The IP department in a pharmaceutical company

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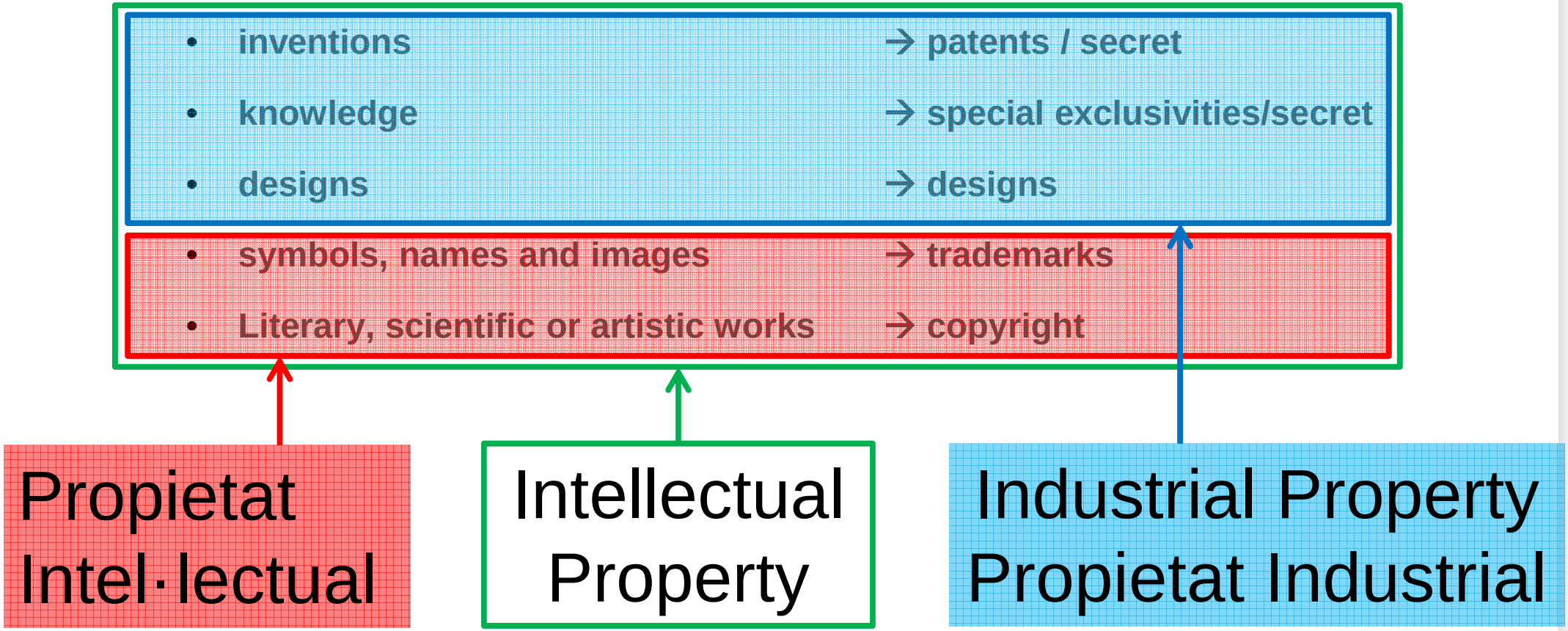
What is ‘IP’?

- **IP means ‘Intellectual Property’. But…**

What is Intellectual Property?

- **Intellectual Property refers to creations of the mind, such as:**
  - **inventions**
  - **knowledge (inventions are part of it)**
  - **designs**
  - **symbols, names and images used in commerce**
  - **literary, scientific and artistic works**

How is IP protected?



How is knowledge protected in pharma industry?

- Inventions -> patents.
- Inventions or any other type of knowledge -> Know-how: industrial secret

Examples:

  - The best pricing strategies for dermatological products
  - Which types of product have higher margins?

How is knowledge protected in pharma industry?

- **Knowledge acquired by developing a new drug: clinical and toxicology studies, stability, etc., included in a registration dossier is protected by law. No other company can rely on it to file a dossier for the same product for a period of some years (data exclusivity).**
- **If a drug is approved for an orphan indication (such as a rare disease), no similar product can be filed for several years for this indication (orphan exclusivity).**
- **Etc.**

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What is a Patent?

A patent is an exclusive right granted by the government for an invention, eg. a product, process or use that provides a new technical solution to a problem.

Protection provided	The patent owner can prevent others from using his/her invention without his permission
Duration	Generally for 20 years
Requirements	Invention must be novel, inventive and industrially applicable
Aim	To reward inventors for sharing their findings with society and making it to progress

Patentability requirements

- **Industrial applicability**

  What is an invention? The invention needs to be useful

- **Novelty**

  What is the prior art? The invention cannot be within the prior art.

- **Inventive step**

  What is obvious? The invention cannot be obvious on the light of the prior art

- **Sufficiency of disclosure**

  Quid pro quo: protection in exchange of disclosing the invention. At expiry, the technology is public.

What is a Patent?

SPC: Supplementary Protection Certificate (EU)

CSP: Certificate of Supplementary Protection (CA)

PTE: Patent Term Extensions (US,…)

Protection provided	Similar to a patent but limited to a product authorized after an administrative review (pharmaceuticals, veterinary drugs, phytosanitary products)
Duration	Up to 5 years
Requirements	Different between jurisdictions
Aim	Compensate for the long and expensive clinical development

What is an Industrial Design?

An industrial design refers to the ornamental or aesthetic aspects of an article.

It may consist of:

- **three-dimensional features**
- **two-dimensional features**

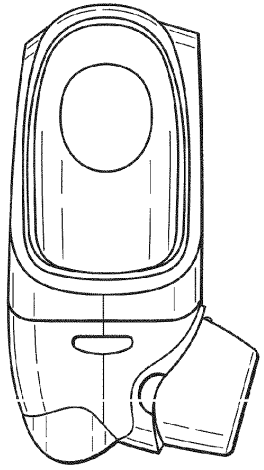


FIG. 4

Duration	Usually range from 10 to 25 years (it depends on the country)
Requirements	New or original and nonfunctional
Aim	An industrial design is primarily of an aesthetic nature. Any technical features of the article to which it is applied are not protected by the design registration (they could be protected by a patent)

What is a trademark?

A trademark is a distinctive sign that identifies certain goods or services produced or provided by an individual or a company.

Duration	For life (as long as it is renewed and used)
Requirements	Distinctiveness, graphical representation…
Aim	Trademarks helps consumers to identify and purchase a product or service based on whether its specific characteristics and quality – as indicated by its unique trademark - meets their needs

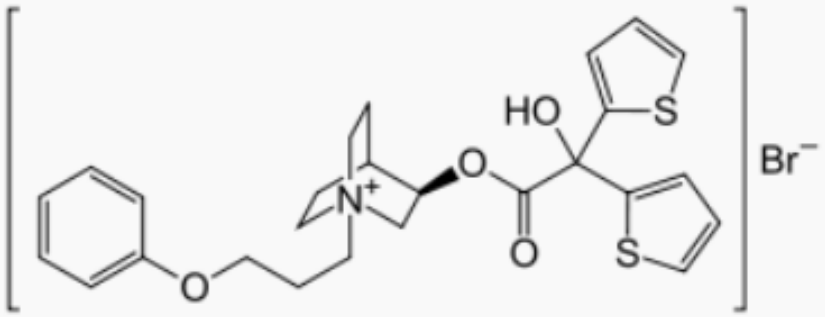
Aclidinium bromide

From Wikipedia, the free encyclopedia

Not to be confused with Acridinium bromide or Clidinium bromide.

Aclidinium bromide (INN) is a long-acting, inhaled muscarinic antagonist approved in the US on July 24, 2012[1] as a maintenance treatment for chronic obstructive pulmonary disease (COPD).[2]

Aclidinium bromide



Systematic (IUPAC) name
[(8*R*)-1-(3-phenoxypropyl)-1-azoniabicyclo[2.2.2]octan-8-yl] 2-hydroxy-2,2-dithiophen-2-ylacetate bromide
Clinical data
Trade names Bretaris Genuair, Eklira Genuair, Tudorza Pressair

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Tasks in the patent department of a pharmaceutical company

- **Following the path of drug discovery & development (I)**

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Tasks in the patent department of a pharmaceutical company

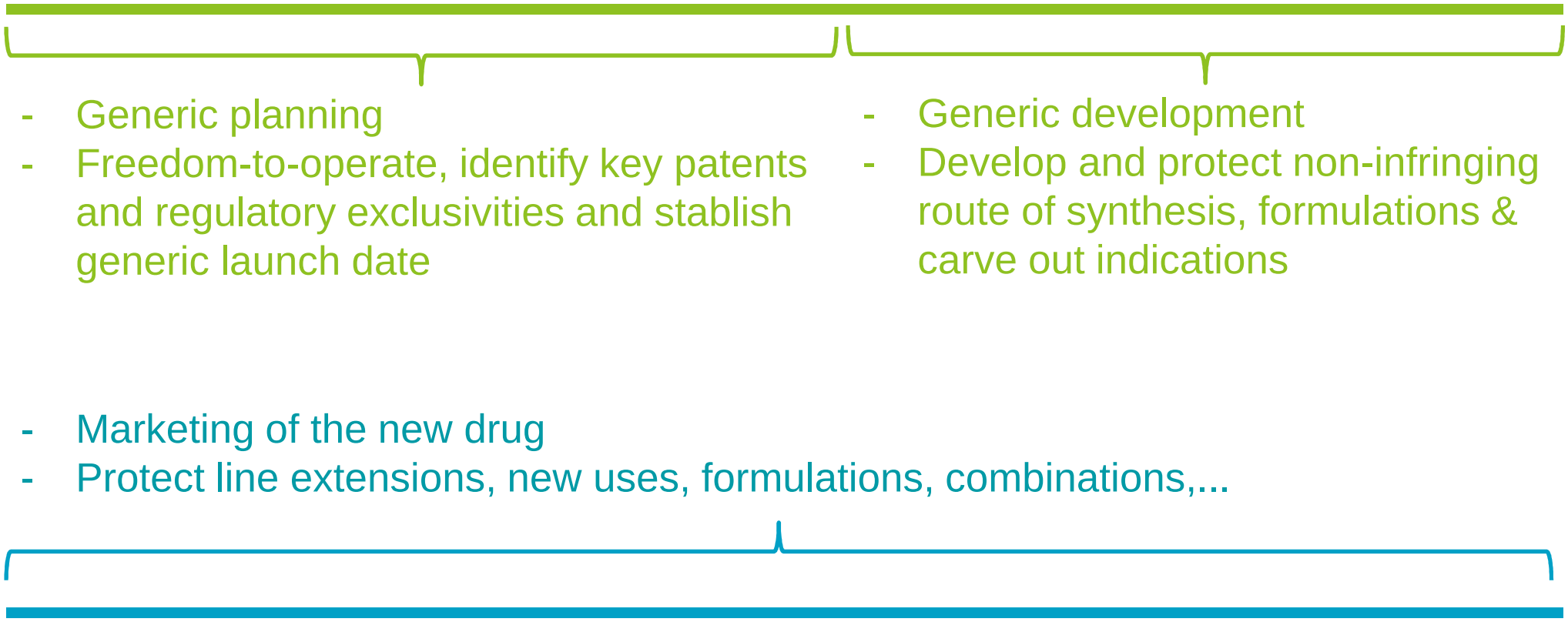
- **Following the path of drug discovery & development (II)**

- Clinical development
- Protect new route of synthesis, uses, formulations, dose scheduling, combinations, …
- Evaluate corporate publications for possible inventions

- Worldwide dossier filing & obtaining MA
- Regulatory requirements (patent listing), Patent Term Extensions, SPC,…

Tasks in the patent department of a pharmaceutical company

- **Following the path of drug marketing (I)**



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Tasks in the patent department of a pharmaceutical company

- **Following the path of drug marketing (II)**

- Generic development
- Invalidate patents (oppositions, IPR, courts)
- Defend against infringement actions
- Licensing out/in

- Marketing of a new drug
- Defend patents and sue possible infringers

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IP Department personnel

The composition depends on the size and type of company and its aims.

Members	
Technical specialists	Chemists, pharmacists, biologists, biotechnologists, engineers, etc. with legal knowledge. They deal mostly with patents and act as internal patent attorneys.
Lawyers	They could be inside the department, cooperate from the Legal Department or be external specialized lawyers. They deal mostly with [pre]litigation activities and general legal counsel.
Paralegals (specialized administrative support)	They deal with the formalities to prosecute and maintain the IP portfolio and can also work from an outsourced IP firm.

Personal skills

- Analytical skills
- Strategic thinking: moving scenarios
- Discipline and patience: not easy to find key documents
- Responsibility: if you fail, your company will suffer
- Self-learning and self-motivation
- Search skills
- Drafting skills (need to be understood)
    - Patent applications
    - Communications to patent offices/courts
    - Internal reports

Career development at an IP Department for patent specialist

- Explore other technical areas
- Legal training specially for European and US patent and pharmaceutical law.

  How to get it?

  - Preparation to be European/Spanish Patent Attorney
  - Learn from your cases looking at the prosecution of some patents and contact with lawyers
  - Litigation experience
  - Many training opportunities: courses, webinars…
  - Numerous blogs discuss IP cases
- Development of language skills

There are plenty of things to learn in this profession and many changes…

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Thank you

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Making
people
better