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INTELLECTUAL PROPERTY RIGHTS
AND
PHARMACEUTICAL PRODUCTS
AND PROCEDURES

CURTAILMENT OF PATENT PROTECTION

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ANCILLARY PROTECTION RELEVANT
TO PHARMACEUTICALS
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.

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.
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
**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

**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
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

SECOND CURTAILMENT:
INADEQUATE PROTECTION OF CONFIDENTIAL DATA
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

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
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”

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
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

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
### DATA PROTECTION: ARTICLE 39.3 IMPLEMENTATION

- **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.

### DATA PROTECTION IN OTHER COUNTRIES

- 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
### 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 |

| it would be unfair commercial use to allow chemical and clinical test data generated by an 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
EARLY WORKING PROVISION INTRODUCED BY SOUTH AFRICA

- 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 (i.e., prohibits stockpiling)
- Need for early market entry and availability of generic equivalents resolved
  - Patent owner’s right to enforce patent curtailed

IN CONCLUSION

- 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

Thank you for your attention

Questions?