

# Personalized Medicine— and university technology transfer

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Universities and research hospitals have been and will be the source of much of the **information** underlying personalized medicine

- Human Genome Project
- The SNP Consortium
- Proteomics Consortium
- Breast Cancer Marker Consortium
- Plus: individual projects identifying pathways and receptors—and from there to relevant alleles
- And, importantly: banks of tissue samples and patient data

# Diagnostics: Stating the Obvious

- Personalized Medicine depends on reliable, usable, reasonably-priced **diagnostics**
  - Clinical segmentation of patients
  - Screening?
  - Self-testing?

# Research institutions' role in diagnostics

## ■ A. The Genetic Differences

- Discovery of the genetic differences
- Discovery of the pathways that these genetic differences influence
- Validation of the clinical significance of these differences

## ■ B. The Technology of Diagnostics

- e.g., microfluidics, controlled release, nanotechnology, sensors, etc.

# Where does university patenting and licensing fit in?

Predicated on:

- Do basic research—with **information** freely available to all
- Patent inventions from the research
- License IP out for development—using exclusivity as an incentive for first-mover early investment in new technology

# Licensing (exclusivity) is the puzzle

■ When is the public interest best served by:

– Putting the “invention” in the public domain

vs.

– Patenting and granting exclusive license to incentivize development

# Gene Markers: To Patent or not to Patent?

- If the invention is the **gene marker** itself, does the model best serve the public in terms of encouraging access, continually-improving technology and healthy competition?

# Exclusivity: balancing incentive to invest with optimizing public access

If there is a strong correlation between a single mutation and a disease, then patenting and licensing may be appropriate

## Examples:

- Athena Diagnostics: Myotonic Dystrophy (MIT)
- Myriad Genetics: BRCA(1,2) breast cancer (University of Utah)

# Exclusivity provides incentive for investment in:

- Test development
- Clinical trials
- FDA approval
- [Patient Counseling Programs]
- Physician and patient education

However, when correlations are weak  
and patterns of multiple genes are  
needed.....

Patenting and exclusive licenses to  
single markers can be counter-  
productive for product development  
and patient benefit

# Patents on individual genes may inhibit investment in multi-marker diagnostics

Potential developer:

- May have to locate and negotiate multiple licenses (each additional marker requiring another negotiation and stacking royalties)
- Potentially could be held hostage for high royalties by a single patent holder if the marker is important
- May be unable to complete a panel of markers if an key marker is exclusively licensed to another

For this reason, many funders of research (information development) are discouraging the patenting of markers by universities

- NIH required that genes sequenced in the Genome Project be placed in the public domain
- Similar NIH requirements for SNP consortium
- Breast Cancer Marker Consortium (foundation funded) has restrictions on patenting and licensing by the universities

# On the other hand: The patenting and licensing model works well for the Technology of Diagnostics

- If the invention is related to the **method** of detection (e.g., microfluidics, sensor technology) then exclusivity is justified
  - The platform, not the gene is the basis of competition
  - Many methods of detection (so you are not eliminating healthy competition)

# Exclusivity to induce investment in the Platforms

- Most new platforms requires substantial investment to make them work economically and reproducibility—and to introduce them to the market
- Patents are critical to protect the investment
- A number of new companies forming based Platforms

# Conclusions?

- It's early days
- Government support for basic research continues to be critical for the fundamental **genetic data** for personalized medicine—and for groundbreaking **platform technology** for diagnostics
- Universities need to be strategic about **what** they patent—in the public interest

Thank you!