

## **SHOULD HUMAN GENES BE PATENTED**

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The international press has not stopped humming with the news that the human genome has been mapped. There is cause for celebration at a truly magnificent scientific feat, which at the same time raises serious concerns about how the genetic material of humans will be handled in future. Uppermost is the question of intellectual property rights. Will human genes be patentable? Who will hold these patents? Will the blueprint of mankind remain free for mankind or will it fall to the unbridled greed of commercialisation? There is nothing sacred about nucleotides or DNA but the notion of patenting human genes seems irreverent and unethical to many. It feels like the prelude to patenting human beings themselves.

The subject of human gene patents has become an important political issue because of the scientific, economic and ethical implications for societies in different countries. India, China, Mexico and Brazil joined the G8 countries (USA, UK, Germany, Italy, Russia, Japan, Canada and France) just a few days ago, to try to find a common approach to this exciting if controversial development. At present there appears to be a consensus against the direct patenting of genes which constitute an inherited patrimony forming part of what is, in the terms of the Universal Declaration on the Human Genome under UNESCO, a "common heritage of humankind". It remains to be seen how much of this initial sensitivity to ethical concerns continues into the future, especially as corporate interests begin to assert themselves.

Historically, Europe, unlike the US, has exhibited greater reticence and ethical sensibility with respect to the patenting of life forms. The European Patent Convention in Articles 52 and 53 speaks out clearly against the patenting of plants and animals. However with the growing importance of biotechnology as an economic sector, European lawmakers have begun to succumb to the pressure of corporations. Significant changes in the European understanding and interpretation of life form patents is discernible in the last few years. Plants have now been patented in Europe and the possible patenting of the highly controversial 'oncomouse' is being discussed. In the initial years, both the patents on the oncomouse and plants were successfully challenged.

Then came the European directive on patenting in biotechnology in 1998. As it stands, the directive does not allow the patenting of 'raw genes' but does allow it once a function has been ascribed to it. The directive however is considered to be poorly drafted. Many feel the European Union does not have legislative or normative competence in the field of ethics and therefore the most important aspects dealing with the ethical aspects of patenting are relegated to the preamble, which is not binding.

There is ambiguity and confusion about how definitions like 'inventions' and 'discoveries' in the context of human genes will be handled in future. Most nations of the world including Europe do not allow patenting of mere discoveries. The US patent law however permits discoveries to be patented in the same way as inventions. Whether or not the distinction

between inventions and discoveries, one patentable, the other not, is maintained, will play an important role in determining the extent to which the human genome will get privatised.

Which way will the decision go? Will the discovery of human genes and their functions (existing as they do, in nature), be considered patentable? The participants of the G8 meeting in France expressed the view that only true innovations made on the basis of the structure of genes could in the future be protected by patents. In other words, the mere discovery of a gene must remain outside the scope of patentability. Biotechnological 'innovation' would start at the identification of the function of a gene through an experimental method, leading to the description of diagnostic or therapeutic applications. The US position is not yet clear, nor that of Japan, a nation that has expressed itself strongly on the new technologies.

In considering the technical aspects of patentability, the main difficulty and the possible conflicts between international patent offices will arise from the definition of a 'function'. Geneticists themselves do not always agree on the subject. Defining function is quite complicated since one gene can have several functions and the same gene in different settings will behave differently. The scientific concept of "gene function" has changed significantly from the early days of genetics. The older understanding of the relationship between a gene and the protein that it is supposed to synthesise has been overtaken by the new evidence of gene regulation.

In my view, human genes or any genes for that matter, should not be patented. These are naturally occurring and simply discovering which functions they perform in nature, can not in all sincerity be considered an 'invention'. If diagnostic kits are developed from the information obtained from the human genome project, these could certainly qualify as patentable products. If medication is developed, specially the protein derived, computer designed drugs, or totally new products are developed based on genetic information, then such special products and processes could be eligible for patents.

Never more clearly than now, does it become apparent that the patent system is simply not suited to protecting biological material which has a high degree of in built variability. No two plants or two humans are the same the patents system was developed for the industrial sector where finite, unchanging products like motors and gear boxes were invented. Even then, if the purpose of the patent law is to reward creativity and innovation so that the society and the inventor benefit, then stretching semantics and contorting definitions to suit commercial interests will become a self defeating exercise very soon. This kind of trickery will perhaps make a quick buck but it will not foster true innovation, which will ultimately be to the detriment of society