Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests

Final Draft Report and Recommendations

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Report Development Timeline

- March 2004 – Identified gene patents and licensing as a SACGHS priority issue; deferred further effort given National Academy of Sciences activity
- October 2005 – Formed a small group to review the NAS report
- March 2006 – Endorsed NAS report's general thrust but saw limitations in terms of its relevance to patient access questions; agreed that more information regarding patient access was needed

Report Development Timeline (continued)

- June 2006 – Decided to move forward with an in-depth study, focused on how gene patents and licensing practices affect patient access to genetic tests
  - Established SACGHS Task Force on Gene Patents and Licensing Practices to guide study
- December 2006 – Duke's Center for Genome Ethics, Law & Policy was commissioned to assist in carrying out components of the study, including case studies
- March 2007 – Organized a primer session on gene patenting and licensing practices to establish foundational knowledge for SACGHS Members

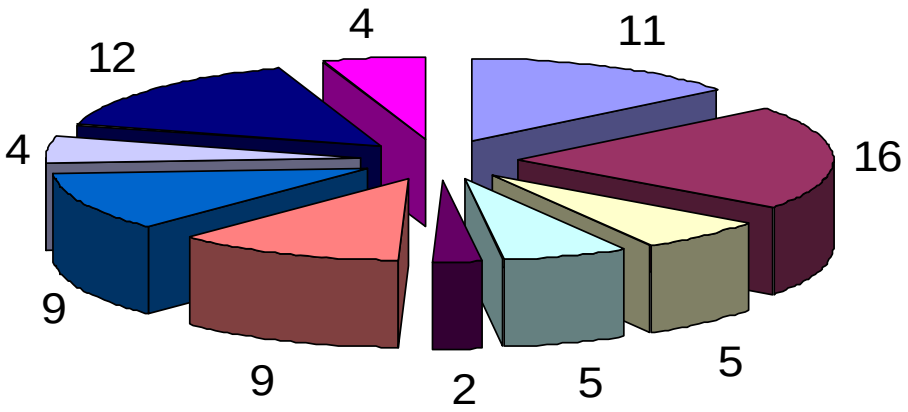
Report Development Timeline (continued)

- July 2007 – Hosted a roundtable on international perspectives on gene patents and licensing practices
  - Task force continued information gathering and began developing report
- December 2008 – Approved public consultation draft report for release
- Public Comment Period from March 9, 2009, to May 15, 2009

Today's Session Overview

- Process for reviewing comments and creating final draft report
- Overview of report
- Presentation of proposed recommendations
- Discussion of findings and conclusions
- Discussion of proposed recommendations

Distribution of Public Comments by Stakeholder* (Total = 77)



Process for Reviewing Public Comments

- Binder of public comments sent to each task force member for their review
- Members of the task force were assigned comments to present for group discussion during teleconferences
- All comments discussed during conference calls

Public Comments

- Were a critical supplement to case studies and literature review
- Confirmed that the patient access issues identified in case studies were not isolated problems
  - Access problems appear to be most problematic for the Medicaid population

Public Comments (continued)

- Highlighted problem of exclusively licensed sole providers not being capable of offering population-wide recommended carrier or newborn screening

- Called for more discussion in the report to the impact of patents on whole genome sequencing, multiplex testing, and other emerging testing innovations

Public Comments (continued)

- Many discussed their opinions and perspectives on patents
  - We especially appreciated comments with concrete examples of benefits or harms
- Some concerned the impact of patents on test development
  - Some commenters thought that patents are not needed for test development
  - Others thoughts patents are needed for test development

Task Force Process for Producing Revised Report

- After reviewing and discussing each comment, we revisited the preliminary conclusions
- We revised the conclusions after considering all evidence—case studies, articles, public comments, previous informational sessions at SACGHS meetings, and public comments during meetings
- We then discussed which policy options made sense as recommendations to propose to the Committee
- Background sections of the draft report were revised to reflect task force discussions and consideration of public comments
- Report was reorganized according to the key questions addressed

Summary of Report’s Main Points

Main Types of Patents Associated with Genetic Tests

- Patents claiming isolated nucleic acid molecules
  - These patents claim isolated nucleic acid molecules whose sequences may correspond to genes, mutated genes, intergenic DNA, etc.
  - These patents are sometimes called “gene patents”
  - For the sake of simplicity, report refers to these patents as “patent claims on genes”

Main Types of Patents Associated with Genetic Tests (continued)

- Patent claims to the act of simply associating a genotype with a phenotype
  - For example, patent might claim “a method of determining a predisposition to disease X comprising testing a body sample of a human for the presence of a mutation in gene A, wherein the presence of a mutation in gene A indicates a predisposition to disease X.”
  - For the sake of simplicity, report refers to these patents as “association patent claims”
- Patent claims to processes for detecting specific genetic sequences
  - A “method” or process of detecting a particular sequence, including a particular mutation, using specific probes, specific primers, etc.
    - In essence, this type of patent is attempting to claim a specific sequence
    - This type of patent should not be confused with patents on innovative methods for general DNA analysis
- Patent claims to a test kit for conducting a specific genetic test

Patents → Exclusive Rights

- How a patent claim on a gene gives exclusive rights to a genetic test:
  - In addition to claiming an isolated gene molecule, these patents may claim primers for amplifying the gene and/or nucleic acid molecule complementary to the gene
  - Because typical methods of testing for the gene in question involve using either patented primers or complementary probes, these methods require the patented molecules
  - Patent holder's ability to exclude others from using the molecule(s) gives the patent holder exclusive rights to testing

Patents → Exclusive Rights (continued)

- How an association patent claim gives exclusive rights to a genetic test:
  - Patent does not claim a molecule but claims method of testing humans for a particular genetic sequence which involves *associating* that genotype with a phenotype
  - Patent holder has exclusive rights to patented process or method, which involves testing for Sequence A and associating sequence A with Disease X
  - Because genetic testing for Disease X (or its predisposition) necessarily involves the patented process—testing sample for A and associating A with Disease X—patent holder has exclusive rights to genetic testing

Patents → Exclusive Rights (continued)

- How a patented processes for detecting a specific sequence gives exclusive rights to a genetic test:
  - Patent claims a process for detecting a specific mutation through probe hybridization, primer-driven amplification and sequencing, or some other means
  - Patent holder has exclusive rights to any genetic test that detects that specific mutation through the patented method

Purpose of Patent System

- Patent system has a utilitarian purpose: “to promote the progress of science and useful arts.”
  - Patents in the U.S. are not awarded as natural rights
- Patents are designed to stimulate scientific progress by offering inventor exclusive, time-limited rights to use, make, or sell invention
- This approach involves a tradeoff between any benefits of patents in stimulating scientific progress and any costs (harms) from patent holder’s ability to exclude others from invention
- Report examines both sides of tradeoff

Examination of the Benefits of Patents in Genetic Testing Arena

Potential Benefits of Patents

- Patent system is intended to promote scientific progress
- Economists recognize three main mechanisms for how patents promote scientific progress:
  - Patents promote progress by stimulating research for the purpose of making discoveries or inventions
  - Patents promote progress by stimulating disclosure of new discoveries and adding to public knowledge
  - Patents promote progress by stimulating investment in post-discovery development.

Potential Benefits of Patents

- Patents promote progress by stimulating research for the purpose of discovery and invention
  - Question: Do patents stimulate genetic research leading to diagnostic tests?
- Patents promote progress by stimulating disclosure of new discoveries
  - Question: Do patents stimulate disclosure of genetic discoveries leading to diagnostic tests?
- Patents promote progress by stimulating investment in post-discovery development
  - Question: Do patents stimulate investment to develop the discovery of a gene-disease association into a genetic test?

Stimulating Research for Discovery and Invention

- Case studies reveal patents stimulate some private investors to fund genetic research.
  - However, academic scientists conduct genetic research not because of patents but because of other motivations
  - Moreover, government provides vast amount of funding for basic life sciences research
  - No consistent findings by case studies or public comments that patents were necessary to stimulate research which leads to the availability of genetic testing

Stimulating Disclosure of Genetic Discoveries

- Researchers already have sufficient existing incentives to disclose genetic discoveries
  - Academic ethos encourages open science and rewards publication and first discovery
- Patents on genes in fact appear to diminish public knowledge because they result in less follow-on research
  - Huang and Murray study: “strict interpretation of our results suggests follow-on genetic researchers forego about one in ten research projects (or more precisely research publications) through the causal negative impact of the gene patent grant.”

Stimulating Investment to Develop Genetic Tests

- Although patented discoveries are developed into tests, unpatented genetic discoveries are routinely developed into clinical genetic testing services
  - Abundant data from case studies reveal that the role of IP was primarily to "clear the market"
    - Prior to granting patents/exclusive licenses, many labs offered tests
  - This is likely because clinical need is sufficiently high (as the main factor motivating development) and development costs are sufficiently low
  - Thus, patents are not needed for the development of testing services
- Patents on genes associated with rare diseases may discourage investment per public comment by laboratory director

Overall Conclusion Concerning Patents' Benefits

- Patents do not serve as powerful incentive to conduct genetics research, to disclose genetic discoveries, or to invest in the development of genetic tests.
- Sufficient incentives and funding for research and development already exist
- As such, the benefits of patents in the area of genetic testing are limited

Examination of the Costs of Patents in Genetic Testing Arena

Costs (Harms) of Patents in Genetic Testing Arena

- Task Force examined whether patents on genes, genotype-phenotype associations, and methods of detecting specific sequences are causing
  - problems in the quality of genetic testing;
  - limitations on the ability of researchers to develop new tests; and
  - limitations on the availability of genetic tests at reasonable prices
    - Through combination of sole provider and multi-payer system

Licensing Refresher

- To evaluate the costs of patents and licensing practices, some background information on licensing is needed.
- A license is an agreement through which the patent holder agrees not to exclude the licensee from using the invention
- Different types of licenses exist
  - Exclusive licenses can create a sole provider of a genetic test—only the licensee has the right to practice the invention
  - Less exclusive forms of licensing, such as non-exclusive licenses and co-exclusive licenses, permit multiple licensees to use patented molecule or method to offer testing

Impact on the Price of Genetic Tests

- Case studies did not reveal a pattern of overpricing for tests that were patented and exclusively licensed relative to tests that were either unpatented or non-exclusively licensed
- Additional findings from case studies:
  - Per-unit price of full-sequence BRCA test comparable to full-sequence tests done at other testing laboratories
  - Price of test for Canavan disease is higher than price for Tay-Sachs test and could reflect patent premium
- Public comment suggested that Athena's SCA testing is needlessly expensive because it involves bundled testing

Impact on Clinical Access to Genetic Tests

- Articles, case studies, and public comments indicate that patents and exclusive licenses have limited the ability of clinical laboratories to offer genetic testing
- Licensing practices that limit the number of clinical labs that can offer a test do not necessarily result in patient access problems
- However . . . Patient access problems most often have arisen when licensing creates a sole provider

Impact on Patient Access to Genetic Tests

- Patient access problems generally have not occurred for patent-protected tests that are broadly licensed
- Most problems occur when tests are exclusively licensed to create a sole provider
  - Case study on LQTS: over a period of 18 months, successive exclusive licensees enforced patent rights even though they were not yet offering a test—”probably had a small but tangible negative effect on patient access.”

Sole Providers, Health Insurance, and Patient Access

- Combination of exclusive licensing to create a sole provider and multiple-payer U.S. health care system often results in patient access problems
  - Sole providers fail to secure coverage from some major payers, including out-of-state Medicaid programs
  - As a result, some patients cannot obtain covered testing
  - Indigent patients, covered by Medicaid, in particular do not obtain testing

Sole Providers, Health Insurance, and Patient Access (continued)

- Hearing Loss case study: Athena has not secured coverage from MediCal for Connexin 26 testing; Connexin 26 mutations account for up to half of all non-syndromic recessive hearing loss cases
  - "Access for these consumers therefore depends on the availability of additional providers who may have contracts with Medicaid or entails direct out-of-pocket payment by consumers. Uncertainty surrounding whether these alternate providers will face enforcement or will stop testing creates an unstable situation."
  - Similar problem exists for SCA testing

Sole Providers, Health Insurance, and Patient Access (continued)

- Sole providers offering testing for Alzheimer disease and LQTS also have had problems securing coverage from particular payers
- Myriad Genetics had this problem too at the outset but now has secured wide coverage from Medicare and private insurers
  - Yet Medicaid patients cannot obtain such testing

Sole Providers, Health Insurance, and Patient Access (continued)

- Information from public comments:
  - Health care providers in Georgia also complained that some sole providers have not secured coverage from private insurers and different state Medicare and Medicaid programs—"end result is that access to a genetic test can be largely influenced by a patient's socioeconomic status and geographic location."
  - Health care provider complained that some sole providers have not secured coverage from Montana Medicaid
  - Parent complained of insurers not covering genetic testing for hearing loss
  - Advocacy group complained that Athena, the sole provider for dystrophin genetic testing, has not secured coverage from some payers, resulting in access problems

Other Problems Caused by Sole Providers

- Observations from public comments:
  - When there is a sole provider, patients cannot obtain second-opinion testing, even when tests have implications for major medical decisions
  - Recommended carrier and newborn screening is not possible when only one lab offers a test; multiple labs needed to handle volume of testing

Conclusion on Patient Access

"For the most part, patents covering genetic tests and related licensing practices do not appear to be causing wide or lasting barriers to patient access. However, the case studies and public comments documented several situations in which patient access to genetic tests has been impeded for segments of the population—especially indigent patients—when these tests are offered by an exclusive provider or a limited number of providers, a practice directly enabled by current patent and licensing practices."

Impact on Quality

- There are recurrent concerns regarding test quality where a test is offered by a sole provider
- Members of task force pointed out that proficiency testing for quality assurance purposes requires that multiple labs offer a particular test
- With samples becoming increasingly labile and smaller, more local laboratories are needed to handle testing—samples sent to a distant sole provider would be subject to degradation
- The competition between multiple laboratories offering a particular test can also lead to innovation in the testing method for that test
  - The example of CF is instructive
  - Lack of exclusivity has led to multiple private and non-private labs who compete to offer quality testing

Sole Providers and Method of Testing

- The existence of a sole provider dictates what method of testing is offered and the testing strategy
  - Bundling is common (e.g. Athena) for heterogeneous conditions but not efficient for the patient or provider
  - Methods are at discretion of a single laboratory
    - e.g. Myriad and deletion testing

The Changing Landscape of Genetic Testing

- Broad consensus exists that genetic testing will increasingly involve multiplex technologies
  - and Whole Genome Sequencing
- Advent of multiplex testing is already an issue with regard to gene patents
  - Labs holding exclusive licenses may block labs doing multiplex testing from reporting results pertaining to their patented genes
  - Potential for blocking situation in LQT testing
- Thus, Task force studied not only the costs of patents on existing tests but also the potential of existing patents to block the development of new tests—specifically, multiplex tests, parallel sequencing of multiple genes, and clinical whole genome sequencing

Potential Impact on Innovations

- No precise figure for the number of genes or associations protected by patents, but studies suggest that a substantial number of human genes are protected by patents
- Concerns have been raised that all of these existing patents on genes and disease-phenotype associations have created a thicket of rights—and a developer would need multiple licenses to develop a multi-gene test
- Patents on genes and associations cannot be invented around
- Controversy exists regarding the legitimacy of patents on genes and associations; some view patents on genes as claiming products of nature and view patents on associations as claiming laws of nature

Potential Impact on Innovations (continued)

- Would new methods infringe patents on genes?
  - Multiplex testing involves probe molecules that would probably infringe corresponding patented nucleic acid molecules
  - Multiple parallel sequencing would typically involve oligonucleotide molecules that would probably infringe corresponding patented nucleic acid molecules
  - There is uncertainty over whether whole genome sequencing would infringe patents on genes

Potential Impact on Innovations (continued)

- Would new methods infringe association patent claims?
  - Association patent claims can be quite broad
    - Claims may be in the following form: “a method of determining a predisposition to Disease X comprising testing a human body sample for a mutation in Gene A, wherein the presence of a mutation indicates a predisposition to Disease X.”
  - Claims such as these do not specify a method of testing, so any method of testing is protected
  - As such, any new form of testing would infringe claims of this breadth, assuming the test included the gene referenced by the patent (WGS would necessarily include all genes, while the other methods include a subset of genes)

Potential Impact on Innovations (continued)

- Would new methods infringe patent claims to processes for detecting specific genetic sequences?
  - It depends on the particular method/process claimed. Some patents claim multiple methods for detecting a specific mutation, including the use of probes and oligo primers. Multiplex tests and parallel sequencing would likely infringe patents such as these. Whether WGS would is unclear.

Potential Impact on Innovations (continued)

- In sum:
  - new methods would probably infringe at least some association patent claims;
  - parallel sequencing and multiplex testing appear likely to infringe patent claims to genes and to methods for detecting those specific genes/mutations; and
  - whole-genome sequencing may or may not infringe patent claims to genes and to methods of detecting specific mutations/sequences.
- Thus, test developers would need multiple licenses to existing patents to develop these new innovations

Potential Impact on Innovations (continued)

- Challenges to obtaining licenses
  - It is often unclear whether licensing rights are available; one way to learn whether rights are available would be to look at existing licenses—however, license terms are often undisclosed
  - Even if one can obtain all needed licenses, all these licenses can lead to royalty stacking; there are also transaction costs involved in having to separately negotiate each license.

Potential Impact on Innovations (continued)

- Patent Thicket May Block or Hinder Development of New Innovations
  - Costs involved in researching patents, separately negotiating each license, and cumulative license fees may discourage development.
  - Even if these costs can be overcome, patent holders who refuse to license could prevent test developers from using a patented gene molecule or association, thereby diminishing the value of multi-gene test (the “blocking” problem)
  - Patents on genes and associations cannot be invented around

Proposed Solutions to Patent Thickets

- Patent Pools
  - Agreement among multiple patent holders to license all patent rights as a package
  - Advantages:
    - Ability to obtain all rights with one license solves royalty stacking problem and problem of licensing transaction costs
  - Disadvantages:
    - Patent pools are voluntary—in biotechnology, patent holders have no inherent incentive to join forces because each holder of a gene patent can offer a single-gene test
    - A hold-out's refusal to participate can limit value of pool
    - Have not proven useful in the genetic testing arena thus far
  - Thus, questions remain as to the viability of this solution

Proposed Solutions to Patent Thickets

- Clearinghouse
  - Patent holders join collective that charges standard licensing fee for each patent
  - Advantages:
    - No need to negotiate license fees
    - Licensing fees capped for those who take multiple licenses
  - Disadvantages:
    - Clearinghouse is voluntary
    - Possibility of holdouts
    - Have not proven useful in the genetic testing arena thus far
  - Thus, questions remain as to the viability of this solution

Additional Challenge to Development of LDTs

- Research to Create LDTs is not Entitled to Experimental Use Exemption:
  - Hatch-Waxman experimental use provision provides exemption from patent infringement liability for using a patented invention for the purpose of developing and submitting information under a Federal law regulating drugs (35 U.S.C. § 271(e)(1))
  - Those using patented molecules during research to develop a CLIA LDT could not invoke this exemption because CLIA is not a Federal law that regulates drugs
  - Conversely, to gain approval for a test kit, developer must submit information on the test's analytical and clinical validity under FDCA (a federal law regulating drugs)
  - Thus, any use of patented molecules, associations, or processes in the course of developing proof of kit's analytical and clinical validity likely would be exempt from infringement

Legal Developments

- Various ongoing cases may alter patentability of genes, associations, and methods of detecting specific sequences:
  - ACLU is representing plaintiffs in a lawsuit challenging the patentability of various claims, including claim to *BRCA1* and *BRCA2* isolated gene molecules, claim to association between BRCA2 and breast cancer, and claims to methods of detecting mutant BRCA1 and mutant BRCA2
  - *Bilski v. Kappos*: may affect patentability of processes for correlating a genotype with a phenotype
  - No one can predict outcome of these cases—better to address pressing concerns through recommending policy and statutory changes

Other Material Reviewed by the Task Force

- Bayh-Dole Act
  - Established uniform policy of allowing academic institutions to retain title to federally-funded inventions
  - Question arose during task force deliberations over whether law gives agencies the authority to require non-exclusive licensing practices
    - But clearly this is not the norm even if that authority exists
- NIH Best Practices for the Licensing of Genomic Inventions
  - Guidance document encouraging non-exclusive licensing whenever possible
- Nine Points to Consider in Licensing University Technology

Other Material Reviewed by the Task Force (continued)

- Organization for Economic Co-Operation and Development's (OECD's) Guidelines for Licensing of Genetic Inventions
  - Best Practice 2.2: "Rights holders should license genetic inventions for health applications, including diagnostic testing, on terms and conditions that seek to ensure the widest public access to, and variety of, products and services based on the inventions."
- NIH Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-wide Association Studies
  - Policy discourages patenting of genotype-phenotype associations
- However such recommendations have existed for some time and uptake is certainly not universal

A Moral Dimension

- Some comments pointed out that moral and ethical issues arise in the context of gene patents and licenses
- Strong sentiment exists that access to one's own genetic information should not be limited or proscribed by patents
  - At the root of the recent court case against Myriad
- Genetic tests are not equivalent to commodities and invoke different considerations than the things most patents and licenses cover

Summing Up

- The patent system is designed to promote progress
- In the realm of therapeutics, strong arguments can be made that patents enable innovation, drive progress and serve an important role
- In the realm of diagnostics, patent-enabled exclusivity primarily results in a narrowing of offerings to patients and physicians
- If access to kitchen appliances were the issue, the situation would be merely lamentable, not cause for changes
- What is at stake—patient access to important medical information—warrants changes to the system

Recommendations

1. Creation of Exemptions from Infringement Liability

The Secretary of Health and Human Services should support and work with the Secretary of Commerce to promote the following statutory changes:

1. *The creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes.*

2. *The creation of an exemption from patent infringement liability for those who use patent-protected genes in the pursuit of research. Related health care and research entities also should be covered by this exemption.*

Other Recommendations

- We recognize that the two proposed statutory changes may not be immediately enacted and thus we made other recommendations for the interim

2. Discouraging Association Patent Claims

The Secretary should use her powers to discourage the seeking, the granting, and the invoking of simple association patent claims; it is the Committee's position that these claims represent basic laws of nature that cannot be invented around.

3. Promoting Adherence to Norms Designed to Ensure Access

A. The Secretary should develop mechanisms to promote voluntary adherence to the principles reflected in NIH's Best Practices for the Licensing of Genomic Inventions*; the Organisation for Economic Co-Operation and Development's (OECD)* Guidelines for Licensing of Genetic Inventions*; the NIH* Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-wide Association Studies*; and* In the Public Interest: Nine Points to Consider in Licensing University Technology*. The Secretary of Health and Human Services should also advocate that professional organizations involved in intellectual property policy and practice in this area work together to build on those norms and practices as they relate to gene-based diagnostics by articulating more specific conditions under which exclusive licensing and nonexclusive licensing of uses relevant to genetic testing are appropriate. Professional societies should work cooperatively to forge consensus positions with respect to gene patenting and licensing policies.*

B. The Secretary should encourage stakeholders (for example, industry, academic institutions, researchers, patients) to continue their work of developing a code of conduct that will enable broad access to such technologies.

4. Enhancing Transparency in Licensing

A. The Secretary should encourage holders of patents associated with genetic tests and their licensees to make information about patent licenses readily available either by making the signed licenses publicly available or by disseminating information about their technology and licensing conditions, including any terms that pertain to the type of license, field of use, and the scope of technologies that are still available.

B. As a means to enhance public access to information about the licensing of patents related to gene-based diagnostics, the Secretary should direct NIH to amend its Best Practices for the Licensing of Genomic Inventions to encourage licensors and licensees to include in their license contracts a provision that allows each party to disclose information about its licenses (including such factors as type of license, field of use, and scope) in order to encourage next-generation innovation.

5. Advisory Board to Assess Impact of Gene Patenting and Licensing Practices

The Secretary should establish an advisory board, which would be available to provide ongoing advice about the public health impact of gene patenting and licensing practices. This advisory board would also be available to receive any reports of problems in patient access to genetic tests from the public and medical community. The board then could review new data collected on patient access and assess the extent to which access problems are occurring. One of the board's missions would also be to recommend what information should be systematically collected through iEdison so that iEdison can be used to research questions about licensing, including whether the licensing of genomic inventions has been conducted in accordance with NIH's Best Practices for the Licensing of Genomic Inventions. The advisory board also could provide input on the implementation of any future policy changes, including the other proposed recommendations in this report.

6. Federal Efforts to Promote Broad Licensing and Patient Access

The Secretary should encourage Federal agencies within the Department of Health and Human Services to undertake the following actions:

A. *Federal agencies should promote wider adoption of the principles reflected in NIH's Best Practices for the Licensing of Genomic Inventions and the OECD Guidelines for Licensing of Genetic Inventions, both of which encourage limited use of exclusive licensing for genetic/genomic inventions.*

B. *Federal agencies should encourage wider use of the Nine Points to Consider in Licensing University Technology. Points two and nine, including their explanatory text, are particularly relevant for genetic tests. For example, the explanatory text under point two recognizes that "licenses should not hinder clinical research, professional education and training, use by public health authorities, independent validation of test results or quality verification and/or control."*

6. Federal Efforts to Promote Broad Licensing and Patient Access (continued)

C. *Federal agencies should explore whether approaches to addressing patent thickets, including patent pools, clearinghouses, and cross-licensing agreements, could facilitate the development of multiplex tests or whole genome sequencing.*

D. *Federal agencies should provide more detailed guidance regarding the licensing of patents associated with genetic tests. In particular, this guidance should encourage the use of diligence terms in licensing agreements, particularly those with exclusivity. Increasing the number of insurers that reimburse for the test or improving the specificity and sensitivity of the test are examples of milestones that a licensee could be required to meet to earn or maintain license rights.*

7. Changing Licensing Policies Governing Federally Funded Research

Because it is unclear whether the Bayh-Dole Act gives agencies authority to influence how grantees license patented inventions, the Secretary should seek clarification about this legal question. If it is determined that such authority exists, the Secretary should promulgate regulations that enable the Department's agencies to limit the ability of grantees to exclusively license inventions resulting from government funding when they are licensed for the genetic diagnostic field of use. Exceptions should also be allowed if a grantee can show that an exclusive license is more appropriate in a particular case, e.g., because of the high costs of developing the test. The Secretary should also direct NIH to make compliance with NIH's Best Practices for the Licensing of Genomic Inventions an important consideration in future grants awards.

8. Providing Needed Expertise to USPTO

The Secretary should recommend that the Secretary of Commerce advise USPTO to:

establish an advisory committee to provide advice about scientific and technological developments related to genetic tests and technologies that may inform its examination of patent applications in the realm of human genes. The Committee believes experts in the field could help USPTO in its development of guidelines on determinations of nonobviousness and subject matter eligibility in this field once pending court decisions such as Bilski v. Kappos *are decided.*