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FUNDACION BBV

INTERNATIONAL WORKSHOP ON THE HUMAN GENOME PROJECT
LEGAL ASPECTS

CLOSING STATEMENT
THE DECLARATION OF BILBAO
& CONCLUSION

Bilbao, 26 May 1993

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LEGAL ASPECTSCLOSING STATEMENT

- I Between 24-26 May 1993 in Bilbao in the Basque Country, Spain, an International Meeting was held on legal aspects of the Human Genome Project. The participants in the meeting included leading scientists and jurists. Amongst the scientists were four Nobel laureates honoured for their original scientific work and several leaders of the Human Genome Project who are in the forefront of the global programme to map (sequence) and describe the genetic make-up of more than 100.000 genes which constitute the human body. Amongst the jurists participating were leading Judges of the highest courts of several countries, legal academics and practitioners. The meeting was sponsored by the Fundación BBV of Spain. It was conducted with the co-operation of the Excm. Diputación Foral de Bizkaia, (Government of Bizkaia). It was held in the University of Deusto, Bilbao. It followed earlier meetings, also sponsored by the Fundación BBV which explored the scientific and ethical implications of the Human Genome Project.
- II The participants recommended that the Fundación BBV should continue its vital work upon this topic of great importance.
- III At the close of the Meeting, the participants adopted by consensus a Declaration (The Declaration of Bilbao). They also recorded a number of the most important conclusions which they had reached as a result of their Meeting. The Declaration and Conclusions follow:

DECLARATION

(The Declaration of Bilbao)

1. This Meeting convenes at a crucial moment in human history. Never, at least since the advent of nuclear fission, has humanity been presented by science with opportunities and dilemmas of such magnitude and complexity. The Human Genome Project is a global initiative, involving scientists and technologists in many lands. As befits its subject, it should develop in a truly global and co-operative way. It should reflect the precious universal quality of human identity. It should develop for the benefit of all humanity, without exception: for people of all races, continents, creeds and opinions. All people of the world are involved in it. The issue is nothing less than the future of humanity.
2. The full mapping of the human genome will open a new era for the investigation of the expression and regulation of genes and their products. It will provide hitherto unavailable insights into normal human physiology and also the pathogenesis of genetic diseases. It will lead to the identification of numerous altered genes. Already a number of these have been identified. But they are only a fraction of the discoveries which lie ahead. As the project proceeds it may be expected that new preventive and ameliorative therapies, targeted at altered genes, will become possible.
3. The project will help to define individual identity with unparalleled accuracy and in previously unimaginable detail. It will also render possible the precise identification of group identities, such as suggested racial differences.
4. The information which will be derived from the Human Genome Project will undoubtedly prove of inestimable benefit to humanity in so far as it permits many human illnesses to be tackled and, in time, ancient diseases, until now incurable, to be treated. Already, the earliest uses of genetic information, discovered as a result of the Human Genome Project, are being adapted to the benefit of patients in many countries.
5. However the participants in the Meeting recalled the many grievous examples of the misuse of scientific experimentation and the unethical eugenics in earlier decades of this century. They serve to alert humanity, science and the law to certain dangers which should be addressed as the Human Genome Project proceeds. The participants were conscious of the possible ways in which genetic information might be used to divide groups and to invade individual human rights. They therefore considered it to be timely to state a number of principles which should be observed.

6. All just and modern societies are based upon the principle of respect for fundamental human dignity. Within such societies we should protect individual human rights. Genetic variations, like social diversity, are the attributes of free people. The notion of a monochrome genetic "perfection" and of the elimination, by genetic means of the precious variety of humanity, is not only socially repulsive. It also presents great risks to the human species which has survived and developed in evolution as a result of the myriad of individual genetic differences. History and the noblest expressions of humanity are replete with individuals of precious achievement but with altered genes. The poet Milton became blind; Goya and Beethoven became deaf; Mahler died of a congenital heart problem. The list is endless. It should not be forgotten.
7. The present moment in world history presents a unique opportunity to mobilize the benefits of the Human Genome Project for the advantage of all humanity. The coincidence of political events and technological advances impose on this generation of human beings the obligation to work in solidarity for the benefit of all future generations-and of our species. The political events promise the possibility of rare international cooperation and, where necessary, regulation in the interest of our planet and its inhabitants. They also promise growing sensitivity to the protection of human rights and dignity both in our own countries and beyond their borders. The technological advances make remarkable changes possible-and bring that message to the four corner of the globe.
8. It will be a tragedy of historic proportions if humanity does not seize the opportunities presented by the Human Genome Project and ensure that they occur within a just framework of appropriate national and international legal regulation. It will be a travesty of justice if the benefits of the Project are not made available to people everywhere who share the common humanity which the Human Genome Project will help to demonstrate.
9. Amongst lawyers and lawmakers there is a need for education in the scientific and technological developments of genetics. And in their implications for the law and society. There is a need for a heightened sense of urgency. And for something of the same spirit of originality that has marked the work of scientists involved in the Human Genome Project. For example, as identified in this Meeting some of the problems of permitting innovative genetic discoveries or inventions to be patented by particular individuals or groups may require reconsideration of the basic concepts of present intellectual property law. The law of patents, copyright and trade secrets developed for an earlier, simpler age and for very different technologies. The advent of informatics demonstrated the need for new legal approaches; but they did not come. The advances of

biotechnology suggest that the need is now even more urgent. Jurists, like the scientists, should rise to this challenge. Governments and legislatures should also respond, as should the relevant international agencies.

10. Amongst scientists there is a need for awareness of the international law which governs human experimentation. There should be a re-dedication to the fundamental principle of the free exchange of basic scientific knowledge. Many of the participants believed that, pending greater understanding of the ramifications of the functions of human genes and to prevent any risk of danger to the species or the environment, there should be an international moratorium on the modification and use of the human germ line. During this moratorium, national and international rules should be developed, having as their dual objects:
- . the protection of humanity and the world in which it lives; and
 - . the just distribution to people everywhere of the benefits of the Human Genome Project whose product belongs ultimately not to individual scientists, nor to sponsoring nations but to human beings in every land: of this generations and of all generations to come.
11. This is a challenge in which we cannot afford to fail. It is one worthy of the closest cooperation of scientists and jurists everywhere. The dialogue of Bilbao should reach out to scientist and lawyers in all parts of the world.

CONCLUSIONS

12. The participants noted a great number of legal problems which will need to be addressed as the Human Genome Project proceeds. Without in any way purporting to exhaust the subjects discussed, the following may be cited by way of illustrations:
- . the protection of the confidentiality of every individual's genetic information and provision of appropriate exceptions;
 - . the implications (if any) of genetic predispositions for culpability in criminal law and for notions of free will upon which that law is based;
 - . the operations of patent law in relation to human genes and sequences

and the adaptation of that law to prevent the stagnation of scientific inquiry and to provide just limits to the proprietary rights necessary to stimulate and fund research;

the provision, by international and national law, by criminal and other sanctions, of clear legal limits on certain forms of genetic engineering (eg. hybridization and, possibly, cloning);

the assurance of just procedures to allow scrutiny of genetic testing as a means of providing identity evidence;

the use and misuse for insurance purposes of genetic information about a proponent for insurance;

the limitation of genetic testing in the employment setting and provision for the implications of genetic knowledge in labour relations; and

the resolution of the tension between the demand of full freedom of research and scientific expression and the protection of other human freedoms which may be endangered by the unwanted spread and use of genetic information about an individual or a group.

13. In free societies, scientific investigation proceeds, as it should, in conditions of freedom: generally unimpeded by excessive legal regulation or bureaucratic control. Self-regulation and peer review by scientific colleagues remain important protections in science for the respect of basic human rights. They will continue to operate in the field of genetics. Premature, ill considered, uninformed and heavy-handed legal regulation should be avoided. Any laws which are prepared on this subject, arising out of the Human Genome Project, should be drawn in close consultation with the scientific community and with deep knowledge of the applicable science and technology. But it is also imperative to consult people who may be immediately affected by the development of the law in question. The general community should also be consulted and regularly informed in appropriate ways. An informed and educated community is less likely to fall prey to irrational fears or unfounded alarm.

14. In general, no use should be made of the genetic information specifically about an individual without that individual's freely given and informed consent or by authority of a law duly made for higher social objective, compatible with a democratic society.

15. It is by no means clear that international regulation has a major part to play, at least at this stage of the Human Genome Project. Diversity in national and sub-national law-making at the early stages of a

technological development has merit. Nevertheless, the variety of global legal and ethical perspectives on genetic should not be underestimated. There are some implications and consequences of the Human Genome Project which will require international regulation. The valuable work of UNESCO and of the Human Genome Project Organisation (HUGO) were noted. However, the participants felt that further attention was urgently needed to the establishment of an international forum or agency with the legitimacy of governmental participation to consider the many social, ethical and legal implications of developments in mapping the human genome. Such a body could include amongst its objects the exchange of information about scientific advances and legal regulation, national and international. High on the list of the activities requiring fresh international treatment is clearly the consideration and design of a new regime of intellectual property law which provides just protection and proper economic reward for innovation involving human genes whilst at the same time defending the common heritage of humanity in the human genome and safeguarding for human beings everywhere, rich and poor, the essential benefit of this most promising development of science.

16. We stand on the brink of a new era for humanity. In it we will come better to understand the origins of our species, its marvelous variety, its common links with all sentient creatures, its place in its environment and the vision of its future. It is essential that the scientists and lawyers of today should respond to the challenge of the new era with humility, imagination and a sense of global justice.

Bilbao
26 May 1993