

# Chapter 2. Intellectual Property Management

## Questions

### Question 2.1. What are the pros and cons of the intellectual property system?

Three conditions are mandatory for a commercial idea to be protected: Newness, usefulness, and non-obviousness. In plain words, it would be impossible in 2010, to protect the invention of trousers (not new), styling one's hair with his bare hands (too obvious), and finally staring at a rainbow (not so useful). As far as the types of protection available are concerned, there are various kinds, for example patents (a new, non-obvious, and useful method of producing a commercial product (e.g. a new medicine), or trademarks (a specially created sign that is not only indicative, but also distinctive). In addition, a trade secret, may describe the not-publicly known method or "recipe" of doing things, or an industrial design, for example, a wrist-watch or a vacuum-cleaner. The intellectual property protection system that has gradually been evolving over more than a century is based on a set of mutual incentives, for either the idea creator-inventor, or the society as a whole. On the other hand, despite its countless incremental evolutions that have taken place to-date, it is still not free of criticism. But let's start from those incentives.

#### Intellectual property incentives

As described above, an inventor is enticed by society to come up with a commercially-applicable idea, that is new and non-obvious, and come forward with an application to protect it, in order to be awarded a regional monopoly (be it national or international). Society's intention is two-fold: first, to provide incentives for a new technology to be widely implemented and second, to stimulate economic growth. It really makes no sense to the society to utilize its natural resources in order to offer a better education, health care, and long-term sustainability to its citizens, while disregarding the creations of their mind, that could potentially supplement the natural resources with intangible resources, i.e. their inventions.

On the other hand, the inventor is asked to prove that her/his idea is new, non-obvious, and has a useful application, while making a detailed description of such an invention. The invention is awarded a financial monopoly that lasts a certain period of years (usually twenty years from filling the application, during which the inventor may commercially exploit it her/himself, or decide to license it to a manufacturer for a given fee or proportion of future commercialization profits - "royalties"). At the end of the given period, the invention loses its monopoly, and fellow society members may utilize the invention or even improve it, and successfully patent their improvement, and so on.

#### Intellectual property criticism

There have been various criticisms against the intellectual property system expressed over the years. Some of them may belong to the philosophical domain, while others may hold huge consequences for mankind. The practical guide you are holding in your hands would soon exhaust its pages in discussing the pros and cons of all such criticisms. Instead, it will only briefly mention some of them, leaving the interested reader of monopoly rights to further her/his knowledge by visiting the websites of either the proponents of the global IP system in existence (such as the international Patent Organizations), or some of the global not-for-profit organizations (NGOs) that have campaigned in favor of a freer IP environment.

First, intellectual property rights usually cover items that are called non-rival, that is goods that may be used by many individuals at a time, for example medicines. Non-rival goods would be those that can only be used by one individual (in other words, what good would a patent be for a medicine that would be so personal, it could only be used by a single individual due to her/his genetic predisposition?). If that's the case, don't medicines that could save mankind from a global, deadly pandemic belong to mankind as a whole?

Second, inventions may have not been invented, if there were a complete vacuum of IP protection in the form of a commercial monopoly. In other words, why would an inventor of earlier years devote an entire life-time, countless man-hours, incalculable expenses, and even his own life (think of a researcher self-injecting himself with a rare vaccine) if there were no incentives to commercialize it? And even if royalties were not his life-long aim, what if recognition went to an early imitator who had no fear of a monopoly

surrounding the invention? OK, fine, fame or fortune would be a sufficient incentive for innovation. But what if the original inventor charged an exorbitant amount to potential recipients of this vaccine injection? How would the society prosper by the researcher becoming super-rich while the masses remained unprotected from the antigen?

Third, how long should the monopolistic period be for a given healthcare invention? Logic would suggest a sufficient period for the inventor to recuperate the invention's research and development costs, and a nominal profit. Here the danger lies in how much were the total R&D costs (not easily accountable for), or how much should the additional profit be in the face of healthcare inequalities. In other words, if societies cannot afford paying for rising healthcare costs (not only medicine-related), while healthcare manufacturers thrive against all expectations, why shouldn't the monopoly protection period be shortened?

Fourth, except for the monopoly protection period, should we be concerned by what "goods" can be protected? In plain words, it is fine to protect a biopharmaceutical, or a medical device with IP protection. What about more "natural", or more "ethereal" goods? Let's be provocative for a minute (it's called writing anyway). How about patenting a genetically-modified micro-organism? Or a plant and an animal? Should we patent a human being (for example, he could have a genetically-modified super-strong muscular system – a "eugenic" clone)? How about the "theory of relativity" – someday it was new, non-obvious, and remains commercially immensely useful. Finally, what about an alien virus arriving to Earth on a meteorite? Or the color of nuclear fusion?

## **Question 2.2. Which are the main types of intellectual property protection?**

TYPE	COVERS	RIGHTS	TERMS	EXAMPLES
Patent	Device, process, composition of matter	Inventor	20 years	Biopharmaceutical
Copyright	Material form of composition	Author, creator	Author's life + 50 years	Books, software, music
Trademark	Identifiable mark		15 years (renewable)	Logo, slogan
Plant Breeder Rights	Variety of plant	Breeder	18 years	Quantum Canola
Industrial Design	Aesthetic design of product	Designer	10 years	Rug, robot design/shape
Trade Secrets	Anything	n/a	Indefinite	Secret sauce, soft-drink recipe

## **Question 2.3. How does an inventor compare with a patent holder under the modern IP protection system?**

The international patent system awards patents to the original inventor, which in the case of healthcare biotechnology is usually a scientist. Obviously, this scientist either works for an academic institution or a company, who are then given rights to this invention, as the inventor's employers who provided her/him with the funds, the facilities, the chemical reagents, the apparatuses, as well as the benefits of working with a team complementing each other's abilities. For example, think of the history-making discoveries of DNA fingerprinting (1984 by molecular biologist Alec Jeffreys; Jeffreys et al. 1985), the polymerase chain reaction (1985 by biochemist Kary Mullis; Saiki et al. 1985), and the genetic sequencing of the human genome (2001, [www.ornl.gov/sci/techresources/Human\\_Genome/home.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml), by both private and government teams). The individual inventor who patented her/his idea on their own, or the respective employer of the biotechnology scientist mentioned above, may then decide to transfer the rights to their invention, to someone who is willing and capable of commercially capitalizing on this invention, for either a one-time fee, or an initially smaller fee plus a proportion of all future profits under patent, the later called a royalty.

All regional patent systems, such as the ones named above, are supervised by Courts who make decisions in times of patent disputes. Therefore, patents can be challenged, they can be found invalid, and they can be annulled. As far as the holders and challengers are concerned, the patents need to be protected, monitored, licensed, sold, further protected with additional patents, researched, re-worked around, challenged, limited, invalidated, negotiated and constantly cared for, by a dedicated team of IP specialists.

## **Question 2.4. Which are the main functions a patent plays in modern society?**

We have previously described how the patent system makes a compromise between the individual inventor's rights to a limited monopoly, and the society's rights to collectively learn and be improved by the invention. In the process, the patents play several important roles simultaneously. Let's study some of them.

First, they provide an **incentive**. The incentive is in the form of monetary reward for the inventor during a period of exclusivity. Without it, there would be no race to invent it, protect it and commercially launch a related product. Second, there would be no incremental knowledge added to the world's heritage if it weren't for the individual inventor describing her/his invention in order for a patent to be issued, thus the patent system encourages the **disclosure** of this specialized knowledge by the individual to the society. Third, patents enjoy a limited **monopoly**, which in the case of biopharmaceuticals lasts for twenty years from the patent application filing. With careful analysis, experienced sales and marketing experts may forecast the future potential earning of this biopharmaceutical during its patent protection period (usually ten years after all required clinical testing and approval procedures are completed and the product is launched under monopoly). Thus, a patent immediately confers a **commercial "value"** to the invention, and patent holders may negotiate these rights should they decide to license them. Fourth, a biopharmaceutical company's patent family (usually called a **"portfolio"**) is a dependable and valuable asset, although an intangible asset liable to patent challenges. In most cases, that's what the biopharma industry thrives on, and that's what leads potential investors and employees alike to follow it to the horizon. In other words, patents indicate value, and value is a strong beacon of future financial success and stability. Fifth, patents are a prerequisite for commercial success, thus attracting profits, which are then re-invested into R&D, thus leading to future patents, and so-on. It is this **positive spiral** of research and discovery that has been driving our societies at a faster pace of development over the last one hundred years, compared with countless centuries before them. Sixth, patents are a prerequisite to the existence of **free enterprise** societies, as opposed to totalitarian state monopolies where originality and invention are discouraged. The future will prove the retrospective value of the patent system in not only technological, but also general society evolution over the years.

#### **Question 2.5. What can a modern biopharmaceutical trademark cover? Describe a detailed example.**

Now, what does a trademark cover? It covers words (Neuron), names (Roche), letters (TCA Cellular Therapy), numerals (454 Life Sciences), drawings (Lunesta), symbols (Efexor XR), colors (Viagra), signs (Avastin), and even music and sounds when promoting these medicines to healthcare professionals or to the public (only some countries allow – See Chapter 9). For reviewing some of the world's best known medicinal trademarks, see the Physicians' Desk Reference ([www.pdr.net](http://www.pdr.net)), or google-search for a trademark's image.

Before we review a famous pharmaceutical trademark holder's example, let's briefly mention the availability of trademarks not belonging to private organizations, but instead to international associations that play a role in biopharma development. For example, a biopharmaceutical company may be given the right to advertise a service quality qualification with the use of a global, well-recognized quality trademark (such as ISO 9000), or the stamp of approval by a regulatory agency, (such as FDA-approved manufacturing facilities), or even a patient association's recommendation (visit the International Alliance of Patients' Associations; <http://www.patientsorganizations.org/>).

#### **Trademark example: GENENTECH**

"Our trademarks - Activase, Avastin, Cathflo, Genentech, Herceptin, Lucentis, Nutropin, Nutropin AQ, Nutropin AQ Pen, Pulmozyme, Raptiva, Rituxan (licensed from Biogen Idec), TNKase, Xolair (licensed from Novartis), and Tarceva (licensed from OSI Pharmaceuticals) - in the aggregate are of material importance. All of our trademarks are covered by registrations or pending applications for registration in the U.S. Patent and Trademark Office (Patent Office) and in other countries. Trademark protection continues in some countries for as long as the mark is used and, in other countries, for as long as it is registered. Registrations generally are for fixed, but renewable, terms." Source: GENENTECH 2008 Form 10-K with Exhibits 23.1, 31.1, 31.2 and 32.1, [www.gene.com](http://www.gene.com)

#### **Question 2.6. How does a trade secret compare with a patent?**

Trade secrets are an alternative to patents. Whether a biopharma company decides to protect its discoveries with one or the other depends on the nature of the secrets to be protected. For example, a patent offers a monopoly protection for a given period of time, while trade secrets are indefinite. A patent requires the secret to be described, and later become publicly known, while trade secrets never divulge this sensitive information. On the other hand, if the trade secret owner does not take proper steps to guard it, or another entity accidentally discovers the same thing, then protection is lost forever. Also, a patent is a guaranteed protection over twenty years, and provided it's not challenged, nothing can legally break it. A

trade secret needs to constantly be guarded from prying eyes of vying competitors or malicious employees, but if it is properly guarded it can last for centuries and beyond. In other words, a patent is more predictable, while a trade secret is more hopeful but lasting.

### **Question 2.7. What are the major methods of obtaining a biotechnology “freedom-to-operate”?**

There are four main methods for a biopharma to get the required freedom-to-operate before it takes a new biopharmaceutical candidate through its rigorous clinical trial process. It can pay for the freedom-to-operate, or it can exchange one of its technologies with somebody else's technology rights. It can also bypass a licensed obstacle by “inventing around” it, or create a “patent pool” with other interested biopharmaceutical or pharmaceutical companies. We will study each of these options in detail.

Paying for it: A biopharma in need of an important patent it does not already own, can request the patent holder to either sell the patent out-right, or license it. For the licensee, it's a go-ahead with its own development plan, which will hopefully repay the costs of acquiring a patent from the outside. For the licensor, it may not be a priority patent, or letting someone else also use it for a different product gives them additional revenue over the patent life. The price of such license or sale is commensurate with the rarity of the patent in question, or the anticipated sales potential of the new product based on the licensed patent.

Exchanging a technology: Two biopharmas holding large patent portfolios on their own, may decide to exchange patent rights on some of their portfolio holdings, that will give them access to much needed new expertise and future sales potentials. For example, one company may hold a patent on fast-screening thousands of candidate molecules, each a chemical modification of an archetype, while the other may hold rights on an animal disease model, for example rat type II collagen arthritis, an animal model useful for the study of rheumatoid arthritis. Once again, terms and conditions are based on future valuations of the technologies involved (See Chapter 4).

Inventing around: A biopharma has managed to sequence the gene responsible for interferon alpha, naturally occurring in the body, and later succeeded in inserting the gene into a host system, eventually producing the recombinant molecule with a given yield (see Chapter 7). Later into development, the use of a patented chromatography column has led to a fifty-fold increase in the yield. Before licensing the expensive rights to the proprietary column used, the internal development department comes up with a similar column, using a different absorbent material which not only is patent-free, but may revolutionize the interferon biomanufacturing in the future. The discovery eventually leads to their own chromatography patent, as well as a means to “invent around” the manufacturing technique.

Patent sharing: Three academic institutions, active in the fields of gene sequencing, come up with complementary ideas for enhancing and accelerating the process of gene sequencing on the way to sequencing the first ever mammalian species' complete genome. Instead of laboring individually for years, in the race to the genome characterization, they come together by forming a patent-sharing pool, each allowing the others to share, use, and improve upon the respective patents, with all eventual improvements to be shared among the three. In the end, their pooled patents attract the interest of a major biopharmaceutical company, which licenses the pool from the three academic parties. In retrospect, if it weren't for the patent pool, no individual parties would have progressed enough in the sequencing, neither would they have access to any significant royalties, nor would the biopharma ever capitalize on the genome knowledge to produce its own therapeutic interventions.

### **Question 2.8. What was the essence of the verdict in the famous U.S. Supreme Court decision in DIAMOND v. CHAKRABARTY, 447 U.S. 303 (1980)?**

In reviewing the U.S. Supreme Court decision, USPTO's MPEP-Chapter 2100 clearly states that “The tests set forth by the Court are:

- (A) “The laws of nature, physical phenomena and abstract ideas” are not patentable subject matter.
- (B) A “non-naturally occurring manufacture or composition of matter — a product of human ingenuity — having a distinctive name, character, [and] use” is patentable subject matter.
- (C) “[A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated  $E=mc^2$ ; nor could Newton have patented the law of gravity. Such discoveries are ‘manifestations of... nature, free to all men and reserved exclusively to none.’”
- (D) “[T]he production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery” [emphasis added] is a “manufacture” under 35 U.S.C. 101.”

Leaving the legalese behind us, natural products can NOT be patented, while recombinant products CAN be patented. In addition, the USPTO may award biotechnology-related patents for a novel method of manufacturing a naturally-occurring protein (manufacturing patents), a device used for its administration into humans (device patents), as well as the use of that protein in treating a disease (use patents), but not all

diseases.

**Question 2.9. Which are the potential filing application avenues for a biopharma company considering filing a patent application?**

There are three potential avenues for a biopharma company considering filing a patent application. First, it may file an application with a national Patent Office, such as the USPTO. Second, it may file an application with a regional Patent Office, such as the EPO or the African Regional Industrial Property Organization (ARIPO, Harare HQ, [www.aripo.org](http://www.aripo.org)), or the Eurasian Patent Office (EAPO, Moscow HQ, [www.eapo.org/eng/ea/](http://www.eapo.org/eng/ea/)). For a thorough international directory of national and regional Patent Offices visit the WIPO's web page at [www.wipo.int/directory/en/urls.jsp](http://www.wipo.int/directory/en/urls.jsp).

Third, the biopharma may also apply to the WIPO and seek patent protection for an invention simultaneously in each of a large number of countries by filing an "international" patent application, which is thus subjected to an "international search" the report of which is communicated to the applicant who may decide to withdraw the application if the report makes the granting of license unlikely. According to WIPO, the procedure under the PCT has great advantages for the applicant, the patent offices and the general public, such as:

"(i) the applicant has up to 18 months more than he has in a procedure outside the PCT to reflect on the desirability of seeking protection in foreign countries, to appoint local patent agents in each foreign country, to prepare the necessary translations and to pay the national fees;

he is assured that, if his international application is in the form prescribed by the PCT, it cannot be rejected on formal grounds by any designated Office during the national phase of the processing of the application; on the basis of the international search report or the written opinion, he can evaluate with reasonable probability the chances of his invention being patented; and the applicant has the possibility during the international preliminary examination to amend the international application to put it in order before processing by the designated Offices;

(ii) the search and examination work of patent offices can be considerably reduced or virtually eliminated thanks to the international search report, the written opinion and, where applicable, the international preliminary examination report that accompany the international application;

(iii) since each international application is published together with an international search report, third parties are in a better position to formulate a well-founded opinion about the patentability of the claimed invention."

Source: WIPO, [www.wipo.int/pct/en/treaty/about.htm](http://www.wipo.int/pct/en/treaty/about.htm)

**Question 2.10. How do biopharmaceutical patents compare with market exclusivities for these products?**

The U.S. FDA provides a useful comparison between patents and exclusivity at its web site ([www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm)). Let's compare these two similar - but not identical - meanings below.

Patents are granted by the patent and trademark office anywhere along the development lifeline of a drug (expired before drug approval, or issued after drug approval, and anywhere in between). Patent information is required to be submitted with all new drug applications at the time of submission of the NDA. If appropriate, the patent information is published at the time of approval of the NDA. For patents issued after approval of the NDA, the applicant holder has 30 days in which to file the patent to have it considered as a timely filed patent. Patents may still be submitted beyond the 30 day timeframe but the patent is not considered a timely filed patent.

Exclusivity is exclusive marketing rights granted by the FDA upon approval of a drug if the statutory requirements are met, and can run concurrently with a patent or not (see 21 C.F.R. 314.108). Exclusivity was designed to promote a balance between new drug innovation and generic drug competition. Some drugs have both patent and exclusivity protection while others have just one or none. Patents and exclusivity may or may not run concurrently and may or may not encompass the same claims. Exclusivity is not added to the patent life. How long is exclusivity granted for? It depends on what type of exclusivity is granted: Orphan Drug (ODE) - 7 years; New Chemical (NCE) - 5 years; "Other" Exclusivity - 3 years for a "change" if criteria are met; Paediatric Exclusivity (PED) - 6 months added to existing Patents/Exclusivity; and Patent Challenge - (PC) - 180 days (this exclusivity is for ANDAs only).

In the United States, the Hatch-Waxman Act (1984) allows for two components: the extension of patent term for brand name companies who have lost term during FDA approval, and protection for generic manufacturers. The Act allows patent holders to seek extension of period lost during FDA approval. It allows for ANDA applications, and it allows for ANDA suitability positions where you can have variations from the drug components. Incentives for the brand name companies include patent term extension and non-patent market exclusivity. For a new chemical, irrespective of patents, you can have up to five years of market

exclusivity because the FDA will not approve a drug of that same chemical entity. Applications for new variations of other drugs that require new clinical investigations can get a three-year extension. There is also 180-day exclusivity for the first generic to successfully challenge a listed drug's patent.

In order to obtain patent term extension under Hatch-Waxman Act, the following criteria must be met: (1) the patent must not have expired; (2) the term must never have been extended; (3) the application must be submitted by the record owner, not a licensee; (4) the product must have been subject to a regulatory review period before market approval; and (5) it must be the first permitted commercial marketing or use of the product. The application must be made within sixty days of market approval.