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DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Best Practices for the Licensing of Genomic Inventions: Fina Notice

AGENCY: National Institutes of Health, Public Health Service, Department c 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 Practice the Licensing of Genomic Inventions [69 FR 67747]. These Best Practices a 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, 200E This Notice presents the NIH's final Best Practices for the Licensing of Genoı 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 32 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 b practices and sought comment and participation by the biomedical research a 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, a 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 publica

on November 19, 2004 in the Federal Register, the proposed Best Practices were made available on the NIH Office of Technology Transfer website and v highlighted in a variety of publications.

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

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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 gene response to the comments is provided below.

1 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 c 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 tes and research purposes has been an area of active debate and controversy. 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 advance the best possible balance between research availability and comme development of these important technologies. In this regard, NIH considers tl fundamental principles and concepts addressed by these Best Practices to b consistent with our grant recipients' responsibilities under the Bayh-Dole Act 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 t use of the term "best practices" would imply these recommendations would b viewed as mandates and auditable prescriptive regulation. One respondent indicated that these Best Practices would lead to an added burden for univer technology transfer licensing offices, as grantees would feel compelled to document and justify reasons for any departures from them in individual licen situations. In response, it is noted that the Best Practices document clearly a specifically articulates that the recommendations are not intended to constitu 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 generall object of best practices to inform practicing professionals to a set of principle against which they should test their judgments in any particular fact situation. such, best practices serve as an industry benchmark for the most current, innovative, and advanced practices. In this regard, as in all others, our grante should expect no less than the best guidance possible from NIH.

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A respondent criticized the proposed Best Practices document for not clearly defining genomic inventions. According to this respondent, the Best Practice document does not distinguish compositions of matter and diagnostic technologies from basic research tools. Consequently, this broad definition o

basic genomic inventions undermines a company's ability to obtain an exclus 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 a genetic inventions. Contrary to respondent's conclusion, the proposed Best Practices document contemplates intellectual property and exclusive licensin be appropriate for certain genomic inventions. The determination of when pat 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 be commercially viable as genomic research tends to be very early stage anc commercial significance may not be immediately apparent. NIH agrees with t interpretation and wished to highlight the need for flexibility on the part of technology transfer professionals in applying these Best Practices. Responsi exercise of this flexibility will help to realize the benefits of the patent system commercializing products as well as maximizing the availability of important research materials.

A number of respondents suggested that using patent protection and exclusi licensing can be the optimal means to ensure a research material or tool is m widely available to the research community. NIH considers this scenario to b 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 th practitioner on specific examples and fact situations that may be addressed b alternative licensing approaches within the scope of these Best Practices recommendations.

A respondent commented on the recommendation that funding recipients res in their licenses the right to use licensed technologies for their own research educational uses, and to allow other non-profit institutions to do the same. Th comment questioned if this recommendation was more restrictive than our Principles and Guidelines for Sharing of Biomedical Research Resources, wh 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, recommendation will be adopted in the final version.

A respondent requested further clarification and examples of when a genomi invention does and does not require further research and development investment. This respondent questioned whether genes, proteins, and DNA a themselves research materials, and whether the designation of these compositions as research materials is dependent on the setting in which they used. In this context, the respondent asked NIH to provide some classes or u as examples to flesh out this distinction. The most appropriate application of 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.

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A number of respondents recommended that NIH promote changes in variou laws and regulations, such as asking the US Patent and Trade Office (USPT to determine before patent protection is awarded what type of patents coverir genetic material would best be disseminated non-exclusively in the marketpl 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 requestec remedies are outside the authority of NIH.

After a careful review of the issues raised by the respondents, NIH has apprc 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 GENOMI INVENTIONS

Introduction

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

Genomic inventions include a wide array of technologies and materials such cDNAs; expressed sequence tags (ESTs); haplotypes; antisense molecules; small interfering RNAs (siRNAs); full-length genes and their expression prodı 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 associa 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.

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Background

Among the benefits derived from PHS conducted and supported biomedical research are effective and accessible new healthcare treatments and service Practical realization of these benefits depends on the ability and willingness c private sector partners to develop and commercialize new technologies arisir from PHS conducted and funded research. For potential preventive, diagnost 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 pat protection on subject inventions made using Government funds and to licens those inventions with the goal of promoting their utilization, commercializatior 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 Prevent (CDC), were given a statutory mandate under the Federal Technology Transf Act (PL 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 p health benefit with the commercial needs of private interests.

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The following represents best practices recommendations to the intramural P technology transfer community as well as to universities, hospitals and other 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 and Developing Sponsored Research Agreements

Patent Protection

Like other emerging technology areas, patents directed to genomic invention 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 bene 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 inven to practical and commercial application. Intellectual property protection shoul sought when it is clear that private sector investment will be necessary to develop and make the invention widely available. By contrast, when significa further research and development investment is not required, such as with m 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 not always apparent at early stages of technology development. As an initial in these instances, it may be prudent to protect the intellectual property rights the invention. As definitive commercial pathways unfold, those embodiments an invention requiring exclusive licensing as an incentive for commercial development of products or services can be distinguished from those that wo best be disseminated non-exclusively in the marketplace.

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Whenever possible, non-exclusive licensing should be pursued as a best practice. A non-exclusive licensing approach favors and facilitates making br enabling technologies and research uses of inventions widely available and accessible to the scientific community. When a genomic invention represents 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 researcl and development by private partners, best practices dictate that exclusive licenses should be appropriately tailored to ensure expeditious development as many aspects of the technology as possible. Specific indications, fields of 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 limited field of use drawn to development of antisense molecules in therapeu

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 conditic

License agreements should be written with developmental milestones and benchmarks to ensure that the technology is fully developed by the licensee. timely completion of milestones and benchmarks should be monitored and enforced. Best practices provide for modification or termination of licenses wl progress toward commercialization is inadequate. Negotiated sublicensing te 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 fin these recommendations helpful in achieving the universal goal of ensuring th public health consequences are considered when negotiating licenses for genomic technologies.

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

Conclusion

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

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