Evaluation Of The Patent System From A SME's Point Of View: A Personal Sight

1.-The European Patent System

The European Patent System was a great step forward when it was signed in 1973, taking into account that previously it was necessary for an applicant to file from the beginning as many national applications as countries the applicant was interested in, or he thought in the future he could be interested in. This circumstance made it necessary to invest a great amount of money, time and effort in prosecuting patent applications throughout the European territory from the beginning, even when it was not yet clear whether there was at all a chance to get the patent granted; additionally, a series of patents with different scope of protection was obtained, as no real uniform patentability criteria along the individual countries existed.

1.1- Advantages of the European System

Therefore, the foundation of the European Patent System provided a lot of advantages to the applicants, especially to individuals and SME. In first instance, it became much simpler to gain an option to obtain patents along the European territory without spending elevated amounts of money from the beginning: the greatest part of the costs was postponed until having a decision about patentability of the invention. The European Patent System also led to the obtaining of homogeneous patents all over Europe, due to a centralised final decision by the EPO (European Patent Office), which was observed without exception by the individual national Patent Offices. The patentability criteria applied by the EPO make sure that in a very high percentage of cases a strong patent is obtained, which is completely enforceable. At this point it seems advisable to also mention the Human Resources of the EPO: in general, our personal experience is that, as well as being good professionals, most of the examiners and administrators have a Customer Service mentality, being most of the times approachable, friendly and helpful when it becomes necessary to directly contact them, either within the prosecution steps of a patent application or also at the margin.

It has to be said that in the last years a great effort has been done by the EPO for adapting the system to the necessities of applicants, especially again those of individuals and SME. The first improvement done is the compromise of providing an opinion to the applicant regarding patentability of the invention within 6 months from filing, in the case the first filing is a EP, in the form of a Search Report. Before this

amendment of the prosecution system, and as it is still the case in most national patent systems, the first opinion was not obtained until almost 18 months after filing; that is, almost half a year after the priority deadline, when the crucial decision of how to geographically extend the patent application, and thus which investments have to be done, has to be taken. Therefore, this improvement has made the decision-taking for the applicants much easier. Another great improvement has been the implantation of the Extended Search Report; as you know, therein even more information than simply the Search Report is given, with details about the compliance of the patentability criteria in view of the cited documents, which provide a much clearer idea of the potential of the application, and make it easier to draft arguments and/or amend the application accordingly, in order to obtain a granted patent, or even to abandon the application if it is sure there is no future for it.

1.2.- Remaining Disadvantages of the European Patent System

In spite of the above, it has to be said that there are still some disadvantages in the European Patent System from the point of view of the applicant.

Regarding the time lapsed between filing and obtaining a final decision, it has to be put forward that in fact, depending upon the particular interest of a company at a certain point of time, it may be interesting for the applicant to delay the obtaining of a final decision, either due to technical or economical reasons; or in contrary, it may be important to have a final decision at the earliest possible point of time to be able to take strategic decisions. At present, the time passed until obtaining of a final decision is quite elevated, in most cases being of at least about 4 years, according to personal experience. Indeed, the European Patent System includes a mechanism for accelerating the process of prosecuting a patent application, namely PACE (programme for accelerated prosecution of European patent applications). It is clear that in order this programme to be effective, the complete implication of the applicant in contributing to the acceleration is necessary. Nevertheless, without intending to generalize this circumstance, our personal experience is that the PACE does in many cases not really lead to an acceleration of the prosecution, although this is strongly dependent upon the technical area to which the respective patent application belongs to.

Although the centralised filing and granting of the European Patent, and the fact that it is being worked strongly towards the optimisation of a European common market, it is still necessary to perform national validations in each individual country in which a granted patent is needed: putting together translation costs and filing costs, the investment necessary at this step is considerable; additionally, the obligation of having to rely upon local patent attorneys in order to get the EP validated, due to national laws, means additional complication and costs for the applicant. All these circumstances make it really complicated for individuals or SMEs to obtain a good patent protection. In addition, it still remains necessary to make the payment of maintenance fees country by country in order to keep the patents alive; the sum of all annuities due to be annually paid is another handicap for SMEs for obtaining and keeping a good patent coverage.

Another fact that has to be emphasized in this context is that litigations in relation with a patent have to take place nationally, without the possibility of having a centralised European litigation. Of course from a different point of view this could be seen as an advantage, as a litigation with a negative outcome has implications in only one country, and no implication in any other country of the EU. Nevertheless, this circumstance creates an atmosphere of uncertainty for many companies.

1.3.- Globalisation: disadvantages for EU based companies

Now that "globalisation" is a prevalent concept, it has to be brought out that most of these disadvantages cause that companies with their main commercial location within the EU are often less competitive than US based companies. Firstly, a very big territory is covered by a US Patent alone; that is, a US based company, with only one patent application and only one maintenance fee during the life of the patent, has protected its rights in their principal market, while a EU based company, although filing only one patent application, will have to comply with elevated expenses for validation and maintaining the individual national patents in order to cover completely their principal market, which in most cases will extend beyond only one country.

In addition, the prosecution of a US Patent is generally much quicker than the prosecution of a EP, which may provide a higher certainty to US based companies, as they know much earlier whether they may count upon patent protection for their developments or not, in order to take commercial and strategic decisions.

Another point to be considered is that, within this constantly globalising world, it would be interesting for applicants to find that two of the most important Patent Offices in the world, namely the European Patent Office and the United States Patent and Trademark Office, reach an agreement in what regards patentability criteria, as currently, although the patentability criteria are equivalent (European Patent Office: Novelty and Inventive Step; US Patent Office: Novelty and non-obviousness), their interpretation is different in many cases.

Another advantage to US based companies is the existence of a grace period, which allows them to file a patent to an invention even if they have already published their invention or sold (or offered to sell) it. This allows them to both either amend an error of disclosing an invention prior to patent filing or permits them to size up whether an invention is worth a patent application by reactions of their public.

1.4.- Community Patent

Just to say that again some important efforts have been done in order to try to equilibrate these existing differences between the US and the EU, by trying to create a new figure, namely the Community Patent. I won't get into too much detail into the outstanding project of implanting a Community Patent. This Community Patent should be similar in concept to the Community Trademark, and thus would lead to obtaining one granted patent valid for all the EU territory, without the need of validating and paying individual maintenance fees. Nevertheless, internal political discussions within the EU, especially around the languages to which the claims and/or description of a Community Patent or Community Patent Application, in order to comply with the compromise of serving as a disclosure of technical progresses, are postponing the final implantation of the Community Patent, in detriment of the European SMEs.

2.- A Pharmaceutical Company's environment

With regard to particularly a pharmaceutical company, it has to be kept in mind that the costs incurred by developing a new medicament are extremely high: great amounts of money have to be invested in Drug Discovery itself, Drug Development, Intellectual Property (patents, trademarks, designs...), Preclinical Studies, Clinical Studies, optimizing the manufacturing processes, etc. Additionally, the

market entry, in comparison with other kinds of products, is greatly postponed due to the delay in obtaining both proper IP protection and market approval.

2.1.- SPCs

The delay due to market approval is partially compensated through the grant of SPCs (Supplementary Protection Certificate). These SPCs extend the protection provided by a patent application to a pharmaceutical product in the market only for the particular embodiment of the marketed pharmaceutical product.

The maximum length of a SPC is 5 years; the length is generally calculated by the formula

"*date of first market approval*" – "*date of patent application*" – "*5 years*"

Just to provide a general idea, in case you are not familiar with SPCs, if the delay of time between filing the corresponding patent application and obtaining the first market approval is 6 years, the duration of the SPC is 1 year. It is proportionally increased, year by year, to the maximum of 5 years, which is reached at 10 years delay; it then remains constant at 5 years, even if the delay increases up to 20 years.

2.2.- Generic Producers vs. Investigating Pharmaceutical Companies

There are many different opinions regarding whether this calculation of SPCs is fair or not to compensate the costs of the investigating companies. Of course, producers of Generic Pharmaceuticals, and consequently also some consumers, which are interested in having access to Generic Pharmaceuticals as soon as possible, generally believe this duration is too long. Nevertheless, it has to be considered that investigating companies have to be sure that, by commercializing the corresponding Pharmaceutical, they retrieve the investments made in the development of this particular Pharmaceutical, the proportional investments made for other Pharmaceuticals that haven't passed either Preclinical or Clinical Phase, and of course obtaining some benefits from the commercialization of the Pharmaceutical. In case this isn't complied with, it has to be kept in mind that Pharmaceutical Companies won't continue investigation in new Pharmaceuticals, at least at the same speed, which would have negative implications for the society.

Up to now, within the European Market, in order to launch a Generic Medicament, it was either necessary to start preclinical and clinical studies once the relevant patent or SPC had lapsed, or the testing had to be performed outside the European territory. This meant that the entry of a Generic Medicament into the market was quite delayed even after the relevant patent or SPC had lapsed. At a first glance, this may seem unfair for the Generic Producer; nevertheless, this circumstance allowed Pharmaceutical Companies to artificially extend the monopoly on the new Pharmaceutical even beyond the SPC.

2.3.- Directive 2004/27/EC

Nevertheless, in the near future, with the new Directive 2004/27/EC, related to medicinal products for human use, at least from the point of view of an investigating company, some interests of Generic Producers seem to be favoured. At least at a first instance, it is projected to have this Directive implemented in Member States' national laws by 30th October 2005. This Directive includes a "Bolar-type provision", similar to the provision created by the Hatch-Waxman Act 1984 in the US: this provision allows Manufacturers of Generic Products to perform any "*necessary studies and trials with a view to the application of marketing approval* " without the risk of infringing a patent or SCP which is still in force:

> *Article 10.6: Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.*

Additionally, it is clearly stated that, in case a generic manufacturer provides appropriate bioequivalence/biosimilarity and bioavailability studies, he can take chance of the pre-clinical and clinical data originally filed by the investigating company, without the need of repeating any pre-clinical and clinical studies:

> *Article 10.1: [...] the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate*

> *that the medicinal product is a generic of a reference medicinal product which is or has been authorised [...]*

Wherein "generic" has to be interpreted as defined in Article 10.2.b:

> *Article 10.2.b: "generic medicinal product" shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. [...]*

Fortunately for the investigating companies, this possibility is limited to medicaments which have been authorized for a minimum of 8 years, and in no case may reach the market before 10 years of the first authorization of the original medicament:

> *Article 10.1: [...] if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community.*
> *A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product. [...]*

2.4.- Trademarks

In this sense, the investigating companies will be forced to make a great investment in the development and filing of trademarks for their medicaments, in order to gain an advantageous position within the market and the clients with respect to Generic Pharmaceuticals.

Take the example of Aspyrin®: almost nobody would enter a Pharmacy asking for Acetylsalicylic Acid, but for Aspyrin. The same applies in the US to the active

substance acetaminophen (in Europe, paracetamole), which is sold as Tylenol®: nobody would ask for acetaminophen.

Conclusions:

As detailed above, many efforts are being done to adapt the European Patent System to comply with the interests of applicants. Nevertheless, much work remains to be done in this sense to optimise the System, if the interests of SME want to be protected.