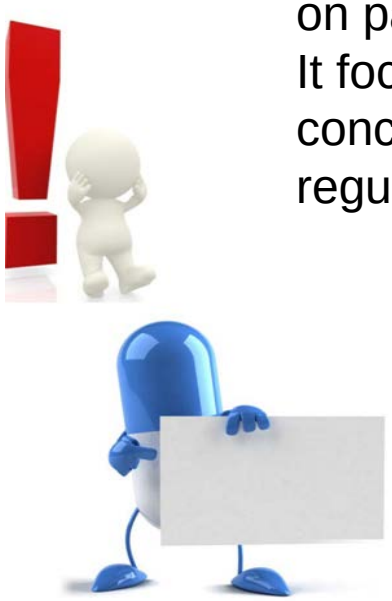
Lesson 6:
Intellectual property and life cycle considerations of pharmaceutical products

EUPATI
European Patients' Academy on Therapeutic Innovation

Disclaimer



This lesson does not purport to be a legal presentation on patents, SPCs or intellectual property.
It focuses on a basic understanding of how these concepts impact upon pharmaceutical products from a regulatory licensing standpoint.

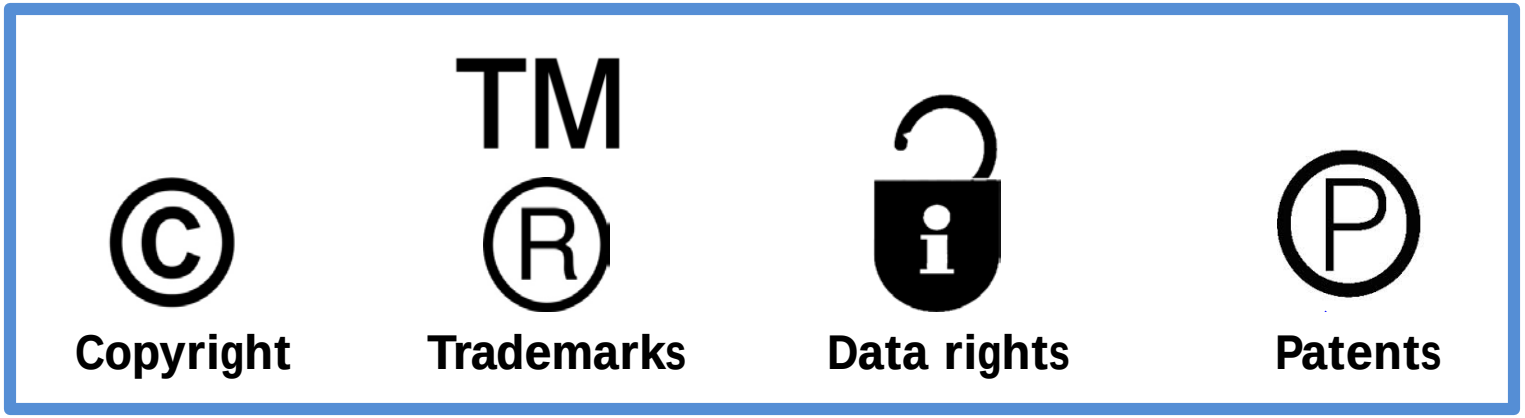
Control of pharmaceutical market access

There are three main points of control for pharmaceutical market access:

Patent Legislation	Regulatory System	Pricing and reimbursement
An intellectual property control	Market exclusivity via data protection	via Health Technology Assessment (HTA)

This lesson looks at the role of patent legislation and the regulatory system, and not at the pricing and reimbursement.

The main forms of **intellectual property** include:



- Other forms exist such as business secrets or first to market.
- The principal means of protecting 'novel' products and processes is by Patents – a concept that has existed since antiquity.

For more information about intellectual property rights, review the Trade-Related aspects of Intellectual Property Rights (TRIPS) agreement available on the World Trade Organisation (WTO) website.

What is a Patent?

- A patent is an exclusive right:
  - Granted in respect of an invention
  - That must be susceptible to industrial application
  - That is new (novelty)
  - That involves an inventive step
- Patents are normally valid for 20 years from the date of filing (full patent).
- Renewal fees are payable at stages throughout the 20 years.

Exclusive right

'Exclusivity'
confers upon its holder, for a limited period, the right to exclude others from exploiting (making, using, selling, importing) the patented invention, except with the consent of the patent owner

- Patents encourage innovation by monetary means; they represent a trade-off of disclosure in return for monopoly.
- Patents have the effect of incentivising innovation but at a cost to consumers – they might allow a higher price to be charged than if there were no patent in existence (welfare loss).
- Considerable time and expense is involved in securing patents – they have to be secured in every country or territory depending on the local legislation.

Key requirements for patentability

Invention

- **Invention**
- **Novelty (newness)**
- **Inventive step**
- **Capable of industrial application**

In Europe, there are many definitions but the test is for the presence of a technical solution to a technical problem. For example, Irish legislation (Patents Act 1964) provides this definition:

- ‘Any new and useful art, process, machine, manufacture, or composition or matter, or any new and useful improvement in any art, process, machine, manufacture, or composition or matter...’

Controversies abound regarding patentability of business practices, software, traditional knowledge, algorithms, as well as various types of biotech and chemical inventions such as stem cells, diagnostic processes, 3D protein and crystalline structures, DNA sequences and animals.

Key requirements for patentability

Novelty (newness)

- Invention
- **Novelty (newness)**
- Inventive step
- Capable of industrial application

Novelty applies when the invention is not already part of the ***'State of the art'***.

'State of the art' is everything made available to the public, in the State or elsewhere, by means of a written or oral description, by use or by any other means, plus any prior Patent application.

Key requirements for patentability

Inventive step

- Invention
- Novelty (newness)
- **Inventive step**
- Capable of industrial application

An invention shall be considered as involving an inventive step if it is not obvious to a person skilled in the art. It is decided on a case-by-case basis.

Key requirements for patentability

Capable of industrial application

- Invention
- Novelty (newness)
- Inventive step
- Capable of industrial application

An invention shall be considered capable of industrial application if it can be made or used in any kind of ***industry***, including agriculture.

'Industry' includes any physical activity of a 'technical character', that is, it can be interpreted as the useful or practical arts rather than the aesthetic arts.

Patent specification

Patent Specification is the key document filed, which outlines:

- Background
- Scope of the invention (abstract)
- Description (enough detailed to permit it to be executed after expiry by a person 'skilled in the art')
- Claims (strict legal text that must set out the essential features of the invention in a manner to clearly define what will infringe the patent)

In deciding when to file the patent, the innovator faces a dilemma – there is invariably a considerable delay between the date of filing and date of grant:

- Filing early may mean the specification is too broad to qualify.
- Leaving it too late may mean the specification has to be narrower in application.

Infringement of a patent (1)

Infringements are enforceable only from the date of grant, but it can be retrospectively enforced to the filing date.

Where the patent is in respect of a product, infringement amounts to making, using, importing or marketing the product without the owner's consent.

Where the patent is in respect of a process, infringement amounts to making, using, importing or marketing of a the product obtained via the process in the patented territory.

Infringement of a patent (2)

1. The patent owner must initially establish a sufficient case on the balance of probabilities that infringement has occurred

2. The burden then shifts to the accused infringer who must argue that they have not infringed on the basis that:
    - Their activities are not encompassed by the terms of the patent
    - The patent relied on lacks novelty or inventive step
    - They benefit from some of the statutory exemptions to infringement

3. The patent right is absolute and can be infringed inadvertently

Who can apply for a patent?

Any person can apply for a patent, but the right initially belongs to:

- the inventor
- someone to whom the inventor transferred the right in law (usually inventor's employee)
- a legitimate successor

The employer is automatically seen as the inventor on many countries if the employee has discovered the invention 'in the course of employment'

It may be necessary to examine the contract of employees to stablish this.

Difficult decisions arise when research workers discover an invention that is not related to their research but which could be of benefit to the pharmaceutical company.

Procedure for securing patents

International treaties exist to allow patent applications to be passed between countries:

- European Patent Convention (EPC)

  It is a bundle of national patents. A single application to the European Patent Office secures patient rights in a number of European countries*

- Patent Cooperation Treaty (PCT)

  Includes most EPC countries plus members in North and South America, Africa and Asia Pacific. A single application can be filed for multiple members.

Patents are territorial

They are valid, applicable and enforceable in the territories where they are approved. Separate applications in every country are costly and time-consuming.

*The European Parliament has approved the creation of a common European Union Patent system, which will cover all member states except Italy and Spain initially

Differences in worldwide patent systems

There are notable differences between the national systems in Europe, as well as those of the EPC and the US patent system :

1. For national US patents, if prior disclosure are made up to one year prior to the filing of the patent application, it does not serve to destroy novelty in the invention.
2. In Europe, only if a prior disclosure was unauthorised will novelty be retained.
3. The US systems work on ‘first to invent’ rather than ‘first to file’.
4. Requirements for a full and detailed disclosure of the invention are more stringently applied in the US.
5. Patens obtained by the EPC and PCT systems are more expensive to obtain due to translation requirements.

The downside of patents is that they may encourage the development of ‘me too’ medicines rather than genuine innovation and can be so restrictive as to block improvements to the original invention

The Supplementary Protection Certificate

The Supplementary Protection Certificate (SPC) is an extension to the patent term available for certain types of patent (including human or animal use or plant protection) to compensate for the reduction in the effective patent life due to regulatory approval timelines:

> The period that elapses between the filing of an application for a Patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the Patent insufficient to cover the investment put into the research.
> Council Regulation

The Supplementary Protection Certificate

The duration of the SPC is calculated as a term equal to the period between the date on which the application for the patent was lodged, and the date of the first authorisation to place the product on the market in the Community, reduced by five years.

The SPC has a maximum duration of 5 years

- If the first marketing authorisation (MA) is issued <5 years after patent filing, no SPC is granted.
- If first MA is issued >5 years but <10 years after Patent filing, the SPC will be equal to the patent filing to the MA issue date minus 5 years.
- If first MA is issued >10 years after patent filing, the SPC will be 5 years.

Supplementary Protection Certificates applicability

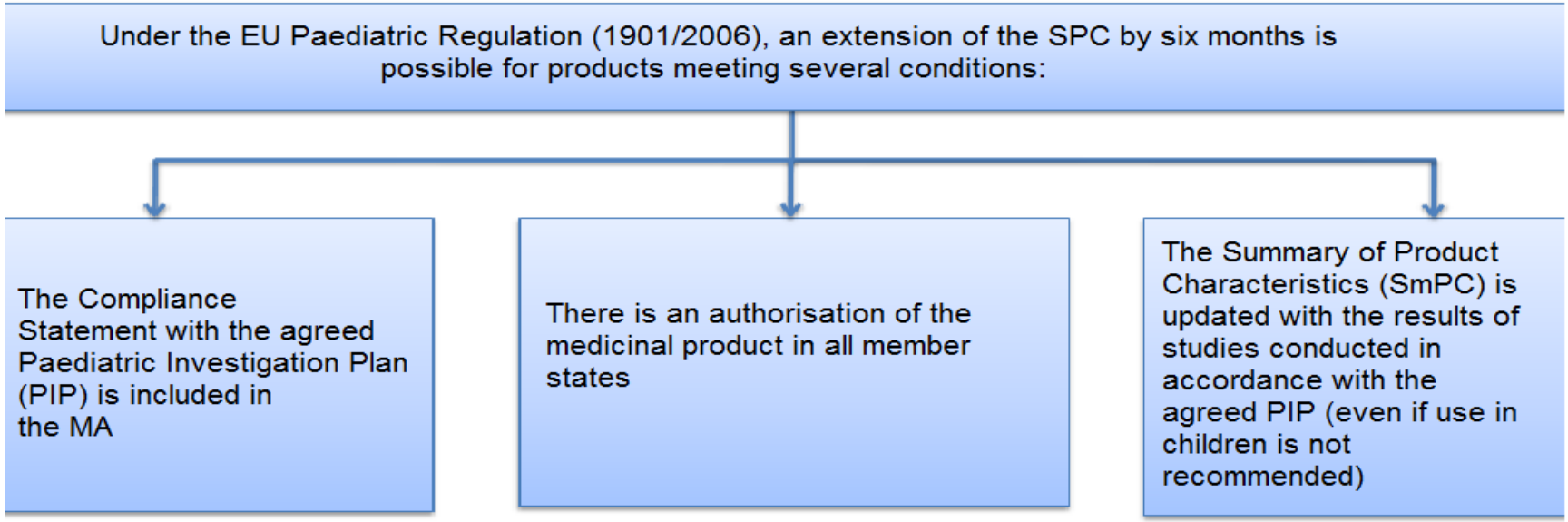
Under the EU law, SPCs are granted in respect of products.

- Products are defined as the active ingredient or combination of active ingredients, of a medicinal product and in respect of which a marketing authorisation (MA) has been granted.
- The SPC benefits the MA holder – this does not have to be the same person as the patent holder.

The patent holder can also apply for a SPC, but only one SPC can be granted in respect of each patent. The SPC has the same effect as the patent.

→ Court cases have been required to clarify applicability of the SPC.

Extension of the Supplementary Protection Certificates



Extensions of the SPC have to be applied for with each National Patent Office where the product is protected by a Patent that qualifies for an SPC EU Paediatric Regulation (1901/2006) can be found at:
http://ec.europa.eu/health/files/eudralex/vol-1/reg_2006_1901/reg_2006_1901_en.pdf

Data exclusivity

A separate system of intellectual property protection exists irrespective of patent law under European regulatory provisions. It affords a period of data exclusivity (and hence market) to the company generating the non-clinical and clinical trial data supporting a marketing authorisation application (MAA).

Data exclusivity covers all data for the product, including registration, subsequent indications and formulations for 8 years.
After data exclusivity expiration, a generic product may receive a label for all indications and formulations, regardless of when the data for the innovator product was filed during the life cycle.

Marketing exclusivity may be extended to 11 years if a significant new indication was added during the first 8 years on the market.
Market exclusivity for orphan medicinal products (10 years) may be extended by 2 years for fulfilment of certain conditions regarding compliance with the PIP under the paediatric regulation.

Patent vs. Data exclusivity

Patent	Data exclusivity
Patents protect the underlying invention for a certain period of time.	It prevents reference to the pre-clinical and clinical data for a certain period of time.
The patent owner generally enforces and defends its patents.	The regulatory authority makes the decision to validate a competitor Marketing Authorisation Application (MAA) where the data exclusivity has expired.
A patent period is 20 years from date of filing, with the possibility of an SPC for a maximum of 5 years.	Data exclusivity is 8 years from the date of first authorisation within the EU, with the possibility of 1 additional year for a new indication.
Patents are nationally issued and apply only in the territory where granted.	Market exclusivity applies to the whole of the EU regardless of whether the Marketing Authorisation is centrally or nationally issued ('exhaustion of right').

Exhaustion of rights

Exhaustion of rights is an exception to Patent rights that is more applicable to Europe than the US.
The principle of exhaustion of rights states that when a product is put into the market in any European country by the owner of the patent or with their consent, the owner cannot subsequently object to the movement or marketing of the product within other member states of the EU – their right is deemed exhausted once it is placed on the market in any one country.

- It arises due to 'conflict' between the facts that patents are nationally limited in scope, whereas free movement of goods is allowed across borders in the EU (Articles 28-30 of EC Treaty).
- Price differentials between member states (particularly price controls on pharmaceuticals) give an incentive to import from cheaper to more expensive member states – this is called parallel importing.