INTERNATIONAL CENTER
FOR TECHNOLOGY ASSESSMENT (CTA)

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DATE: March 22, 2000

TOTAL PAGES: *4*

NOTES:

Enclosed are the Comments from the International Center for Technology Assessment in response to the PTO's Revised Utility Examination Guidelines.

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ICTA INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT

March 22, 2000

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COMMENTS CONCERNING THE PATENT AND TRADEMARK OFFICE'S REVISED UTILITY EXAMINATION GUIDELINES

Dear Mr. Nagumo/Ms. Therkorn:

Pursuant to the notice published at 64 *Federal Register* 71440 (December 21, 1999), The International Center for Technology Assessment ("ICTA") submits the following comments in response to the Patent and Trademark Office's ("PTO") Revised Utility Examination Guidelines. ICTA is a non-profit organization in Washington, DC. ICTA's mission is to assess the impacts of emerging technology on human health, animal welfare, and the environment. ICTA has had significant involvement in furthering patent legislation in the past several years including providing legal analysis to relevant legislators and testifying at congressional hearings and PTO public hearings. Further, ICTA has conducted significant research on an extensive number of patents issued by the PTO for transgenic animals and is currently preparing a report on the patenting of human materials.

ICTA is concerned about the large number of patents being issued for gene sequences. Since NIH researcher Craig Venter first attempted to patent human gene sequences nearly a decade ago, the agency's policy on the patentability of such material has been inconsistent and legally incoherent. The PTO has completely failed to arrive at a cognizable policy on the utility of such patents. The current guidelines should instruct examiners to deny patent applications when the gene sequence is present in any species or organism, including humans because

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such applications fail to fulfill the "utility" requirements of U.S. patent law. Obviously, finding sequences in a naturally occurring organism may be a "discovery," however there is no legal basis for patent examiners to find that these sequences are patentable "inventions."

Under U.S. patent law, "products of nature" are not patentable subject matter. Diamond v. Chakrabarty, 447 U.S. 303 (1980). Despite this requirement, companies are competing to patent human genes. Already, as many as 70,000 of the 100,000 human genes discovered may be under patent application before the PTO. The public has a strong interest in keeping the human genome freely accessible not only for the use of scientific research, but also because it is the foundation of human life and thus should not be patented by any *one* person. The recent public announcement by President Clinton and British Prime Minister Tony Blair underscores this Administration's commitment to keeping the humane genome from becoming patentable property of a few biotechnology corporations.

As for plants and animals, only a small percentage of the genomes of different species of plants and animals have been determined. Based upon this lack of information, it is currently not possible to determine whether the majority of nucleic acid sequences are a patentable "invention" or simply a "discovery."

According to the revised guidelines, an invention is patentable if it demonstrates theoretical utility. Allowing the patenting of a gene sequence that resembles a previously discovered sequence is not acceptable. In Chakrabarty, 447 U.S. 303, the Supreme Court held that a genetically modified micro-organism was patentable - not naturally occurring gene sequences.

Consistent with U.S. patent law, the PTO should tighten its rules and guidance by rejecting patent applications for gene sequences derived from naturally occurring organisms. The PTO should also clarify its interpretation of patent law by expressly stating that the discovery of genetic sequences from naturally occurring organisms belongs to the public and not to private individuals or corporations.

Under the current revised utility guidelines, the misuse of the patent system will continue. Only by preventing ownership over genetic sequences will the public be able to freely access and study the basic gene sequences of life.

Sincerely,

Andrew Kimbrell (TDL)

Andrew Kimbrell