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VACANCY

Congress of the United States
OFFICE OF TECHNOLOGY ASSESSMENT
WASHINGTON, DC 20510-8025

MEMORANDUM

TO: Persons interested in the Human Genome Project and DNA patents
FR: Ami S. Jaeger, Project Staff
RE: OTA Workshop, "Legal Issues in Patenting Human DNA"
DA: April 27, 1993

As part of its assessment *The Human Genome Project and Patenting Human DNA Sequences*, the congressional Office of Technology Assessment (OTA) will hold a workshop focusing on legal issues. This meeting will be held on Thursday, May 20, 1993, 8:30 a.m. - 4:00 p.m. at OTA (first floor conference center, 600 Pennsylvania Avenue, SE, Washington, DC).

Enclosed for your information are a list of invited workshop participants and meeting agenda. You are welcome to observe all or part of this day-long meeting; please note working papers are available only to workshop participants. Additionally, conference facility security is strictly enforced. You will be screened with a metal detector and your personal belongings will be checked.

There is no need to register for the meeting, but do not hesitate to call me (202/228-6679) with any questions. I regret that lunch will be available only for workshop participants and OTA staff.

Office of Technology Assessment

THE HUMAN GENOME PROJECT AND PATENTING HUMAN DNA SEQUENCES

Advisory Panel

LeRoy Walters, Panel Chair
Kennedy Institute of Ethics
Georgetown University
Washington, D.C.

Charles Auffray
Genethon
Evry, France

David Botstein
Department of Genetics
Stanford University Medical Center
Stanford, CA

Robert M. Cook-Deegan
Division of Biobehavioral Sciences
and Mental Disorders
Institute of Medicine
Washington, D.C.

Rebecca S. Eisenberg
University of Michigan Law School
Ann Arbor, MI

James F. Haley, Jr.
Fish and Neave
New York, NY

Max D. Hensley
Gilead Sciences, Inc.
Foster City, CA

Thomas D. Kiley
Hillsborough, CA

William A. Linton, III
Promega Corp.,
Madison, WI

Lita L. Nelsen
Technology Licensing Office
Massachusetts Institute of Technology
Cambridge, MA

Deborah Nickerson
Department of Molecular Biotechnology
University of Washington
Seattle, WA

David A.A. Owen
Industrial Collaboration and Licensing
Medical Research Council
London, England

J. David Roessner
School of Public Policy
Georgia Institute of Technology
Atlanta, GA

Joseph Straus
Max Planck Institute for Foreign
and International Patent, Copyright,
and Competition Law
Munich, Germany

J. Craig Venter
The Institute for Genomic Research
Gaithersburg, MD

Teri S. Willey
Purdue Research Foundation
West Lafayette, IN

Ronald G. Worton
Department of Genetics
Hospital for Sick Children
Toronto, Canada

Marilyn Ziemer
Warner-Lambert
Morris Plains, NJ

Statement of Work

ETHICAL CONSIDERATIONS IN PATENTING HUMAN DNA SEQUENCES

The congressional Office of Technology Assessment (OTA) is undertaking an assessment of the legal, social, and ethical implications of patenting human DNA, in response to a request from Senator Edward M. Kennedy, Chairman, Committee on Labor and Human Resources, Senator Mark O. Hatfield, Ranking Minority, Committee on Appropriations, and Senator Dennis DeConcini, Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary. This contract shall provide a report to be used as part of this assessment. The report shall investigate the ethical issues presented by patenting of human DNA. All written documents generated as part of their contract may be used in part, or in whole, in support of the assessment.

The contract report will be used in part, or in whole, by OTA staff to prepare portions of the study. Comments from external reviewers might be sought for all or parts of the contract report. In addition, the contract documents may be used to support congressional testimony or other public statements by OTA.

Scope of Contract

The contractor shall prepare a report which provides a complete analysis of ethical and philosophical views posed by human gene patents and commercialization of gene research. The report shall include discussion of at least one the following:

- Apart from notions of heredity, how does one's genetic identity serve to establish one's self-identification? On a broader plane, how is society's concept of the individual linked with genetic identity? More importantly, explore the degree to which genes are part of the notion of human dignity.
- Where does one draw the line between allowing patents on human DNA and prohibiting the patenting of a human? Assuming that human DNA sequences have already been patented, devise an ethical model which draws lines between permissible patenting of human DNA and impermissible human DNA patents. Where do the following fall along the permissive continuum: fragments, sequence, gene, multi-gene complex, entire organ, entire organism (human being)?
- How do property rights square with notions of individualism and ownership of humans (ie: slavery)? Explore the notion of ownership. If a company or the government "owns" a gene (or a sequence), do they own it as it appears in you and I, or only as it appears in a petri dish in the laboratory? As an aside, compare the buying and selling of human eggs, sperm, and donation of embryos in the context of assisted reproduction with philosophical notions of ownership. Is ownership justifiable if the owner does not have exclusive rights or access to the gene?
- Given that there are many genetic sequences that are identical between humans, animals and even yeast, how does our genetic identity translate into a sense of human identity and humanness?

Schedule of Deliverables

OTA Staff Contract

Robyn Y. Nishimi, Ph.D., Project Director (202) 228-6690, or
Ami S. Jaeger, J.D. (202) 228-6679.

ethics.ws