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Patenting in the Pharmaceutical Field: First and Second Medical Use for Biologicals	Dr. Ute Kilger, Patent Attorney, Vossius & Partner
Covering Liability Issues in Clinical Trials	Dr. Jan Dirk Heerma, Partner, SJ Berwin LLP
Introducing the UK Clinical Research Network - Clinical Trials with the UK National Health System	Prof. Dr. Richard S. Kaplan, Associate Director, UK Clinical Research Network
Study Design and IP – Important Factors for Successful Licensing	Dr. Peter Hug, Global Head of Pharma Partnering, F. Hoffmann-La Roche AG (enquired)
Prolonging IP's Life Span – Data Protection SPCs and the Law of Pedriatic Use	Dr. Christian Kilger, Patent Attorney, Vossius & Partner
Efficient Clinical Trials – Lessons learned	Dr. Wolfgang Söhngen, CEO, Paion AG (enquired)
Closing Remarks	Dr. Hans-Rainer Jaenichen, Partner, Vossius & Partner

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BIOCOM Projektmanagement GmbH | Brunnenstraße 128 | 13355 Berlin | Germany
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IP

New patent law – the EPC 2000

Dr. Christian Kilger & Dr. Ute Kilger, Patent Attorneys Vossius & Partner, Berlin

The European Patent Convention (EPC) 2000 will come into force on 13 December, 2007. When the London Agreement also goes into force at the beginning of next year, many changes will take place in European Patent Law. What this means for patent applicants will be discussed in this article. The present "collection of laws/statutes", the so-called European Patent Convention (EPC) including Articles and Rules, supplemented by jurisdiction, was heavily revised at a diplomatic conference in November of 2000. The revised EPC that is coming into force at the beginning of December 2007 has so far been ratified by 24 member states. States which did not ratify the new EPC – and as a result are no longer members of the EPC – include France, Italy and Germany. There is no reason to assume that this will not change. The object of the revision was to increase the efficiency, flexibility and user-friendliness of European patent systems, as well as to encourage deregulation and adjustment to existing treaties such as TRIPS and PLT 2000.

The EPC 2000 represents the introduction of a central limitation and revocation procedure. The patent holder is given the option to limit or withdraw his/her own patent. What would be the point in that? Here an example: a patent holder wants to sue a competitor for patent infringement. Recently, however, he searched the state-of-the-art in his field and discovered that his patent claim is not new over its entire scope. In order to own a legally valid patent, he would have to limit his patent claim to subject matter that is new and not obvious over the state-of-the-art. One might say now that in the nullity suit that could be expected from such a scenario, the patent may be limited as well. The problem in this case is that, if the patent holder sues the alleged infringer without limitation, he is actually strengthening the position of the alleged infringer, as the reply is usually in the form of a nullity suit to destroy the patent of the adverse party. The alleged infringer has therefore been given greater power. In Germany, the key phrase is "state-of-the-art prejudicial to novelty". In the case of infringement, the alleged infringer will file a request for suspension of proceedings with the Regional Court, and in the nullity proceedings before the Federal Patent Court, he will attack the patent's novelty. Thus, ideally, the plaintiff would like a patent "without deficiencies". With the EPC 2000, the patent owner is able to "repair" his patent. Another example is the "notorious" Edinburgh Patent comprising the claim "animal transgenic stem cells including embryonic stem cells". There was a heated discussion surrounding the question of whether the English term "animal stem cells" also includes human stem cells, and therefore also human embryonic stem cells and their modification or use. The latter should not be patentable. Let's assume that by granting the patent, the examiner made a mistake, since human embryonic stem cells were comprised by the patent. It would have been much simpler if, upon realisation of the mistake, the patent holder could have had the option of repairing his deficient patent. However, not only were the patent holder's hands tied - there was no way the Patent Office could correct the mistake either. The resulting spectacular opposition proceedings ended up being used by political groups to discuss the question of stem cell research. In future, the patent holder would have the opportunity to limit proceedings by introducing the word "non-human", thus limiting his own claim.

Patentability

EPC 2000 also strengthens protection for medical indications, namely by the introduction of purpose-limited product protection for medical indications.

Let us be clear: an absolute protection of products in medicinal use will, of course, continue to exist. In other words, if a completely new substance is found which, as a medicinal product, is suitable against disease X, then said substance per se can be protected for any use, including non-medicinal use. Purpose-limited product protection for medicinal indications will be available in addition to absolute product protection. An example: let's assume that substance X was known to be an effective medicinal product against disease X. Later, the producer discovers that this substance is also suitable as a medicinal product against disease Y. Up until now, because therapeutic methods were excluded from patentability, only the following claim could be granted: "Use of substance X for the production of a medicinal product for the therapeutic use against disease Y". When defending said claim against a third party in court who, despite a standing patent on this medicinal product for the therapy of disease Y, was selling same, patent holders have had serious problems in some European countries – including France. Now with the EPC 2000, the patent holder is granted protection for "substance X for the treatment of disease Y". It is to be expected that clear prod-

European Patent Office in Munich

uct claims like these are defended more easily and will be accepted in all European countries.

Further processing

If time limits are exceeded, an application may be "lost". In principal, revival is possible by means of two methods: further processing and re-establishment. Further processing of a patent is relatively uncomplicated; the omitted act is completed, a small fee is paid, and a letter is written requesting further processing. Unfortunately, up to now, further processing was only admissible in connection with few time limits. Now the possibility for further processing has been extended to a large number of time limits, facilitating the revival of an application for the applicant. "Re-establishment", however, is difficult to obtain. It requires the submission of statutory declarations by patent attorneys' assistants stating that they omitted time limits, notwithstanding many years of experience and excellent training, and despite the patent attorney's control. Even if pursued, these measures are not always successful. One should bear in mind that a strict observance of all time limits despite the possibility of further processing is always a preferable scenario, since further processing can be expensive.

It will also be possible, one year after the filing of the initial application, for example, in Germany or in Europe, to file a patent application effective throughout the entire world while claiming the earlier initial priority date. Up to now, this was no longer possible if you had missed the time limit the first time around. Priority date was the most fatal of all time limits. Now, according to the new European Patent Convention 2000, at least re-establishment (cf. above) is possible within a term of two months. One must bear in mind, however, that even under the EPC, a missed priority date should be avoided at all costs. Re-establishment is not easily obtained.

European patent at low cost

A European patent application is examined in a central grant procedure by the European Patent Office, and the patent is granted if all patentability criteria are met. Once the patent has been granted, any person can file an opposition with the EPO within nine months after the patent has been granted. After the patent is granted the patent "falls apart into" individual national patents – into a German part, a French part, a British part and so on. At present, for every country in which the European patent enters the national phase a translation has to be filed. This involves very high costs. In March 2007, Malta became the 32nd member state of the European Patent Convention. If protection were sought for all thirty-two European countries, the patent would have to be translated into all of these national languages. With average costs amounting to €3,000 for a patent application of average size, 20 countries would mean translation costs of €60,000. The London Agreement, a convention based on the free consent of the member states, eases the translation requirements considerably. The countries signing the Agreement will no longer demand a translation of the complete European patent. Only claims will have to be translated into the national languages, while translation of the description will no longer be necessary. This will reduce translation costs considerably. Despite the London Agreement having been decided upon in 1999 and amended in 2000, it is not yet in force. To date, the following states have signed the Agreement: Germany, Great Britain, The Netherlands, Switzerland, Iceland, Latvia, the Principality of Liechtenstein, Monaco and Slovenia. The parliaments of Sweden and Denmark have also already ratified the Agreement. Thus, the London Agreement will probably come into effect before long in twelve of the thirty-two countries of the European Patent Organisation. France has been hesitant to sign the Agreement for years, but in November 2007, the French parliament voted to sign. If the ratification of the London Agreement were to follow at the beginning of next year in France, it would come into effect three months later. Let's hope that further countries will also enter into the agreement.

Conclusion

The patent procedure will hopefully become more effective, less expensive and more flexible through the changes described, as well as through further changes the new European Patent Convention will bring about. This is particularly important for medium and small-scale enterprise applicants, which will then no longer refrain from filing a European patent application simply because the costs are too high.