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Travaux Préparatoires EPC 1973

Comment:

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INTER-GOVERNMENTAL CONFERENCE
FOR THE SETTING UP OF A EUROPEAN
SYSTEM FOR THE GRANT OF PATENTS

Brussels, 23 February 1972

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- Secretariat -

NOTE

Subject: Art. 9, paragraph 2 (e) in the Second Preliminary Draft
of the Convention establishing a European System for
the Grant of Patents, stage reached on 26 November, 1971.

Drawn up by: Danish Delegation

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NOTE

from the Danish Delegation

concerning

Art. 9, par. 2(e) in the Second Preliminary Draft
of the Convention establishing a European System
for the Grant of Patents, stage reached on
26 November, 1971

The broad wording of the article has given rise to doubts as to whether it comprises the use of new drugs consisting of or containing known chemical compounds which, unexpectedly, are found to have a therapeutical effect. This has induced a number of international organisations to protest against the extensive wording and to propose various additions, e.g. EIRMA in BR/149/72, UNICE in BR/146/71, IAPIP in BR/158/72, and, in the course of the oral debate, several other organisations. During the consideration of the question by the Government Conference the Danish delegation was invited to express its viewpoints in writing for the use of Working Party I during its further consideration of the subject.

The Danish delegation shares the opinion that the provision in question is too extensive if it is to be understood as indicated by the said organisations and finds that, if that is the case, Article 9, par. 2(e) comprises two different problems, i.e. in the first place the question about treatment of the human body and in the second place the question about the patenting of inventions of the use of chemical compounds as pharmaceutical products. In our opinion only the first of these two subjects belong under Article 9, par. 2.

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Article 9, par. 2 gives a non-exhaustive enumeration of examples of intellectual innovations which are not comprised by the concept of inventions and which are, consequently, outside the scope of the word "invention" in Article 9, par. 1. Such intellectual innovations comprise traditionally certain inventions in whose exploitation the human organism is acted upon. It is here a question of cases where the actual exploitation of the invention affects the human or animal body, and not of cases concerning the invention of substances - well-known or novel - which in the form of drugs, foodstuffs, or stimulants are intended to act upon the organism. The reasons for excluding such inventions from the concept of invention are ethical and similar considerations. As far as that goes the provision belongs under Article 9, par. 2, but considering the doubt which prevails everywhere as regards the scope which, for these reasons, may be given to this modification of the concept of invention it seems to be important that the provision does not get a too extensive wording.

The question of the patentability of inventions which comprise a new use of known chemical compounds is not a question of the concept of invention; the patentability must here be determined according to the provisions of par. 1 so that the question of inventive height (non-obviousness) and industrial application determine whether or not the invention is patentable. It does not seem possible to assume that inventions of this nature which are recognized as inventions in other fields are excluded from the concept of invention because the use is a medical one, considering that a therapeutical effect is otherwise definitely regarded as the grounds for patentability. In this connection

it should be noted that in the case of patenting of new drugs the medical use will normally be decisive of the inventive height since the inventive height of the new chemical compound may, as such, be very small because the existence of such compounds is often obvious.

In view of what has been said the rule should probably be restricted to apply to methods for the physical treatment of the human body, etc. Such a wording will for instance include surgical methods, massage methods and the like as well as inventions which are solely in the nature of a prescription for the physical administration of drugs.

The consequence of such a restriction will be that patents for uses in the medical field are in principle treated in the same way as within other fields of technology. The provision in Article 9, par. 2 should consequently not have the result that the question of the patentability of the invention is determined by the nature of the claims laid down in the patent application. The fact that a known substance is presented in a novel form can probably not be considered decisive unless the novel form as such constitutes an invention; in the majority of cases the circumstance motivating the patentability will probably be the new therapeutical effect which is best expressed in a claim for the use of the substance or for a remedy for medical use containing the substance.

Another thing is that a patent for a special use of a known substance in a known form will usually be of very little value and that the demand for inventive height will no doubt imply that it will very seldom be possible to grant a patent for a new medical use of a substance which is previously known as a drug.

The European Patent Office should be free to form its own practice as regards the drawing up of patents for the use of substances in the said field as well as in other fields. In our opinion this should also apply to the field of diagnosis where patent practice in the European countries has developed according to a uniform pattern, a practice which can naturally be continued and developed within the European Patent Office.

In view of what has been said above the Danish delegation proposes the following wording:

Article 9, paragraph 2:

- (e) "Methods for the physical treatment of the human or animal body by surgery or therapy, as well as diagnostic methods performed on the human or animal body".

The question has been raised whether the patenting of drugs, etc. should result in special rules to exempt the medical profession from responsibility for any patent infringement. General consideration for the public health should probably imply that doctors cannot be held responsible for the prescription of the use of drugs, whether or not these drugs or their use might be protected by patents, just as chemists should be free from responsibility when preparing a drug in accordance with a prescription drawn up in concrete terms by a doctor.

Rules of that kind do not, however, belong under the Convention, but should be established by the national legislation to the extent deemed necessary by the individual countries.
