EUROPEAN PATENT ORGANISATION

- Committee on Patent Law -

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Info 2

12th Meeting (Munich, 1. - 3.02.2000)

Munich, 01.02.2000

Orig.: English

SUBJECT: Revision of the EPC: Articles 52(4) and 54(5)

DRAWN UP BY: *epi*

ADDRESSEES: Committee on Patent Law (for information)

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This document has been distributed **in English only.**

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epi

Institut der beim Europäischen Patentamt zugelassenen Vertreter

Institute of Professional Representatives before the European Patent Office

Institut des mandataires agréés près l'Office européen des brevets

Ausschuß für europäische Patentpraxis
European Patent Practice Committee
Commission pour la Pratique du Brevet Européen

Der Vorsitzende . The Chairman . Le Président

00 49 89 2399 5219

Paris, January 31, 2000

SACEPO Secretariat
European Patent Office
D-80298 München
GERMANY
Attn.: G. Kolle

Revision of the EPC: Articles 52(4) and 54(5)

Dear Mr. Kolle:

The **epi** is in favour of a revision of the EPC in order to provide a better patent protection in the medical field as well as a decrease of the present legal uncertainty resulting from the so-called "Swiss claims" defined by the Enlarged Board of Appeal in its decision G5/83.

The amendment proposed in document SACEPO 1/00 appears however insufficient to achieve those goals.

According to the proposal namely, the scope of protection of a "first medical use" compound claim appears limited to the specific use disclosed in the application.

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The **epi** is in favour of retaining the present possibility for protection by "*compound claims*" for the "*first medical use*" as defined for example in decision T128/82 (Hoffmann Laroche) where it was clearly indicated that the inventor of a first medical use is entitled to a scope of claims covering all therapeutic uses.

It is clear namely that the inventor of such a first medical use not only makes an invention which may be of great importance for treating diseases, but also has recognized generally speaking that a given product substance or composition can be administrated to the human being without significant toxicity problems. He also has often conducted clinical testing and developed chemical processes for preparing bulk drug. The investments therefore are extremely high. This clearly justifies the grant of a claim covering all therapeutic uses.

The inventor should not be obliged in such a first medical use to define the specific disease in the claim. There is always the potential of generic competitors to develop the same drug for a related disease condition and to argue that they fell outside of the claims.

Therefore, the present situation should be retained in the first medical use with the inventor having no need to define all possible uses although a full disclosure may be necessary in the description of the patent.

In order to cover further medical uses invented after the invention of the first medical use, the **epi** would also favour a further amendment of Article 54(5) making clear that claims also in the format of "*compound for use*" but this time limited to the specific disclosed use, would be available to the inventor of any further medical use.

This could be attained by adopting the proposal indicated in SACEPO 1/00 in addition to the present wording which would remain unamended.

Sincerely yours,

Axel CASALONGA

Encl.: Proposal

January 31, 2000

PROPOSAL

Current version	Proposed version
Article 54 **Novelty**	**Article 54** **Novelty**
(1) – (4)	**unchanged**
(5) The provisions of paragraphs 1 to 4 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 52,paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.	(5) The provisions of paragraphs 1 to 4 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 52,paragraph 4, provided that **this use** [...] is not comprised in the state of the art **or provided that its use for any method referred to in that paragraph is not comprised in the state of the art.**