoor & Fisher's view is that ARIPO is not effective and we recommend filing national applications in these countries.



ARIPO

This table summarises the validity and effectiveness of ARIPO trade mark registration in the member states:

Validity/ enforceability	Not effective or valid:	Fully valid and enforceable
Territories	Eswatini Gambia Lesotho Liberia Tanzania Uganda	Botswana Cape Verde Malawi Mozambique Namibia São Tomé e Príncipe Zimbabwe

Tanzania Court rules ARIPO trade marks not enforceable



Lakairo Industries Group Co. Ltd & Others v. Kenafric Industries Ltd & Others

- 26 September 2025: Tanzania's Court of Appeal confirmed that ARIPO trade marks designating mainland Tanzania are not enforceable.
- The Banjul Protocol has not been incorporated into the *Trade and Service Marks Act, 1986*.
- ARIPO trade mark registrations have no legal effect in mainland Tanzania.

Implications

- Suspension from ARIPO system: Tanzania removed from ARIPO's list of designated states.
- No legal protection for existing ARIPO trade marks in Tanzania.
- Disputes and anti-counterfeiting actions based solely on ARIPO rights will fail.
- National trade mark registration is now the only valid route for protection.

Recommendation

1. File national applications with Tanzania's Trade Marks Office
2. Review existing portfolio and **re-file** key ARIPO trade marks nationally in Tanzania in order to retain validity.
3. Monitor potential infringement risks due to unenforceable ARIPO rights

International Registrations in Africa



International Registrations (IRs) in Africa (cont.)

There are two requirements for IRs to be valid and effective:

- The Madrid Protocol must be adequately recognised by domestic legislation. This varies between civil and common law territories.
- The national Registries must process and examine IRs in accordance with their domestic legislation.

Validity/enforceability	Not effective or valid: Domestic law does not provide for the Madrid Protocol	Validity vulnerable to challenge	Fully valid and enforceable
Territories	Eswatini Lesotho Zambia	Botswana Gambia Ghana Kenya Liberia Malawi Namibia OAPI (regional organisation) São Tomé e Príncipe Sierra Leone Tunisia Zimbabwe	Algeria Cape Verde Egypt Madagascar Mauritius Morocco Mozambique Rwanda Sudan



More about OAPI and Madrid

Timeline

- **5 March 2015:** OAPI joined the **Madrid Protocol**. Initially, **no provisions** in the *Bangui Agreement* to recognise or protect International Registrations (IRs). IRs were **not valid or effective** in OAPI for several years.
- **1 January 2022:** Amendment to the *Bangui Agreement* introduced a **legal framework for IRs** in OAPI. **Article 9(3)** states that IR designations “shall have the effect of a national deposit in each Member State that is also party to that Treaty.”
 - This could mean IRs are valid **only in OAPI states** that are **Madrid Protocol members**.
 - Currently **no OAPI member states** have joined the Madrid Protocol individually.

Summary

- OAPI claims it **can sign IP treaties** (like the Madrid Protocol) **on behalf of its members**.
- Questions remain about **OAPI’s authority** to bind individual states.
- If challenged, **courts would likely uphold OAPI’s position**, recognising IRs.

Procedural and practical issues



- **Low refusal rates** may indicate poor examination.
- **Failure to record limitations** in national registers.
- Lack of **Statements of Grant** (e.g. Namibia).
- **Provisional refusals** delayed or mishandled.
- Risk of **misleading records** and **unenforceable rights**.
- **OAPI** - whilst IRs are now covered by the Bangui Agreement and would probably be recognised by the Courts we have residual concerns about their validity and effectiveness.

Summary



- The Madrid Protocol offers efficiency but requires a strategic approach in Africa.
- Do not rely solely on ITMRs – assess each country individually.
- Combine ITMRs with national/regional applications where needed to ensure enforceable trade mark protection.

Recommendation

1. Conduct ITMR audits for all African designations.
2. Engage local counsel to verify enforceability.
3. Consider national or regional filings where ITMRs are ineffective.
4. Implement docketing systems and pre-filing searches to manage deadlines and reduce risk.

Trade mark licensing

Licensing



- All jurisdictions in Africa permit the licensing of trade marks and make provision for the recordal of licensees.
- Provisions and laws vary from jurisdiction to jurisdiction.
- In the majority of territories, failure to record a licensee is that use by the licensee may **not** be relied upon in non-use cancellation actions.
- Only recorded licensees may, under prescribed conditions, institute infringement proceedings or be party to them.
- A number of African territories follow laws similar to the 1938 United Kingdom Trade Marks Act, whereby only use by a trade mark owner or a recorded licensee (registered user) is considered “permitted use”.
- Only “permitted use” is sufficient to defeat a non-use cancellation action.
- There is also a risk that insufficiently controlled use by an unrecorded licensee may be considered to be deceptive or confusing and for that reason, render the trade mark registration vulnerable to cancellation..

Oppositions, enforcement & anti-counterfeiting

Oppositions



- We strongly recommend having **watch services** in place that cover Africa.
- Early surveillance and timely filing of oppositions are critical given the difficulty in post-registration cancellation / invalidation.
- Pirate filings / squatters on the Registers.
- Protection for core marks is a must.
- Oppositions remain an essential enforcement tool for maintaining brand exclusivity where court actions may be slow or costly.



Oppositions (cont.)

- Routinely encounter third party marks that are either identical copies of core marks, or well-known marks or filed in bad faith.
- Rule of territoriality: Without prior trade mark applications / registrations in the particular territory, difficulty increases.
- Some territories are first to file and prior use will not be recognised.
- Protection of well-known marks – use locally is critical.
- Prior use may be used as a basis for an opposition in common law territories (generally); carries an evidentiary burden.
- Bad faith is difficult ground to pursue; evidence based.



Oppositions (cont.)

Procedure

- Grounds of opposition stated upfront.
- Depending on the territory, evidence may be filed later.
- Defended or undefended.
- Success by default – where applicant's do not respond to an objection
- Sending C&D letters is another tool available, usually prior to filing an opposition
- Non-use – Separate claims are required by the party seeking cancellation.

Enforcement



- Effective protection is available in most African countries for **registered** trade marks. Each has an acceptable standard of legal remedies and capacity.
- If you have a trade mark registration you can enforce it by instituting trade mark infringement proceedings.
- In English speaking African countries such as Kenya, you can rely on the common law tort of Passing Off if you do not have a trade mark registration - more onerous as significant evidence is required to support your case.
- Remedies include civil, criminal and customs-based actions. Relief includes:
 - Interdict / interim injunction;
 - Permanent injunction;
 - Damages;
 - Seizure and forfeiture of infringing goods;
 - Fines and/or imprisonment.

Anti-counterfeiting



- Counterfeiting is a problem in Africa, but it is not insurmountable. A number of countries have specific anti-counterfeiting legislation and authorities.
- The most important thing brand owners can do as a first step is the simplest: register the trade mark.
- Whilst East Africa is known to be a major entry point for counterfeit goods, counterfeiting hotspots and bad faith filings are prevalent across the continent:
 - Algeria
 - Angola
 - Ghana
 - Kenya
 - Madagascar
 - Malawi
 - Mauritius
 - Morocco
 - Mozambique
 - Nigeria
 - South Africa
 - Sudan
 - Tanzania (mainland)
 - Tunisia
 - Uganda
 - Zambia
 - Zanzibar
 - Zimbabwe
 - Countries in OAPI

Anti-counterfeiting (cont.)

- Customs watch notices or surveillance requests are effective and available in Africa.
- Highly recommended to inform customs officials about your registered trade marks in their country.
- This map indicates countries in red where it is possible to file formal customs records or surveillance requests.
- For a successful anti-counterfeiting programme, brand identification training is important otherwise it is difficult and at times impossible for customs and/or police to identify and detain possible counterfeit goods.

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Anti-counterfeiting (cont.)



- For a successful anti-counterfeiting programme the following strategies are recommended.
 - Regular Brand Identification Training.
 - Use of ad hoc investigators in Africa.
 - Regular contact and support to Government agencies.
- We have recently carried out training in Tanzania, Namibia, Kenya and Nigeria.

Brand Identification Training

Training conducted in Namibia.



Brand Identification Training

Training conducted in Kenya.



Brand Identification Training (cont.)

Training conducted in Nigeria.



Country focus - Kenya



Requirement for ACA Recordal of IP rights

- Kenya introduced what has been dubbed a ‘dual registration’ system. What this means is that it is mandatory for IP owners who import goods into Kenya to register the IP rights that relate to those products with the Kenyan Anti-Counterfeit Authority, (“**ACA**”).
- Brand owners should have registered with the ACA (by 1 January 2023) trade marks that are applied to goods that enter into Kenya. This deadline has since been informally and indefinitely extended, but recordal is still strongly recommended. The ACA continues to encourage brand owners, in a phased approach, to register.
- Considerable detail is required for recording: details of the country of manufacture, identities of foreign users, and digital photos of the goods.
- These requirements (aimed at aiding the authorities in the fight against counterfeiting) are onerous but important.
- ACA Recordals must be renewed annually.
- Failure to register with ACA will constitute an offence.

We strongly suggest that companies proceed with filing their core marks in Kenya

Country focus – Kenya (cont.)



- Kenya has specific anti-counterfeiting legislation in place to fight counterfeiting unlike many other East African countries.
- The ACA is a specialised authority specifically formed to assist trade mark owners with search and seizure operations (“**raids**”) in the market place and ports of entry.
- The Anti-counterfeit Act (13/2008) (“**Act**”) came into effect to combat prolific trade in counterfeit goods in Kenya.
- The Act brings a number of benefits including:
 - Trade mark owners can take action against counterfeits.
 - Inspectors can search and enter premises with a view to seizing counterfeits.

Country focus – Kenya (cont.)



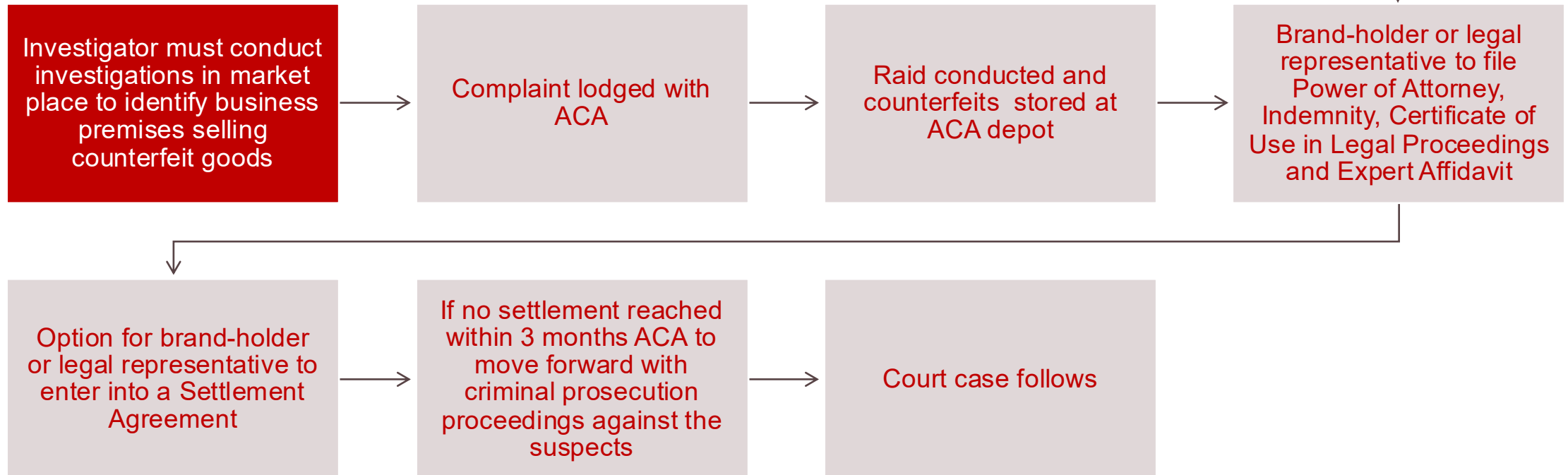
Lodging a complaint

- An owner of an IP right may lodge a complaint with the ACA.
 - Must provide evidence that a *prima facie* offence in terms of the Act has been committed.
 - Must satisfy the ACA that the complaint is legitimate and complies with the other requirements of the Act.
- An inspector will search and enter the identified premises with a view to seizing counterfeit goods.

Country focus – Kenya (cont.)



Procedure for conducting a raid with the ACA



Country focus – Kenya (Cont.)



Destruction of Counterfeits

ACA officials and Spoor & Fisher with seized counterfeit goods at a destruction site in North Eastern Kenya.



Raids in other African jurisdictions

Examples of raids in other African jurisdictions



Cameroon



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Examples of raids in other African jurisdictions



Ghana



Examples of raids in other jurisdictions (cont.)



Nigeria



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Examples of raids in other jurisdictions (cont.)



Tanzania



Africa trade mark updates

Ethiopia



Accession to Paris Convention

- Deposited its instrument of accession to the Paris Convention with WIPO on 15 May 2025.
- Entered into force 15 August 2025.
- Ethiopia joining the Paris Union underlines its commitment to strengthening its legal and institutional framework for IP protection and innovation.

Tanzania



Trade Mark Recordals

- All trade marks for goods imported into mainland Tanzania must be recorded.
- Applications for recordal must be submitted to the Chief Inspector for review and approval/rejection.

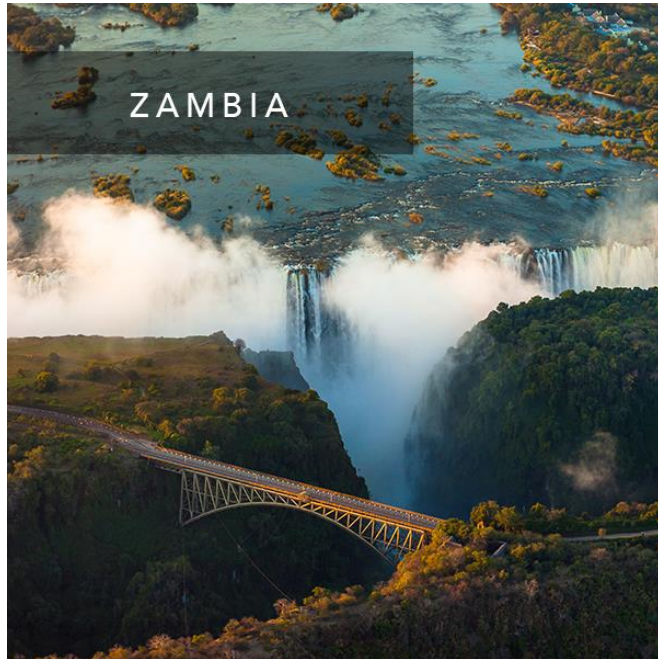
Recordal Application Requirements

- Full details of the entity recording the mark (e.g., incorporation info, address, contacts).
- Details of any subsidiary or affiliate under common ownership.
- Details of foreign licensees or authorized users (e.g., distributors) and nature of use.
- Copies of registered trade mark certificates.
- Classes of interest.
- Details of at least one manufacturer (in Tanzania or elsewhere).
- Photographic representations of goods bearing the marks.
- Power of Attorney.



Paul Ramara with the Director General of the FCC in Tanzania

Zambia



New Trade Marks Act, 2023 came into force on 31 December 2025.

Key Developments under the New Act include:

- Service mark protection is now available strengthening brand protection for businesses in the services sector.
- Well-known marks protection is now available.
- Trade mark registrations will now be granted and renewed for a period of 10 years.
- Multi-class applications are now permitted, allowing applicants to cover multiple goods and services classes in a single filing but pending the issuance of new regulations, official fees are expected to continue to apply on a per-class basis.
- International Registrations (IRs) – although the New Act empowers the Minister to implement the Madrid Protocol by regulation, no such regulations have been issued yet, meaning IRs designating Zambia currently have no legal effect or enforceability. It is also our understanding that future implementation is unlikely to apply retrospectively.

Final thoughts

Key Take-Aways



- Africa requires a customised, country-by-country IP strategy.
- Beware of the pitfalls of regional and international systems.
- A robust filing strategy is essential – register your trade marks.
- Record licences – from a non-use perspective.
- Enforcement is effective but requires preparation.
- File customs watches or surveillance requests where possible and conduct training of officials.
- Anti-counterfeiting measures work when trade mark registrations are in place.
- Stay alert to ongoing African IP developments.