

**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration**

[I.D. 081798B]

**Marine Mammals**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Issuance of permit amendment.

**SUMMARY:** Notice is hereby given that Dr. Robin Baird, Biology Department, Dalhousie University, Halifax, Nova Scotia, B3H 4J1 Canada, has been issued an amendment to scientific research Permit No. 926.

**ADDRESSES:** The amendment and related documents are available for review upon written request or by appointment in the following offices:

Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713-2289);

Regional Administrator, Northwest Regional Office, NMFS, NOAA, 7600 Sand Point Way, NE., BIN C15700, Seattle, WA 98115, (206/526-6150);

Regional Administrator, Alaska Regional Office, NMFS, NOAA, 709 West 9th Street, Federal Building, Juneau, Alaska 99802 (907/586-72212); and

Regional Administrator, Southwest Regional Office, NMFS, NOAA, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802-4213 (562/980-4001).

**FOR FURTHER INFORMATION CONTACT:** Jeannie Drevenak, 301/713-2289.

**SUPPLEMENTARY INFORMATION:** On June 30, 1998, notice was published in the **Federal Register** (63 FR 35568) that an amendment of permit No. 926, issued June 6, 1994 (59 FR 31217), had been requested by the above-named individual. The requested amendment has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR Part 216), the Endangered Species Act (ESA) of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the Regulations Governing the Taking, Importing, and Exporting of Endangered Fish and Wildlife (50 CFR part 222).

Issuance of this amendment, as required by the ESA, was based on a finding that such permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of the endangered species which is the subject

of this permit; and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: September 15, 1998.

**Ann D. Terbush,**

*Chief, Permits and Documentation Division,  
Office of Protected Resources, National  
Marine Fisheries Service.*

[FR Doc. 98-25462 Filed 9-22-98; 8:45 am]

BILLING CODE 3510-22-F

**DEPARTMENT OF COMMERCE****Patent and Trademark Office**

[Docket No. 980605148-8148-01]

**Request for Comments on Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶ 1 "Written Description" Requirement; Extension of Comment Period and Notice of Hearing**

**AGENCY:** Patent and Trademark Office, Commerce.

**ACTION:** Notice of hearings, extension of comment period and request for comments.

**SUMMARY:** The Patent and Trademark Office (PTO) will hold public hearings, and it requests comments, on issues relating to the "written description" requirement under 35 U.S.C. 112 ¶ 1. 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 4, 1998, and Friday, November 6, 1998, starting each day at 9 a.m. and ending no later than 5:00 p.m.

Those wishing to present oral testimony at either of the hearings must request an opportunity to do so no later than Friday, October 30. Speakers may provide a written copy of their testimony for inclusion in the record of the proceedings no later than November 12, 1998.

To ensure consideration, written comments should be received at the PTO by November 12, 1998. Written comments and transcripts of the hearings will be available for public inspection on or about Monday, November 16, 1998.

**ADDRESSES:** The November 4th hearing will be held at the Marriott Long Wharf, Salons D, E, F, 296 State Street, Boston, MA 02109. Questions regarding the facilities and lodging should be directed to the Marriott Long Wharf, TEL (617) 227-0800, FAX (617) 227-2867.

The November 6th hearing will be held at The Sheraton San Diego Hotel & Marina, West Tower, Coronado Ballroom, 1590 Harbor Island Drive, San Diego, CA 92101-1092. Questions regarding the facilities and lodging should be directed to The Sheraton San Diego Hotel & Marina, West Tower, TEL (619) 291-2900, FAX (619) 692-2337.

Requests to testify should be sent to Mary Critharis by telephone at (703) 305-9300, by facsimile transmission at (703) 305-8885, or by mail marked to attention of Mary Critharis addressed to the Assistant Commissioner for Patents, Box 4, Washington, DC 20231. No requests for oral testimony will be accepted through electronic mail.

Written comments should be addressed to Box 8, Commissioner of Patents and Trademarks, Washington, D.C. 20231, marked to the attention of Scott A. Chambers, Associate Solicitor, or to Box Comments, Assistant Commissioner for Patents, Washington, D.C. 20231, marked to the attention of Linda S. Therkorn. Comments may be submitted by facsimile transmission to Scott A. Chambers at (703) 305-9373, or to Linda S. Therkorn at (703) 305-8825. Comments may be submitted by electronic mail to [scott.chambers@uspto.gov](mailto:scott.chambers@uspto.gov), or to [linda.therkorn@uspto.gov](mailto:linda.therkorn@uspto.gov).

Written comments and transcripts of the hearings will be maintained for public inspection in Suite 918 of Crystal Park Two, 2121 Crystal Drive, Arlington, Virginia. Transcripts and comments provided in machine readable format will be available through anonymous file transfer protocol (ftp) via the Internet (address: [comments.uspto.gov](http://comments.uspto.gov)) and through the World Wide Web (address: [www.uspto.gov](http://www.uspto.gov)).

**FOR FURTHER INFORMATION CONTACT:** Scott A. Chambers by telephone at (703) 305-9035, by facsimile transmission at (703) 305-9373, by mail to his attention addressed to Box 8, Commissioner of Patents and Trademarks, Washington, DC 20231, or by electronic mail at [scott.chambers@uspto.gov](mailto:scott.chambers@uspto.gov); or Linda S. Therkorn by telephone at (703) 305-8800, by facsimile at (703) 305-8825, by mail to her attention addressed to Box Comments, Assistant Commissioner for Patents, Washington, D.C. 20231, or by electronic mail at [linda.therkorn@uspto.gov](mailto:linda.therkorn@uspto.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶ 1, "Written Description" Requirement were published at 63 FR

32639, June 15, 1998, and at 1212 O.G. 15, July 7, 1998. The period for comment on the Interim Guidelines was originally set to end September 14, 1998. The period for comment is now extended. Comments will be accepted by the PTO until November 12, 1998.

These guidelines are intended to assist examiners at the PTO in finding the attributes necessary to support the written description requirement of 35 U.S.C. 112 ¶ 1, in view of *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), and the earlier cases *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993), and *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991). The PTO endeavors to provide clear guidance to Office personnel in their task of administering the law so that consistent results are achieved. To ensure that examiners know when applicants have satisfied the requirements, the guidelines identify criteria supporting the determination that an application is in compliance with statutory requirements. The PTO invites the public to assist it in identifying the appropriate descriptive attributes that Office personnel should rely on in their determinations.

The PTO requests comments from any interested member of the public on the interim guidelines. Although the guidelines are directed primarily to written descriptions of biotechnological inventions, they reflect the current understanding of the PTO and apply across the board to all relevant technologies. Because these guidelines govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

## II. Issues for Public Comment

Interested members of the public are invited to testify or to present written comments related to the written description requirement, including the following issues.

1. Is the methodology in the interim guidelines accurate? If not, please:

- (a) Identify any legal and/or technical inaccuracies;
- (b) Identify any changes to the guidelines that would improve their accuracy; and
- (c) Provide explanations and/or legal basis for your comments.

2. Do the guidelines list the appropriate relevant factors and descriptive attributes to consider in determining whether the written description requirement of 35 U.S.C. 112 ¶ 1, is satisfied? If not, please:

- (a) Identify factors and descriptive attributes which have been omitted;

- (b) Identify any examples or parts of the analysis which are over inclusive; or
- (c) Explain any changes which would improve the analysis.

3. Should the scope of these guidelines be limited to certain technologies? If so, please:

- (a) Identify the technologies that should be encompassed, and
- (b) Give reasons why the guidelines should not encompass other technologies generally.

4. Should the scope of these guidelines encompass all technologies? If so, please:

- (a) State reasons why the guidelines should encompass technologies in addition to those discussed in the interim guidelines;
- (b) Give specific, factual examples that the guidelines should address, and how 35 U.S.C. 112 ¶ 1, applies to the examples; and

- (c) If these examples are subject to a rejection, how that rejection could be overcome.

5. How should "possession of the invention" be defined for purposes of applying the written description requirement?

6. How should the transition terms "having" and "consisting essentially of" be treated within the context of nucleotide and amino acid sequence claims?

7. How should the guidelines be expanded to specifically address process and/or product-by-process claims?

- (a) Please suggest examples of process or product-by-process claims you want to see addressed in the guidelines, and how 35 U.S.C. 112 ¶ 1, applies to the examples;

- (b) Suggest how the examples of process or product-by-process claims should be analyzed under the guidelines; and

- (c) If these examples are subject to a rejection, how that rejection could be overcome.

8. How should the final guidelines address the deposit of a biological material made under 37 CFR 1.801?

- (a) Please suggest how the date of deposit should be considered with respect to establishing possession of the invention at the time of filing;

- (b) Suggest what significance should be assigned to a deposit in assessing compliance with the written description requirement; and

- (c) Comment on the extent to which a deposit of biological material may be relied on to support the addition of sequence information or the correction of sequence information in the originally filed application.

9. What impact will the guidelines have on issued patents, currently

pending applications, or applications to be filed after publication of the final written description guidelines?

10. Is there any basis in law or fact for treating expressed sequence tags (ESTs) differently than any other nucleic acid under the written description requirement?

11. Are there additional issues related to other statutory requirements of Title 35 invoked in the patenting of ESTs? If so, please set forth those issues separately and specifically.

## 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 have 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 presented before the day of the hearing for additional time for testimony.

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., ASCII or plain text), or as 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.

Dated: September 16, 1998.

**Bruce A. Lehman,**

*Assistant Secretary of Commerce and  
Commissioner of Patents and Trademarks.*  
[FR Doc. 98-25355 Filed 9-22-98; 8:45 am]

BILLING CODE 3510-16-P

#### COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

##### Amendment and Redesignation of Import Limits for Certain Cotton, Wool and Man-Made Fiber Textiles and Textile Products and Silk Blend and Other Vegetable Fiber Apparel Produced or Manufactured in the Philippines

September 16, 1998.

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

**ACTION:** Issuing a directive to the  
Commissioner of Customs increasing  
and amending the coverage of limits.

**EFFECTIVE DATE:** September 23, 1998.

**FOR FURTHER INFORMATION CONTACT:**  
Janet Heinzen, 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  
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:** Section 204 of the Agricultural  
Act of 1956, as amended (7 U.S.C. 1854);

Executive Order 11651 of March 3, 1972, as  
amended.

In a Memorandum of Understanding  
(MOU) dated August 19, 1998, the  
Governments of the United States and  
the Republic of the Philippines agreed  
to amend the coverage of Group II to  
include Categories 361, 369-S and 611  
and to increase the 1998 Group II limit.

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 62 FR 66057,  
published on December 17, 1997). Also  
see 62 FR 64361, published on  
December 5, 1997.

**Troy H. Cribb,**

*Chairman, Committee for the Implementation  
of Textile Agreements.*

#### Committee for the Implementation of Textile Agreements

September 16, 1998.

Commissioner of Customs,  
*Department of the Treasury, Washington, DC  
20229.*

Dear Commissioner: This directive  
amends, but does not cancel, the directive  
issued to you on December 1, 1997, as  
corrected on December 23, 1997, by the  
Chairman, Committee for the Implementation  
of Textile Agreements. That directive  
concerns imports of certain cotton, wool and  
man-made fiber textiles and textile products  
and silk blend and other vegetable fiber  
apparel, produced or manufactured in the  
Philippines and exported during the twelve-  
month period which began on January 1,  
1998 and extends through December 31,  
1998.

Effective on September 23, 1998, you are  
directed to amend the Group II designation  
to include the coverage of Categories 361,  
369-S<sup>1</sup> and 611. Categories 361, 369-S and  
611 shall be sublevels in Group II. Import  
charges already made to these categories  
shall be moved to Group II. The 1998 limit  
for Group II shall be increased to 190,612,355  
square meters equivalent<sup>2</sup>.

The Committee for the Implementation of  
Textile Agreements has determined that  
these actions fall within the foreign affairs  
exception of the rulemaking provisions of 5  
U.S.C. 553(a)(1).

Sincerely,

**Troy H. Cribb,**

*Chairman, Committee for the Implementation  
of Textile Agreements.*

[FR Doc. 98-25388 Filed 9-22-98; 8:45 am]

BILLING CODE 3510-DR-F

<sup>1</sup> Category 369-S: only HTS number  
6307.10.2005.

<sup>2</sup> The limit has not been adjusted to account for  
any imports exported after December 31, 1997.

#### COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

##### Adjustment of Import Restraint Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Thailand

September 16, 1998.

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

**ACTION:** Issuing a directive to the  
Commissioner of Customs adjusting  
limits.

**EFFECTIVE DATE:** September 23, 1998.

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

The current limits for certain  
categories are being adjusted, variously,  
for special shift, carryforward and  
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 62 FR 66057,  
published on December 17, 1997). Also  
see 62 FR 65246, published on  
December 11, 1997.

**Troy H. Cribb,**

*Chairman, Committee for the Implementation  
of Textile Agreements.*

#### Committee for the Implementation of Textile Agreements

September 16, 1998.

Commissioner of Customs,  
*Department of the Treasury, Washington, DC  
20229.*

Dear Commissioner: This directive  
amends, but does not cancel, the directive  
issued to you on December 5, 1997, by the  
Chairman, Committee for the Implementation  
of Textile Agreements. That directive  
concerns imports of certain cotton, wool,  
man-made fiber, silk blend and other  
vegetable fiber textiles and textile products,  
produced or manufactured in Thailand and  
exported during the twelve-month period  
which began on January 1, 1998 and extends  
through December 31, 1998.