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Europe

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The European Union has 15 member states: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the UK. Thirteen new states are at various stages of proceedings for joining the European Union: Turkey, the Czech Republic, Estonia, Hungary, Poland, Slovenia, Cyprus, Romania, Slovakia, Latvia, Lithuania, Bulgaria, Malta.

In the course of these proceedings, national laws are being amended, and new laws implemented, when required.

The European Court of Justice has established two principles over the years: the direct applicability of Community law in each member state, and the primacy of Community law over conflicting national law.

Community law can, *inter alia*, take the form of Regulations, which apply automatically in a member state, and Directives, which need to be transposed into the national law of each member state.

The European patent system (a single patent application, leading to a bundle of patents which, upon grant are subject to national law) covers a broader territory than the European Union: all EU member states, as well as Bulgaria, Cyprus, the Czech Republic, Estonia, Liechtenstein, Monaco, Slovakia, Switzerland and Turkey.

A European Patent may also be "extended" into the following states: Albania, Lithuania, Latvia, the former Yugoslav Republic of Macedonia, Romania and Slovenia.

How does ownership of intellectual property rights arise in your jurisdiction and what rights do inventors retain?

Contrary to the situation in the United States, the right to an invention in Europe is acquired on a *first-to-file* basis. Both individuals and moral persons may file patent applications. Inventors' rights are dealt with by national law and are thus specific to each member state.

Alongside national rights, there exist a number of Community and European rights:

- Community Design (Regulation 6/2002/EC of December 12 2001)
- Community Trade Mark (Regulation 40/94/EC of December 20 1993)
- European Patent (European Patent Convention of October 5 1973)
- Community Patent: discussions are ongoing since the 1960s, one of the key issues being the choice of official languages. A proposal for a Community Regulation was issued on July 5 2000.

What kind of claims are permissible in your jurisdiction?

The European Patent Office (EPO) routinely grants claims in the classic categories of product, process and use. Certain member states of the European Patent Convention (EPC), in particular Austria, Greece and Spain, had originally reserved the right not to accept pharmaceutical composition claims for their territories. These reserves no longer exist and thus, at present, all member states of the EPC accept product, process and use claims for pharmaceutical inventions. Exceptions may still exist, however, as far as the national laws of some of the member states are concerned. For example, a national patent in Monaco cannot be granted with claims to pharmaceutical products. It is thus necessary to take the European Patent route if this type of protection is desired.

Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are considered as being unpatentable by virtue of Article 52(4) of the European Patent Convention (EPC).

However, the Enlarged Board of Appeal of the European Patent Office (EPO) has, in its decisions G 1/83, G 5/83 and G 6/83, allowed the patenting of such methods provided that the claims are drafted in the so-called "Swiss claim" format, as follows: "Use of a product X for the preparation of a medicament Y treating a disease Z" (second medical use).

A recent proposal for amendment of the EPC would specifically authorize claims for products destined for a specific use, ie without having to resort to the artifice of Swiss-type claims.

Claims for screening methods (research tools) are granted by the EPO, provided that the classic conditions for patentability are met (novelty, inventive step, industrial application, clarity and sufficiency of disclosure). However, so-called "reach-through" claims concerning the

products identified by the screening methods are not generally granted unless these products are clearly characterized by specific features, and not simply by the screening method, thus allowing their novelty to be determined.

The EU Directive on the Legal Protection of Biotechnological Inventions (Council Directive 98/44/EEC of July 6 1998) was to have been transposed in all member states by July 30 2000. For the moment, only four states have done so, and some others have draft bills pending.

Legally speaking, the EPO is not bound by the Directive, since it is not an EU member state. However, the European Patent Organization very rapidly demonstrated its willingness to comply with the terms of the Directive by transposing its most important provisions into the Implementing Regulations of the EPC in the form of New Rules 23b to 23e which entered into force on September 1 1999. Thus, these provisions apply to all European Patent applications.

Even before the inclusion of these new rules in the EPC, the EPO had already granted patents with respect to higher life forms. In particular, the famous "oncomouse" patent was granted by the EPO's Examining Division with claims for "transgenic non-human mammalian animals". These claims were subsequently restricted in scope to "transgenic rodents " during proceedings before the Opposition Division (the Opposition Division's decision is now on appeal to the Boards of Appeal of the EPO).

It should be noted that claims to gene sequences will now only be allowed by the EPO if the patent application discloses a credible function for said sequence (Rule 23e(3), and the Opposition Division's decision in the *ICOS* case dated June 20 2001). This is in line with the Directive as well as with the US Patent and Trademark Office's current practice.

The European Union has not yet set any common rules for the protection of know-how and trade secrets.

How are know-how and trade secrets protected in your jurisdiction?

However, it is stated in various EU laws that know-how and trade secrets are protected by virtue of their secrecy. Therefore, if not patentable (process, etc), the sole manner for protecting said rights is confidentiality.

Violation of such rights would have to be dealt with by the national laws and courts of each EU member state.

As general information, several EU Regulations dealing with licensing of know-how and trade secrets, and most particularly with the question of unfair competition and free trade, exist.

Council Regulation (EEC) 1768/92 of June 18 1992 created a supplementary protection certificate (Community SPC) for medicinal products. Certain member states had already created national SPCs (notably France and Italy) and thus the Community SPC was an attempt to provide a uniform system for all member states of the European Union.

Is there any form of pharmaceutical patent term extension available in your jurisdiction (eg supplementary protection certificate) and if so how does it apply?

The Community SPC allows the patent holder of either a national or a European basic patent to extend the patent term with respect to an active ingredient (or combination of active ingredients) which has received a marketing authorization in one of the countries of the EU. It is not necessary that the patent in question be a product patent. According to the definition of the term "basic patent" as provided in Article 1(c), the patent may also be a process patent or a patent for the application of a product.

The application for a Community SPC must be made either within six months from the grant of the first marketing authorization in the European Community or, where the marketing authorization was granted before the grant of the patent, within six months of the date of grant of the patent.

The scope of protection is strictly limited to the product for which the marketing authorization was obtained. Thus, only that portion of any claim which directly concerns the product for which the marketing authorization was granted benefits from the extended patent term. This is in contrast to SPCs created under national law of certain member states. In particular, France had created SPCs by its law of June 25 1990, which allowed the extension of the patent term for all claims referred to in the SPC application, even if they concerned products other than the specific product for which marketing authorization was granted.

The duration of the extension of the patent term is either 15 years from the granting of the marketing authorization or five years from the date of expiry of the patent, whichever is shorter.

It should also be mentioned here that Council Regulation 1610/96 of July 23 1996 created a supplementary protection certificate for plant protection products (Community SPPC) which defines a similar regime for plant protection products as that described above in relation to medicinal products. This Regulation indicates (according to point 13 of the preamble) that the SPPC covering a particular plant product also applies to the derivatives of said product (salts and esters) if the basic patent covers said derivatives; alternatively (at point 14 of the preamble) a separate SPPC may also be granted for specific derivatives of a particular plant product if specific patents exist with regard to said specific derivatives.

This interpretation has been accepted by national patent offices as also applying to applications for Community SPCs and is thus of particular importance where, for example, a particularly active salt of an active ingredient is discovered and subsequently patented.

Is there any form of protection for the data submitted for the regulatory approval of medicinal products in your jurisdiction (eg regulatory data exclusivity) and if so how does it apply?

This type of protection was first formalised in the EU by way of Council Directive 87/21/EEC of December 22 1986 amending Council Directive 65/65/EEC of January 26 1965. These Directives and others have recently been codified in a single text and have now been repealed.

Directive 2001/83/EC of November 6 2001 on the Community code relating to medicinal products for human use provides, in its article 10 point 1 (a) (iii) [corresponding to Article 4 point 8 (a) (iii) of Directive 87/21/EEC] that results of toxicological and pharmacological tests or clinical trials shall not be required to obtain a marketing authorization. In other words, an

abridged procedure can be used if it can be demonstrated that "the medicinal product is essentially similar to a medicinal product which has been authorised within the Community (...) for not less than 6 years (...). This period shall be extended to 10 years in the case of high-technology medicinal products (...). Furthermore, a Member State may also extend this period to 10 years by a single decision covering all medicinal products marketed in its territory (...). Member States are at liberty not to apply the 6-year period beyond the date of expiry of a patent protecting the original medicinal product."

One may wonder what an "essentially similar" product is. A ruling by the European Court of Justice (ECJ) on December 3 1998 shed some light on that term. In case C-368/96, the ECJ held that "a medicinal product is essentially similar to an original medicinal product where it satisfies the criteria of having the same qualitative and quantitative composition in terms of active principles, of having the same pharmaceutical form and of being bioequivalent, unless it is apparent in the light of scientific knowledge that it differs significantly from the original product as regards safety or efficacy".

The ECJ also held that such a product essentially similar to a product which has been authorized for more than six or 10 years and is marketed in the member state for which the application is made, may be authorized, under the abridged procedure "for all therapeutic indications", and "for all dosage forms, doses and dosage schedules already authorised for that product".

It should be pointed out however, that a proposal (COD/2001/0253) for a Directive to amend Directive 2001/83/EC is under discussion. One of the proposed changes is the harmonization at 10 years for the data protection period.

Is there any form of protection available in your jurisdiction for studies directed to the regulatory approval of drugs for use in conditions with low prevalence ("orphan" drug protection) or for use in paediatrics?

Regulation 141/2000/EC of December 16 1999 on orphan medicinal products came into force on January 22 2000. It applies as from the date of adoption of the implementing Regulations provided in article 3(2) and article 8(4): ie Regulation 847/2000/EC of April 27 2000, which came into force on April 28 2000.

According to said Regulations (Article 3 of 141/2000/EC), a medicinal product is considered to be an orphan drug if it can be shown that it is:

- intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10 thousand persons in the Community when the application is made, or
- that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Community and that without incentives it is unlikely that the marketing of the medicinal product in the Community would generate sufficient return to justify the necessary investment; and
- that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by the condition.

Once a marketing authorization is obtained for an orphan drug, "the Member States shall not, for a period of 10 years, accept another application for a marketing authorisation, or grant a marketing authorisation or accept an application to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar product" (Article 8.1 of 141/2000/EC).

This period may be reduced to six years if, at the end of the fifth year, it is established that the criteria of Article 3 are no longer met (Article 8.2 of 141/2000/EC).

Also, no protection applies when the holder of the marketing authorisation for the original orphan drug is unable to supply sufficient quantities of the product, or if the second applicant can establish that the second medicinal product, although similar to the orphan medicinal product already authorised, is safer, more effective or otherwise clinically superior (Article 8.3 of 141/2000/EC).

The terms "significant benefit", "similar medicinal product" and "clinically superior" are defined in the implementation Regulation (Article 3.2 of 847/2000/EC).

Contrary to the situation elsewhere, for example in the US, there are no incentives for the performance of clinical trials for uses in paediatrics. However, the potential benefits of such incentives have been the subject of public debate in recent years.

This led to Council Resolution 2001/C 17/01 of December 14 2000 on paediatric medicinal products, inviting the Commission to make appropriate proposals in the form of incentives, regulatory measures or other supporting measures in respect of clinical research and development.

A consultation document by the Commission was published in February 2002. It mentions in particular the introduction of an extended period of market exclusivity in exchange of the carrying out of such paediatric trials.

In relation to clinical trials for paediatric uses, one should mention Directive 2001/20/EC of April 4 2001 on good clinical practice in the conduct of clinical trials, in particular clinical trials on minors (Article 4). Member states must implement this Directive in their national laws by May 1 2003, with effect at the latest on May 1 2004.

Is there a defence to patent infringement in your jurisdiction in respect of experiments and, if so, are clinical trials covered by this defence?

This is a question which is in fact treated at the national level in the member states of the European Union. Most of the member states of the EU have passed legislation, generally as a part of their patents acts, providing for an experimental and/or research use exemption. The question as to whether clinical trials are covered by the experimental use exception is also at present a matter for the national laws of the member states to decide.

None of the present members of the EU have incorporated a so-called Bolar provision into their national legislation. (The Bolar provision gets its name from legislation in the US. The specific aim of such legislation is to allow clinical trials just before the expiry of the patent term in order to allow generic products to come onto the market very soon after expiry of patent protection.)

However, certain eastern European countries, which are involved in the accession process to the EU (for example, Poland) have passed, or are on the verge of passing, Bolar provisions into their legislation.

The subject has also been hotly debated within the EU for a number of years. The member states have now come to an agreement, which was helped along by the fact that the WTO recently considered that Canada's Bolar provision complied with the TRIPs agreement.

Thus, the European Commission issued late last year a Proposal for a Regulation "laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products" which includes a provision which would allow the performing of clinical trials for generics despite the existence of patents and SPCs. It remains to be seen when this Regulation enters in force, and if the mentioned provision is kept in the final text.

Can intellectual property rights be used in your jurisdiction to prevent the importation and distribution of goods placed on the market by or with the consent of the IP right owner in another jurisdiction?

The answer to this question is fairly clear as it has long been judged that international exhaustion of rights is not recognized. Hence, intellectual property rights may be used to prevent parallel imports into EU territories.

With respect to the distribution of goods within the EU, the rule is that once the owner of IP rights has marketed or given his/her consent to market his/her goods, it is no longer possible to prevent a third party from selling, marketing, importing or exporting those goods within the EU.

This matter has been affirmed several times by the European Court of Justice. See particularly the following cases: *Silhouette* (C-355/96); *BMW* (C-63/97); *Parfums Christian Dior* (C-337/95); *Sebago, Ancienne Maison Dubois* (C-173/98).

At the time when this article went to press, discussions were pending with respect to the recognition of the doctrine of international exhaustion of rights in the European Union.

What relief is available from the courts in your jurisdiction?

There is no unique Community court dealing with the enforcement of intellectual property rights. Litigation is carried out on a national basis, though the European Court of Justice (ECJ) may be consulted by national courts on specific questions.

With respect to patents, there are ongoing discussions about a court at the Community level, as well as about the Community Patent and a protocol on the settlement of litigation concerning European patents.

The proposal for a Council Regulation on the Community Patent provides that actions concerning the validity, infringement and use of the Community patent are of the exclusive jurisdiction of the Community Intellectual Property Court (CIPC), which will comprise a Chamber of First Instance and a Chamber of Appeal. Other actions, *inter alia* the right to a patent, remain within the jurisdiction of national courts.

A structure paper of an optional Protocol on the settlement of litigation concerning European patents has been presented for information to the participants of the intergovernmental conference held in London on October 16 to 17 2000, to open discussions. The Protocol discusses the possibility of a common European patent court of first and second instance or, alternatively, of second instance only. Both the infringement and validity of European Patents would be dealt with by the European court.

As far as Community trade marks are concerned, if the OHIM rejects a trade mark application, the applicant can, after an internal appeal at the OHIM, bring the case before the Court of First Instance, a single Community court, and then possibly, if still unsuccessful, up to the ECJ.