# Genomic Inventions: Evolving NIH Licensing Policies & Practices

S A C G H S 12th Meeting
Adelphi, MD 3/27/2007

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**National Human Genome Research Institute**
**National Institutes of Health**

# “We are in the age of *Homo economicus*. Human genetic material is increasingly an object of commerce.”*

*Knoppers, B. M., Hirtle, M., and K. Cranley Glass, “Commercialization of Genetic Research and Public Policy,” *Science* pgs. 2277-2278, Vol. 286 1999.

# National Institutes of Health

- One of the world's premier biomedical research centers//engine for biomedical research & innovation
- 27 Institutes, Centers and Divisions (ICDs)
- FY2006 budget of ~$28B; intramural budget ~$3B
- Extramural (univ., hospitals, etc.) = 60,000 awards to 3,000 organiz./year)
  - Grants can be thought of as 0% interest gov. loans /analogous to early stage seed capital
- **Intramural (on campus)** = 18,000 employees; 5,000 MDs and PhDs; 2000+ intramural R&D projects
  - Collaborate w/ public and private sector scientists
  - Technologies & inventions available for licensing

# NIH Intramural Patent Principles

**Generally, NIH will NOT Patent if:**

- No further R&D is needed (ex. Research Tools)
- Low Public Health Priority and/or lack of commercial interest
- Patenting will hinder technology transfer/access to inventions

**Generally, NIH will Patent if:**

- High Public Health Priority
- Patenting will Facilitate access to technology
- Necessary for Investments in R&D

# NIH Intramural Licensing Principles

- **Public Health Benefits**
- **Expeditious Development & Granting of Only the Appropriate Scope of Rights (e.g. use of specified fields of use and enforceable benchmarks)**
- **Optimize number of New Products (= non-exclusive licensing is preferred especially for broadly enabling technologies and diagnostic applications)**
- **Availability of Technology for Research / Licensees must permit research uses by others**
- **Fair Financial Return (…the bottom line isn't so important. Really!!)**

# Technology Transfer Mechanisms

- **CRADAs**
  - CRADA collaborator gets option to exclusively license subject inventions (scope of license must match scope of research plan)
- **Patent Commercialization Licenses (in order of lowest to highest "cost")**
  - Non-exclusive
  - Co-exclusive
  - Exclusive
    - Narrow (by field of use, ex. by disease(s), technology platform, specific application, etc.
    - Broad (NIH rarely does this type)
- **Non-Patent Licenses (used for unpatented biological materials)**

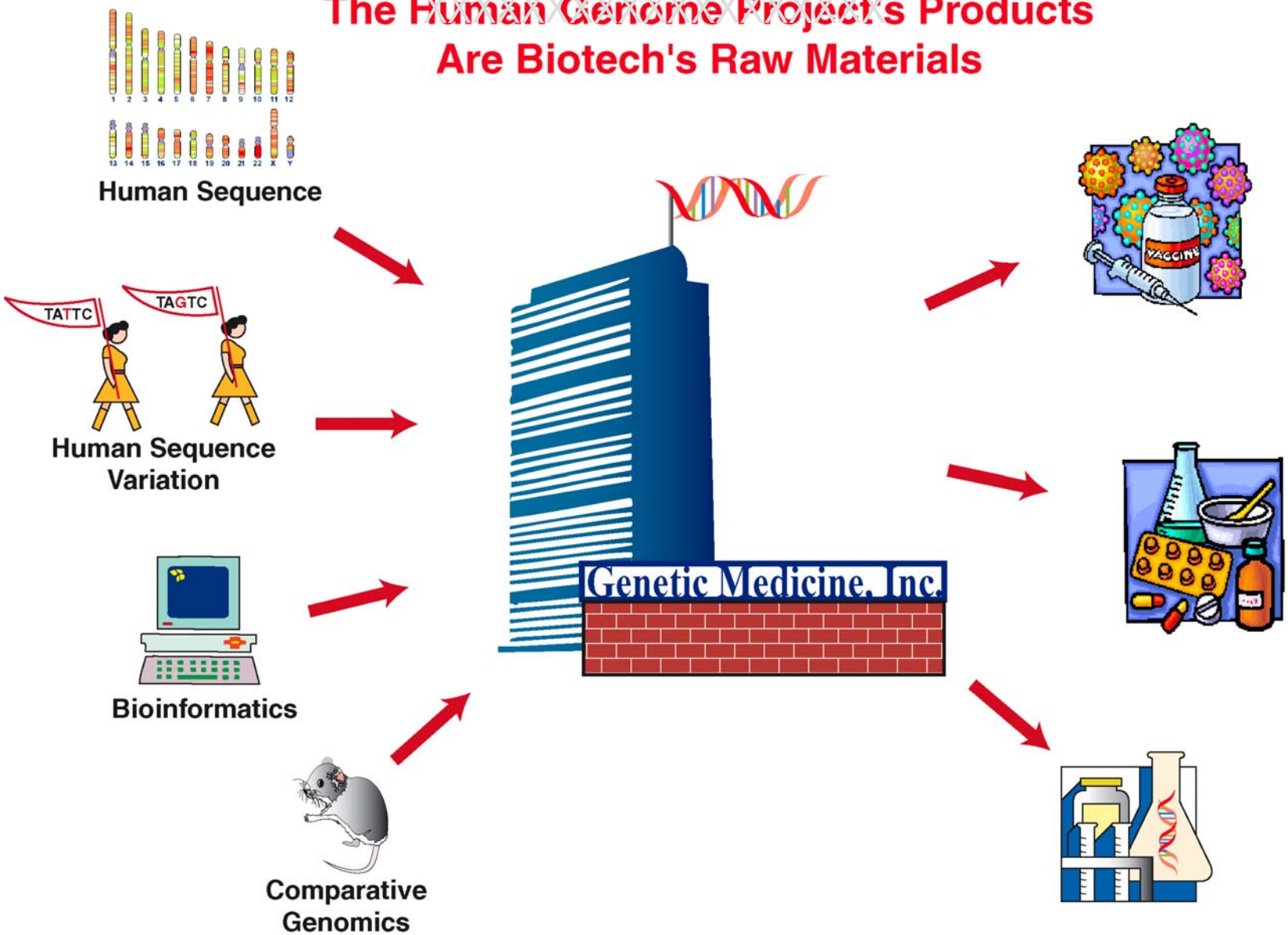
# NIH Intramural Licensing Statistics

- >300 Employee Invention Reports/Year (*not terribly impressive given $3B annual intramural budget; quality is high; mostly early-stage inventions)
- >80% of Licenses are Non-Exclusive (note: this is exactly the opposite of what happens in academia)
- >85% of Licenses are with U.S. companies
- 52% of Licenses are with small firms

# Genes, Patents, NIH Intramural & NIH Grantees

- **Since its founding in 1990 the NHGRI has had a policy of free and open access to genetic data**
- **NHGRI and the NIH as a whole supports the filing of patents when inventions are associated with potential products**
- **Our grantees are mostly free to patent & license as they wish**
  - "Acceptable" IP sharing plans sometimes required
  - Voluntarily adherence to guidance document "NIH [Intramural] Best Practices for the Licensing of Genomic Inventions"
  - DECs sometimes used (removal of Bayh-Dole rights)

# Academic Research Enterprise's
# The Human Genome Project's Products
# Are Biotech's Raw Materials



athena diagnostics

# Technology Spotlight

## List of Patents

| Test Code | Test Name | U.S. Patent No. |
|---|---|---|
| 815 | *ABCD1* (Adrenoleukodystrophy) DNA Sequencing Test | 5,644,045 |
| 871 | *BBS1* (BBS) DNA Sequencing Test | 6,962,788 |
| 872 | *BBS2* (BBS) DNA Sequencing Test | 7,008,782 |
| 827 | ABCC8 (CH) DNA Sequencing Test | 6,054,313 |
| 178 | ADmark® Alzheimer's Evaluation | 4,666,829, 5,593,846, 5,508,167, 5,861,257, 6,027,896, 5,843,779, 6,114,133, & 6,121,003 |
| 109 | ADmark® ApoE Genotype Analysis & Interpretation (Symptomatic) | 5,508,167, 6,027,896, & 5,716,828 |
| 174A | ADmark® Asymptomatic PS-1 Analysis & Interpretation | 5,840,540, 6,194,153 |
| 177 | ADmark® Phospho-Tau/Total-Tau/Ab42 CSF Analysis & Interpretation (Symptomatic) | 4,666,829, 5,593,846, 5,861,257, 5,843,779, 6,114,133, & 6,121,003 |
| 174S | ADmark® Symptomatic PS-1 Analysis & Interpretation | 5,840,540, 6,194,153 |
| 493 | Aprataxin DNA Sequencing Test | 7,119,186 |
| 531 | Atlastin (SPG3A) DNA Sequencing Test | 7,108,975 |

athena diagnostics

# Technology Spotlight

## List of Patents **Licensed by Athena**

Compiled by David Ledbetter, Ph.D. Emory Univ.

| Test Code | Test Name | U.S. Patent No. | **Patent Assignee** |
|---|---|---|---|
| 815 | *ABCD1* (Adrenoleukodystrophy) DNA Sequencing Test | 5,644,045 | **INSRM, Paris** |
| 871 | *BBS1* (BBS) DNA Sequencing Test | 6,962,788 | **U. Iowa** |
| 872 | *BBS2* (BBS) DNA Sequencing Test | 7,008,782 | **U. Iowa** |
| 827 | ABCC8 (CH) DNA Sequencing Test | 6,054,313 | **Baylor** |
| 178 | ADmark® Alzheimer's Evaluation | 4,666,829, 5,593,846, 5,508,167, 5,861,257, 6,027,896, 5,843,779, 6,114,133, & 6,121,003 | **U. California** |
| 109 | ADmark® ApoE Genotype Analysis & Interpretation (Symptomatic) | 5,508,167, 6,027,896, & 5,716,828 | **Duke** |
| 174A | ADmark® Asymptomatic PS-1 Analysis & Interpretation | 5,840,540, 6,194,153 | **Lever Bros. Co** |
| 177 | ADmark® Phospho-Tau/Total-Tau/Ab42 CSF Analysis & Interpretation (Symptomatic) | 4,666,829, 5,593,846, 5,861,257, 5,843,779, 6,114,133, & 6,121,003 | **U. California** |
| 174S | ADmark® Symptomatic PS-1 Analysis & Interpretation | 5,840,540, 6,194,153 | **Lever Bros. Co.** |
| 493 | Aprataxin DNA Sequencing Test | 7,119,186 | **Athena** |
| 531 | Atlastin (SPG3A) DNA Sequencing Test | 7,108,975 | **U. Michigan** |

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|---|---|---|---|
| 680 | Autosomal Dominant Ataxia Evaluation | 5,741,645, 6,251,589, 5,834,183, 5,840,491, 5,853,995, 6,303,307, 6,280,938, 6,514,755, 7,118,893, and 7,119,186 | **U. Minnesota** |
| 870 | Bardet-Biedl Syndrome Evaluation | 6,962,788; 7,008,782 | **U. Iowa** |
| 244 | Carpal Tunnel Syndrome Evaluation | 5,306,616, 5,780,223, & 5,645,993 | **Baylor** |
| 326 | Chronic Demyelinative Neuropathy Profile | 5,306,616, 5,691,144, 5,645,993, 5,780,223, 6,001,576 & 6,599,756 | **Baylor** |
| 270 | Co-GM1 Triad™ Antibody Test | 5,989,829, 5,985,578, 6,824,999 | **Wash. U** |
| 690 | Complete Ataxia Evaluation | 5,741,645, 6,251,589, 5,834,183, 5,840,491, 5,853,995, 6,303,307, 6,280,938, 6,514,755, 7,118,893, and 7,119,186 | **U. Minnesota** |
| 421 | Complete CADASIL Evaluation | 6,537,775, 6,995,257, 7,138,234 | **INSERM, France** |
| 399 | Complete CMT Evaluation | 5,306,616, 5,691,144, 5,780,223, 5,645,993, 6,001,576, 5,876,927 | **Baylor** |
| 390 | Complete CMT Evaluation (Old) | 5,306,616, 5,691,144, 5,780,223, 5,645,993, 6,001,576, 5,876,927 | **Baylor** |
| 286 | Complete Dejerine-Sottas Neuropathy Evaluation | 5,876,927 | **U. California** |
| 182 | Complete DMD Evaluation - Females | 5,621,091 | **Boston Children's** |

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|---|---|---|---|
| 528 | Complete Hereditary Spastic Paraplegia Evaluation | 6,924,126, 7,108,975 | CNRS, France |
| 243 | Complete HNPP Evaluation | 5,306,616, 5,780,223, & 5,645,993 | Baylor |
| 129 | Complete Myotonia Evaluation | 5,955,265; 5,977,333; 6,902,896 | MIT/U. Wales |
| 126 | Complete Myotonic Dystrophy Evaluation | 5,955,265 & 5,977,333 | MIT/U. Wales |
| 525 | Complete Tuberous Sclerosis Evaluation | 6,207,374 | MRC, UK |
| 819 | Congenital Hyperinsulinism Evaluation | 6,054,313 | Baylor |
| 245 | Congenital Hypomyelination Evaluation | 5,876,927 | U. California |
| 321 | Connexin 26 DNA Sequencing Test | 5,998,147, 6,485,908 | Institut Pasteur |
| 329 | Connexin Related Deafness Evaluation | 5,998,147, 6,485,908 | Institut Pasteur |
| 133 | Connexin32 DNA Sequencing Test | 5,691,144 & 6,001,576 | Athena |
| 108 | DM1 DNA Test | 5,955,265 & 5,977,333 | MIT/U. Wales |
| 110 | DM2 DNA Test | 6,902,896 | U. Minnesota |
| 297 | Dominant CMT Evaluation | 5,306,616, 5,691,144, 5,780,223, 5,645,993, 6,001,576, & 5,876,927 | Baylor |
| 561 | Dysferlin Blood Test | 7,172,858 | Mass. General Hosp |
| 626 | Dystonia (DYT1) DNA Test | 6,387,616 | Mass. General Hosp |
| 100 | Dystrophin Test | 5,541,074, 5,621,091, 5,239,060 | Boston Childrens |
| 640 | Early Onset Obesity (MC4R) Evaluation | 5,622,860, 5,703,220 | U. Michigan |
| 881 | Endocrine Hypertension (HSD11B2) Evaluation | 5,883,240 | Baker Med Res Inst |
| 296 | Entrapment Neuropathy Evaluation | 5,306,616, 5,780,223, & 5,645,993 | Baylor |
| 410 | EPM1 DNA Test | 6,432,635 | Helsinki U. |

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|---|---|---|---|
| 829 | Familial Hypocalciuric Hypercalcemia (CASR) Evaluation | 5,688,938 | Brigham & Womens |
| 119 | Friedreich Ataxia DNA Test | 6,150,091 | Baylor/INSERM |
| 261 | GALOP™ Antibody Test | 6,121,004 | Wash. U. |
| 832 | GCK (MODY2) DNA Sequencing Test | 5,541,060 | U. Chicago |
| 831 | HNF4A (MODY1) DNA Sequencing Test | 6,187,533 | U. Chicago |
| 834 | IPF1 (MODY4) DNA Sequencing Test | 6,274,310 | Mass. General |
| 841 | IPF1 (NDM) DNA Sequencing Test | 6,274,310 | Mass. General |
| 545 | KCNQ2 DNA Sequencing Test | 6,413,719 | U. Utah |
| 145 | MAG 'Dual Antigen® Antibody Test | 6,599,756, 6,951,763 | Athena |
| 817 | Male Precocious Puberty *(LHCGR)* Evaluation | 6,635,445 | Takeda Chem. Ind. |
| 839 | Monogenic Diabetes (MODY) Evaluation | 6,187,533, 5,541,060, 6,274,310 | U. Chicago |
| 274 | Motor Neuropathy Profile-Complete | 5,989,829, 5,985,578, 6,077,681 & 6,599,756 | Wash. U. |
| 259 | Motor Neuropathy Profile-Standard | 5,645,993, 5,780,223 5,989,829, 5,985,578, 6,077,681 & 6,599,756 | U. Utah |
| 276 | Multifocal Neuropathy Evaluation | 5,989,829 & 5,985,578 | Wash. U. |
| 134 | Myelin Protein Zero (MPZ) DNA Sequencing Test | 5,876,927 | U. California |
| 363 | NeoCerebellar Degeneration Paraneoplastic Profile with Recombx™ | 5,603,934, 5,807,705, 5,668,013, 5,925,526 & 6,387,639 | Sloan-Kettering |
| 369 | NeoComplete Paraneoplastic Profile with Recombx™ | 5,603,934, 5,614,371, 5,668,013, 5,786,451, 5,807,705 5,925,526 & 6,387,639 | Sloan-Kettering |

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|---|---|---|---|
| 359 | NeoEncephalitis Paraneoplastic Profile with Recombx™ | 5,603,934, 5,807,705 & 6,387,639 | Sloan-Kettering |
| 844 | Neonatal Diabetes Mellitus Evaluation | 6,274,310 | Mass. General |
| 365 | NeoPLAST® Basic Paraneoplastic Profile | 5,603,934, 5,614,371, 5,668,013, 5,786,451, 5,807,705 & 5,925,526 | Sloan-Kettering |
| 360 | NeoSeM® Basic Paraneoplastic Profile | 5,603,934, 5,807,705, 5,668,013, 5,925,526, & 6,193,948 | Sloan-Kettering |
| 478 | NeoSensory Neuropathy Paraneoplastic Profile with Recombx™ | 5,603,934, 5,807,705, & 6,193,948 | Sloan-Kettering |
| 720 | Nephrotic Syndrome Evaluation | 6,207,811, 6,924,110 | |
| 730 | NPHS1 (Nephrin) Sequencing Analysis | 6,207,811 | |
| 710 | NPHS2 (Podocin) Sequencing Analysis | 6,924,110 | INSERM, France |
| 300 | OPMD DNA Test | 6,828,430 | McGill U. |
| 860 | Osteogenesis Imperfecta Evaluation | 6,265,157 | Allegheny/T. Jeff |
| 327 | OtoDx™ Aminoglycoside Hypersensitivity Test | 5,506,101 | Cedars-Sinai |
| 398 | Partial CMT Evaluation - Demyelinating Only | 5,306,616, 5,691,144, 5,780,223, 5,645,993, & 6,001,576 | Baylor |
| 392 | Partial CMT- Axonal Only | 5,645,993, 5,691,144, 6,001,576, & 5,876,927 | U. Utah |
| 391 | Partial CMT- Demyelinating Only | 5,306,616, 5,691,144, 5,780,223, 5,645,993, & 6,001,576 | Baylor |
| 103 | Partial DMD - del/dup only - Females | 5,621,091 | Boston Childrens |
| 101 | Partial DMD - del/dup only - Males | 5,621,091 | Boston Childrens |
| 183 | Partial DMD - Sequencing only | 5,621,091 | Boston Childrens |

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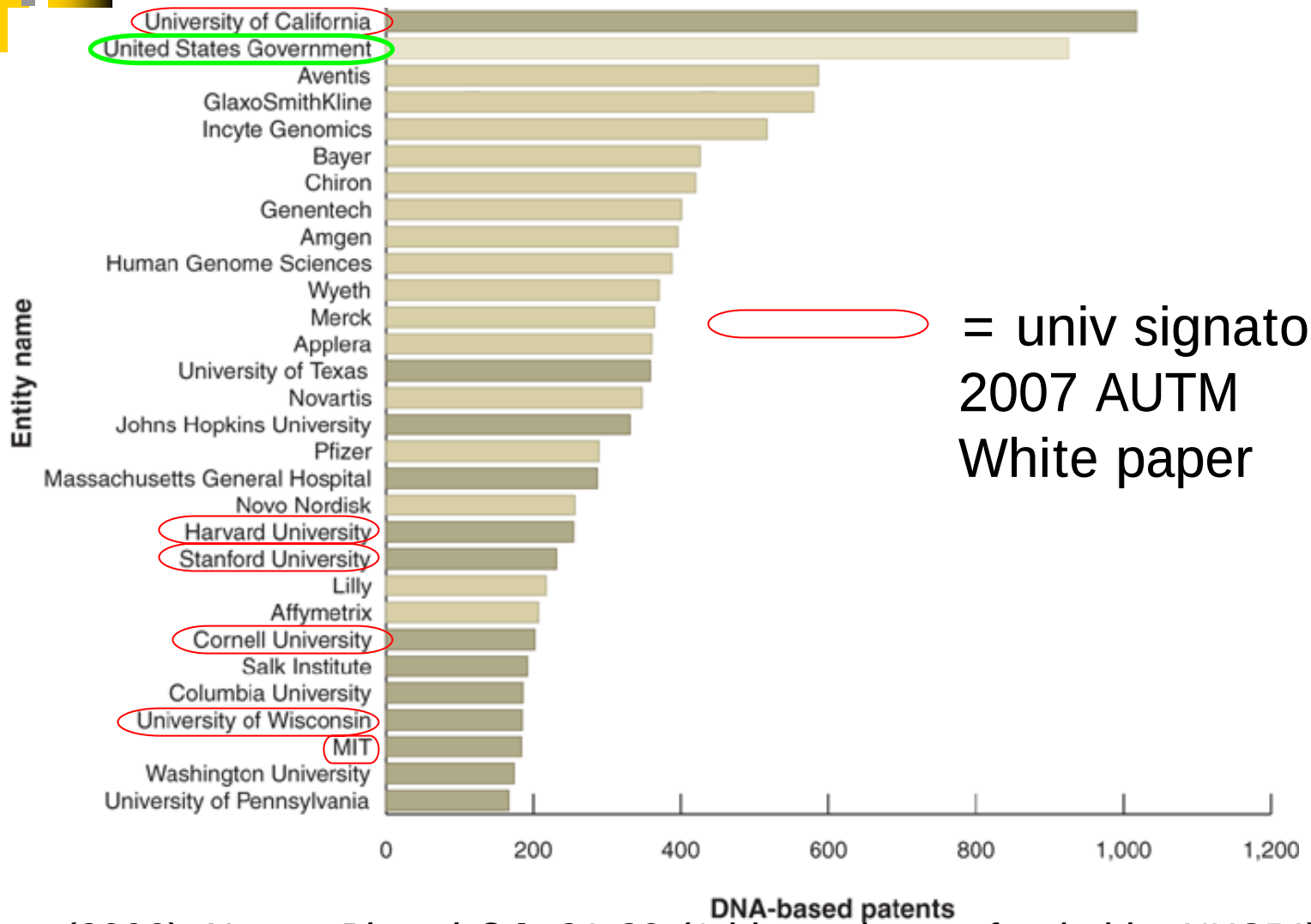
|---|---|---|---|
| 728 | PKDx™ Familial Mutation Evaluation | 5,654,170, 6,031,088, 6,228,591, 6,485,960, 6,656,681, 6,916,619 | Johns Hopkins/ Genzyme |
| 725 | PKDx™ Sequencing Analysis | 5,654,170, 6,031,088, 6,228,591, 6,485,960, 6,656,681, 6,916,619 | Johns Hopkins/ Genzyme |
| 131 | PMP22 Duplication/Deletion DNA Test | 5,306,616, 5,780,223, 5,645,993, & 5,599,920 | Baylor |
| 416 | Progressive Myoclonus Epilepsy Evaluation | 6,432,635 | Helsinki U. |
| 118 | Recombx™ CAR (Anti-Recoverin) Antibody Test | 5,786,451 | U. California |
| 122 | Recombx™ MaTa Antibody Test | 6,387,639; 7,026,450 | Sloan-Kettering |
| 120 | Recombx™ Hu Antibody Test | 5,603,934 & 5,807,705 | Sloan-Kettering |
| 115 | Recombx™ Ri Antibody Test | 5,614,371 | Sloan-Kettering |
| 125 | Recombx™ Yo Antibody Test | 5,668,013 & 5,925,526 | Sloan-Kettering |
| 371 | SCA1 DNA Test | 5,741,645, & 5,834,183 | U. Minnesota |
| 372 | SCA2 DNA Test | 6,251,589 | SRL, Inc. (Japan) |
| 105 | SCA3 (Machado-Joseph Disease) DNA Test | 5,840,491 | |
| 373 | SCA6 DNA Test | 5,853,995, 6,303,307 | Res. Dev. Found |
| 374 | SCA7 DNA Test | 6,280,938, 6,514,755, 7,118,893 | U. Minnesota |
| 384 | SCA8 DNA Test | 6,524,791 | U. Minnesota |
| 535 | SCN1A DNA Sequencing Test | 7,078, 515 | Bionomics Ltd. |
| 264 | SensoriMotor Neuropathy Profile | 5,443,952, 6,020,140, 5,603,934, 5,807,705 & 6,599,756 | Wash. U |

| | | | |
|---|---|---|---|
| 262 | SensoriMotor Neuropathy Profile-xp | 5,443,952, 5,603,934, 5,807,705, 6,020,140, 6,121,004 & 6,599,756 | **Wash. U.** |
| 265 | Sensory Neuropathy Profile | 5,603,934, 5,807,705, 5,443,952, 6,020,140, 6,193,948 & 6,599,756 | **Sloan-Kettering** |
| 263 | Sensory Neuropathy Profile-xp | 5,603,934, 5,807,705, 5,443,952, 6,020,140, 6,121,004, 6,193,948 & 6,599,756 | **Sloan-Kettering** |
| 234 | Small Fiber Painful Axonal Neuropathy Profile | 5,443,952, 5,807,705, 5,603,934 & 6,020,140 | **Wash. U.** |
| 530 | Spastin (SPG4) DNA Sequencing Test | 6,924,126 | **CNRS, France** |
| 111 | Spinal Muscular Atrophy Test | 6,080,577; 7,033,752 | **INSERM, France** |
| 210 | Sulfatide Antibody Test | 5,443,952, 6,020,140 | **Wash. U.** |
| 833 | TCF1 (MODY) DNA Sequencing Test | 6,187,533 | **U. Chicago** |
| 836 | TCF2 (MODY5) DNA Sequencing Test | 6,187,533 | **U. Chicago** |
| 523 | TSC Familial Mutation Evaluation | 6,207,374 | **MRC, UK** |
| 524 | TSC2 DNA Deletion Test | 6,207,374 | **MRC, UK** |
| 522 | TSC2 DNA Sequencing Test | 6,207,374 | **MRC, UK** |

# The Top 30 Holders of U.S. DNA Patents: US Gov is #2




= univ signatory of 2007 AUTM White paper

Pressman (2006) *Nature Biotech* **24**: 31-39 (*this study was funded by NHGRI)

# Gene Patents Go Mainstream

parade.com

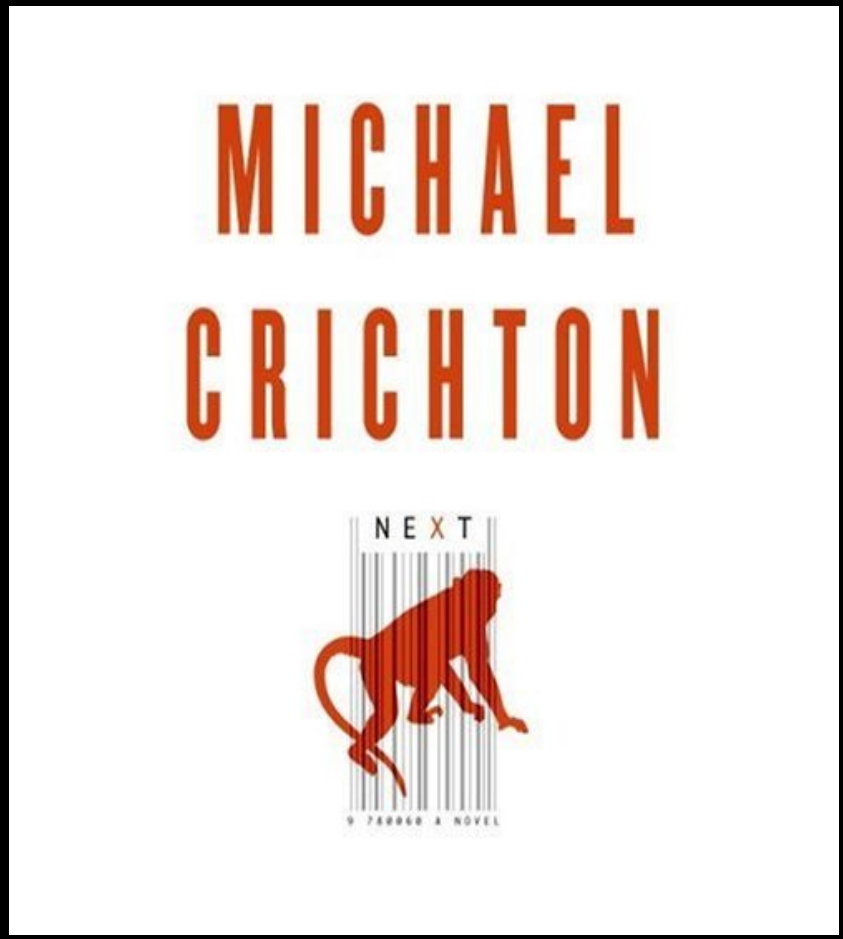
Intelligence Report®

**“How Gene Patents Are Putting Your Health at Risk”**

**By Lyric Wallwork Winik**

**November 26, 2006**

# Crichton's Recommendations




- # 1 Stop patenting of human genes
- #5 Rescind the Bayh-Dole Act

# A Timeline: Significant Events in the Short History of Gene Patenting in the U.S.

- Late 1970's-80s: mol bio revolution/start of U.S. biotech industry
- 1980;1984 Cohen-Boyer patents issue
- 1980 Diamond vs. Chakrabarty Supreme court decision
- 1990 Human Genome Project begins
- 1991 NIH files a patent application on ESTs (inventor: J. Craig Venter; later abandoned)
- 1996 USPTO holds hearing on gene patents & limits # of seq. to 10/patent applic.
- 1997 PTO says "EST patents are OK" [utility as "probe" acceptable]

# Timeline continued

- 1998 controversial Incyte EST patent (human protein kinase homologs) issues
- 1999 PTO issues interim revised Utility Guidelines for biotech patents
- 2000 “Working draft” of human genome completed; Clinton-Blair statement sends NASDAQ/biotech stock values plummeting
- 2001 PTO issues final Utility Guidelines for biotech patents
- 2001-2002 Weldon-Rivers proposed legislation to allow clinical labs the unfettered use of DNA/gene patents
- 2002 Nuffield Council on Bioethics report on “The Ethics of Patenting DNA”
- 2003 Human Genome Project completed

# Timeline continued: 2005 to Today

- Murray *Science* paper—18% of known human genes are patented (2005)
- NAS Study "Reaping the benefits of genomic and proteomic research: intellectual property rights, innovation and public health" (2005)
- NIH Best Practices for the Licensing of Genomic Inventions published (2005)
- OECD draft & final guidelines on the Licensing of Genetic Inventions (2004; 2006)
- Crichton book *Next* (11/06) & NYT editorial piece (2/07) published
- Thomas *Nature Biotech* paper "DNA Patenting: The End of an Era?" (2/2007)
- Weldon/Becerra "Genomic Research and Accessibility Act" bill introduced (2/07)
- AUTM white paper (3/07) "In the Public Interest"

# Gene Patents, the PTO & Congress

- **PTO determines patentability of inventions**
  - LEGAL DETERMINATION ONLY
  - As long as satisfy legal and technical requirements PTO will issue a patent
  - ***U.S. patent law does NOT to take into account ethical, social or policy considerations/ implications***
- **PTO has finally developed fairly reasonable policies regarding patentability of genes, ESTs and SNPs—it took years and years**
- **Weldon-Becerra 2007 bill—proposes banning all patenting of human genes**
- **My take: *STOP WORRYING ABOUT GENE PATENTS; FOCUS ON ACCESS. IT IS THE LICENSING OF KEY PATENTS THAT REALLY MATTERS.***

# Genomic Research and Diagnostic Accessibility Act of 2002 (HR3967) * A Valiant Attempt...

- Introduced by Lynn Rivers (D-Michigan) and Dave Weldon, MD (R-Florida)
- Proposed to "exempt from patent infringement [those] individuals who use patented genetic sequence information for non-commercial research purposes."
- Proposed to exempt "medical practitioners" who use gene/DNA-based diagnostic or prognostic tests
- Supported by patient advocacy groups, medical societies, public health specialists and regional diagnostic labs

*Abate, T., "Do Gene Patents Wrap Research in Red Tape?" *San Francisco Chronicle*, March 25, 2002

# Genomic Research and Accessibility Act Bill (HR977) A Bad Idea.....

- Co-sponsors Weldon (R-FL) and Becerra (D-CA); Feb '07
- "..prohibit the patenting of human genetic material" (not retroactively)
- Silly—are there really any unknown human genes left to find?
- Doesn't address the key public health concern of access, choice/quality and affordability of DNA-based diagnostic tests

# ACMG Statement on Gene Patents and Accessibility of Gene Testing*

- Genes and their mutations are naturally occurring substances that should not be patented (IRRELEVANT—they are patentable)
- Patents on genes with clinical implications must be very broadly licensed
- Licensing agreements should not limit access (through excessive royalties and other unreasonable terms

*American College of Medical Genetics (Aug. 2, 1999)
www.faseb.org/genetics/acmg/pol-34.htm

# NIH Strategy for Ensuring Accessibility and Affordability of Gene/DNA-based Diagnostics

- Publish (place in public domain)
- Execute $1^0$ non-exclusive licenses for human disease gene/diagnostic-type inventions
- Give limited field(s) of use and include mandatory sub-licensing provisions in exclusive licenses
- Developed “Best Practices” guidance document for use by Grantees

# Best Practices for the Licensing of Genomic Inventions (2005)

- This isn't new—we just put down in writing what NIH intramural has been doing for years
- Grantees are not required to follow these recommendations
- Negotiate non-exclusive or co-exclusive licenses whenever possible
- Include provisions to ensure continuing availability of invention for further research (for all not just the inventor's institution)

# NIH Best Practices for the Licensing of Genomic Inventions

- Include provisions for mandatory sublicensing by exclusive licensees
- Avoid direct licensing to virtual developers
- Negotiate and execute “narrow” exclusive licenses for specific indications, technology platforms or fields of use and/or territories if exclusivity is needed
- Include developmental milestones/benchmarks & performance-based royalty payments
- Monitor & enforce terms

# White Paper: In the Public Interest: Nine Points to Consider in Licensing University Technology

- A sensible, thoughtful & balanced approach that might just work! Some overlap with NIH Best Practices
- Technology-neutral (however diagnostic tests are specifically mentioned)
- Signed by big name universities (big in research, big in reputation and big in royalty income)
- Endorsed by AUTM and AAMC (so far)
- Just released 3/6/2007—partially a response to recent negative press ("The Kept University," "The Trouble with Tech Transfer" and criticism of Bayh-Dole Act)

# In the Public Interest Highlights

- **Reserve the right to practice licensed inventions for research and education use for non-profits and gov orgs**
  - Licenses should NOT hinder clinical research, professional education and training, use by public authorities or independent validation of test results
  - Licensing of a single gene for a diagnostic may be counterproductive
- **Avoid broad exclusive licenses; only give those rights necessary to encourage commercial development**
- **Ensure broad access to research tools**

# Some Possible Remedies*?

- Compulsory licensing of DNA/gene-based inventions for all diagnostic uses
- Create true "research exemption" for non-commercial uses of gene patent inventions (*Madey vs. Duke* ) in U.S. patent law
- Create patent pools (voluntary sharing by patent owners of their key IP with members of a consortia in exchange for access to those other members' IP)
- Encourage cross-licensing OR set up clearing houses for genetic inventions
- Adopt an "open source" approach to biological licenses

*See also "The Ethics of Patenting DNA" Nuffield Council Report (2002)

# Possible Remedies contin.

**For Gov Grantees: put in place new guidelines governing the appropriate licensing policies for these types of inventions (NIH has a guidance on "Best Practices for the licensing of genomic inventions")**

- http://ott.od.nih.gov/NewPages/LicGenInv.pdf
- Academia doesn't like NIH telling them how to manage their IP/inventions (a threat to their Bayh-Dole rights and autonomy)
- Are NIH grantees or are companies the source of the perceived problem? Is there any data?

# Options for Other Government Agencies & Universities to Consider

- **Adopt NIH best practices for licensing of genomic inventions such as:**
  - Non-exclusive licensing for diagnostics
  - Limit exclusive licensing to therapeutics and vaccines
- **Adhere to University-AAMC White Paper recommendations from "In the Public Interest: Nine Points to Consider in Licensing University Technology"**
  - 11 major research universities and AAMC have signed on as of March 2007
  - Doesn't focus on particular technologies

# Patent, Licensing & Technology Transfer Information:

- Office of Technology Transfer, NIH
  - **www.nih.gov/od/ott/**
- Association of University Technology Managers (AUTM)
  - **www.autm.net**
- Licensing Executives Society (LES)
  - **www.les.org**
- United States Patent and Trademark Office (USPTO)
  - **www.uspto.gov**

# For more NIH information

- Technology Transfer Office, NHGRI
  - **Building 12A Room 1033**
  - **tel: (301) 402-2537/ (301) 594-2235**
  - **fax: (301) 402-9722**
  - **e-mail: cdriscol@mail.nih.gov**
- http://www.genome.gov
  - **NHGRI technologies**
  - **technology transfer information sources**
  - **electronic mail links to staff**
- http://ott.od.nih.gov
  - All NIH technologies
  - On-line technology transfer training module