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Some Basic Principles of Patents

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Abstract: This article gives a basic introduction to patents, dealing with the questions of what a patent is and what rights it gives, how a patent may be applied for, what inventions are patentable, and what are the functions of the patent specification and claims.

Keywords: Claims · Conventions · Industrial applicability · Inventive step · Novelty · Patents · TRIPs

1. What is a Patent?

1.1. *Grant of Patents*

A patent may be defined as a grant by the state of exclusive rights for a limited time in respect of a new and useful invention [1]. These rights are usually limited to the territory of the state granting the patent, so if protection is wanted in a number of countries, patents must be obtained in all of them, either through national patent offices or through an international body such as the European Patent Office (EPO).

The reason why states grant patents is the benefit which results to the state by technological progress as represented by the commercialization of inventions. 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 if he knew that an imitator could copy his product as soon as it was marketed, without incurring any research costs?

For a patent to be granted for an invention, the invention must be applicable in industry, must be new, and must involve an inventive step, that is, must not be obvious. Novelty and non-obviousness must be determined with respect to the 'prior art', which usually means everything published before the patent was first filed.

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1.2. *Rights Given by Patents*

It is important to realize that a patent does not give the positive right to practice the invention, but only the right to exclude others from doing so. The patentee's freedom to use his own invention may be limited by legislation or regulations having nothing to do with patents, or by the existence of other patents. For example, owning a patent for a new drug does not give the right to market the drug without permission from the regulatory authorities, nor does it give the right to infringe an earlier existing patent. The patent owner may enforce his exclusive right in the courts; if the patent is valid and infringed, the court can order the infringer to stop his activities, as well as making him pay damages. A patent owner may also, if he wishes, grant licenses allowing the licensee to do something which he would otherwise be excluded from doing by the patent, usually in return for financial compensation such as royalties on the sale of products falling within the patent rights.

It is also important to distinguish between ownership of an invention or a patent and ownership of goods which fall under the patent. The question of who owns the goods is completely different from that of who owns the patents. The fundamental distinction between the ownership of patents and the ownership of things which are patented is often misunderstood or deliberately misrepresented, so that for example patents granted for transgenic animals are described as giving ownership of 'life', and patents for isolated human genes are talked of as if they gave property rights over human beings.

The exclusive rights given by a patent are granted only for a limited period of time. In most countries the term of a patent is now 20 years from the filing date, but some countries allow extensions of term for patents for pharmaceutical and agrochemical products to make up for the fact that marketing is delayed by the need to obtain regulatory approval. Once this term has expired, or the patent has been abandoned earlier by non-payment of the renewal fees needed to keep it in force, anyone is free to use the invention. The public is able to do so because the patent specification is published (usually 18 months after the first filing date) with a description which must be sufficient to enable the invention to be carried out by a skilled person.

2. International Agreements

2.1. *The Paris Convention*

The 1883 International Convention for the Protection of Industrial Property (Paris Convention) is now adhered to by most countries [2]. The basis of the Convention is one of reciprocal rights, so that an applicant or patentee who is a national of one Convention country shall have the same rights in a second Convention country as a national of that second country has. The most important practical result of the Convention is the possibility of claiming so-called Convention priority for applications made outside one's home country. The system is such that if an application for a patent is made in one Convention country, corresponding applications may be filed in other Convention countries within one year from the first filing date, and 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 mean that the later filing is regarded as lacking novelty.

For example, suppose that XYZ AG files a patent application for a new product A in Switzerland on June 1, 2000. At any time up to June 1, 2001 it may file corresponding applications in as many other Convention countries as it chooses, claiming priority from the Swiss application. If in the meantime a description of product A is published, this publication will not affect the validity of the patent rights. On the other hand, if before June 1, 2001 XYZ decides that it has no real interest in selling the product, it can save itself the trouble and expense of filing in other countries. If it were not for the Convention, a decision whether or not to file in, say, ten countries would have to be taken at the time of first filing, and a lot of money and effort would be wasted on protecting inventions which might be unpatentable or commercially uninteresting.

2.2. *The European Patent Convention (EPC)*

The European Patent Convention [3] has been adhered to by all the countries of the European Union (EU) together with Cyprus, Monaco, Switzerland and Liechtenstein, 19 states in all (a designation of Switzerland automatically includes Liechtenstein). All states which subsequently become members of the EU must join the EPC, if they have not already done so. Furthermore, European patents may be extended to a number of East European states which are not members of the EPC. As an alternative to filing separate patent applications at each national patent office, the EPC provides for the grant of patents in any or all of the contracting states by means of a single patent application in English, French or German examined for patentability by the European Patent Office in Munich. However, once it is granted, the European patent is not a single unitary patent but is a bundle of national patents subject to national laws on validity and infringement. The European procedure has many advantages, but one negative point is that it is necessary to translate the European patent into the national language in nearly all designated member states, which imposes large and unnecessary costs. The EU Commission is presently preparing plans for a unitary EU patent, which may be preferred by industry if the translation requirements are less strict, and if there is a reliable European judicial authority to decide on issues of validity and infringement.

2.3. *The Patent Cooperation Treaty (PCT)*

The PCT entered into force in January 1978 and has now been ratified by over 100 countries including all European Patent Convention states, USA, Japan, China and Russia [4]. The PCT, like the Paris Convention, is administered by the World Intellectual Property Organization (WIPO), a UN organization with its headquarters in Geneva. It does not create a supranational patent office, nor does it grant a 'world patent', but it does simplify the process of filing patent applications simultaneously in a number of countries. Under the PCT, a single application may be filed in any national patent office and may designate any number of PCT contracting states.

The application is passed to a patent office acting as International Searching Authority (ISA), which carries out a search for relevant prior art, and the application is published, together with the search report, 18 months after the priority date. Under the basic procedure, the applicant then has two months in which to prepare all necessary translations, and within 20 months from the priority date the application is delivered to the national patent offices of the designated states and treated from then on as a national application in each country. As an optional second phase, a preliminary examination on patentability may be carried out by an International Preliminary Examining Authority (IPEA) and the results sent with the application to the national patent offices within 30 months (instead of 20 months) from the priority date. The European Patent Office can act as both ISA and IPEA for PCT applications filed in Switzerland, and can also be the designated office carrying out the further examination and grant procedure for EPC member states.

2.4. *GATT-TRIPs*

The General Agreement for Tariffs and Trade (GATT) was set up in 1948 to deal with multilateral trade issues. The latest round of GATT negotiations, the Uruguay Round, led to the establishment of the World Trade Organization (WTO), which became operational on January 1, 1995. The agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) [5] was adopted as an integral part of the Final Act of the Uruguay Round, so that all countries which become members of WTO must accept the provisions of TRIPs as part of the deal. The TRIPs agreement covers a whole range of intellectual property issues including patents, trademarks, geographical indications, industrial designs, integrated circuits, copyright and trade secret protection, as well as general provisions about basic principles, enforcement, and dispute resolution.

TRIPs requires WTO member states to introduce strong patent protection, the most important elements of which are: a minimum term of 20 years from filing; patent protection to be available for all chemical compounds, including pharmaceuticals; patent rights to be without discrimination as to whether products are locally made or imported; enforcement procedures to be effective, fair and equitable, and not unnecessarily costly.

Prior to the TRIPs agreement a number of countries discriminated against pharmaceutical patents by allowing automatic compulsory licences in this field. This meant that the patent owner could not use the patent to exclude others, but only to collect royalties from imitators, the royalties often being fixed at arbitrarily low levels. Under TRIPs, compulsory licenses are allowed only under strict conditions, and on an individual basis.

3. The Patent Specification

3.1. *The Description*

A patent specification is a legal as well as a scientific document, which serves a different purpose from that of a paper in a scientific journal, and should be read in a different way. It consists usually of three parts: an abstract giving a summary of the invention, used chiefly for search purposes and having no legal significance; a description of the invention, which must be sufficient to enable a skilled person to reproduce the invention, and which in chemical cases will normally contain a number of examples; and finally a set of claims. Academic scientists are sometimes distrustful of patents as sources of scientific information because many chemical patents contain what are called 'paper examples' which were never actually carried out. Of course, an author of a scientific publication who added 'paper examples' would be guilty of fraud on the scientific community, and it is perhaps natural for scientists to feel that the same should apply to authors of patents. The cases are not the same, however. The inclusion of a 'paper example'

in a patent is not a false representation that the compound has been made; it is an honest representation that it is predictable that the compound can be made in that way.

3.2. *The Claims*

The claims serve the important legal purpose of defining the scope of the exclusive rights given by the patent. It is not an infringement of the patent to make or do something which is not covered by the wording of the claims, as interpreted by the responsible court. The claims must be supported by the description, but will often be broader in scope than the specific embodiments of the invention described in the examples.

All patent claims may be broadly divided into product claims and process claims. Product claims claim a physical entity, for example a machine or a chemical compound. Process claims (sometimes called method claims) cover the act of doing something, for example manufacturing a product, using a product in a particular way, or even treating a disease (although the last of these may be excluded from patentability in some countries). For chemical inventions, product claims may include not only chemical compounds *per se*, but also *e.g.* optical isomers, crystal forms, alloys, mixtures and formulations. Process claims may cover methods of preparation of new or old compounds, purification processes, processes for using compounds, *e.g.* in dyeing fabrics, *etc.*

A compound *per se* claim is infringed by someone making, using or selling the compound, irrespective of how it is made. A claim to a process for making the compound is infringed not only by carrying out the process, but by using or selling the product of the process, but the same compound made in a different way would not infringe. Prior to TRIPs, many countries would grant only process claims and not product claims, either for all chemical compounds or for specific classes such as pharmaceuticals. Such process claims were of very limited value, because even if they covered the best commercial method for making the compound, they were normally easy to evade by using a less than optimum alternative.

A single patent may contain claims of more than one category, for example a group of chemical compounds and a process for making them. Within a particular category, *e.g.* the compound claims, there will usually be a number of claims starting with a broad claim to a large group of compounds, going on to more limited claims to specific sub-groups, and ending with specific claims to individual preferred compounds. This is to give a fall-back position in the event that the broad claim is invalid; for example if a non-preferred compound within the scope of the main claim is later found to have been published before the priority date, then the main compound claim, and possibly some intermediate claims will be invalid, but the narrow claims to the preferred compounds should be unaffected and could still be enforced against an infringer.

4. What Can Be Patented?

There are three simple requirements for a patentable invention as set out in the European Patent Convention. These are that the invention must be new; that it must involve an inventive step; and that it must be capable of industrial application [6]. Identical or similar provisions apply in most other countries. There are in addition certain matters which are specifically excluded from patent protection in the EPC.

4.1. *Novelty*

Nothing can be patentable which is not new, since if a patent were to be granted for something already known, this would unjustly take away rights which the public previously had. This is why allegations that patents will prevent indigenous peoples from using their traditional medicines are false. Any patent which tried to block the use of traditional knowledge would be invalid and unenforceable. Unfortunately this also means that patents are not a suitable means for indigenous peoples to protect their intellectual property, and some new form of IP rights would have to be found. The EPC and most countries apply the concept of 'absolute novelty'; that is, that an invention is new if it is not part of the 'state of the art', the state of the art being defined as everything that was available to the public by written or oral publication, use or any other way, in any country in the world, before the priority date of the invention [7]. Some countries still have 'local novelty', according to which only publications within that country can destroy the novelty of an invention. More common is the 'mixed novelty' system, which is the law in the USA. Here a later patent application is rendered invalid by written publication anywhere in the world but by use of the invention only in the home country; that is, prior use or oral publication in a foreign country would not invalidate if there was no written description.

It must also be remembered that whereas the rest of the world uses the 'first-to-file' system, in which the date of the first patent filing (the priority date) is all-important, the USA still adheres to the 'first-to-invent' system. Here the critical date is the date of invention, and if two people independently make the same invention, the patent goes to the one who can prove the earlier invention date in a complex (and expensive) process called 'interference'. Accordingly, for the USA, prior art is what was known before the invention date, rather than before the filing date, but with the proviso that if there has been a publication of the invention, the US patent must be applied for within twelve months of the publication date. This means that an inventor may still obtain a valid US patent even if he or she publishes the invention before filing a US application, so long as the application is made within the twelve-month period; the publication is not prior art since by definition you cannot publish your invention before you have invented it. Many US academic inventors have relied on this so-called 'grace period' only to find later that they were unable to obtain a patent in any other country, the basic recombinant DNA patent of Cohen & Boyer being a good example. Proposals are being made to introduce a grace period within the EPC, supposedly by analogy with the USA, whereby an inventor's own publication within twelve months before his filing date would be excluded from consideration as prior art. In fact the US 'grace period' is not analogous to this, and makes sense only in the context of the first-to-invent system. A European grace period would cause so many complications within the first-to-file system that its disadvantages would outweigh any benefits to inventors.

4.2. *Inventive Step*

Once the scope of a patent claim has been determined, it should be relatively easy to determine objectively whether or not it is novel. The question of whether or not a claim involves an inventive step is one that is much more difficult, since to some extent judgment of what is or is not obvious must be a matter of subjective interpretation.

The reason for requiring the presence of an inventive step before granting a patent is that the ordinary worker in that field should remain free to apply his nor-

mal skills to making minor variations of old products. Thus the person to whom the invention must be non-obvious if it is to be patentable is 'the person skilled in the art'; a competent worker but without imagination or inventive capability [8]. For chemical patents the person skilled in the art may normally be considered as the average qualified industrial chemist, and for complex inventions such as in the field of biotechnology, the 'person skilled in the art' may be considered to be a team of highly qualified scientists. It does become somewhat absurd to suppose that such a team could be competent but non-inventive, considering that its members would, if employed in industry, be expected by their company to make inventions as part of their normal duties, and, if academic scientists, would be expected by their university to produce original scientific work, which amounts to much the same thing. The point is that obviousness should be judged by someone with average qualifications and imagination for those in the field.

In considering obviousness, there is no quantitative restriction on the size of the inventive step; *i.e.* the invention is patentable if it involves any inventive step, no matter how small. How the invention was made, whether as a result of planned research, a flash of inspiration, or even pure chance, is not relevant to the question of obviousness. An invention may be simple without being obvious, indeed producing a simple solution to what appears to be complex problem is often highly inventive. It is often very easy to reconstruct an invention with the benefit of hindsight, as a series of logical steps from the prior art, but it does not necessarily follow that the invention was obvious, especially if there is evidence that the invention was commercially successful, or supplied a need. The question 'If the invention was obvious, why did no one do it before?' is usually a relevant one to ask, although there may often turn out to be a good reason why no one would bother to try.

A disclosure formed by combining two documents together is not novelty-destroying, although it may be relevant to the question of inventive step. Nevertheless the prior art document must be interpreted in the light of the common general knowledge of the skilled worker in the relevant field as of the date of publication of the document. Needless to say, there is a grey area between what is clearly common general knowledge (for example something in a standard reference book used by everyone in the field) and what is simply another publication.

4.3. *Industrial Applicability*

The third basic requirement of the EPC is that the invention should be capable of industrial application. Industrial application is broadly defined, and includes making or using the invention in any kind of industry, including agriculture [9]. Methods of medical treatment or diagnosis performed on the human or animal body are defined as being incapable of industrial application, although substances invented for use in such methods are patentable. In the USA, the criterion is that the invention should be 'useful', which is also broadly interpreted. In the USA, unlike the EPC, methods of medical and surgical treatment are patentable.

Although methods of medical treatment are not patentable under the EPC, nevertheless the invention that an old compound not previously known to have any medicinal properties can be used as a drug can be protected by claiming 'Substance X as a pharmaceutical'. The invention that a known drug has a new and unrelated pharmaceutical activity can be protected by a claim of the type 'Use of substance X in the manufacture of a medicament for the treatment of disease Y', commonly known as a 'Swiss-type' claim because the Swiss patent office was the first to accept claims of this type. The reason for the exclusion of medical and surgical treatment is that it is felt that doctors should be free to treat their patients without having to worry about whether they are infringing a patent. However, it might have been better to allow such claims and provide that individual treatment by a medical practitioner was excluded from infringement, rather than to rely upon the semantics of the Swiss-type claim.

4.4. *Specific Exceptions*

The EPC makes certain specific exceptions to patentability, which apply whether or not the invention is capable of industrial application. Artistic works and aesthetic creations are not patentable, and are generally not industrially applicable either; but scientific theories and mathematical methods, the presentation of information, business methods, and computer programs as such are also unpatentable, although they may very well be applied in industry [10].

Animal and plant varieties are not patentable in countries adhering to the EPC, although in the USA plants may be protected either by normal utility patents or by special plant patents for plant varieties. In some European countries new plant varieties, although not patentable, can be protected by plant breeders' rights granted under the UPOV convention [11], and the Enlarged Board of Appeal of the EPO has recently decided that in principle any invention relating to plants which is not protectable under UPOV should be patentable (if new and unobvious). Thus broad claims to transgenic plants are patentable even if the claims include plant varieties within their scope. A further exclusion from patentability within the EPC is that of inventions the publication or exploitation of which would be contrary to *ordre public* or morality [12]. This provision, designed to ensure that patents would not be granted for inventions such as improved letter bombs, which would be repugnant to the vast majority of people, has been seized upon by green activists in their attempts to prevent all patenting of living organisms, on the basis that 'patenting of life is immoral'. Just because a small group of demonstrators dressed up in animal costumes objects to something does not make it immoral. As the Enlarged Board of Appeal of the EPO pointed out recently, the fact that the European Parliament recently approved the Directive on the patenting of biotechnological inventions makes it absurd to allege that such patenting is repugnant to the vast majority of Europeans.

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[1] P.W. Grubb, 'Patents for Chemicals, Pharmaceuticals and Biotechnology', OUP, Oxford, **1999**.
[2] The text of the Paris Convention may be found at *www.wipo.org/eng/iplex/wo_par0_.htm.*
[3] The text of the EPC may be found at *www.european-patent-office.org/epc97/index.htm.*
[4] The text of the PCT may be found at *www.wipo.org/eng/pct/texts/page/wopct001.htm.*
[5] The text of the TRIPs agreement may be found at *www.wto.org/eol/e/pdf/27.trips.pdf.*
[6] Art. 52 (1), EPC
[7] Art. 54(2), EPC
[8] Art. 56, EPC
[9] Art. 57, EPC
[10] Art. 52(2), EPC
[11] The text of the UPOV Convention may be found at *www.upov.int/eng/convntns/1991/Act1991.htm.*
[12] Art. 53(b), EPC