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National Society of Genetic Counselors

March 26, 2012

Saurabh Vishnubhakat
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Dear Mr. Vishnubhakat:

The National Society of Genetic Counselors (NSGC) is responding to the U.S. Patent and Trademark Office's request for comments on genetic diagnostic testing.

NSGC's Position Statement on Human Gene Patenting:
NSGC supports an individual's access to medical technology and services. NSGC believes that patent holders granting exclusive licenses on human nucleic acid sequences will hinder the development and cost-effectiveness of genetic testing, particularly when the analysis of multiple genes or the entire genome is necessary to assess the risk or existence of disease.

NSGC appreciates the previous work that USPTO has conducted on accessibility and we encourage USPTO to continue to seek out genetic counselors and NSGC for expertise on genetic diagnostic tests. Further, we respectfully request that USPTO consider the following comments and recommendations of NSGC, as well as NSGC's white paper on human gene patenting.

Currently, how widely available are primary genetic diagnostic tests? How often are such tests prescribed? What are the limitations, if any, on the availability of primary genetic diagnostic tests? If there are limitations on such availability, what are the consequences in terms of the quality of care, human health and medical costs of such limitations? How has the practice of medicine, the quality of care that patients receive, and medical costs and insurance coverage been affected, if at all, by the availability of primary genetic diagnostic tests?

While GeneTests cites approximately 2,300 clinical gene tests, the extent to which these are available depends on patents and exclusive licensing agreements, which often create access barriers.

Primary genetic testing is widely available in the United States as hundreds of CLIA-approved laboratories offer it. Peer-reviewed medical journals have published indications for genetic testing and a search of the National Guideline Clearinghouse (http://www.guideline.gov/) returns almost 200 guidelines outlining the appropriate use of genetic tests developed by professional societies.

Limitations/barriers in accessing genetic tests are considerable and include patents, licensing agreements, cost, insurance coverage, geography, socioeconomic status of the patient, and primary healthcare providers' knowledge of such tests. These limitations impact the ability of primary genetic testing to influence medical decisions and management in areas such as oncology, cardiology, and pediatrics. If access to testing is limited, physicians may be prevented from making early diagnoses and intervening with medical management recommendations before problems may manifest, or in early stages in which treatment is most effective.

Primary diagnostic genetic tests are also critical to preventive care and early treatment. Such tests identify a patient's risk level pertaining to developing a specific type of disease or condition. Without such targeted screening and surveillance, practitioners do not have the data necessary to avoid unnecessary screening and surveillance in low- risk individuals. This results in ordering unnecessary, general tests that result in higher costs and less-effective outcomes.

What is the amount and scope of patenting in the field of genetic diagnostic testing? What role, if any, does patenting play in the availability of primary genetic diagnostic testing?

The first gene patent was granted in 1982 to the University of California. Today, about 20 percent of human genes are patented. Certain genes, gene mutation sequences, and DNA sequences have all been awarded patents. Of the patent holders, about 60 percent are private research companies and 30 percent are universities. For-profit organizations generally support gene patents as it enables them to collect revenue necessary to offset initial research and development costs. The revenue may allow them the security to fund further research and genetic test development.

Patents often create access issues. Lack of transparency resulting from exclusive licensure agreements and costs specifically related to the effects of patents on clinical labs may cause labs to preemptively discontinue tests rather than pay patent rights. There is a lack of understanding regarding the role that patents play in the lab decision-making process and there should be increased transparency.

With respect to primary genetic diagnostic tests, how widely available are independent second-opinion genetic diagnostic tests? What are the various organizational methods used to make such independent second opinion genetic diagnostic tests available? Another limitation regarding insurance coverage is that many insurers would not cover any second-opinion genetic test even though coverage for primary testing is actually fairly good. In this situation, the patient would likely need to pay out of pocket if such testing were ordered. Are any such limitations organizational, associated with the level of quality or demand, or driven by other internal or external factors?

Second opinion-genetic tests are uncommon for a variety of reasons. If the primary genetic test yields a result that is abnormal but in-line with the clinical impression, there often is no reason to doubt the accuracy of the results. Second opinions may be an option if the primary genetic test yields a negative (normal) result that does not coincide with clinical impression – or if the primary genetic test result interpretation is doubtful.

One potential limitation on the availability of independent second-opinion diagnostic tests is exclusive licensing from gene patents. For cases in which only one laboratory offers a certain genetic test, second-opinion tests are not available. If a number of laboratories offer a genetic test, second-opinion genetic tests are readily available.

Coverage of such second-opinion tests may be lacking as many insurance plans do not recognize multiple laboratories. Additionally, in some cases, the sensitivity of the tests offered through an in-network laboratory may not be equivalent to tests offered through an out-of-network laboratory.

What impact does the availability of independent second opinion genetic diagnostic tests have on the level of care that physicians are able to provide? Does the current level of availability of independent second opinion genetic diagnostic tests affect the medical decisions and judgment of physicians? Does the current level of availability of independent second opinion genetic diagnostic tests affect the quality of care received by patients? Does the current level of availability of independent second opinion genetic diagnostic tests affect the reliability of information presented to patients? Are there practical consequences of the current availability of independent second opinion genetic diagnostic tests, in terms of patient health, quality of life, and longevity? In terms of the practice of medical care? Are these consequences, if any, relatively rare, or common and widespread?

In the strictest definition of second-opinion testing, i.e. a patient obtains a result from a primary lab and would like a second laboratory to confirm this result, the availability and potential impact of a second-opinion test can be significant. This is especially the case if there is reason to doubt the results or if there is a strong desire to confirm the primary test result.

For example, if an error was made on the primary test, there would be no way to confirm this if the second opinion test is not available due to patents and/or exclusive licensing. In this scenario, patients might make life-altering treatment decisions based on an incorrect test result. This could result in unnecessary treatments/interventions or insufficient screening and surveillance for

symptoms associated with a gene mutation. The commonly quoted error rate for most clinical labs is 1 percent, but in practice, it is likely much lower. While errors are rare, when they do occur they can dramatically impact a patient's care.

Is the availability of independent second-opinion genetic diagnostic tests related in any manner to innovation in the health care field, especially as relates to the introduction of new or improved techniques associated with existing genetic tests and diagnostic methods?

Exclusive licensing arrangements permitted under current patenting practices may prohibit development of some tests and in other cases generate cost barriers for licensing and diagnostic test development. As a result, commercial diagnostic laboratories may not be able to develop and offer second-opinion genetic tests. This may stifle or impede the development of new and improved testing techniques, limiting patient access to second-opinion tests or hindering improved testing techniques.

To the extent that independent second opinion genetic diagnostic tests are not available, what are the appropriate methods for making them more widely provided? What entities or institutions, if any, should play an active role in ensuring that independent second opinion genetic diagnostic tests are more widely provided? What is the basis for your recommendation in terms of providing the maximum benefit at the appropriate level of cost? What entities or institutions, if any, should not play a role in ensuring that independent second opinion genetic diagnostic tests are more widely provided?

The only way to ensure availability of independent second-opinion diagnostics tests is for the patent holder to issue a license that is not so cost prohibitive as to 1) prevent other laboratories from offering the test and 2) prevent interested patients from undergoing such tests. If patents on nucleic acid sequences continue to be awarded, public policy should be geared toward controlling and regulating licensure costs.

What public policies, if any, should the federal government explore in order to ensure that independent second opinion genetic diagnostic tests are more widely provided? Is the widespread availability of such tests the only issue the Federal Government should consider in fashioning such public policies? Are there public policies that the Federal Government should not explore?

Under the current system whereby genes, gene mutation sequences, and DNA sequences can be subject to patent, the only way to ensure access to independent second-opinion diagnostics tests is for the patent holder to issue a license that is not so cost prohibitive as to 1) prevent other laboratories from offering the test, and 2) prevent interested patients from undergoing such tests. If patents on nucleic acid sequence continue to be awarded, public policy should focus the effects of exclusionary rights for those patents and the effect of those exclusions on access and cost.

What effects, if any, do patents and exclusive licenses have on genetic diagnostic testing? What effects, if any, do patents and exclusive licenses on genetic diagnostic tests have upon the development of new testing procedures? What effects, if any, do patents and exclusive licenses on genetic diagnostic tests have upon how new testing procedures are performed? What effects, if any, do patents and exclusive licenses on genetic diagnostic tests have upon the interpretation of testing results? What effects, if any, do patents and exclusive licenses on genetic diagnostic tests have upon the further improvement of testing procedures?

Patents and exclusive licenses reduce the number of labs that are able or willing to administer tests. This creates bottlenecks in patient care, increases turnaround time, and may affect the ability to provide timely, appropriate care. Patents generally increase costs as labs charge more to cover the licensing fees.

Issuing licenses continues to be a concern in gene patenting. Some support such patenting as long as non-exclusive licenses are granted and royalty and other licensing fees are set at a financially reasonable level. Others favor exclusive licensure because it protects a licensee from direct competition. Also licensees may be more willing to financially invest in the research and development of a specific gene test, as he/she is not racing against the work of a competitor.

Opponents to gene patenting argue that as specific gene variations affect more than one disease pathology, gene patents and exclusive licensure will inhibit other researchers from developing and offering additional or alternative diagnostic testing for such diseases. Progress in offering multi-gene testing technologies will likely encounter increasing barriers and costs due to exclusive licensing arrangements that gene patenting practices currently allow. This will further stifle new and innovative testing techniques and prevent patients from benefiting from such tests.

Furthermore, newer methods may misrepresent or be misunderstood as to the coverage of patented genes. For instance, aCGH chips may/may not have coverage of the patented genes, depending upon chip design. Without knowing this information, physicians may not know whether they should order additional testing for disorders wherein deletions or duplications are common.

Similar issues arise in whole genome/exome sequencing and the reporting of patented genes. The potential benefits and future applications of large-scale medical sequencing could be thwarted by the practice of "patent stacking," involving multiple patents on a single sequence, requiring researchers to enter into licensing agreements with different patent holders.

Rather than undergo a single diagnostic test using genomic sequencing through one laboratory, consumers will have to undergo multiple tests through multiple testing companies, which is time consuming and expensive to the consumer and can result in increased healthcare costs.

Patents and exclusive licenses hinder acceptance and understanding of new tests and methods. If labs are unable to access more current methods but are unwilling to lose the market slot, certain test methodologies may persist because they are less dependent upon specific gene sequence or more difficult to claim as covered under the patent. This adversely affects patient care for diseases that patented methods could better detect.

The USPTO maintains that patenting does not limit innovation and instead encourages research because it requires the patent holder to publicly disclose a gene sequence. Other researchers then use this information as a starting point to improve or create a test. In its guidance, the USPTO assumes it rare for a commercial patent holder to impose burdensome licensure rules on academic and non-profit research bodies.

There are instances in which the holder of a gene patent refused to publicly share data on rare genetic variants of unknown clinical significance (VUS) within specific genes. For example, for many years, Myriad Genetic Laboratories, which holds the patent for the BRCA1 and BRCA2 genes, contributed VUS data to the Breast Cancer Information Core (BIC) mutation database. The BIC is an open-access resource maintained by the National Human Genome Research Institute to coordinate the detection, interpretation and dissemination of breast cancer mutation data.

In late 2004 Myriad stopped depositing additional VUS data into the BIC. Since population-based data – both genotypic and phenotypic – is critical to understanding the role of these variants in disease, withholding such information impedes accurate interpretation of genetic tests and forces clinicians and patients to rely on a single laboratory's interpretation.

Patents and exclusive licensing hinders improvement as they increase patient, provider, and payer costs, as they must use multiple tests instead of one test. For example, aCGH/exome sequencing cannot detect or fully report patented genes and tests for these disorders and must be ordered separately. If patented genes are not included, pursuing aCGH/exome sequencing as an all-in-one analysis is pointless. As labs merge or are bought out, an inadvertent monopoly on testing occurs.

What are the pecuniary costs associated with genetic diagnostic testing? Are there substantial differences between the pecuniary costs of patented genetic diagnostic tests and unpatented genetic diagnostic tests? To the extent that there are cost differences, are these differences attributable to the patents themselves, or are there other factors that may be driving the differences? Are there substantial differences between the pecuniary costs of patented genetic diagnostic tests and unpatented genetic diagnostic tests available for the same medical disorder? To the extent that there are cost differences, are these differences attributable to the patents themselves, or are there other factors that may be driving the differences?

In today's market, genetic tests run between $200-$400 for analysis of a single or small number (~3) of mutations, and can cost up to $1,000-$1,500 per gene for comprehensive genetic analysis of an entire gene. The latter typically covers direct DNA sequencing and additional analyses to detect other mutations not found with sequencing, such as large deletions and/or duplications, can cost an additional $500-$1,000/gene. Thus, complete gene analysis can cost between $1,500-2,500/gene.

Changes in technology, such as the development of multi-gene testing technologies, will likely drive the cost of genetic testing down. This is already becoming evident, with one laboratory offering genetic testing for six genes, mutations which cause an increased risk of colorectal cancer, at a cost of $2,500. Testing for these six genes in labs using more traditional technologies cost over $$6,530

What effect does pecuniary cost have on patient access to genetic diagnostic tests? What effect does the cost of primary genetic diagnostic testing have on the likelihood that patients will request such tests? What effect does the cost of an independent second opinion genetic diagnostic testing have on the likelihood that patients will request such tests? What effect does the cost of primary genetic diagnostic testing have on the likelihood that physicians will prescribe such tests? What effect does the cost of independent second opinion genetic diagnostic testing have on the likelihood that physicians will prescribe such tests?

In most healthcare settings, patients do not request genetic tests without healthcare provider's recommendation. If a provider recommends a primary genetic test, he/she discusses costs with the patient – and in most cases, pre-authorization with the insurance company is initiated. If the patient's insurance plan does not cover the test, or if the patient does not have insurance, the patient must pay for out of pocket, which can cost between $200 to several thousand dollars (see above).

Second-opinion tests are rarely requested in practice, although this is based only on anecdotal evidence. If a patient wishes to have a test result from a primary lab confirmed, several factors determine whether insurance would cover the second opinion. For some genetic tests, second-opinion tests are not available because the only lab offering the test holds the patent and/or exclusive license.

Healthcare providers typically offer genetic tests based on the likelihood of identifying a mutation and based on medical necessity – not cost.

How extensive is medical insurance coverage for genetic diagnostic testing? What are the differences, if any, between the level of insurance coverage available for genetic diagnostic tests covered by patents and the level of insurance coverage of unpatented genetic diagnostic tests for the same diseases or disorders?

Genetic test are now widely covered by most third-party payers, and many are covered by Medicaid and Medicare. To date, no evidence suggests that insurers base the decision to cover a genetic test on whether it is a patented gene or test but costs are an issue.

What effect does insurance coverage have on patient access to genetic diagnostic tests? What effect does the insurance coverage of genetic diagnostic testing have on the likelihood that patients will request such tests? What effect does the insurance coverage of independent second-opinion genetic diagnostic testing have on the likelihood that patients will request such tests? What effect does the insurance coverage of genetic diagnostic testing have on the likelihood that physicians will prescribe such tests? What effect does the insurance coverage of independent second-opinion genetic diagnostic testing have on the likelihood that physicians will prescribe such tests?

Given the high cost of comprehensive genetic tests, most patients will not undergo testing if the cost is not partially or completely covered by insurance. This is the case for both primary and secondary genetic tests.

Healthcare providers typically offer genetic tests based on the likelihood of identifying a mutation and medical necessity – not cost or whether the insurance will cover the test.

NSGC appreciates the opportunity to provide comments. We look forward to collaborating with USPTO to ensure that genetic diagnostic tests are effective and accessible.

Sincerely,

Brenda Finucane, MS, CGC
President

Backgrounder on Human Gene Patents
Prepared For the NSGC Board of Directors
By the NSGC Public Policy Committee
September 11, 2009

Overview

The United States patent system is intended to preserve an inventor's right of ownership over a new and useful process, machine, manufacture, composition of matter, or improvement. (1) While preserving the right of ownership, the patent system is also intended to spur the introduction of innovation into the public marketplace. In exchange for the rights offered under the patent, an inventor agrees to release details of the patented subject to the public. This disclosure gives other inventors the opportunity to use the information as the building block for further innovations and improvements.

To be patentable, a subject must be novel and useful. A subject that was known, used, or published by others in the United States or a foreign country, or which is not substantially different from an existing subject is not considered novel. Another prong of the novelty test is that the subject must be "non-obvious," meaning that it is not something that would be easily apparent to someone with skill or expertise in the field related to the subject. To be useful, a subject must serve a purpose and be able to achieve the purpose stated in the patent application. (1)

Patents are granted by the US Patent and Trademark Office (USPTO), an agency of the Department of Commerce. Once a patent is awarded, it is the responsibility of the patent holder, not the USPTO, to enforce the patent. If the patent holder identifies a party in violation of the patent, the patent holder may bring a suit in federal court. The patent holder can seek an injunction, ordering the other party to immediately cease activities in violation of the patent and/or financial damages for any profit lost due to the patent violation.

Patents last for 20 years from the time the patent application was filed. During this time, the patent holder has the exclusive right to bar others from "making, using, offering for sale, or selling or importing the invention." (1) The patent holder may issue licenses, allowing others to make, use, offer for sale, sell, or import the patented subject. The patent holder and licensee enter into an agreement that sets guidelines for permissible use of the subject under the patent, royalty fees for use of the subject, and other provisions. (1) A patent holder has the option to grant exclusive or non-exclusive licenses. A non-exclusive license means that the patent holder grants the same rights to all licensees. (2) Under an exclusive license, the patent holder grants a specific use or right to a licensee and promises not to extend that same use or right to other licensees. (2) Once a patent expires, anyone is free to use the subject under any of the previously barred uses and the patent holder no longer holds the right to issue licenses. For example, generic versions of a pharmaceutical drug emerge once a patent expires, since other companies are now allowed to sell the formula originally protected under the patent.

The issuance of licenses has been an issue in gene patenting. Some have supported gene patenting as long as non-exclusive licenses are granted and that royalty and other licensing fees

are set at a financially reasonable level.(3) Those in favor of exclusive licensure state that it protects a licensee from direct competition.(4) Therefore, the licensee is more willing to financially invest in the research and development of a specific gene, knowing that they are not racing against the work of a competitor.

The first gene patent was granted in 1982 to the University of California. Today, about 20 percent of human genes are patented. Genes, gene mutation sequences, and DNA sequences have all been awarded patents. Of the patent holders, about 60 percent are private research companies and 30 percent are universities.(5) For-profit organizations have generally been supportive of gene patents because without the ability to place licenses on gene sequences, they would not be able to collect the revenue required to offset initial research and development costs. (6) This revenue gives them the security to fund further research and genetic test development.

In 2001, the USPTO released guidance upholding gene patents in the language of the patent statute (35 U.S.C. §101). The USPTO maintained that patenting does not limit innovation; rather it encourages research by others since it requires the patent holder to publicly disclose the details of a gene sequence. Based on this disclosure, the idea is that other researchers benefit from the information as a starting point for a new use or improvement to a test. In its guidance, the USPTO assumed that it would be rare for a commercial patent holder to impose burdensome licensure rules on academic and non-profit research bodies. (7)

The Supreme Court has never directly addressed the legality of gene patents, but has ruled on several cases that address the patentability of subjects found in nature. If a case on gene patenting reaches the Supreme Court, it is expected that the Court will reference the following decisions.

- *Diamond v. Chakrabarty*: Upheld idea that anything in nature cannot be patented. However, if a natural substance or organism is isolated and purified by man into a form that is not found in nature, then it can be patented. (8)
    - Case involved a bacterium created in a laboratory. Although it is a living organism, it could not be found in nature; therefore, it could be patented.
    - 2001 USPTO guidance enforces idea that genetic sequences are isolated and purified into a form that is not found in nature; therefore, they are patentable.
- *LabCorp v. Metabolite*: Upheld patent for both an amino acid test and the natural correlation between the amino acid and Vitamin B. (9)
    - Dissenting opinion stated that the correlation was a description of a natural phenomenon and should not be patented.
    - Dissent supports the idea that patents encourage funding for research, but says that the Court should also have considered the harm to the public when researchers are forced to abandon projects because a subject is patented.
- *In re Bilski*: Federal Circuit Court decision requires that a patentable process rely on a particular machine or transformation of a material into a different state. (10)

- This case involves mathematical-based business processes, but decision could invalidate many gene and genetic test patents, which do not meet the above criteria. (11)
- The Supreme Court is scheduled to hear the *Bilski* case in October.

Implications – positive/negative and immediate/downstream

While a fair amount has been written on this topic, it has primarily been in editorial and commentary format, which, although informed and thoughtful, does not document resulting benefits or harms to the general public. (11, 12) Efforts to document the consequences of human gene patenting have not substantiated significant or unremedial harms, although their authors urge ongoing monitoring of the situation or recommend improvements to current USPTO guidelines. (13, 14, 15)

Statements that patent protections for genes, mutations and DNA sequence are beneficial include:

1. Patents are an economic driver that bring advances and innovation into the marketplace
2. Development of new tests and drugs requires massive investment which will happen only under a system, such as the patent system, that insures investors some opportunity for return on their investment.
3. "[G]enetic tests from companies with exclusive licensing rights are no more expensive or harder to access than those offered by various providers under non-exclusive license." (14)
4. "Reports of researchers being blocked from access to patented DNA sequences or being sued for infringement are extremely rare, and workarounds are not difficult from a legal perspective" (14)
5. While access to patented technologies is necessary to advance research, the claim that patents impede or delay advances and innovation are primarily anecdotal, although there are some documented incidents of patents causing limited access to some specific genetic tests. (16)
6. The genetics community has been sensitized by several, high profile patent conflicts involving genetic testing (e.g. Canavan Disease) but these are more the exception than rule. (17, pg 20)

Statements that patent protections for genes, mutations and DNA sequences are not beneficial and might be harmful include:

1. Patents generate high fees for licensing and diagnostic testing development and this limits patient access to necessary information.
2. Exclusive licensing may inhibit patients from seeking a second opinion or from accessing testing through a laboratory with which their insurance plan does not cooperate.
3. Patient education literature developed by a company that holds the patent on a diagnostic or therapeutic may be biased, given the company's commercial interest.
4. Exclusive licensing agreements inhibit biomedical and clinical research
5. There is variation across industries and technologies as to the benefits of patent protections, yet there is insufficient analysis to say "…that patents induce additional

research and development investment in the service industries and service functions of the manufacturing economy." (15)

6. The media's prominent coverage of the ACLU lawsuit against Myriad Genetics is, rightly or wrongly, setting a tone for acrimony and lack of trust by the general public.
7. In the past, research that has, in part, been funded through Federal (tax payer funded) grants have allowed some private industry claims to patent rights in spite of their use of publically funded sources.
8. Participants/subjects have participated in research that has lead to the development of a patentable gene or test for which they may not be compensated

NSGC Priorities With Regard to Gene Patenting

NSGC's broad priorities include:

1. Ensuring that patients have timely access to quality genetic services and testing
2. Ensuring the trust and safety of the public with regard to genetic services
3. Encouraging the research and innovation of genetic services
4. Relevance to the NSGC Code of Ethics
    a. Section I, point 6: Acknowledge and disclose circumstances that may result in a real or perceived conflict of interest.
    b. Section IV, point 6: Keep the public informed and educated about the impact on society of new technological and scientific advances and the possible changes in society that may result from the applications of these findings.
    c. Section IV, point 8: Adhere to laws and regulations of society. However, when such laws are in conflict with the principles of the profession, genetic counselors work toward change that will benefit the public interest.

PPC Recommendations

The committee has a fundamental problem with the patenting of nucleic acid sequence data. We believe that sequence data qualifies as matter that exists in nature, natural phenomena, which would fall outside of the scope of patentable subjects. We do not recognize the difference between the isolation of a genetic sequence found in nature, which is the legal argument used to allow the existing sequence patents, and the isolation of a naturally-occurring element or mineral, which was specifically excluded by the original Patent Act.

We do not have a problem with the patenting of biomedical innovations as a mechanism for bringing advances into the marketplace if the patents are awarded for truly innovative procedures for isolating a sequence, unique tests, or novel treatments not commonly known to those in the field of genetic research. Our concern lies in the patenting of the DNA sequence itself.

Given that the USPTO currently awards patents on nucleic acid sequences, providing patent holders with the discretion to control access through licensure agreements, we have the following concerns about potential negative effects on the future of genetic and genomic medicine:

1. Progress in developing and offering multi-gene testing technologies will likely encounter increasing barriers and costs due to exclusive licensing arrangements allowed under current gene patenting practices;
2. The potential benefits and future applications of large-scale medical sequencing could be thwarted by the practice of "patent stacking," involving multiple patents on a single sequence, requiring researchers to enter into licensing agreements with different patent holders; and
3. As specific gene variations are revealed to be involved in more than one disease pathology, gene patents and exclusive licensure will complicate the ability for other researchers to develop and offer additional or alternative diagnostic testing for diseases other than the disease for which the patent is filed.

From a public policy standpoint, we believe the aforementioned concerns may potentially:

- Lead to significant limitations in genetic research, which are counter to the intent of the Patent Act;
- Stifle the development of innovative tests due to the inability of other researchers to access a sequence for other conditions; and
- Create exorbitant licensure costs that will be passed on to the consumer.

From our research on the issue, we believe that NSGC could make two arguments against future gene patenting. The first is a legal argument against the courts' and USPTO's current interpretation of the patent statute. Under the statute, a subject cannot be patented if it naturally occurs in nature. We disagree with the current ruling that an isolated nucleic acid sequence is not naturally occurring matter. If the courts were to adopt this position, all issued gene patents would be dissolved.

The second is a public policy argument focusing on the negative implications that may arise as a result of continued gene patenting. Rather than arguing against existing statutory language and judicial interpretations of patentable matter, this argument would focus on our concern that continuing to award gene patents will create barriers to efficient research and innovation, potentially delaying the delivery of new tests and treatments to the public. We believe that these implications are a serious concern, where the risk of interfering with the public's access to healthcare outweighs the exclusivity benefits enjoyed by the patent holders.

As genetic counselors whose mission is "to ensure the availability of quality genetic services," we believe that NSGC can make a strong public policy argument on behalf of the genetic counseling profession. While a legal argument could most likely be made against the patenting of DNA sequences, the Public Policy Committee believes that this argument would need to be supported by an analysis of complex legal issues that are outside the scope of expertise of our profession.

Therefore, we recommend that the NSGC Board make a public policy statement against future gene patenting. We believe that patenting of nucleic acid sequences has the significant potential to hinder the innovation that the patenting system is intended to promote. Our concern is that if this type of patent continues to be awarded, it may lead to downstream barriers to the development of genetic tests and personalized medicine treatments that will benefit the public.

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