Genetics, genomics and the patenting of DNA

Review of potential implications for health in developing countries

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Foreword

Rapid advances in genetic technology and human genome research make it almost certain that genetics and genomics will become more and more important for health improvement. If used appropriately, this knowledge will provide many exciting future opportunities to achieve better health for all people. However, it is clear that many individuals, groups and nations have concerns about the use and exploitation of genetic data and genome technology. Biomedical research in human genetics can lead to the development of diagnostic and pharmaceutical products. Patents may be necessary to raise funding to develop such products commercially, but patenting also has the potential to impede access to genetic materials, to the ultimate detriment of service delivery to those with genetic disorders, especially in developing countries.

While governments have long relied on patents and other forms of intellectual property to foster innovation, in recent years there has been some concern that patents on genes may hinder research in the public sector, and push costs too high for widespread access to medical products and services, particularly for complex diseases such as heart disease, cancer, diabetes and asthma. However, the extent of the impact of patents on genomics innovation and on access to genetic services continues to be a matter about which there is great disagreement. The Human Genetics Programme, with this initiative, aims to draw together existing arguments and evidence to present a picture of the current landscape of the debate, from a pubic health perspective.

Genetics differs from many areas of research in that important new knowledge can come from an individual, a family, or an ethnic group with a particular genetic variant. Genetic material, and the information it encodes, therefore has the dual quality of being both personal and communal. The human genome and the segments of DNA that constitute it likewise would appear to have conflicting status of being both proprietary, and a common heritage. Intellectual property is a system developed with the ultimate end of promoting the public good by fostering the creation of useful new products. An important challenge is how to square the seemingly competing needs of inventors and communities to ensure an equitable distribution of benefits.

This report does not look to define policy, but to highlight areas of contention, suggest avenues for further investigation and stimulate dialogue among different stakeholders. Thus, the report may serve as a point of departure for professionals and public health officials to develop policies and appropriate practices. It expresses the view of the authors and does not necessarily represent the policies of the World Health Organization.

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Human Genetics Programme

Acronyms

ABS	access and benefit sharing
ACHR	Advisory Committee on Health Research
AIPPI	International Association for the Protection of Intellectual Property
ARIPO	African Regional Industrial Property Organization
BGI	Beijing Genomics Institute
BRCA	breast cancer gene
CAS	Chinese Academy of Science
CBD	Convention on Biological Diversity
CHGC	Chinese National Human Genome Centre
CVC	citrus variegated chlorosis
DMD	Duchenne muscular dystrophy
DNA	deoxyribonucleic acid
EMR	exclusive marketing right
EPO	European Patent Office
EU	European Union
EST	expressed sequence tag
FAPESP	State of São Paulo Science Foundation
HGP	Human Genome Project
HUGO	Human Genome Organisation
IP	intellectual property
IPR Commission	Commission on Intellectual Property Rights
IPRs	intellectual property rights
JPO	Japan Patent Office
LDCs	least developed countries
MCH	Miami Children's Hospital
OECD	Organisation for Economic Cooperation and Development
ONSA	Organisation for Nucleotide Sequencing and Analysis
PCR	polymerase chain reaction