QUESTIONS AND ANSWERS REGARDING THE ACCELERATED PROCESSING OF RECOMBINANT DNA INVENTIONS, INCLUDING THOSE WHICH CONTRIBUTE TO THE SAFETY OF RESEARCH IN THIS FIELD

1. Is it true that the Commerce Department recently "exempted" private researchers from their obligation to comply with the "Recombinant DNA Guidelines" issued by the National Institutes of Health?

No, it is not true. The Department of Commerce has no authority, and it certainly has no desire, to excuse members of the public from any obligation they might have to comply with regulations issued by another Government agency. The fact of the matter is that the NIH "guidelines" have no legal effect upon private sector research in the United States, nor do they have any extraterritorial application. The only parties who are required to follow the NIH guidelines are those whom the Federal Government pays to conduct recombinant DNA research.

2. What exactly is the Department of Commerce order which has mistakenly been interpreted as having "exempted" private-sector researchers from a legal obligation to comply with the NIH guidelines.

The full text of the Department's announcement accelerating the processing of recombinant DNA patent applications filed with the U.S. Patent and Trademark Office is reprinted on the next page.

DEPARTMENT OF COMMERCE

Patent and Trademark Office

RECOMBINANT DNA

Accelerated Processing of Patent Applications for Inventions

In recent years revolutionary genetic research has been conducted involving recombinant deoxyribonucleic acid ("recombinant DNA"). Recombinant DNA research appears to have extraordinary potential benefit for mankind. It has been suggested, for example, that research in this field might lead to ways of controlling or treating cancer and hereditary defects. The technology also has possible applications in agriculture and industry. It has been likened in importance to the discovery of nuclear fission and fusion. At the same time concern has been expressed over the safety of this type of research. The National Institutes of Health (NIH) has released guidelines for the conduct of research concerning recombinant DNA. "Guidelines for Research Involving Recombinant DNA Molecules," published in the FEDERAL REGISTER of July 7, 1976, 41 F.R. 27902–27943. NIH is sponsoring experimental work to identify possible hazards and safety practices and procedures.

In view of the exceptional importance of recombinant DNA and the desirability of prompt disclosure of developments in the field, the Assistant Secretary of Commerce for Science and Technology has requested that the Patent and Trademark Office accord "special" status to patent applications involving recombinant DNA. Upon appropriate request, the Office will make special patent applications for inventions relating to recombinant DNA, including those that contribute to safety of research in the field. Requests for special status should be written, should identify the application by serial number and filing date, and should be accompanied by affidavits or declarations under 37 CFR 1.102 by the applicant, attorney or agent explaining the relationship of the invention to recombinant DNA research. Requests also must include a statement that the NIH guidelines cited above or as amended in the future are being followed in any experimentation in this field, except that the statement may include an explanation of any deviations considered essential to avoid disclosure of proprietary information or loss of patent rights. The requests will be handled in the same manner as requests to make applications special that relate to energy or environmental quality. See Manual of Patent Examining Procedure 708.02.

Dated: January 7, 1977.

C. MARSHALL DANN,
Commissioner of Patents and Trademarks.

Approved: January 10, 1977.

BETSY ANCKER-JOHNSON,
Assistant Secretary for Science and Technology.

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3. What types of patent applications are eligible for this "special" processing?

Two types of inventions are eligible for accelerated processing under the new order. These are (1) inventions which involve recombinant DNA itself, and (2) inventions which will promote safety in the conduct of recombinant DNA experimentation.

4. What must an inventor do to be eligible for "special" processing?

First, he must request it. Second, if he is actively conducting recombinant DNA research, he must certify that he is in compliance with all portions of the NIH guidelines covering research in this field, save those which by their nature would result in the loss of proprietary or patent rights.

5. Are "special" patent applications subjected to the same rigorous examination accorded to other patent applications?

Yes. The actual examinations procedures are identical; only the waiting time prior to initial examination and between office actions is eliminated.

6. How much time is saved by "special" processing?

The period of time between receipt of a patent application and final action thereon may be shortened by as much as six months. In other words, the patent containing the invention disclosure can be published six months earlier than is usually the case.

7. Are there other types of patent applications (i.e., not related to recombinant DNA) which are eligible for "special" processing?

Yes. Certain types of "energy" inventions and "environmental" inventions have been eligible for "special" processing for some time. In addition, any inventor over sixty-five or in ill health qualifies for "special" processing, regardless of the nature of his invention.

8. Why is it desirable to have accelerated processing?

Accelerated processing means earlier disclosure of the discoveries set forth in patent applications. This is universally recognized as desirable from a public interest standpoint, and it is particularly desirable where the application of these discoveries is intimately associated with the preservation of human life and health.

Accelerated processing also means that the inventor's 17-year patent term begins to run earlier than it otherwise would. This is sometimes, but not always, perceived as a desirable result from the inventor's point of view.

9. If early public disclosure in the form of issuance of a patent is universally considered to be desirable from a public interest standpoint, why not permit all inventors to accelerate the processing of their recombinant DNA inventions, if they so desire, without regard to the question of compliance with the NIH guidelines?

As mentioned earlier, accelerated processing is sometimes, but not always, perceived as advantageous by the inventor. If the inventor perceives no advantage in accelerated processing, he will not ask for it. To the extent that "special" processing is perceived as a valuable benefit by the inventor, the Department is in a position to bargain for additional valuable consideration on behalf of the public. That consideration, the Department decided, should be in the nature of compliance with the containment precautions and other substantive elements of the NIH guidelines.

The Department could, of course, accelerate all DNA related applications without regard to the wishes of the particular inventor concerned. If it did this, however, it would lose its "bargaining" position: it could not thereafter trade expedited processing for substantial compliance with the NIH guidelines. Furthermore, if expedited processing were automatic, inventors who consider themselves disadvantaged by this treatment could simply delay the submission of their applications.

10. Does the Department's offer to accelerate the processing of recombinant DNA patent applications apply to foreign inventors?

Yes. The offer is extended to all inventors, whether domestic or foreign, who seek a U.S. patent. It encourages all researchers throughout the world to adopt the containment precautions and other substantive elements of the NIH guidelines. The earlier disclosure of discoveries in this field benefits not only the U.S. public but the entire world.

11. Does the U.S. Patent and Trademark Office receive a significant number of patent applications from foreign inventors?

Yes. Foreign inventors are responsible for more than half of the high-technology patent applications filed in the U.S. Patent and Trademark Office.

12. If a private-sector research institution does not accept Government funding for recombinant DNA research, can the Government presently require compliance with the NIH guidelines?

There is no existing statutory authority by which the Government can require such institutions to comply with the NIH guidelines. However, by authorizing the accelerated processing of recombinant DNA patent applications, the Government can require in return that such applicants certify their compliance with the NIH guidelines, either in whole or in part.

13. Why did you not ask for 100 percent compliance with the NIH guidelines as a precondition for accelerated processing?

There are two reasons. From the inventor's point of view the disincentives attached to such a precondition (i.e., the loss of all foreign patent rights and the placing in jeopardy of all domestic patent rights) would greatly outweigh any benefits he could expect to receive from accelerated processing. In the face of such a precondition, virtually all inventors would choose to forego "special" processing. As a result, the public would get neither early disclosure nor substantial compliance with the guidelines.

Second, a demand for full compliance with the guidelines by researchers in the private sector could be counterproductive. If an inventor were to comply with the guidelines in every particular, he would be obliged to complete his investigation within one year if he wished to preserve U.S. patent rights in the disclosure made to the Government prior to the commencement of his experimentation. Such a requirement could conceivably lead to an unnecessary and undesirable acceleration of his research schedule.

14. Why do the guidelines require researchers to forfeit their patent rights as a precondition for entering upon recombinant DNA research?

The guidelines do not do this directly. As originally drafted, they were intended to apply only to Government-funded research. The difficulty lies in the fact that disclosures made to the Government by private researchers are not adequately protected by present law against further release to other competitive researchers and to the public at large. Such further disclosures are legally akin to "publication," and publication is an absolute bar to the filing of patent applications in most foreign countries. In the United States, the patent application must be filed within one year of publication.

15. Can an inventor obtain a U.S. patent on a recombinant DNA organism.

No. With the exception of certain asexually reproduced plants, living organisms (whether recombinant or otherwise) are not patentable in the U.S. A case challenging the Department's refusal to issue a patent on a recombinant microorganism is now pending in the courts. Great Britain has already issued a patent on this microorganism.

16. If no U.S. patent can issue on a recombinant DNA organism, what are the recombinant DNA inventions which are eligible for accelerated processing?

Such an invention could conceivably encompass the production by a recombinant microorganism of a new antibiotic which was useful in the treatment of disease. A patent might then issue on the method of production, or on the antibiotic itself, or both, but not on the recombinant organism.

17. When the U.S. Government grants a patent to an inventor does it not thereby consent, either expressly or impliedly, to his commercialization of that invention in the United States?

It does not. The right conferred upon an inventor by the patent grant is the right to exclude others from practicing the invention in question. It not infrequently happens that the inventor himself cannot lawfully commercialize his invention in the United States because there exists some law or regulation which bars the sale or use of the patented article or process. For example, patents are generally issued on new drugs long before the Food and Drug Administration licenses the sale of such items.

18. Can't we change the U.S. patent laws so as to permit 100 percent compliance with the guidelines without destroying patent rights?

While a change in U.S. patent laws could conceivably ameliorate this problem somewhat, there is little hope that the entire world would follow our example. Furthermore, the inventor would still lose those proprietary rights which he was not intending to patent.

19. Is there some easy way around this impasse?

Yes. A different set of guidelines could be issued for the conduct of privately-funded research. These guidelines could provide for the same type of disclosure mandated by the present NIH guidelines, while preserving these disclosures from "publication."