

**Business Perspectives on Patents:
Biotech and Pharmaceuticals Federal
Trade Commission / Department of
Justice Hearings**

Barbara A. Caulfield

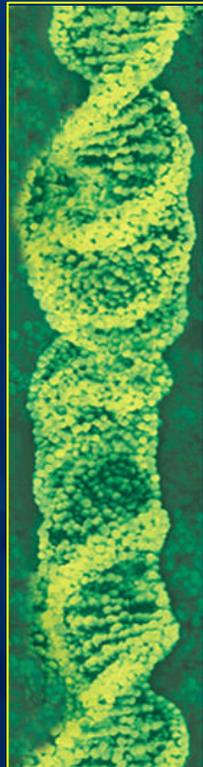
Executive Vice President & General Counsel

Affymetrix, Inc., March 19, 2002

Baseline

- Genomic research - early stages
- Tools - developing
- Databases - bioinformatics developing
- Public importance of rapid research built on public database
- Oncology - worldwide research
- Novel research in infant science and infant markets

Understanding Genomes

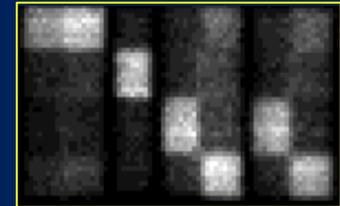


**Sequence
Database**

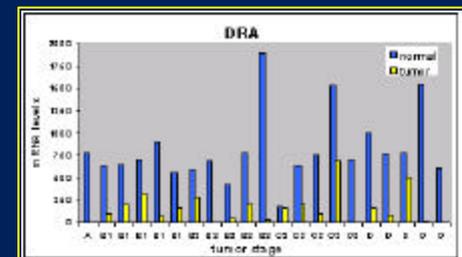
Variability



Function

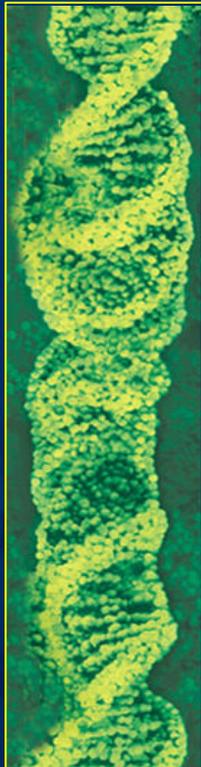


**Genotype
(DNA Analysis)**



**Expression
(RNA Analysis)**

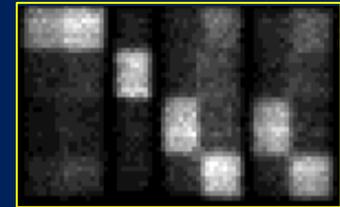
Tools to Understand Genomes



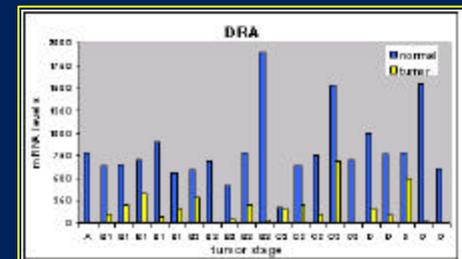
**Sequence
Database**



**Research
Tools**



**Genotype
(DNA Analysis)**



**Expression
(RNA Analysis)**

Fundamental Questions

- Who owns the genome?
- Who controls access to the genome?
- Who can monetize the genome?

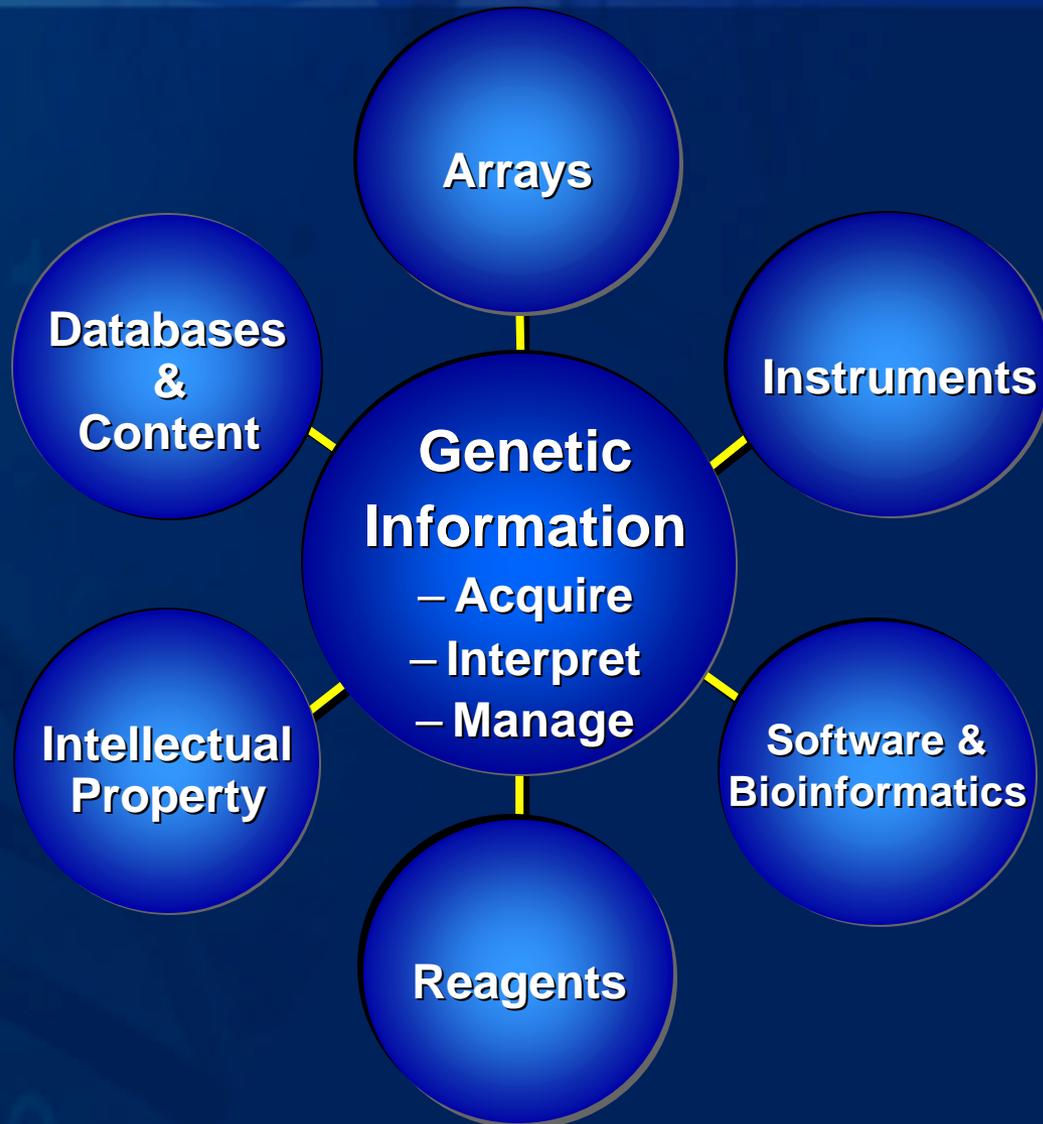
Should Naturally Occurring Gene Sequences be Patented

- The “land grab” in gene patents
- Rewarding early innovators vs. the cost to society
- Chilling effect on both public and private sector research
- Alternatives to patents on naturally occurring gene sequences

Patent Acceleration

- Explosive growth in patents
 - Doubling of patent filings by US corporations, 1988 - 2000
- Three-fold increase in patent litigation, 1981 - 2000
 - Costs proportionately much higher in biotech
- Licensing
- Research moving offshore - US competitive position
 - “Brain drain” impacts US competitive position

Components of Research Market



Codification of the Research Exemption

- Exists only as a “gentleperson’s agreement”
- To encourage universities and other non-profits to be *Innovation Incubators*
- Needed to bring rules of the road, both to researchers and to patent holders
- Distinction between commercial and noncommercial is key, with requirements that research be available in the public domain

A Patent Licensing Database

- License database minus trade secrets
- Maintained by government entity
- Brings sunshine to the licensing process
- Infant market

PTO

- Recent BIO/Pharma agreement with FDA on PDUFA III a possible model

Actions

- Codify research exemption
- Monitor patent process
- Strict penalties for patent misuse
- License database
- Specific examination of component integration