

NIST programs; the facilities construction program; the strategic planning for the Information Technology Laboratory; and a laboratory tour. On December 6, 1995, the agenda will include presentations on Investing in Public Technology Companies; report of the Board on Assessment on NIST programs; and a report on the NIST Laboratory Role.

DATES: The meeting will convene December 5, 1995, at 1:00 p.m. and will adjourn at 11:45 a.m. on December 6, 1995.

ADDRESSES: The meeting will be held in Lecture Room A (seating capacity 70, includes 36 participants), Administration Building, at NIST, Gaithersburg, Maryland.

FOR FURTHER INFORMATION CONTACT: Chris E. Kuyatt, Visiting Committee Executive Director, NIST, Gaithersburg, Maryland 20899, telephone number (301) 975-6090.

Dated: November 7, 1995.

Samuel Kramer,

Associate Director.

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Patent and Trademark Office

Notice of Hearings and Request for Comments on Issues Relating to Patent Protection for Nucleic Acid Sequences

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice of hearings and request for comments.

SUMMARY: The Patent and Trademark Office (PTO) will hold public hearings, and it requests comments, on issues relating to patent protection for nucleic acid sequences. Interested members of the public are invited to testify at public hearings and to present written comments on any of the topics outlined in the supplementary information section of this notice.

DATES: Public hearings will be held on Wednesday, November 29, 1995, from 9:00 a.m. until 1:00 p.m., and Thursday, December 7, 1995, from 9:00 a.m. until 1:00 p.m.

Those wishing to present oral testimony at any of the hearings must request an opportunity to do so no later than Monday, November 27, 1995, for the November 29 hearing, or Tuesday, December 5, 1995, for the December 7 hearing.

Speakers may provide a written copy of their testimony for inclusion in the

record of the proceedings no later than Monday, December 18, 1995.

Written comments will be accepted by the PTO until December 18, 1995.

Written comments and transcripts of the hearings will be available for public inspection on or about Monday, January 22, 1996.

ADDRESSES: The November 29 hearing will be held from 9:00 a.m. until 1:00 p.m. at the University of California, San Diego, The Mandeville Auditorium/Recital Hall, Muir Campus, La Jolla, California.

The December 7 public hearing will be held from 9:00 a.m. until 1:00 p.m. in Suite 912, Commissioner's Conference Room, Crystal Park Building No. 2, 2121 Crystal Drive, Arlington, Virginia.

Requests to testify should be sent to Esther Kepplinger by telephone at (703) 306-2714, by facsimile transmission at (703) 308-6879, or by mail marked to her attention addressed to the Assistant Commissioner for Patents, Box DAC, Washington, D.C. 20231. No request for oral testimony will be accepted through electronic mail.

Written comments should be addressed to the Assistant Commissioner for Patents, Box DAC, Washington, D.C. 20231, marked to the attention of Esther Kepplinger. Comments may also be submitted by facsimile transmission at (703) 308-6879, with a confirmation copy mailed to the above address, or by electronic mail over the Internet to "sequence@suspto.gov."

Written comments and transcripts of the hearings will be maintained for public inspection in Suite 520 of Crystal Park One, 2011 Crystal Drive, Arlington, Virginia. Transcripts and comments provided in machine readable format will also be available through anonymous file transfer protocol (ftp) via the internet (address: sequence@suspto.gov).

FOR FURTHER INFORMATION CONTACT: Esther Kepplinger by telephone at (703) 306-2714, by facsimile transmission to (703) 308-6879, by electronic mail at ekepplin@uspto.gov, or by mail marked to her attention addressed to the Assistant Commissioner for Patents, Box DAC, Washington, D.C. 20231.

SUPPLEMENTARY INFORMATION:

I. Background

With the growth of the biotechnology industry have come significant changes in the process of research, development and commercialization of biotechnology inventions. For at least a decade, patent applications claiming nucleic acid sequences, such as genes composed of

deoxyribonucleic acid ("DNA"), have been examined and granted patent rights by the PTO. These sequences typically encode known proteins or proteins for which applicant discovered a function. Scientific and technological advances have permitted researchers to identify large numbers of gene fragments rapidly. Armed with databases containing the sequences of known genes, they can identify a novel sequence. The ease of sequencing large numbers of random nucleic acid fragments has resulted in the filing of a growing number of patent applications each claiming thousands of nucleic acid sequences. This is a serious problem for the PTO. While the PTO has recently acquired sophisticated and costly hardware and software necessary to search applications containing such sequences, their examination will significantly burden the existing system and may necessitate the acquisition of many additional, expensive, massively parallel processor computers to complete examination in a reasonable time.

PTO estimates that the computer search time for one hundred sequences is about fifteen hours and the examiner time for evaluating the sequence search results is about sixty-five hours. The estimated cost for computer search time for one hundred sequences is \$1500. Although the number of cases involving large numbers of sequences presently before the PTO is small, it is estimated that the cost to search and examine these cases will be \$8 million. These estimates represent searches by a massively parallel processor computer of commercially available databases.

Applications that claim excessively long sequences present similar challenges, since the claimed sequence must be broken up into numerous smaller sequences in order to be searched.

An additional issue has been raised relating to what is known as the Human Genome Initiative (HGI).

The HGI is a project to obtain the entire DNA sequence in the human genome. Many of the benefits expected from the HGI are due to the characterization of expressed nucleic acid sequences in the human genome and their protein products.

Some individuals believe that expressed nucleic acid sequences in the human genome should not be patentable because of the possibility that a patent to a gene fragment could preclude future use of the gene or its protein product. This, it is argued, could inhibit future research efforts to isolate the entire gene or to develop medically beneficial protein compounds. Others believe that

the benefits of the patent system should not be withheld from this area of technology, because research and development would be drastically curtailed due to the inability to protect capital investments or to reap financial rewards from those investments. Appropriate policies must be established to address these challenges.

II. Issues for Public Comment

Interested members of the public are invited to testify or to present written comments related to the above topics, including the following issues:

1. Is there a more cost-effective way to examine applications containing large numbers of sequences or excessively long sequences, in view of the PTO's limited human and computer resources?
2. How should the significantly higher cost associated with searching applications claiming large numbers of sequences or excessively long sequences be underwritten? For example:
 - (a) By fees from all applications?
 - (b) By fees from the biotechnology industry applications only?
 - (c) By fees from those specific applications involving large numbers of sequences or extraordinarily long sequences?
3. Will the patenting of a complete genome of an organism inhibit rather than promote advancement of the biotechnology arts? If so, why?
4. Will the patenting of human genome fragments inhibit rather than promote advancement of the biotechnology arts? If so, why?

III. Guidelines for Oral Testimony

Individuals wishing to testify at the hearings must adhere to the following guidelines:

1. Requests to testify must include the speaker's name, affiliation, title, phone number, fax number, mailing address, and Internet mail address (if available).
 2. Speakers will be provided between seven and fifteen minutes to present their remarks. The exact amount of time allocated per speaker will be determined after the final number of parties testifying has been determined. All efforts will be made to accommodate requests for additional time for testimony presented before the day of the hearing.
 3. Requests to testify may be accepted on the date of the hearing if sufficient time is available on the schedule. No one will be permitted to testify without prior approval.
- A schedule providing approximate times for testimony will be provided to all speakers the morning of the day of the hearing.
- Speakers are advised that the schedule for testimony may be subject

to change during the course of the hearings.

IV. Guidelines for Written Comments

Written comments should include the following information:

1. Name and affiliation of the individual responding.
2. If applicable, an indication of whether comments offered represent views of the respondent's organization or are the respondent's personal views.
3. If applicable, information on the respondent's organization, including the type of organization (e.g., business, trade group, university, non-profit organization) and general areas of interest.

Information that is provided pursuant to this notice will be made part of the public record. In view of this, parties should not provide information they do not wish publicly disclosed. Parties who would like to rely on confidential information to illustrate a point being made are requested to summarize or otherwise provide the information in a way that will permit its public disclosure.

Parties offering testimony or written comments should provide their comments in machine readable format, if possible. Such submissions should be provided by electronic mail messages over the Internet, or on a 3.5" floppy disk formatted for use in either a Macintosh or MS-DOS based computer. Machine readable submissions should be provided as unformatted text (e.g., ACSII or plain text), or formatted text in one of the following file formats: Microsoft Word (Macintosh, DOS or Windows versions) or WordPerfect (Macintosh, DOS or Windows versions).

V. Guidelines for Comments via Internet

Comments received via the Internet should include the same information requested in the guidelines set out for written comments.

VI. Other Information

Questions regarding the facilities and lodging in the La Jolla, California, area should be directed to the University of California, San Diego, Special Events, by phone at (619) 534-6386, or by fax to (619) 534-0905. Parking permits are required for on-campus parking and may be purchased in advance through the Parking Office or on November 29 at Information booths at the university. Questions regarding parking should be directed to the Special Events Parking Office at (619) 534-9682, or by fax to (619) 534-9685.

Dated: November 8, 1995.

Bruce A. Lehman,

*Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks.*

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COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of an Import Limit for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Fiji

November 7, 1995.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs increasing a limit.

EFFECTIVE DATE: November 15, 1995.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-4212. For information on the quota status of this limit, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927-5850. For information on embargoes and quota re-openings, call (202) 482-3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The current limit for Categories 338/339/638/639 and the sublimit for 338-S/339-S/638-S/639-S are being increased for carryover.

A description of the textile and apparel categories in terms of HTS numbers is available in the **CORRELATION:** Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see Federal Register notice 59 FR 65531, published on December 20, 1994). Also see 60 FR 16622, published on March 31, 1995.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist