***INTELLECTUAL PROPERTY RIGHTS IN COMPARATIVE HEALTH LAW***

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PART I - INTRODUCTION

**Chapter 1: The Role of Intellectual Property Rights in the Health Industry**

**§ 1 - General Presentation of the Intellectual Property Rights -**

1. Trademarks
2. *The functions of trademark law*

**Trademark law serves several functions** that are, in fact, closely intertwined. First, it is an instrument of **product differentiation**. Trade signs are useful to identify a certain good or service as well as its source and origin. They are a way of distinguishing the products of an undertaking from those of other competitors. But trademarks also function as a **vehicle of advertising**. They are a shorthand way of communicating with customers by promoting a certain image and reputation. Eventually, trademark law offers a **reward of investment** by preventing imitating competitors from reaping both the financial and reputation-related rewards that are associated with a trade sign. Trademarks thus create incentives for quality production. **All those different features share a common purpose: improving market transparency**. In fact, trademarks play a key role in the supply of information. Both the market efficiency and the ability to make informed choices depend on the protection of trade signs. They operate in the public interest.

1. *Trademarks relating to Pharmaceuticals*
2. **In Europe**

The provisions relating to trademark protection under the Community system apply universally to all goods and services, and there are **no specific rules in the field of pharmaceutical**. However due to their nature and the necessity of the protection of Public health, pharmaceuticals are **subject to a control on the adoption** for use of trademarks. The aim of the European Commission is also to protect consumers.

The appreciation of the **risk of confusion** arising between pharmaceuticals takes account of both the highly specialized nature of this field and the overriding necessity to protect public health.

1. **In France**

The provisions relating to trademark protection of shapes and colors in France apply universally to all goods and services and there are no specific rules in the field of pharmaceutical goods. Nevertheless, due to their nature and the necessity of the protection of Public Health, pharmaceuticals are subject to a specific administrative

The French Code of Public Health provides that the “Agence Nationale de Sécurité du Médicament et des Produits de Santé” (ANSM)” is responsible for the checking of pharmaceutical trademarks and the granting of the mandatory authorization required to market goods bearing this mark.

1. **In the United States**

Because dangerous prescription errors can occur as a result of confusion from “look alike” or “sound alike” drugs, both the federal Food and Drug Administration (FDA) and the PTO have rules, regulations, and requirements governing the clearance and approval of a pharmaceutical trademark.

1. Copyrights

Copyright relates to literary and artistic creations, such as books, music, paintings and sculptures, films and technology-based works (such as computer programs and electronic databases). In certain languages, copyright is referred to as authors’ rights.

Unlike protection for inventions, **copyright law protects only the form of expression of ideas, not the ideas themselves**. Anything can be protected under copyright law if three conditions are met: fixation, expression and originality.

1. Industrial Designs

**Design is where function meets form**. An industrial design constitutes the ornamental or aesthetic aspect of an article. An industrial design may consist of three dimensional features, such as the shape of an article, or two dimensional features, such as patterns, lines or color.

1. Patents

**A patent provides the legal basis for a commercial monopoly and provides an exclusive monopoly in relation an innovative product or process**. A patent covers the application of the concept. In other words, a patent covers how an article works, what an article does and what is is made from.

**§ 2 - Intellectual Property Rights in the Health Industry -**

Intellectual property rights are commonly seen as one of the most important economic assets of any corporate entity or research organization. **IP generally refers to ‘creations of the mind’** (or knowledge). In today’s global economy, knowledge is emerging as one of the most fundamental economic forces. Strong IP systems can incite funding into knowledge development and, thus, promote innovation. This is particularly relevant for **the pharmaceutical industry, which depends on patent protection to support its investments into medical research**.

**Chapter 2: Background to the modern patent system**

**§ 1 - The Nature and Origins of Patent Rights -**

1. What is a patent?
2. *Exclusionary Right*

The right to prevent others from carrying out the invention claimed in a patent may be enforced in the courts: if the patent is valid and infringed, the courts can order the infringer to stop its activities, as well as provide other remedies, such as damages.

1. *Property Right*

**A patent is a piece of intangible property**. It may be dealt with in the same sort of ways as tangible but property but inventions also differ from tangible property.

1. *Limited duration*

A term of **twenty years from the filing date** is today the international minimum standard set by the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement under the General Agreement on Tariffs and Trade (GATT) and is now adhered to by nearly all countries.

1. Why granting a patent?

« *One man should not be afraid of improving his possessions, lest they be taken away from him, or another deterred by high taxes from starting a new business. Rather, the prince should be ready to reward men who want to do these things and those who endeavor in any way to increase the prosperity of their city or their state.*»

Niccolo Machiavelli, The Prince (1514)

**The consideration for the granting of patents, in general, is the benefit that results to the state by technological progress** as represented by the commercialization of inventions. The connection between the granting of patents and the commercialization of inventions is simply that the existence of patent rights **removes part of the risk involved in investment in a new development**. Who, after all, would be willing to invest large sums of money in a new project knowing that an imitator could copy the product as soon as it was marketed without incurring any research costs? **The justification for the patent system is that it provides an inventive for investment in new ideas**.

**§ 2 - Harmonization of Patent Law -**

1. International Developments
2. *The Paris Convention*

The most important practical result of the Convention is the **possibility of claiming Convention priority for applications made outside one’s home country**. The system is such that if an application for a patent is properly made in one Convention country, corresponding applications may be filed in other Convention countries within one year from the first filing date; if certain conditions are met, these later applications will be entitled to the priority date of the first application. This means that they will be treated as if they were filed on the same day as the first application, so that a publication of the invention after the first filing date but before the filing date of the later application, will not invalidate the later filing.

1. *The European Patent Convention*

However, a European patent **is not a unitary right**, but a group of essentially independent nationally-enforceable, nationally-revocable patents, subject to central revocation or narrowing as a group pursuant to two types of unified, post-grant procedures: a **time-limited opposition procedure**, which can be initiated by any person except the patent proprietor, and **limitation and revocation procedures**, which can be initiated by the patent proprietor only. The EPC provides a legal framework for the granting of European patents, via a **single, harmonized procedure** **before the European Patent Office**. A single patent application, in one language, may be filed at the European Patent Office in Munich or at a national patent office of a Contracting State, if the national law of the State so permits.

1. *The Future Unitary Patent*

**Number of patent applications in the world in 2016**:

* 1,3 Million before the Chinese State Intellectual Property Office (SIPO);
* 606 thousands before the United States Patent and Trademark Office (USTPO);
* 318 thousands before the Japan Patent Office (JPO);
* 209 thousands before the Korean Intellectual Property Office (KIPO);
* 159 thousands before the European Patent Office (EPO).

On 17 December 2012, agreement was reached between the European Council and European Parliament on the **two EU regulations that made the unitary patent possible through enhanced cooperation at EU level**. All EU member states except Spain and Croatia now participate in the enhanced cooperation for a unitary patent.

The legislative package consists of the **Unified Patent Court Agreement** and two EU Regulations, **Regulation 1257/2012** on the Unitary Patent and **Regulation 1260/2012** on the translation regime for UPs.

**The agreement includes**:

1. The creation of a European Patent with unitary effect (UP)
2. The creation of a specialized patent court (UPC)

**The UP is expected to provide significant cost savings for translations and annuities compared to validation of the European Patent in a large number of countries**.

* The cost for a UP in the twenty-six participating states is currently targeted to be approximately the same as the current cost for validating and maintaining a patent in UK, Germany, France, and the Netherlands only.
* This could also lead to patent protection in many countries where applicants currently seldom validate due to high costs relative to the market size.
* Another advantage of the UP would be the possibility to obtain an injunction effective in all participating states following a relatively fast proceeding (targeted to be twelve months or less) before a specialized court.
1. *The Patent Cooperation Treaty (PCT)*

**Under the PCT, a single international application may be filed in one of the official receiving offices, or at WIPO itself, and potentially gives rights for all PCT contracting states**. An initial ‘international phase’ during which a search and possibly also a preliminary examination is carried out, is followed after 30 months by a ‘national phase’, during which selected national or regional patent offices conclude the examination process and grant (or refuse) the patent. The international application may claim priority from an earlier national, regional, or PCT application if filed within the normal twelve-month period of the Paris Convention.

1. The TRIPS Agreement as a Powerful Harmonization Tool
2. *A minimal patent protection*

**According to TRIPS, practically all countries of the world are obliged to have patent systems in which compounds, including pharmaceuticals, can be patented per se for a term of at least twenty years, and with clear standards for the enforcement of patent rights**.

1. *Access to Medicines and Compulsory Licenses*

**Compulsory Licenses** allow domestic entities (public or private) to import, produce, and distribute patented goods **without the patent-holders’ consent**. TRIPS allows countries to determine the grounds on which they grant Compulsory Licenses, provided that a set of procedural conditions are met.

**However this was a an instrument of limited utility for developing countries that lack the ability to produce drugs locally,** which makes threats to issue compulsory licenses for local production empty threats. For developing countries, the ability to use Compulsory Licenses to lower the price of drugs depends on the ability to **import** generic versions from somewhere else. **But doing so is difficult, on account of the restrictions that TRIPS placed on Compulsory Licenses in exporting countries**. Article 31(f) of TRIPS restricted compulsory licensing to predominantly for the supply of the domestic market: issuing a Compulsory License to produce medicines mostly for export was not compliant with TRIPS.

This problem was recognized in 2001 by the Doha WTO ministerial conference that took a decision to find an “expeditious solution” to the problem. This became known as the Paragraph 6 mechanism after the section of the Doha declaration that addressed the issue. Since 30 August 2003, a waiver to Article 31(f) has been in place that **allows WTO Members to issue Compulsory Licenses specifically for export to address needs notified by other countries under the system**. The waiver formed the basis for a permanent amendment of the TRIPS Agreement (Article 31bis) which came into force on 23 January 2017 and replaces the waiver.

1. *Dispute Procedure*

A feature of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) is that for the first time there is a **dispute procedure that can lead to economic sanctions against the member that is in violation of GATT**. But TRIPs does not give directly enforceable rights to natural or legal persons.

PART II - WHAT CAN BE PATENTED

There are three simple requirements for a patentable invention, as set out in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, the European Patent Convention (EPC), and in the laws of EPC member states:

1. **The invention must be new.**
2. **It must involve an inventive step.**
3. **It must be capable of industrial application.**

The same three requirements are met with in one form or another in the United States, Japan and indeed in practically every country that has a patent system at all. **There are in addition certain matters that are specifically excluded from patent protection**.

**Chapter 1: The Requirements in Europe**

**§ 1 - Patent Subject Matter for Pharmaceutical Inventions -**

Biotechnology, according to the United Nations Conventions on Biological Diversity as of 1993, is any **technological application that uses biological systems, living organisms or derivatives** thereof to make or modify products or processes for specific use. They have been used for thousands of years (in wine and beer making). Rule 26 EPC provides a number of general definition in this field

As a general rule, **biotechnological inventions are in principle considered to be patentable under the EPC**, as long as they comply with the EPC ‘standard’ requirements and do not fall within the provided exclusions (Rule 27 EPC).

**Article 53 EPC deals with general exceptions to patentability under the EPC**:

« *European Patents shall not be granted in respect of:*

1. *Inventions the publication or exploitation of which would be contrary to ‘ordre public’ or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;*
2. *Plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof*
3. *Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods. »*
4. Inventions contrary to « *ordre public*» and morality

Article 53(a) EPC excludes from patentability inventions contrary to «*ordre public* » and morality. **Non-limitative examples are listed in Rules 28 and 29 EPC**. Such exclusions include processes for cloning humans, processes for modifying the germ line identity of human beings, and uses of human embryos for industrial or commercial purposes. This list is merely illustrative for the concept of inventions contrary to «*ordre public* » and morality (Directive 98/44/EC, rec. 38).

1. Essentially biological processes for the production of plants or animals

A process for the production of plants or animals is **«** ***essentially biological*» if it consists entirely of natural phenomena** such as crossing or selection — Rule 26(5). When assessing whether a process is « *essentially biological* » or not, one has to take into account the **totality of the human intervention in the process**, **and its impact on the result thus achieved** (BA, T320/87). However, human intervention in a process does not necessarily render it patentable under Article 53(b) EPC.

1. Methods for treatment of the human or animal body

**Article 53(c) EPC explicitly excludes the patentability of certain methods of treatment and diagnostics**: « *European patents shall not b granted in respect of: (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practices on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.* » In general, **methods for medical treatment and diagnostics performed on the human body are thus excluded from patentability under the EPC**.

1. *Treatment by Therapy*

As a general definition, treatment by therapy involves the treatment to cure, relieve or prevent pain, illness, disease, discomfort, malfunction of the body or incapacity. However, with the entry into force of CBE 2000, and in particular of Article 54(5), a **known substance for use in a specific method for treatment is considered as patentable, provided that such use is not comprised in the state of the art**.

1. *Treatment by Surgery*

**Surgery is defined in terms of the nature of the treatment, rather than in terms of the results or purpose** (Guidelines GL G-II-4.1.2). Cosmetic surgery is also excluded from patentability, just as therapeutic surgery. A typical example of method of treatment by surgery within the meaning of Article 53(c) would be a method for grafting an plant into a patient’s body.

1. *Diagnostic Methods*

According to the Board of Appel (T385/86), diagnostic methods within the meaning of Article 53(c) EPC were defined as « t**hose whose results immediately make it possible to decide on a particular course of medical treatment**. »

1. *Dosage Regimens*

According to the interpretation of **second medical use** made by the Boards of Appeal, where it is already known to use a medicament to treat an illness, Article 54(5) EPC does not exclude patenting the medicament for use in a different treatment by therapy of the same illness. Such a patent is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art.

**§ 2 - Novelty, Utility and Inventiveness Requirements -**

The general criteria for patentability under the EPC are set forth in **Article 52(1) EPC**: « *European patents shall be granted for any inventions which are susceptible of* ***industrial application****, which are* ***new*** *which involve an* ***inventive step***. »

1. Novelty
2. *General principles*

The novelty contemplated by the EPC is « ***absolute novelty*** » which means that the state of the art comprises everything that was made available to the public before the priority date of the invention, **no matter how or where the disclosure took place**.

**A disclosure formed by combining two documents together is not novelty destroying**, although it may be relevant tot the question of inventive step. It is not necessary that the prior reference disclose word for word the subject of the invention. **An invention may be anticipated by a so-called « *implicit disclosure*»**.

**EPC sets out two main limitations** to the concept of absolute novelty: non-prejudicial disclosures and obligation of secrecy.

1. *Novelty for Pharmaceutical Inventions — Art. 52(1) and 54 EPC*

**The use of a known product, exhibiting a novel technical effect, is considered as novel under Art. 54(1) EPC**. Said technical effect is viewed as novel if it was not described or suggested in the previous disclosure.

1. *Novelty for Biotechnological Inventions — Art. 52(1) and 54 EPC*

**R.27(a) EPC defines what can be viewed as a further novelty criterion for Biotechnological inventions**: « *Biotechnological inventions shall also be patentable if they concern: biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature; Such biological material may be considered as new, since technically not available to the public.* »

1. Industrial Application

Under the provisions of **Article 57 EPC** « *An invention shall be considered as susceptible of industrial application if it can be* ***made or used in any kind of industry****, including agriculture*. »

1. Inventive Step

**Art. 56, the EPC** provides that « *An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is* ***not obvious to a person skilled in the art***. »

**The person skilled in the art** is « *an ordinary practitioner aware of what was common general knowledge in the art at the relevant date. He/she should also be presumed to have had access to all elements comprising the state of the art* ».

**What is obvious** is what does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art, i.e. something which does not involve the exercise of any skill or ability beyond that to be expected of the person.

1. Sufficiency of Disclosure

The **sufficiency of disclosure** requirement for European Patent applications is set forth in **Art. 83 EPC** : « *The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art*. » The **clarity** requirement on the other hand is set forth in **Art. 84 EPC**: « *The claims shall define the matter for which protection sought. They shall be clear and cozies and be supported by the description.* » The requirements can overlap.

**Chapter 2: The Requirements in France**

**§ 1 - General Patent Information -**

1. Legal framework

The French Patent & Trademark Office is called the « ***Institut National de la Propriété Industrielle***» or National Institute of Industrial Property (French PTO).

In France, the main legal text relating to patents is the « *Code de la Propriety Intellectuelle* » or French Intellectual Property Code (IPC), and more specifically **Articles L. 611-1 *et seq* and Articles R. 611-1 *et seq***.

1. Patent protection

**An invention can be protected in France using several routes**: a French patent application, a French utility certificate application, a European application designating France and/or a PCT patent application designating the EPO.

Generally speaking, the protection is **20 years from the filing date**, except for the French utility certificate, which only affords a **6-year protection**. The other exception in terms of duration of protection is the Supplementary Protection Certificate (SPC), which extends the patent term for pharmaceutical inventions.

**§ 2 - Who Can File -**

**The French system is on a « first-to-file » basis**. An application can be filed by one or several individuals and/or legal entities. The industrial property right belongs to the inventor(s) or his/her/their successor(s) in right. For the purposes of the proceedings before the French PTO, the applicant(s) is(are) deemed to be entitled to the industrial property right (Art. L. 611-6 IPC).

**There are specific provisions in the IPC regarding inventions made by employees and civil servants** (Art. L.611-7 IPC). Briefly summarized, and in the absence of any contractual provision more favorable to the employee, the title to the invention is defined as follows:

* The employer is entitled to the industrial property right if the invention stems from an explicit inventive mission assigned to the employee. The employee is then entitled to a « *supplementary remuneration* ». A recent Decision of the Cour de Cassation confirmed that said supplementary remuneration is due to the inventor, independently of the filing of an application (*Produits Dentaires Pierre Rolland vs Gérard Zimny*).
* Otherwise, the invention belongs to the employee.
* If the invention was made during the execution of the employee’s functions or in the field of activity of the employer, or with the knowledge or use of technologies or means of the employer or of data acquired by the employer, then the employer has a right to the invention. The employee is entitled to a « fair price ».

**§ 3 - Patentable Subject Matter for Pharmaceutical Inventions -**

1. Alignment with the European position

**In this matter, France is very much aligned with the position of the EPO and the provisions of the EPC**. Generally speaking, any invention, be it a process or a product, may be protected by an industrial property title provided that it is new, inventive, and has industrial applicability. **Simple discoveries are excluded from patent protection**. Therefore, natural products or substances are not patentable per se as they result from a simple discovery. However, patentability may be considered it a technical process is used to isolate or produce said products or substances.

1. Remaining divergences with the European position
2. *New dosage of a known molecule*

**It is well established that inventions pertaining to a new dosage of a known molecule are patentable at the European Patent Office**. In France, however, only very few decisions address this issue, and more generally the case law on medical use claims is rather sparse.

1. *The adoption of the European Biotech Directive*

**Special consideration must be given to the European Biotech Directive, which as all European Directives, must be adopted into French Law to have legal effect**. According to French law, a claim to a gene sequence is limited to the technical application of a specific function associated with said sequence.

It should be noted that it is not necessary under European Law to directly adopted the entire text of a Directive into National Law. However, the adoption, while not necessarily being word-for-word, must not depart from the spirit of the Directive.

**French Article L. 611-19 IPC provides that a patent shall not be granted for « *products exclusively obtained from essentially biological processes … nor for their parts or the genetic information they contain***. This is contradictory to the Directive that provides for the patentability of an element isolated from the human body or produced by a technical process even if it preexisted under a « natural state ».

**§ 3 - Novelty, Utility, Inventiveness and Sufficiency of Disclosure -**

1. Novelty
2. *In General*

**From a general standpoint, the novelty contemplated by the IPC is « *absolute novelty*»**. However, there is a difference between French patent law and the EPC in the assessment of novelty. **Under the IPC, the prior reference must manifestly disclose the invention in order to anticipate it**. This requirement has no correspondence under the EPC and makes the interpretation of novelty stricter before the French PTO than before the EPO.

1. *Novelty in the Pharmaceutical field*

For a long time, French law did not consider a novel use of a known product as patentable. However, France now being member state of the EPO, **novel uses/novel applications of a known product are no longer excluded from patentability.** Hence, as a principle, it is possible to obtain protection for a novel and inventive use of a known product and this applies also the pharmaceutical products.

1. Industrial Application

**The IPC interprets the characteristics of industrial application in very broad terms** as including any physical activity of « technical character » i.e. an activity which belongs to the useful or practical arts as distinct from the aesthetic arts.

1. Inventive Step and Sufficiency of Discloser

**There is no substantial difference with the EPC**. Note however that in the current state of law, the examination of a French patent application is limited – the INPI does not have the power to reject a patent application for lack of inventive step.

**§ 4 – PACTE Law: Making French Patents More Attractive -**

The PACTE bill, adopted at first reading by the National Assembly on Tuesday, October 9, 2018, contains several patent provisions aimed at promoting innovation and facilitating the growth of SMEs.

From this point of view, the main contributions of the bill concern the **promotion of French utility certificates** (Article 40), the **establishment of an opposition procedure before the “INPI” French PTO** (Article 42) and **the strengthening of the examination procedure before the INPI** (Article 42 bis). The Special Commission charged with examining this bill also considered various amendments to the bill, including the creation of a "provisional" patent application, which could soon be launched. **These proposals, partly inspired by the German model, could make the French patent more attractive, particularly to SMEs**.

**Chapter 3: The Requirements in the United States**

**§ 1 - Introduction -**

1. General requirements
2. *What is a United States patent?*

A United States patent is a property right granted by the government of the United States to an inventor « *to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States* ». for a limited time in exchange for public disclosure of the invention when the patent application is published or when the patent is granted.

**Legal framework**: U.S. patents are mainly governed by the framework set forth by

*The 1952 Patent Act (United States Code Title 35)*

*The America Invents Act (AIA)*

* + **Since March 16, 2013 there are two patent systems operating side by side**:
		- One for patent applications filed before March 16, 2013.
		- One for patent applications filed on or afterwards.
1. *What are the conditions to obtain a patent?*

**An inventor must file a patent application with the USPTO**

*The invention must be:*

* + **Patentable**
	+ **New**
	+ **Useful**
	+ **Non-obvious**
	+ **The application must also contain**
		- An enabling disclosure of how to practice the invention.
		- A set of claimswhich clearly and concisely describe the invention.
1. History

The most fundamental change to the patent laws of the United States since 1952 has been the passage of the AIA on September 16, 2011, and the most fundamental change in the AIA was the redefinition of what it means for an invention to be novel. Prior to the AIA, novelty was based on what was publicly known, reported, etc. before the date the application was filed. In addition, the scope and definition of the prior art has also changed, as has the definition of the grace period.

**§ 2 - Patent Validity -**

1. Patent eligibility

**Subject matter requirements under §101**:

*Four categories of inventions or discoveries eligible for protection*

* + - * **Processes; machines; manufactures; compositions of matter**.

*Three specific exceptions to §101’s broad patent-eligibility principles*

* + - * **Laws of nature; physical phenomena; abstract ideas**.

*The invention must ‘satisfy the conditions and requirements of this title’.*

* + - * **Novel (§102); non obvious (§103); fully and particularly described (§112)**.
1. *Biotechnology and products of nature*

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| **Diamond, CPT v. Chakrabarty (1980)** |
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| **Mayo Collaborative Services v. Prometheus Laboratories (2012)** |
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| **Association for molecular pathology v. Myriad Genetics (2013)** |
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1. *Computer related invention / method of doing business*

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| **Bilski v. Kappos (2010)** |
| * Patent application claiming a procedure to instruct buyers/sellers how to protect against risk of price fluctuations on energy market. Included simple mathematical concept + familiar statistical approaches.
* Application rejected: it involved an abstract idea and was not implemented on a specific apparatus. The Federal Circuit held the test for patentability under §101 was the machine-or-transformation test: the claimed process (1) is tied to a particular machine; or (2) transforms an article into something else.
 | * Adopting an limitative definition of §100(b) creates uncertainty for the patentability of computer software and other emerging technologies. Similarly, definition of process does not exclude business methods.
* The machine-or-transformation test is only a useful clue and investigative tool but not the sole criterion to determine patentability of inventions in the Information Age as shown by Court’s precedents.
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| **Is the machine-or-transformation test the only one for patent eligibility under § 101?** (No) |

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| **Alice Corp v. CLS Bank International** |
| * Alice owns patents concerning a computerized trading platform that deals with financial transactions in which a third party settles obligations between two others so as to eliminate settlement risks. Alice’s patents address the risk by using the third party as the guarantor.
 | * Adopting a limitative definition of §100(b) creates uncertainty for the patentability of computer software and other emerging technologies. Similarly, definition of process does not exclude business methods.
* The machine-or-transformation test is only a useful clue and investigative tool but not the sole criterion to determine patentability of inventions in the Information Age as shown by Court’s precedents.
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| **Are claims regarding computer-implemented inventions patent-eligible subject matter?** (No) |

1. Utility

**35 U.S.C.A. §101**

*An invention must be useful to receive patent protection*

* + - * **The utility requirement is one that is rarely invoked**.

**35 U.S.C.A. §112(a)**

*Patent applications must include a description of how to use the invention disclosed*

* + - * **A rejection may alternatively be couched in the language of this provision**

**The utility requirement**

*What satisfies the utility requirement?*

* + **An invention providing some benefit to society with a minimum level of usefulness**
		- Does not need to be superior to existing products or processes.
		- Must be capable of use and shown to be operable to perform the functions and effect the intended result which benefits some minimum human purpose.

*What does not satisfy the utility requirement?*

* + **An invention that is illegal, immoral, or harmful**
	+ **Utility for pure research and investigation**: there must be immediate and practice
1. *General principles*

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| **Lowell v. Lewis** |
| * P had to prove his pump invention was useful.
* The case set forth the contours of the utility requirement which persist today.
 | * The word useful is incorporated into the act in contradistinction to mischievous or immoral. The usefulness requirement of the Patent Act is satisfied if the invention is not frivolous or injurious to the well being, good policy, or sound morals of society.
* Plaintiff’s pump need not surpass the pumps in common use in order to receive patent protection.  If the invention serves no purpose, the invention may sink into disregard, but it will remain patentable.
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| **Should the claimed invention be superior to known technologies?** (No) |

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| **Juicy Whip v. Orange Bang** |
| * Juice Whip has a patent for a dispenser that has the appearance of a pre-mix dispenser but functions as a post-mix dispenser, which decreases maintenance and stimulates impulse buying in the same time.
* The court concluded that the invention lacked utility because its purpose was to increase sales by deception, though imitation of another product. It creates an illusion whereby customers believe that the fluid contained in the bowl is the actual beverage that they are receiving when it is not.
 | * An invention is useful if it is capable of providing some identifiable benefit. The utility requirement is satisfied if one product can be altered to make it resemble another, because that is a benefit.
* The principle that inventions are invalid if they are mainly designed to serve immoral purposes has not recently been applied broadly. Even if the invention was considered deceptive, that does not mean it is unpatentable. Other agencies and Congress have the task of protecting customers from fraud and deception in the sale of food products.
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| **Does the post-mix dispenser that looks like a pre-mix dispenser lack utility?** (No) |

1. *Utility in chemistry and biotechnology principles*

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| **Brenner, Commissioner of Patents v. Manson (U.S. SC 1966)** |
| * Ringed & Rosenkranz filed a Mexican PA in 1956 and a U.S. one in 1959 concerning a process to synthetically produce a certain class of steroids.
* Manson filed a U.S. PA four years later claiming he invented the process before, thus requesting interference be declared to find that his patent application had priority over the one filed earlier. If he proves he is the first inventor, he will be entitled to obtain a patent on it. To have an interference declared there are strict rules to follow (heavy burden of proof).
* PTO declined to initiate the interference as applications did not show that he knew the use for the chemical compound produced by process at the relevant time.
 | * Mason relies on two narrow arguments:
* *Such steroids could reduce tumors in mice, and a homologue close to his steroid had proven effective in doing so*. Rejected: in this branch of chemistry the usual rules that structure similarities do not hold
* *His process would be a useful step in further research which might develop other useful processes and compounds*. Rejected: field of interest not sufficient to constitute utility for purposes of §101.
* CS focuses on the benefit derived by the public from an invention with substantial utility: a process patent in the chemical field which has not been developed and pointed to the degree of specific utility creates a monopoly of knowledge which should be granted only if clearly commanded by the statute.
* Dissent (J. Douglas): a workable chemical process which is both new and sufficiently non obvious to satisfy the patent statute is by its existence alone a contribution to chemistry and useful.
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| **Is a process or a product which has no known use or is only useful as an object of scientific research eligible for patent?** (No) |

1. Novelty

**A patentable invention must be new**

*A claimed invention is anticipated if*

* + **It was pervasively known or used by others in the United States**
	+ **Or described in a patent or printed publication anywhere in the world**
	+ **Before the date of filing by the applicant for the patent**
		- If a single source contains all the elements of an invention and the source qualifies as prior art under subsection of 35 U.S.C. § 102, then anticipation is established.

**Determination of novelty requires two distinct inquiries**

*Identify the references that qualify as ‘prior art’*

*Determine whether any of those references fully anticipates a claim*

**The reforms introduced by the Leahy-Smith America Invents Act**

*From the long-standing first-to-invent principle*

*To the first-inventor-to-file priority principle*

1. *The Statutory Bars — AIA §102(a)(1)*
2. **Public Use**

*Public use occurs when an inventor puts the invention on display*

* + **Even though by its very nature an invention is completely hidden from view**
		- As part of a larger machine or article, if the invention is otherwise used in its natural and intended way and the larger machine or article is accessible to the public. (43)

*Experimental use however is not a public use and therefor not a bar to lovely*

* + **A use is experimental if its represents a bona fide effort to perfect the invention or to ascertain whether it will answer its intended purpose**

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| **Egbert v. Lippman** |
| * Egbert complained of the breaking of their corset steels. Mr. Barnes made a pair that would not break.
* Ms. Egbert used the redesigned steels for many years, placing them in new corsets as the old wore out. In 1863, Mr. Barnes had his wife cut open a corset and display the steels to another person. Three years later Barnes obtained a patent on his design.
 | * Barnes gave the steels to Ms. Egbert without any obligation of secrecy or for any purpose of experiment she might have exhibited them to any person she pleased, or made other steels of the same kind, and used or sold them without violation of any condition or restriction imposed by the inventor. The invention was complete at the time Mr. Barnes gave Ms. Egbert the steels and he slept on his rights for 11 years.
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| ***Moleculon Research Corp v. CBS*** |
| * Moleculon, the owner of a patent on a Rubik’s Cube puzzle cube puzzle sued CBS for infringement.
* More than a year before the PA, the inventor constructed several paper models of his puzzle, which confirmed the feasibility of his' conception, showed these puzzles to several friends, and brought a working prototype into his office and demonstrated how it worked to the president of Moleculon.
 | * Declined to follow Egbert: the inventor retained control over the puzzle's use and the distribution of information concerning it despite the fact that neither his friends nor the president of Moleculon had not entered into any express confidentiality agreement.
* The presence or absence of a confidentiality agreement is not dispositive of the public use issue but is one factor to be considered along with the time, place, and circumstances of the use which show the amount of control the inventor retained over the invention
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| **An inventor’s private use of the invention for his or her own enjoyment is not a public use** |

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| ***Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts*** |
| * Meduna who worked for Mettallizing invented a new process for reconditioning metal parts. Mettallizing began using the process to recondition the machine parts of their customers, but made a deliberate effort to keep it a secret. More than a year later, they applied for, and received a patent on the process.
* Kenyon began using a similar process and Mettallizing sued for copyright infringement. Kenyon argued that the patent was invalid because the process was in public use for more than a year before being patented.
 | * §102(b) only applicable if inventor himself is profiting off the invention: using the process commercially counts as a public use, and invalidates a patent. If a third-party had invented the same process, but was working in secret, that would not invalidate an inventor's patent.
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| **Secret commercial exploitation of an invention by the inventor = public use under pre-AIA §102(b)** |

1. **On Sale**
	* **Definite sale or offer to sell more than 1 year before the effective filing date**
		+ According to case law « if any commercial exploitation does occur it must be merely incidental to the primary purpose of the experimentation to perfect the invention » (44) in order to constitute an experimental sale.

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| ***Pfaff v. Wells Electronics*** |
| * P contracted by TI to develop a computer component
* *P presented sketches and entered into a selling agreement with TI (even though no prototype yet). It then sent the designs to a manufacturer to mass produce it. Managed to make first component < 1 year prior to P’s filing date.*
* *P was issued patent 3 years later. P brought infringement action against W (produced competing socket)*
* DC: since the reduction to practice occurred less than a year before the filing date Pfaff was entitled to patent protection. For an offer for sale to take place, the invention being offered must be reduced to practice.
* CA: invention substantially complete when OFS made.
 | * It is the 1st inventor to conceive rather than the 1st to reduce to practice who established the right to patent. Inventions may be patented before reduced to practice (The Telephone Cases: Bell filed before constructing).
* *Pfaff could have obtained a patent when he accepted the purchase order from Texas Instrument (1981).*
* The Court favors a two-pronged test
* *Invention is subject to an offer*: *commercialization + reliance on formality of contract formation (other party can make it into a binding contract by simple accepting)*
* *Invention is ready for patenting: renamed the notion of ‘constructive reduction to practice’*
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| **An invention subject of a commercial offer for sale ≠ be patented a year after it is ready for patenting** |

1. **Information otherwise available to the public**
	* **Focuses on whether invention was available and not the means by which it got there**

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| ***In Re Lister*** |
| * PTO rejected the claims of Dr. Lister for a method of playing golf using a tee for most of the shots.
* The applicant had submitted a manuscript describing the invention to the copyright office more than a year before filing an application.
 | * Useful guideposts for developing a § 102(b) defense: keyword-searchable databases such as Westlaw or Dialog provide a higher level of public accessibility than the Copyright Office's automated database.
* Highlights the importance of developing the specific facts needed to establish a § 102(b) defense including date a prior art publication was first publicly disclosed.
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| **Is a manuscript publicly accessible by virtue of being in the copyright office?** (No) |

1. **Disclosure in United States Patent Applications**
	* **The first-inventor-to-file rules of the AIA apply to a patent application if**
		+ Filed within one year of any public disclosure by the inventors (the grace period); and
		+ Before a public disclosure or patent application of a different inventor. However, one’s own public disclosure (made less than a year before one’s application) will remove as prior art an earlier filed application with that year period.

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| ***Alexander Milburn v. Davis-Bournonville*** |
| * Cifford invented a new type of welding torch and filed a patent application, describing the new torch but not claiming one specific improvement.
* Whitford came up with the same improvement and filed a patent on the improvement. Both Clifford and and Whitford’s patents were granted.
* Milburn countersued and claimed that Whitford's patent was invalid, arguing that Clifford invented the improvement first.
 | * Clifford's description in his PA satisfied the requirement of reduction to practice even though he had not made a claim on that specific improvement.
* *A description that would bar a patent if printed in a periodical or in an issued patent is equally effective in an application so far as reduction to practice goes.*
* If the USPTO was 'divinely efficient' they would grant patents on the same day that they were filed. Any delay is the fault of the inefficient USPTO and inventors should not be punished for that.
* Patent applications which are generally secret until the patent is issued count as the prior art despite the fact that they aren't available in the public domain. The ruling was later codified in 35 U.S.C. §102(e).
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| **For the purposes of anticipating a subsequent invention does U.S. patent disclosing an invention date from the date of the filing of the patent application?** (Yes) |

1. *The Grace Period Bars — AIA § 102(b)*

**Disclosure made one year or less before the filing date shall not be prior art if**

*Alternative conditions:*

* + - * **Disclosure by inventor or another who obtained subject matter disclosed from inventor;**
			* **Subject matter disclosed previously publicly by the inventor or another who obtained the subject matter disclosed from the inventor.**

*One-year grace period after a first disclosure of an invention within which to file PA*

**The date of filing is important because subsection (b) of 35 U.S.C. § 102 currently makes prior art dated more than a year before the filing date in the United States a « statutory bar ».** That is, the applicant is not allowed to prove a date of invention earlier than one year before the earliest U.S. (or international) filing date to which the application was entitled to overcome such prior art.

1. Non-obviousness

A claim is not patentable if the differences between the subject matter sought to be patented and the prior art are such that the **subject matter would have been obvious at the time the invention was made to a person having ordinary skill in the art** to which the subject matter pertains.

The § 103 test set forth in *Graham* is a **four-part inquiry** comprising, not only three elements of the primary consideration of obviousness (scope and content of the prior art, differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art), but also evidence of secondary considerations when such evidence is present.

1. *Level of Skill in the Art*

The hypothetical person of ordinary skill in the art is a person who is not extraordinarily innovative, nor a researcher of inexhaustible patience, but is a person who thinks conventionally in matters affecting the art in which he or she is skilled. **Ordinary skill means at least the ability to understand the technology and make modest adaptations or advances**.

1. *Secondary considerations*

Such secondary considerations include unexpected results, commercial success of the invention, whether the invention solved a long felt need, copying of the invention by others in the field, and failure of others to solve the problem that the inventor solved.

The objective indicia or « secondary considerations » of non-obviousness, however, **do not control the analysis when there is an otherwise strong case of obviousness**, such as one based upon art not considered by the PTO during prosecution.

1. *Prima Facie Obviousness Based Upon Structural Similarity*

**Structural similarity between claimed and prior art subject matter**, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, **creates a prima facie case of obviousness** that the burden (and opportunity) then falls on an applicant to rebut that prima facie case.

Such rebuttal or argument can consist of a comparison of test data showing that the claimed compositions possess unexpectedly improved properties or properties that the prior art does not have.

1. Disclosure — Section 112

In return for the exclusivity granted by the patent, the applicant must make a full disclosure of the invention: the patent’s specification and claims must describe the invention, enable the practice of the claimed invention, and disclose the « best mode » for implementing the claimed invention. The requirement to disclose the best mode differs from the other requirements of section 112 in that, the AIA removed the failure to disclose the best mode as a basis for invalidity or unenforceability in a patent validity or infringement proceeding.

PART III - OBTAINING REGULARORY APPROVAL FOR

 A NEW PHARMACEUTICAL PRODUCT

**Chapter 1: The Drug Approval Process in Europe**

A medicinal product may be marketed in the EU only **when a MA has been issued** by a competent authority of a Member State for its own territory (National authorization) or when a MA has been granted for the whole territory of the European Community by a Community authority (a Community authorization), according to Regulation (EC) No. 726/ 2004 (OJ L 136, April 30, 2004).

**§ 1 – Competent Authorities -**

1. National Authority

Each state of the European Community has an authority competent for granting MAs for medicinal products which are intended to be marketed only on the national territory according to the “national procedure”,

1. The European Medicines Agency

The community authority competent to issue MA is the EMA provided for in Title IV of Regulation (EC) 726/ 2004. Headquarters of said European Agency are established in London, Great-Britain. **The EMA is competent to grant MAs for drugs which are intended to be marketed in several countries of the European Community**.

**§ 2 – Overview of the Different Community Procedures -**

1. Mutual Recognition Procedure

This procedure is used when a MA is under examination or has been granted in one State (Reference State) and concerns a product which is intended to be marketed in at least one other State of the European Community.

1. *Procedure Initiated by a Member State*

“*Where a Member State is informed that an application for authorization falling under the scope of a mutual recognition procedure is already under examination by another Member State (Reference State), the said Member State “shall decline to assess the application and shall advise the Applicant that Art. 27 to 39 apply*” (Art. 17(2) of Directive 2001/ 83/ EC as amended by Directive 2004/ 27/ EC).

1. *Procedure Initiated by a Market Authorization Holder*

When a first authorization has been granted, the MA Holder may request one or more Member States to mutually recognize the MA granted by the Reference State.

1. Centralized Procedure

**This procedure is compulsory for the medicinal products identified in Part A of the Annex to the Regulation**.

1. Medicinal products developed by means of one of the following biotechnological processes.
2. Medicinal products for veterinary use intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals.
3. Medicinal products for human use containing a new active substance which, on the date of entry into force of this Regulation, was not authorized in the Community, for which the therapeutic indication is the treatment of any of the following diseases.
4. Medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No. 141/ 2000. Art. 3.2, 5.8 and 8.4 were modified by Regulation No. 596/ 2009.

**§ 3 – Different Types of Marketing Authorization Applications -**

1. Abridged Applications

These applications are authorized only if the MA Applicant can demonstrate that:

* **The product is “essentially similar” to a product authorized in a country concerned by the application** and that the Applicant has obtained the consent of those responsible for the marketing of the original proprietary medicinal products to use the pharmacological, toxicological or clinical data contained in the corresponding dossier in order to examine his own application (informed consent applications).
* **The medicinal product is “essentially similar” to a product which has been authorized within the Community** for not less than 6/ 10 years and which is marketed in the Member State for which the application is made (generic applications).
1. Orphan Drugs

**"Orphan drugs" are medicinal products intended for diagnosis, prevention or treatment of life-threatening or very serious diseases or disorders that are rare**. These drugs are called “orphan” because under normal market conditions the pharmaceutical industry has little interest in developing and marketing products intended for only a small number of patients. As a result the potential market for new drug treatment is also small and the drug companies industry would actually incur a financial loss.

1. Traditional Herbal Medicines

The Commission adopted the Directive 2004/ 24/ EC of the European parliament and of the council (March 31, 2004) which amends, as regards traditional herbal medicinal products, Directive 2001/ 83/ EC on the community code relating to medicinal products for human use. It provides in particular, a simplified registration procedure for herbal medicinal products with a traditional use of at least 30 years, tests and trials on safety and efficacy can be replaced by information on traditional use. The Directive also established a Committee for Herbal Medicinal Products. It is part of the EMA and is in charge of, in particular, performing the different tasks arising from Art. 16, and establishing Community monographs for traditional herbal medicinal products.

**Chapter 2: The Drug Approval Process In France**

**§ 1 – In General -**

A medicinal product may be marketed in the European Union only when a MA has been issued by a competent authority of a Member State for its own territory (National authorization) or when a MA has been granted for the whole territory of the European Community by a Community authority (a Community authorization).

**§ 2 – The Competent Authority: The ANSM -**

In France, the competent authority is the ANSM (Agence Nationale de Sécurité du Médicament et des Produits de Santé).

**§ 3 – The French National Procedure -**

French national procedure is provided for in the Public Health Code (“ Code de la Santé Publique”) articles R 5121-21– R5121-62. Said procedure is tending to disappear since it is limited to products intended to be marketed only on French territory. However, it can be used as the first step in the mutual recognition procedure.

**Chapter 3: The Drug Approval Process in The US**

**§ 1 - Background -**

1. Food, Drug and Cosmetic Act (FDCA)

In 1938, Congress passed the Food, Drug and Cosmetic Act (FDCA). The prior Food and Drugs Act of 1906 had proven to be much of a failure, as many lethal drugs and dangerous cosmetics found their way to consumers, legally, under the 1906 Act. Furthermore, during the presidency of Franklin D. Roosevelt, consumer rights groups began to exert more influence on the political process. In response to such critics, Congress passed the act that most affected the regulatory responsibilities of the Food and Drug Administration (FDA) as it exists today.

1. Public Health Service Act

**The Public Health Service (PHS) Act of 1944 added a definition for biologics** as well as regulatory scheme for the same. 42 U.S.C. §252(i).

**§ 2 - The New Drug Application -**

1. The role of FDA in the development of a new drug

**All new drugs need proof that they are effective and safe** before they can be approved for marketing. The FDA’s role begins when the drug’s sponsor wants to test the diagnostic or therapeutic potential of the drug in humans. Prior to initiating any clinical trials, a new drug’s sponsor must file an Investigation New Drug (IND) application with the FDA in order for the FDA to assure that research subjects will not be subjected to unreasonable risk.

1. The Investigation New Drug (IND)

**When filing the IND application must contain information on three areas**:

*Animal pharmacology and toxicology studies*

* + **Preclinical data assessing whether a product is safe for initial testing in humans**

*Manufacturing information*

* + **Composition, manufacture, stability and controls used for manufacturing the drug**

*Clinical protocols and investigator information*

* + **To assess whether the initial-phase trials will expose subjects to unnecessary risks**
1. The Filing of a New Drug Application (NDA)

**Upon completion of all three phases of clinical trials** the drug sponsor files a NDA with the DFA to obtain approval to market the drug in the U.S. The NDA includes both the data gathered from tests on animals and the human clinical trials of an IND. The NDA must provide enough detailed information for FDA reviewers to be able to determine whether the drug is safe and effective.

**Upon approval, the FDA may also grant exclusive marketing rights to an NDA applicant**. Exclusivity is a statutory provision and is granted to an NDA applicant if statutory requirements are met. The FDA may grant different types of exclusivities, including 5 years for a New Chemical Entity (NCE), 7 years for Orphan Drugs (ODE), 3 years for changes to the drug if criteria are met, and Pediatric Exclusivity, which is 6 months added after all other exclusivities have expired.

PART IV - PATENT TERM AND TERM EXTENSIONS

**Chapter 1: The European Supplementary Protection**

**§ 1 – General Principles -**

A European Patent has a term of twenty years starting from its filing date. Council Regulation (EEC) 1768/92 of June 18, 19992 created a **Supplementary Protection Certificate** (Community SPC) for medicinal products. Certain Member States had already created national SPCs (in particular France) and thus the Community SPC was an **attempt to provide a uniform system for all Member States of the EU**.

The Community SPC allows the patent holder of either a **national or a European basic patent to extend the patent term with respect to an active ingredient** (or a combination of active ingredients) **which has received a Marketing Authorization** in of the countries of the European Community.

**The duration of the extension of the patent term** is either **fifteen years from the patent** of the first Marketing Authorization in the European Community, or **five years from the date of expiry of the patent**, whichever is shorter.

**§ 2 – Interpretation Problems -**

**The SPC is granted after an examination by the corresponding national patent office**. The criteria of examination are not completely harmonized between national patent offices and, consequently certain discrepancies may exist. This gave rise to **many decisions of the ECJ on different articles of Regulation No 469/2009**.

1. On the matter of combination
2. *On the matter of combination*

**National industrial property offices cannot grant a SPC relating to active ingredients which are not identified in the wording of the claims** of the basic patent relied on in support of the application for such certificate.

Where the patentee has already obtained an SPC on the basis of a Marketing Authorization for a single product, **the patent holder is precluded from obtaining a second SPC on the basis of the same patent for a combination product which includes another active ingredient which is not protected as such by the patent** (*CJEU, December 12, 2013, C-443/12, Actavis v. Sanofi*).

1. On the matter of product

**National industrial property offices cannot grant a SPC for an active ingredient whose effect does not fall within the therapeutic indications covered by the Marketing Authorization** (*CJEU, C-631/13, Forgren v. Österreichisches Patentamt*)

**It is possible on the basis of a patent which protects several products, to obtain several SPCs in relation to each of those different products**. Each of those products should, however, be protected as such by that basic patent and be contained in a medicinal product and subject to a Marketing Authorization (*CJEU, December 12, 2013, C-484/12, Georgetown University v. Octrooicentrum Nederlan*).

**Chapter 2: The French Supplementary Protection**

**In France, two types of supplementary protection certificates (SPCs) used to be**:

* French SPCs codified as art L. 611-2 and L. 611-3 of the IPC;
* Community SPCs.

**Only Community SPC applications can now be filed in France**. However, French SPCs applied for prior to July 21, 1992 (date of publication of EC 1768/ 92) or granted prior to January 2, 1993 (date when EC regulation came into force) may still be or come into force.

**Chapter 3: The US Supplementary Protection**

**§ 1 – General Principles -**

The process for approval of a new drug described above can take a substantial period of time. During this time, the applicant seeking approval cannot market the drug. Thus, if the drug is patented, only a few years of patent exclusivity may remain when the FDA finally approves the drug. In order to assure owners of patents covering drug products a reasonable period of patent exclusivity, **Congress enacted 35 U.S.C. § 156 in 1984, which provides a mechanism by which the term of a patent can be extended**. **The patent term extension, however, is subject to several limitations**.

**§ 2 – Interpretation Problems -**

When the term of a patent is extended under 35 U.S.C. § 156, the extension applies only to claims that literally read on the approved product on which the extension was based. **Thus, whether a claim may be extended depends on the definition of the terms “claim” and “product.”**

1. On the matter of claims

**To claim a product has been interpreted narrowly to encompass only the literal scope of the claim**.

1. On the matter of products

Whether a product is within the literal scope of the claim also depends on how the term “product” is defined. A patent claim must read literally on an approved product in order to be eligible for a patent term extension,