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Consultation response on the final report of the Committee on patent protection of biotechnological inventions (SOU 2008:20)

The National Council on Medical Ethics, SMER is an advisory body to the Government. Its task is to review medical ethics issues in a societal perspective. One might think that, of the many items in the final report, SMER should first and foremost be interested in the donation of human biological material, research on human embryonic stem cells and possibly, access to and the conditions for using medicines and diagnostic methods in health care. But the Council has followed the issue about patents based on human DNA sequences with a broad and critical approach since the EC-directive was adopted and its implementation in Swedish legislation. The fundamental position of the Council is that patents, particularly concerning human DNA sequences, cannot be discussed solely in a patent law perspective. There are consequences as regards ethics both at the individual and the societal level from these patents that warrant particular considerations.

The Council appreciates the way the Committee in parts of the report treats ethics issues in connection with patents on biotechnological inventions but it does not consider that ethical perspectives sufficiently permeate the conclusions of the Committee. The Council agrees with the Committee about the need for monitoring the outcome of the current case on human embryonic stem cell lines at the European Patent Office (EPO) in order to assess possible consequences for Swedish legislation, and to review the development with regard to future methods for producing 'embryonic' stem cells. SMER is within its remit actively observing the development in this area of research.

When the European Directive was adopted, after many years of discussions and compromising, the prerequisites that the Directive was build on were already out of date due to the rapid development of knowledge in genetic research. The intention of the directive was to create harmonisation at European level, but such harmonisation has hardly been achieved as several member states in different ways have diverted from the directive when implementing it in national legislation. These countries reservations about the Directive should influence other member states as well to consider actions for a revision of the directive.

One of the areas which has developed considerably is the knowledge about complex inheritance, i.e. polygenetic as opposed to monogenetic causes of for example disease. These causal links have consequences for the bio-patent area that are only indirectly referred to by the Committee.

In a previous consultation response (2002-02-25) about the ministerial report Ds 2001:49 Legal protection of biotechnological inventions – implementation of directive 98/44/EC, SMER objected to the proposed amendments in the Patent Law that were subsequently introduced in 2004. In summary the Council considered that:

- the proposed amendments §1a and §1b should be rejected
- Sweden should oppose any patenting of the human body and its parts even if the latter had been isolated and

- Sweden should consequently promote a revision of the EC-directive 98/44 and of corresponding practice according to other instruments.

In a response to a questionnaire from the Committee (2005-12-20), the Council argued that patent protection of DNA sequences and their use must be applied with great caution. Many patents on DNA sequences have been approved on doubtful grounds which has been exposed in cases when the EPO has had to retreat in patent cases. The effect of such patents are extensive because the patent holders are protected with regard to all possible use of the sequences. The Council therefore recommended, against the background of a report from The Nuffield Council on Bioethics, that the patentability of DNA sequences is discussed in perspective of different possible applications such as genetic diagnosis, research tools, gene therapy and production of medicines. The conclusions of the Nuffield Council were among others that applications concerning product protection of genetic diagnostic tests would only be approved on rare occasions if the criterion inventiveness were to be strictly implemented. A strict implementation of the criterion usefulness would counteract patents on DNA-sequences as research tools. Product protection would not be possible to apply to the use of DNA sequences in gene therapy since the link between gene and disease is already known.

SMER furthermore revisited the contradiction in the Law where it is stated on one hand that the human body, including its genes, in its various developmental stages is not patentable whereas on the other hand it is possible to patent a DNA sequence that has been isolated from the human body. In this respect the Council agrees with the criticism against the EC-directive behind the law that has often been voiced in the debate.

In its response to the questionnaire, SMER also pointed at the fact that the rules for the use of human biological material in research specifically refer to the patients/donors informed consent and their option to withdraw their consent (opt out). This regulation reflects society's consideration of personal integrity and autonomy. The patenting procedure should also reflect this consideration. As far as possible it should for example be checked whether patient information preceding a donors informed consent did contain information about possible patent applications based on results/material from the research. In order to make this happen, both guidelines and the Law on ethics review of research with human subjects may need revision.

Contrary to the Committee's assessment that the advantages of product protection outweigh its disadvantages and therefore status quo should be accepted, SMER is of the opinion that the type of protection cannot be discussed separately from an assessment of the consequences of the development of practice and patents in this area. For example, when it comes to compulsory licensing, the discussion of the report is limited to a comparative analysis of the legal framework under which such licensing can be issued. The Council feels here that a discussion is lacking about why compulsory licenses so seldom are issued and who benefits or is at a disadvantage by this state of affairs. SMER furthermore considers that it is premature to draw conclusions about consequences of product protection in the health care sector. The Committee hence dismisses possible disadvantages too lightly and SMER feels that the report is lacking a more basic health economics analysis of the consequences for the health care sector of various bio-patents.

SMER thus makes a different assessment than the Committee when considering product protection and recommends that Sweden in the EU and EPO promotes use protection for DNA sequences, regardless of origin, that occur in humans.

In summary, it is the opinion of SMER that:

- Patents are not ethically neutral and therefore ethics assessments should be part of the patenting procedure.
- the consequences for bio-patents of polygenetic systems need further review
- Action should be taken to ensure, as far as possible, that donors in research have been informed that the results may be patented. Guidelines as well as the Law on ethics review of research with human subjects may need revision in this respect.
- In order to assess possible consequences for Swedish legislation, it is necessary to closely follow EPO's handling of human embryonic stem cell lines in particular, and development at large concerning new methods for producing such stem cells.
- It is premature to draw conclusions about consequences of product protection for the health care sector. This item therefore needs continued attention.
- The EC-directive on legal protection of biotechnological inventions ought not to have been adopted in its current version.
- The directive also should not have been implemented in Swedish law the way it did.
- Sweden should take action to promote a revision of the directive.