

# THE IPR SYSTEM AND ITS RELEVANCE TO GENETIC INVENTIONS

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By considering only Article 27 of the TRIPs Agreement, a patent should be granted for an invention which is new, non obvious and susceptible of an industrial application ; this applies whichever technological field the invention comes from. Therefore a genetic invention should be treated as any other invention coming from any other technological field ; however this issue of patenting genetic inventions, including but not limited to human genes, gives rise to a large debate in the public.

This debate appears at a time when the development in the biotechnologies is accelerating : the description of the human genome was completed well before the most optimistic date which was put forward ; for some human genes, their function has been described and major hopes are offered to patients suffering from genetic diseases. But there is a conflict between : i) the necessity of protecting inventions in this field, through the patent system for instance and ii) the ethical and philosophical considerations to be respected in this field where inventions are related very closely to life and human beings.

Such a debate, which is necessary in our societies, could be facilitated if the patent system was better known, particularly by the public who needs clearly to be taught about. In this respect, it must be pointed out that some misconcepts are often applied to the patent system, mostly by those who are against the patentability of genetic inventions ; among these misconcepts, we have to tell the public and to repeat and repeat again that :

## **1 - A patent is not an obstacle for the circulation of information**

A patent has a twofold role : the first one is to give its owner an exclusive right, enabling this owner to prevent a non authorized party to reproduce, without its permission, the patented invention ; the second role is a documentary one : the scientific information related to the invention is freely accessible for the public, as it is the case for the information published in a scientific journal.

Leaving aside the USA where the system is a little bit more complex, in almost all the countries in the world there is an automatic publication of the patent application as filed 18 months after the filing date or, when applicable, the priority date ; this is the situation in Europe, in Japan or in Canada, but also in many other countries. This 18 month period can be reduced upon request of the applicant.

It is to be reminded that this free access is the counterpart of the monopoly which is granted to the patentee ; one speaks very often of the patent being a contract between the patentee and the society : the patentee will get an exclusive right – a monopoly – limited in its duration (20 years from the filing date) and in its territorial extent (the country, or group of countries, where the patent application is filed) provided the applicant, who is the future

patentee, gives a free access to the public of the scientific information related to the invention. This information must be sufficient for a person skilled in the art to reproduce the invention and in case this information is not sufficient to reach this goal, there is a ground for invalidating the patent.

Besides this scientific access, there is a commercial access to the invention which will be free only upon expiration of the patent.

It is also important to point out that this early publication, 18 months after the filing, will give opportunities to any person to know *i)* what has been done by its competitors, *ii)* what is possible for said person to do in terms of its own researches and/or exploitation ; this publication will enable also any person to be aware of a potential and future monopoly and to follow the prosecution of the case before the patent office having published the patent application : interestingly the set of claims, defining and limiting the monopoly, when granted can present a substantial reduction in its scope as compared with that appearing in the early publication.

As a conclusion for this first misconception, it can be said that the patent system, through this early publication, and later on through the publication of the granted patent, is not, on the contrary, an obstacle for the circulation of information ; in this respect, keeping the secret on an invention by not filing a patent application nor publishing in a scientific journal represents indeed such an obstacle.

## **2 - A patent does not bar the research**

According to the patent system, as it was mentioned above, in almost all the countries of the world, there is a publication of the patent application as filed, 18 months after the filing date (or the priority date when applicable).

When this publication occurs, any person, at least according to the European patent legislations, has the possibility of reproducing on an experimental basis the invention disclosed in the patent application and likely to be patented later on. Stated differently, for a scientific team reproducing in its laboratory such an invention, there is no infringement ; furthermore this team can improve the invention, by finding a new method of manufacturing a product and/or a new application for such a product, such as a medicine.

It will be also possible for this team, to protect such improvements by filing a patent application protecting them : if the above mentioned method of manufacturing or application is new and non obvious, there is no reason why a patent office will refuse the granting of a corresponding patent and such granting is not considered as an act of infringement as such.

It is to be pointed out that the commercial exploitation remains an act of infringement in case the owner of the earlier patent does not authorize said exploitation, by means of a license for instance. As it will be discussed later on in this presentation, there are legal means in order to force, in some particular cases, the patentee to grant a license to the author of the improvements.

### **3 – A patent is not an appropriation right**

As already mentioned, a patent is an exclusive right, enabling its owner to prevent non authorized people to reproduce the patented invention without its authorization ; this concept of the patent as an exclusive right has been clearly re-affirmed in the TRIPs Agreement. This means that the rights which are granted to a patentee do not include the right to exploit the invention : it is up to other regulation to grant such a right, such regulation being completely separate and different from the patent system ; as an exemple, in the case of medicines, it is up to the health authorities to decide whether a medicine can be commercialized and at which price. Many drugs have been patented but never received such an authorization (a visa) for their commercialization and many drugs have received such an authorization even in the absence of a patent protecting them, either because the drug as such is not patentable or because a prior patent protecting the original drug has expired (case of generics).

But in any case, the patentee is not the proprietor of the invention : it is not because the patentee has received the above mentioned exclusive right that it is proprietor of said invention. This is particularly important in the genetic inventions field : the owner of a patent covering a human gene is not the owner of this gene. As a result, the assertion according to which the patenting of human genes means the appropriation of life is a complete misconception and the clear cut proof that those who are asserting such untruth have a very poor knowledge of what is the patent system.

Quite regularly, the patent system, as such, is under serious attacks ; some topics are more sensitive : limited access of medicines in developing countries, patentability of software and/or business methods, patentability of living matter (plants, animals) and of elements issued from a human body.

As a matter of fact, it is not always easy to justify the patent system for those topics above mentioned ; it is still more difficult when the scope of claims is unduly broad. The breadth of claims is not to be blamed as such, provided these claims are clearly supported by the specification and take into consideration the prior art. A fair balance between the scope of claims and the public interest will be reached if all actors contribute in such direction. By actors, it is meant :

\* the applicants : it is fair for an applicant to seek for the broadest claims possible but such an applicant must also be conscious that it is not its interest to have a set of claims not fully supported by the specification : in case of lack of support, the patent can be revoked before the European Patent Office or other offices where an opposition procedure is applicable ; moreover, such a patent can be invalidated by a national Court : this risk is not theoretical.

\* the patent offices : they must be really critical in appreciating the prior art ; the role of a patent office is not, or should not be, to grant widely patents in order to attract more « clients » : its role is to grant good patents, realizing a fair balance between the wish of the applicant and the public interest. This role is not easy to fulfill and needs professional examiners, chiefly in hi-tech fields, including genetic inventions ; but the fulfillment of such obligations will be helpful in justifying the patent system towards the public.

\* the third parties : they are often aware of elements of the prior art unknown by the examiners ; by providing the examiners with such new elements, they will contribute in reaching this balanced position above mentioned. The opposition procedure is a good

opportunity for achieving this purpose ; this is particularly the case with genetic inventions and more generally with the biotech field where the prior art frequently consists in articles published in scientific journals, in posters presented during congresses or in oral presentations of scientists, all of these elements being scarcely available to the examiners.

In Europe, it should be noted that according to the European Patent Convention, any person is entitled to file an opposition ; this included the patentee itself until the decision of the Enlarged Board of Appeals (the recent modification of the European Patent Convention enabling the patentee to limit its patent on a voluntary basis is a good initiative and must be approved). Leaving aside the problem of the patentee, it should be pointed out that the interested persons are not limited to the competitors of the patentee ; in some specific cases where the patent has been granted in contradiction with basic principles, the opponents can be associations, political parties or even governments (there is some recent exemple where the German and the Italian governments lodged an opposition against a European Patent granted for the culture of mammalian cells). Legally, there is no impossibility either for a patent office to be an opponent in such specific fields : in doing so such a patent office will appear not only as a « granting office » but also as warranting the respect of the balanced situation that was mentioned above.

Finally, one should not forget that genetic inventions have an impact on public health. Even if there is a consensus on the necessity of a patent system (in the absence of such a system a pharmaceutical company will not be in a position of recovering its investment), such a patent system has not to be an obstacle for improvement of public health.

It means that when an invention is patented and is really important for public health, this invention must be exploited : the medicine must be commercialized, the method of diagnostic must be available for the public.

In the great majority of cases, there will be no problem and the patentee will exploit its patent either directly or indirectly through licenses ; but in those cases where there is no serious exploitation, the national authorities must have at their disposal the possibility of granting compulsory licenses (either in case of a dependent patent, or in case this lack of exploitation impairs public health). These licenses are allowed by the TRIPs Agreement and the national authorities must not be reluctant in using this possibility.

By doing so the authorities will give a further justification for the patent system ; it should be noted that the French authorities have recently prepared a draft law, broadening the scope of application of licenses granted in the interest of public health : the new provisions will not be limited to medicines, but also to processes, medical apparatus, kits and methods of diagnostic, encompassing therefore all inventions having a direct impact on public health. It is intended to present this draft law at the French Parliament within the next weeks ; hopefully, this law could be enacted within a short period of time.