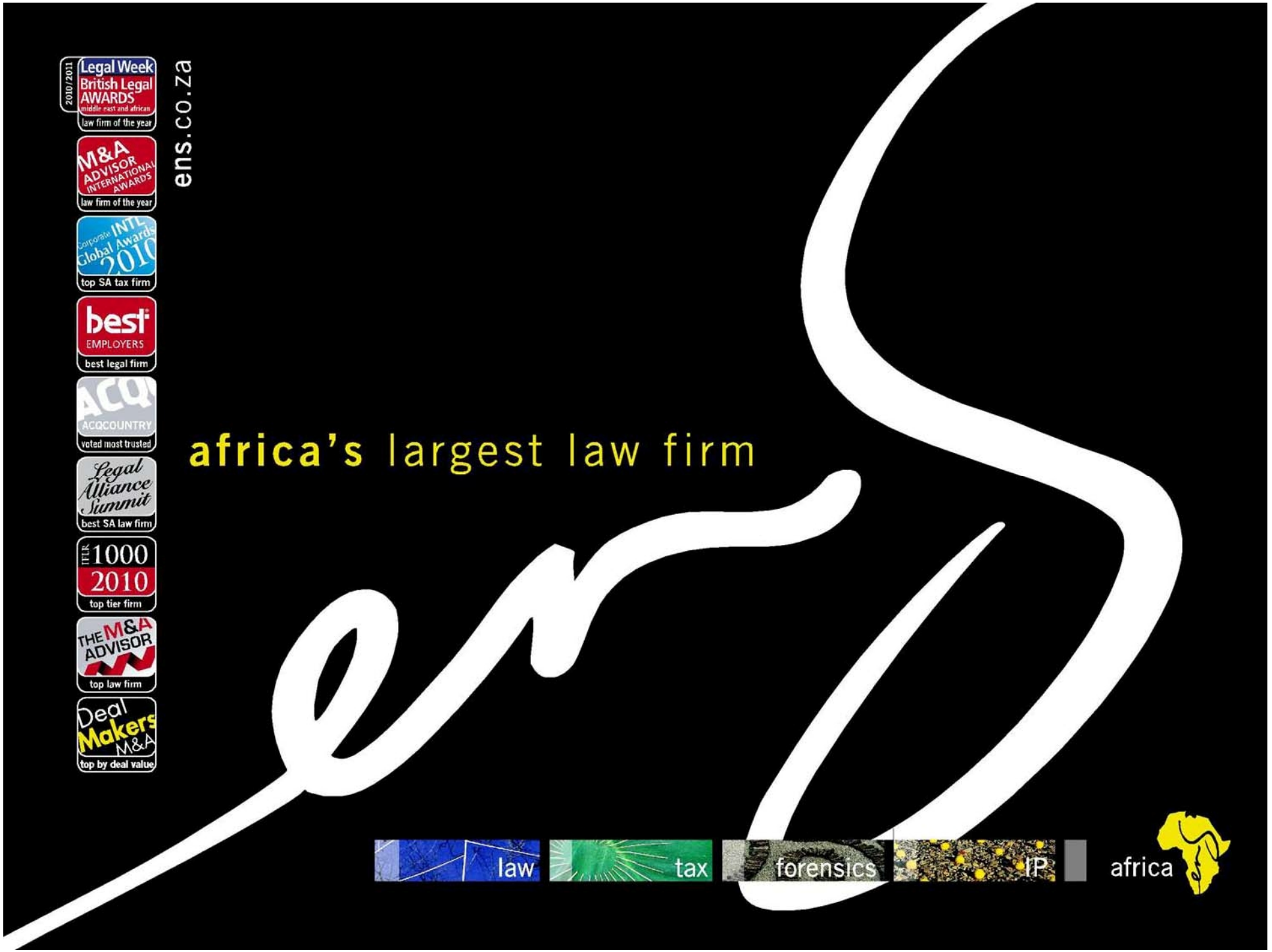
2010/2011
Legal Week
British Legal AWARDS
middle east and african
law firm of the year
M&A ADVISOR INTERNATIONAL AWARDS
law firm of the year
Corporate INTL Global Awards 2010
top SA tax firm
best EMPLOYERS
best legal firm
ACQCOUNTRY
voted most trusted
Legal Alliance Summit
best SA law firm
ITLR 1000 2010
top tier firm
THE M&A ADVISOR
top law firm
Deal Makers M&A
top by deal value
ens.co.za
africa's largest law firm
law
tax
forensics
IP
africa

Generic drugs - Legal issues and patent situation in South Africa

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what is intellectual property (ip)?

Your ideas are Intellectual Property.

Intellectual Property (IP) Law protects the products of the intellect which are capable of commercial exploitation.

Intellectual property includes:

- patents,
- registered designs,
- copyright,
- plant breeders' rights
- trade marks, and
- trade secrets/know-how.

Patents protect ideas in industrially realisable form. A patent can protect a new product, a new process or a new use of a product.

Registered Designs protect the outward appearance of industrially produced articles.

Trade Marks are badges of origin - they serve to identify products and distinguish them from those of competitors.

Copyright protects works of artistic or literary merit.

Plant Breeders' Rights protect new, distinct, uniform and stable varieties of plants.

Know How is an unregistered body of confidential and/or proprietary knowledge developed over time which results in an optimised product or process. It usually resides with key personnel and is only of value whilst confidential.

IP in a typical pharmaceutical product

BOTTLE CAP
Could be protected by a patent, a utility model or by design rights.

FORMULATION
Protected by both patent and know-how.

PANADO THE LOGO AND THE COLOURS
are all registered trade marks.

LABEL DESIGN AND INSTRUCTIONS
Protected by copyright.

BOTTLE
Protected by registered design.

patents

What is a Patent?

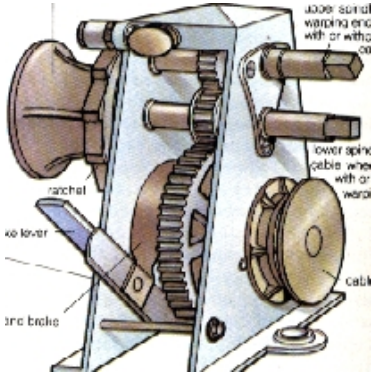
"... an agreement between an inventor and the government of a country, in which the inventor agrees to publish his or her invention, and in return the government agrees to give the inventor exclusivity on the use of the invention for a limited time."

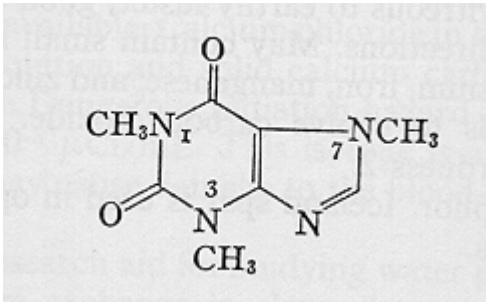

CERTIFICATE

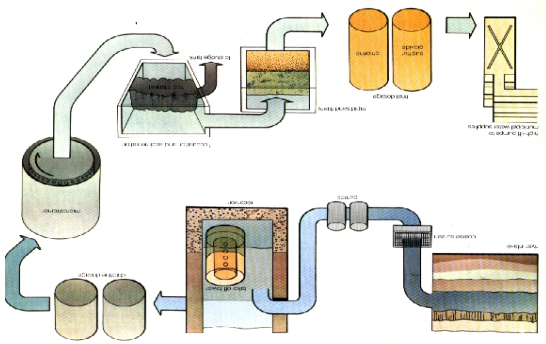
patents protect a principle underlying an invention

An invention can be:

- a new apparatus / machine
- a new product
- a new method or process







requirements for patentability

- **Novel**
  - must not have been made public, in any way (e.g. by oral disclosure, use, trial, printed publication in any language) anywhere in the world, before the date on which an application for a patent is filed

- **Inventive**
  - not obvious to a person “skilled in the art”

- **Capable of application in trade, industry or agriculture**
  - must be commercially useful

patent infringement

- Section 45 provides that the effect of a patent is to grant the patentee in South Africa, for the duration of the patent, the right to exclude other persons from **making, using, exercising, disposing or offering to dispose of or importing the invention**, so that they may enjoy the whole profit and advantage accruing by reason of the invention

acts of infringement

Infringement of Process Patents

- The Patents Act provides that **claims for a process or an apparatus** for producing any product **extend to the product**
- Importation into South Africa of a product made in another country by a South African patented process, when the product is the **direct product** of the process, is an act of infringement
- The **onus is on the patentee** to show that the product has been made by the patented process, unless the product is also novel, in which case the onus is on the third party
- It is **not certain** if infringement would extend to a product that has **undergone further processing** (i.e. material change), as this has not yet been tested by our Courts

acts of infringement

Doctrine of Equivalents

- The leading case for a chemical patent was *Stauffer Chemical Co*, where the Court held that the doctrine of infringement by the substitution of equivalents applied only in respect of unessential features or integers of a claim and that **if an essential integer is substituted, there can be no infringement**

acts of infringement

Contributory Infringement

- This is determined under the South African common law where a **person induces or procures the committing of an infringing act**
- The person's **subjective intent** is an important factor in determining whether there has been wrongful or unlawful conduct and hence infringement

relief for infringement

- An **interdict** (i.e an injunction) preventing further infringement: either **final or temporary**
- An order for the **delivery up for destruction** of any infringing product or any article or product of which the infringing product forms an inseparable part
- **Damages for infringement** in the form of patrimonial loss, actual or prospective, sustained through the infringement (or reasonable royalty)
- **Costs of suit** for the successful party

defenses for infringement

- **Non-infringement** of the patent and/or that the **patent is invalid**

- A **counterclaim for revocation** of the patent on any one or more of the grounds of revocation set out in the Patents Act

- **Special defenses** in terms of the Patents Act (discussed later)
  - "Bolar" provision
  - **No** research exemption

defenses for infringement

Parallel Imports of Pharmaceuticals and Patent Infringement

- The Patents Act provides:
  - *Sale of a patented article* ***by or on behalf of a patentee or his licensee*** *shall, subject to other patent rights,* ***give the purchaser the right to use and dispose of that article***
- The Court in *Stauffer Chemical Company* held that where a patentee himself, or his agent or assignee within the scope of his authority sells or disposes of the patented article, that **article is freed from all restraints** which the patentee's monopoly had imposed on it

patent infringement and “bolar” provisions

- Before a generic can be launched onto the market, the manufacturer must **obtain registration** from the South African MCC. The requirements for registration of a generic drug before use/sale in the Republic, include:

  - providing test results which to show the efficacy, safety and stability of the product; and
  - submitting a sample of the product to the MCC

- Interestingly, South Africa has **no research or scientific use exclusion** in our Patents Act

- Accordingly, **scientific research** on a patented invention **may amount to an act of infringement**

patent infringement and “bolar” provisions

- Section 69(A) of the South African Patents Act provides that it is not an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention **on a non-commercial scale solely** for purposes **reasonably related to the obtaining, development and submission of information required under any law** regulating the **manufacture, production, distribution, use or sale of any product**

- Note, though, that **stock-piling of the generic is not allowed**

recent overview of generics in SA: case law

- The number of patent litigation cases in relation to pharmaceutical products in South Africa is fairly small. Two of the most recent cases are:
  - TAC intervened as *amicus curiae* in the SCA case of ***Sanofi Aventis v Cipla Medpro***, raising a **public interest defence** based on a plea to the court that the generic drug Doxetaxel and/or Cipla Doxetaxel should be available to provide those suffering from cancer with a cheaper and equally effective medication.
  - Court held that this defence was fatally flawed and TAC were merely there to support Cipla, and not to act in the capacity of a friend of the Court. Overall, **Sanofi's appeal was upheld** and **Cipla was interdicted** from procuring or inducing, aiding and abetting, advising, inciting or instigating or assisting any other person to infringe the Sanofi patent.
  - Most recently, in ***Pharma Dynamics v Bayer*** handed down on 19 September 2014 in the SCA, the court upheld the decision of the Patent Commissioner to grant an interim interdict in favour of Bayer, thereby **preventing Pharma Dynamics from selling their generic equivalent**, Ruby of an oral contraceptive, Yasmin that is patented by Bayer.

overview cont.

- TAC and Medicines Sans Frontiers (MSF) have been vocal in their opinion that in South Africa **affordable versions of life-saving medicines are being missed out on** because generic competition is blocked by frivolous or **invalid patents** present on the patents register due to the **lack of substantive examination**.
- One response to this view is the initiative by the South African DTI to publish the widely criticised **draft National Policy on Intellectual Property** (4 September 2013), *inter alia* suggesting a patent examination system and stricter patentability requirements. In reality, these proposed changes are likely to **take some time to be put into practise**.
- However, changes made to the South African patent system and the Patents Act **are not the only way** to approach the problem of insufficient access to affordable medicines, as there are **already** existing various **provisions within South African Law** which could be leveraged to provide for affordable access to medicines.

compulsory licencing

- South Africa is a signatory to the Doha declaration which allows for measures to be taken to protect public health and promote access to medicines for all, including
  - compulsory licenses,
  - the terms on which these licenses are granted, and
  - the right to determine which situations qualify to circumvent patent monopoly rights.
- The South African Patents Act includes various provisions which give effect to the measures set down by the Doha declaration

compulsory licencing

- A Minister of State may **use** an invention for **public purposes** on agreed upon conditions (Section 4)

- A Minister may **acquire** any invention or patent on behalf of the State on **agreed upon conditions**. (Section 78)

- **Compulsory licenses** may be applied for on various grounds (Section 56)

compulsory licencing

- In particular in re affordable access to medicines, subsection **(1)(c)**
  - a compulsory licence can be applied for in a case where the **demand** for the **patented article** in South Africa is **not being met to an adequate extent and on reasonable terms**
  - Our courts have indicated that "**adequate extent**" means **sufficient for the needs of South Africa** and that a lack of "**reasonable terms**" may be evidenced by **public dissatisfaction** with the **prices**
  - Seems that a **lack of access to affordable medicine may meet the requirements** for such a compulsory licence application

compulsory licencing

- Possibly also of relevance is subsection **(1)(e)**

  – the **price** of the patented article **is excessive** compared to **country of manufacture**

  – i.e. where the demand for the patented article in South Africa is being met by importation but where the price charged in South Africa is excessive in comparison to countries where the patented article is manufactured and there is no good reason for the substantially higher price

compulsory licences

- To date, **no acquisitions of patents** have been made by the State in terms of **Sections 4 and 78**
- Also, not many compulsory licenses have been applied for in the Court of the Commissioner of Patents.
- The **only pharmaceutical product compulsory licence application** to the Court has been *Syntheta (Pty) Ltd v Janssen Pharmaseutica NV and Novartis AG*, where the Court found that **no abuse of rights had been demonstrated** by the applicant.

Medicines and Substances Control Act

- Outside of the Patents Act, the Medicines and Substances Control Act includes measures **supporting the supply of affordable medicines**.

- **Section 15 C** of this act provides that the Minister of Health can, despite the provisions of the Patents Act, **limit certain rights of owners of medicines**, and therefore, the **infringing acts of third parties** can be **allowed** in certain circumstances

Medicines and Substances Control Act

- Secondly, in a more limited provision, the Act also sets out that the Minister can prescribe conditions on which a **generic medicine can be imported** by a person who is **not the holder of the registration certificate** for a registered medicine.

- However, the medicine must have originated from the site of manufacture of the **original manufacturer**.

court proceedings to deal with invalid patents

- Another option, albeit a costly one, is to **use the courts** for application to **revoke a granted patent** that is **invalid**

- Although there is **no formal obligation on a patentee** to ensure that their South African patent does not contain invalid claims, if it can be shown that the patentee **was aware of the invalidity, our Courts will often penalise the patentee** for knowingly allowing their patent to remain on the Patent Register in an invalid form

patent invalidity and revocation

- For example, during **revocation proceedings**, the court may decide that a patent should be upheld, but on condition that certain **amendments are made**

- In this case, or where the patentee applies for amendments to be made during the revocation proceedings, the **Court has a discretion as to awarding of costs** and the **conduct of a patentee** who knowingly allowed an invalid patent to remain on the register will be **taken into account** and the patentee may have **costs ordered against him**

patent invalidity and revocation

- Therefore, although amendment after grant is a longer process and there will be a delay in the taking of action against the infringer, particularly if the amendment application is opposed, it is **preferable to amend prior to instituting infringement proceedings**

- One reason for this is that there is the **possibility that there will be no opposition** if the amendment application is made prior to instituting proceedings. If made **during infringement proceedings**, there would most **likely be opposition**

- The other is that a **delay in making the amendment application** prior to legal proceedings being instituted may be adversely interpreted by the Court, who may **penalise the patentee for knowingly allowing their patent to remain in an invalid form**

patent invalidity and infringement

- In **infringement proceedings** in respect of a patent which has been amended, the Court **may refuse to award damages** in respect of any acts of **infringement committed before the amendment** was allowed

- Furthermore, the Court may take into consideration the **patentee's conduct** in knowingly allowing the specification and claims to be maintained in invalid form **when deciding the date from which damages are to be calculated and the quantum of damages**

contact me for more information

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thank you

law tax forensics IP africa

level 3 BBBEE: AA rating