

How Does Private Sector Handle Licensing Of Genetic Discoveries?

By Lin Sun-Hoffman, Ph.D, J.D.

Disclaimer: The talk represents my personal view and does not represent Applied Biosystems' view.

Typical Claims In A Gene Patent

- Nucleic acid
- Protein
- Method for detecting a gene
- Method for making proteins
- Method for screening
- Antibody



More Gene Patent Claims

- Method for diagnosing a disease by monitoring a gene (mutation) or protein expression
- Method for treating a disease by targeting a gene using an agonist or an antagonist



Why Do Companies Use Genes?

- Pharmaceutical companies: targets for screening small molecules
- Biotech: targets for large molecule therapies, antibody or protein treatment
 - Erythropoietin
 - Human Growth Hormone
 - Rituxan and Herceptin



Why Do Companies Use Genes?

- Diagnostics: disease association studies
 - Mutations associated with certain diseases
 - BRCA1 and BRCA2
- Research tool companies: probes/primer, arrays

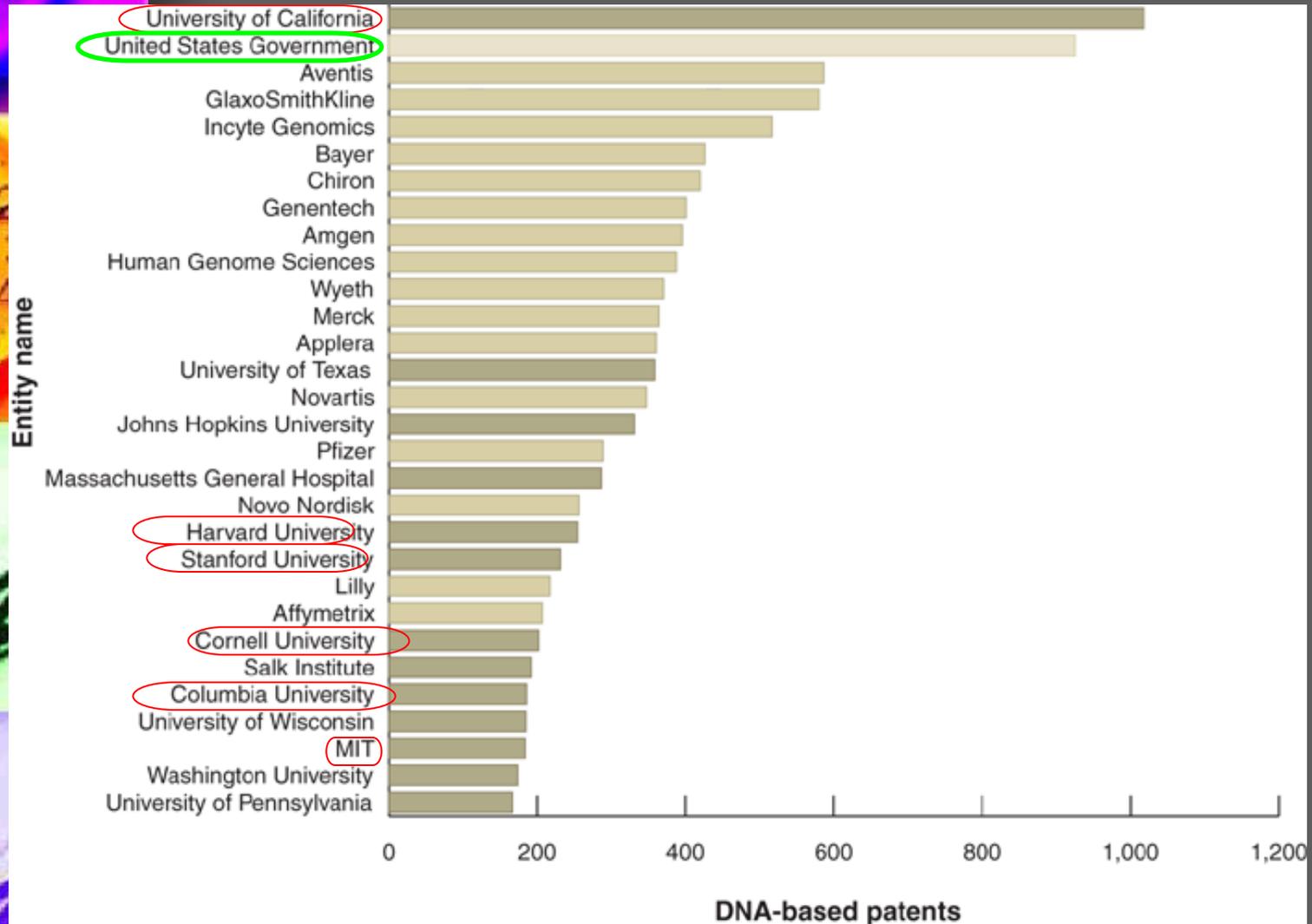


Gene Patent Holders

- Academics
- US government
- Industry-biotech or pharmaceutical companies



The Top 30 Holders of U.S. DNA Patents:



Accessibility to the Gene Patents

- Freedom-to-Operate
 - Majority of the genomic information is either in the public domain or patented
- If no FTO
 - Either seek license or design around



Access Gene Patents

- Academic Institutes/US government:
 - Licensees are downstream developers to obtain in-license opportunities
 - Typically non-exclusive



Access to Gene Patents

- Biotech companies:
 - Many big players are the owner of the gene patents:
 - Out-license
 - Internal develop and out-license non-exclusively
 - Use for internal development exclusively: BRCA 1 and BRCA2.



Type of Agreements

- Straight license agreement
 - Tends to be nonexclusive and usually from genomic companies or academic institutes.
- Collaboration agreement
 - Big pharma or biotech company to co-develop a product.



Exclusive v. Nonexclusive

- Diagnostic: typically non-exclusive
 - Can be licensed for different indications or licensed to various parties
- Therapeutics: prefer exclusive to multiple fields



Payments

- Royalty only
- Annual licensing fee
- Milestone
- Upfront
- Combination thereof



Factors Influencing Royalties

- Stage of the development
- Type of the technology
- Strength of IP
- The area of the field of utility
(how big the market is)



Royalty Determination-DX

■ Diagnostics:

- Tends to ask for lower royalties, 2-3%
- Usually multiple licenses required for enabling a test (royalty stacking consideration, and cumulative could be up to 30%)



Royalty Determination-RX

- Therapeutics: expected revenue is usually 10x more than Dx, the royalties are higher and could be 5%-8%



Royalty Determination

■ In-licensing:

- IP position: claim scope and patent term
- Royalty stacking issue
- Potential Revenue
- Rx v. Dx

■ Out-licensing:

- Company size
- Market size
- Term of use
- Rx v. Dx



Concerns from Gene Patent Owners

- Right to own the gene patents, but hard to detect a user because a gene is usually used at R&D stage
 - Merck v. Integra: protect the right of gene patent R & D stage
- Revenue is usually low and it also depends on a product



Concerns from Non-Patent Holders in the industry

- The strength of the IP
 - The scope of the gene patent,
 - Inconsistency of the PTO standard
 - Some patents are difficult to search
- The stage to use the gene: early stage or product development stage



Reality Check

- Majority genes are patented
- Licensing a gene patent is possible either exclusively or nonexclusively, but one needs to consider royalty stacking
- Enforcement of gene patents is difficult unless a product is developed





Thank You