

PROMISE OF THE HUMAN GENOME: - Does India have a role

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One of the biggest stories to break at the turn of the century was the mapping of the human genome. Underway as a multi-nation effort for the last ten years, the news that the blue print of man was now decoded has raised hopes and unleashed disquiet in equal measure. 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. 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, specially as corporate interests begin to assert themselves.

Regarding the technical patentability of human genes, 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 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.

Another difficulty and the source of 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 however are developed from the information obtained from the human genome project , these could certainly qualify as patentable products.

Putting aside the ownership question for now, what are the possibilities that arise from this development? Is it all good? All bad? Is there a role for India in this scheme? The answers

are mixed. On the one hand, there is the very real risk of personal genetic information being abused. On the other, this development opens up fantastic possibilities in medicine, specially preventive medicine. One of the really ambitious targets of the "postgenomic era" is personalized medicine through 'designer drugs'. Current practice is to try out which drug has the best effect on a certain heart patient. But instead, on the basis of personal genetic profiles drafted with genetic chips, it should be possible to determine in advance which form of treatment promises the patient the greatest relief with the least side effects. And yes, India could play a very significant role, contributing to the understanding (and cures) of several categories of disease, more than perhaps any other country, because of its special social structure.

On the bad front, it is rightly feared that if the genetic profile of an individual reveals a propensity for a serious disease or a heritable heart condition, insurance companies and potential employers would discriminate against such candidates. People with genetic traits predisposing to disease may not get jobs. Medical insurance companies may not be willing to cover them. Even though this kind of data would probably be kept confidential, we have seen time and again that such confidentiality can be breached quite easily. This fear is therefore not imagined but real. Legislators and society will have to bring forth enormous will to prevent discrimination of this kind.

Since it got underway, the Human Genome Project has held the promise of providing drugs that apart from providing cures for cystic fibrosis and other genetic disorders, could also treat more common diseases like cancer, cardio-vascular diseases, Alzheimer's dementia and rheumatism by treating the underlying causes of these diseases. With the blueprint in hand though, the situation does not look as straightforward as one had hoped.

Experiments on mice, in which specific genes were eliminated, have shown that it is often impossible to predict how healthy, or otherwise, the animal will be on the basis of individual genetic traits. This should be taken as a warning against inferring that a supposedly negative gene in humans automatically indicates a health defect. But genetic researchers remain confident that patients will soon benefit from detailed information on their individual genetic codes. In members of families with hereditary cancer of the colon, for instance, doctors can search for a genetic characteristic causing the disease. Patients with the defect would then be advised to have a prophylactic operation.

But another instance, the identification of a breast cancer gene in families exhibiting hereditary breast cancer, highlights the complicated issues arising from predictive genetic tests. There is not enough information to say for sure whether a woman possessing this gene will actually develop a cancer. Nor is it known whether the breast cancer will develop when the patient is 35 or not until she is 75. Since there is no certain way of preventing the outbreak of the disease, the only advice is to go for regular check-ups in young adulthood.

As for India, it offers a rich resource for studying functional genomics or the functional aspects of the genetic map. With its caste based communities intermarrying among themselves, India provides rare genetic material in family pedigrees. Good genes like mathematical ability and bad genes like for breast cancer are concentrated in families and communities because of selective inter-marriage. These inbred communities can reveal the

inheritance pattern of genes and functional genomics can reveal what these genes actually do. This is a powerful combination allowing the scientist to understand how genetic disease is transmitted and how, by understanding gene function, it can be treated.

Therapy aside, genetic research is also expected to bring diagnostic improvements. It will improve the scientists' understanding of clinical processes such as Alzheimer's disease and Arthritis. Once the processes of disease have been understood, ways can be found to treat the conditions. With the aid of genetic chips hardly bigger than a postage stamp, it will soon be comparatively easy to identify the individual variations in the genome of a healthy and a sick person. With precision diagnosis of this kind, it will be easier to match a therapy.

The human genome has opened up endless possibilities. It has certainly pushed the frontiers of science in a most dramatic way. The understanding and treatment of disease will be a major beneficiary of this breakthrough. The challenge before mankind is how it will treat this information. Will it be used in the service of all, will it be a tool to alleviate sickness and suffering, will it offer hope to those earlier doomed by the relentless march of degenerative diseases like Alzheimer? Or will it end up in the hands of a few, making money for the rich and powerful that will control the key because they hold the patents.

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