published by B5 srl
Via Cesare da Sesto, 10
20123 Milano - Italy
Tel. 0039 02 83241119
Fax 0039 02 8376457
www.b5srl.com

The new European Patent Convention: How might it affect the pharmaceutical industry?

ROBERTO PISTOLESI

Dragotti & Associati
Via Turati 32
20121 Milano, Italy
Tel +39 02 29014418
Fax +39 02 29003139
pistolesi@dragotti.com
www.dragotti.com

On December 13, 2007, the new European Patent Convention, i.e. the so called EPC 2000 (1), entered into force. All 32 current EPC contracting states have now acceded to the Convention, together with Norway and Croatia, which are due to join the EPO on 1 January 2008

By using the same expressions of the European Patent Office (2) itself, the EPC 2000 was originated by several factors, namely:

- *the alignment of the former convention (3) with the GATT TRIPS and with the Patent Law Treaty;*
- *a judicious modernisation of the European patent system;*
- *enhancing flexibility and deregulation;*
- *meeting users' needs and expectations;*
- *streamlining the procedures and mastering the EPO's growing workload.*

This resulted in several major and minor changes which have been introduced both in the Convention and in the related Implementing Regulations (4). In the present article I will not comment each single change in details – the whole *Pharmachem* magazine wouldn't have enough space for such a purpose...– but I will focus on those changes which, in my opinion, might have a direct or indirect impact on the pharmaceutical industry and, more in detail, on those aspects of the pharmaceutical industry which are somehow connected to Intellectual Property (5).

The first great change relates to the methods for treatment of the human or animal body by surgery or therapy and to the diagnostic methods practised on the human or animal body. In the former convention, i.e. in the EPC 1973, such methods were originally excluded from patentability by virtue of Art. 54(2); that is, by the "fiction" of their lack of industrial applicability, since the article expressly recited that those methods *shall not be regarded as inventions which are susceptible of industrial application*. In the new EPC 2000 those provisions have been transferred to Art. 53(c), which now more simply recites that European patents *shall not be granted in respect of* .... such methods.

This is apparently only a "cosmetic change", which should not affect the protectability of 2nd therapeutical uses, but which has the purpose of making clear the real reasons for such exclusions, namely the interest of public health, and not their alleged lack of industrial application.

The real and not only "cosmetic" change has been introduced in new Arts. 54(4) and 54(5): as a matter of fact, new Art. 54(4) provides for the *patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Art. 53(c)* whereas new Art. 54(5) provides for the *patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Art. 53(c).*

This means that the new EPC 2000 eliminates any legal uncertainty on the patentability of 2nd or further therapeutical uses since it unambiguously permits purpose-related product protection for each further new therapeutical application of a substance or composition already known as a drug. Apparently, this new type of protection is essentially equivalent to that formerly afforded by the so-called "Swiss type" claim (6); however, it clarifies that the protection covers the way the claimed substance or composition would be used and it is not affected by whether, how and where the related pharmaceutical composition would be manufactured.

As a matter of fact, the wording formerly accepted for the "Swiss type" claim was *use of compound X for the* ***manufacture of a medicament*** *(7) for the treatment of disease Y*; on the contrary, the wording

which will be accepted after the entry into force of the EPC 2000, that is since December 13, 2007, will be *compound X for treating disease Y* – although the former wording will still be accepted.

As it shall be easily appreciated, this change should in principle simplify the work of national courts facing litigations concerning the alleged infringement of a patent covering a second therapeutical use of a known compound; in fact, national judges will no longer have to evaluate the scope of protection of claims somehow related to the manufacture of a substance or composition when the allegedly infringing act has nothing to do with a manufacturing process but, for instance (at least from the point of view of the patent holder), might be put into practice simply by filing a request for a marketing authorization for a generic drug with the competent national regulatory body. Furthermore, although national courts and boards of appeal of the patent offices of most contracting states have generally followed the approach of the EPO with respect to the construction and interpretation of "Swiss type" claims (8), such a tendency cannot be generalized, at least based on the position of the appeal division of the Dutch patent office (9).

It seems therefore that the amendments introduced by the EPC 2000 into new Arts. 54(4) and 54(5) should provide patent holders with more straightforward and thus probably more easily enforceable claims covering a second therapeutical use of a known compound.

Nevertheless, despite the more intuitive wording provided for by the new EPC 2000, claims covering a new therapeutical application will still have a completely different format in Europe than in the USA; the format currently accepted in the USA for second therapeutical use claims is in fact *a method for treating disease Y which comprises administering compound X to a patient in need of such a treatment*; this means that the claims of a US application claiming priority from a European one will need to be amended in order to avoid formal objections; the same will apply of course to the claims of a European patent application claiming priority from a US one, which will also need to be amended in order to avoid falling within the exclusion of new Art. 53(c).

The second relevant change introduced into the EPC 2000 relates to the so-called "Protocol on the Interpretation of Art. 69", which has been modified by the introduction of new Art. 2 and which recites that *for the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims;* the goal of such a new article was that of harmonizing, throughout all the EPC contracting states, the application and interpretation of Art. 69 which, on its turn recites that *the extent of protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims (10)*.

The national courts of contracting states have tried, since the birth of the EPC itself, in 1973, to develop a harmonized practice for interpreting the scope of protection of a patent; however, despite some progress, case law has failed so far to develop Europe-wide uniform criteria to determine whether the scope of protection of a claim must be limited to its literal wording or whether (and if so how!) it can be broadened outside the literal language to encompass features which are equivalent to and differ only unsubstantially from the claimed invention.

New Art. 2 of the protocol has now apparently filled the gap, by clarifying that the scope of protection of a patent can be extended to encompass *any element which is equivalent to an element specified in the claims*; however, it has not provided any indication about how to determine whether an element which is outside the literal scope of a claim can be considered equivalent to an element literally falling within the scope of the claim. This is in my opinion a real limit of the new European patent convention, in particular if we consider that, during the discussions which took place at the diplomatic conference which originated it, several interesting proposals were made in order to improve the "Protocol" in a way which should have ensured a more harmonized interpretation of Art. 69. In particular, proposals were made:

- to provide a definition of equivalency – *obvious to skilled person that "element achieves substantially the same result"* (11);
- and to temporarily locate it – *equivalence of elements to be evaluated "at the time of the alleged infringement".*

At the end, however, such proposals have not been accepted, leaving users (i.e. patentees, alleged infringers, lawyers, patent attorneys and judges) without any tool for establishing how much a patent claim can be broadened beyond its literal content; as a consequence, the road towards harmonization appears to be very long and troublesome and only future case law will let us know whether harmonization will ever be reached or whether national courts will still have different approaches with respect to this topic.

Furthermore, one of the biggest failures of the diplomatic conference is in my opinion probably that of not having accepted the proposal of amending the "Protocol" to recite that *due account should be taken of any "statement unambiguously limiting the extent of protection" made by the applicant in the application or patent or during grant or validity proceedings.* Such an approach, which is very similar to the so-called *prosecution history estoppel*, commonly adopted in the USA, would have certainly helped third parties to establish, by studying the examination procedures of a given European application or patent (12), whether a planned activity would likely be considered an infringement of said European application or patent by a national court of a contracting state. This of course does not mean that third parties will not have the possibility of trying to better define the scope of protection of a European patent by studying its prosecution history: this will still remain an option. There is however no legal certainty that the conclusions which might be drawn by such an analysis would be accepted and given the same weight by national courts of different contracting states (and, in certain cases, also of the same contracting state).

Another important change introduced in the EPC 2000, and which might play an important role in the never-ending battle between originators and genericists, relates to the introduction of the limitation/revocation procedure. New Art. 105a(1) provides in fact that: *At the request of the proprietor, the European patent may be revoked or be limited by an amendment of the claims. The request shall be filed with the European Patent Office in accordance with the implementing regulations. It shall not be deemed to have been filed until the limitation or revocation fee has been paid* whereas new Art. 105a(2) specifies that *the request may not be filed while opposition proceedings in respect of the European patent are pending.*

The purpose of the limitation procedure (13) is in principle that of restoring the validity of a patent, for instance when the patentee becomes aware of a relevant prior art document which was not considered during the examination procedure, thus avoiding disputes and enhancing the legal certainty; such a procedure is less costly than several national procedures, designed to be faster and it can be used to reach results that cannot be obtained in a national procedure; moreover, it has an *ab initio* effect and it is an *ex parte* procedure.

The most interesting feature of such a procedure is that the patentee has no obligation to explain the reason why the limitation of a patent is requested; in fact, as made clear by new Rule 92(2)(d) of the Implementing Regulations, *where limitation of the patent is requested... the request shall contain...the complete version*

of the amended claims and, as the case may be, of the amended description and drawings.

This means for instance that the patentee does not have to provide the European Patent Office with copy of the prior art document/s affecting the validity of the patent as granted; and it also means that the Examining Division, which is the competent body of the EPO for taking decisions with respect to limitation and revocation requests (14), shall only examine whether the requested amendment of the claims actually limits the patent (and it is not designed to protect something else) and whether the amended claims meet the clarity requirements (15). Otherwise stated, the assignee of a patent covering a specific compound, who becomes aware of a prior art document disclosing the same compound, could file a request to have the patent limited to the specific therapeutical use of said compound, provided such a use is disclosed (although not necessarily claimed) in the patent as granted.

Such a possibility would however create a situation of legal uncertainty for all those third parties that have become aware of the invalidity of the granted patent and, in good faith, have made effective preparations for exploiting the product claimed in such a patent. Just to make a practical case, the "originator" might be the assignee of a patent claiming a specific compound, endowed with a defined therapeutical action, which however is not expressly covered by the claims. A genericist, that is interested in placing on the market a generic copy of the patented drug, becomes aware of a prior art document disclosing the claimed compound (but for a different use) and thus starts invalidation proceedings in one or more designated countries, seeking for the revocation of the national portion/s of such a patent. Under the provisions of the former EPC 1973, by doing so the genericist would have placed the originator in a "no way out" situation, since in several EPC contracting states the claims of a patent cannot be further limited once an invalidation action against such a patent is pending; consequently, the patent would have likely been revoked, thus leaving the genericist free to market the formerly patented drug.

However, under the provisions of the new EPC 2000, the originator would have the possibility of filing, at any time (and in particular after having received notice of the invalidation action filed by the genericist), a request for having the claims of the patent limited to the specific therapeutical use mentioned in the specification and for which the drug is marketed. The originator would thus be now in the condition to enforce the (formerly invalid!) patent, by starting an infringement action against the genericist; moreover, since the effects of the limitation procedure are *ab initio*, he would also be in the condition to recover past damages – if any.

The last important amendment to the new EPC 2000 and which should also play a relevant role in future chemical-pharmaceutical patent litigations is represented by the so-called "attorney evidentiary privilege", which has been introduced by new rule 153(1)(2). Such a new rule recites in fact that *where advice is sought from a professional representative in his capacity as such, all communications between the professional representative and his client or any other person, relating to that purpose ... are permanently privileged from disclosure in proceedings before the European Patent Office, unless such privilege is expressly waived by the client. Such privilege from disclosure shall apply, in particular, to any communication or document relating to: (a) the assessment of patentability of an invention; (b) the preparation or prosecution of a European patent application; (c) any opinion relating to the validity, scope of protection or infringement of a European Patent or a European Patent application*.

This new rule has been introduced to align the provisions of the new EPC with the "attorney-client-privilege" in the USA, which is applied to all aspect of law involving communication between client and attorney and which prevents disclosure of information that could be relevant to a legal proceeding. In particular, the new rule draws its language from the definition of the evidentiary privilege in US law as cited in Bristol-Myers Squibb vs Rhone Poulenc Rorer (16), according to which the disciplinary rules of European patent attorneys did not confer the equivalent of the US attorney-client-privilege, leaving thus open to discovery in US proceedings all information between a European professional representative and his client. Starting since December 13, 2007, such information should in principle be no longer "discoverable", apparently placing EP attorneys on the same level as their US colleagues; the question is now whether the European patent attorney-client privilege will be effectively invoked in the USA and, if so, what will be covered and under which conditions.

In conclusion, it seems that the new EPC 2000 will probably meet many of the practical needs and expectations which originated it, in particular in terms of filing and prosecution procedures. From the point of view of the protection conferred by a European patent is seems however that the new convention will certainly meet the needs of the patent holders rather than those of third parties; in particular, from an originator vs genericist perspective, it appears that the new "Protocol on the Interpretation of Art. 69" and the new limitation procedure have provided originators with new powerful instruments to broaden or limit the scope of protection of European patents, depending on the circumstances and needs, but have not provided genericists with any equivalent tool to define/clarify the scope of a patent. Of course, we are at a very early stage of the new convention and, as it always happens in similar cases, only future case law will allow us to draw the proper conclusions.

REFERENCES AND NOTES

1) Since it was revised by the Diplomatic Conference held in Munich on November 20 to 29, 2000
2) Also referred to as the EPO
3) i.e. the EPC 1973
4) As well as in the Protocol on Interpretation of Art. 69, which will also be discussed in the present article
5) For a more complete understanding of the EPC 2000 please refer to VISSER D. *The Annotated European Patent Convention 2000*, 14th revised edition, Vol.II; H. Tel Publisher: Eindhoven, NL, 2006
6) That is the format originally considered patentable for 2nd therapeutical uses by the EPO – see the decision of the Enlarged Board of Appeal G5/83 – *Official Journal of the EPO* **1985**, 64
7) Or pharmaceutical formulation/composition
8) See UK High Court of Justice "Second medical use/Wyeth and Schering" – *OJ EPO* **1986**, 175;
FR Cour de cassation, "Alfuzosine" – *OJ EPO* **1995**, 252;
UK High Court of Justice, "Bristol-Myers Squibb vs Baker Norton Pharmaceuticals" – *R.P.C.* **1999**, 253
9) *OJ EPO* **1988**, 405
10) This is the wording of new Art. 69(1); for the purposes of the present article, I do not deem necessary to report also the wording of Art. 69(2)
11) Such a definition is quite similar to the standard adopted in the USA, where infringement under the doctrine of equivalents can be found when the accused product "performs substantially the same function in substantially the same way to obtain substantially the same result" – see Graver Tank & Mnfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608, 85 U.S.P.Q. 328, 330 (1950); see also Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 42 (1929)
12) Which are available free of charge on the web site of the EPO
13) In the present article I will focus on the limitation procedure and I will not comment on the revokation one
14) Rule 91 of the Implementing Regulations
15) Art. 84 EPC
16) Southern District of New York, April 19, 1999