Report from the SACGHS Patents and Access Task Force

Debra Leonard, M.D., Ph.D.
Chair, SACGHS Patents and Access Task Force
March 28, 2006

SACGHS Task Force Members

- Debra Leonard, Chair
- Emily Winn-Deen
- Jim Evans

SACGHS Task Force Charge

1. Review the NAS report and assess whether issues and questions raised by SACGHS are addressed
2. Determine whether there are areas that warrant further exploration and/or attention by SACGHS

BACKGROUND

Concerns raised by SACGT:

> ". . . gene patenting and licensing practices may be having adverse effects on accessibility to and the cost and quality of genetic tests."

Secretary's Advisory Committee on Genetic Testing
November 17, 2000

BACKGROUND

SACGT's Recommendations to HHS:

- Concerns and questions about possible adverse effects on access should be assessed more fully
- Further study by appropriate experts should be initiated

BACKGROUND

HHS' Response to SACGT:

- Agreed that patents raise important issues that need further exploration
- NHGRI ELSI program was initiating a study to gather further data on DNA-based patents
- NIH Office of Technology Transfer planned to work with HHS to determine whether further steps needed to be taken

BACKGROUND

NHGRI Funded-Study:

- Pressman L, et al., The Licensing of DNA patents by US academic institutions: an empirical survey. *Nature Biotechnology* **24**, 31-39 (January 2006)
  - Focused on DNA-based patents and licensing practices at research institutions

BACKGROUND

Other Studies of DNA-Based Patents

- Sevilla C, et al., Impact of gene patents on the cost-effective delivery of care: the case of BRCA1 genetic testing. *Int J Technol Asses Health Care* 2003 Spring;19(2):287-300.

- Cho MK, et al., Effects of patents and licenses on the provision of clinical genetic testing services. *J Mol Diagn*. 2003 Feb;5(1):3-8

SACGHS Task Force Charge – Part 1

Review the NAS report and assess whether issues and questions raised by SACGHS are addressed

SACGHS Task Force
Review of NAS Report

The Task Force is generally supportive of the first 12 NAS recommendations that relate to research issues and focus on ensuring that the public investment in genomics and proteomics is optimally benefiting society.

SACGHS Task Force Review of NAS Report

- Recommendations 1-11 address concerns related to research

- Recommendation 12 addresses extraordinary circumstances where the public health is threatened and suggests remedies through the courts

SACGHS Task Force Review of NAS Report

- Recommendation 13 is the only recommendation that relates specifically to clinical practice.
  - The SACGHS Task Force questions its feasibility in light of current realities of clinical laboratory operations and regulations.

SACGHS Task Force
Review of NAS Report

- None of the recommendations address questions related to the economic impact of DNA-based patents and licensing practices.

SACGHS Task Force
Review of NAS Report

- Research issues were well thoroughly investigated and the recommendations address most research concerns
- Clinical practice and economic impact issues of concern to SACGHS were not addressed by the NAS recommendations

NIH Response to NAS Report

NIH Intellectual Property working group has been established to review the NAS recommendations and develop options for implementing those addressed to NIH.

SACGHS Task Force Recommended Next Steps

1. Convey to the Secretary of HHS support for the first 12 NAS recommendations, emphasizing those recommendations that are within the Secretary's authority to affect (i.e., recommendations 1, 2, 3, 4, and 11).

SACGHS Task Force Recommended Next Steps

2. In particular, SACGHS should emphasize the need to implement recommendation 4, i.e., enforcement and monitoring of the requirement that funded investigators share published materials.

SACGHS Task Force Recommended Next Steps

3. Consider recommending that the Secretary use HHS' resources to educate researchers and clinicians on their rights and responsibilities with regard to intellectual property, especially on the lack of a research exemption for use of patented information/materials.

SACGHS Task Force Charge – Part 2

Determine whether there are areas that warrant further exploration and/or attention by SACGHS

SACGHS Task Force Recommended Next Steps

- Explore issues related to:
  - Licensing of genomic inventions and its impact on clinical practice
  - Economic impact of patenting and licensing of genomic inventions
  - Patent thicket, patent pooling, and current legislation

Areas of Impact on Clinical Practice Identified in the NAS Report

- Patient access
- Competitive perfection of tests
- IRB-approved clinical research in academic medical centers, regardless of funding sources
- Professional education and training
- Independent validation of test results
- Regulatory compliance

Goals for Today's Discussion

1. Discuss and come to consensus on whether to forward a letter to the Secretary related to the NAS report and whether to include the Task Force recommendations:
   - Express SACGHS' support for the first 12 recommendations
   - Highlight Recommendation 4
   - Suggest efforts be made to educate researchers and clinicians on intellectual property issues
2. Determine if SACGHS research questions are sufficiently addressed

Goals for Today's Discussion

3. Given that the NAS report does not address SACGHS' concerns related to clinical practice and economic impacts, should SACGHS move this from a monitoring to a working issue?

Goals for Today's Discussion

4. Proposed ways forward:
   - Hear from the NIH IP working group established to address the NAS recommendations
   - Review data from research supported by the ELSI program as a result of SACGT concerns
   - Explore the areas in clinical practice identified by the NAS report through a panel discussion with those who reported to NAS
   - Explore the experiences and patent policies in other countries (i.e. Canada, EU)
   - Monitor outcome of Supreme Court patent case

LabCorp vs. Metabolite

- Summary of question heard by the Supreme Court on March 21, 2006
  - Can a monopoly be validly claimed over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result?

Findings in Pressman, et al

- Important nuances of licensing practices are missed if the focus is on exclusive and non-exclusive licenses.
- Licenses are commonly ‘exclusive by field of use.’
- Institution studied are largely in agreement with the NIH guidelines for research tools and genomic inventions.

Findings in Pressman, et al

- Patenting and licensing behaviors are sensitive to market forces.
- DNA-based patents have declined every year since 2001 due to greater selectivity and due to patent costs including patent prosecution, maintenance and management costs.