Patentability of new uses under the European Patent Convention and the "Swiss Formula"

Please note that the European Patent Convention (EPC) was amended by the Act revising the EPC of 29.11.2000 on 13 December 2007. Therefore, the "Swiss formula" is no longer required under the EPC. However, it can still be used to justify the broad interpretation of the methods of treatment exception under Article 27.3 (a), TRIPS Agreement, thus excluding patents for new uses.

The old Article 52.4 [new Article 53 (c) EPC 2000] contains the language of the "methods of treatment" exception of Article 27.3 (a), TRIPS Agreement. In implying this provision, the EPO distinguishes between first and second medical uses.

Where *second medical uses* are concerned, the old Article 54.5, EPC [new Article 54.4 EPC 2000] constrains the EPO to deny *product* patents. According to this provision, the provision of the EPC regarding novelty shall not exclude the patentability of any substance or composition, comprised in the state of art, for use in a method referred to in the old Article 52.4 EPC ("methods for treatment" exception), *provided that its use for **any** method referred to in that paragraph is not comprised in the state of the art*. In other words, the known product is only patentable if its claimed new use is novel for **any** of these methods. As regards second medical use, however, the product has already been used as a medical product before and its use could therefore no longer be considered "new" for any of the methods enumerated under the new Article 53 (c) of the EPC.

In theory, the old Article 52.4 EPC could even have obliged EPO to also deny *process* patents for second medical uses. The Board of Appeal of the EPO held, however, that the objective of the old Articles 54.5 and 52.4 EPC was to preclude the protection of medical uses of known compositions under a product patent, as a composition lacked novelty if its use in "any" method of treatment was comprised in the state of art. However, they did not intent to prohibit the protection of such claims under process patents. The Board of Appeal therefore held that claims to the use of a product for the manufacture of a medicament for a new and inventive medical use were patentable (G05/83 EISAI/Second medical indication [1985] O.J. EPO 64).

The EPO thus established the so-called "Swiss formula" of process claims construction, referring in the claims to how the drug is *manufactured* (in order to achieve a certain purpose), rather than to its *use* (which would have raised the question of compatibility with the old Article 52.4 EPC – which has the same wording as Article 27.3 (a), TRIPS Agreement).

Under the new EPC 2000, an additional provision (new Article 54.5) was introduced which provides that a known substance may nevertheless be patentable for a *specific use* as a medical product, provided such specific method of use is not comprised in the state of the art. Third parties are thus free to use the product in a way not covered by the use-bound product patent. Thus, use-bound product claims under the new Article 54.5 EPC are similar to process claims regarding the protection of *methods of using* the product. Use-bound product claims are different from process patents, however, as far as the protection of *methods of making* the product is concerned. They protect *all* possible methods of making the product, whereas process patents only protect a *specific* method of making the product.

As to *first medical use*, EPO allows even *product* patents that are not use-bound. The fact that the product has been used for some other non-medical purpose does not destroy novelty in the medical field in the EPC Member States.

Patentability of new uses under the new EPC as compared to the old EPC

	Old EPC		New EPC	
	First medical uses	**Second medical uses**	**First medical uses**	**Second medical uses**
P R O D U C T	+ (see old 54.5 EPC)	--	+ (see new 54.4 EPC)	+ but limited to a specific use (use-bound product claims) (see new 54.5 EPC)
P R O C E S S	+ According to general principles of patentability	Swiss formula	+ According to general principles of patentability	Swiss formula

Old 52.4 EPC -> new **53 (c)** EPC (= 27.3 (a), TRIPS)
Old 54.5 EPC -> new **54.4** EPC