

THE NATIONAL ACADEMIES

Advisers to the Nation on Science, Engineering, and Medicine



Overview of Committee on Intellectual Property Rights in Genomics and Protein Research and Innovation

Joint Project of Board on Science, Technology, and Economic Policy
and
Science, Technology, and Law Program

David Korn

AAMC

September 19, 2004



Committee Membership

✍ Shirley Tilghman (Chair)
✍ President, Princeton University

✍ Hon. Roderick McKelvie (Vice Chair)
✍ Partner, Fish & Neave

✍ Ashish Arora
✍ Professor, Economics and Public Policy,
Carnegie Mellon University

✍ Helen Berman
✍ Professor, Department of Chemistry
and Chemical Biology,
Rutgers University

✍ Joyce Brinton
✍ Director, Office for Technology and
Trademark Licensing, Harvard Univ.

✍ Stephen Burley
✍ Chief Scientific Officer,
Structural GenomiX, Inc.

✍ Q. Todd Dickinson
✍ Intellectual Property Counsel, GE
✍ Formerly, Commissioner, USPTO

✍ Rochelle Dreyfuss
✍ Pauline Newman Professor of Law,
New York University Law School

✍ Rebecca Eisenberg
✍ Robert and Barbara Luciano Professor
of Law, University of Michigan

✍ Charles Hartman
✍ General Partner, CW Group



Committee Membership, cont'd.

- ✍ Dan Kevles
- ✍ Stanley Woodward Professor of History, Yale University
- ✍ J.O. and Juliette Koepfli Professor of the Humanities, *Emeritus*, California Institute of Technology

- ✍ David Korn
- ✍ Senior Vice President for Biomedical and Health Sciences Research
- ✍ AAMC

- ✍ George Milne
- ✍ Corporate Officer and President of Central Research, Pfizer, Inc. (ret.)

- ✍ Richard Scheller
- ✍ Executive Vice President, Research, Genentech

- ✍ Rochelle Seide
- ✍ Partner, Baker Botts LLP

- ✍ Robert Waterston
- ✍ Professor and Gates Chair, Genome Sciences, University of WA

- ✍ Nancy Wexler
- ✍ Higgins Professor of Neuropsychology, Columbia University and
- ✍ President, Hereditary Disease Foundation

- ✍ Brian Wright
- ✍ Professor of Agricultural and Resource Economics, UC Berkeley



Charge to Committee

NIH asked the Academies to study and report on:

1. Trends in the number and nature of US-issued patents being granted to technologies related to genomics and proteomics
2. The procedures the U.S. Patent and Trademark Office and other patent offices (specifically Europe and Japan) are applying in acting on these applications
3. How the patenting of genomic and proteomic inventions and/or licensing practices for these inventions is affecting research and innovation
4. Based on the committee's findings, steps the NIH and others might take to ensure the productivity of research and innovation involving genes and proteins.



The IP Committee Has an Informative Web Site

http://www7.nationalacademies.org/step/STEP_Projects_Proteomics.html



Topics/Issues Examined By Committee

- ✍ US Patent and Trade Office Policies/Procedures/Operations
- ✍ Patenting Criteria
 - ✍ Utility
 - ✍ Novelty & Non-Obviousness
 - ✍ Written Description/Enablement
 - ✍ Scope of Claims
- ✍ Overview of International IP Policies and Practices
- ✍ Managing the Patent Thicket



Topics/Issues Examined By Committee, con't.

- ✍ Research Exemption

- ✍ Does One Exist?

Madey v. Duke University
CAFC October 2002

- ✍ Does One Exist? **Not at all Clear!**



Experimental Use Exemption

**Justice Joseph Story, 1813:
Whittemore v. Cutter**

“It could never have been the intention of the legislature to punish a man, who constructed....a [patented] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”



Experimental Use Exemption

**Justice Joseph Story, 1813:
Sawin v. Guild**

Patent infringement must concern

“..the making [of the invention] with the intent to use for profit, and not for the mere purpose of philosophical experimentation, or to ascertain the verity and exactness of the specification...”



Experimental Use Exemption

CAFC *Madey v. Duke University*, 2002

“...any act in the furtherance of the alleged infringer’s legitimate business and not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense...”



Experimental Use Exemption

CAFC *Madey v. Duke University*, 2002

“Our precedent clearly does not immunize use that is in any way commercial...[nor] any conduct that is in keeping with the alleged infringer’s legitimate business, regardless of commercial implications...”

Such activities as obtaining research grants and educating students “unmistakably further the institution’s [Duke’s] legitimate business objectives..”



Topics/Issues Examined By Committee, con't.

- ✍ Research Exemption

- ✍ University Experience Post-Madey v Duke

- Study in Progress (AAMC, AAU, COGR, AAAS)

- ✍ Draft Models – AIPLA



Topics/Issues Examined By Committee, con't.

Statutory exemption for use of patented subject matter only to discern or discover:

- ✍ Validity and scope of protection
- ✍ Features, properties, inherent characteristics
- ✍ Methods of making or using
- ✍ Alternatives to, improvements on, substitutes for



Topics/Issues Examined By Committee, con't.

- ✍ Patenting/Licensing/MTAs
 - ✍ Overall Trends in Industry and at Universities
- ✍ Research Tools/Diagnostics
 - ✍ Effect of Gene Patents on Genetic Testing and Research
 - ✍ Effect of Gene Patents on the Practice of Medicine



Statutory Exemptions

✍ **Hatch-Waxman, 1984**

Permits activities and uses reasonably related *solely* to developing information required to secure FDA approval (generics).

✍ **Frist-Ganske, 1994**

Permits medical practitioners to practice patented medical and surgical procedures on a body, but excludes the practice of processes that would violate biotech patents, and explicitly, the provision of clin.lab. services regulated under CLIA.



Committee Meeting Schedule

- ✍ December 13-17, 2004: International Workshop, Bellagio, Italy
- ✍ February 11-12, 2005: 6th Committee Meeting, Washington, DC
- ✍ April 21-22, 2005: 7th Committee Meeting, Washington, DC
- ✍ Report Release June 2005