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This month, the policy section of GenInfo features interesting items on the controversial topic of biotech patents. India passed the last amendment to its patent law that was necessary for it to conform to the TRIP requirement and, through a similar undertaking, Belgium now meets the requirement of European *Directive 98/44 EC* on the patenting of biotechnological inventions. Gene patents are also one of the topics discussed in the latest report from the Canadian Biotechnology Advisory Committee on biotechnology and the health of Canadians.

For those interested in population genomics I recommend reading our editorial on genetic databases co-written by Anne Cambon-Thomsen, Clémentine Sallée, Emmanuelle Rial-Sebbag and Bartha M. Knoppers.

Finally a reminder that you can submit any interesting new piece of information on the ethical, legal or social issues of human genetics for inclusion in our forthcoming "Subscriber's contribution" section.

>> [Click here if you wish to post a submission](#) <<



NEWS

The "News" section of GenInfo provides a brief listing of events for the coming year (if organized by our team or partner organizations). We are also pleased to include a "Publications" section with a summary of books, articles and editorials published by members of our team.

PUBLICATIONS

BOOK CHAPTERS & ARTICLES

Y. Joly, *Integra v. Merck : The resurrection of the American research exemption?* Montreal, Centre for Intellectual Property Policy, 2005, online : <<http://www.cipp.mcgill.ca/db/news/00000025.pdf>>

Abstract: Monday, June 13th, 2005, the Supreme Court of the United States decided in a unanimous opinion to reverse the Court of Appeals' decision in *Integra v. Merck*, suggesting that better days may lie ahead for pharmaceutical research. This decision is a step in the right direction in terms of improving access to pharmaceutical products. [case commentary]

Y. Joly, "Genetics and Life Insurance: A Challenge to Privacy?", (2005) 25(9) *The Lawyers Weekly* 14.

Abstract: According to a recent privacy survey commissioned by the Canadian government, 91% of Canadians felt that insurance companies should not be allowed access to their customers' genetic information for insurance underwriting. In this climate of growing anxiety about possible genetic discrimination in Canada, the insurance industry would be well advised to abandon its current defensive position and adopt a more proactive approach. A moratorium on the part of Canadian insurers would not only appease popular anxiety, it might also prevent the enactment of specific legislation that would be premature at this early stage of the genetic revolution.



GENEDIT

The primary focus of the editorial GenEdit, which is written exclusively for HumGen, is to enhance our current understanding of policy statements related to human genetics through comparative international, legal and socio-ethical analysis.

CURRENT ISSUE

Volume III No.1 (2005)

Populational Genetic Databases: Is a Specific Ethical and Legal Framework Necessary?"

Anne Cambon-Thomsen, Clémentine Sallée, Emmanuelle Rial-Sebbag, Bartha Maria Knoppers

PAST ISSUES

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Newborn Screening, Banking and Consent

Claude Laberge, Linda Kharaboyan, Denise Avard

Volume II No.2 (2004)

Genetics and Life Insurance : A Comparative Analysis

Trudo Lemmens, Yann Joly and Bartha Maria Knoppers

Volume II No.1 (2004)

Protecting Genetic Information: A Comparison of Normative Approaches

Patricia Kosseim, Martin Letendre and Bartha Maria Knoppers

Volume I No.1 (2003)

Stem Cells in a Pluralistic Society: Consequences of Proposed Canadian Legislation

Dorothy C. Wertz, Marie-Hélène Régnier and Bartha Maria Knoppers



NEW LAWS & POLICIES

The following section contains new policy (legal, socio-ethical) statements on human genetics from international, regional and national sources.

We are constantly searching for documents to enrich our databank. If your organisation has published policy statements relating to genetics, or if you are aware of such new publications, kindly send us the relevant information and we will consider including it in the databank.

India/Government, *The Patents (Amendment) Act, 2005, No 15 of 2005*, India, April 5, 2005, http://www.patentoffice.nic.in/ipr/patent/patent_2005.pdf (date accessed: May 17, 2005).

The Indian Parliament has passed the Patents (Amendment) Bill 2005 that will replace the Patents (Amendment) Ordinance 2004 earlier issued by Government of India in December 2004. The Patents (Amendment) Bill 2005 introduces a product patent regime for food, chemicals and pharmaceuticals. India was required to introduce product patent protection in these sectors from 1.1.2005 in accordance with the obligation under the TRIPS Agreement of the WTO. To fulfill this requirement, the Government of India had issued an Ordinance in 2004. The Ordinance was to be approved by the Parliament. While introducing the Patents (Amendment) Bill 2005 in the Parliament, Government introduced certain changes from the provisions in the Ordinance.

Belgium/Government, *Loi modifiant la loi du 28 mars 1984 sur les brevets d'invention, en ce qui concerne la brevetabilité des inventions biotechnologiques*, Belgium, May 13, 2005, http://www.ejustice.just.fgov.be/cgi/article_body.pl?language=fr&caller=summary&pub_date=2005-05-13&numac=2005011224 (date accessed: May 30, 2005) [French version available only].

UNESCO, *The Tehran Statement*, Tehran, March 18, 2005, http://portal.unesco.org/shs/en/file_download.php/6ae2882ee85eb422dc9467861ba60e53TehranStatement.pdf (date accessed: June 7, 2005).

Gender and Justice in the Gene Age (Planning Committee), *A Feminist Meeting on New Reproductive and Genetic Technologies*, New York, May 2005, <http://www.gjga.org/report.pdf> (date accessed: June 7, 2005).

Gender and Justice in the Gene Age (GJGA) was a landmark meeting to discuss the political, social and ethical challenges presented by emerging reproductive and genetic technologies. It was the first U.S. meeting in many years to engage the issues of reproductive and genetic technologies within a framework that reflects the values and commitments of feminists who work from a global social justice and human rights perspective. Co-sponsored by the Center for Genetics and Society; the Committee on Women, Population and the Environment; and Our Bodies Ourselves, this meeting gathered some 65 participants including activists, academics and public intellectuals from feminist, disability, women's health, social justice and racial justice organizations. Most were from the U.S., but an important number came from Latin America, India, Canada, the UK, and Germany.

National Academy of Science - Institute of Medicine (IOM), *Cord Blood: Establishing a National Hematopoietic Stem Cell Bank Program*, Washington, April 14, 2005, <http://www.iom.edu/report.asp?id=26386> (date accessed: April 26, 2005).

Blood from umbilical cords--a byproduct of normal childbirth--is a good source of potentially life-saving stem cells, called hematopoietic progenitor cells (HPCs), the type of stem cells also found in bone marrow and mobilized peripheral blood that give rise to various kinds of blood cells.

Transplants of these stem cells have saved the lives of roughly 20,000 Americans with leukemia, lymphoma, sickle cell anemia, and several other illnesses in recent years. However, thousands of patients who might benefit from a transplant die every year waiting for a match. Although 22 public banks have been established in the United States to collect, store, and distribute donated cord blood containing these cells, these banks operate without any centralized coordination.

Recognizing the need for a national system for the collection, distribution, and use of cord blood, the U.S. Congress asked the Institute of Medicine to review the options for such a system and to make recommendations on the ideal structure of a national program.

The committee recommended that the U.S. Department of Health and Human Services should establish a new National Cord Blood Policy Board to set rules for the banking and use of lifesaving stem cells derived from donated umbilical cord blood. The department's Health Resources and Services Administration also should call for proposals to identify an

organization that would manage daily operations of cord blood banking and allocation nationwide.

Council of Europe, *Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research*, Strasbourg, January 25, 2005, <http://conventions.coe.int/treaty/en/treaties/html/195.htm> (date accessed: June 15, 2005).

This Additional Protocol to the Convention on Human Rights and Biomedicine on Biomedical Research builds on the principles embodied in the Convention, with a view to protecting human rights and dignity in the specific field of biomedical research. The benefits for human health of the acquisition of knowledge from research utilising systematic methodologies in the sphere of biomedicine are widely acknowledged. The distinction between medical research and innovative medical practice derives from the intent behind the intervention. In medical practice the sole intention is to benefit the individual patient, not to gain knowledge of general benefit, though such knowledge may emerge from the clinical experience gained. In an intervention for the purpose of biomedical research the primary intention is to advance knowledge so that patients in general may benefit. An individual research participant may or may not benefit directly.

Human Genetics Society of Australasia (HGSA), *Presymptomatic and Predictive Testing for Genetic Disorders*, Australia, April 1, 2005, [http://www.hgsa.com.au/PDF/Predictive%20testing%20\(General\)%20APRIL%202005.pdf](http://www.hgsa.com.au/PDF/Predictive%20testing%20(General)%20APRIL%202005.pdf) (date accessed: June 15, 2005).

These practice guidelines have been developed to describe some of the issues and principles that apply in presymptomatic and predictive testing. They are intended to guide all health professionals who undertake such testing. Those using these practice guidelines should be aware of other sources of information and guidelines such as those listed at the end of this document. Users should also note that there may be relevant Commonwealth and State laws which would take priority.

Human Genetics Society of Australasia (HGSA), *Predictive Testing in Children and Adolescents*, April 2005, <http://www.hgsa.com.au/PDF/PREDICTIVE%20TESTING%20IN%20CHILDREN%20VESRION%202%5B1%5D.%20RELEASED%20APRIL05.pdf> (date accessed: June 15, 2005).

These guidelines should be read in conjunction with the HGSA Guidelines, Presymptomatic and Predictive Testing for Genetic Disorders. As noted in those Guidelines,

- children should only have presymptomatic and predictive testing when the resulting information will be used to help with their health management in the immediate future
- the age at which testing can be offered to a child should be given flexible consideration by the testing team
- where the risk status for a disorder has been established for a child, either prenatally or after birth, the child should be informed that the information will be available once he/she has reached a level of maturity consistent with understanding its implications
- an asymptomatic at-risk child's DNA should not be collected and stored for research or for possible future use by the child or the family
- presymptomatic and predictive DNA testing should not be used to determine a child's suitability for adoption.

Canadian Biotechnology Advisory Committee, *Biotechnology and the Health of Canadians, A Report from the Canadian Biotechnology Advisory Committee on Biotechnology and Health Innovation: Opportunities, Challenges and Public Policy*, Ottawa, December 2004, [http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/BHI-Final_Dec-13-04-E.pdf/\\$FILE/BHI-Final_Dec-13-04-E.pdf](http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/BHI-Final_Dec-13-04-E.pdf/$FILE/BHI-Final_Dec-13-04-E.pdf) (date accessed: June 15, 2005).

Under the overarching theme of *Biotechnology in Canadian Society*, CBAC has assessed the role of biotechnology in health innovation and the implications of recent and prospective developments for Canadian public policy. This report provides an overview of the role or potential role of biotechnology in relation to the various factors that influence health; discusses some of the social and ethical considerations involved in the application of biotechnology; describes a framework for public policy related to biotechnology; and uses the framework to make a series of recommendations to the federal government that are specifically related to biotechnology-based health innovation

Australia/Government (Productivity Commission), *Impacts of Medical Technology in Australia, Productivity Commission Progress Report*, Melbourne, April 2005 <http://www.pc.gov.au/study/medicaltechnology/progressreport/medicaltechnology.pdf> (date accessed : June 15, 2005).

Medical technology is generally seen as an important driver of increased healthcare expenditure. There are concerns that spending pressures may intensify with the ageing of the population and likely future medical advances, raising questions about the benefits and costs of new technologies and processes for evaluating them. Against this background, the Australian Government asked the Commission to undertake a research study detailing the impact of advances in medical technology on healthcare expenditure, and the associated costs and benefits for the community.

Swedish National Council on Medical Ethics, "Opinion on Directive 98/44/EC on the Legal Protection of Biotechnical Inventions, and its Implementation in Sweden", (2005) 11, *Science and Engineering Ethics*, p. 113-115, <http://www.smer.gov.se/english/opinion/patent.eng.htm> (date accessed: June 28, 2005).

The following statement is the formal opinion by the Swedish National Council on Medical Ethics concerning the implementation of Directive 98/44/EC of the European Parliament concerning legal protection of biotechnical inventions, and the implications and implementation of this Directive in Sweden.

UK Newborn Screening Programme Center, *Newborn Blood Spot Screening in the UK: Policy and Standards*, London, April 2005, http://www.nelh.nhs.uk/screening/cpd/policies_standards.pdf (date accessed: June 20, 2005).

This first document Policies and Standards for Newborn Blood Spot Screening forms the 'core' of the series, setting out the policy position on each aspect of newborn blood spot screening and the standards to be implemented across the UK. It is intended to provide the key policy information and will be a useful resource for a variety of health professionals but of particular benefit to Directors of Public Health at Strategic Health Authority (or Health Board) and Primary Care Trust level, Departmental Screening Leads, Laboratory Directors, Heads of Midwifery, Heads of Midwifery Schools, Child Health Records Departments, and Specialist Commissioners. It concentrates on screening for phenylketonuria and congenital hypothyroidism. Standards for cystic fibrosis are being developed and will be included in the next version to be published in 2006.

Council of Europe, *Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research*, Strasbourg, January 25, 2005, http://www.coe.int/T/E/Legal_Affairs/Legal_co-operation/Bioethics/Activities/Biomedical_research/195%20ER%20recherche%20biomedicale%20e.pdf (date accessed: June 20, 2005).

Association of Reproductive Health Professionals, *Position Statement, Screening and Prevention of Reproductive Cancers and Breast Cancer*, Washington, April 16, 2005, <http://www.arhp.org/aboutarhp/positionstatements.cfm?ID=30#2> (date accessed: June 20, 2005).

ARHP supports successful, evidence-based strategies that reduce the incidence, morbidity, and mortality of reproductive cancers and breast cancer.

Canadian Institutes of Health Research, *Updated Guidelines for Human Pluripotent Stem Cell Research*, June 7, 2005, Ottawa, June 7, 2005, <http://www.cihr-irsc.gc.ca/e/28216.html> (date accessed: June 28, 2005).

While CIHR was working on the development and implementation of its Guidelines, the federal government was working on legislation on assisted human reproduction, including the use of human embryos for research. In March 2004, Bill C-6: an Act Respecting Assisted Human Reproduction and Related Research, became law. The Act applies to the derivation of stem cells from human embryos, but does not apply to research using human embryonic stem cell lines that have already been derived. However, the updated Guidelines do apply to both types of research.



DRAFTS

Japan/Government, Ministry of Education, Culture, Sports, *Science and Technology, White Paper on Science and Technology 2004, Science and Technology and Society in the Future*, Tokyo, 2004, <http://www.mext.go.jp/english/news/2005/04/05051301.htm> (date accessed: June 14, 2005).

This report deals with measures taken to promote science and technology under the provision of Article 8 of the Science and Technology Basic Law (1995 Legislation No.130). This report introduces, in Part 1 and Part 2, trends in the diverse activities of science and technology, and in Part 3, helps deepen readers' understanding of the measures taken to promote science and technology. Under the title of "The Future of Science and Technology and Society," Part 1 analyzes qualitative changes in society, such as the realization of economic prosperity and the advance of globalization due to developments in science and technology, and the deepening relationship between science and technology and society, such as the appearance of global environment problems and other new societal issues, and shows the issues and policies needed to build the optimum future relationship between science and technology and society, toward the establishment of an advanced science- and technology-oriented nation. Part 2 compares the science and technology activities of Japan and other major countries, using multiple kinds of data.

Switzerland/Government, *Loi fédérale sur les brevets d'invention (modification du projet)* Berne, 2005, http://www.ige.ch/F/jurinfo/documents/Revision%20LBI%202001_Projet%20%20Loi_Consultation_01-11-29.pdf (date accessed: June 22, 2005) [French version available only].



FAQ

The judicial, ethical and social concerns raised in the regulative texts that provide the framework for human genetics are complex. Our goal, with the Frequently Asked Questions (FAQ), is to approach these questions in such a way as to render them accessible.

Q What is a genetic database?

A More than a collection of data or tissues, a genetic database contains genetic, medical, biochemical, demographic, lifestyle or genealogical data. Genetic databases are methodically organized to facilitate clinical use or research.

According to the Commission de l'éthique, de la science et de la technologie du Québec (CEST), genetic databases can exist in several forms. Some contain DNA samples, cell samples or tissues samples (brain or heart donations following death). Information contained in databases varies. It can be genetic, proteomic (pertaining to proteins) or medical. Psychological or socio-economic information can also be included.

Certain databases contain information on an entire population, or sub-population (for example, a portion or region of the population that has a particular disease). These databases are often used for genetic research projects .

For more FAQs, visit HumGen's FAQ section at <http://www.humgen.umontreal.ca/int/faq.cfm?lang=1>



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