

Points to Consider in Preparing License Agreements for Patented Genetic Tests

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of the Economics Committee:

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Background and Rationale

The American College of Medical Genetics believes that gene testing must remain widely accessible and affordable and that the development of safe and effective genetic tests should not be hindered.¹ Other medical societies are also concerned about the patenting of human genes and mutations.²⁻⁸ It should be noted that some patent holders (including, for example, some patient support groups) have sought to license broadly without any up-front fees or ongoing royalties.

* A key concern expressed is that patents or exclusive license agreements can restrict the availability of genetic tests resulting in limited access to medical care and lower quality of medical care, along with harms to medical education and medical research.

* Broad availability of genetic testing services will help maximize the public benefit of the Human Genome Project and can be best accomplished by ensuring appropriate licensing of patented technologies used by healthcare providers who provide genetic testing services.

This document is intended to provide specific points to consider for each of the key license terms that have impact on access to patented genetic tests in health care, teaching, and research. This document is not intended to provide detailed legal language suitable for an actual license agreement or to provide coverage of all possible situations that may arise in the licensing of specific patents affecting genetic testing.

Non-exclusive license or sublicense

* Making a license or sublicense available to any qualified health-care provider or institution with the required Federal (CLIA) and state licensure to perform clinical genetic testing would increase access to genetic tests.

Reasonable royalty

* Genetic testing services may require the right to use a specific gene sequence and/or specific mutations in a gene. Voluntary limiting of royalties for use of individual genes would improve access to testing. Appropriate limits to royalties may differ according to whether:

1. discoveries were made during publicly funded research. Some have suggested that appropriate reimbursement might be 2% of the published Medicare reimbursement for the test or of actual reimbursement, whichever is less or

2. discoveries were made entirely with private funding. Some have suggested that appropriate reimbursement might be 4% of the published Medicare reimbursement for the test or of actual reimbursement, whichever is less.

Low-volume exemption

In some cases, patent holders indicate that a major reason for requesting licenses is to maintain the validity of a patent, with profit to the licensee a secondary consideration, especially for low volume labs.

* Because some clinical labs operate at a very low volume for specific tests (i.e. training labs, rare disease testing labs), it may be inappropriate to require such licensees to pay a minimum annual royalty as well as an up-front license fee.

* There are administrative costs to licensor and licensee associated with payment of royalties and, for low-volume labs, these costs become a high percent of the royalty for the licensor. Waiving royalties for very low volume labs may minimize these costs.

* Therefore, in some cases, royalties might be waived when the licensee's financial obligation to licensor is less than \$1000 per year or a sliding scale might be implemented based upon the number of tests performed.

Royalty cap

Some testing services may require rights to use both generic testing technology and/or multiple genes and mutations, each with a patent and therefore each requiring a license. Generally speaking, royalty costs are not reimbursed by third-party payors, so high royalty costs can prevent laboratories from offering tests altogether.

* In order to keep tests affordable, it may be necessary when multiple licenses are required to provide the test service, to limit the sum of all royalties due. Some have suggested that all royalties should not exceed 15% of the published Medicare reimbursement for the test or of actual reimbursement, whichever is less.

* In order to achieve such limits consideration should be given where necessary, to proportionately reduce royalties due for each individual license to maintain an overall cap of 15% on the sum of all royalties.

Optional non-profit use of royalties

* Licensor might offer the licensee the option of making payments in lieu of royalties to an appropriate non-profit organization that supports research, treatment, education or patient and family support in the field of human genetic disease.

Reporting of information to calculate royalties

* Required reporting should be limited to essential business information needed to calculate royalties (usually the number of clinical tests performed in a given time period).

* Reporting should be the responsibility of the laboratory that performs the test, rather than laboratories that collect or transmit specimens to the testing laboratory.

Clinical standards and regulatory compliance

* Testing, interpretation, and reporting should be performed according to the best medical and scientific judgment of the licensee, and in compliance with applicable laws and standards of health-care licensing and accrediting bodies.

* Quality assurance activities should be performed under the auspices of neutral third parties, where possible. Patent holders generally should not be the arbiters of quality

assurance and regulatory compliance on the part of the licensee, as this may pose a conflict of interest for the patent holder.

Publication of information

It is in the interest of all parties to promote scientific research and quality assurance.

* Therefore, it is important that all license agreements permit the licensee to make public all information necessary for this purpose derived from performance of the licensed test, provided that all such disclosures are in full compliance with applicable Federal and state laws and regulations governing research on human subjects and the privacy of medical information.

* Some have suggested that the simplest way to assure this principle is achieved is to permit licensees to publish without restriction.

Non-exclusive access to proprietary materials and information

It is generally accepted that the licensee is not obligated to release to the licensor proprietary materials or information resulting from performance of the licensed test. However, licensee may enter into an agreement with a third party to release such materials or information. The original licensor also has interest in such information and may be placed at a disadvantage in future uses of its original patent.

* Therefore, it may be appropriate that agreements between licensors and licensee stipulate that, if a licensee enters into such an agreement with a third party, the original licensor may also request and receive access to the same materials or information, on terms no less favorable than those offered to the third party.

Termination

Maintaining access to genetic testing service during the term of a patent depends upon maintaining license agreements. Termination of agreements can have a substantial negative impact on the availability of essential services during the term of a patent.

* Therefore, the license agreement should be terminated only for the exceptional causes such as substantive breach of agreement by the other party, loss of licensee's CLIA license to perform clinical molecular-genetic testing, invalidation of licensed patent, and/or termination of licensed clinical testing services by the licensee.

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