

# Patenting and Licensing of the Breast Cancer Susceptibility Genes - *BRCA1* and *BRCA2*

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# Overview

- Brief History of Myriad, *BRCA1* and *BRCA2*
- Technology Development and Commercialization
- Quality Clinical Service
- Research
- Insurance Coverage
- Provider Education
- Patient Awareness
- Summary

# The Challenge

Over 1,000,000 people in the US carry mutations predisposing them to cancers that are preventable or treatable at an early stage

– fewer than 3% know it

# History of *BRCA1*

- 1991 *BRCA1* linked to chromosome 17 by Mary-Claire King (UC Berkeley)
- 1994 *BRCA1* cloned at U of Utah in Mark Skolnick's lab and published by 40 collaborators
- 1994 First US patent filed by U of Utah, NIEHS and Myriad
- 1996 Commercial test publicly available
- 1997 First US patent awarded

# *BRCA1* Co-discoverers

- National Institute of Environmental Health Sciences (NIEHS)
- University of Utah Research Foundation
- University of Laval/Endo Research – Quebec
- Hospital for Sick Children – U of Toronto
- University of Tokyo
- Myriad Genetics, Inc.

# History of *BRCA2*

- 1995 *BRCA2* cloned at Myriad/ U of U by Mark Skolnick & collaborators
- 1995 First *BRCA2* patent filed in US by U of U and other institutions
- 1996 Commercial launch of clinical service
- 1998 First *BRCA2* patent granted in US

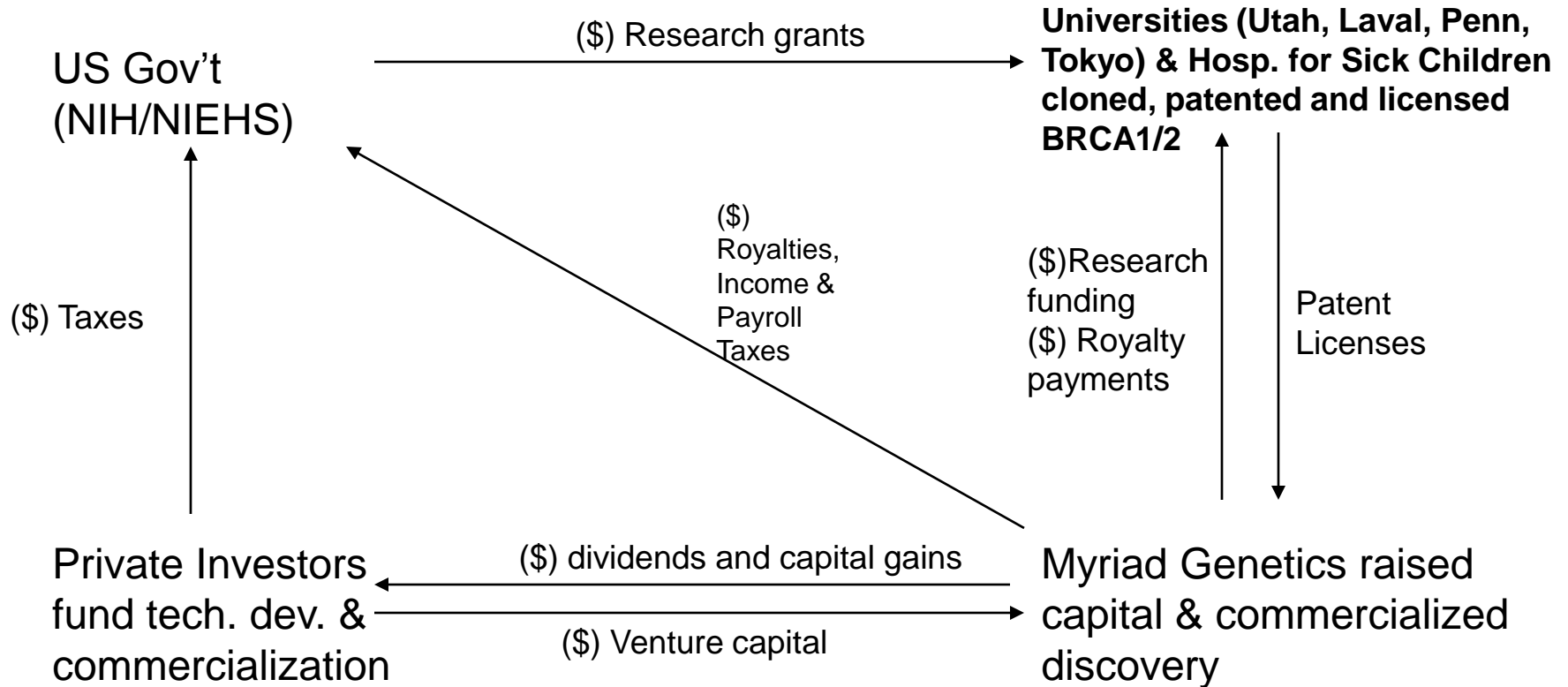
# *BRCA2* Co-discoverers

- University of Utah Research Foundation
- Hospital for Sick Children – U of Toronto
- University of Pennsylvania
- Myriad Genetics, Inc.

# Myriad Genetic Laboratories, Inc.

- 1994-1995 Development of process and laboratory to perform high throughput sequencing 1994-1995
- Oct. 1996 Clinical launch of BRACAnalysis® (*BRCA1* and *BRCA2*)
- Sept.2000 Clinical launch of COLARIS® (*MLH1* and *MSH2*) for HNPCC
- May 2002 Clinical launch of COLARIS AP® (*APC*) for FAP/AFAP
- Aug. 2002 Addition of large rearrangements panel for BRACAnalysis®
- Dec. 2002 Clinical launch of MELARIS® (*p16*)
- July 2004 Addition of large rearrangement detection to COLARIS®
- July 2004 Addition of *MYH* mutations and large rearrangement detection to COLARIS AP®

# The BRCA Discovery Model



# BRCA Test Development and Commercialization

- Investment required to bring BRCA testing to the clinic
- Patents facilitated
  - technology development,
  - state-of-the-art laboratory
  - business operations
  - broad access
  - clinical development & improvement
- These activities are not funded through typical research grant mechanisms
- Return on Investment
  - dividends
  - capital gains
- Obligation to licensors and investors to develop, commercialize and protect the intellectual property

# BRACAnalysis<sup>®</sup>: Example of a High-Quality Clinical Service

- Full Sequence Analysis of BRCA1 and BRCA2
  - (both directions = 35kb)
- Large rearrangement analysis
- <3-week turnaround time
- Patient and provider field/phone clinical support
- Confirmation of all positives

# Myriad supports Research

- Publicly disclosed discovery and sequence of genes
- No restrictions on follow-on research into genes
  - > 4300 BRCA1 and BRCA2 publications to date
- Offered high quality, high throughput sequencing services for researchers
  - *E.g.*, NCI MOU - now in sixth year (> 5500 tested through 70 NCI/NIH/DOD projects)
- Participate in Breast Cancer Information Core (BIC) mutation database
  - > 22,000 reports of >3000 unique mutations
  - Host annual meetings
- Publish mutation prevalence tables to assist in identification of high risk patients

# Access: Insurance Coverage

- Myriad invests in educating insurers about and securing contracts for predisposition testing
- Contracts with payers representing >130 million individuals
- Coverage from payers representing >200 million individuals
- On average, >90% of charges reimbursed  
<10% out of pocket (insurance co-payments)
- Added protection against fear of insurance discrimination:  
Test results only reported to ordering provider/designee

# Access: Provider Education & Infrastructure

- Society-based initiatives (ASCO, AMA, ONS, SSO, ACMG, AGA, NSGC, ASHG, etc.)
  - CME events, monographs, medical conventions, slide sets
  - Communicate guidelines for testing/management
- Education for providers to expand access & availability
  - Field/phone based sales and clinical support
    - Grand rounds, tumor boards, lecture series
  - >1000 US facilities now offer HBOC genetic services(12 in 1997)
- Tools and services to facilitate access
  - Reimbursement assistance program
  - Patient assessment and education tools
  - Prevalence Tables
  - Website for Providers and patients
  - Post-testing resources

# Access: Patient Awareness

- Awareness initiatives
  - Facility and advocacy outreach programs, brochures, advertising, website
- Patient Identification and Assessment
  - Red Flags program
  - Family History Questionnaire
  - Mutation prevalence tables/ slide rule
- Informed Consent tools
  - Videos, Counseling Tools

# Summary

BRCA patent protection enables:

- Investment to develop the discovery for the public benefit
- Funding and resources for further research (royalties, licensing fees, taxes, etc.)
- Investment in improvements to further enhance the quality of the test and genetic services
- Investment in provider education to expand service and access
- Better healthcare

# The Challenge

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