

THE WHITE HOUSE

WASHINGTON

October 1, 1999

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Human Genome

MEMORANDUM FOR THE PRESIDENT

FROM: NEAL LANE *Neal*

SUBJECT: GENOME PATENTING

This memorandum responds to your query regarding the merits of genome patenting. Genome patenting is a complex issue that has been debated since large-scale DNA sequencing became feasible in the late 1980s.

**What is patentable?**

Patents have been granted to applicants who can show that they have obtained a genomic DNA sequence, can describe the protein product encoded by that gene, and can demonstrate the function of the protein in a living organism. Substantial uncertainty exists regarding the patentability of partial or full gene sequences when the applicant does not disclose information regarding the function or utility of the gene and its encoded protein product. The U.S. Patent and Trademark Office (PTO) has granted at least one patent on a partial gene sequence but is rethinking its position. PTO convened a public hearing on Nov. 5, 1998 to obtain public comments on draft guidelines describing the necessary elements for obtaining a patent on genome sequences. I understand PTO plans to issue new draft guidance by November 1.

In 1991, NIH filed patent applications claiming over 6,000 partial gene sequences obtained in the laboratory of Dr. J. Craig Venter but has never appealed PTO's denial of these patents. Under Harold Varmus, NIH adopted a policy promoting open access to research tools, including genomic sequence data.

PTO and NIH have been at loggerheads over the criteria necessary to obtain patents on genomic DNA sequence data, although they agree more generally on the value of patents on the results of later-stage genome research in stimulating investment in health care product development.

**What should be patented?**

NIH discourages grantees from seeking patents on so-called raw human genomic DNA sequence data. In 1997, NIH, DOE and the U.K.'s Wellcome Trust, partners in the international Human Genome Project, adopted a policy (attached) requiring grantees funded specifically to generate large-scale human genomic DNA sequence to deposit such data in a public database within 24 hours of its generation, thus rendering it unpatentable. A September 20th *London Guardian* article inaccurately portrayed this as a new policy designed to preclude all gene patents. (Press guidance on this article is attached.)

The rationale for freely disseminating raw human genomic DNA sequence data is that such broad public access will *promote innovation* and encourage its use in the development of downstream products. Moreover, the non-profit supporters of genomic research believe patents on early-stage genome data are a *disincentive to innovation*. That is, drug companies and other innovators may be reluctant to invest in product development on the suspicion that, having done so, they will learn belatedly that a patent has been granted on a gene sequence critical to their product. This will necessitate negotiation of a license for marketing to proceed. This is not an unreasonable fear, as some companies describe such patenting as their principal goal, and it may be years before the existence of such patents becomes known. While most agree on the value of patents for genes about which there is known function or clear utility (for example, diagnostic genetic tests), exclusive licenses on these patents are controversial due to their potential for restricting the availability of new health care advances.

Not surprisingly, industry views on patenting the early results of genome sequencing are mixed, depending on the company's business strategy. A few companies hope to be able to obtain patents on large numbers of raw gene sequences. One significant occurrence is the April 15th announcement of a consortium formed among 10 of the world's foremost pharmaceutical companies to create a public database of the genetic markers that distinguish one person from another. These markers will be valuable for identifying specific genes involved in common and rare diseases, developing new diagnostic tests, and creating new "personalized" medicines, based on an understanding of minute genetic variations. Members of this consortium believe that it is preferable to have these indicators of human genetic diversity in the public domain, as opposed to dealing with the licensing issue at a later date. They clearly do not feel that making this information public hampers their efforts to develop downstream products based on genetic information or threatens their future intellectual property rights.

The Bayh-Dole Act and other technology transfer statutes give Federal grantees and contractors the right to apply for patents on the results of government-funded research. The NIH-DOE policy requiring rapid access to raw human genomic DNA sequence data precludes the patenting of such information, but once an investigator has determined the biological significance of such information, obtaining a patent is straightforward. It seems a reasonable course of action to continue the policy of making raw human genomic DNA sequence widely available to the largest possible number of inventors, thus stimulating further innovation and product development.

I believe PTO's guidelines will reflect a bright line approach allowing patents on gene sequences only when the inventor can demonstrate how such sequences might be used. I believe this approach is the right one for advancing science and for ensuring rapid development of products based on that science. The current climate of uncertainty regarding the boundaries of patentability is a disincentive to genomic product development, and issuing the guidelines will help resolve this problem.

Attachments

cc: John Podesta  
Bruce Reed  
David Beier

**The National Human Genome Research Institute****NHGRI Policy Regarding Intellectual Property of Human Genomic Sequence****POLICY ON AVAILABILITY AND PATENTING OF HUMAN GENOMIC DNA SEQUENCE PRODUCED BY NHGRI PILOT PROJECTS (FUNDED UNDER RFA HG-95-005)**

April 9, 1996

This document describes the policy of the National Center for Human Genome Research with respect to availability and patenting of human genomic DNA sequence produced under grants funded as a result of RFA HG-95-005. In conformity with the existing spirit and philosophy of the Human Genome Project and in response to the recommendations of advisors and the expressed wishes of the community, NHGRI seeks to make DNA sequence information available as rapidly and freely as possible.

#### Background

The Human Genome Project (HGP) is an international research effort, begun in 1990, which has the scientific goals of generating maps of the human genome[1] and producing the complete sequence of the human DNA by the year 2005. The project was undertaken in the U.S. following the advice of several scientific committees that emphasized its importance in creating a resource that "will facilitate research in biochemistry, physiology and medicine"[2], "have a major impact on health care and disease prevention"[2] and provide "enormous scientific and technological advances... having both basic and commercial applications" [3]. At NIH, the National Human Genome Research Institute (NHGRI) was founded to implement the HGP.

The HGP has progressed rapidly, even beyond optimistic expectations. The initial mapping goals are nearly completed and recent improvements in DNA sequencing technology and capacity have led many scientists, including NHGRI advisors, to conclude that complete sequencing of human genomic DNA should begin. Early in 1995, NHGRI issued RFA HG-95-005 to solicit grant applications for pilot projects to test strategies that can potentially scale up to sequence the human genome. The applications received in response to the RFA were peer reviewed in the fall of 1995 and approved by the National Advisory Council for Human Genome Research in January 1996. A set of grants will be funded by April 1996.

At the inception of the HGP, the planners emphasized that, in order to reap the maximum benefit from the HGP, human DNA sequence should be freely available in the public domain. The NIH Ad Hoc Program Advisory Committee on Complex Genomes stated that "Distribution of and free access to the databases (containing the sequence data) must be fully encouraged. Thus, the data must be in the public domain, and the redistribution of the data should remain free of royalties." [3] Similarly, the National Research Council stated: "...access to all sequences and material generated by these publicly funded projects should and even must be made freely available..." [2]. Most recently, an international group of scientists, from both the public and private sectors, who are already involved in genomic DNA sequencing, passed a unanimous resolution that "all human genomic DNA sequence information, generated by centers funded for large-scale human sequencing, should be freely available and in the public domain in order to

encourage research and development and to maximize its benefit to society"[4].

There are very strong scientific arguments that human genomic DNA sequence should be freely available and in the public domain:

o The human genomic DNA sequence is unique. Although there are many other types of information that contribute to the understanding of human biology, e.g., DNA sequence of model organism genomes, in the end, the only source of definitive information about the human is the human sequence.

o The human genomic DNA sequence is a vast resource. It contains a very large number of genes and an enormous amount of additional biological information. It is anticipated that the sequence resource will be the basis for many useful inventions and patentable products. It will take many researchers years to find and characterize all of the genes and other functional elements within the sequence and to use that information to develop products and other approaches that will improve the health of the American people.

o The human genome is a bounded resource. Once the genome has been sequenced, few or no opportunities will exist for discovery of new information that will not make reference to, or be dependent on, that first sequence. Thus, it is important to ensure maximum access of a large number of parties to the initial genomic DNA sequence as it is generated, to provide a broad opportunity for development of new products.

#### Policy

It is therefore NHGRI's intent that human genomic DNA sequence data, generated by the projects funded under RFA HG-95-005, should be released as rapidly as possible and placed in the public domain where it will be freely available. In order to implement this policy, NHGRI will require that grantees under RFA HG-95-005 adopt a policy of rapid release of data to public databases. This policy will be made a condition of the award.

In NHGRI's opinion, raw human genomic DNA sequence, in the absence of additional demonstrated biological information, lacks demonstrated specific utility and therefore is an inappropriate material for patent filing. NIH is concerned that patent applications on large blocks of primary human genomic DNA sequence could have a chilling effect on the development of future inventions of useful products. Companies are not likely to pursue projects where they believe it is unlikely that effective patent protection will be available. Patents on large blocks of primary sequence will make it difficult to protect the fruit of subsequent inventions resulting from real creative effort. However, according to the Bayh-Dole Act, the grantees have the right to elect to retain title to subject inventions and are free to choose to apply for patents should additional biological experiments reveal convincing evidence for utility. The grantees are reminded that the grantee institution is required to disclose each subject invention to the Federal Agency providing research funds within two months after the inventor discloses it in writing to grantee institution personnel responsible for patent matters. NHGRI will monitor grantee activity in this area to learn whether or not attempts are being made to patent large blocks of primary human genomic DNA sequence.

During this pilot period, NHGRI will be soliciting opinions and collecting evidence from the broad scientific and commercial sectors to allow an evaluation of whether the approach described above is sufficient to ensure that sequence generated by these grants is maximally useful to the research and commercial sectors. If not, NIH will consider a determination of exceptional circumstance to restrict or eliminate the right of parties, under future grants, to elect to retain title.

**The National Human Genome Research Institute**

## NHGRI Policy on Release of Human Genomic Sequence Data

March 7, 1997

At the Second International Strategy Meeting on Human Genome Sequencing (Bermuda, 1997), attendees affirmed the principle that was set out at the First (1996) International Strategy meeting, that primary genomic sequence should be rapidly released. Specifically, the report of the first meeting stated that "sequence assemblies should be released as soon as possible; in some centres, assemblies of greater than 1 kb would be released automatically on a daily basis." The discussions at the 1997 meeting confirmed NHGRI's conclusions that it is extremely important for its large-scale sequencing program to be functioning in a manner consistent with this principle, that such rapid release is technically feasible, and that such unfinished DNA sequence data have already been found to be useful by the larger scientific community. NHGRI has determined, therefore, that its grantees engaged in large-scale genomic DNA sequencing should now be automatically releasing sequence assemblies of 2 kb or larger within 24 hours of their generation. (the trigger for data release is 2 kb, instead of 1 kb, in order to ensure that the released sequence be comprised of at least two sequence reads. Investigators who wish to release smaller assemblies may do so.) Any laboratory funded by NHGRI for large-scale human genomic sequencing must develop and submit to NHGRI a plan to implement such a data release program, which must be implemented within one month of its being approved by NHGRI. No non-competing or competing renewal will be funded until an acceptable plan has been approved. Mandatory data release as described above will be made a condition of the award for any grant funded by NHGRI for large-scale human sequencing.



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**Context:** *Today's London Guardian ran a story stating that Prime Minister Tony Blair and President Clinton are negotiating a deal to obtain intellectual property rights on the human genome, thereby precluding private sector ventures in this area. U.S. and U.K. government officials have been discussing the possibility of issuing a statement endorsing data access principles already adopted by an international consortium of human genome researchers, but the article's references to government efforts to block private sector patents are inaccurate. The President and Prime Minister have not been involved in these discussions.*

**Background:** The international Human Genome Project is funded primarily by the National Institutes of Health and Department of Energy in the U.S., and the Wellcome Trust, a non-profit philanthropy in the U.K. Researchers funded by these organizations developed the so-called "Bermuda Principles" under which human genome sequence data is deposited in a publicly-accessible database within 24 hours of being generated. For the past year not-for-profit partners have been discussing the possibility of a memorandum of understanding with Celera Genomics, a U.S. company beginning human genome sequencing. However, data access has remained a sticking point in development of the M.O.U. The public Human Genome Project does not maintain intellectual property rights to the data.

**Is the President discussing a deal with the U.K. Prime Minister to stop entrepreneurs from profiting from gene patents?**

- A. No. The President has not been engaged in these discussions. Government officials in both countries are in general agreement that DNA sequenced data developed under the Human Genome Project ought to be made freely available so as to promote progress in biomedical research and the rapid application of such information to the development of treatment, prevention and cure of human disease. We believe that a joint statement in support of this data access policy might be valuable.

**Q. Who will own the data from the Human Genome Project?**

- A. All data are to be deposited daily in publicly accessible databases to ensure that scientists around the world have unfettered access, free of charge, to the wealth of information and can use it in their research to understand human disease, develop new diagnostics and therapeutic interventions, and improve the health of our citizens.

Because data are deposited daily in publicly accessible sites, no patent protection on raw fundamental genome information arising from the Human Genome Project will be sought by participants.

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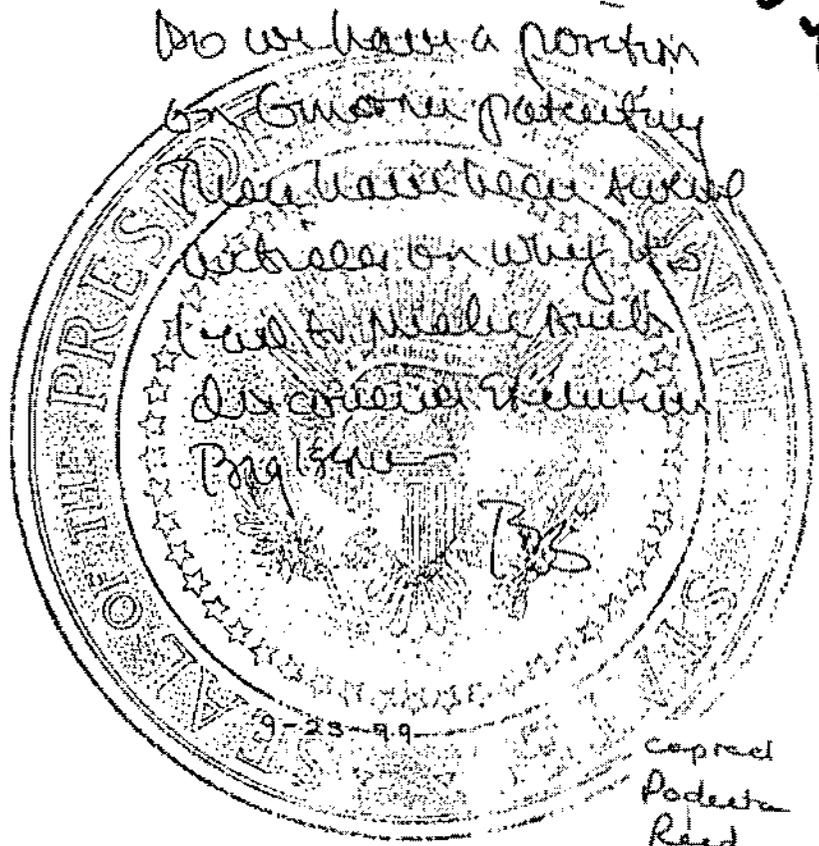
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THE WHITE HOUSE  
WASHINGTON

November 17, 1999

ACTION

MEMORANDUM FOR JOHN PODESTA

FROM:

NEAL LANE *from for HL*

SUBJECT:

POSSIBLE JOINT U.S.-U.K. STATEMENT ON THE HUMAN  
GENOME PROJECT

Background

Almost one year ago, Harold Varmus reported to me that Prime Minister Tony Blair was interested in issuing some form of joint government-to-government statement on the human genome project. The statement (draft attached) has evolved into an endorsement of the policy of making human genome sequence data freely available within 24 hours of its generation. This practice is now a requirement for recipients of funds from the three principal not-for-profit partners in the international Human Genome Project: the NIH, DOE and U.K.'s Wellcome Trust. I have had a number of discussions about the merits of issuing a high-level statement with my U.K. government colleagues, Lord Sainsbury, Minister for Science, and Sir Robert May, Chief Scientific Advisor to the Prime Minister, as well as with Dr. Michael Morgan, CEO of the Wellcome Trust's Genome Campus. All three support such a statement and Morgan reports today that the Prime Minister has just given his approval.

The draft statement made the news on September 20th with an article in the London Guardian that was largely inaccurate in portraying it as a means for preventing entrepreneurs from obtaining patents (article and our press guidance are attached). It is true that public deposit renders information unpatentable. However, the statement is carefully worded to endorse free access to "fundamental data on the human genome, including the human DNA sequence and its variations," and does not criticize subsequent intellectual property claims to protect discoveries based on such sequences. Thus, the statement has limited relationship to patenting genome-based products. Issuing the statement might be useful in addressing the persistent confusion left by the Guardian article.

Next Tuesday, November 23<sup>rd</sup>, the Human Genome Project international partners will hold a multi-site event to mark the sequencing of the billionth DNA base pair (roughly one-third of the entire human genome). DHHS submitted a POTUS scheduling request with the hope of announcing the joint statement, in addition to another initiative that is not completed, but that we might discuss at a later date. Participants across the U.S. and the Sanger Centre in Cambridge, U.K., will be linked via satellite. Secretary Richardson's attendance is confirmed, and Secretary Shalala may also attend. Their roles will be to extol the virtues of the genome project, but they will not address the joint statement. Lord Sainsbury is prepared to represent the Prime Minister

on the U.K. side to announce his approval of the joint statement, if the President agrees to do the same. If so, I can be available to speak on his behalf next Tuesday at the National Academy of Sciences, the local event site.

Decision on issuing a joint U.S.-U.K. statement:

Yes       No       Let's discuss

Possible Action:

The President and Prime Minister Blair will meet informally in Florence on Saturday. Perhaps they could discuss this issue briefly and agree to a coordinated announcement of the joint statement on Tuesday, November 23.

Attachment

cc: Bruce Reed  
Sandy Berger  
Thurgood Marshall, Jr.  
Leon Fuerth  
David Beier  
Chris Jennings

**DRAFT**

**JOINT STATEMENT TO ENSURE THAT  
DISCOVERIES FROM THE HUMAN GENOME PROJECT  
ARE USED TO ADVANCE HUMAN HEALTH**

In the last decade of the twentieth century, scientists from around the world initiated one of the most significant scientific projects of all time: to determine the DNA sequence of the entire human genome, the human genetic blueprint. Progressing ahead of schedule, human genome research is rapidly advancing our understanding of the causes of human disease and will serve as the foundation for development of a new generation of effective treatments, preventions, and cures. To realize this promise, fundamental data on the human genome, including the human DNA sequence and its variations, must be made freely and broadly accessible to scientists everywhere. The human genome is the fundamental shared heritage of all humankind. Unencumbered access to this information is essential to enable discoveries that will reduce the burden of disease and promote health around the world. We applaud the decision by scientists working on the Human Genome Project to release information about the human DNA sequence and its variants rapidly into the public domain, and we call on all scientists worldwide to adopt this policy.