University joins Industry: IP Department

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Ferrer International, SA
Topics

- What is IP?
- Importance of IP in the pharmaceutical industry
- IP Department: tasks and responsibilities
- Personal skills
- Career development at an IP Department
What is Intellectual property?

- 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
Types of IP protection

- **Know-how:** industrial secret

- **Inventions:** Patents and Utility model

- **Industrial design:** protect the external form/appearance of the object

- **Trademarks:** recognizable sign, design or expression with graphic representation which identifies products or services in the market
A patent is an exclusive right granted for an invention, e.g., a product or process that provides a new technical solution to a problem.

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

- **Industrial applicability**
  What is an invention?

- **Novelty**
  What is the prior art?

- **Inventive step**
  What is obvious?

- **Sufficiency of disclosure**
  *Quid pro quo*: protection in exchange of disclosing the invention. At expiry, the technology is public.
Pharma Industry

- Development cost very high: molecule screening, very few new chemical entities reach the market
- Full development
How is Knowledge protected in Pharma Industry?

- Inventions or any other type of knowledge ➔ **Secret**

- Inventions ➔ **Patents:**
  - Product patent
  - Process patent
  - Salt or crystalline form patent
  - Formulation patent
  - Use patent

- 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).
Acridinium 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).\[2\]
Abstract

The invention provides 3(R)-(2-hydroxy-2,2-dithien-2-ylacetoxy)-1-(3-phenoxypropyl)-1-azoniabicyclo [2.2.2] octane in salt form, pharmaceutical compositions comprising it, and methods of using it for treatment of respiratory disorders, alone or in combination with other bronchodilatory compounds.
Inhalation composition containing aclidinium for treatment of asthma and chronic obstructive pulmonary disease

This invention relates to a novel dosage for aclidinium and to novel methods and formulations for the treatment of respiratory diseases, especially asthma and chronic obstructive pulmonary disease (COPD), using aclidinium.
EP2100598 tries to protect a given dose

1. A pharmaceutical composition for inhalation comprising aclidinium in the form of a dry powder of a pharmaceutically acceptable salt in admixture with a pharmaceutically acceptable dry powder carrier, providing a metered nominal dose of aclidinium equivalent to about 200 micrograms aclidinium bromide.

3. A pharmaceutical composition according to claim 1 in the form of a multi-dose dry powder formulation for administration in a multidose dry powder inhaler device calibrated to provide a metered nominal dose of aclidinium equivalent to about 200 micrograms aclidinium bromide.

5. The pharmaceutical composition according to any of the preceding claims wherein the pharmaceutically acceptable carrier is lactose particles.
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

<table>
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<th>Duration</th>
<th>Usually range from 10 to 25 years (it depends on the country)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirements</td>
<td>New or original and nonfunctional</td>
</tr>
<tr>
<td>Aim</td>
<td>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)</td>
</tr>
</tbody>
</table>
United States Design Patent

Inhaler

Inventors: Gregor John McLennan Anderson, Ware (GB); Matthew Spencer Collins, Sheffield (GB); David Vincent Elliman, Halstead (GB); Richard David Lintern, Huntingdon (GB); Andrew Michael Kelly, Ware (GB); Allen John Pearson, Huntingdon (GB); Paul Kenneth Rand, Ware (GB); Mark Digby Tewcher, Bristol (GB); James Anthony West, Bristol (GB)

Assignee: Glaxo Group Limited, Greenford, Middlesex (GB)

Description

The ornamental design for an inhaler, as shown and described.
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 (if you renew and use it)
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
Word Mark: TUDORZA PRESSAIR


IC 044. US 100 101. G & S: Medical information services, namely, providing health information in the field of respiratory diseases and disorders via a global computer network *, excluding medical information services concerning the use of medical gases in the field of respiratory diseases and disorders*. FIRST USE: 20120724. FIRST USE IN COMMERCE: 20120724

Mark Drawing Code: (3) DESIGN PLUS WORDS, LETTERS, AND/OR NUMBERS

Design Search Code: 03.17.01 - Wings, birds'

Serial Number: 85896045

Filing Date: April 5, 2013
The mark consists of the colors green and off-white applied to the entire surface of the product. The drawing is lined to indicate the color green.

IC 005. US 006 018 044 046 051 052. G & S: pharmaceutical preparation for the treatment of sexual dysfunction. The mark consists in part of the configuration of the goods consisting of a diamond-shaped dosage tablet, combined with the color blue as applied to the entire surface of the goods.
Importance of IP in the Pharmaceutical Industry

- The main asset of a pharmaceutical company is its Intellectual Property
- If the rest of competitors could immediately copy a newly approved products, pharma companies could not compensate for the cost of development for new drugs
- When patent protection for a blockbuster drug approaches, companies need to have found suitable replacement products or companies are forced to be restructured...
- For OTC (non-prescription) products trademarks are a key driver for sales.
- IP experts are highly valued
IP department: tasks and responsibilities

- Find or assess possible new products
- Protect the IP generated
  - Design a strategy for protection
  - Identify and propose what can be protected or kept secret
  - File applications for patents, designs, trademarks
  - Prosecute applications
  - Defend your granted rights in opposition/invalidation procedures
  - Assess if third parties infringe
  - Enforce such rights
- Freedom to Operate reports (FTO): detailed analysis of the reference drug and the patents covering it
- Assess the IP of other companies for:
  - products your company is planning, developing or marketing (avoid infringement) or
  - products offered for licensing.
- Take actions to oppose (at the patent offices) or invalidate (at the courts) rights that limit your company’s business
Examples of tasks

- Find relevant documents to defend your patents or attack a third company patent and assess them.
- Provide advice to the management on the strength of the IP protection of a technology to be acquired.
- Find when generic competition can start? How should generics be developed? (useful for generics and innovator companies)
### IP department personnel

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

<table>
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<tr>
<th>Members</th>
<th>Members Description</th>
</tr>
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<tbody>
<tr>
<td>Technical specialists</td>
<td>Chemists, pharmacists, biologists, biotechnologists, engineers, etc. with legal knowledge. They deal mostly with patents and act as internal patent attorneys.</td>
</tr>
<tr>
<td>Lawyers</td>
<td>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.</td>
</tr>
<tr>
<td>Paralegals (specialized administrative support)</td>
<td>They deal with the formalities to prosecute and maintain the IP portfolio and can also work from an outsourced IP firm.</td>
</tr>
</tbody>
</table>
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
- Drafting skills
  - Patent applications
  - Communications to patent offices/courts
  - Internal reports
- Communication skills: need to be understood.
Ideal knowledge for dealing with pharma patents

- Understanding of science behind inventions
  - Chemical processes: Organic/Inorganic Chemistry
  - Solid State Chemistry: Crystalline/amorphous structure for polymorphs patents
  - Pharmaceutical technology: formulation patents
  - Pharmacokinetics/Pharmacodynamics for indication patents or patents claiming PK parameters
  - Mechanics: for device patents
  - Biotechnology

- Searching skills

- Legal background
  - Patent and Pharmaceutical law
  - Case law

- Languages: English is a must, French and German can help.

- Knowledge of the Pharmaceutical Industry
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

- Interesting work if you want to be in contact with the technology without being in the laboratory

There are plenty of things to learn in this profession and many changes...
What can be next?

- Examiner in EPO, OEPM
- Be promoted to senior specialist, head of IP Department (head of another department)
- Move to another technical department depending on your technical background
- Move to Licensing/Business development
- Move to private practice as patent attorney

In my experience more than 80 % of the patent specialist remain motivated and in the profession for many years.
The job is somehow ‘addictive’: you want to know how the plot develops, if you are going to win the cases you deal with.
People that do not like it realize it soon (in less than one year).
POSITION IN ORGANIZATION
Department: IP
Reporting to: R&D Head
Staff in charge: 2
Location: Barcelona headquarters
Contact: recruiting@galenicium.com (Subject: IP Manager)

EDUCATION
- Bachelor’s degree in Chemistry or related disciplines (Life Science)
- Qualified as an European Patent Attorney
- Excellent level of business English and Spanish, spoken and written. Other language skills will be a plus
- Excellent computer skills, specifically Excel, Word, Outlook and Power Point

SUITE SKILLS
- Self-sufficient, critical, disciplined, decisive, methodical, confident, hardworking, dynamic, creative and proactive
- Strong analytical frame of mind and problem solving capabilities. Strong attention to detail
- Strong organizational, planning and time management skills. to design, monitor and enforce work plans
- Ability to effectively prioritize and execute projects/demands on time in a fast paced environment is crucial
- Highly responsible and capable to work under pressure
- Ability to communicate clearly the timelines and important milestones
- Good in negotiations. Persuasive and encouraging
- Strong interpersonal skills. Supportive and able to build effective working relationships throughout the organization. Create dynamic work environment empowering team members
- Excellent written and oral communication skills
- Leadership skills and influencing
- Ability to increase technical knowledge and apply new skills

PREVIOUS EXPERIENCE REQUIRED
- The candidate will have a minimum of 3-5 years of experience in intellectual property in pharmaceutical industry (Patent drafting and filing procedure in Europe)
- Strong knowledge of regulations, guidelines and European registration processes
- Good knowledge of Good Clinical Practices and international clinical regulatory requirements
- Knowledge of the drug development process
- Basic knowledge of patent laws of India and USA

RULES AND RESPONSIBILITIES
- Assist in developing the most effective national and world-wide patent strategies and portfolios for company products and projects
- Development of patentability, validity, infringement and freedom-to-operate opinions
- Prosecution of patent rights, mainly in Europe and USA
- Drafting notice of oppositions and representing Galenicium in oral proceedings
- Execute patent evaluation reports
- Analysis of patents and scientific literature on various development projects
- Search in specialized databases/literature and resolution of technical problems
- Drafting and filing of patent applications
- Respond to IP related queries
- Follow IP policies and provide critical and clear IP advice to internal members
- Follows Galenicium Safety, Health, and Environmental policies and procedures
- Empower IP team to archive objectives on time
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- Basic knowledge of patent laws of India and USA
Oferta de trabajo: Técnico de patentes en el sector químico-farmacéutico

Somos un laboratorio de genéricos en expansión en la Comunidad de Madrid, que actualmente estamos incrementando nuestra actividad en I+D.

Estamos buscando una persona con experiencia en el campo de patentes, tanto de APIs como de producto terminado, para unirse a nuestro departamento de desarrollo y colaborar activamente en la estrategia de la compañía.

Si cuentas con la experiencia, formación (total o parcial) como agente europeo de patentes, y quieres trabajar en una compañía joven y ambiciosa, ponte en contacto con nosotros o envíanos tu currículum vitae a través del email: Marisabel.Garcia@adecco.com

Ferrer Internacional, S.A., a company working in the fields of chemistry, pharmacy, biotechnology and nutrition, would like to recruit a patent professional to support product development, business development and marketing areas.

We are looking for:
- chemistry or pharmacy graduates or PhDs,
- at least 5 years relevant experience, analytical skills, thoroughness,
- self-organized, client-oriented and hard-working candidates,
- excellent written communication skills,
- excellent command of English, German and French a plus,
- advanced knowledge with Office tools (Word, Excel, Outlook)
- experience in prior art searching (PatentBase, STN, SciFinder, etc.).

Qualification as a European Patent Attorney, at least partially, would be a plus.

Functions related to the position include:
- supporting pipeline selection,
- designing protection strategies for innovation,
- drafting patentability reports and freedom-to-operate opinions,
- drafting and prosecuting patent applications,
- performing online searches
- taking part in litigation in cooperation with the Legal Department.

Ferrer offers training and professional opportunities with an experienced team, a learning environment, permanent contract, flexible working hours and numerous social benefits.

The position is based in Sant Cugat del Vallès.

Potential candidates should send their CVs to: asala@ferer.com
Para nuestras oficinas en Barcelona:

**EXPERTOS EN PATENTES**

**MECÁNICA**
**ELECTRONICA**
**NANOTECNOLOGÍA**
**FARMACÉUTICO**

**Funciones:**
Redacción y revisión de solicitudes de Patentes tanto nacionales, PCT y europeas.
Búsqueda de antecedentes e informes tecnológicos.
Asesoramiento a clientes nacionales e internacionales.

**Requisitos:**
- Conocimiento en Patentes y uso de bases de datos.
- Experiencia en el sector.
- Idioma perfecto.

**Horario:**
L-V: 9:15-14:00 y 16:00-19:00
Vi-U: 9:30-14:30

**Posibilidad de horario a tiempo parcial**

**Remuneración:**
En función de la experiencia y capacidad personal.

Interesados: contactar al 933857800 o jorge@iser.com
Thank you

Georgina Marjanet
name@ferrer.com