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CMS European Patents Review

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Introduction

Welcome to the 2009 edition of the CMS European Patents Review. Once again our European offices have collaborated to bring you a snapshot of key patent issues from around Europe. This year the emphasis is on pan-European issues, with our headline articles considering topics of international significance while comments from lawyers around Europe summarise the position from national perspectives.

2008 saw some important developments in European patent law. The Review considers the impact of EPO Enlarged Board of Appeal's decision on the long-running prosecution of WARF's patent application for primate embryonic stem cells, the EPO President's referral to the Enlarged Board of Appeal of questions on the patentability of software and the European Commission Competition Directorate's preliminary report on their investigation into potentially anti-competitive patent practices in the pharmaceutical industry, as well as discussing issues such as patent standards, the experimental use exception and the patentability of second medical uses of known pharmaceutical products.

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Stem cells and the Enlarged Board's decision in WARF's patent application

In 2008, stem cells hit the headlines with the European Patent Office (EPO) ruling that inventions concerning products which can only be obtained by the use and destruction of human embryos cannot be patented.

Germany

In December 2006, the Federal Patent Court (BPatG) ruled on a case similar to the one recently decided by the EBoA. The patent in question (DE19756864) was declared invalid as far as it concerned specific cells derived from stem cells from human embryos. In the view of the court, any invention that necessarily required the destruction of human embryos was excluded from patentability, even if such destruction was not part of the claims but only an unavoidable side-effect. Unlike the EBoA, the court held that the legal and factual circumstances at the time of the validity judgment, and not of the application, were decisive. However, the court found that a possibility of procuring embryonic stem cells without destroying a human embryo had not been demonstrated by the patent owner.

Mirroring the ongoing debate on the restrictive German legislation on embryonic stem cell research, several authors have criticised the decision. One criticism was that, even under German legislation, research with embryonic stem cells is permitted under certain circumstances, and that the results of such lawful research must not be prohibited from patentability. The patent owner has appealed the decision to the Federal Court of Justice.

Thirteen years since the Wisconsin Alumni Research Foundation (WARF) lodged its patent application for primate embryonic stem cells and after a long history of decisions and challenges, the EPO's highest decision-making body issued its final judgment on the application on 25 November 2008. In a restrictive interpretation of the European Patent Convention's rules on public order and morality, the Enlarged Board of Appeal ("EBoA") ruled that applications relating to products which could be prepared only by destroying human embryos would be refused, even if the application did not specifically describe the method involving this destruction and a new method had been found since the application was filed which avoided such destruction.

Legal background

The European Patent Convention (EPC) precludes patents where the commercial exploitation of the invention is contrary to "ordre public" (public order) and morality (Article 53(a)). The fact that such exploitation may be illegal or prohibited under the laws of some or all contracting states does not automatically deem an invention to fall within Article 53(a).

However, with the agreement of the non-EU Contracting States to the EPC, the EPC was amended in 1999 to reflect the Directive on the Legal Protection of Biotechnological Inventions (the "Directive"), which prohibits the granting of patents for inventions which concern "uses of human embryos for industrial or commercial purposes". In effect rule 28(c) (formerly 23d(c)) of the EPC, which reflects the Directive, deems certain inventions as being contrary to morality under Article 53(a).

The patent application

In 1995, WARF applied for a patent (EP 0770125) entitled "Primate embryonic stem cells" in respect of methods for maintaining and using such primate (including human) embryonic stem cell cultures. WARF described this process to the EBoA as a pioneering invention by which one of its experts was "the first to successfully isolate and culture human embryonic stem cells that can grow in vitro."

WARF did not apply for a patent for a human embryo nor for the use of a human embryo for an industrial or commercial purpose. Nevertheless, the EPO rejected the application in 2004 on the basis that it involved the use of human embryos, in particular as, at the priority date, the embryos had to be destroyed to produce the stem cell culture. WARF appealed. In March 2008 the Technical Board of Appeal referred a number of legal questions to the EBoA including whether rule 28(c) EPC forbids the patenting of claims directed to products (here: human embryonic stem cell cultures) which – as described in the application – at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said procedures are derived, if the said method is not part of the claims.

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The EBoA's hearing was conducted on 24 and 25 June 2008, prior to which over 160 submissions from third parties were received.

Decision of the EBoA

The EBoA held that the legislators of the Directive and the Implementing Regulations of the EPC intended to exclude inventions such as WARF's from patentability. Therefore it was not necessary for the EBoA to consider issues of morality and whether that standard is to be a European-wide one or not.

Also, technical developments made only after the filing of a claim could not be taken into consideration when assessing that claim. The EBoA said: "lack of any disclosure in the application as filed putting the skilled person in possession of a way to carry out the invention complying with Rule 28(c)… cannot be cured by the occurrence of subsequent technical developments." If it could, there would be legal uncertainty and potential unfairness to anyone else who later provided for an innocuous way to carry out the invention, the EBoA said.

The EBoA stressed that its decision did not cover the patentability of inventions relating to human stem cells or human stem cell cultures in general, but only "inventions concerning products (here: human stem cell cultures) which can only be obtained by the use involving their destruction of human embryos".

Impact

The decision will bind the EPO unless or until the EPC or Directive is amended. Accordingly, the EPO will refuse patent applications for uses of products derived from human embryos which involve their destruction.

As the EBoA stated, the decision concerns a narrow question and the ongoing impact of the decision is questionable given that it is now possible to create human embryonic stem cells without using and destroying human embryos.

Spain

Spain adheres to the criteria established in the report issued by the European Group on Ethics in Science and New Technologies (GEE).

The Directive excludes from patentability elements of the human body, processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and the use of human embryos for industrial or commercial purposes.

These provisions have raised some doubts in the European Commission as to whether stem cells or human germ lines are patentable. The GEE considers both stem cells, and those cell sequences not modified through a laboratory treatment, unpatentable, as they do not have an industrial application. However, the GEE considers patentable "those germ lines modified through genetic or in vitro treatments that confer the same an industrial application". The protection includes processes for the production of these cells, provided that they meet the general requirements of patentability (novelty, inventive step and industrial application).

The most recent case in Spain has been the discovery of and subsequent patent application for a new protein, GSRA2, which is located in the outer part of the membrane that surrounds stem cells, which has helped the researchers to purify stem cells in vitro, and discover how they move without suffering damage.

Poland

Polish law is harmonised with the European Patent Convention and the Directive with regards to the patentability of human embryos. In particular, it expressly excludes from patentability any biotechnological inventions in which human embryos are used for industrial or commercial purposes, because these are seen as breaching public order and morality.

In general, the Polish Patent Office accepts the idea of patenting inventions in which stem cells are used – to illustrate, in 2007 a patent was granted for a method of obtaining stem cells from cord blood (PL 195 516 B1). However, the Office will undoubtedly be influenced by the EBoA's decision and, as a result, inventions involving the use of human embryos for industrial or commercial purposes will not be granted patent protection in Poland.

Patent standards

Intellectual property rights, and in particular patents, are the lifeblood of technology companies. The monopolies conferred by patent rights make research and development economically viable. Without patent protection, innovation would be severely hampered. However, in new areas of technology, patent protection has the drawback that it can prevent competitors from developing interoperable products.

France

Although potential conflicts between patents and standards are important, no specific decision has yet been issued in France.

Some standard bodies have established principles to ensure the disclosure of relevant information. For instance, the national standard body AFNOR provides (as does the CEN and ISO) that essential trade marks and patents shall be declared by the patentee and mentioned within the standard. However, one cannot be certain that the list of declared patents is exhaustive. In order to ensure that a patentee will not abuse his position to impede a competitor from complying with a standard, a system of compulsory licensing may be a solution. There are no specific provisions in the French IP code providing for compulsory licensing in this situation, but, in a software case of 12 July 2005, the Cour de Cassation ordered a compulsory licence to be granted on a provisional basis.

One way of addressing this problem is by the development of patent standards. Typically, patent standards are set by a standard-setting body established for the purpose and consisting of representatives of companies operating in the relevant sector. There are three legally recognised standardisation bodies in Europe, which are the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (Cenelec) and the European Telecommunications Standardisation Institute (ETSI). Member States also have national standards bodies, for example the British Standards Institution (BSI) in the UK. There are also various ad-hoc standards created by informal industry groups.

Inevitably, compliance with the standard will involve the use of patented technology, to the benefit of the proprietors of such patents, who will be able to license the technology to others. Clearly conflicts of interest arise where such patentees also participate in the standard-setting process. To avoid this, members of standard-setting bodies are typically asked to disclose patents they own which they consider to be essential to complying with the standard, and to agree to license such patents to others on fair, reasonable and non-discriminatory, or FRAND, terms.

Standards should, therefore, benefit all parties. Patentees obtain a guaranteed revenue stream; licensees can be sure of accessing patented technology on reasonable terms; and the public benefits from the innovation and interoperability fostered by the standard. However, patent standards raise a variety of complex legal issues, some of which have already been the subject of litigation, and as a result there remains considerable uncertainty in this area.

One problem is that standard setting has the potential to breach competition law. If they were to collaborate to set the terms on which essential patents will be licensed, participants in standard-setting bodies would risk breaching Article 81 of the EC Treaty, which prohibits agreements which may prevent, restrict or distort competition. Further, conferring "essential" status on a patent in relation to a standard instantly gives the patentee a dominant position, as third parties can only gain market access by using the patent. If the patentee abuses that dominant position, it will breach Article 82 of the EC Treaty.

Standard-setting bodies have, to date, tended to address the Article 81 problem by avoiding setting specific licensing terms in advance. They simply specify that the terms must be FRAND, or a variation thereof, and leave it to the parties to negotiate licensing terms. The drawback of this approach, however, is that it relies on the patentee to make an unbiased assessment of whether its own licensing terms are fair. In a recent speech, Competition Commissioner Neelie Kroes referred to this difficulty, suggesting that the inclusion of proprietary technology "may increasingly entail ex ante disclosure of maximum royalty rates". However, she did not make any suggestion as to how the Article 81 problem might be overcome, other than that she would be willing to work with standard-

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setting bodies to address the problem. The failure to set licensing terms in advance, meanwhile, allows patentees to impose conditions on the licensing of their patents that the licensees do not consider to be FRAND, which might constitute abuse of a dominant position, in breach of Article 82. In 2007, the Commission initiated proceedings against US chipset manufacturer Qualcomm, a participant in the setting of 3G standards for mobile telephony, on the basis that their licensing arrangements were not FRAND.

Another issue has been the over-declaring of essential patents. Some patentees take the view that, in a negotiation over standardised technology, the more patents a party has, the stronger a position he is in: my twenty essential patents trump your ten, so the net flow of royalties should be to me. This has led to patents which are not in fact necessary to the standard being declared as "essential", and a royalty being demanded on them. However, because of Article 81 concerns, standard-setting bodies have no mechanism to assess the essentiality, or otherwise, of patents. In *Nokia v Interdigital* [2007] the English High Court dealt with this problem by granting a declaration of non-essentiality in respect of patents previously declared as essential.

Conversely, the failure to declare essential patents (on time or at all) can constitute a breach of Article 82. In 2007 the Commission sent a statement of objections to the US company Rambus, a manufacturer of dynamic random access memory chips. It alleged that Rambus's failure to disclose patents for these products, despite having participated in a standard-setting body that had set a standard to which Rambus's patents were essential, constituted an abuse of a dominant position. In a more recent US case, *Qualcomm v Broadcom* [2008], Qualcomm's failure to disclose its essential patents adequately led to the Court ordering that their patents would be unenforceable against people using them in the context of complying with the relevant standard.

Another potential conflict between patent standards and competition law is the area of patent pools. Patent pools are agreements between patentees to make their patents available to each other for their mutual benefit. A patent pool is an agreement between undertakings, and so has the potential to breach Article 81 by distorting competition within the market. However, Article 81(3) provides for exceptions where the benefits of the agreement outweigh the anti-competitive effects, so, if the patent pool contributes to improving technology to the benefit of the consumer, there may be no competition problem.

Patent standards are becoming increasingly important to industry, and the law in this area will continue to develop. In recognition of this, ETSI adopted new Guidelines for Antitrust Compliance on 27 November 2008. These confirmed that essential patents should be disclosed as early as possible in the standard-setting process, that admission to membership should be based on clear, neutral and objective criteria, and that participation in ETSI should be open.

Bulgaria

The current statute governing national standards in Bulgaria is the National Standardization Act. It introduces the principles of international and European standardization. The Bulgarian Standardization Institute, which is a member of the European Institutions CEN and CENELEC and the international standardization organizations ISO and IEC, administers the Act. In 2008, the Institute adopted 1910 new European standards.

Currently Bulgarian national standards comply with the requirements of 35 EU Directives. At the moment there are no standards that explicitly refer to patents. There are different standards addressing different areas of technology and manufacture, which can be subject of innovations and inventions, including technology, construction, technical security, chemistry, biology and metallurgy. Thus all those standards indirectly apply to inventions in one of those areas that can be given patent protection. According to the Bulgarian National Group of AIPPI there can be conflicts between IP rights and standards. They can arise during the preparation and setting up of the standards and may affect the patent's novelty.

Patentability of software in Europe

The patentability of computer programs in Europe has been a contentious topic for many years, primarily because of the vociferous, conflicting views of, on the one hand, the free software and open source lobby, and, on the other, the software industry. Since the European Parliament rejected the proposed Software Patent Directive on 6 July 2005, prospects of a harmonised EU patent law for computer software appear to have receded.

Bulgaria

According to Article 6(1) of the Bulgarian Patents and Utility Models Registration Act, patents shall be granted to inventions which are new, involve an inventive step and which are susceptible of industrial application. Pursuant to Article 6(2) and (3) of the Act computer software "as such" shall not be patentable.

However, even though the wording of the Bulgarian statute follows that of the EPC, unlike the EPO, the Bulgarian Patent Office has not granted patents to computer programs to date and there is no prospect of it doing so unless the legislation is expressly amended.

Article 52(1) of the European Patent Convention ("EPC"), as amended, provides that patents shall be granted for inventions in all fields of technology, provided that they meet the essential requirements for patentability: that the invention is new, involves an inventive step, has the potential for industrial application and is not within any of the specifically excluded categories of invention set out at Article 52(2). The excluded categories of invention set out at Article 52(2) include mathematical methods, mental acts and programs for computers.

Nevertheless, and contrary to popular misconception, software patents are commonly granted in Europe, provided that they comply generally with the requirements of the EPC. The European Patent Office has accepted more than 30,000 software patents.

The reason for this is that the subject matter and activities referred to in Article 52(2) are not absolutely excluded from patentability. Article 52(2) qualifies Article 52(3) by providing that the subject matter and activities set out in Article 52(2) are excluded from patentability only to the extent to which the invention consists of excluded subject matter "as such". This indicates that computer programs, mental acts and mathematical methods are not excluded from patentability under all circumstances. However, the extent and nature of the "as such" qualification is the focus of contention.

Free software pressure groups argue that the "as such" qualification should be construed narrowly, and that, as a general principle, software should not be patentable. They advance two main legal arguments in this regard: first, that Article 52(2) expressly excludes software; and, secondly, that the algorithms of which source code is composed are just mathematical methods, which are also excluded. Software manufacturers, on the other hand, argue for a broader interpretation of the "as such" qualification.

The excluded matter set out at Article 52(2) consists solely of abstract concepts, which are therefore said to be lacking technical features. On this basis, the EPO Boards of Appeal have concluded that the "as such" qualification is to be taken to permit software having a "technical effect" to be patented.

However, the nature of the required technical effect has been the subject of much debate. It is clear that an invention will not be excluded from patentability merely because it uses a computer program. It is also clear that the use of a computer does not of itself give the invention the necessary technical effect. Nor does an effect on the internal workings of a computer give an invention the necessary technical character. The EPO's Guidelines for Examination now provide that "normal physical effects are not, of themselves, considered sufficient to endow the computer program with a technical character".

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In other respects, however, it has been said that some of the decisions given by the EPO Boards of Appeal on the nature of the required technical effect are contradictory. In order to settle some of the points of uncertainty, Alison Brimelow, President of the EPO, referred a series of questions to the EPO Enlarged Board of Appeal on 22 October 2008. Among the inconsistencies which her referral seeks to resolve are the following:

- Board of Appeal decision T 1173/97 emphasised the necessity for the invention to have a technical character, while T 424/03 appeared to suggest that the presence of a technical character was less important than the need for the claim to be in a specific form, such as "computer implemented method";
- Decision T 1173/97 found that a computer program will be patentable if it has a technical character going beyond the normal technical effects resulting from the involvement of a computer, but decision T 258/03 suggested that, where a claim is phrased as a "computer-implemented method" rather than a computer program, no technical means other than the computer itself are required;
- Decisions T 163/85 and T 190/94 required a technical effect on a physical entity in the real world, while decisions T 125/01 and T 424/03 suggest that the technical effect could be confined to the computer; and
- Decisions T 833/91, T 204/93 and T 769/92 considered that the act of writing a computer program constituted a mental act and was therefore excluded from patentability, while decisions T 1177/97 and T 172/03 indicated that implementing a function on a computer system always involves technical considerations and should therefore not be automatically excluded from patentability.

The Enlarged Board of Appeal has yet to give its reply to these questions. However, when the English patent judge, Lord Justice Jacob, following his decision in *Aerotel* in 2006, requested a similar clarification, it was refused on the basis that the request conflicted with EPC Article 112(b). Article 112(b) provides that the President of the EPO may refer a point of law to the Enlarged Board of Appeal where two Boards of Appeal have given different decisions on that question. Jacob LJ's request was refused because the then President considered that there were insufficient differences between Board of Appeal decisions to justify a reference. However, the cases cited in Ms Brimelow's referral all pre-date Jacob LJ's request. It is therefore possible that the Enlarged Board of Appeal may refuse to consider the referral for the same reason. While proper clarification of the extent to which software may be patented would be welcome, it is therefore doubtful whether the Enlarged Board of Appeal will even consider the referral, let alone whether any decision it makes will provide useful clarification of this murky area of patent law.

France

The patentability of software is also under debate in France. Two recent decisions issued by the Paris first instance courts confirm the patentability of inventions embodying computer programs. First, in a 2005 case, the defendant claimed for the revocation of a patent on the grounds that the patent concerned a computer program "as such". The court held that the patent related to a process which had technical effects and that the fact that this process involved computer programs would not have any consequences on the patentability of the invention, as long as these computer programs were not claimed as such (Tribunal de Grande Instance of Paris, June, 10 2005). More recently, in a 2007 case, the Court of Paris had to consider the validity of a patent related to a device, a process and a computer system for the automatic delivery of discount coupons. The object of the invention was in fact a "computer implemented method". The defendant claimed that the invention did not have a technical effect and merely concerned the files. The court found that the patent did not aim at protecting the files but a computer system, the patentability of which was not discussed (Tribunal de Grande Instance of Paris, November 20, 2007).

Hungary

Pursuant to the Hungarian Patent Act, any novel invention that involves an inventive step and is industrially applicable shall be patentable in any area of technology. However, no patent shall be granted to a computer algorithm, software or idea in itself. Patentability of computer programs shall be restricted insofar as the patent is claimed for them exclusively. In practice, however, if the subject matter of the patent makes a technical contribution to the state of technology, then the software will become patentable in the form of a "computer-implemented invention", provided it complies with the requirements set out in the Patent Act. For example, computer controlled machines and computer controlled production and regulatory processes, and regulatory, controlling or other processes used as the bases of the software, are patentable.

Patents for second medical uses clarified by EPC 2000

The EPC, which was concluded 1973, set out the procedure for the grant of European patents. The EPC is separate from the European Union and has a different membership.

Hungary

In line with the revision of the EPC, the Hungarian law on second medical uses was amended as of 13 December 2007.

The new provisions apply to all patent applications, whether filed before or after the amendment. Applications previously filed in the Swiss form may be amended accordingly.

The amendment is not expected to result in substantive changes in legal practice, in the sense that the scope of protectable inventions will not change. There is also no change as to what criteria may be applied to define the scope of protection; protection only extends to the claimed therapeutic application.

Currently there are 35 EPC members. European patents have the same effect, and are subject to the same conditions, as national patents in the state in which the European patent is granted, unless the EPC provides otherwise.

European patents are generally available for any invention which is new, involves an inventive step and is capable of industrial application. However, there are certain specific exceptions to patentability. These include methods of treatment of the human body.

A key condition for patentability is novelty. An invention is considered to be new if it does not form part of the state of art. Generally, the state of art is held to comprise everything made available to the public, anywhere in the world, by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

However, on occasion new therapeutic uses for known pharmaceutical compounds are identified. As novelty is a condition for the protection of inventions, the question arises as to whether a second medical use is patentable. In 1984 the EPO Board of Appeal held that "it is legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case in which the process of manufacture as such does not differ from known processes using the same active ingredient" (G 5/83 (EISAI)). Here, the Board was following the doctrine of the Swiss Federal Intellectual Property Office, which had accepted applications for second medical uses for some time. For this reason, claims for second medical uses in the form "use of compound X in the manufacture of a medicament for the treatment of Y" are generally known as "Swiss claims".

However, some national courts doubted the legitimacy of Swiss claims. As national courts determine the validity of European patents on the basis of national law, it was uncertain whether Swiss claims were enforceable.

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In November 2000 the EPC was comprehensively revised. The revised EPC – known as EPC 2000 – came into force on December 13, 2007. Article 54 of EPC 2000 expressly provides for purpose-related protection for second medical uses of known substances or compositions.

Under Article 54, it is now clear that new uses of substances and compositions which form part of the state of art shall be patentable provided that:

- the new use of the substance or composition is not part of the state of art, involves an inventive step and is susceptible of industrial application; and
- the substances or compositions are used for a methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.

However, under EPC 2000 further questions have arisen. In 2008 the Technical Board of Appeal considered whether a particular medicament, which is already known to treat a particular illness, can be patented for use in a different therapy for the same illness.

Previous case law concerned only the use of a known medicament to treat a new illness, not the use of a known medicament to treat the same illness by a different therapy. The Technical Board of Appeal therefore referred the following question to the Enlarged Board of Appeal:

"Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented under the provisions of art 53 lit c and art 54 para 5 EPC 2000 for use in a different, new and inventive treatment by therapy of the same illness?" (T 1319/04)

The proceedings before the Enlarged Board of Appeal are still pending. The Board's decision is eagerly awaited.

Russia

Russia is not a member of the EPC and under the patent law adopted in 1992 it was possible to patent an invention for a second use of a known invention. Accordingly, second medical use patents were allowed. In 2003 Russian patent law was amended to exclude the wording upon which second medical use patents relied. This resulted in uncertainty as to whether second medical use patents were permitted.

Unfortunately, the replacement of the patent law by Part IV of Russian Civil Code in 2008 has not brought any clarity to this issue. As under the EPC, an invention is provided with legal protection if it is new, has an inventive step and is susceptible of industrial application; however in Russia there are no exceptions for methods of treatment of the human body. The current practice remains controversial and unclear and requires legislative clarification.

A unified European patent system: where are we now?

Discussion of a unified European patent system involves consideration of proposals both for a unitary Community Patent and for a unified court system for the existing European Patent.

Belgium

Belgian practitioners have expressed their preference for a regime similar to the Community trade mark system, with limited territorial effect. That system provides for a flexible and balanced solution. The basic rule must remain that the courts of the defendant's domicile have jurisdiction as regards the infringement, but the claimant may exercise limited forum shopping in the countries where the infringement takes place and may select a jurisdiction where, for example, it may have more confidence in the local court. This limited territorial effect gives a reasonable restriction on forum shopping and balances protection of the defendant with protection to the claimant in the countries where the infringement takes place. The solution should also reflect the need to harmonise the law of infringement.

Even if the draft Agreement on the European Patent Court provides for unified substantive law, some important issues remain uncertain, for example the doctrine of equivalents. It would be preferable for there to be legislation on these points, rather than having to wait for future case law before patentees and possible infringers know what the legal landscape will be.

Background

The Community Patent, as proposed, would allow individuals and companies to obtain a unitary patent throughout the European Union. However, although a Community Patent was first proposed as long ago as the 1970s, at least three separate attempts to introduce it have failed. Most recently, renewed efforts from the European Commission resulted in a Community Patent Regulation proposal in 2000, which failed due to insoluble disagreements regarding the translation requirement and the priority to be given to the various translations in the event of inconsistencies between then. The proposal for the creation of a unified Community Patent judiciary was criticised for its overly centralised jurisdiction, which caused concern because of the perceived need for infringement proceedings to take place close to the place of infringement. There was also criticism that the proposal did not consider the creation of a judicial system for the European Patent.

The European Patent Convention (EPC) only harmonises the application, granting and opposition process for European Patents. Once a European Patent has been granted, it takes effect as a bundle of national patents in the designated states. Infringement and invalidity claims regarding the national patents must be filed before the relevant national courts. The enforcement of national patents originating from a European Patent in different member states is therefore expensive and creates the risk of inconsistent decisions. For this reason, a working party on litigation was set up in 1999 to propose an optional convention on the creation of a centralised judicial system for the European Patent. The working party published a draft for a European Patent Litigation Agreement ("EPLA") in November 2003. However, the EPLA draft was also eventually abandoned because some EPC contracting states, also being members of the European Community, objected to the creation of a new independent jurisdiction outside the European Community framework.

Recent developments

The debate about the Community Patent and a European Patent Court system was reopened by the European Commission in January 2006 when it started a public consultation on "how future action in patent policy to create an EU-wide system of protection can best take account of stakeholders' needs". The results of this consultation were summarised in a white paper entitled "Enhancing the patent system in Europe". The white paper identified an urgent need for a Community Patent. To avoid unnecessary costs and inconsistent decisions, the white paper proposed a centralised patent judiciary, which would deal with litigation on both the European Patent and the proposed Community Patent. The European Commission stressed that consensus could be built on the basis of an integrated approach which combined features of the EPLA and the proposal for a Community Patent. In 2008, there was a proposal for the use of automated translations to solve the language issue,

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which has been partially responsible for blocking progress on the Community Patent. The Slovenian presidency of the Council of the European Union brought forward a draft law regarding the European Patent Judiciary based on previous work of the Portuguese and German presidencies.

The current proposal for a European Patent Court system includes a Community Patent Court, which would also be competent for European Patents to the extent that EPC contracting states wished to join the system. A convention under Article 300 of the EC Treaty would be required to implement this proposal.

The required next step is to refer a question to the European Court of Justice as to whether the proposed European Patent Court system complies with the EC Treaty insofar as it would have jurisdiction also with respect to the future Community Patent. Originally, it was envisaged that the ECJ would reply during the Swedish presidency of the Council, which will be in the second half of 2009, but this timeframe now appears unlikely to be met, and a further delay is to be expected.

Open issues

Discussions about the creation of a European Patent Court for both the European Patent and the future Community Patent have made some progress recently. However, there are important questions still not resolved.

The legal authority of automated translation is uncertain. Further, the future role of national patent offices in the examination and grant of a future Community Patent is currently dominated by the idea of "work sharing". This, however, creates the risk of a fractured examination process and potential competence conflicts, though one solution would be to delegate examination of Community Patents, as well as European Patents, to the EPO. Finally, there is still the unsolved question of how the maintenance fees will be allocated between member states.

With regard to the European Patent Court system, it remains unclear whether the validity of the patent should be considered in the course of infringement proceedings or through a separate invalidity claim, during which the infringement proceedings would be stayed. There are also concerns about the quality of foreign and/or technical judges and, thus, the workability in practice of multinational local chambers. Also, the question of which language the proceedings will be conducted in has not been resolved. Finally, the competence and role of the European Court of Justice is still open.

Although the European Commission has now asked the Council for authorisation "to open negotiations for the adoption of an agreement creating a unified patent litigation system", there still appear to be considerable obstacles on the road to a European Patent Court.

France

French authorities are in favour of the Community Patent and the European Patent Court. Accordingly, France ratified the London Agreement of 17 October 2000 which relaxed the rules regarding the translation of European patents. Moreover, during the French presidency of the EU, the Minister of Justice declared that the French government was determined to continue the work already commenced regarding the Community Patent and a unified system for patent litigation.

However, the European Patent Court is likely to increase the cost of patent litigation in France. A study by the EPO regarding the European Patent Court shows that the cost of patent proceedings before the French courts is between €50,000 and €200,000, but that the same proceedings before the European Patent Court are expected to cost between €90,000 and €400,000. Nevertheless, the study demonstrates that the European Patent Court will provide a cost saving on patent proceedings in more than one country.

Poland

In 2005, the Polish government accepted EU proposals for a Council Decision conferring jurisdiction on the European Court of Justice in disputes relating to the Community Patent, justifying its decision by saying that a centralised patent judiciary would lead to unitary rulings and would enhance the reliability of patent protection. According to an opinion on the proposed Community Patent system, which was prepared in 2008 at the request of the Polish Ministry of Economy, there are no strong arguments against the current EU proposals. Establishment of a centralised court system will lead to significant savings (in particular for SMEs) and will avoid inconsistent rulings being given on the same facts by different national courts.

At present, there are no specialised IP courts in Poland. Protection of industrial property rights is divided between the Polish Patent Office and the administrative and civil courts. The European debate regarding creation of a European Patent Court will inevitably also increase debate in Poland on the creation of a specialised industrial property rights court, which has been the subject of ongoing discussions over the past few years.

Stretching the monopoly: supplementary protection certificates

Under EU Regulation n°1768/92 (the SPC Regulation), supplementary protection certificates (SPCs) may be granted to holders of patents relating to medicinal products for which marketing authorisation has been granted. The purpose of an SPC is to extend the duration of patent protection for a medicinal product to reflect the loss of part of the period of patent protection caused by the often lengthy process of obtaining marketing authorisation for a new medicinal product.

Italy

In 2007, the Court of Rome confirmed the legitimacy of new legislation providing for the maximum term of Italian SPCs to be progressively reduced from 18 years, as it was previously, to five years, in accordance with the SPC Regulation.

The Italian SPC term reduction was introduced, and has now been confirmed, despite the objections of the pharmaceutical industry. It is expected to facilitate the entry of generic medicines on to the Italian market.

Scope

Subject to certain conditions, an SPC is available for any active ingredient or combination of active ingredients of a medicinal product protected by a patent in the territory of a Member State of the EU, which, prior to being placed on the market as a medicinal product, was subject to an administrative authorisation procedure.

The ECJ has ruled that "product" must be interpreted strictly to mean "active substance" or "active ingredient". "Product" therefore does not include a method of use of an active ingredient protected by a basic patent.

An SPC may be granted if, in the Member State of the EU in which the application for the certificate is submitted, and at the date of the application:

- the product is protected by a patent in force;
- a valid authorisation to place the product on the market as a medicinal product has been granted;
- this authorisation is the first authorisation to place the product on the market as a medicinal product; and
- the product has not already been the subject of an SPC.

Subject matter of protection

The protection conferred by an SPC extends only:

- to the product covered by the authorisation to place the corresponding medicinal product on the market; and
- for any use of the product as a medicinal product that has been authorised before the expiry of the SPC.

Accordingly, an SPC is not available for any medicinal product for which the patentee did not obtain a marketing authorisation.

In case C-202/05, the ECJ ruled that in a case where a patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product, and consequently that an SPC will not be available for that patent.

The ECJ has however held that, where a product in the form referred to in the marketing authorisation is protected by a patent in force, the SPC can cover that product in any of the forms in which it enjoys the protection of the patent.

This issue still remains unclear since Patent Offices and national courts may have their own practices. This may mean that SPC applications filed in various Member States may be granted in some but rejected in others.

Therefore, despite the ECJ's role in the interpretation of the SPC Regulation, the European SPC system is not fully harmonised.

By Jean-Guillaume Monin (CMS Bureau Francis Lefebvre)

Once granted, an SPC confers the same rights as conferred by the patent and is subject to the same limitations and obligations.

Duration of SPCs

An SPC takes effect at the end of the patent term. It continues for a period equal to the period between the date on which the patent was filed and the date on which marketing authorisation was granted, less five years, provided that the total duration of the SPC may not exceed five years.

The duration of the SPC may be extended by six months where the application includes the results of studies conducted in compliance with an agreed paediatric investigation plan. However, the duration of the SPC may be extended only once.

Application for an SPC or an extension of its duration

The SPC application must be lodged within six months of the date on which the marketing authorisation was granted. Where the marketing authorisation is granted given before the patent is granted, the application for an SPC shall be lodged within six months of the date on which the patent is granted.

An application for the extension of an SPC may be made when lodging the application for the SPC or when the SPC is pending and the appropriate requirements have been fulfilled. Such application must be lodged not later than two years before the expiry of the SPC.

The SPC application must be lodged with the competent industrial or intellectual property office of the Member State which granted the patent or on whose behalf it was granted and in which the marketing authorisation was obtained, unless the Member State designates another authority for the purpose.

The application for an extension of the duration of an SPC must be lodged with the competent authority of the Member State concerned.

Notification of an application for an SPC or for an extension of the duration of an SPC, and the fact that an SPC has been granted, shall be are published by the Authority in charge, in each Member State, of the grant of the SPC.

Germany

The ECJ decision in case C-202/05 has been criticised in Germany. It has been argued that the exclusion from SPC protection of patents for second medical uses of active ingredients is inconsistent with the purpose of the SPC Regulation and with recitals No. 13, 14 and 17 of EC Regulation No. 1610/96 (the Plant Protection Products SPC Regulation).

According to recital 13 of the Plant Protection Products SPC Regulation, an SPC protects not just an active substance but also, where the basic patent covers both, the substance's various derivatives (salts and esters). However, under recital 14, other SPCs may be granted for derivatives of the substance if such derivatives are the subjects of other patents. This becomes relevant when a derivative has unforeseen characteristics. In that situation, the derivative is treated as a new "active substance" that can be independently patented and covered by an SPC. On that basis, it is argued that SPCs should also be available for patents for second medical uses. It is further argued that allowing SPCs for second medical use patents would be consistent with the objectives of the SPC Regulation. Placing a new medicinal product on the market requires a new marketing authorisation, even if that product is a new use of a previously known compound. Obtaining that marketing authorisation still requires investment in research and causes delays to commencing marketing, which reduce the effective life of the patent. This, it is said, justifies the grant of an SPC in these cases too.

Russia

Russian IP legislation does not provide for a concept of an SPC as a separate title of protection. However, it is possible to extend the term of a patent itself, if the patented product is a medicine, pesticide or agrochemical substance the entry on to the market of which was delayed because of the need to obtain marketing authorisation. The patent extension procedure and the nature of the extension is similar to the rules on SPCs.

In October 2008, new Administrative Rules on patent term extension were adopted. It is expected that these rules, when they come into force, will simplify the patent extension procedure.

The experimental use defence to patent infringement

The European Patent Convention (EPC) provides that the rights conferred on the proprietor of a European patent shall, in each EPC contracting state, be the same as the rights conferred by a national patent in that state. Accordingly, the scope of rights under European patents, and exceptions to infringement, are not stipulated by the EPC but are governed by national law.

Germany

Section 11 No.2 of the German Patents Act (PatG) transcribes Article 27(b) of the CPC. This provision does not cover experiments that merely use a patented product such as a research tool. However, apart from that, Section 11 No.2 PatG is construed broadly by German jurisprudence. In particular, the provision also extends to experimental uses that aim to find additional applications for known products, particularly pharmaceuticals. Also excepted are experiments with the goal of collecting data needed to obtain regulatory approval for a tested pharmaceutical. On the other hand, experiments conducted to an extent not justified by experimental purposes, or aimed at effectively impeding the distribution of the patent holder's product are not excepted. The reason is that such experiments do not serve technical advancement, but are rather used as means for competitive purposes.

In addition, Section 11 No.2(b) PatG excepts experiments, including studies as well as practical procedures, which are necessary for obtaining regulatory approval. The provision transcribes Article 10(6) of the Directive and is supposed to permit producers of generics to conduct the necessary steps to obtain regulatory approval even before the patent has expired.

Although use of a patented invention is generally an infringing act, nearly all national patent laws in Europe provide for an exception for experimental use.

Although the Community Patent Convention (CPC) never came into force, these national provisions transcribe, almost word for word, Article 27(b) of the revised 1989 draft of the CPC. This provides that "rights conferred by the patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention".

This exception is necessary to ensure that technical and scientific research and developments are not unduly impeded. It is unclear whether this provision is to be regarded as a restriction on the exclusive rights of the patentee or as an exemption providing a defence in an infringement case.

The scope of the experimental use exception remains uncertain. Concerns have been raised regarding its application. The aim of the experimental activity will usually be the essential factor in determining whether the use falls within the exception. Courts also consider whether the objective of the experiments is to make new discoveries regarding the subject matter of the invention or merely to find a new application for an existing technology. They also consider the commercial objectives of the act. A distinction is also often made between experiments "on" a patented invention and experiments "with" the subject matter of the invention referring to the issue of research tools, being experiments where the patented invention is used as a research tool to make other investigations. There are, therefore, also concerns regarding how this experimental use exception applies to research tools.

Case law is not consistent throughout Europe, and national courts have come to different conclusions on these issues. In particular, some courts take a liberal view of the exception while other countries interpret it narrowly.

Judicial consideration of the experimental use exception in European countries has mainly arisen in connection with pharmaceutical patent disputes. One of the main questions has been whether tests or clinical trials aiming at the grant of marketing authorisation may be conducted during the patent term.

If clinical trials do not fall within the exception, this will delay the entry of a generic product to the market. However, clinical trials for the purpose of obtaining marketing authorisation are evidently not carried out only for the progress of scientific research but also have clear commercial purposes.

By Solène Vilfeu (CMS Bureau Francis Lefebvre)

Directive 2001/83/EC on the community code relating to medicinal products for human use (the "Directive"), as amended by Directive 2004/27/EC, was intended, among other things, to clarify the status of experiments done in the process of obtaining marketing authorisation.

Article 10(6) of the Directive provides that conducting the necessary studies and trials to take advantage of the accelerated process for obtaining marketing authorisation for a generic of a reference medicinal or biological product shall not be regarded as contrary to patent rights or supplementary protection certificates for medicinal products. However, this exception does not apply to studies conducted for obtaining marketing authorisation for a new indication for a well-established substance (Article 10(5)) or new combination (article 10b).

EU Member States were required to implement the Directive by 30 October 2005 at the latest. As with all EU directives, national authorities chose the form and method by which the Directive was implemented into their national law.

Although the general principle of the experimental use exception is now established, its implementation may be inconsistent between Member States. Indeed, the wording of Article 10(6) invites inconsistent interpretation, as the Directive does not define terms such as "necessary studies and trials" and "practical requirements".

European countries are concerned about these different treatments of the exemption and consistently try to narrow down the differences that might exist between national laws. As a result, there have several recent reviews in European countries such as in Switzerland and Belgium. In other countries, such as the UK, consultations have been made with the aim of improving the functioning of the IP system and of achieving further international harmonisation of the experimental use exception.

UK

Section 60(5)(b) of the Patents Act 1977 provides: "An act, which, apart from this subsection, would constitute an infringement of patent for an invention, shall not do so if… it is done for experimental purposes relating to the subject-matter of the invention".

This exception has been interpreted narrowly. The UK Courts have ruled that it does not protect:

- trials carried out with a view to securing regulatory approval; and
- use of the subject matter of the invention as a research tool.

However, tests or trials that have a collateral commercial aim are allowed provided that they are otherwise experiments.

The UK Intellectual Property Office (UKIPO) has been undertaking a consultation to examine the effect of these provisions and identify stakeholder concerns with a view to seeking practical solutions to any significant concerns. UKIPO has indicated that its report will be published later in 2009.

EC pharmaceutical sector inquiry

On 8 July 2009, the European Commission (DG Competition) presented the results of its pharmaceutical sector inquiry under the EC competition rules. This had been preceded, in November 2008, by a preliminary report which attracted widespread attention for its severe criticism of the originator industry. It is notable that, in its final report, the Commission has significantly softened the tone of its criticisms.

However, in its final report the Commission has confirmed its preliminary view that some originator companies' patent practices are anticompetitive and indicated that it intends to step up antitrust enforcement in the industry. The Commission identified a portfolio of strategies, a so-called "tool-box", used by originator companies to delay or block market entry of generic products.

Patent clusters and filing of divisionals

The Commission found that originator companies develop strategies to extend the scope and duration of their patent protection by filing numerous patents for the same products, known as "patent clusters" or "patent thickets", before the main patent covering a drug expires. The final report stresses that patents are to be evaluated by the statutory criteria for patentability, but nonetheless confirmed the Commission's finding that an important objective of this approach is to delay or block the market entry of generics. The report noted that the number of pharmaceutical-related patent applications before the European Patent Office almost doubled during the period 2000-2007 and that blockbuster medicines are protected by up to 1,300 current or pending applications within the EU. It also said that documents obtained from originator companies indicated that they were aware that some of their patents might not be strong.

Another instrument that originator companies use, according to the Commission, is the filing of divisional patent applications, allowing the applicant to split an initial parent application. The underlying concern is that examination of divisional applications may continue even if the parent application is withdrawn or revoked, leading to legal uncertainty for generic companies.

Patent litigation

The Commission expressed a general concern about what it considers to be excessive patent litigation. There has been a four-fold increase in patent cases between 2000 and 2007. Generic companies won the majority of cases in which a final judgment was given (62% of total, rising to a 71% success rate in cases brought by the generic company). Although in its final report it stresses that enforcing patents in court is legitimate and a fundamental right, the Commission was concerned that litigation may be being used not on its merits, but as a signal to deter generic entrants, noting that the average duration of cases is 2.8 years. Generic companies won 75% of oppositions before the European Patent Office, but almost 80% of these procedures took more than 2 years.

By Rogier de Vrey (CMS Derks Star Busmann)

Settlements

The report suggested that patent litigation settlements between originator and generic drug companies are often made to keep generic companies off the market. A significant proportion of these settlements involve a value transfer (i.e. direct payment or a form of licence, distribution agreement, or "side deal" in exchange for dropping challenges against the patent).

Interventions before regulatory bodies

The Commission observed that some originator companies have interfered in generic applications for marketing authorisation and pricing and reimbursement status at a national level, by questioning the safety and quality of generic medicines in comparison with the equivalent branded product. The Commission noted that such "patent linkage" conflicts with EU law. When these patent-related matters resulted in litigation, the claims of the originator companies were upheld in only 2% of cases.

Second generation products

The Commission found that originator companies launched second-generation medicines in relation to 40% of products that lost exclusivity between 2000 and 2007. They invested large amounts in marketing, intending to convert patients to the new second-generation medicine before the generic equivalent of the first generation product appeared on the market. The Commission noted that some stakeholders questioned the actual improvements to therapeutic benefits delivered by certain categories of changes to product formulations.

Competition between originator companies

In addition to the effect of these strategies on generics, the report also looks into the relationship between originator companies. The Commission observes that some originator companies use defensive patent strategies, which consist of filing patent applications with the main purpose of frustrating advancement of competing medicines by rival originators rather than of protecting the exclusivity of drugs to be developed based on the patent.

France

In France, as in other EU countries, there is tension between intellectual property rights and competition law, especially in the pharmaceutical sector.

Using the monopoly conferred by their patents and sometimes their dominant positions acquired during the term of the patents, originator companies often attempt to delay or block the entry of generic drugs to the market. Several uncompetitive practices have been punished by French Courts (C.Cass 13/01/09 Schering-Plough vs. Arrow Generiques), such as defamation against generic drugs combined with unfair business conditions such as stock saturation, direct selling, more favourable payment deadlines for pharmacies and tied sales. However, predatory activity by a dominant party, can only be punished on objective criteria, such as its effects on other market participants (C.Cass 17/03/09, GlaxoSmithKline). Thus, unfair practices could constitute an abuse of dominant position.

Nevertheless, the simple fact of registering and defending patents is not abusive in itself, unless systematic practices are carried out intentionally to block the market entry of competitors (Cons.Concurrence. 21/09/01).

If generic companies prove abuse by originator companies, penalties on the originaotr company can include fines, publication of the court decision and obligatory licensing.

Poland

Generic products make up a significant proportion of the Polish pharmaceutical market, as a result of which the position of innovator companies is not as strong as in Western Europe. It is therefore unusual to hear of innovator companies seeking to delay or block the introduction of generic products on the Polish market by anticompetitive methods.

If such acts were to take place, the Polish antimonopoly authority, the Office of Competition and Consumer Protection, would be likely to intervene. In the context of IP rights, the Office has issued decisions against Polish copyright management organisations for anticompetitive behaviour such as abuse of a dominant position. In such cases, the Office can impose a financial penalty of up to 10% of the revenue earned by the infringer in the year preceding the year in which the penalty is imposed.

Hungary

The so called "tool-box" is not the main focus of the Hungarian Competition Authority (HCO). The HCO has instead focused on the pharmacy liberalisation project. In Hungary, some pharmaceutical products may not only be purchased in pharmacies but also in other outlets, such as petrol stations and health and beauty stores. The HCO examined why certain manufacturers did not permit the distribution of their products via outlets other than pharmacies, even though such products fulfilled the criteria for wider distribution. However, although the HCO suspected that this might be due to an anticompetitive agreement, it in fact found no breach of competition regulations.

With regard to generic products, Hungary has implemented a generic program favouring the cheaper generic products within the social security system. As a result, the number of new originator products has significantly decreased, leading to reduced competition and to a limited choice of novel treatments for patients. To address this, it is intended that savings realised through the preferntial use of generics would be invested in R&D for new innovations. However, it is as yet unclear what the long-term effects on the market will be.

Conclusions

The final report's conclusions are grouped in four main areas:

- **Competition law scrutiny and enforcement** - This will continue. Specific competition infringement proceedings will be opened on a case by case basis, and some are already underway. The Commission will monitor settlements which limit generic entry and include a value transfer from the originator to the generic company.
- **Patent framework** - Stakeholders generally accept the need for a Community Patent and a unified specialised patent litigation system in Europe to simplify and accelerate patent grant and enforcement. Initiatives by the European Patent Office to ensure a high quality standard of patents granted and to accelerate procedures were also supported.
- **Marketing authorisations** - The Commission wishes to see full and effective implementation and enforcement of the current regulatory framework. National competent authorities should respect time limits, a factor which can benefit originators when first seeking approval and generics when seeking to launch a copy. The Commission wishes to discourage vexatious third party submissions in marketing authorisation procedures and particularly wishes to ensure that allegations of intellectual property infringement are excluded from the process.
- **Pricing and reimbursement** - The Commission invites Member States to consider automatic pricing and reimbursement mechanisms for generic products. Third party submissions on patent, bioequivalence and safety issues should not be taken into account by competent authorities at this phase. Member States should respect existing procedural time limits in this area and exchange best practice on generic policies.

To some extent the final report is a retreat by the Commission's competition directorate, with its enthusiasm curbed by other Commission services. Clearly the Commission as a whole is better informed about the challenges faced by originator and generic companies. The competition directorate in particular seems to recognise that the originator/generic debate cannot be seen simply in competition law enforcement terms but also depends on the detailed implementation of the patent and regulatory systems. In other words, change needs to happen in areas where the Commission has no direct powers.

But overall the Commission can rate the pharmaceutical inquiry as a success. Right or wrong, it has succeeded in giving prominence to the originator/generic debate and has had the almost undivided attention of the pharmaceutical industry globally for the last 18 months. It can be expected that the Commission will try to maintain this profile when pursuing the four main areas which it has identified.

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