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AMP Position Statement: Gene Patents and the Exclusive Licensing of Genetic Discoveries

Background: Concerns about the use of patents and exclusive licenses to limit molecular testing

Many disease-associated genes in humans and their pathogens have been identified in recent years, and more will be discovered in the coming decades. Advances in modern genomic technologies and the ability to conduct genome-wide association studies will contribute to this progress and will usher in an era of personalized, predictive, and pre-emptive health care. Clinical laboratories in both the public and private sectors translate and develop many of these discoveries into molecular diagnostic assays and seek to make these tests widely available as clinical services for the public good. In this role, clinical laboratories and laboratory professionals are vital to the translation of scientific discoveries to patient care.

Clinical laboratories can only develop these important tests when they have access to the broadest base of genomic discoveries. This access is more critical as modern technology platforms allow for increasingly sophisticated tests that encompass a greater range and diversity of content from the genome. Coinciding with the sequencing of the human genome, the US Patent & Trademark Office has historically granted broad patents on genomic discoveries, including individual genes, and large numbers of new patent applications are continuously under review. Frequently, patent holders and their exclusive licensees are choosing to monopolize molecular testing by restricting other health care providers and facilities from developing or performing tests covered by these patents and licenses.

AMP believes:

- Molecular test services are medical procedures. As such, they should be widely available to promote optimal patient care, medical education, and medical research.
- The research, development and practice of molecular testing is essential to medical practice, the education of physicians, researchers and health-care professionals, and the continued improvement of the quality of medical care.
- While attaching intellectual property rights to true acts of invention such as new therapeutics, diagnostics, or technology platforms is essential to encourage investment and reward innovation, a single gene or a sequence of the genome is a product of nature and should not be patentable.
- Gene patents can serve as a disincentive to innovation in molecular testing because they deny access to a vital baseline of genomic information that cannot be "invented around." Moreover, threat of enforcement from a patent holder and ensuing litigation costs lead to a chilling effect as clinical laboratories are reluctant to develop new tests that could directly benefit patients.
- In addition to the concern about gene patents, exclusive licenses that confine molecular testing to a single provider are detrimental to the public interest by limiting patient access to testing,

restricting medical practice and research, impeding the advancement of medical knowledge and enhancement of the public's health through informed clinical decision-making. Moreover, no governing standards currently exist that would prohibit the practice of granting exclusive licenses.

- Most patented discoveries of pathogen or human genes can be effectively translated into molecular tests provided they are licensed on a non-exclusive basis and licenses are easily obtainable, both in financial and practical terms.

AMP recommends:

- The patenting of single genes, sequences of the genome, or correlations between genetic variations and biological states should be discontinued, either as a result of judicial review or through an act of Congress.
- Entities, including higher educational and research institutions, that currently hold gene patents, should not grant exclusive licenses to these patents.
- To ensure that access to innovative molecular tests remains widely available and affordable to patients, financial terms for test licenses should be reasonable and “sole source” tests should be prohibited. License agreements should also be free of any terms that limit the number of tests that can be performed by a laboratory or regulate the technical performance or clinical uses of the test. License agreements should likewise be free of terms that inappropriately limit research related to testing or the public dissemination of the resulting research findings.
- Physicians, researchers, clinical laboratory directors, patient advocates, government officials, research funding agencies and other stakeholders should work cooperatively to develop alternative models to gene patents and exclusive licenses. These innovative models should increase patient access to health care and achieve greater benefit from the existing body of intellectual property linked to the human genome.

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