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**Patents' Choice Problem in Pharmacy:  
Legal and Economic Aspects**

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Dr. Gregory T. Papanikos  
President  
Athens Institute for Education and Research

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## **Patents' Choice Problem in Pharmacy: Legal and Economic Aspects**

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### **Abstract**

Patents play a significant role in the high cost pharmacy business. Every time the pharmaceutical company must secure the exclusive rights to its invention and choose the appropriate and correct protection for its new active pharmaceutical ingredients or finished dosage forms among international, European or one/several national patent systems. Companies create so called "patent house".

The main treaties that encourage and protect the innovations and promote the economic development in the pharmaceutical sphere are:

1. On the international level:
  - The Paris Convention for the Protection of Industrial Property (1883) – the first major international agreement relating to the protection of industrial property rights, including patents;
  - The Patent Cooperation Treaty (1970) – the Treaty was amended in 1979, and modified in 1984 and 2001 with the WIPO participation,
  - The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is administered by the WTO (1994),
  - [The Patent Law Treaty](#) was signed in 2000 and came into force in 2012.
2. On the European level:
  - The Convention on the Grant of European Patents (1973), or the European Patent Convention (EPC), is a multilateral treaty.
3. On the national level:
  - Laws of different states – Collection of Laws for Electronic Access (CLEA) database.

The economic aspect to a large extent depends on balance among the payments for the laboratories, experienced specialists, patent costs and expected profit. At the same time the increased competition determine the demand for specialized kinds of patents which can block access to this market for other companies, and increase the commercial value of the invention. There can be used umbrella patent, scarecrow patent, nuisance patent, dead-wood patent, dormant patent etc. or its combination.

The company's patent choice depends on many factors of inner and external character but the most essential are legal and economic aspects of it.

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**Keywords:**

## Introduction

The economy of “brick and mortar” is finished. Now we are living in a world of innovation-oriented activities which rely largely on R&D, patents, software and human resources, at the same time in a world of the services sector, globalisation, deregulation, information technologies spreading – these factors make markets and their environments unpredictable and low manageable. New knowledge provides the basis for starting and sustaining business competitiveness. In today’s world, the knowledge is becoming the main element in differentiating enterprise from its competitors. Protecting this new knowledge is a key to remain ahead in competition, in some cases – to survive. Questions of generation, valuation, protection and exploitation of intellectual property assets are the integral part of business strategy for success in the marketplace. These questions can be resolved by using approaches and instruments first of all in law, economy, management and accounting. This article focuses mainly on the legal and economic aspects of it.

The pharmaceutical industry is a multi-billion dollar industry with about 200 major companies making it up. Pharmaceutical companies conduct all new medicines as the result of lengthy, costly and risky research and development (R&D):

- By the time a medicinal product reaches the market, an average of 12-13 years will have elapsed since the first synthesis of the new active substance<sup>1</sup>;
- The cost of researching and developing a new chemical or biological entity was estimated at € 1,059 million (\$ 1,318 million in year 2005 dollars) in 2005<sup>2</sup>;
- On average, only one or two of every 10,000 substances synthesised in laboratories, will successfully pass all the stages to become marketable medicines<sup>3</sup>.

If major companies do not come out with a successful, billion-dollar medicine (blockbuster drug) once a year, they may see a major impact on their revenue numbers at the end of the fiscal term. In 2006, Pfizer, Johnson & Johnson, and Eli Lilly did not get approval from the Food and Drug Administration (FDA) to market their medicines, and their share prices collapsed<sup>4</sup>.

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<sup>1</sup>European Federation of Pharmaceutical Industries and Associations (EFPIA) (2008): *The Pharmaceutical Industry in Figures*. Brussels: 2008 Edition.

<sup>2</sup>DiMasi, J.A.& H.G. Grabowski (2007). The cost of biopharmaceutical R&D: is biotech different? *Managerial & Decision Economics* 28:469-479. Tufts University, Centre for the Study of Drug Development.

<sup>3</sup>European Federation of Pharmaceutical Industries and Associations (EFPIA) (2008): *The Pharmaceutical Industry in Figures*. Brussels: 2008 Edition.

<sup>4</sup>*The global Pharmaceutical Industry. International Trade and Contemporary Trends*. Available at <https://web.duke.edu/soc142/team2/firms.html> [15 May 2013].

Pharmaceutical industry is knowledge based that's why intellectual assets have become strategic factors for value creation by pharmaceutical firms. Pharmaceutical market is highly concentrated with developed competitive environment. Since 2008, it has become even more aggressive as the basic patents for blockbusters were expired<sup>1</sup>.

### **Patent – Competitive Weapon**

One of the key quality characteristics of the pharmaceutical market is the presence of significant barriers such as patents to entry for potential competitors to it. Also patent is one of the main instruments in the intellectual property protection. It defends either new product or new process. A patent is an exclusive right granted by the government patent or intellectual property office to an inventor/its holder for a certain period of time to prevent third parties from exploiting an invention for commercial purposes without authorisation.

The scope of protection conferred by the patent is defined by the patent claims. The claims must be drafted in a clear and concise manner and must be fully supported by the disclosure of the invention. The disclosure of an invention should be written in such a form that a skilled person in a pharmaceutical or chemical area is able to practice the invention. The claims of a patent fulfil a vital role. They demarcate the scope of the patentee's monopoly rights. Patent attorney writing the claims must avoid both the prior art and the exceptions and exclusions to patentability, so in this case form can prevail over substance.

Even in 20 years – the term it is usually granted from the date on which the patent application was filled - after the claims were first written the words worth would be decided in litigation to determine whether the claims are valid and/or have been infringed. Even technical meaning may end up being given to entirely different meaning due to legal rather than scientific analysis<sup>2</sup>.

Nowadays during patent litigation growth the value of claims is significant. They determine what are the invention and the scope of protection to be accorded to that invention.

In practice, patents are used not only to exclude competitors but also to allow a third party to make, use, offer for sale, sell or import the patented invention through licensing, either in return for a payment of royalties (or some other consideration) or free of charge, for a certain field of use, in a certain territory (which may be for the life of the patent)<sup>3</sup>.

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<sup>1</sup>*The global Pharmaceutical Industry. International Trade and Contemporary Trends.* Available at <https://web.duke.edu/soc142/team2/firms.html> [15 May 2013].

<sup>2</sup>Norman, H. (2011). *Intellectual Property Law Directions* First Edition. *Directions series*, Oxford Press.

<sup>3</sup>WIPO (2012). *IP Facts and Figures*. Available at [http://www.wipo.int/export/sites/www/free\\_publications/en/statistics/943/wipo\\_pub\\_943\\_2012.pdf](http://www.wipo.int/export/sites/www/free_publications/en/statistics/943/wipo_pub_943_2012.pdf) [15 May 2013]



The validity is also limited to the territory: there is no world or international patent. Each invention could be patented in one or several countries. In the latter case it results in a “family” of patents referring to the concerned invention.

## **Legal Aspects**

The main treaties that encourage and protect the innovations and promote the economic development and for the pharmaceutical sphere are<sup>1</sup>:

The Paris Convention for the Protection of Industrial Property (1883) – the overall Convention to industrial property regulates including patents. The substantive provisions of the Convention fall into three main categories: national treatment, right of priority, common rules.

The Patent Cooperation Treaty (PCT) was signed in 1970 and came into force in 1978. The PCT now has 145 contracting states. The Treaty makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an “international” patent application.

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) (1994) relates to the inclusion of certain intellectual property rights, including patent protection, under the auspices of the World Trade Organisation (WTO). It ensures a minimum threshold of IP rights applies in all member states that are members of the WTO. It also provides that the available term of protection shall not end before the expiration of a period of 20 years counted from the date of filing the patent application. The most significant change in area of public health was the requirement that pharmaceutical products be patentable in developing countries from 2005.

Patents are only available for patentable subject matter, generally defined as “invention” in patent law. The Paris Convention did not regulate what is considered patentable and, until the TRIPS there was considerable diversity in national law and practice in this respect. In 1988, at an early stage in the TRIPS negotiations, a WIPO report cited 49 countries that either did not grant patent protection for pharmaceutical products (such as a new chemical compound with medicinal effect) and processes (such as a method of producing the medicine) at all or only provided a limited form of such protection. Some of these countries also excluded pharmaceutical processes.

The Patent Law Treaty (PLT) was signed in 2000 and entered into force on April 28, 2005, aims to harmonise and streamline formal procedures in respect of national and regional patent applications and patents, making those procedures more user-friendly.

The Convention on the Grant of European Patents (1973), or the European Patent Convention (EPC) establishes the European Patent Organisation (EPO) (a non-EU body with 38 Member States), since 1 August 1992. The revised version of the European Patent Convention (EPC 2000) came into force on 13

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<sup>1</sup>WIPO-Administered Treaties. Available at <http://www.wipo.int/treaties/en/> [15 May 2013]

December 2007. The EPC has established a single European procedure for the grant of patents on the basis of a single application and created a uniform patent law designed to provide easier, cheaper and stronger protection for inventions in the contracting states.

Pharmaceutical, chemical firms with easily copyable products and technologies depend more on local intellectual property rights system, particularly in respect of patents<sup>1</sup>.

### **Procedure of Patent Receiving**

There are several possibilities for receiving (seeking) patent protection.

The enterprise can follow the national procedure in each state in which it wants to receive a patent or can take the European procedure and protection that cover all designated contracting states. In case of European protection, the pharmaceutical company has to choose between the direct European procedure and the Euro-PCT protection.

Direct European procedure: company should follow the EPC only; Euro-PCT procedure divided into two steps: the international one – according the PCT, and the second (regional) step is governed by the EPC before the EPO.

A European patent is granted after an examination the patentability requirements of the EPC which also are the basis for the assessment of its validity by national court (Art. 69, 138 EPC).

The extent of the protection conferred by the European patent is equal for all the contracting states and offer a high presumption of validity, meanwhile the national patent generally leads to national rights with differing extents of protection. The pharmaceutical company can file a request for limitation or revocation of its own patent.

From the economic point of view it is comfortably that one can decide at each stage of the procedure, having in mind the results of the completed stages, whether to pay or not the fee for the next stage (Art. 2 The Implementing Regulations of the European Patent Convention and the Rules relating to Fees the EPC (RFees))<sup>2</sup>.

Taking into account the fees levied for the European grant procedure, costs for representation by a single agent and the cost of conducting the proceedings in a single language (in one of the three official languages of the EPO (English, French, German)), a European patent as a rule costs about as much as three or four national patents. Art. 9 RFees the Implementing Regulations and the Rules relating to Fees.

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<sup>1</sup>Alikhan, Sh. & R. A. Mashelkar (2004) *Intellectual Property & Competitive Strategies in the 21st Century*. The Hague: Kluwer Law International.

<sup>2</sup>The European Patent Convention and the Rules relating to Fees the EPC, the Implementing Regulations. Available at <http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/index.html> [13 May 2013]

A European patent application shall be filed in one of the official languages or, if filed in any other language, translated into one of the official languages in accordance with the Implementing Regulations.

In addition, if the enterprise is from a contracting state whose language is not one of the EPO's official languages; it can enjoy certain advantages as regards languages and fees if the enterprise uses an official language of its contracting state Art. 14(1) RFees.

The standard term of a European patent is twenty years as from the date of filing. Provided that the annual renewal fees are duly paid, in most of the EPC contracting states patents remain in force for the maximum term Art. 63 EPC.

The European patent grant procedure lasts about three to five years from when the application is filed. It breaks down into two main stages.

The first comprises formalities examination, search report preparation and the drafting of an opinion on whether the application and the invention, to which it relates, seems to meet the requirements of the EPC. The second comprises substantive examination.

In the first of these stages there is no need for active involvement of the enterprise unless the Receiving Section finds formal deficiencies. However, in the second stage - substantive examination - its application is assigned to an examining division, which usually communicates with enterprise or its representative before deciding whether to grant the patent or refuse the application.

Competent preparation of the patent application and of all procedural steps before the EPO is a crucial factor in ensuring that the examination procedure runs quickly and satisfactorily<sup>1</sup>.

### **Economic Aspects**

The commercial value of a patent could not be seen in patent documentation and depends on many factors such as the size of the potential market, the ability of a patent holder to promote products based on this patent, etc. Besides, patent has advantages and disadvantages such as a limited time of protection, difficult receiving procedure, etc., to minimize these minuses is possible with the help of economic, accounting and management instruments.

The use of the patent databases in the planning and evaluation of R&D is a necessity. Patents give precious indications on which companies hold a technology, on inventors, on the length of ownership, on the free availability of a product when term of the patent is expired, etc.

The role of patent law in developing new medical technologies depends also on specific decisions made at different stages in the development process, in terms of whether and when to obtain patent rights, and how to exercise them.

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<sup>1</sup>How to get a European patent? Guide for applicants. Part 1. 14th edition (2010). Published by European Patent Office. Available at [http://documents.epo.org/projects/babylon/eponet.nsf/0/7bacb229e032863dc12577ec004ada98/\\$FILE/EPC\\_14th\\_edition.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/7bacb229e032863dc12577ec004ada98/$FILE/EPC_14th_edition.pdf) [13May 2013]

Firstly, it can establish proprietary market advantage through exclusivity (the protection of core technologies and business methods). Exclusivity also enhances competitiveness as it can effectively block competitors through clustering and bracketing and it can provide intellectual property-protected entry into a new market<sup>1</sup>.

Secondly, using intellectual property by practicing it (using and exploiting it) is a basic economic value creation strategy.

Thirdly, intellectual property can create economic value through the generation of licensing income and cross-licensing strategies.

Lastly, a strong intellectual property portfolio can also improve a firm's financial performance as it can enhance corporate value and attract new capital<sup>2</sup>.

The pricing of drugs depends on numerous factors including development costs, research costs, similarities to other drugs on the market, improvement upon other drugs and who are buying these drugs. Hospitals, and government organizations, such as the military and Medicaid are able to negotiate the lowest prices because of their power and volume that they buy the goods. Local pharmacies and independent patients pay the highest costs, especially those buying drugs to treat life-threatening diseases<sup>3</sup>.

The patent choice problem is directly linked to a defined product opportunity, usually represented by an ongoing R&D development project. There are many things that can influence to the worth of it in the pharmaceutical industry: the project can fail at any stage of development; the costs of every stage are vary, but sometimes unpredictably in times; the time – by years; the medicine may not gain a licence, etc. In the face of such uncertainties the valuation of intellectual property assets in pharmaceuticals is of vital importance. The company must ascertain the assets and liabilities of the target using a Due Dilligence. One of the strategic decisions for pharmaceutical company relates determining first of all patenting strategy as far as patents are their main tool of intellectual property protection.

The company should schedule all patents that relate to its products, services, operations or names; all documents concerning the registration of patents, the patent application; all agreements concerning purchase, sale or license of proprietary rights, royalties and maintenance, patents; documents relating to claims or disputes concerning products, services or proprietary rights owned or used by the company<sup>4</sup>.

Constant management and enforcement of patents with the advices of companies' patent attorney and a full audit of all company's intangible assets

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<sup>1</sup>Rivette,K.G. & D.Kline (2000) "Discovering new value in intellectual property". *Harvard Business Review*. Available at <http://hbr.org/2000/01/discovering-new-value-in-intellectual-property/ar/1> [12 May 2013]

<sup>2</sup> Ibid., 8

<sup>3</sup>The Global Pharmaceutical Industry Political Determinants: Governments and Trade Agreements that Affect the Industry. Available at <https://web.duke.edu/soc142/team2/political.html#pricing> [11 May 2013]

<sup>4</sup>IP Due Diligence Checklist (Page 5 of 14). Available at <http://www.digitaldataroom.com/IP-Due-Diligence-Checklist.html> [11 May 2013]

will help to reduce of unauthorized use of patents by competitors and avoid unauthorized use of others companies patents; better understand market and company place on it, generate a profit and choose the right type of patent.

The economic aspect to a large extent depends on balance among the payments for the laboratories, experienced specialists, patent costs and expected profit. At the same time the increased competition determine the demand for specialized kinds of patents which can block access to this market for other companies, and increase the commercial value of the invention.

There are different types of patents: according to the covered territory European, regional, national and multinational for several states. The cost implication is also an important factor to keep in mind where the patent is to be protected internationally. The PCT minimizes international patent costs to a large extent. Filing regional patent applications is an effective patent protection strategy. Regional filings provide several advantages, such as standardized the filing procedures, the minimization of translation costs and an exemption of the requirements of substantive examination in some designated countries.

Market conditions and increased competition determine demand for both traditional patents (basic (for example, for Pfizer the patent for Lipitor is a basic one), combination), and a number of non-traditional, created using high-patented technology, specialized kinds of patents, among which specialists identify umbrella patent (or blocking patents – patent that not supported by the patent practice, or too general (patent, that has wide application) to sue the person who will be able to implement it in practice), scarecrow patent (patent, gotten solely to prevent the exploitation of the invention by others), nuisance patent (patent with no commercial value, but it prevents a competitor from the patenting), dormant patent (unused patent, the patent for the non-applicable invention), submarine patent - patent remaining in the "shadow", while the company is not rich enough to be able to implement it, etc. or its combination.

In 2009 the Irish court ruled in favour of the claimants, Ivax Pharmaceuticals, Ireland that under Irish law GlaxoSmithKline's Irish combination patent for Seretide, an inhaled respiratory treatment for asthma and COPD, was not valid. The decision relates solely to the Irish combination patent for Seretide and is not binding in any other jurisdiction<sup>1</sup>.

According to the patent filing strategies patents can be offensive or defensive. An offensive strategy aims to leverage exclusive rights over a technology in order to extract economic returns either from exclusive use of the patented technology or from licensing arrangements. A defensive patent strategy is aimed solely at protecting the inventor or patent owner's freedom to operate (FTO) using its own technology by avoiding a situation in which a competitor obtains exclusive rights to it<sup>2</sup>.

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<sup>1</sup>GSK Provides Update On Seretide Litigation. (2009) *PBR Staff Writer*. Available at [http://www.pharmaceutical-business-review.com/news/gsk\\_provides\\_update\\_on\\_seretide\\_litigation\\_090626](http://www.pharmaceutical-business-review.com/news/gsk_provides_update_on_seretide_litigation_090626) [15 May 2013]

<sup>2</sup>PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION. AVAILABLE AT [http://www.wto.org/english/res\\_e/booksp\\_e/pamtiwhowipowtweb13\\_e.pdf](http://www.wto.org/english/res_e/booksp_e/pamtiwhowipowtweb13_e.pdf) [15 MAY 2013]

Strategies of pharmacy companies for maintaining the top priority patents and medicines are different. Companies do patent minor modifications to existing medicines; invent new processes to make old medicines, new formulations of old medicines, new packaging of old medicine and many other variations.

The profitable life for medicine patents is often far less than twenty years because it starts as soon as the patent was filed and not from the moment of first sales on the market. Between these two moments the process of approval of the new medicine extended (lasted). One of the ordinary patent strategies is “evergreening” - patenting of new forms or other minor variations of existing products with no additional therapeutic value and display limited inventiveness, is used to prolong patent protection. It is creating a negative effect on access to medicines, as well as on further innovation. For example, AstraZeneca obtained the patent on Nexium (esomeprazole), this medicine was identical to the AstraZeneca’s Prilosec (omeprazole) the patent protection of which was about to expire. This type of strategy works only if consumers and doctors are persuaded to buy “new” medicine, which can be even more expensive than the previous one. So, the producer has to pay for new patent, one more ads campaign but the game is worth of extra costs for!<sup>1</sup>

The second common strategy employed by pharmaceutical companies is the creation of “patent clusters” or “patent family” by filing numerous additional patents for the same medicine with variations of the same product, especially for blockbuster medicines. Usually they do it very late in the life cycle of a medicine, when the main patent is about to expire. These patent clusters make it more difficult for generic competitors to develop a generic version of the original medicine without infringing one of the numerous patents filed around one medicine. The number of patents also increases the risk of potentially costly litigation.

Members of “patent families” may be related to each other by priority claims as far as subsequent applications in other countries usually claim the priority of a first application. There is a variety of different family concepts since subsequent filings can claim several priorities of different earlier applications. Databases may use different definitions of what makes up a “patent family” and that’s why search results based on “patent families” may be different for different databases<sup>2</sup>.

There are some other patent strategies:

- Patent counterclaim - a method of protection against patent suits: the defendant accused the plaintiff that he had violated the defendant's patent.

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<sup>1</sup>Jonathan J. Darrow, Debunking the “Evergreening” Patents Myth. (2010). *Harvard Law Record*. Available at <http://www.law.harvard.edu/academics/degrees/gradprogram/sjd/sjd-current-students/2010-debunking-the-evergreening-patents-myth,-harv-l-record.pdf> [10 May 2013]

<sup>2</sup>Promoting Access to Medical Technologies and Innovation. Available at [http://www.wto.org/english/res\\_e/booksp\\_e/pantiwhowipowtoweb13\\_e.pdf](http://www.wto.org/english/res_e/booksp_e/pantiwhowipowtoweb13_e.pdf) [10 May 2013]

- Cross-licensing - an agreement between two parties, where each of them gives the other party licenses to its patents.
- Patent troll - a person who has a portfolio of patents solely for the purpose of receiving royalties, without any attempt to implement patent applications in practice. Since patent trolls do not produce anything, Patent counterclaims against them do not work.
- FUD = Fear, uncertainty and doubt - intimidation, intentional creation of doubt and uncertainty for Company B by Company A, which has a patent (or a patent package) for a similar technique/product, without concrete evidences. Often the goal of the company A is the destabilization and the subordination of the company B on the conditions of the company A.

Before the patent time have expired it is possible to use the practise of innovation including marketing the result from an invention or the successful branding of the innovation, etc. that is sometimes called "Value transference".

Value transference helps to build and sustain a competitive advantage for many years beyond the life of a patent using a combination of patent, industrial design and trademark (for technological innovation as well).

The case of aspirin® provides a good example of using trademark for extending commercial benefits. Knowing that patents have a limited duration, the Bayer Company embarked upon promoting a trademark for its new product. When the Aspirin patent expired, the company continued to benefit from the sale of aspirin through its established trademark Aspirin®.

A famous case where multiple regimes of property are used on a first mover compound is that of AstraZeneca (AZ) and its blockbuster proton pump inhibitor (ppi) Prilosec® for chronic gastro esophageal reflux disease or GERD.<sup>35</sup> Long before the compound patent expired (2001), AZ professionals the idea of advertising Prilosec as “The Purple Pill” and delivering it to market with corresponding unique trade dress. Through clever, direct to consumer advertising, AZ was able to build an equivalence between the state of the art GERD solution and “The Purple Pill”.

This next drug with slightly improved efficacy was introduced to the marketplace in early 2001 and branded as “today’s purple pill”. The agent of transference common to both pills was the colour purple... This careful value transference executed across multiple generations of ppi product formulations sustained the US\$ 6 billion annual AZ revenue for the ppi product category through 2006.

The forward looking private sector enterprises in most countries understand the value of the IP, and are keen on its effective protection. The intellectual property system assists in keeping their products competitive in the marketplace, recovers their R&D costs, provides requisite security against patent misuse.

## **Conclusions**

The pharmaceutical industry is a very competitive and high cost one. The intellectual property rights, and first of all such its type as patents, is one of the key instruments of the new active pharmaceutical ingredients or finished dosage forms protection.

For successful commercialisation of patented inventions, the company must keep a regular documented record of detailed information of the inventive activities, it helps in preventing and/or resolving disputes, concerning patent ownership and/or infringement of patents belonging to others, in drafting of precise claims and specifications. Patenting alone does not guarantee a marketing success. Legal professionals play a crucial role in overcoming all before mentioned difficulties, but for effectively reconcile opportunity with pharmaceutical market context and allocate resources to realize a profit, the knowledge of economics, marketing, finance, etc., and all possible combinations of it are required. The economic aspects must take into account at every stage of new medicines development.

The patents' choice problem in pharmacy is really hard as far as there are many new types of patents and strategies of their using or misusing. The value creation process in pharmacy has transformed, making it necessary to update methods for the choice and use of intellectual property rights in general and patents in particular.

The company's patent choice depends on many factors of inner and external character but the most essential are legal and economic aspects of it.

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