Life sciences patent strategies in Europe

The European market can be a daunting one, due to the lack of a unified patent system. However, life sciences companies can employ a number of tactics in order to arrive at a successful IP strategy for patent protection

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Europe represents a large market consisting of over 500 million consumers, yet no unified patent protection is available. Non-European companies seeking patent protection in Europe are likely to run into problems when trying to obtain and maintain efficient patent protection, unless they familiarise themselves with the characteristics of the European patent systems. In this article we focus on five tactics for a successful IP strategy for patent protection in Europe. These tactics are especially relevant for life sciences companies, but are also in many ways valid for companies in general.

Tactic 1: Costs v geographical coverage

Considering the relatively high costs of patent protection in Europe, you need to consider how much you are willing to invest in order to obtain and maintain patent protection for your invention in Europe. In order to find the right strategy, you must consider a number of issues, such as where your products have the greatest market potential and where competing production is more likely to occur.

The lack of uniform European patent rights makes it essential to adopt a strategy for finding the right balance between costs and geographical coverage for national patent rights since, in contrast to the existing unified Community IP rights (eg, the Community trademark and Community design), there is no Community patent system in place. However, discussions have been ongoing for a long time and there may be developments in this area within the next few years.

Europe consists of some 50 different countries, of which 27 are members of the EU. The EU is often considered the most important part of the European market as a whole.

All European countries have national patent systems and companies interested in patent protection in Europe may, of course, make their selection from among them at an early stage and file applications in only these countries. This strategy will be the least costly where there is an interest in obtaining protection in only a limited number of countries — although this is seldom the case for a life sciences company.

Much of the time the geographical area of interest is larger and companies often prefer to postpone the final geographical selection for as long as possible. The most common way to obtain patent protection in Europe is therefore through the European Patent Office (EPO), and the advice given below is particularly relevant for patent protection obtained in this way.

The EPO, which from 1st January 2009 numbers 35 member states, makes it possible to obtain patent protection via the European Patent Convention (EPC) in all of these states, as well as in the three so-called extension states, through a single patent application. However, once granted, the patent rights will be considered as national rights. The EPC system may be used for direct filing of a first application, filing of an application for which priority is claimed or filing of a Euro-PCT via the PCT system.

Tactic 2: Interact at an early stage

As European practitioners, we are often faced with the task of submitting PCT applications from non-European companies at the regional phase before the EPO. Unfortunately, however, we are often engaged too late in the process to be able to contribute fully to strong patent protection.

Once the regional phase before the EPO has commenced, no further additions may be made to the application text. The applicant is thus stuck with the status of the application as filed at the PCT phase, which can lead to a number of problems in regard to some of the special legal requirements pertaining in Europe.

In order to avoid unnecessary trouble, a general recommendation is to involve your European partner at an early stage of the patent application process. Minor adjustments and adaptations to the specification and claims can often make a huge difference in terms of successfully making amendments and presenting arguments during substantive examination before the EPO. This, in turn, significantly improves the chances of obtaining strong patents in Europe - patents which will also have a better basis for surviving litigation.

Companies for which the EPC countries are an important market should in fact consider involving the European partner in the preparation of the priority application. Experience shows that when working out a detailed description covering the most important aspects of the invention, most effort usually goes into preparing the first version of the patent application. To ensure that European aspects are covered in the most advantageous way, these are best taken into account from the very beginning.

Tactic 3: Be aware of legal differences

The lack of convergence between jurisdictions is troublesome, since this may force companies to make national or regional exceptions to their international IP strategy and possibly weaken the IP portfolio, even to the extent of rejection of patent applications. If this lack of convergence and the legal differences between patent systems in different countries or regions are taken into account at an early stage, the negative consequences can be minimised.

Since the US and European markets are often the most important for life sciences companies, the advice below is of greatest relevance to companies considering the US as their first market.

Drafting and prosecution aspects

Although there are many similarities between the patent laws in Europe and the US, there are also some important differences – even more so when it comes to patent practice. These legal differences need to be taken into consideration when preparing patent applications, and in particular when drafting claims and prosecuting applications before the EPO.

Perhaps one of the best-known differences compared to the US system is that methods of treatment practised on humans or animals are not patentable in Europe. In Europe, claims for such inventions must be worded in other ways. Good news in this context is that it is no longer necessary to use the often complicated wording of the so-called Swiss-type claims for protecting second or further medical use, since the EPC 2000 (ie, the revised EPC which entered into force in December 2007) allows for purpose-related product protection for such inventions.

Another problem which non-European and especially US companies often run into is that the EPO normally accepts only one independent claim per category.

Also, the EPO is trying to discourage applicants from filing long, complex applications by increasing the fees, a move which will especially affect applications within the life sciences industry, since these are often more extensive than applications involving other technical fields. From 1st April 2009, applicants will have to pay €200 for each claim after the first 15 and €500 for each claim after the first 50. In addition, a fee of €12 will be payable on filing for each page over 35.

Legal differences also arise during the examination stage at the EPO when seeking to overcome any objections that the examiners might raise, especially when it comes to proving the non-obviousness of an invention. Unlike in the US, the EPC encourages the use of the so-called "problem solution" approach, which means that the invention is seen as providing a solution to a technical problem objectively defined based on the prior art.

Another legal difference during prosecution is of major importance insofar as making amendments is concerned. The EPC allows only amendments to the claims and the description that are fully supported in the application as filed. In practice, this means that amendments can be made only based on what is already written in the application, basically on a word-by-word basis.

Post-grant aspects

There are also important post-grant legal

differences which, if managed properly, can be used to your advantage.

In the US, there are re-examination and reissue procedures. In Europe, there is instead a system for post-grant opposition. This system enables you to centrally challenge your competitors' patents after grant. Unfortunately, it works both ways and thus also gives your competitors the opportunity to challenge your patents. However, the opposition procedure is available only for a limited time after grant of a patent; if a patent is challenged after expiry of this time limit, it must be done in a national court in each country of interest.

Since December 2007 there has also been a system in place for so-called central limitation. In contrast to the opposition system, central limitation may be applied for only by the patent owner. When used properly, it is a cost-effective way of strengthening your own patent - for example, if national litigation procedures are pending.

Litigation aspects

You should also be aware of legal differences in relation to litigation. It is well known that compensation levels in Europe normally do not reach the same levels as in US litigation. In Europe, you will not find the same procedural provisions as you may be accustomed to in patent litigation in the US in relation to discovery provisions or jury trials.

The main feature that you should note, however, is the fact that Europe has no single jurisdiction. As mentioned above, European patents are a bundle of national patents. Thus claimants and defendants bear the risk of multiple suits in a number of European countries concerning the same patent issue.

Multiple suits may also result in infringement, invalidity counterclaim or revocation actions, which are subject to different procedures within Europe. In some countries there is even a separation between infringement and patent revocation actions, even though in most countries the same court has competence to hear both invalidity and infringement actions. Multiple suits may also result in the different national courts servicing contradictory results.

These national differences within Europe may also result in forum shopping. Claimants or defendants may prefer national courts that deal exclusively with patent cases, rather than pursuing litigation in a country with no such exclusive court. Differences in costs and in the speed of proceedings may also give rise to forum shopping.

There have been attempts to resolve this complex situation. For example, there is a proposal to establish a uniform jurisdiction for European patents under the draft European Patent Litigation Agreement (EPLA). The intention is to create a unified system for litigation on European patents.

Antitrust law aspects

When commercialising your European patents, you should also note legal differences under antitrust law. With respect to patent licensing, such an agreement may restrict competition and would require exemption under the Technology Transfer Block Exemption Regulation in order not to be subject to Article 81(1) of the EC Treaty, which prohibits anti-competitive agreements.

Refusal to deal in the licensing of a patent could also be controversial under Article 82 of the EC Treaty. Although there is no general obligation on a dominant firm to license a patent to a third party, a refusal to license a patent may still be subject to scrutiny under antitrust rules. There is a lack of convergence between US and EU antitrust rules on this point.

Tactic 4: Maintain business focus

Today, most companies regard a strong IP portfolio as an essential factor in order to succeed on the market. Yet building a strong IP portfolio will often be a large investment for many companies.

Therefore, as with any other investment, it is essential to monitor closely the resources spent on IP. However, this is rare in practice, as an application for European patent protection is often considered as merely an extension of the US patent rights.

However, as we have shown in this article there are important legal differences which will affect the strength of the IP portfolio. But why lose your business focus when entering into the European phase? Your European IP partner simply needs to have the correct understanding of your company's strategic business goals in order to get the most out of your patent rights.

Typically, European practitioners have very limited information about the client companies they are asked to represent through foreign agents. They are provided with a ready-made patent application, which at the time of drafting will have mirrored the needs of the client.

Yet these needs might have changed by the time of national/regional entry of a PCT application due to a change in business focus or sometimes due to acquisitions. The latter is especially common within the life sciences sector, where smaller companies

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usually do not have the resources to develop the final product, but are instead focused on the initial research phase.

This means that the main focus of the application as presented to the European patent attorney may not be optimal, although the representative normally presupposes that it is. In addition, it should be kept in mind that the prosecution phase before the EPO could be quite lengthy - often several years - and further strategic shifts are in most cases made before a final decision is reached.

However, without any contact with the European practitioner, this important information may be totally overlooked. Keeping the European agent updated on your business goals creates greater opportunities for the patent to fulfil your expectations.

Tactic 5: Active choice of European IP partner

Most non-European firms do not actively choose their IP partner, even though their IP portfolio may be the company's most valuable asset.

To get the most out of your patent work in Europe, you should ensure that you have effective cooperation with your European partner, either directly or through your local agent. You should seek partners which are interested in establishing long-term relationships and are willing to invest time and effort in getting to know your business.

Do not be afraid to demand a proactive approach. Patent attorneys working in isolation from the client companies are always at risk of making claim amendments which have not been thoroughly analysed from a commercial point of view. Such amendments may be detrimental if the final scope of the patent does not cover the product you intend to put on the market. *iam*

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