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September 15, 1981

Mr. LeRoy Randall
Patent Branch
National Institutes of Health
Westwood Building
Bethesda, MD 20014

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Dear Mr. - Randall:

Office of the President

I am in receipt of a letter dated August 10, 1981, from Charles U. Lowe, MD, Chairman NIH patent board, requesting that we provide to you certain information. In order that you may appreciate the scope of this information collection request, a copy of Dr. Lowe's letter is enclosed.

Regretfully, we must decline to respond to this information collection request for a number of reasons. In the first place, we do not accept the characterization of PL 96-517 as having made the IPA into law. The effect of PL 96-517 is not to make the reporting requirement stipulated in the IPA "a matter of statutory mandate as of July 1, 1981", but rather to eliminate such reporting requirement.

In the letter from Dr. Lowe, an inclusion from Thomas E. Malone, PhD, acting director NIH, refers to OMB bulletin 81-22 as having set forth "proposed policies and procedure governing such patent agreements". On the contrary, and I quote, OMB bulletin 81-22 specifies that "after July 1, 1981, this bulletin and 35 USC 200-206 (PL 96-517) shall take precedence over any conflicting agency regulations or policies."

A principle difficulty with the information you request is that it encompasses information which would have been included in the IPA reporting rather than OMB bulletin 81-22. The administration information requests specified in 5 and 6 of bulletin 81-22 (which are taken from the federal regulations of July 2, 1981, implementing PL 96-517) could in no sense be construed to include the breadth of information to which this information collection request refers. It must be emphasized that while the policies set forth in OMB bulletin 81-22 have been described by Dr. Malone as "proposed", nevertheless they are interim procedures which, until changed in the finalization process, have the force of law.

PL 96-517 and its implementing regulations have the purpose of eliminating the variety of procedures that have been generated by federal agencies formulating their own patent policies. The wisdom of such initiative is well