Branch (UTMB) Campus in Galveston, Texas.

The decision was based upon review and careful consideration of the impacts identified in the Final EIS and public comments received throughout the NEPA process. The decision was also based on UTMB's extensive expertise in biological medical research, its experience in operating BSL–2, –3 and –4 laboratories (only five other operational BSL–4 laboratories exist in the United States), and its infrastructure as a regional medical center being able to fulfill the purpose and need to provide national biocontainment facilities. Other relevant factors included in the decision, such as NIAID's mandate to conduct and support research on agents of emerging and re-emerging infectious diseases were carefully considered.

Dated: March 29, 2005.

Leonard Taylor, Jr.,

Acting Director, Office of Research Facilities Development and Operations, National Institutes of Health.

[FR Doc. 05–7249 Filed 4–8–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Best Practices for the Licensing of Genomic Inventions: Final Notice

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

ACTION: Notice.

SUMMARY: On November 19, 2004 the National Institutes of Health (NIH) published for public comment in the **Federal Register** proposed Best Practices for the Licensing of Genomic Inventions [69 FR 67747]. These Best Practices are recommendations to the intramural Public Health Service (PHS) technology transfer community as well as to PHS funding recipients. Comments on the proposed Best Practices were requested with a deadline of January 18, 2005. This Notice presents the NIH's final Best Practices for the Licensing of Genomic Inventions together with NIH's response to the public comments received.

FOR FURTHER INFORMATION CONTACT: Bonny Harbinger, Ph.D., J.D., NIH Office of Technology Transfer, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Fax: (301) 402–3257; E-mail: *harbingb@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

NIH recognizes the importance of public involvement in the development of best practices and sought comment and participation by the biomedical research and development communities regarding the proposed Best Practices for the Licensing of Genomic Inventions (Best Practices). To this end, NIH sought comments from the public as well as grantees and academic, not-for-profit, and private sector participants in the biomedical research and development communities. In order to solicit comments from as many interested parties as possible, the draft was presented in various venues. In addition to the publication on November 19, 2004 in the **Federal Register**, the proposed Best Practices were made available on the NIH Office of Technology Transfer Web site and were highlighted in a variety of publications.

In response to the November 19, 2004 proposal, NIH received 12 letters, each of which contained one or more comments. Comments were received from an academic institution, scientific foundations, a biotechnology company, industry trade associations, professional societies, individual researchers, and other individual respondents.

Comments and Agency Response

The majority of comments generally supported the Best Practices and some expressly stated support for non-exclusively licensing of genomic inventions. Most requested further clarification about a variety of different issues. A general response to the comments is provided below.

Respondents criticized the singling out of this area of technology for special treatment as poor policy precedent. NIH disagrees with this representation. Genomic inventions have evoked special attention in the legal community as evidenced by various U.S. Patent and Trademark (USPTO) guidelines and court decisions directed to the criteria required to meet the non-obviousness, utility, and written description patentability standards for genomic inventions and discoveries. Similarly, the availability of genomic inventions for diagnostic testing and research purposes has been an area of active debate and controversy. As a major source of funding and research leading to the discovery of genomic inventions, NIH has an obligation to address these special issues to promote and advance the best possible balance between research availability and commercial development of these important technologies. In this regard, NIH considers the fundamental principles and concepts addressed by these Best Practices to be consistent with our grant recipients' responsibilities under the Bayh-Dole Act as well as our prior publications, including our Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources.

Respondents commented on the identification of these recommendations as ''best'' practices as opposed to ''good'' practices. The respondents reasoned that use of the term ''best practices'' would imply these recommendations would be viewed as mandates and auditable prescriptive regulation. One respondent indicated that these Best Practices would lead to an added burden for university technology transfer licensing offices, as grantees would feel compelled to document and justify reasons for any departures from them in individual licensing situations. In response, it is noted that the Best Practices document clearly and specifically articulates that the recommendations are not intended to constitute additional regulations, guidelines, or conditions of award for any contract or grant. These Best Practices create no new auditable regulation. While not imposing regulations or requirements on any licensing situation, it is generally the object of best practices to inform practicing professionals to a set of principles against which they should test their judgments in any particular fact situation. As such, best practices serve as an industry benchmark for the most current, innovative, and advanced practices. In this regard, as in all others, our grantees should expect no less than the best guidance possible from NIH.

A respondent criticized the proposed Best Practices document for not clearly defining genomic inventions. According to this respondent, the Best Practices document does not distinguish compositions of matter and diagnostic technologies from basic research tools. Consequently, this broad definition of basic genomic inventions undermines a company's ability to obtain an exclusive license to a composition of matter or a commercially viable diagnostic test. In response, it is noted that NIH intends the Best Practices to apply broadly to all genetic inventions. Contrary to respondent's conclusion, the proposed Best Practices document contemplates intellectual property and exclusive licensing to be appropriate for certain genomic inventions. The determination of when patent protection and exclusive licensing is necessary derives from the specific fact situation attendant the nature of the invention and its market;

not its inclusion within any particular definition of genomic inventions.

A respondent indicated concern that it is difficult to know whether a discovery will be commercially viable as genomic research tends to be very early stage and its commercial significance may not be immediately apparent. NIH agrees with this interpretation and wished to highlight the need for flexibility on the part of technology transfer professionals in applying these Best Practices. Responsible exercise of this flexibility will help to realize the benefits of the patent system in commercializing products as well as maximizing the availability of important research materials.

A number of respondents suggested that using patent protection and exclusive licensing can be the optimal means to ensure a research material or tool is made widely available to the research community. NIH considers this scenario to be consistent with both these Best Practices and our earlier research tool guidelines. Indeed, such scenarios emphasize the need for the proposed flexibility by technology transfer professionals in implementing these general principles and best practices, and militate against suggestions for focusing the practitioner on specific examples and fact situations that may be addressed by alternative licensing approaches within the scope of these Best Practices recommendations.

A respondent commented on the recommendation that funding recipients reserve in their licenses the right to use licensed technologies for their own research and educational uses, and to allow other non-profit institutions to do the same. The comment questioned if this recommendation was more restrictive than our Principles and Guidelines for Sharing of Biomedical Research Resources, which states this right should apply to internal use of research tools by for-profit institutions. In response it is not the intent to be more limiting and, therefore, the recommendation will be adopted in the final version.

A respondent requested further clarification and examples of when a genomic invention does and does not require further research and development investment. This respondent questioned whether genes, proteins, and DNA are themselves research materials, and whether the designation of these compositions as research materials is dependent on the setting in which they are used. In this context, the respondent asked NIH to provide some classes or uses as examples to flesh out this distinction. The most appropriate application of the principles set forth in our recommendations is fact and setting dependent. As such, our object is to set forth general principles and leave it to the licensing professional to decide how the general principles can best be applied.

A number of respondents recommended that NIH promote changes in various laws and regulations, such as asking the U.S. Patent and Trade Office (USPTO) to determine before patent protection is awarded what type of patents covering genetic material would best be disseminated non-exclusively in the marketplace and then excluding such genomic material from patent protection. Another suggestion was that NIH should remind the USPTO that a better way than licensing benchmarks to address product development is to incorporate a requirement into U.S. patent law that the actual patent holder must use or develop the invention, as exemplified by European patent law. The requested remedies are outside the authority of NIH.

After a careful review of the issues raised by the respondents, NIH has approved these Best Practices with a single change related to the comment about reserving internal research use for for-profit institutions.

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 (*https://s-edison.info.nih.gov/iEdison*). 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 (P.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/spons_research.html*).

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 institutions to do the same, consistent with the Research Tools Guidelines.

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: April 5, 2005.

Mark L. Rohrbaugh,

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

[FR Doc. 05–7247 Filed 4–8–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Director's Council of Public Representatives.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Director's Council of Public Representatives.

Date: April 28, 2005.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: Among the topics proposed for discussion are: (1) NIH Director's update; (2) update on conflict of interest; (3) update on public access; (4) NIH response to COPR's recommendations and formal reports to the NIH Director; and (5) discussion and public comment.

Place: National Institutes of Health, Building 31, C–Wing, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20852.

Contact Person: Jennifer E. Gorman Vetter, NIH Public Liaison/COPR Coordinator, Office of Communications and Public Liaison, Office of the Director, National Institutes of Health, 9000 Rockville Pike, Building 1, Room 344, Bethesda, MD 20892, (301) 435–4448, *gormanj@od.nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person