

DARE TO FLY

INTELLECTUAL PROPERTY

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INTELLECTUAL PROPERTY
EXPERT
FERRER

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The IP department in a pharmaceutical company

Me

- **PhD in Chemistry**
- **European Patent Attorney**
- **17+ years in the patent field (16+ in the generics and innovator pharmaceutical industry)**



Cost of developing a drug

New estimate puts cost to develop a new drug at **\$1B**, adding to long-running debate

<https://www.biopharmadive.com/news/new-drug-cost-research-development-market-jama-study/573381/>



Getty Images

AUTHOR

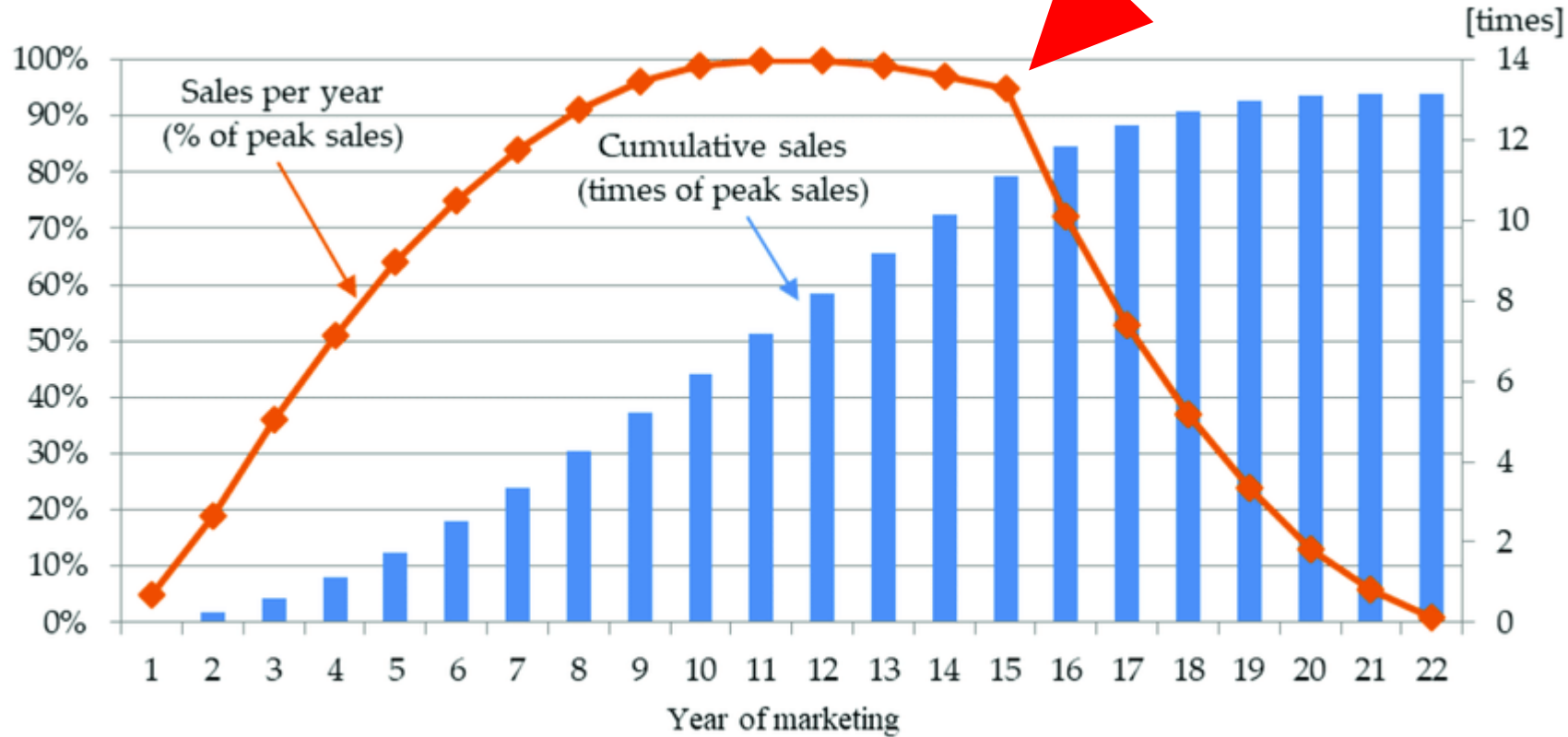
Jonathan
Gardner

@ByJonGardner

U.S. biopharmaceutical companies spent about \$1 billion to bring each of their new drugs to market between **2009 and 2018**, according to a new analysis published in JAMA on Tuesday.

What is 'IP'?

Patent Cliff



March 2018 *Sustainability* 10(4):993 (DOI: [10.3390/su10040993](https://doi.org/10.3390/su10040993))

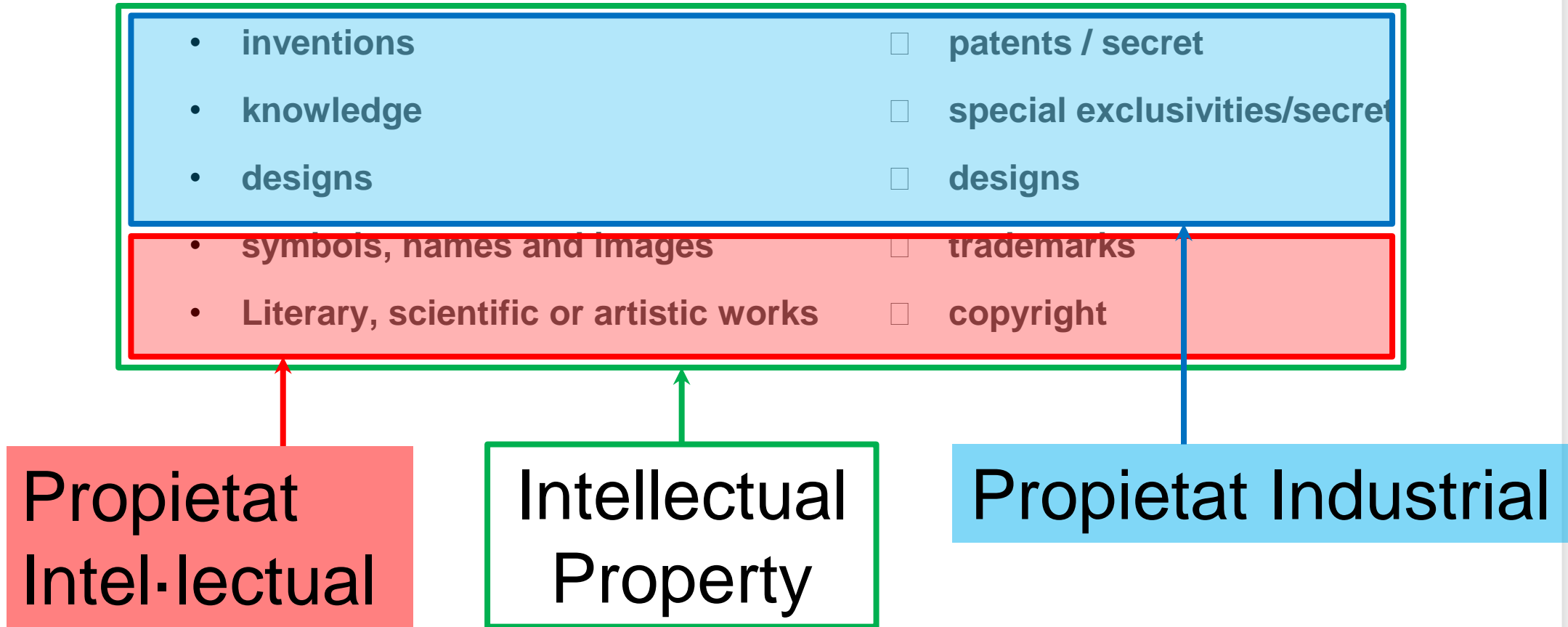
What is 'IP'?

- IP means 'Intellectual Property'. But...

What is Intellectual Property?

- Intellectual Property refers to creations of the mind, such as:
 - **knowledge**
 - Inventions
 - Secrets
 - **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: Trade secret

Examples:

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



How is knowledge protected in pharma industry?

- **Data exclusivity:**
 - **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).**
- **Orphan exclusivity:**
 - **For a drug approved for an orphan indication (such as a rare disease)**
 - **no similar product can be filed for several years for this indication.**

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

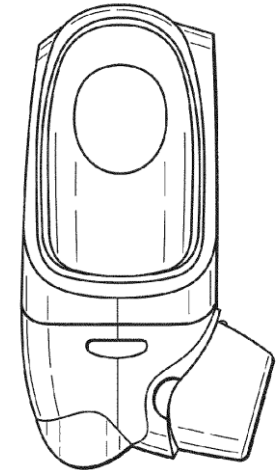


FIG. 4

| | |
|--------------|--|
| 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 |

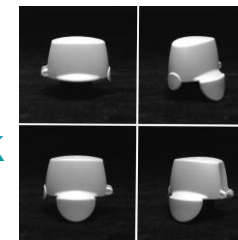


How a medicament is protected

The availability of different modalities of intellectual property (patents, industrial designs, trademarks) allows to prepare a protection strategy so complex that can take to block competitors.

Denominative trademarks (Respimat, Spiriva)

3D trademark



Industrial design



Figuratives and mixed trademarks

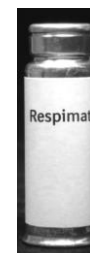
Mixed denominative trademarks



Boehringer
Ingelheim

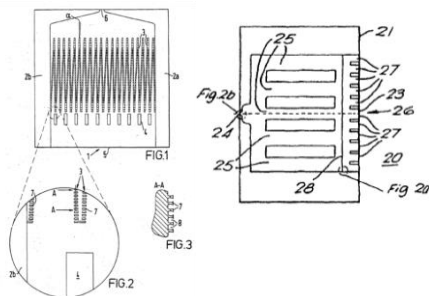


3D
Trademark

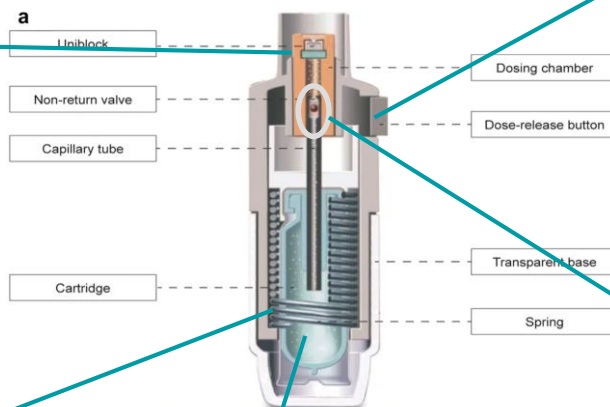
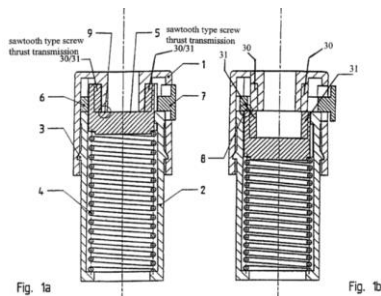


How a medicament is protected

WO02051840,
WO9916530
(nozzle – microstructured filter)



WO9720590 (locking mechanism for spring-actuated mechanism)



WO04024340
(Blocking device for a sprung lock with a spring operation)

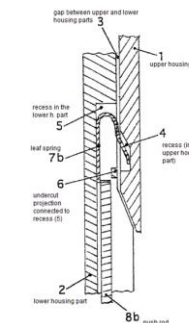
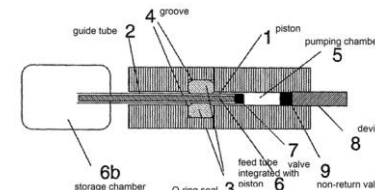


Fig. 2

WO04024340
(annular seal to avoid contact of liquid with air)



WO0023037
(cartridge with closure cap)

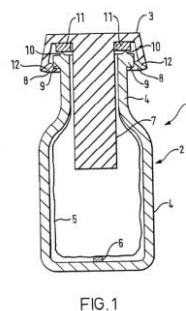
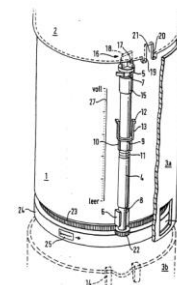


FIG.1

WO9827959
(propellant-free inhalation solution)



WO9724586
(mechanical counter)

Tasks in the patent department of a pharmaceutical company

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



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)


- Generic planning
- Freedom-to-operate, identify key patents and regulatory exclusivities and establish generic launch date

- Generic development
- Develop and protect non-infringing route of synthesis, formulations & carve out indications

- Marketing of the new drug
- Protect line extensions, new uses, formulations, combinations,...

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 the new drug
 - Defend patents and sue possible infringers
- 

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...

Thank you

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15/Mar/2023
Barcelona



The logo icon consists of a stylized, white, rounded shape that resembles a lowercase 'f' or a similar letter, set against a green background.

ferrero
for good