Dated: November 12, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–25647 Filed 11–18–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Best Practices for the Licensing of Genomic Inventions

AGENCY: National Institutes of Health, Public Health Service, Health and Human Services (HHS).

ACTION: Notice of proposed best practices for the licensing of genomic inventions; request for comments.

SUMMARY: The Public Health Service's (PHS) primary mission is to acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people. PHS seeks to maximize the public benefit whenever PHS owned or funded technologies are transferred to the commercial sector. These best practices for the licensing of government-funded genomic inventions are recommendations to the intramural PHS technology transfer community as well as to PHS funding recipients.

DATES: Comments must be received no later than January 18, 2005.

ADDRESSES: Comments on the proposed best practices must be submitted to: Dr. Bonny Harbinger, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, Maryland, 20852; telephone: (301) 594–7700; e-mail: *harbingb@mail.nih.gov*.

SUPPLEMENTARY INFORMATION:

Best Practices for the Licensing of Genomic Inventions

Introduction

The Public Health Service's (PHS) primary mission is to acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people. This mission is advanced by the intramural research efforts of government-owned and -operated laboratories and by the extramural research efforts funded through grants and contracts. PHS seeks to maximize the public benefit whenever PHS owned or funded technologies are transferred to the commercial sector. Motivated by this goal, we offer the following best practices for the licensing of government-funded genomic inventions.

Genomic inventions include a wide array of technologies and materials such as cDNAs; expressed sequence tags (ESTs); haplotypes; antisense molecules; small interfering RNAs (siRNAs); full-length genes and their expression products; as well as methods and instrumentation for the sequencing of genomes, quantification of nucleic acid molecules, detection of single nucleotide polymorphisms (SNPs), and genetic modifications. Much of the value associated with the commercial use of these technologies involves nucleic acid-based diagnostics, potential gene therapy applications, and the development of new DNA- and RNA-based therapeutics.

Background

Among the benefits derived from PHS-conducted and -supported biomedical research are effective and accessible new healthcare treatments and services. Practical realization of these benefits depends on the ability and willingness of private sector partners to develop and commercialize new technologies arising from PHS conducted and funded research. For potential preventive, diagnostic, and therapeutic products, the interest of the private sector in commercializing new technologies often depends on the existence of patent protection on the technology in the United States and foreign countries.

The Bayh-Dole Act of 1980 allows PHS grantees and contractors to seek patent protection on subject inventions made using Government funds and to license those inventions with the goal of promoting their utilization, commercialization, and public availability. Recipients of PHS grants and contracts have a role in implementing the requirements of the Bayh-Dole Act (*http://s-edison.info.nih.gov/iEdison/www.iedison.gov*). In 1986, Federal laboratories, including PHS research laboratories at the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC), were given a statutory mandate under the Federal Technology Transfer Act (Pub. L. 99–502) and Executive Order 12591 to ensure that new technologies developed in those laboratories were transferred to the private sector and commercialized.

PHS recognizes that patenting and licensing genomic inventions presents formidable challenges for academic and government technology transfer programs because of the complexities in bringing these technologies to the marketplace in a way that balances the expansion of knowledge and direct public health benefit with the commercial needs of private interests.

The following represents best practices recommendations to the intramural PHS technology transfer community as well as to universities, hospitals and other non-profit PHS funding recipients. These recommendations are not intended to constitute additional regulations, guidelines or conditions of award for any contract or grant, although they are consistent with existing policies set out in Sharing Biomedical Research Resources (*http://ott.od.nih.gov/NewPages/RTguide_final.html*) and Developing Sponsored Research Agreements (*http://ott.od.nih.gov/NewPages/text-com.htm*).

Patent Protection

Like other emerging technology areas, patents directed to genomic inventions tend to issue with claims that are broad in scope. Public health-oriented technology transfer must balance the rewards of broad intellectual property protection afforded to founders of enabling genomic inventions with the benefits of fostering opportunities for those striving to improve upon those innovations.

Therefore, in considering whether to seek patent protection on genomic inventions, institutional officials should consider whether significant further research and development by the private sector is required to bring the invention to practical and commercial application. Intellectual property protection should be sought when it is clear that private sector investment will be necessary to develop and make the invention widely available. By contrast, when significant further research and development investment is not required, such as with many research material and research tool technologies, best practices dictate that patent protection rarely should be sought.

Best Licensing Practices

The optimal strategy to transfer and commercialize many genomic inventions is not always apparent at early stages of technology development. As an initial step in these instances, it may be prudent to protect the intellectual property rights to the invention. As definitive commercial pathways unfold, those embodiments of an invention requiring exclusive licensing as an incentive for commercial development of products or services can be distinguished from those that would best be disseminated non-exclusively in the marketplace.

Whenever possible, non-exclusive licensing should be pursued as a best practice. A non-exclusive licensing approach favors and facilitates making broad enabling technologies and research uses of inventions widely available and accessible to the scientific community. When a genomic invention represents a component part or background to a commercial development, non-exclusive freedom-to-operate licensing may provide an appropriate and sufficient complement to existing exclusive intellectual property rights.

In those cases where exclusive licensing is necessary to encourage research and development by private partners, best practices dictate that exclusive licenses should be appropriately tailored to ensure expeditious development of as many aspects of the technology as possible. Specific indications, fields of use, and territories should be limited to be commensurate with the abilities and commitment of licensees to bring the technology to market expeditiously.

For example, patent claims to gene sequences could be licensed exclusively in a limited field of use drawn to development of antisense molecules in therapeutic protocols. Independent of such exclusive consideration, the same intellectual property rights could be licensed non-exclusively for diagnostic testing or as a research probe to study gene expression under varying physiological conditions.

License agreements should be written with developmental milestones and benchmarks to ensure that the technology is fully developed by the licensee. The timely completion of milestones and benchmarks should be monitored and enforced. Best practices provide for modification or termination of licenses when progress toward commercialization is inadequate. Negotiated sublicensing terms and provisions optimally permit fair and appropriate participation of additional parties in the technology development process.

Funding recipients and the intramural technology transfer community may find these recommendations helpful in achieving the universal goal of ensuring that public health consequences are considered when negotiating licenses for genomic technologies.

PHS encourages licensing policies and strategies that maximize access, as well as commercial and research utilization of the technology to benefit the public health. For this reason, PHS believes that it is important for funding recipients and the intramural technology transfer community to reserve in their license agreements the right to use the licensed technologies for their own research and educational uses, and to allow other non-profit institutions to do the same.

Conclusion

PHS recognizes that these recommendations generally reflect practices that may already be followed by most funding recipients and the intramural technology transfer community with regard to licensing of genomic and other technologies. PHS also acknowledges the need for flexibility in the licensing negotiation process as the requirements of individual license negotiations may vary and may not always be adaptable to these best practices.

Dated: November 14, 2004.

Mark L. Rohrbaugh,

Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 04–25671 Filed 11–18–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Apoptosis in Liver Cells.

Date: December 14, 2004.

Time: 3 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lakshmanan Sankaran, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 777, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *Is38oz@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 15, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–25668 Filed 11–18–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, Mortality and Fecundity in Two-sided Search for Male.

Date: December 1, 2004.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Marita R. Hopmann, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Building, Room 5B01, Bethesda, MD 20892 (301) 435–6911, *hopmannm@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and