



# PROPRIETARY DRUGS AND GENERICS

## A never ending conflict of the pharmaceutical industry?

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Industrial innovation can be substantially protected in two manners:

- Through secret know-how
- By obtaining Intellectual Property rights

# THE PATENT IN THE PHARMACEUTICAL FIELD

There are many types of patents but those that more applies to medicaments are the patents for invention

- Duration – 20 years
- Elements of a medicament that can be protected:
  - the active substance
  - the first medical use (substance X for use as a medicament)
  - the second medical use (use of the substance X in the production of a medicament for treating disease Y)
  - the production process
  - the intermediate compounds
  - the pharmaceutical composition

# THE EFFECTS CONFFERRED BY THE PATENT

A patent owner has the right to impede third parties to reproduce a claimed invention for all the life of the patent

In other words a generic producer cannot commercially exploit a patented medicament at least till the corresponding patent is in force

# EXHAUSTION OF THE PATENT RIGHTS

20 years and then?

The patent owner:

- SPC (Supplementary Protection Certificate)
- New patent application
- New marketing authorization

# SPC

In life science, patent owners enjoy an effective patent life, which is substantially shorter than 20 years due to the time required to obtain a marketing authorization of the patented medicament.

Supplementary protection certificates (SPC) are now conferred in many Countries (CH, EU, US, JP) in order to compensate such a shorter effective patent life.

SPCs have to be requested when the basic patent is still valid, they are conferred to human and animal medicaments and have a duration varying from Country to Country (patent is usually extended of about 2-5 years)

# SPC (follow)

## The exception of Liechtenstein

The existence of legislative discrepancies between EU and Switzerland make the choice of the Country where first to ask for a marketing authorization, decisive in order to obtain the better SPC duration

# THE NEW PATENT APPLICATION

## *The polymorph saga*

Polymorphism is the ability of a solid material to exist in more than one form or crystal structure

Patents on new polymorph forms of a known active substance are currently granted

A choice among thousands of possibilities

- screening of bioequivalent salts of the active substance object of the basic patent
- The importance of a suitable characterization

Patentability requirements are becoming more strict: the requirement of the technical effect

# *THE NEW MARKETING AUTHORIZATION*

A marketing authorization on a specific medicament confers exclusive right of commercialization of the latter for a certain number of years (even if the medicament is not patent protected)

The attainment of a new marketing authorization for a medicament already present in the market (and for which the corresponding patent is expiring) concerning a change of the medicament destination (from prescribed medicament to medicament OTC-Over The Counter) grants a further period of exclusivity (three years in the USA)

# EXHAUSTION OF THE PATENT RIGHTS

20 years and then?

The generics producer:

- The “Bolar exemption” and the request of a marketing authorization
- New patent application

# THE “BOLAR EXEMPTION”

According to the “Bolar exemption”, before the expiration of a patent or of a corresponding supplementary protection certificate related to a medicament X, a generics producer can start conducting the necessary studies and trials with a view of obtaining market approval for the medicament X as a generic. The consequential practical requirements of such activity shall not be regarded as infringing the existing patent rights

This exemption is however not valid in any Country and it might be implemented differently from Country to Country

The producer of generic medicaments should thus be very careful in adopting such exemption

# THE “BOLAR EXEMPTION” (follow)

The EU introduced a new experimental use exemption provision in Directive 2001/83/EC (Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use; as modified by Directive 2004/27/EC) to be implemented by the member states

As Switzerland is not a member of the EU, it is developing its “own” Bolar provision. The Swiss government made implemented a Bolar provision in the current Swiss Patent Law Reform. However, the Law Reform is still not in force

# THE NEW PATENT APPLICATION

Also the generic producer can use the patent system to acquire or erode the market of proprietary medicaments

New patent applications are more and more filed by generic producers in connection with new medicament production processes or new crystal structures (polymorphs) or more active metabolites or new galenic formulations of a known medicament

# PROPRIETARY DRUGS vs. GENERICS

Different strategies to defend or acquire a same market

- The Owner of proprietary drugs
  - file new patent applications or publish search results?
  - new marketing authorizations
  - improve the chemical physical characteristics present in the pharmacopeia (i.e. higher purity)
- The generics producer
  - file new patent applications
  - attack the validity of existing patents to anticipate the attainment of a marketing authorization



THANKS FOR THE ATTENTION!

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