

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

JUN 26 1992

Honorable Michael J. Astrue
General Counsel
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Astrue:

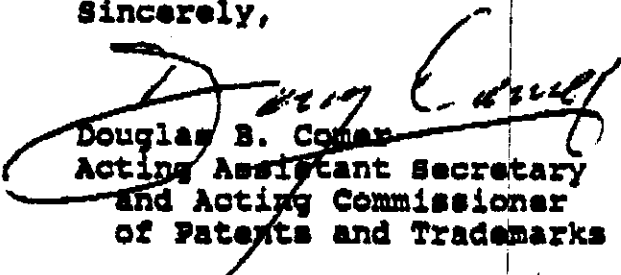
Thank you for your letter of 18 June 1992, requesting that action be suspended on patent applications filed by the National Institutes of Health (NIH) relating to a large number of human genetic sequences.

NIH has attracted international attention, both among a large sector of the scientific community working on human genome research and among the intellectual property community seeking protection for the products of biotechnology, by its initiative to seek patent protection for certain results of research done on the Human Genome Project. Notwithstanding your apparent conclusion that some, as yet unidentified, portion of the applications does not meet the threshold legal requirements for a patentable invention, there is a keen public interest in an official view on the patentability of the subject matter in these applications.

It also should be noted that under 37 CFR 1.56, applicants have a duty of candor and good faith in conducting business before the Office, which includes a duty to submit information to the Office that is known to be material to the patentability of a pending claim. Information may be submitted to the Office in the manner prescribed in 37 CFR 1.97 and 1.98.

In view of the strong public interest in identifying and resolving any issue of patentability presented in these applications, and the fact that NIH may cancel any subject matter from the pending patent applications that it does not consider to be patentable, there is no compelling reason for the Patent and Trademark Office to suspend action on the NIH applications at this time. As a matter of fact, an action already has been mailed in the first NIH application. It is anticipated that review of the second application will be completed before the end of the summer.

Sincerely,


Douglas B. Comar
Acting Assistant Secretary
and Acting Commissioner
of Patents and Trademarks