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UNIVERSITEIT VAN PRETORIA
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YUNIBESITHI YA PRETORIA

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

CURTAILMENT OF PATENT PROTECTION

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CURTAILMENT OF PATENT PROTECTION

ANCILLARY PROTECTION RELEVANT TO PHARMACEUTICALS

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SETTING THE SCENE

- patent protection is intended to protect, for a specified period of time, the creative outcome of innovation, the intangible product of R&D in any field of technology
  - TRIPS Art 27.1: patents shall be available for any inventions, whether products or processes, in all field of technology
  - TRIPS Art 33: term of a patent shall not be less than 20 years
- patent protection confers on the patent owner the right to enjoy the whole profit and advantage accruing by reason of the invention
  - TRIPS Art 28, Patents Act s.45(1): the patent owner shall have the exclusive right to prevent third parties without the owner's consent from making, using, offering for sale, selling or importing the patented product
  - exclusive IP right is granted by the State as a quid pro quo for the inventive and development input

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

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SETTING THE SCENE

- in practice the patent rights for an invention in the pharmaceutical field and the exclusive rights in respect of the R&D outcomes in that field are curtailed
  - the intangible asset represented by the inventive concept and the R&D investment to develop a marketable product does not enjoy full protection
  - the balancing of rights within the system is disturbed
- there are different ways in which the IP protection is curtailed, and different reasons for such curtailment
  - reduction in effective term of patent protection
  - inadequate protection of confidential data against unfair commercial use
  - early competition and market access by generic equivalents
- in the light of such curtailment, certain forms of ancillary protection for pharmaceutical inventions may be justified

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FIRST CURTAILMENT:

REDUCTION IN EFFECTIVE TERM OF PATENT PROTECTION

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INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

EFFECTIVE TERM OF PATENT PROTECTION

- the previous Patents Act 37 of 1952 granted a patent term of 16 years from date of complete specification
  - provided for a maximum 5 year extension of term on ground of inadequate remuneration
  - extensions for pharmaceutical patents were granted on the basis of lost income due to time lost for regulatory approval
- the current Patents Act 57 of 1978 grants a patent term of 20 years from date of application
  - no provision for extension of term
- s.45(1) of Patents Act, 1978 provides that the patent owner "shall have and enjoy the whole profit and advantage accruing by reason of the invention"
  - to enjoy the whole profit and advantage patent owner must
    - be able to exploit the invention for the full term
    - be able to prevent others from exploiting during the full term

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EFFECTIVE TERM OF PATENT PROTECTION

- in the case of patents for pharmaceutical products, exploitation by the patent owner can only take place after marketing authorisation
  - on average, due to registration procedure, marketing authorisation takes about 3 years, so that exclusivity term for exploitation is reduced
- enforcement of patent rights by the patent owner can only take place after grant
  - a patent is deemed to be granted on date of publication in the Patent Journal
  - on average, due to pendency of applications during examination, grant is about 2 years after application, so that exclusivity term for enforcement is reduced
- so, curtailment of term for both exploitation and enforcement

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EXTENSION OF TERM OF PATENT PROTECTION

- in other countries two different models have been used to restore the curtailed patent term
  - extension of term
  - supplementary protection certificates (SPCs)
- Australian model: since 1998 extension of term of a patent is granted for a pharmaceutical substance where regulatory approval takes more than 5 years
  - maximum period of 5 years extension
  - calculated: period from date of patent until regulatory approval less 5 years
  - certain limitations on infringing acts during extended period

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EXTENSION OF TERM OF PATENT PROTECTION

- EU model: since 1993 supplementary protection certificates are granted for pharmaceutical products where marketing authorisation takes more than 5 years
  - maximum period of extension is 5 years
  - calculated: date of patent application to date of marketing authorisation less 5 years
  - country specific extension
  - maximum 15 years of exclusivity from first MA in EU
- question to be considered: should SA legislature consider an extension of term provision?
  - for example, in those cases where regulatory process takes more than 3 years

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SECOND CURTAILMENT:

INADEQUATE PROTECTION OF CONFIDENTIAL DATA

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PROTECTION OF CONFIDENTIAL DATA

- confidential data generated by a business is accepted to be an asset: intangible but worthy of protection
- generally the protection of confidential data aims to prevent unauthorised disclosure
  - however, in some cases the unauthorised use of the information to the benefit of a competitor may pose a greater problem than the mere disclosure thereof
- TRIPS requires member countries to protect, independently of patents, confidential information against unauthorised disclosure and unfair use
  - TRIPS specifically requires member countries to protect certain types of confidential data against "unfair commercial use" to the detriment of the owner

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PROTECTION OF CONFIDENTIAL DATA

- TRIPS Art 39.3: member countries which require the submission of undisclosed data to obtain marketing approval, eg for pharmaceuticals, shall protect such data
  - data expressly includes undisclosed test or other data, eg clinical trial data
  - origination of the data must have involved "considerable effort"
  - data must be protected against disclosure (except where necessary to protect the public)
  - data must be protected against unfair commercial use, particularly if disclosure is made in the public interest

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DATA PROTECTION: TRIPS ARTICLE 39.3

- Art 39.3 does not specify the nature and scope of protection to be given to undisclosed data
- no indication of nature or extent of protection, nor of nature of "unfair commercial use"
  - any use of such data to provide a commercial benefit to a competitor is likely to be "unfair commercial use"
- Art 39.3 does not specify the level of uniqueness when data will qualify for protection
  - no indication of nature or quantum of "considerable effort" to generate the data
  - in the case of pharmaceutical inventions, clinical trials and biosafety testing consume a significant proportion of total R&D time and expenditure; generally accepted as requiring "considerable effort"

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DATA PROTECTION: TRIPS ARTICLE 39.3

- in South Africa, applicants for marketing approval of medicines are required to submit prescribed data on safety, efficacy, quality of the product
  - s.15 and reg.22 Medicines and Related Substances Act, 1965
- this data is scientifically unique, confidential and of great commercial and strategic value to the applicant
- rationale for Art 39.3 protection: it would be unfair to a company, making a substantial investment in generating the data to demonstrate safety, for such data to be available to or to be used by competitors
  - "unfair commercial use" if competitors no longer have to incur comparable expenditure to generate data
  - generally referred to as regulatory data protection

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DATA PROTECTION: ARTICLE 39.3 IMPLEMENTATION

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- South Africa has not yet passed legislation to implement Art 39.3
  - no statutory provision to prohibit the use by MCC/RA of clinical and other data submitted by company A for marketing approval, in processing application of company B for a "me-too" registration
- developed countries have legislation to regulate the market entrance by so-called "second applicants"
  - systems generally try to strike a balance between an abbreviated/expedited drug application process, and a period of data exclusivity protection
- different protection models used in USA and EU
  - different protection periods in other countries

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DATA PROTECTION: ARTICLE 39.3 IMPLEMENTATION

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- in USA: in 1984 legislation introduced data protection provisions, with "abbreviated new drug application" and "similar drug" procedures for generic drugs
- in 2007 US Food, Drug and Cosmetic Act introduced new drug marketing and data exclusivity periods
  - a 5-year period of data and marketing exclusivity for new drugs containing a new chemical entity or new active moiety
    - no "abbreviated new drug applications" or "similar drug applications" may be submitted or processed during this period
  - a 3-year period of marketing exclusivity for new uses/ indications of drugs where the active moiety was previously approved but new clinical trials done
    - "abbreviated" and "similar" drug applications may be received and processed; approval only effective after expiry of this period

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DATA PROTECTION: ARTICLE 39.3 IMPLEMENTATION

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- in EU: in 1987 an EEC Directive initially introduced data protection provisions, with an abridged application procedure for generic equivalents
- a revised data protection system under a 2004 Directive applies to drugs submitted for marketing authorisation after 30/10/2005
  - period of data protection determined by the 8+2+1 formula
  - an initial 8-year data exclusivity (and market exclusivity) period, with a subsequent 2-year market exclusivity period
  - further 1-year period of market exclusivity if data originator gets authorisation for a new therapeutic indication

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DATA PROTECTION IN OTHER COUNTRIES

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- data protection provisions have been enacted in different countries with varying periods of exclusivity
  - EU: 8 years + 2 years + 1 year
  - USA: 5 years or 3 years
  - Australia: 5 years
  - Canada: 6 years + 2 years
  - Switzerland: 10 years, or 3 + 5 years
  - Singapore: 5 years
  - Mexico: 5 years
  - Chile: 5 years
  - Bolivia: 5 years (Andean Pact)
  - Bulgaria: 6 years or 10 years (for high tech)
  - China: 6 years
  - Egypt: 5 years
  - Jordan: 5 years

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ARGUMENTS RELATING TO DATA PROTECTION

- TRIPS Art 39.3 protection is independent of the subsistence of patent protection
  - thus data protection could delay generic entry even where no patent exists, or where patent has expired
- from public health perspective, chemical and clinical test data should be in the public domain, since it contains important medical information; this implies disclosure of data
  - eg in case of side-effects further analysis may be necessary
- from societal perspective, no sense for generic competitor to repeat costly tests and clinical trials if bio-equivalence can be reliably demonstrated; this implies use of data for registration of competitors
  - repetition of tests would frustrate access to cheaper drugs

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ARGUMENTS RELATING TO DATA PROTECTION

- it would be unfair commercial use to allow chemical and clinical test data generated by a originator company to be used for expedited marketing approval for generic equivalent
  - data protection would justify investment by originator companies in comprehensive clinical tests to ensure marketing of safe and effective medicines
- this “benefit” of data protection to originator companies is counter- balanced by early working “benefit” to generic companies – Bolar provision
  - generic companies allowed to do clinical trials and other tests during term of patent – s.69A Patents Act
- but, TRIPS Art 39.3 requires member countries to provide protection – so, the debate continues

THIRD CURTAILMENT:

EXPEDITED MARKET ACCESS FOR GENERIC EQUIVALENTS

EARLY WORKING PROVISION FOR GENERICS

- TRIPS Art 30: member countries may provide for limited exceptions to the exclusive rights of patents
  - exceptions to take into account legitimate interests of third parties
  - exceptions must not unreasonably conflict with normal exploitation by patent owners or prejudice legitimate interests of patent owners
- Art 30 accepted as basis for early working (Bolar-type) provision, for generics to obtain marketing approval during patent term of original drug
  - WTO dispute panel held that Art 30 allows a provision to permit generics during patent term to use patented subject non-commercially for marketing approval
  - stockpiling for later commercial use is not permissible

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EARLY WORKING PROVISION INTRODUCED BY SOUTH AFRICA

INTELLECTUAL PROPERTY RIGHTS AND PHARMACEUTICAL PRODUCTS AND PROCEDURES

- in SA, section 69A of the Patents Act introduced a Bolar-type provision
  - provision not expressly limited to pharmaceutical products; no discrimination as to technology
  - permits non-commercial use, exercise, disposal or importation of patented subject matter solely for the purpose of obtaining, developing and submitting information required for regulatory approval of product
  - prohibits possession of patented subject matter for any other purpose (ie prohibits stockpiling)
- need for early market entry and availability of generic equivalents resolved
  - patent owner's right to enforce patent curtailed

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IN CONCLUSION

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- it should be recognised that the current medicines regulatory system, operating in conjunction with the current patent protection system, aims for but does not yet provide a balanced system
  - owners of pharmaceutical patents lose part of their period of exclusivity due to regulatory delay
  - owners of confidential data submitted for marketing authorisation cannot prevent the use of such data to benefit competitors
  - owners of pharmaceutical patents cannot prevent competitors from using the patented subject matter during the term of the patent to prepare and obtain market authorisation

IN CONCLUSION

- a balanced system could be restored by
  - introducing legislative provisions to permit extension of patent term or provide supplementary protection in appropriate circumstances to compensate for lost time
  - introducing legislative provisions to provide for an appropriate period of protection of confidential data submitted by originator applicants for purposes of market authorisation to prevent unfair commercial use
- the need for a balanced system is an issue to be considered by policy makers
  - in the meanwhile, the need for a balanced system remains part of the international debate

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Thank you for your attention

Questions?