The American Society of Human Genetics
Policy Statement

April 2010

Guiding Principles on PROTECTION OF INTELLECTUAL PROPERTY Patenting and Licensing in the Genetic Testing Arena

The following basic principles guide the specific positions and actions taken by the Board of Directors of the American Society of Human Genetics (ASHG) related to issues of patenting and licensing.

1. **Protection of Intellectual Property**

   It is appropriate for scientists, whether in the private or public sector, to be able to take steps to appropriately protect intellectual property. Institutions have standing policies that require scientists to disclose intellectual property to the institution so that appropriate steps may be taken to pursue commercialization.

   These principles have been delineated in both law (the Bayh-Dole Act) and in practice at universities, both private and public. It is the responsibility of scientists (faculty members or trainees) to know and uphold their institutional obligations. Scientists and their employers must also evaluate the disclosure in light of the current interpretation of patentability of genetic findings, especially as recent applicable court case rulings are altering the landscape regarding patents of genes and genetic tests continually.

   It is also critical that scientists understand that they are in the position to have expectations of their university administration and technology transfer offices to accept reasonable demands during the steps of disclosure, protection and commercialization of discoveries and protected intellectual property. For example, while exclusive licensing may be more straightforward than negotiating and signing multiple non-exclusive licenses, the latter may be in the best interest of both patients and the scientific community.

   Scientists and administrators must also be clear about the sometimes subtle differences between research and clinical testing in translational research programs, so that research exemptions may be interpreted correctly. Clear articulation of definitions and claims around testing and diagnostics as compared to therapeutic applications must also be a principle of practice.

2. **Quality of testing**

   It is essential that the scientific community, both researchers and clinicians, demand the highest possible standards for genetic testing, including:

   - The requirement that labs participate in proficiency testing as developed and organized by recognized entities such as CAP or New York State;
   - The appropriate certification of laboratories doing the testing by entities such as CLIA; and
   - Adequate quality control mechanisms to be in place for the review of the tests themselves.

3. **Access to testing**

It is critical to patients and providers that access to genetic testing not be limited as a result of exclusivity of licensing or inappropriately exorbitant cost of tests. In addition to the imposition of fiscal constraints around monopolies created by exclusivity, second opinions are rendered impossible. Patients may suffer in a situation where not every mutational test is available or being performed by the organization holding the exclusive license to a gene patent.

There are multiple labs already capable of performing extensive genetic testing, including full genome or exome sequencing. Severe limitations imposed by patent claims and licensing terms related to individual tests will deter and delay the implementation of these technologies. The concept and availability of full genome testing in the rapidly advancing era of individualized medicine will be rendered impossible if current patterns of claims around genetic test of individual genes continue.

One initial mechanism that would help address all of these issues would be the establishment of a legitimate registry of genetic tests, with the information on that registry being maintained by an independent party, with access to the information by all patients and providers.