University joins Industry: IP Department

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Georgina Marjanet Ferrer International, SA

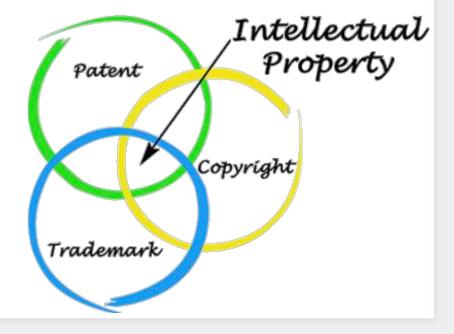


Topics

- > 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?

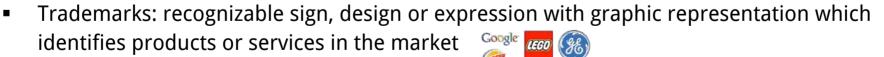
- IP means 'Intellectual Property'. But... What is Intellectual Property?
- Intellectual Property refers to creations of the mind, such as:
 - inventions
 - knowledge (inventions are part of it)
 - \circ designs
 - symbols, names and images used in commerce
 - literary, scientific and artistic works



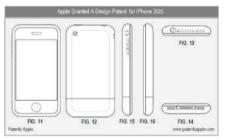
Types of IP protection

- Know-how: industrial secret
- Inventions: Patents and Utility model













A patent is an exclusive right granted for an invention, eg a product or process that provides a new <u>technical</u> 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?

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 <u>same product</u> for a period of some years (<u>data exclusivity</u>).
- If a drug is approved for an orphan indication (such as a rare disease), no <u>similar</u> product can be filed for several years for this indication (<u>orphan exclusivity</u>).



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Aclidinium bromide

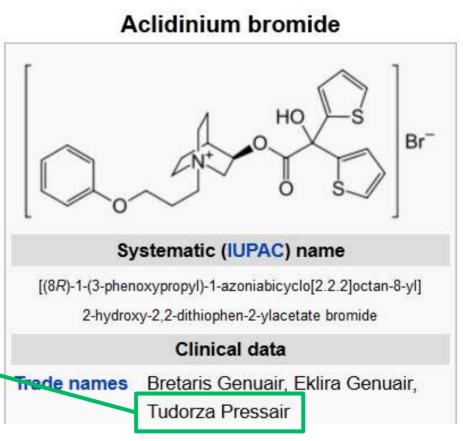
From Wikipedia, the free encyclopedia

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]



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(12) United States Patent Fernandez Forner et al.

US 7,078,412 B2 (10) Patent No.: (45) Date of Patent: Jul. 18, 2006

(54)	QUINUCLIDINE DERIVATIVES AND		EP	0801067	10/1997
20000	MEDICINAL COMPOSITIONS CONTAINING			1087750 B1	8/1999
	THE SAME		FR	2012964	3/1970
			GB	1219606	1/1971
(75)	Inventors: Maria Dolors Fernandez Forner, Barcelona (ES); Maria Prat Quiñones, Barcelona (ES); Maria Antonia Buil Albero, Barcelona (ES)	Barcelona (ES); Maria Prat Quiñones,	HU	178679	6/1982
			WO	WO 91/04252	4/1991
			WO	WO 92/04345	3/1992
		WO	WO 9632150	10/1996	
		reaction for the contract (155)	WO	WO 00/47200	8/2000
(73)	Assignee:	: Almirall Prodesfarma AG, Baar (CH)	WO	WO 0104118	1/2001
			WO	WO 01/50080 A2	7/2001

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.





(11) EP 2 100 598 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication: (51) Int Cl.: A61K 9/14 (2006.01) A61K 9/72 (2006.01) 16.09.2009 Bulletin 2009/38 A61K 45/06 (2006.01) A61K 31/46 (2006.01) (21) Application number: 08382009.2 (22) Date of filing: 13.03.2008 (84) Designated Contracting States: (72) Inventors: AT BE BG CH CY CZ DE DK EE ES FI FR GB GR Lamarca Casado, Rosa HR HU IE IS IT LI LT LU LV MC MT NL NO PL PT 08018, Barcelona (ES) RO SE SI SK TR De Miguel Serra, Gonzalo 08029, Barcelona (ES) **Designated Extension States:** AL BA MK RS (74) Representative: Elzaburu Marquez, Alberto (71) Applicant: Laboratorios Almirall, S.A. Elzaburu S.L.P., 08022 Barcelona (ES) Miguel Angel, 21, 2° 28010 Madrid (ES)

(54) Inhalation composition containing aclidinium for treatment of asthma and chronic obstructive pulmonary disease

(57) 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.

An industrial design refers to the <u>ornamental or aesthetic aspects</u> of an article. It may consist of: •three-dimensional features •two-dimensional features



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)

(12) United States Design Patent (12) Anderson et al.

(10) Patent No.:US D639,931 S(45) Date of Patent:** Jun. 14, 2011

(54) INHALER

- (75) Inventors: Gregor John McLennan Anderson, Ware (GB); Matthew Spencer Collins, Shefford (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 Teucher, Bristol (GB); James Anthony West, Bristol (GB)
- (73) Assignee: Glaxo Group Limited, Greenford, Middlesex (GB)

FOREIGN PATENT DOCUMENTS

EM 000688023-0001 5/2007 (Continued)

OTHER PUBLICATIONS

U.S. Appl. No. 12/377,412, filed Feb. 13, 2009.

(Continued)

Primary Examiner — Ian Simmons Assistant Examiner — Christopher Lee (74) Attorney, Agent, or Firm — James P. Riek

(57) **CLAIM** The ornamental design for an inhaler, as shown and described.

DESCRIPTION



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



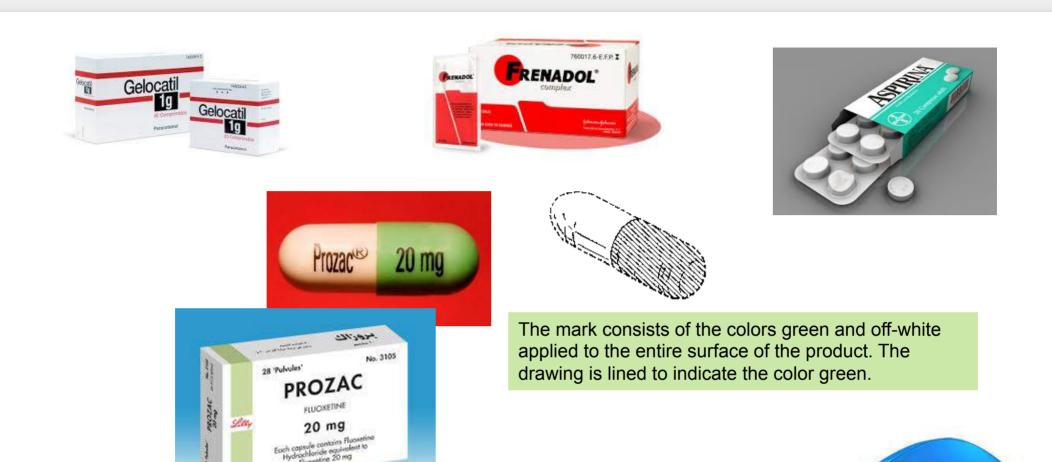
Word Mark TUDORZA PRESSAIR

Goods and IC 016. US 002 005 022 023 029 037 038 050. G & S: Printed matter, namely, brochures, pamphlets, posters, newsletters, and patient educational materials, all concerning the treatment of respiratory diseases and disorders *, excluding printed matter with information concerning the treatment of respiratory diseases and disorders with medical gases. FIRST USE: 20121210. FIRST USE IN COMMERCE: 20121210

> 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







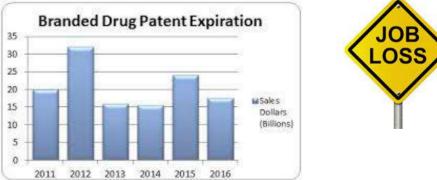
IC 005. US 006 018 044 046 051 052. G & S: pharmaceutical preparation for the treatment of sexual dysfunction. The mark consists in part of the configuration of the goods consisting of a diamond-shaped dosage **tablet**, combined with the color blue as applied to the entire surface of the goods.

Viagra

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.



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.

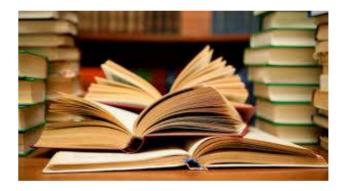
Personal skills

- 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
- 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).





Job offer: IP MANAGER

POSITION IN ORGANIZATION

Department: IP Reporting to: R&D Head Staff in charge: 2 Location: Barcelona headquarters Contact: recruiting@galenicum.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

SUITABLE SKILLS

- Self-sufficient, critical, disciplined, decisive, methodical, confident, hard working, 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
- O Ability to communicate clearly the timelines and important milestones
- O 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

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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

ROLES 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
- Orafting notice of oppositions and representing Galenicum 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 Galenicum Safety, Health, and Environmental policies and procedures
- Empower IP team to archive objectives on time
- 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

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: <u>Marialsabel.Garcia@adecco.com</u>

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Position: Senior Patent Advisor

Departament: Intellectual Property

Ferrer Internacional, SA, 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:

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- 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 (PatBase, 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 Vallés.

Potential candidates should send their CVs to: asala@ferrer.com



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EXPERTOS EN PATENTES:

MECÀNICA ELECTRÒNICA NANOCTECNOLOGIA FARMACEUTICO

Funciones:

Redacción y revisión de solicitudes de Patentes tanto nacionales, PCT y europeas. Búsquedas de anterioridades e informes tecnológicos Asesoramiento a clientes nacionales e internacionales.

Requisitos:

Ingles perfecto Conocimientos en Patentes y en uso de base de datos Experiencia en el sector

Horario:

L-J : 9-14:00 y 16:00-19:00 V: 8:30 -14:30

Posibilidad de horario a tiempo parcial

Remuneración:

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En función de la experiencia y capacidad personal Incorporación inmediata con contrato fijo

Interesados: contactar al 933637900 o jorge@isern.com



Motivated People!



At BALDER we are looking for two talented and ambitious Patent Attomey Trainees: one for our electromechanical & telecom team, and one for our chemical team.

Mare specifically, we are looking for persons who:

- have a suitable technical education (e.g., mechanical or electrical engineering, or physics, organic/pharmaceutical chemistry and/or polymer chemistry)
- are capable of expressing themselves very well, both analy and in writing, at least in English and Spanish (the knowledge of additional languages being an asset)
- are enthusiastic
- are creative
- are capable of working independently, but understands what it means to be part of a team
- preferably have experience of patent related work and enjoy it, or have good reasons to believe that they would enjoy it.

Initially the selected persons will be working at our Modrid office. However, after an initial phase of training and adaptation, also other locations can be considered.

So what do we offer? Well, we believe that we are able to offer at least the following:

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- a motivating environment, in the inspiring company of some of the very best
- professional education & training under the supervision of top-of-the-range European patent attorneys
- ✓ a competitive salary

BALDER is an IP boutique founded in 2012 by an international team of senior IP professionals who considered talent, inowiedge and experience to be necessary, but not enough: consistently offering above-average quality IP work products requires a motivated team of professionals. Working with us is demanding and rewarding (

In spite of the crisis here in Spain, the firm has been successful; from July 2012 to September 2016 we have more than tripled our size. We are now looking forward to welcoming two new members into the team.

For more information about us, please, have a look at our website (<u>www.balderip.com</u>). If you are interested in one of these two positions, please, send your CV together with a letter in English explaining why you would be an appropriate candidate, to <u>cv@balderip.com</u>. Obviously, we will treat your job application confidentially.

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Thank you

Georgina Marjanet name@ferrer.com

