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Intellectual Property Specialists




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Innovative Medicines  
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# TRAINING COURSE

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## INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

### ASPECTS OF PATENT LITIGATION

by  
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INTELLECTUAL PROPERTY RIGHTS AND  
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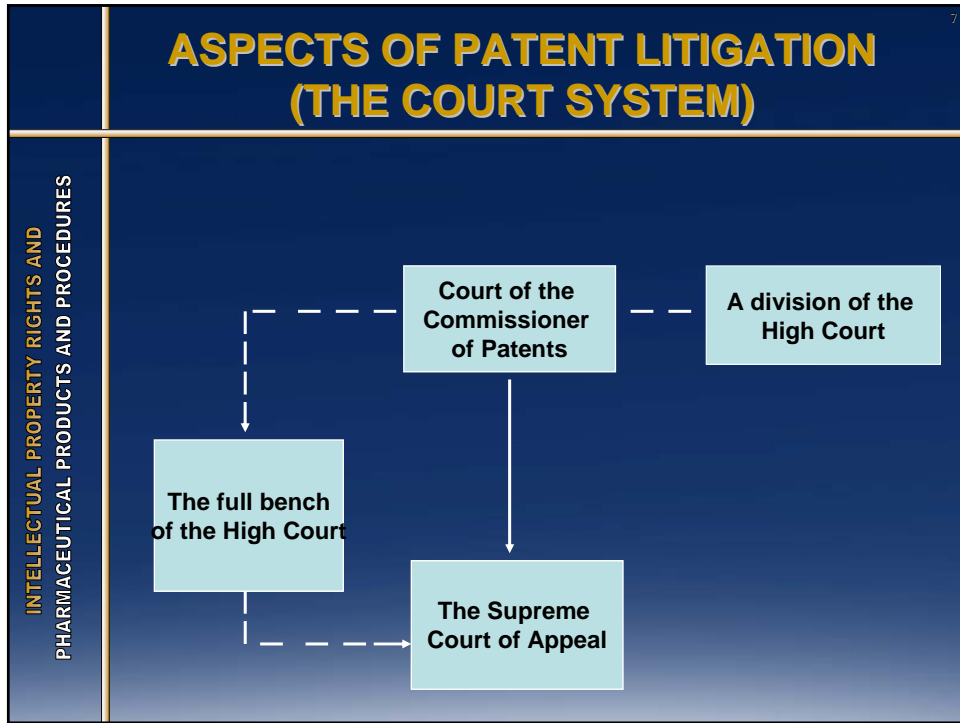
# ASPECTS OF PATENT LITIGATION

	<h2 style="text-align: center;">ASPECTS OF PATENT LITIGATION (OVERVIEW)</h2>
<b>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</b>	<ul style="list-style-type: none"><li>■ Introduction</li><li>■ The Court System</li><li>■ Infringement</li><li>■ Invalidity</li><li>■ A case study</li></ul>

	<h2 style="text-align: center;">ASPECTS OF PATENT LITIGATION (INTRODUCTION)</h2>
<b>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</b>	<p style="text-align: center;">“...the law of capital punishment is far more complicated than I portrayed it ... A Supreme Court Judge once remarked that the only thicket of similar legal obscurity is patent law”</p> <p style="text-align: center;">Richard North Patterson</p>

	<h2 style="text-align: center;">ASPECTS OF PATENT LITIGATION (INTRODUCTION)</h2>
<b>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</b>	<p style="text-align: center;">“In patent litigation an application of Murphy’s Law has special significance: if a word or a sentence is capable of two interpretations, the reader will choose the wrong one .... In spite of the narrow point of interpretation the parties were nevertheless able to generate a record of 1300 pages”</p> <p style="text-align: center;">HARMS JA</p>

	<h2 style="text-align: center;">ASPECTS OF PATENT LITIGATION (INTRODUCTION)</h2>
<b>INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</b>	<p style="text-align: center;">“If one looks at the broad picture ... the applicant is a manufacturer that relies on its patent protection to recoup the cost of its research and development. The respondent is a manufacturer of generic products that are manufactured without the expense of original research. For that reason, it is wrong to argue that the applicants can retain market share by reducing market prices. The open market is only something to which they have to submit on expiry of the patent”</p>



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- ## ASPECTS OF PATENT LITIGATION (INFRINGEMENT)
- INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES
- Section 45 (1) “ The effect of a patent shall be to grant to the patentee in the Republic... the right to exclude other persons from *making, using, exercising, disposing or offering to dispose of, or importing the invention*, so that he or she shall have and enjoy the whole profit and advantage accruing by reason of the invention”
  - Section 45 (2) “ The disposal 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, offer to dispose of and dispose of that article”

	<h2 style="color: yellow;">ASPECTS OF PATENT LITIGATION (INFRINGEMENT)</h2>
<p style="color: yellow; font-weight: bold;">INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</p>	<ul style="list-style-type: none"> <li>■ Section 67 (1) “ 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”</li> <li>■ Section 67(2) “ 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, unless the contrary is proved, shall be deemed to have been obtained by that process”</li> </ul>

	<h2 style="color: yellow;">ASPECTS OF PATENT LITIGATION (INFRINGEMENT)</h2>
<p style="color: yellow; font-weight: bold;">INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES</p>	<ul style="list-style-type: none"> <li>■ Section 69A (1) “ It shall not be an act of infringement... 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 obtaining, developing and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product”</li> <li>■ Section 69A (2) “ It shall not be permitted to possess the patented invention...for any purpose other than for the obtaining, development or submission of information...”</li> </ul>

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## ASPECTS OF PATENT LITIGATION (INFRINGEMENT)

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Relief

- Interdict (injunction)
- Delivery-up
- Damages (non-punitive)
- In lieu of damages payment of a reasonable royalty
- Costs of Suit
- Account of Profits may be introduced into SA law

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## ASPECTS OF PATENT LITIGATION (INFRINGEMENT)

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Preliminary injunction

- at least a prima facie right (could be open to doubt)
- irreparable harm
- balance of convenience
- no other satisfactory right
- urgency
- application proceedings (no oral evidence)
- 2-4 months

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## ASPECTS OF PATENT LITIGATION (INFRINGEMENT)

**Infringement Action**

- Clear right
- Oral evidence of experts
- Discovery procedure
- 18-24 months

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## ASPECTS OF PATENT LITIGATION (INVALIDITY)

- No substantive examination of SA patent application-depository system
- Any party may attack validity after grant
- Revocation application or defence in an infringement action

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## ASPECTS OF PATENT LITIGATION (INVALIDITY)

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Common grounds of Revocation

- Lack of novelty
- Lack of inventive step
- Lack of clarity
- Lack of utility
- Lack of sufficiency

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## ASPECTS OF PATENT LITIGATION (INVALIDITY)

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Routine procedure

- Amendments are allowed after grant provided that
  - ❖ No new matter is added
  - ❖ The claims are fairly based on the specification before amendment
  - ❖ The nature of the amendment is to limit the scope of the claims
- Not unusual to allow the application to proceed to grant and to carry out post grant amendments in the event that the patent is likely to be enforced
- There are certain pitfalls in following this approach



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## ASPECTS OF PATENT LITIGATION (INVALIDITY)

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A partially valid patent

- Single invalid claim renders entire patent invalid and unenforceable (even if the claim is not being asserted)
- May only lead to a technical delay in a trial but could be fatal to the applicant's cause in preliminary injunction proceedings
- A post-grant amendment can be opposed which could lead to a protracted and costly dispute concerning the allowability of the amendment

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## ASPECTS OF PATENT LITIGATION (CASE STUDY)

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Pfizer v Cipla (Norvasc) (2005)

- Through an oversight the claims were rendered unclear
- An application for a correction of a clerical error was made simultaneously with the preliminary injunction application
- Court accepted explanation and found errors were clearly clerical errors
- Preliminary injunction granted 8 weeks after launch

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## ASPECTS OF PATENT LITIGATION (CASE STUDY)

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### Lundbeck v Cipla (2008)

wherein R is hydrogen or F, a labile ester group.

Common ground that Claim 7 erroneously refers to the (+) enantiomer rather than the (-) enantiomer and clearly impossible for R to be “hydrogen or F”

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## ASPECTS OF PATENT LITIGATION (CASE STUDY)

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### Lundbeck v Cipla (2008)

- Evidence of reputable expert from Oxford University that the ordinary person skilled in the art would have understood the offending words to be clerical errors
- Explanations given by the patentee explaining the nature of the error (the patent attorney passed away) plus alleged inconsistencies between affidavits and foreign prosecution
- Court found should have been carried out by way of amendment but would have the effect of broadening the scope so not allowable
- Preliminary injunction refused

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**Thank you for  
your attention  
Questions?**