




**Adams & Adams**  
Intellectual Property Specialists



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# TRAINING COURSE

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## INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

### Patent Protection for Pharma Products

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**INTELLECTUAL PROPERTY RIGHTS AND  
PHARMACEUTICAL PRODUCTS AND PROCEDURES**


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## Patent protection for pharmaceutical products and processes, and limitations to such protection

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

## 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

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## 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

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## METHOD OF TREATMENT CLAIMS AND ALTERNATIVES

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- 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 – ie the pharmaceutical product **for use** in treating an ailment;
  - ❖ The second medical indication – ie **use of** an active ingredient **in the manufacture** of a medicament to treat an ailment; and
  - ❖ A process to manufacture the product




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## METHOD OF TREATMENT CLAIMS AND ALTERNATIVES - CONTINUED

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- 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*



## METHOD OF TREATMENT CLAIMS AND ALTERNATIVES - CONTINUED

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

## 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



## SOCIO ECONOMIC CONSIDERATIONS - CONTINUED

- 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;*

.....



Expropriation

- State Rights – acquisition of patents

## TAKE A BREATH - QUESTIONS



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## Socio Economic Considerations - Continued

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- **Compulsory Licensing**
  - ❖ This may be accessed in terms of:
 

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graph TD
    A[This may be accessed in terms of:] --> B[The Patents Act]
    A --> C[The Competition Act]
    B --> D[Abuse of Patent Rights]
    C --> E[Abuse of Dominance]
          
```

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## SOCIO ECONOMIC CONSIDERATIONS - CONTINUED

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- **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

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## SOCIO ECONOMIC CONSIDERATIONS – CONTINUED

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES



- **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 ?

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## PATENTING STRATEGIES

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- **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.

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**Thank you for  
your attention  
Questions?**