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Brief Introduction to Patent System in Particular Chemical and Biotechnological Processes

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Today, patents continue to be vital to the chemical, pharmaceutical, agricultural, materials, energy and biotechnology industries.

But what is a patent?

A patent may be defined as a grant by the state of exclusive right for a limited time in respect of a new and useful invention that has become available to the public.

And now? What is an invention? I like the following definition: an invention is an original solution of a technical problem.

These rights are in general limited to the territory of the state granting the patent, so that an inventor wishing protection in a number of countries must obtain separate patents in all of them. The name “patent” is a contraction of “letters patents” (Latin *litterae patentes*, “open letters”) which means a document issued by or in the name of the sovereign, addressed to all subject and with the Great Seal pendant at the bottom of the document so that it can be read without breaking the seal.

It is important to note that the rights given by a patent do not include the rights to practice the invention, but only to exclude others from doing so. A pharmaceutical drug is a good example of it: it is not possible to market a patented drug without obtaining a Marketing Authorization by the Competent Health Authority, like FDA in US or EMA in Europe. The patent is clearly not enough.

There is another example in which a patent is not enough, i.e. when there are other preexisting third party rights. In the very common situation where A has a patent for a basic invention and B later obtains a patent for an improvement to this invention, then B is not free to use his invention without the permission of A, and A cannot use the improved version without asking a license from B. This is the great aspect of a patents: the second may be more important of the first!! Or we can even think in these terms the small may be clever than the big.

A patent is nevertheless a piece of property, and may be very valuable (Apple vs. Samsung!). Although intangible property, it may be dealt with in the same sort as tangible property such a real estate. Just as the owner of a house may live in it himself sell or rent to another, mortgage it, or even have it demolished, so a patentee may keep his patent rights, assign the patent to someone else, grant someone else a license to do something covered by the patent, mortgage the patent (i.e. use the patent as a security for a loan), or of course abandon the patent to the public.

In any event no patent can go on indefinitely (as a trademark for example, Coca Cola). A patent had always a limited duration: in some cases in the past 14 years from the Grant date (UK), 17 years from the date of Grant (US and Canada), now worldwide 20 years from the filing date.

The term of available patent protection is more important in some industries than others. In the pharmaceutical industry, for example, where it takes many years for a product to reach the market (10-12 years from the patent filing on best average), and where the same product, once introduced, can usually be sold for 20 years or more, it is vital to obtain as long a patent term as possible. On the other hand, in an industry in which products can be brought to the market quickly but are rapidly replaced by newer products, the patentee is more interested in obtaining rapid grant of an enforceable patent than in prolonging patent term. For products which require a long approval process before marketing, such as pharmaceuticals and agrochemicals, it is now possible to obtain extension of the standard patent term in the USA, Europe and Japan.

When and where patents started their life? Apparently in Venice. In 1474 there was already a decree in the Republic of Venice on the protection of inventions which still sound modern today. In the following text, the footnotes indicate the modern concepts which we would apply to the provisions:

> *There are in this city, and also there come temporarily, men from different places[1] and most clever minds, capable of devising and inventing all manner of ingenious contrivances. And should it be provided, that the works and contrivances invented by them, others having seen them could not make them and take their honour, men of such kind would exert their minds, invent and make things which would be of no small utility and benefit to our State[2]. Therefore, …..each person who will make in this city any new and ingenious contrivance, not made heretofore in our dominion[3], so that it can be used and exercised[5], shall give as soon as it is reduced to perfection[4], so that it can be used and exercised[5],shall give notice of the same[6]……It being forbidden to any other in any territory and place of ours to make any other contrivance in the form or resemblane[7] thereof, without the consent of the author up to ten years[8]. And, however, should anybody make it, the aforesaid author and inventor will have the liberty to cite him before any office of this city[9], by which office the aforesaid who shall infringe be forced to pay him the sum of onwe hundred ducates[10] and the contrivance be immediately destryed[11]. Our government shall be at liberty to take and use in his need any of said contrivances, provided that no others than the authors shall shall exercise them[12].*

1. Rights not limited to local nationals.
2. General economic benefit as consideration for the grant.
3. Local novelty requirements.
4. Reduction to practice required.
5. Sufficiency requirements.
6. Disclosure a condition of patenting.
7. Infringement not limited to exact copies.
8. Fixed term of protection.
9. Infringement action before administrative bodies.
10. Damages for infringement.
11. Delivery up and destruction of infringing goods.
12. Limited government us provisions (only inventor can supply).

In 1594 Galileo was granted a Venetian patent for an irrigation machine. By this time, the length of the patent term had increased to 20 years. In spite of this high degree of sophistication, the Venetian patent system fell into disuse as the power and importance of Venice declined, whereas the English system has remained continuously in effect to the present day from the Statute of Monopolies of 25 May 1624. There are early patents granted before the Statute of Monopolies, for example the first and second English patents for inventions (in 1449 and 1552) both related to glass making techniques which were known in continental Europe, but not established in England.

A mention has to be given to the establishment of the United States Patent and Trademark Office (USPTO, www.uspto.gov) in 1790 and to the particular importance given to the inventor mentioned in the 1788 Constitution, Article 1, section 8:

The Congress shall have Power ….To promote the Progress of science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive right to their respective Writings and Discoveries.

Furthermore, these words of the Constitution appear to be the basis for the practice that whereas in most countries questions of precedence between two patent applications claiming the same invention are resolved on the simple basis that the first to file an application has priority, in the USA the patent was granted, subject to certain conditions, to the person who first made the invention. Now, since 2013, the Patent Law changed in the USA and they now are a “first to file” instead of a “first to invent” Country.

The modern patent was born with the International Convention for the Protection of Industrial Property signed in Paris in 1883 by eleven Countries, now 175 Countries are members of this Convention.

The most important practical result of this 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 Conventions countries within one year from the first filing date, and if certain conditions, these later applications will be entitled to the priority date of the first application.

Now, the European system (www.epo.org) and the PCT system (www.wipo.org) are available to applicants in order to easily designate all the European Countries, plus other Countries not yet members of the European Union, or the 148 Countries members of the Patent Cooperation Treaty, comprised the European countries.

Most patents of interest to chemists cover compositions of matter (new chemical compounds, mixtures, pharmaceuticals) or processes (e.g., synthesis of a drug). Under the patent laws of some countries it is even possible to patent things such as 3D atomic structures, structural databases, biological sequences, and their uses, which may result from the genomics field. Other types of patents are issued for machines, products, business methods, plants and industrial designs.

To obtain a patent, the inventor must file certain documents, and the invention itself must exhibit the qualities of **Novelty**, **Utility** (usefulness), and **Inventive step** (unobviousness, ingenuity), defined as follows:

- Novelty: The concept that the claimed invention must be totally new. The invention must never have been made public in any way, anywhere in the world, before the date on which the patent application is filed.

- Utility: The invention has some practical utility, and is fit for some practical, desirable or commercial purpose. For a chemical, utility might mean that it shows a beneficial property, such as a pharmacological effect, or it might be an intermediate that is used in synthesizing a product that has an end use.

- Inventive step/ingenuity: The invention must not be obvious to an observer who is "skilled in the art". This assumes that the claims defining an invention in a patent application must involve an inventive step that, when compared with what is already known (i.e., **Prior Art**), would not be obvious to someone who is an expert in that field.

In addition, the invention must be disclosed in a clear and complete manner in the patent application. There can be no secret ingredients or information withheld from the application. This is known as the **Disclosure** requirement. Most countries publish patent applications 18 months after the filing or priority date.

Patents will not be granted for an invention that has already been publicly disclosed in another patent application or article, or through public use or sale. Even a posting on the internet can negate the criterion of novelty. In the U.S., an inventor cannot obtain patent protection if an article is published about the invention more than one year before the filing is made. In other parts of the world the patent would be invalidated on the first day of publication of the article. Much of the information in the patent literature is, in fact, never published in any other format.

However, some scientists denigrate patents as information sources since the titles, descriptions, and claims tend to use general, broad terminology, rather than the precise wording typically found in journal articles or other forms of primary scientific literature. This is a mistake if we take into consideration the fact that the most important multinational Pharma or Biotech Companies have a strict regulation in what is possible to publish. As a consequence patent applications filed by such Companies may be the only way to become aware of what they are doing. Certainly, reading a patent application is not like reading a scientific publication but the scientist can avoid the part, generally long and boring, of the description dedicated to general formulae, variable meanings written more for patent attorneys, examiners or judges and focusing instead on the Experimental section or in the part of the description where general processes for preparation are disclosed. In the Experimental section it is then possible to read preparation of compounds and biological data relating to them. The data reported here are reliable since it is necessary to report data that it is possible to reproduce by a third party. Moreover, activity data relating to all the exemplified compounds may be very important in order to get patents in some jurisdictions such as China, Japan and South Korea.

In general, patents are not granted for discoveries, scientific theories and naturally occurring substances. Inventions that are deemed to be contrary to the public good (terrorist devices) or having national security implications (nuclear weapons) may be unpatentable. Some countries restrict or prohibit patenting of diagnostic, therapeutic and surgical methods of treatment for humans or animals, as in Europe.

Patent searching is often undertaken in order to prove novelty, either prior to filing a patent application or during the prosecution of a patent application. This process is known as **Prior Art Searching** or **Patentability Searching**. In this case, the older patent literature is quite important. A second type of patent search involves **Infringement**, i.e., trying to determine whether someone else is illegally claiming the rights to an invention that is yours. In this case, the search must be exhaustive, but is limited to the last 20 years or so. **Validity** searches are conducted in order to locate prior art that invalidates one or more claims in a published application or issued patent. **Clearence** searches (also known as “freedom-to-operate” or “right-to-use”) are conducted prior to using a process or manufacturing a product that might be patented by another party. **State-Of-The-Art** searches are comprehensive searches of the patent and non-patent literature conducted to determine the current state of development of a specific technology or technical field.

Patent offices disseminate patent information in a variety of ways. Historically, this was done by publishing abstracts of issued patents and printed copies of patents. In the U.S. and a few other countries, copies of patents were distributed to academic and public libraries designated as patent depositories. Beginning in the mid-1990s, patent offices utilized the internet to disseminate patent information. In 1994 the USPTO launched the first public patent database on the internet. The European Patent Office (EPO) launched its Espacenet (www.epo.org) patent database in 1998. Patent offices also sell patent data (at nominal prices) to commercial patent information companies, most notably Thomson Reuters, IFI CLAIMS, LexisNexis, and Questel, that incorporate it into their database products. The internet abounds with free patent databases created by academics, librarians, entrepreneurs, collectors, and patent enthusiasts. Some of the most notable include Google Patents, FreePatentsOnline and Patent Lens.

Patents are covered in many chemical literature abstracting and indexing services. One of the most important of these is *Chemical Abstracts*, which is published by the Chemical Abstracts Service, a division of the American Chemical Society. The online version of CA is called SciFinder. CA/SciFinder currently includes patents from more than 60 countries. Approximately 18 percent of the documents indexed in CA/SciFinder are patents.

A major category of chemical inventions is that of new processes for the preparation of known compounds. These may be completely new and applicable for a wide range of end-products.

Such a process is patentable since it will be easy to specify at least one industrially applicable end-product which can be made using it, and furthermore such processes may involve the use of noel reagents which could themselves be patentable as new compounds. However, the majority of such advances in general synthetic chemistry are made in university laboratories and are published in the scientific literature rather than patented.

In industrial laboratories, research on new synthetic methods is generally applied to particular commercially important compounds. Such methods may range from an entirely new synthetic route representing the first commercially feasible method of producing a whole new group of compounds to a minor improvement in the established process for a single product.

In deciding whether or not to seek patent protection for such an invention one must balance the relative merits of obtaining patent protection and maintaining the new process as secret know-how. A patent costs money should be applied for only if a commercial benefit is expected from it. If the process of the invention is such that it cannot be determined from the end product or other evidence such as trace quantities of characteristic by-products whether or not a competitor is using it, then any patent rights will be unenforceable. The patent will then have value only to the extent that the competitors are ethical enough to respect patents which they know they could infringe with impunity. What is worse, the publication of the patent application inform competitors how to carry out the invention.

Keeping a process invention as secret know-how will be feasible only if the invention cannot be deduced from the end-products, but if it is feasible it does have certain advantages. First, it costs nothing over and above the normal overheads of maintaining business security; secondly, it gives nothing away to competitors; and, thirdly, the effective period of monopoly can in theory be prolonged indefinitely and is not limited to the term of patent protection. On the other hand, if the secret is lost other than by theft, or if someone else in independently makes the same invention, the original inventor can do nothing about it.

If someone else does make the same invention and patents it, there is a risk of being liable for infringement of the new patent. In most European countries, and in Japan, if someone has been using the invention, or made serious and effective preparations to use it, before the priority date of the patent, that person has the right to continue it. However, it must be possible to document this prior use, and the permitted usually cannot be expanded, for example by building another factory for the process. In the USA there is no right of prior use and the earlier invention would not invalidate the later patent because the first inventor concealed the invention. Alternatively, it may be useful to publish the invention without disclosing too much details in short articles or in Internet. This disclosure may be novelty destroying in respect of other possible patent applications.

On balance it is preferable in many cases not to patent process improvement inventions, since such patents are extremely difficult to enforce. However, if it is intended to keep a process as a trade secret, documentary evidence must be kept of when preparation to use the process started and when actual began. It must also be made clear to employees that this is a secret. If this is not done an employee who leaves and joins a competitor may not feel under any particular obligation of confidentiality with regard to the process, and it is in this way that trade secrets may most easily be lost. The same behavior has to applied to other people at risk to disclose the invention, such as e.g. plant manufacturers which have to be carefully contracted.

In Europe it has always been the rule that if a group of compounds is new and inventive, then not only are claims to the compounds *per se* patentable, but so also are claims to the process for the preparation of the compounds, even if the starting are known and the process itself is known as a method for making similar compounds. Similarly, if an intermediate compound is novel and inventive, then a process for making known co-products from the intermediate will be patentable, even if the process is known for similar starting materials. In the USA, however, such “analogy process” claims were held be unpatentable unless they were inventive in themselves. They may not be particularly important, since if the product itself is patented, a claim to a process for making it adds little protection, unless there are novel intermediates which may constitute a strategic way to protect the business.

However, the biotech company Amgen found itself seriously disadvantaged because although it had a patent for recombinant host cells expressing erythropoietin (EPO), a known substance, it was unable to obtain a claim to the conventional process for obtaining EPO by culturing those cells. When Chugai made such cells in Japan and imported into the USA, the importation could not be stopped because the imported product was not the product of a patented process. As a result of lobbying from the biotech industry, *In re Durden*, was legislatively overruled by the Biotechnology Patent Protection Act of 1993, which amended the Patent Law so that a biotechnological process is not be regarded as obvious if it uses or results in a novel and unobvious composition of matter. This legislation has the serious defect that it has effect only for one specific field of technology.

A manufacturer who finds that a product he wishes to sell or a project he wishes to develop or a process we wants to perform appears to be covered by someone else’s patent rights may have to obtain a licence from the other person in order to be free to go ahead. The first thing to do is to carry out a full evaluation of the patent situation. If the patents are in force, and may still be kept in force beyond the likely date of introduction of the project (bearing in mind any possible extensions of term such as SPCs or Supplementary Protection Certificates granted in some Countries (Europe, USA, Japan) to extend the patent term of a patent covered a medicinal product), an assessment of their validity is of prime importance.

If the patent rights appear to be valid, an ethical company will respect them and approach the patentee to seek a licence; the project must be abandoned unless a licence can be obtained on commercially acceptable terms, which will often be possible between research-based companies. The licence required is a non-exclusive licence under the specific patent rights, or, which may be preferable, a covenant not to sue in respect of the project in question under any patent rights held by the other party. The terms, may fro example, involve payment by means of a lump sum or a running royalty on sales, or it may be necessary to grant a cross-licence in exchange.

In conclusion of this brief excursus in the patent world my advice would be to not be afraid of patents and use this historical tool for first to be informed about the most updated scientific developments of who can't publish the results freely and second for improving business opportunities.