Journal of Genetic Counseling, Vol. 11, No. 4, August 2002 (© 2002)

DNA-Sequence Patenting: National Society of Genetic Counselors (NSGC) Position Paper

Nathalie McIntosh,[1,12] Bonnie R. Braddock,[2] Kelly J. Branda,[3] Karen Eanet,[4] Simon Goldberg,[5] Stephanie A. Kieffer,[6] Lisa Primiano,[7] Nada Quercia,[8] Kelly A. Taylor,[9] Judith Tsipis,[1] Beverly M. Yashar,[10] and Anne Yesley[11] (the National Society of Genetic Counselors DNA-Sequence Patenting Position Paper Working Group)

In November 2000, the Genetic Services Committee of the National Society of Genetic Counselors (NSGC) convened a working group to draft a position paper on patenting of DNA-sequences. The mandate of the group was to produce general position statements that support the perspective and needs of consumers of DNA-based genetic tests and therapies (our patients and their families) and participants in DNA-based genetic research. After review and discussion of the literature on DNA-sequence patenting issues, the working group drafted position statement points that support current United States Patent and Trademark Office (USPTO) guidelines; broad licensing of DNA-sequence patents; nonenforcement of DNA-sequence patents in noncommercial research; reasonable royalty rates; an informed consent process for research participants that discloses whether they can share in any financial rewards relating to the project; the development of guidelines for licensing of DNA-sequence patents; and the establishment of oversight

[1]Department of Biology, Brandeis University, Waltham, Massachusetts.
[2]Section of Genetics, Upstate Medical University, Syracuse, New York.
[3]Dana Farber Cancer Institute, Boston, Massachusetts.
[4]Harvey Institute of Human Genetics, Greater Baltimore Medical Center, Baltimore, Maryland.
[5]American Medical Association, Chicago, Illinois.
[6]Clinical Genetics, University of Alberta Hospital, Edmonton, Canada.
[7]Office of Technology Licensing, Stanford University, Palo Alto, California.
[8]Division of Clinical and Metabolic Genetics, Hospital for Sick Children, Toronto, Canada.
[9]Department of Molecular Physiology and Biophysics, Vanderbilt University, Nashville, Tennessee.
[10]Department of Ophthalmology and Visual Sciences, University of Michigan, Ann Arbor, Michigan.
[11]Athena Diagnostics, Inc., Worcester, Massachusetts.
[12]Correspondence should be directed to Nathalie McIntosh, Brandeis University, Genetic Counseling Program, MS008, 415 South Street, Waltham, Massachusetts 02454; e-mail: mcintosh@brandeis.edu.

organizations to monitor licensing of DNA-sequence patents. These position statements were approved by the NSGC Board of Directors in the fall of 2001.

KEY WORDS: patenting; DNA-sequence; position paper; licensing; royalties; genetic testing; genetic therapies; National Society of Genetic Counselors (NSGC).

In the interest of individuals and families coping with genetic disease or the risk of genetic disease, the National Society of Genetic Counselors (NSGC) advocates that genetic testing and genetic therapies be commercially available and financially accessible to all. The NSGC recognizes that there can be substantial costs for technological innovation in the development of commercially available genetic tests and therapies, and acknowledges the important role that DNA-sequence patenting can have in encouraging and promoting such innovation. The United States Patent and Trademark Office (USPTO) currently awards DNA-sequence patents based on the criteria of novelty, nonobviousness, and specific, substantial, and credible utility. Patent owners have the right to prevent others from practicing their invention for 20 years from the day the patent application is filed. While acknowledging the role that DNA-sequence patents can have in bringing valuable tests and therapies to market, the NSGC is concerned about possible negative implications that DNA-sequence patents may have for individuals and their families. Therefore, the NSGC encourages the judicious and ethical implementation of all DNA-sequence patents so that the costs of genetic testing and genetic therapies are minimized while promoting innovation, further research and development, and the commercial availability of genetic tests and genetic therapies.

Specifically, the NSGC supports

–current USPTO guidelines for the patenting of DNA-sequences which state that, in order to be patentable, sequences must have a well-established utility that is specific, substantial, and credible.

–broad licensing of DNA-sequence patents that are important for the diagnosis, treatment, management, predictive testing, and/or risk assessment for genetic disease. Exclusive licensing of a DNA-sequence patent is supported only when specifically necessary to bring a genetic test or therapy to market.

–nonenforcement of DNA-sequence patents when practiced in a noncommercial, research setting.

–reasonable royalty rates for licensees of DNA-sequence patents, that do not significantly increase the cost of genetic testing or therapy, and that do not hinder accessibility to genetic testing or therapy.

–an informed consent process for research participants that discloses whether the research may result in the development of proprietary products or assays, and whether study participants can share in any financial rewards.

–the development of guidelines for licensing of DNA-sequence patents that will protect the rights of individuals and families who are affected by these genetic diseases, and the establishment of oversight/regulatory organizations to monitor appropriate implementation (e.g. the Secretary's Advisory Committee on Genetic Testing).

ACKNOWLEDGMENT

The NSGC DNA-Sequence Patent Position Paper Working Group acknowledge the support and contributions of Kristin Niendorf, Chair of the NSGC Genetics Services Committee, to this project.