DATE: June 4, 1976

TO : Those Interested in Recombinant DNA

FROM : Robert M. Rosenzweig
Vice President for Public Affairs

SUBJECT: Thoughts on the Patent Question

The proposal to seek patent protection for discoveries arising from research on recombining DNA has aroused at Stanford a range of emotions that includes enthusiasm, dismay, and most of the stops in between. That this is so is not surprising, for Stanford scientists have been centrally involved in the research that produced the ability to recombine DNA elements, in the public policy debate over the kinds of research that might safely be allowed to proceed and the safeguards for any such research, and in the "invention" for which patent protection is being sought. In a situation in which different points of view exist among individuals, and in which some individuals are ambivalent or conflicted, it is especially important to define the issues clearly. Dispute, if there is to be any, should be over real differences about real issues. The purpose of this memorandum is to state the issues as clearly as I am able to do it. I hope that readers of it will help, by their comments, to add still greater clarity to the discussion.

I The Effect of Patents on the Conduct of Science

It is probably the case that most scholars have had a good deal more experience with the use of copyrights than with the use of patents. However, both devices are expressions of a single purpose and are in fact authorized in a single section of the Constitution:

[The Congress shall have power]...

> To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries;...(Article I, Section 8)

An elaborate structure of copyrights, patents, licenses, litigation, special courts, and so forth, has grown from that spare statement. I cite it because it seems to me useful to recall that the purpose of the Founders (and the English law on which they built) in providing for patents, was indistinguishable from one of the central purposes of the university, "to promote the progress of science and the useful arts."

It is, perhaps, ironic that a major theme in the present debate is the fear that if scientists are forced to think about the patentability of their work, there will be an unhealthy increase in secrecy and that the progress of science

which depends on prompt, free, and open communication will be compromised. While the academic world is not without experience in the use of patents, it is characteristically without good evidence of the effects of their use. To state the matter in the negative, though, I have seen no evidence that the fairly common expectation of patentable inventions that characterizes some areas of engineering or chemistry has inhibited the progress of science in those areas or has damaged openness and collegiality.

It could, of course, happen, and it is impossible to prove that it will not happen in the biomedical sciences. It is fair to observe, however, that other developments in recent years have posed what might have been thought in prospect to be serious threats to the openness of science -- more serious in fact than the patent system. For example, the adoption of research funding based almost exclusively on competitive applications to government agencies might have led to the kind of secrecy that characterizes competition for government contracts in business in industry. That it has not, is encouraging evidence of the strength of the values that prevail in science and in academic institutions, and it suggests that it is those values, rather than the addition or subtraction of particular incentives, that will determine the way science is conducted in the future

II Commercial Development and Basic Research

The report of the University of Michigan committee that recommended that recombinant DNA research be permitted under appropriate controls started by rejecting the notion "that any and all such research should be permitted because freedom of inquiry is an absolute freedom that must never be abridged." Indeed, few people today would argue in support of so extreme a statement of scientific freedom.

Perhaps the chief limiting factor, the one that is most likely to generate a demand for controls, is the element of risk. Some hazards are so great and so imminent as to render the research that produces them unacceptable -- atmospheric nuclear explosions are such a case. In other instances judgments must be made that balance the magnitude and likeliness of risk against the size and probability of benefit. Nowhere in recent years has that balancing been argued so publicly among scientists as in the debate over the future of recombinant DNA research. To an outsider, reading the literature of that debate, one fact stands out: there would be no debate were it not for the enormous prospective benefits that are predicted to accrue from continuation of the research. Were it not for those benefits it is highly unlikely that funding agencies would find it politically possible to accept the degree of risk that is

inherent in the method. Indeed, public concern aside, it seems likely that the balance of scientific judgment would be quite different were not the prospect of benefit both great and imminent.

If that assessment is correct, or even nearly so, then it is essential to address squarely the nature of the links among research, development, and commercial exploitation. It is not acceptable to justify taking the risks of pursuing a line of research by pointing to its benefits unless one is also willing to aid--or at least not inhibit--the process of bringing those benefits to fruition. The ability of a company to hold exclusive license for a long enough period of time to justify the risk of investment in the development of a product is an important part of that process. The value of a patent is precisely to make such a license possible. Those who argue that the patent-license process has adverse consequences so severe as to bar its use, must accept the responsibility of proposing feasible alternatives to assure useful development, or face the prospect of inhibiting the very benefits that serve to justify the basic research. The obligation seems to me inescapable.

III The University's Financial Condition

While I do not believe that personal profit is a base or ignoble motive, it happens that no member of the Stanford faculty stands to be enriched personally as a result of this patent. The departments involved, the Medical School, and the University would be the beneficiaries of success. It is a fact that the financing of private universities is more difficult now than at any time in recent memory and that the most likely prediction for the future is that a hard struggle will be required to maintain their quality. I do not want to overstate the weight of this fact on the matter at hand, but neither should it be ignored. Clearly, there are things that we would not want Stanford to do, even though doing them might be profitable. To put the point as precisely as I can, we cannot lightly discard the possibility of significant income that is derived from activity that is legal, ethical, and not destructive of the values of the institution.

IV Conflict of Interest and Public Policy

As I indicated at the outset, the special force of the patent question for Stanford comes from the fact that Stanford scientists have been leaders both in the science of recombinant DNA and the public policy of the subject. A question of special moment, therefore, is whether their future impact on public policy would be diminished by the

fact (or inferences from the fact) that Stanford stands to gain from the commercial exploitation of the science. Some of the individuals involved believe that that will happen. Here, too, it is impossible to prove the negative. In any event, their concerns must be taken seriously because their ability to affect policy is a valuable asset to them and to the University. Let me suggest some ways in which the appearance of conflict of interest might be mitigated.

1. It is essential that the University be open about the entire process. We should not try to hide our actions or disguise our motives.

2. Before the decision is finally taken to press for patent protection, the leaders of the most relevant public agencies, e.g., NIH, the President's Science Advisory Council, should be consulted. We should seek their agreement that the decision is a proper one and their willingness to say so publicly.

3. If the conduct of basic research carries safety hazards, the conduct of commercial development programs will be many-fold more dangerous. The restraints of government regulation will be largely absent and the restraints of peer pressure may well be overwhelmed by the pressure to produce results. So far as I can tell, no serious thought has yet been given to the development end of the safety issue. Here, Stanford could make a genuine contribution. We might consider, for example, the establishment of a committee (not unlike the existing Human Subjects Review Committees) consisting of scientists and non-scientists and perhaps including persons from outside the University. This committee would review licensing proposals to evaluate the hazards of the proposed line of development compared to the likely benefits; it might also advise on laboratory and testing precautions required in the conduct of the work.

It is within our power, in short, to act to protect our faculty's important role in public policy deliberations. Guarantees are not possible, but reasonable assurances are. We should see if those are obtainable.

This is an incomplete catalog of issues and arguments, but it includes what seem to me the central ones. If I have missed some important ones, they should be added; if my analysis of the issues is defective, it should be corrected. It will be clear to readers by now that my strong preference is to press for patent protection and a responsible licensing program. However, if the reaction to our inquiries suggests that a serious and damaging perception of conflict of interest would result from that course of action, then I would strongly urge caution until safer (although undoubtedly less rewarding and effective) mechanisms can be devised. I solicit the views of all who read this.