Patent protection for pharmaceutical products and processes, and limitations to such protection
**INTRODUCTION**

- *Sui generis* nature of patent protection for pharmaceutical products and processes as a result of:
  - Ethical;
  - Socio;
  - Economic; and
  - Political considerations

- Limitations to the extent of patent protection may be found in the Patents Act 57 of 1978 and other non Intellectual Property legislation

**METHOD OF TREATMENT CLAIMS – ETHICAL CONSIDERATIONS**

- Patents may relate to:
  - a product;
  - a process for the manufacture of the product;
  - a particular use of a product; and
  - a method of doing something

- In the pharmaceutical context a “method of treating a patient by administering a product” is problematic. From an ethical point of view such an invention would:
  - Hamper the ability to treat a patient for fear of patent infringement;
  - Create a conflict of interests if licensed under the patent; and
  - Have a negative effect on doctor-patient relationship
METHOD OF TREATMENT CLAIMS AND ALTERNATIVES

In South Africa:
- An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body shall not be patentable.

The following are however patentable:
- Methods of treatment practiced outside the human body;
- The pharmaceutical product per se;
- The first medical indication – i.e. the pharmaceutical product for use in treating an ailment;
- The second medical indication – i.e. use of an active ingredient in the manufacture of a medicament to treat an ailment; and
- A process to manufacture the product.

METHOD OF TREATMENT CLAIMS AND ALTERNATIVES - CONTINUED

Limitations to alternative claims:
- Enforcement of a process claim is difficult because it requires information about the alleged infringing process;
- Deeming provisions in terms of the Patents Act.

A claim in respect of a patent for a process or an apparatus for producing any product shall be construed as extending to such product when produced by the process or apparatus claimed.

If the invention for which a patent is granted is a process for obtaining a new product, the same product produced by a person other than the proprietor of the patent or a licensee under that patent shall, unless the contrary is proved, be deemed, in any proceedings, to have been obtained by that process.
First medical indication dependent on the claimed use;

- Second medical indication dependent on (i) the use of the active to (ii) manufacture a medicament to (iii) to treat the specific medical indication

**THEREFORE:**

- The broadest form of protection lies in a pure product claim as this does not depend on:
  - the process used;
  - the intended use or purpose;
  - the use thereof to manufacture a medicament

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**SOCIO ECONOMIC CONSIDERATIONS**

- Pro generic limitations to intellectual property
  - Section 69(A) of the Patents Act – the Bolar Provision
    
    *It shall not be 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 and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product*

- Facilitates registration of a generic
Section 15(C) of the Medicines and Related Substances Act

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

(a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;

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Expropriation

State Rights – acquisition of patents
Socio Economic Considerations - Continued

- Compulsory Licensing

  - This may be accessed in terms of:

    The Patents Act
    The Competition Act
    Abuse of Patent Rights
    Abuse of Dominance

SOCIO ECONOMIC CONSIDERATIONS - CONTINUED

- Compulsory Licensing under the Patents Act

  - Inadequate working in the Republic of South Africa;
  - Demand in Republic of South Africa not being met or to a reasonable extent;
  - Prejudice as a result of a refusal to license on reasonable terms;
  - Demand being met by importation but the price for the imported product is excessive when compared to the country from which it is imported.

  The section therefore envisages “the loss of valuable intellectual property rights and thus the applicant must present clear and satisfactory evidence of its averments.”

  - Aftira LTD v Carlton Paper of SA 1992 BP 331
SOCIO ECONOMIC CONSIDERATIONS – CONTINUED

- Compulsory Licensing under the Competition Act

  - Patentee may be dominant solely by virtue of having a patent;
  - Competition Act must be seen as:

    “legislative measures which aim to discharge the state’s positive obligations in respect of express entitlements – such as ensuring access to medicines – in a manner that does not lead to the arbitrary deprivation of property.”

  - Treatment Action Campaign Complaint against MSD (PTY) Limited
  - Compulsory license an appropriate remedy?

PATENTING STRATEGIES

- Incremental Patenting (ever – greening)

  - Effective life of patent protection for a pharmaceutical – about 4 to 6 years;
  - No extension of the 20 year term of a patent available in South Africa;
  - Unlikely that at the time of patenting potential improvements have been fully explored and recorded.

  - India – introduced third requirement to patentability in respect of improved products namely that the Patentee needs to show a difference in efficacy

    Raises the bar in obtaining a patent.
Thank you for your attention.

Questions?