Comment 41 National Academy of Sciences/Bruce Alberts

March 22, 2000

**Q. Todd Dickinson**
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box 8
Washington, DC 20231

Attention: Mark Nagumo

Dear Mr. Dickinson:

Thank you for this opportunity to comment on the Patent and Trademark Office (PTO) Revised Utility Examination Guidelines that were published for public comment in the Federal Register for December 21, 1999. The Revised Utility Examination Guidelines on which the PTO has requested public comment address the "utility" requirement under the patent statute.

Last week President Clinton and British Prime Minister Blair issued a joint statement applauding the decision by scientists working on the Human Genome Project to release raw fundamental information about the human DNA sequence into the public domain and commending other scientists around the world to adopt this policy. The joint statement noted that to realize the full promise of human genome research, raw fundamental data on the human genome, including the human DNA sequence and its variations, should be made freely available to scientists everywhere in order to promote discoveries that will reduce the burden of disease, improve health around the world, and enhance the quality of life for all humankind. The joint statement also noted that intellectual property protection for gene-based inventions will play an important role in stimulating the development of important new health care products.

In a separate statement issued last week, the PTO reaffirmed that U.S. patent policy remains unaffected by the Clinton-Blair joint statement and that genes and other genomic inventions remain patentable so long as they meet the statutory criteria of utility, novelty and non-obviousness. The PTO statement also called attention to the Revised Utility Examination Guidelines that have been issued for public comment.

The events of last week underscore the tremendous importance of current research efforts involving the human genome and the related intellectual property issues concerning "ownership" of the human genome. Through both public and private efforts, we are poised on the brink of having a complete “map” or description of the human genome, including all of the genes in the

cells of human beings that govern the entire biochemical fabric of human life. The potential implications for increasing humankind's understanding of the structure and functioning of the human body at the most minute and fundamental levels and for finding new drugs and treatments for curing human diseases are enormous.

At the same time, the prospect of a healthcare revolution resulting from the discoveries that will flow from the mapping of the human genome has stimulated huge private investments in anticipation of these new discoveries and new technology. The healthcare revolution will not happen, of course, without such private investments, and patent protection is an important consideration in making such investments. As a result, thousands of gene-related patent applications are pending, including applications making broad patent claims on genes and gene fragments.

Patent protection is based upon the underlying principle that public disclosure of valuable new discoveries through the patent process should be rewarded by patent monopolies over the use of such discoveries for a limited period of time. But the benefits received by the public from patents and patent disclosures must be reasonably commensurate with the monopoly benefits conferred. See *In Re Fisher,* 427 F.2d 833, 839 (C.C.P.A. 1970) (claim scope must be commensurate with the scope of what the patentee has given the public).

Scientists are concerned that at this very early stage of human genome research, granting broad patents on genes, or possibly even fragments of genes, might seriously impede the research and development that will be necessary to realize the promise of the human genome sequence in generating significant new treatments and cures for human disease. Given the enormous potential significance of this genome, the act of granting broad monopoly patent rights to any portion of the human genome should be regarded as extraordinary and should occur only to reward new discoveries that confer benefits of comparable significance for mankind.

In *Brenner* v. *Manson,* 383 U.S. 519 (1966), the U.S. Supreme Court defined the "utility" requirement addressed by the Revised Utility Examination Guidelines in the following terms: "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point -- where specific benefit exists in currently available form -- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." 383 U.S. at 534-35. The Court also went on to state that "[t]hese arguments for and against the patentability of a process which either has no known use or is useful only in the sense that it may be an object of scientific research would apply equally to the patenting of the product produced by the process." 383 U.S. at 535. These words are strikingly relevant to today's concerns regarding the danger of granting broad patents on human genomic material based upon minimal discoveries.

Of course, the "utility" requirement is only one of a number of factors affecting the availability and scope of patent protection for inventions based upon genetic material. Other important requirements include enablement, the written description requirement for DNA molecules, and the limitations on patentable subject matter. But the "utility" requirement is an

important constraint on patent claims that would improperly benefit private interests without significant benefit to the public interest.

Those who would patent human DNA sequences without real knowledge of their utility are staking claims not only to what little they know at the moment, but also to everything that might later be discovered about the genes and proteins associated with the sequence. They are, in effect, laying claim to a function or use that does not yet exist. For example, it is a trivial matter today — using a computer search of public databases — to use DNA sequences to identify new genes with particular types of biochemical functions. Such a discovery should not be rewarded with a broad patent for future therapies or diagnostics using these genes when the actual applications are merely being guessed at.

For many reasons, human genetic material raises patent issues of unique political, economic, and human significance and importance. To the maximum extent possible, the human genome sequence should be freely available for use by all both as part of our basic human heritage and to fully realize the enormous benefits that this information promises.

Granting broad monopoly patent rights to any portion of the human genome should be an extraordinary and uncommon event clearly required by statute. Patent protection should be focussed instead on the new treatments and drugs that will result from the research and development efforts of many different individuals and companies working from the basic information in the human genome sequence. Wise administration of the various requirements of the patent law, including the utility requirement, can help to achieve this important objective.

Sincerely,

Bruce Alberts
President
National Academy of Sciences