
Guest editorial

Research on the human genome and patentability – the ethical consequences

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Abstract

The genome is one of the primordial elements of the human being and is responsible for human identity and its transmission to descendants. The gene as such ought not be appropriated or owned by man. However, any sufficiently complete description of a gene should be capable of being protected as intellectual property. Furthermore, all utilisations of a gene or its elements that permit development of processes or new products should be patentable. Ethics, in the sense of moral action, should come into play from the very first stages of research into the human genome. Protection of intellectual and industrial property is of purely legal concern and need not provoke ethical consideration. By contrast, the use of the results of, and in particular the commercialisation of products deriving from, research into the human genome, ought to be subjected to ethical consideration and control. Considering the economic and societal stakes of such research, ethical analysis ought to be at an international level if mistakes and unforeseen risks of conflict are to be avoided.

Résumé

Le génome est un des éléments primordiaux de l'être humain: il est responsable de son identité et de la transmission de celle-ci à la descendance.

Le gène, en tant que tel, ne peut donner lieu à une appropriation par l'homme. Cependant, toute description suffisamment complète d'un gène, doit donner lieu à protection de la propriété intellectuelle. D'autre part, toute utilisation du gène ou de ses éléments, permettant l'obtention de procédés ou de produits nouveaux, doit donner lieu à brevet.

L'éthique, en tant que morale de l'action, devrait intervenir dès les premiers stades de la recherche sur le génome humain.

La protection de la propriété intellectuelle et de la propriété industrielle est de l'ordre purement juridique et ne doit pas faire intervenir de considération éthique. En

revanche, l'utilisation des résultats, et notamment la commercialisation des produits issus des recherches sur le génome humain, doit être l'objet d'un contrôle fondé sur la démarche éthique.

Compte tenu des enjeux économiques et sociaux d'une telle recherche, l'approche éthique doit se situer au niveau international afin d'éviter les dérives et les risques de conflit encore imprévisibles.

Forty years have passed since the discovery of the DNA double helix by Watson and Crick and the award of the Nobel Prize for chemistry to Mullis for the discovery of gene amplification. The period has been a rewarding one for the development of research on the human genome, the components of which have now been located on the chromosomes and chemically identified in the form of nucleotide sequences. We are now at a crossroads and we must know or decide where to draw the line regarding gene patentability and the use of the patented products. Although there are still some areas of obscurity, the chemical sequences of several thousand genes have been identified, thanks to human genome research programmes.

The gene has two vital functions: the transmission of hereditary material to descendants and induction, through the transcription mechanism of a specific synthesis, expressing a precise function.

The commercial potential of genes and their nucleotide sequences is obvious, particularly in the preparation of human products such as insulin, growth hormone or antihemophilic factors, and for developing diagnostic kits for genetic diseases and prenatal diagnosis, and ultimately for gene therapy.

In view of the high commercial stakes, and in the absence of an exact knowledge of the function of all nucleotide sequences identified from the human genome, we are faced with the problem of how to protect such sequences while ensuring that ethical rules are respected. These rules are founded on the need to recognize the integrity of the human body and the identity and autonomy of individuals.

Human bioethics may be seen to be founded on three principles: respect for human dignity, ie, respect for the human being and the identity of the individual; respect for knowledge, and in particular

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intelligence and the scientific approach; and a rejection of disproportionate financial gain and respect for fair reward, whether in terms of payment or social recognition.

Learning, the instrument of knowledge, allows human beings to take possession of what we are and of our surroundings. Knowledge requires intelligence and intuition. It is for humanity a means of discovering the universe and invents its own modalities of expression. These may be languages or software and may be used as tools or instruments: they express an aspect of our human identity. The process of discovery leads us to identify natural laws, mechanisms or objects which already exist independently of human beings. Invention on the other hand is the process whereby humans can construct new elements that they can use. Invention is the result of human ingenuity and knowhow.

In these circumstances, no one can have the right to monopolize a discovery, as every discovery is part of the natural order to which human beings themselves belong. Human beings must treat any discovery with an attitude of humility rather than one of ownership. Nevertheless, any inventive process requiring intelligence can be claimed non-monopolizing and a fair reward expected. It is this principle which is behind patent law.

The human genome cannot be patented *as such*, nor can its components. This is true not only for the human genome but for those of all living creatures. Identification of the genome, and of the genes of which it is made up and of the nucleotide sequences which describe the composition of these genes, constitutes a discovery. In a specific sociocultural context, the genome is responsible for the transmission of inherited characteristics. This gives the identity to the individual. It is this that explains why, in the organism, the gene occupies a unique position, far more significant than its function as biochemical machinery involved in the transcription mechanism for the synthesis of specific products. The genome cannot – must not – be patented any more than a natural living being can be. Neither the human body nor its component parts can properly be regarded as assets to be marketed; as sources of financial gain. Patent law cannot in principle apply to DNA sequences without any precise function. Not only is this unacceptable in principle – were it not so accepted, institutes and scientists would be tempted to protect their intellectual property by keeping their results for their own use, to the detriment of all.

Under these circumstances, the problem facing us can be put very simply: on the one hand the functions of the gene or the nucleotide sequence are discovered and known. In this case patenting is possible, provided that the claim relates to an inventive manufacturing process which is new and can be applied. On the other hand, the function is not yet known and patenting is *not* possible: then it is necessary to find another means to protect intellectual property.

Any obstacle to the free movement or exchanges of data relating specifically to such sequences, will impede scientific progress.

It is therefore necessary to protect DNA databanks, for instance, by devising a specific identification process for each sequence. This will provide the opportunity to recognize the intellectual property related to the added value brought by each worker or working group.

Copyright law is probably not suitable since it primarily protects reproduction of information and not the use by a third party. Something more akin to the legal systems for the protection of software might be more appropriate.

Assimilating genetic sequences to *chemical molecules* would probably be a quicker way of arriving at a system of protection, particularly since, alongside natural sequences, artificial nucleotide sequences can now be generated by computer, as for instance, with drug design. The new and inventive character of the latter is obvious. A genome sequence could be regarded as a chemical product and this would require it to be treated as such from the point of view of industrial property. This would in no circumstances minimize the real ethical problems linked to the *use of results of research* on the human genome, and in particular the consequences of the industrial and commercial use of patents granted judiciously. A patent is not a licence. A patent does not confer unrestricted rights to commercialize something. The use of the product in the market has to be controlled by law.

Research on the human genome will lead to genetic testing, prenatal diagnosis, gene therapy and to research into predisposition to disease. Even if it is vital to make allowances for socio-cultural developments, respect for the broad ethical principles will prevent different countries outbidding each other in a world dominated by economics and industrial competitiveness. Thus every government has a duty to take account of the ethical, social and legal aspects of scientific progress, in the framework of a new deal between science and society.

Conclusion

It seems necessary to distinguish between: science and technology; patents, and use and commercialisation. *Science and technology* are consequences of knowledge and knowhow. They are the consequences of human intelligence, and they must be recognised as factors of progress for humanity.

Patents recognize human intervention for the realisation of a process and, or a product, and protect inventors against unfair reproduction and use of their inventions. The criteria are novelty, inventiveness and utility. *Use and commercialisation* incorporate not only the possibility of utilisation but also usefulness.

Patents should be the exclusive responsibility of a patent office. But the patent office should be

responsible for nothing but the patents. Patent offices are not responsible for ethical aspects but only for the protection of intellectual and industrial properties.

Human bioethics is involved in the two other categories, science and technology on the one hand and use and commercialization on the other. Science and technology cannot be developed solely as the province of science and ingenuity. While scientists are responsible for the development of science if they seem to push their ideas forward too far, society must – and will – point this out to them. The control of financing is one useful means of doing this. Thus, an ethical way of thinking is necessary for science and scientists as well as for engineers.

Utility should not be limited to utilitarianism and the use of the results and products of science and technology should more and more be controlled by

society. This is the role of national laws or national guidelines, taking into account social and cultural norms. But these national processes have to respect general bioethical principles, internationally accepted and related to fundamental human value.

Today, advances in science and medicine make it necessary to lay the foundations for a new social contract; failure to do so will not only undermine the relationship of trust between doctor and patient, between scientists and public perception of science but, more broadly, between individuals and society. Any such failure might thus seriously undermine the very society in which we live and lead to conflicts whose consequences are alarmingly unpredictable.

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News and notes

European Bioethics Seminar

The title of the fourth European Bioethics Seminar is Health Care Issues in Pluralistic Societies. The seminar will be held from 7–11 August 1995, in Nijmegen, the Netherlands.

It will be conducted by scholars from a number of European nations. Special attention will be given to European traditions in health care ethics. The seminar is designed (1) to provide the participants with both a theoretical and practical understanding of contemporary and pressing issues in bioethics and (2) to educate the participants on a range of topics and problems that are the focus of current debates, both within health care institutions and in society at large.

Lectures and discussion groups will be designed to attend to five principal topics: (1) Foundation and History of Bioethics; (2) The Person: Procreation and Reproduction; (3) The Person: Suffering and Death; (4) Person and Community,

and (5) The Human Body. All lectures and parallel sessions will be conducted in English.

The seminar is primarily directed to health care providers (for example, physicians, dentists, nurses, health lawyers, hospital administrators, bioethics committee members), and teachers in the areas of ethics, philosophy and theology. Senior students undertaking courses of study in the health professions are also invited to participate.

The fee is 900 DFL (approximately 420 ECU, 515 US\$ or 51,500 Japanese yen). The fee includes tuition, course materials, lunches, two dinners, and refreshments.

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