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To
Senate Community Affairs Committee Inquiry into Gene Patents

According to the Invitation to provide written submission concerning the inquiry I enclose a document that is a condensed version of my reservation to the report from the Swedish Committee on Patent Protection for Biotechnological Inventions.

Background

I have been member and expert of the Committee on Patent Protection for Biotechnological Inventions set up in 2005 by the Swedish Government. The mission of the Committee has been to follow case law development after implementation in Swedish law of the Directive 98/44/EC on the legal protection of biotechnological inventions. Another part of the mission was to follow up the effects on health care and research of patents in the field of biotechnology. When the Committee delivered its report to the Minister of Justice in February 2008 I made some remarks concerning the Committee's conclusions. This document is a condensed version of my reservation to the Committee's proposals.

General considerations

In my opinion the Directive on the legal protection of biotechnological inventions does not sufficiently consider the essential biological conditions. In the Directive the fundamental patent principle that patent can only be granted for an unambiguous invention is disregarded. Thus, according to the Directive patents can be granted for biological material isolated from a human being.

There are no differences between DNA as it is known in the human body and as it can be produced industrially outside the human body. The genetic information is identical irrespective of if it has been discovered in nature or constructed.

Isolating genes and DNA sequences is today a routine procedure. The inventive part consists in establishing the function of the genes and what they can be used for. To clone and sequence a piece of DNA is nowadays a routine procedure without inventive height. Neither does it involve any large economical investment. Already at the time when the Directive was adopted the biological facts that the Directive was based on were obsolete.

In my opinion Sweden should oppose any patenting of parts of the human body even when they have been "isolated". According to my view the Directive should have been renegotiated. In consequence, I consider that Sweden now should work for a revision of the Directive.

Biopatents need ethical consideration

Compared to traditional patents, patents on biological material such as the human DNA or embryological stem cells, so called biopatents, in different ways threaten

ethical values such as human dignity and integrity, and there is a risk for discrimination. Patent law ought to, as all kinds of law, reflect the ethical values that are the foundation of our society. Ethical consideration is needed on at least two different levels. One is a general ethical analysis from the viewpoint of the individual and society. Another is an analysis of the criteria of patentability for biopatents.

The integrity of the individual must be protected

Patents are considered to serve important purposes for society through incentive to significant development. In the long run the Directive may increase the risk for an opposite effect. The confidence of the general public can be weakened as patents on genes strongly touch every individual and therefore also the individuals integrity and dignity.

The anxiety that many people experience when patents on human genes are discussed must be taken seriously. It has to be taken seriously because otherwise there is a risk that it will obstruct the aim of the patent system. The ethical examination of patents on biotechnological inventions must be further developed. An open communication between the patient, the researcher and the patent owner is important and should be promoted. In my opinion the ethical review of a research project needs to be supplemented. As a requirement for approval from the ethics review board each participant included in a project should be informed if the research aims at a patent application. The individual should be given the possibility to decide for himself if hers or his DNA can be used in connection with a patent application. With such a prerequisite the integrity of the individual can be protected.

The Committee also had the task to consider the need for increased collaboration between authorities involved in assessment of ethical issues concerning patent applications involving biotechnical inventions. During the work of the Committee I suggested that a researcher in an application to a research ethics review board should state if the result of the research in the future might lead to a patent application. The handling officer at the patent authority could then, by reading the application and the decision from the ethics review board, be able to decide if a patent application should be reviewed particularly from an ethical point of view.

Patented genetic tests must be available to health care

Genetic or diagnostic tests protected by patents must be available for health care on reasonable conditions. Licences must therefore be given at reasonable costs. So far licences have only been considered for diseases with monogenetic inheritance.

For diseases with complex inheritance licenses for diagnostics and drugs have so far not been considered. Patent thicket and royalty stacking will probably be obstacles for the development of both tests and drugs for diseases with this kind of inheritance. Most diseases with this kind of inheritance are common diseases and therefore of special importance to health care.

Another serious situation may develop when new vaccines for serious epidemical diseases need to be developed. In my view there is a risk that the patent system delays or in the worst scenario prevents the development of necessary vaccines.

The possible difficulties in developing genetic tests and drugs for diseases with complex inheritance as well as vaccines is alarming. Research should be promoted to develop methods that could make it possible to avoid the serious consequences of patent thicket and royalty stacking.

I strongly recommended that these potential problems are taken seriously because of the consequences for society. I fear that the patent system may collapse because of this. To prevent problems in the future it is utterly important to gather knowledge when there is still time to do so. Approaches for solutions are probably to be found outside the existing patent system.

Benefit sharing is one such interesting approach by which the benefits that research projects give can be shared by all parties involved and therefore everybody will be interested to develop the product. Benefit sharing might also make it easier for people in general to view and understand how important any patent system is for the development of society.

Effect on costs for health care

There is a significant risk that development of biotechnical drugs will increase the cost for medicine in the future. The costs for genetic tests and drugs developed as a consequence of discoveries of genes and gene functions should not be underestimated. According to information available the cost for a certain genetic test may to 50 % be due to the cost for patent licenses.

The development in genetics now offers the possibility to investigate the complete genetic variation in one individual at one occasion. Thus only one single analysis is needed to find the genetic part of the cause to an individual's current and future diseases. When this becomes possible the focus of health care will shift from treatment of diseases to early identification and prevention.

If health care in the future focuses on early identification and prevention of diseases the costs for patent licensing will be considerable. The advantage for the individuals is obvious but the licensing costs may be insurmountable if health care has to pay a license fee on every gene that is tested. This development also makes it possible for large drug companies owning patents on genetic testing and medicine to make great profits for common diseases that most people only have an increased risk to develop.

Absolute product protection

When it comes to patents on human genes I think there is good reason to follow the request of the EU parliament to EPO and the member states to restrict the dimension of protection to only include concrete function of the gene described in the patent application. There are many good reasons to consider the urgent request from the EU parliament.

Conclusions

Patents on biotechnical inventions are an important incentive for development of new drugs. Immaterial knowledge therefore probably needs some kind of protection even in the future. If the patent system shall be able to persist there is urgent need for more research and development regarding the patent system design and function. Such research might also bring the system to be more in harmony with the development of societal values and fundamental ethical principles.

My most important objection concerns questions of ethical nature. Contrary to the Committee I consider that all legislation must be in harmony with fundamental ethical values to make people understand and respect them.

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