EISAI/Second medical indication G 05/83 [1979-85] EPOR B241 (1985)
(European Patent Office, Enlarged Board of Appeal)

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Summary

The Enlarged Board of Appeal decided on the 5th December 1984 on the question of novelty and second medical indications. It held that a patent must not be granted for claims directed to the *use* of a substance or composition for the treatment of the human or animal body by therapy. However, a patent may be granted with claims directed to the use of a substance or composition for the *manufacture* of a medicament for a specified new and inventive therapeutic application ("Swiss claim").

The facts

The Technical Board of Appeal for Chemistry had referred the following question to the Enlarged Board of Appeal (hereinafter EBoA): whether a patent with claims directed to the use can be granted for the use of a substance or composition for the treatment of the human or animal body by therapy. Put differently, the Board was asked to consider the question of "second medical indications". Second medical indications arise where a patent applicant seeks protection for a new medical use for a product that has already been used as a medicine in the prior art, but for a different indication. The relevant invention referred to "use of butoxybenzylhyoscyamine bromide in pharmaceutical compositions against deafness and tinnitus".

The legal issues

Application of the Vienna Convention on the Law of Treaties

Before addressing the relevant legal question, the EBoA clarified its approach to the interpretation of the European Patent Convention.[1] It finds the rules of the Vienna Convention on the Law of Treaties applicable even if they are not so *ex lege*.[2]

Therapeutic Use Claims for Substances and Compositions in General

The relevant question of law in the present case concerned the patentability of claims of "second medical indication" ("Swiss" or "Swiss-type use claim").

The European Patent Convention (hereinafter: EPC) allows both method claims and use claims; the EBoA, however, finds no difference in substance between these two claims.[3] It holds that a claim directed to the "use of a substance or composition for the treatment of the human or animal body by therapy" is not different in content from a claim directed to "a method of treatment of the human or animal body by therapy with the substance or composition".[4]

Because of the provisions of article 52(4)[5], the normal type of use claim, meaning a claim that protects the new use of a known product, is not open to pharmaceutical

[1] The case at hand was one of the first group of cases brought before the EBoA.
[2] Relevant are especially art. 31 and 32 of the Vienna Convention on the Law of Treaties. The Board summarizes these two articles under § 5 of its decision.
[3] See §11 of the decision.
[4] Ibid.
[5] Art. 52 (4) EPC 1973 corresponds now to Art. 53(c) EPC 2000.

inventions directed to the use of medicaments in a method of medical treatment. This provision under the EPC 2000 reads as follows:

Article 53
Exceptions to Patentability
European patents shall not be granted in respect of:
[…]
(c)
methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

This provision is based on the concept laid down in Article 27.3(a) of the TRIPS Agreement, which provides that Members may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals. The rationale behind this authorization is to immunize physicians in their every-day work from claims of patent infringement. WTO Members are free to interpret this provision as being limited to physicians' every-day practice, or to extend it to also cover the industrial use of new medical indications.[6]

In the case at hand, the Board found no evidence in either the terms of the EPC nor the legislative history of the articles that second and subsequent medical indications were to be excluded from patent protection, other than by a purpose-limited claim. Therefore, in the jurisdiction of the EPC, Swiss type of use claims directed to the manufacture of substances or compositions for use in any methods for treatment of the human or animal body or directed to the use of a substance or composition for the preparation of a pharmaceutical product are not prohibited by article 52(4) and are capable of industrial application within the meaning of Art. 52 (1) and 57 EPC. [7]

According to the Board, Art. 54 (5) EPC 1973 affirms the patentability of any substances or compositions comprised in the state of the art *for use* in a method referred to in Art. 52(4) EPC 1973 under the condition that its use for any such method is not comprised in the state of the art. Thus, Art. 54(5) EPC 1973 establishes that (a) a purpose-limited product claim is possible for a first (new) pharmaceutical use of a known substance or composition and (b) the required element of novelty in this claim must be found in the new pharmaceutical use.[8]

Concerning Swiss type of use claims (claims directed to the second or subsequent use of a known pharmaceutical in the manufacture of a medicament that is not novel in itself but whose use for a new indication is novel), the novelty must accordingly be found in the new second therapeutic use itself.[9] Hence, claims concerning second medical indications in the form of a specified new and inventive therapeutic application can be granted a patent under the EPC.

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[6] See UNCTAD, Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide, 2011, p. 51/52. Available at https://unctad.org/system/files/official-document/diaepcb2009d19_en.pdf

[7] See also the last sentence of Article 53 (c) as cited above.

[8] Note that under the EPC 2000, Article 54 (4) expressly provides for the patentability of claims related to a first and novel medical use of a known product.

[9] Note that under the EPC 2000, Article 54 (5) expressly provides for the patentability of claims related to any subsequent and novel medical uses of products that have been used before in a method of medical treatment. This provision makes the recourse to Swiss claims superfluous, as it provides a legal basis for use-bound product claims.

Points of significance

- The EBoA considers method claims and use claims to be essentially the same. It does not accept any artificial distinction between the two. The claim for a method of treatment of the human or animal body by therapy with the substance or composition is in plain conflict with Art. 52 (4) EPC 1973 (53 (c) EPC 2000). Therefore, no patent containing either of these claims can be granted.
- Under the EPC, the exclusion from patentability of method of treatment claims shields physicians' every-day practice from allegations of patent infringement. The provision is not used, however, to also exclude from patentability industrial uses of new medical indications. To avoid conflict with the medical treatment exclusion under Art. 52 (4) EPC 1973, the specific "Swiss claims" format was adopted. Accordingly, a patent may be granted for claims directed to the use of a known substance or composition (comprised in the state of the art) for the *manufacture* of a medicament for a specified new and inventive therapeutic approach - be it the first, second or subsequent medical indication (provided the specific use of the substance or composition is not comprised in the state of the art).
- The Swiss claims format appears no longer required under the revised EPC 2000:
    - Article 54 (4) expressly provides for the patentability of claims related to a first and novel medical use of a known product.
    - Article 54 (5) expressly provides for the patentability of claims related to any subsequent and novel medical uses of products that have been used before in a method of medical treatment.
    - Article 54 (4) and (5) provides a legal basis for "use-bound" (or "purpose-limited") product claims.
- The requirement of novelty is to be assessed against the novelty of the new medical indication.
- WTO Members are free to interpret corresponding Article 27.3(a) of the TRIPS Agreement as being limited to physicians' every-day practice, or to extend it to also cover the industrial use of new medical indications (as opposed to the approach under the EPC).

Key words

Patent, patentability, patent-eligibility, new uses, novelty, Swiss-type claim, Enlarged Board of Appeal, method claim, use claim, Art. 52(1) EPC 1973, Art. 53(c) EPC 2000, European Patent Convention, industrial application, pharmaceuticals, purpose-limited claim, use-bound claim.

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