Patentability of Methods of Medical Treatment and Medical Devices in Europe

By Antonio Maschio

The European Patent Convention (EPC) proscribes the patenting of methods of medical treatment. The reason for this exclusion, which was present in the original EPC (EPC 1973), is that public health in the member states would be at risk if patent rights could be used to impede physicians in the normal course of practicing medicine. Such an exception to patentability is recognized and permitted under the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) in Article 3a, § 5 (patents). However, the EPC does not proscribe the patenting of products that have medical applications, be they pharmaceuticals or medical devices such as scalpels, staplers, surgical sutures, and stents. This article will discuss the implications of the statutory exclusions on the patenting of methods of medical treatment and medical devices.

Medical Uses

The legislators framing EPC 1973 recognised that the prohibition on patenting methods of medical treatment would make the patenting of medical-related inventions very difficult. According to the general novelty requirements under the EPC, a claim directed to a known chemical compound for a new use (compound X for use Y) would be considered to lack novelty over previous disclosures of compound X, whatever the use. Moreover, for pharmaceutical products, traditional use claims (use of compound X for purpose Y) were treated as unallowable method-of-treatment claims if purpose Y was a therapeutic or surgical procedure.

This resulted in an imbalance in the scope of patent protection available for chemical compounds. For example, if a known compound were discovered to have an application in paint technology that had previously not been recognized, it would not be possible to apply for a patent directed to the compound for use in paint, as this would be anticipated by the original disclosure of the compound itself, considered "suitable for use" in paint. However, traditional use claims (use of compound X in paint) could also be directed to a new method for painting or a novel method for manufacturing paint using this compound.

On the other hand, for a newly discovered pharmaceutical application of a known chemical compound, the method-of-treatment prohibition meant that no corresponding method claims or use claims would be allowable, leaving no route for patent protection. In view of this, a special exception to the laws of novelty was created for medical uses in EPC 1973. Under this exception, a known chemical compound would not anticipate a claim to that same compound for a medical use, provided that no medical use was known in the art.[1] Thus, the first medical use claim, "compound X for use in medicine," was born.

Second Medical Use

The exception to the laws of novelty for existing chemical compounds with no previous medical use did not extend to new medical indications of a known medical compound. Thus, only the first medical use of a known chemical compound could be patented, but not any second or further uses. For example, a known analgesic could not have been patented for use in the treatment of Alzheimer's disease, no matter how surprising and inventive that application might have been. This problem was recognized by the European Patent Office. In decisions G1/83, G5/83, and G6/83,[2] the Enlarged Board of Appeal considered the matter in detail and approved a type of claim that was not directed to a method of treatment but that still permitted the patenting of novel second and further medical indications. This claim was referred to as the Swiss claim, after the then-practice of the Swiss Federal Intellectual Property Office. Also known as a second medical use claim, this claim takes the form "compound X for use in the manufacture of a composition for the treatment of disease Y."

The Swiss claim structure falls into two parts. The first part of the claim, "compound X for use in the manufacture of a composition," removes the claim from the ambit of methods of treatment. It is a claim directed to the manufacture of a product, not any therapeutic or surgical method, and therefore falls outside the exclusion of Article 53(c) EPC.[3] The owner of such a patent thus has recourse only against the manufacturer or seller of the composition and not against the physician.

Antonio Maschio is a partner, life sciences specialist, and European patent attorney at Edwards Angell Palmer & Dodge Innovations LLP. Resident in the firm's London office, he may be contacted at *amaschio@eapdlaw.com*.

The second part of the claim, which describes the use of that composition, provides the novelty of the claim; if the use is not part of the prior art, the claim is novel. As noted by the Enlarged Board of Appeal, when the medical compound itself is new (for instance for reasons of dosage, formulation, or synergistic combinations), then novelty is not at issue. When the medical compound is identical to a known medical compound except for the use to which it was being put, the Enlarged Board ruled that it was "justifiable by analogy" to the provisions of Article 54(5) EPC 1973[4] to recognize its novelty of use. However, it also stated that this exception could be allowed only for "claims to the use of substances or compositions intended for use in a method referred to in Article 52(4) EPC."

In EPC 2000, these decisions of the Enlarged Board of Appeal are codified in Article 54(5) EPC, which exempts subsequent medical uses of existing medical compounds from the prohibition on patenting methods of medical treatment. Swiss claims remain an acceptable alternative claim format under EPC 2000.

Medical Devices

Medical science extends to physical devices for use in therapy and surgery, as well as to pharmaceuticals. When such devices are novel, their patentability is generally not affected by the prohibition on patenting methods of treatment; the device can normally be claimed as such using a standard product claim format. Problems arise, however, when the device is already known but its use is novel. For instance, a suture coated in a specific manner, known for use in heart surgery, might be unexpectedly useful in tendon reattachment in the ankle due to its previously unappreciated tensile properties.

It is necessary to consider the language of the EPC in detail to appreciate why the problems arise. Article 53(c) EPC states that:

> European patents shall not be granted in respect of:
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> …
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> (c) Methods for the treatment of the human or animal body by surgery or therapy …; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Here, we see that product claims specifically do not fall under the exclusion. Thus, it is possible to patent a new drug or a new surgical device; the medical method-of-treatment prohibition does not apply to products in general, with substances and compositions being a particular example of a product.

Article 54(4) EPC provides the exemption to the normal laws of novelty for first medical uses:

> (4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c) … .

In this case, the exemption applies *only* to substances and compositions. Therefore, although Article 53(c) specifically holds that products in general do not fall under the prohibition against patenting medical treatment methods when claimed as products, Article 54(4) focuses only on compounds and compositions and so does not extend the exemption of Article 53(c) to other products, such as medical devices. Article 54(5) EPC uses the same language in respect of second medical uses.

The same limitations exist in the equivalent provisions of EPC 1973. This was reflected in the Enlarged Board decision G5/83, which noted that the exception to the medical treatment prohibition for the purposes of novelty applied only to "substances and compositions."[5]

Can Uses of Medical Devices Be Protected?

The EPC statutory provisions do not provide for the patentability of new medical uses for medical devices. In the revision of EPC 1973 into EPC 2000, the regulatory provisions concerning the EPC were intentionally moved, as far as possible, out of the Articles and into the Rules. The reason for this was that Rules can be changed by the Administrative Council, which is relatively easy. Changing Articles requires a congress of the member states, which is very difficult to arrange. Because the law concerning second medical use inventions was left in the Articles, we can conclude that the drafters did not contemplate that these provisions would change in the foreseeable future. Therefore, it is unlikely that there will be a change in the law that will help in patenting uses of medical devices.

The other avenue for legal change is through the case law of the Boards of Appeal of the EPO. Although the Boards cannot change the law, their decisions can influence its interpretation.

In decision T1020/03, a Technical Board of Appeal of the EPO examined G5/83 and the relevant Boards of Appeal case law since G5/83 in some detail. The decision restates the principles of G5/83 and in particular separates the issue of avoiding the prohibition under Article 53(c) EPC from the issue of novelty under Article 54 EPC. According to this decision, it is not

necessary for there to be any novel principle involved in the use of a substance for the manufacture of a composition. The novelty may instead lie exclusively in the recited medical use of the composition, as long as that use is one that is permitted by Article 53(c) EPC.

In the hypothetical coated suture case, the first part of the claim could read, "use of coating composition X in the manufacture of a coated suture." This use in itself is not new, because the coated suture was known in the art. However, the second part of the claim could recite a novel medical application, in this instance, "for use in tendon reattachment in the ankle," that, according to T1020/02, could be sufficient to impart novelty under Article 54(5) EPC.

Without this Swiss construction, under EPC 2000 the claim would assume the structure: "Coating composition X for use in tendon reattachment in the ankle, wherein the coating composition is applied to a suture … ." Such a claim, however, may lack clarity under Article 84 EPC, since the coating composition itself does not perform the reattachment; a Swiss claim formulation might therefore be preferred. The alternative formulation under EPC 2000 ("Coating composition X, and a suture, for use in tendon reattachment in the ankle, wherein the coating composition is applied to the suture … .") is somewhat clumsy and might also attract objections under Article 84 EPC.

Thus, for medical devices we can avoid the problem by using a Swiss claim, if the medical device includes at least one component that can reasonably be interpreted to be a "substance or composition." But what of a case in which the medical device is, for example, a scalpel, and the invention resides in a new method of using the scalpel in a specific surgical technique?

In order to fit such a claim within the foregoing principles, it would be necessary to recite the manufacture of the scalpel. Following T1020/03, it might be possible to claim, for example, the "use of an alloy of steel and chromium in the manufacture of a surgical implement," with a recitation of the novel surgical technique following this introductory phrase. Although such a claim seems logically sound, there are two problems. The first is that it is unusual for there to be basis in a European application for such a claim, since most applications requiring reformulations of methods of surgery are based on US-filed documents where such approaches are not necessary. The second is that the claim could be construed as being overly evasive, in that it clearly tries to avoid a prohibition on patenting methods of surgery by choice use of language. On the other hand, however, it is conceptually and structurally no different from the original—and acceptable—second medical use claim.

The Future: G2/08

On April 30, 2008, a Technical Board of Appeal referred to the Enlarged Board of Appeal questions concerning the patentability of dosage regimes in a method of therapy. In particular, the Technical Board asked whether it could be possible to patent a new pharmaceutical use, where the disease to be treated was identical to that of the prior art, and the only difference was in the dosage of the medical compound. These were the facts in T1020/03. Moreover, the Enlarged Board has also been asked to comment on any special considerations that it believes should be made when interpreting Article 53(c) and Article 54(5) EPC.

In her comments filed on January 29, 2009, the president of the European Patent Office urged the Enlarged Board of Appeal to consider the question broadly and to comment on the patentability of medical use inventions in general. Unfortunately, there is no requirement that the Enlarged Board extend its comments to medical devices; however, one can hope that the Enlarged Board will make a full and proper analysis of the issues raised in G5/83 and T1020/03, especially in view of the changes that have taken place under EPC 2000.

Practical Considerations

The EPC does not allow claims directed to methods of surgery or therapy, but it does allow claims directed to the use of substances and compositions in methods of manufacture. Moreover, specifically in the medical field, novelty can be obtained by recitation of a novel medical application. Therefore, wherever possible, these types of patent applications should contain the basis for a claim directed to using a substance or composition in manufacturing a medical device for a new and non-obvious medical use, especially if that underlying device is not itself novel.

Notes

1. *See* Art. 54(5) EPC 1973. In today's EPC 2000, *see* Article 54(4) EPC in conjunction with Articles 54(2) and 54(3) EPC.
2. The three decisions are fundamentally the same. Decisions of the EPO Boards of Appeal are available online; *see www.epo.org*.
3. Or Article 52(4) EPC 1973.
4. Article 54(4) EPC 2000.
5. *See* § 21 of the Reasons for Decision in G5/83.