§ 510.600 [Amended]
■ 2. Section 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications is amended in the table in paragraph (c)(1) by removing the entry for “Anthony Products Co.” and in the table in paragraph (c)(2) by removing the entry for “000864”.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS
■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

§ 520.1720a [Amended]
■ 4. Section 520.1720a Phenylbutazone tablets and boluses is amended in paragraph (b)(3) by removing “000864”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS
■ 5. The authority citation for 21 CFR part 522 continues to read as follows:

§ 522.480 [Amended]
■ 6. Section 522.480 Repository corticotropin injection is amended in paragraph (b)(2) by removing “000864” and by adding in its place “061623”.

§ 522.540 [Amended]
■ 7. Section 522.540 Dexamethasone injection is amended in paragraphs (b)(2)(i) and (c)(2) by removing “000864” and by adding in its place “061623”.

§ 522.1010 [Amended]
■ 8. Section 522.1010 Furosemide is amended in paragraph (b)(2) by removing “000864” and by adding in its place “061623”.

§ 522.1720 [Amended]
■ 9. Section 522.1720 Phenylbutazone injection is amended in paragraph (b)(1) by removing “and 059130” and by adding in its place “059130, and 061623”; in paragraph (b)(2) by removing “Nos. 000010 and 000864” and by adding in its place “No. 000010”; and by removing paragraph (b)(4).
■ 10. Section 522.1883 is revised to read as follows:
§ 522.1883 Prednisolone sodium phosphate.
(a) Specifications. Each milliliter of solution contains 20 milligrams (mg) prednisolone sodium phosphate (equivalent to 14.88 mg of prednisolone).
(b) Sponsor. See No. 061623 in § 510.600(c) of this chapter.
(c) Conditions of use in dogs—(1) Amount. Administer intravenously in a dosage of 2 1/2 to 5 mg per pound of body weight, initially for shock and shock-like states, followed by equal maintenance doses at 1-, 3-, 6-, or 10-hour intervals as determined by the condition of the animal.
(2) Indications for use. Administer when a rapid adrenal glucocorticoid and/or anti-inflammatory effect is necessary.
(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
■ 11. Section 522.1962 is amended:
(a) By revising paragraphs (a) and (c)(3); and
(b) By removing footnote 1.
(c) By adding in its place “057561, 059130, and 061623”.
■ 12. Section 522.2062 Promazine hydrochloride.
(a) Specifications. Each milliliter of solution contains 50 milligrams (mg) promazine hydrochloride.
(c) Amounts and indications for use.
(1) * * * * *
(2) Limitations. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
■ 13. The authority citation for 21 CFR part 529 continues to read as follows:

§ 529.1044a [Amended]
■ 14. Section 529.1044a Gentamicin sulfate intrathecal solution is amended in paragraph (b) by removing “000864, 057561, and 059130” and by adding in its place “057561, 059130, and 061623”.
Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

DEPARTMENT OF COMMERCE
Patent and Trademark Office
37 CFR Part 1
[Docket No. 2003–P–021]
RIN 0651–AB61
January 2004 Revision of Patent Cooperation Treaty Application Procedure
AGENCY: Patent and Trademark Office, Commerce.
ACTION: Final rule.
SUMMARY: The United States Patent and Trademark Office (Office) is amending the rules of practice to conform them to certain amendments made to the Regulations under the Patent Cooperation Treaty (PCT) that will take effect on January 1, 2004. These amendments will result in the addition of a written opinion in PCT Chapter I, as well as a simplification of PCT designations and the PCT fee structure. In addition, the Office is adjusting the transmittal, search, and international preliminary examination fees for international applications filed under the PCT to be more closely aligned with the actual average costs of processing a PCT application and conducting a PCT search and international preliminary examination under the new process.
FOR FURTHER INFORMATION CONTACT: Richard R. Cole, Legal Examiner, Office of PCT Legal Administration (OPCTLA) directly by telephone at (703) 305–6639, or by facsimile at (703) 308–6459.
SUPPLEMENTARY INFORMATION: During the September-October 2002 meeting of the Governing Bodies of the World Intellectual Property Organization (WIPO), the PCT Assembly adopted various amendments to the Regulations under the PCT that enter into force on January 1, 2004. The amended PCT Regulations were published in the PCT Gazette of December 5, 2002 (49/2002), in Section IV, at pages 25004–61. The purposes of these amendments are to: (1) Improve coordination of international search (Chapter I of the PCT) and international preliminary examination (Chapter II of the PCT) through the provision of an enhanced international search and preliminary examination system; (2) simplify the PCT by changing the concept and operation of the designation system and the fee system; and (3) simplify signature and other filing requirements. Enhanced International Search and Preliminary Examination System: Under the enhanced international search and
preliminary examination system, the written opinion currently established during the Chapter II procedure by the International Preliminary Examining Authority (IPEA) has been added to the Chapter I procedure. Accordingly, the International Searching Authority (ISA) will be responsible for establishing a preliminary and non-binding written opinion on whether the claimed invention appears to be novel, to involve an inventive step and to be industrially applicable. In the event that a Demand for international preliminary examination is timely filed by applicant, the written opinion of the ISA will be considered to be the written opinion of the IPEA. If a Demand is not timely filed, the written opinion of the ISA will form the basis for the issuance, by the International Bureau (IB) on behalf of the ISA, of an International Preliminary Report on Patentability (Chapter I of the Patent Cooperation Treaty) ("IPRP"), which will be communicated to all designated Offices and made available for public inspection after the expiration of thirty months from the priority date.

Under the revised system, the time limit for filing a Demand for international preliminary examination has changed. Specifically, the Demand must be filed within the later of: (1) Three months from issuance of the international search report and the written opinion of the ISA (or, if a search cannot be made, of the declaration under Article 17.2(a)); or (2) twenty-two months from the priority date. See PCT Rule 54bis.1(a). Any Demand made after the expiration of this time limit will be considered as if it had not been submitted. See PCT Rule 54bis.1(b). Any arguments or amendments in response to the written opinion of the ISA must be submitted within the time limit for filing the Demand to ensure consideration by the IPEA. It is noted that applicants may still desire to file the Demand prior to the expiration of nineteen months from the priority date in order to delay entry into the national stage for those few remaining Contracting States that have taken a reservation to the thirty-month time limit in Article 22(1).

As in current PCT Chapter II procedures, the IPEA will still establish an international preliminary examination report, though the report will now bear the title "International Preliminary Report on Patentability (Chapter II of the Patent Cooperation Treaty)." This report will be established within the applicable time limit under PCT Rule 69 (usually within twenty-eight months from the priority date).

Under the revised system, payment of the international preliminary examination fee and handling fee is not required until the later of one month from the filing of the Demand or twenty-two months from the priority date. See PCT Rules 57.3(a) and 58.1(b). However, where the IPEA and the ISA are the same and the IPEA wishes to start examination at the same time as the international search, the IPEA may require that the examination and handling fees be paid within one month of an invitation by the IPEA to pay such fees. See PCT Rule 57.3(c).

Automatic Indication of All Designations Possible under the PCT; Relaxed Signature and other Filing Requirements; Simplified Fee System:
Under the amendments to the Regulations of the PCT, upon filing an international application, applicant will obtain automatic and all-inclusive coverage of all designations available under the PCT, including all kinds of protection as well as both national and regional patent protection. See PCT Rule 4.9. Similarly, the mere filing of a Demand will constitute the election of all designated States. See PCT Rule 53.7. Thus, applicants need not, at the time of filing the international application, specifically designate individual Contracting States, or choose certain kinds of protection or indicate expressly whether national or regional protection is sought. Such matters will be resolved in the national phase.

This automatic and all-inclusive designation system overcomes a current pitfall for applicants who have inadvertently omitted specific designations upon filing the international application and such designations were not, or could not be, timely confirmed under PCT Rule 4.9(c). For example, if the original international application papers did not contain at least one designation, an international filing date could not be accorded as of the initial receipt date of the application papers. See PCT Article 11(1)(ii)(b). Furthermore, even in those applications containing at least one designation, PCT Rule 4.9(b) required that any additional States and/or additional kinds of protection be confirmed by the submission of a written notice, accompanied by payment of the appropriate confirmation fee, within a relatively short time period (i.e., fifteen months from the priority date). This time period was frequently overlooked by applicants. Under the new system of automatic designations/elections, the current procedures for precautionary designations and later elections become unnecessary and have been eliminated from the PCT Rules. This will reduce the workload on the PCT Receiving Office (RO) and IPEA by eliminating processing of precautionary designations and later elections, as well as petitions relating to omitted designations.

As a further benefit of the automatic designation system is the simplification of the PCT fee system. Under the current PCT fee structure, both a “basic” fee and a “designation” fee are required. Moreover, these fees are due at different times in different amounts depending on when they are paid. Under the new system, these fees have been eliminated in favor of a single international filing fee (comprised of two fee components, a first fee component for up to thirty sheets of paper and a second fee component for sheets of paper in excess of thirty) due at one time.

As a consequence of the automatic designation system, applicant/inventors will have to be named in the international application. To alleviate hardships with regard to obtaining signatures of all the applicants named on the Request, PCT Rule 26 has been amended to provide that, for purposes of Article 14(a)(i), the international application will be considered as signed in accordance with the PCT Regulations if the Request has been signed by at least one applicant. See PCT Rule 26.2bis(a). In addition, if there is more than one applicant, PCT Rule 26.2bis(b) provides that, for purposes of PCT Article 14(1)(a)(ii), it is sufficient that the identifying information (i.e., address, residence and nationality) be provided for only one applicant who is entitled under PCT Rule 19.1 to file the international application with the RO. This means that for purposes of filing an international application with the United States Receiving Office (RO/US) as the competent RO, this information must be provided with respect to at least one applicant who is a citizen or resident of the United States. Notwithstanding the amendments to PCT Rule 26, a designated/elected Office may still require applicants to furnish, during the national stage, confirmation of the international application by the signature of any applicant who has not signed the Request and any missing identifying information. See PCT Rule 5bis.1(a).

PCT Rule 90.4 has been revised to permit the RO, ISA, and IPEA to waive the requirement for a patent attorney, except in instances of applicant initiated withdrawals under PCT Rule 90bis.
Discussion of Specific Rules

Title 37 of the Code of Federal Regulations, Part 1, is amended as follows:

Section 1.14: Sections 1.14(g)(1)(ii) and 1.14(g)(3) are amended to exclude members of the public from obtaining a copy of the written opinion of the United States International Searching Authority (ISA/US) until the expiration of thirty months from the priority date of the international application. Under PCT Rule 44ter.1 (as amended), the ISA is not permitted to allow access to the written opinion of the ISA before the expiration of thirty months from the priority date unless authorized by the applicant.

Section 1.413: Section 1.413(c) is amended to reflect the additional major function of the ISA/US of preparing and transmitting written opinions.

Section 1.421: Section 1.421(b) is amended to remove reference to § 1.425 (§ 1.425 is removed). Under PCT Rule 26.2bis(a) (as amended), the international application will be considered to satisfy the signature requirement for purposes of PCT Article 14(1)(a)(i) if the request is signed by at least one applicant (except that all of the applicants’ signatures will still be required for withdrawals, see discussion of § 1.421(g)). Accordingly, the current requirement in § 1.425 that the failure of an inventor to sign the request in an international application designating the United States will only be excused where the inventor could not be found or reached after diligent effort or refused to sign the request will no longer be applicable. Section 1.421(b) is also amended to include the requirement of § 1.424 that joint inventors must jointly apply for an international application. Section 1.424 is removed (see discussion of § 1.424).

Section 1.421(c) is amended as a consequence of the change to PCT Rule 4.9, as the United States will always be designated upon filing of an international application.

Section 1.421(d) is amended to reflect the change to PCT Rule 90.4(d) permitting the RO to waive the requirement for a separate power of attorney.

Section 1.421(f) is amended to clarify that for purposes of requests under PCT Rule 92bis to effect a change in an indication concerning the applicant, agent or common representative, such requests may be required to be signed by all applicants.

Section 1.421(g) is amended to remove Rule 92bis of PCT Rule 92bis as unnecessary and to clarify that for purposes of withdrawals under PCT Rule 90bis of the international application, designations, priority claim, demand or elections, the request for withdrawal must be signed by all applicants. Furthermore, where the request for withdrawal is signed by an attorney, agent, or common representative, a power of attorney from the applicants appointing that attorney, agent or common representative will be required. This clarification is consistent with PCT Rule 90.4(e) (as amended), which prohibits the RO, ISA, IPEA, and IB from waiving the separate power of attorney requirement in cases of withdrawals under Rule 90bis. An exception to this signature requirement is made in cases where an inventor cannot be found or reached after diligent effort. See PCT Rule 90bis.5(b).

Section 1.424: This section is removed. The requirement in § 1.424 regarding the naming of joint inventors in international applications will be moved to § 1.421(b). The further requirement relating to signature requirements of joint inventors including reference to § 1.425, will no longer be applicable (see discussion of § 1.421(b)).

Section 1.425: This section is removed (see discussion of § 1.421(b)).

Section 1.431: Section 1.431(b)(3) is amended to remove reference to § 1.424 (§ 1.424 is removed). Sections 1.431(c) and (d) are amended to reflect the new fee structure applicable to international applications under revised PCT Rule 15. Specifically, the international “basic fee” and “designation fee” have been combined into a single “international filing fee.” In addition, the late payment fee provision of § 1.431(c)(1) is amended as a consequence of this new fee structure, consistent with amended PCT Rule 16bis.2.

Section 1.432: Section 1.432 is amended to reflect the change to PCT Rule 4.9, which provides that the filing of the request shall constitute: (1) The designation of all Contracting States that are bound by the PCT on the international filing date; (2) an indication that for those States for which PCT Articles 43 or 44 apply, the filing of the request constitutes an indication for the grant of every kind of protection which is available by way of the designation of that State; and (3) an indication that the international application is, for those States to which PCT Article 45(1) applies, for the grant of a regional patent and also, unless PCT Article 45(2) applies, a national patent. As a consequence of the “automatic” designation system provided under revised Rule 4.9, the procedure under former PCT Rule 4.9(b) and (c) regarding confirmation of precautionary designations has been eliminated from that rule, and therefore, is removed from § 1.432.

Section 1.434: Section 1.434(d) is amended to remove the requirement that international applications designating the United States must include the address and the signature of the inventor except as provided by §§ 1.421(d), 1.422, 1.423 and 1.425. Under PCT Rule 26.2bis (as amended), if there is more than one applicant, it is sufficient that the request is signed by only one of them, and that the address is provided with respect to one of the applicants who is entitled, in accordance with Rule 19.1, to file the international application with the RO. Section 1.434(d)(3) is also redesignated as new § 1.434(e) for clarity.

Section 1.445: Section 1.445(a)(1) is amended to increase the transmittal fee from $240.00 to $300.00. 35 U.S.C. 376(a) authorizes the Office to (inter alia) prescribe the transmittal fee, search fee, supplemental search fee, and preliminary examination fee for PCT international applications. This transmittal fee amount more accurately reflects the Office’s actual average costs of processing international applications, and is also consistent with the filing fee for applications under 35 U.S.C. 111(a) proposed by the Office in the 21st Century Strategic Plan (information concerning the Office’s 21st Century Strategic Plan is available on the Office’s Internet Web site http://www.uspto.gov).

Section 1.445(a)(2)(ii) is amended to reduce the search fee charged by the ISA/US where there is a corresponding prior U.S. application filed under 35 U.S.C. 111(a) from $450 to $300. Section 1.445(a)(2)(ii) is also amended to clarify the conditions for obtaining benefit of the reduced search fee where there is such a prior corresponding application. Pursuant to PCT Rule 42.1, the ISA/US has, in most cases, only three months to establish the International Search Report. In order for the ISA/US to be able to utilize the benefits of a search conducted in a prior corresponding application filed under 35 U.S.C. 111(a), the Office must be informed of the prior corresponding application in sufficient time and in such manner so as to permit the Office to utilize the search and examination conducted in the prior application. Accordingly, § 1.445(a)(2)(ii) is amended to require applicants to timely furnish adequate identifying information of the prior U.S. application in order to qualify for the lower search fee. Specifically, applicants must identify the prior nonprovisional application by U.S. application number upon filing the application.
Section 1.480(a) is amended to reflect the new time limits in PCT Rule 57.3 and Rule 58.2 for submitting the handling and preliminary examination fees.

Section 1.480(d) is added, consistent with PCT Rule 53.7 (as amended), to provide that the filing of a Demand shall constitute the election of all Contracting States that are designated and bound by Chapter II of the Treaty on the international filing date. Accordingly, it will no longer be necessary to specify in the Demand those States that are elected.

Section 1.480(e) is added to provide that any Demand filed after the expiration of the applicable time limit in PCT Rule 54bis.1(a) shall be considered as if it had not been submitted. See PCT Rule 54bis.1(b) (as amended).

Section 1.481: Section 1.481(a) is amended to provide that the handling fee and preliminary examination fee that are due are those fees in effect on the date of payment of the handling and preliminary examination fees. See PCT Rules 57.3(d) and 58.1(b).

Section 1.482: Section 1.482(a)(1) is amended to increase the preliminary examination fee charged by the IPEA/US from $490 to $600 if the international search fee was paid to the United States Patent and Trademark Office as an ISA (the preliminary examination fee charged by the IPEA/US if the international search fee was not paid to the United States Patent and Trademark Office as an ISA will remain at $750). This increase is necessary to cover the additional cost associated with conducting the preliminary examination by the IPEA/US. For the same reason, as well as reasons set forth with regard to the increase in the supplemental search fee under § 1.445(a)(3), § 1.482(a)(2) is amended to increase the additional preliminary examination fee for examining additional inventions to $600 (regardless of whether the international search fee was paid to the United States Patent and Trademark Office as an ISA). This increase is necessary to cover the additional cost associated with conducting the preliminary examination by the IPEA/US. The same reason, as well as reasons set forth with regard to the increase in the supplemental search fee under § 1.445(a)(3), § 1.482(a)(2) is amended to increase the additional preliminary examination fee for examining additional inventions to $600 (regardless of whether the international search fee was paid to the United States Patent and Trademark Office as an ISA).

Section 1.482(b) is amended to refer to revised PCT Rule 57 as it relates to handling fee requirements.

Section 1.484: Section 1.484(b) is amended to refer to revised PCT Rule 69.1 as to when the IPEA/US may start international preliminary examination. PCT Rule 69.1 was revised to prohibit the IPEA from starting preliminary examination until it is in possession of, inter alia, the written opinion of the ISA. PCT Rule 69.1 provides for two exceptions to this requirement. Both exceptions apply when the IPEA and the ISA for the international application are the same authority. The first exception permits the IPEA to start examination of the application as the international search, subject to certain limitations. See PCT Rule 69.1(b). The second exception occurs when the ISA considers the conditions under PCT Article 34(2)(c)(i) to (iii) to be fulfilled. In such cases, a written opinion by the ISA need not be established. See PCT Rule 69.1(bbis).

Sections 1.484(e) through (g) are redesignated as §§ 1.484(g) through (i), respectively. Section 1.484(e) now provides, consistent with PCT Rule 66.1bis, that the written opinion of the ISA shall be considered to be the written opinion of the IPEA/US. Section 1.484(f) now provides that the IPEA may establish further written opinions, subject to the conditions specified in § 1.484(d). Establishment of additional written opinions by the IPEA is provided for in PCT Rule 66.4(a).

Section 1.484(g) is amended as a consequence of the amendment to § 1.484(f).

Section 1.484(h) is amended to provide clarification regarding conducting personal and telephonic interviews with the examiner under the revised system.

Response to comments: The Office published a notice proposing changes to the rules of practice to conform them to certain amendments made to the Regulations under the Patent Cooperation Treaty (PCT) that will take effect on January 1, 2004. See January 2004 Revision of Patent Cooperation Treaty Application Procedure, 68 FR 32441 (May 30, 2003), 1271 Off. Gaz. Pat. Office 147 (June 24, 2003) (proposed rule). The Office received two written comments (one from an intellectual property organization and another by a patent practitioner) in response to this notice. The comments and the Office’s responses to the comments follow:

Comment 1: One comment suggested that § 1.14 should provide that the written opinion of the International Searching Authority is available to third parties upon publication of the international application instead of at thirty months as provided in § 1.14.

Response: The suggestion has not been adopted. PCT Rule 44ter.1, which is set to enter into force on January 1, 2004, provides that the International Searching Authority, unless requested or authorized by the applicant, shall not allow access to the written opinion of the International Searching Authority by any person before the expiration of thirty months from the priority date. Therefore, the suggested change to § 1.14 would be inconsistent with the requirements of the PCT.

Comment 2: One comment suggested that the rules be amended to provide that if applicant timely files a Demand with Article 34 amendments to the
claims, the examiner be required to render a new written opinion. The comment indicates that without such a provision, the IPEA/US, in adopting the written opinion as established by the ISA, will be delivering to applicants written opinions which are totally inconsistent with the claims as amended.

Response: The suggestion has been adopted in part. Under the enhanced search and examination system, the IPEA/US will not deliver to applicants a written opinion which does not take into account the claims as amended. In general, under the procedures established under the enhanced search and examination system, a written opinion will be established by the ISA, and upon filing of a Demand by applicant, that written opinion will be considered to be the first written opinion of the IPEA. In turn, any amendments under PCT Article 34 which are timely filed, either with or subsequent to the Demand, will be considered to be a response to that written opinion. In response to the Demand and any amendments, the IPEA/US will then issue one of the following: (1) A further written opinion under § 1.484(f) if such is warranted; or (2) an international preliminary examination report under § 1.484(g). In both instances, the response by the IPEA will fully take into consideration any amendments which have been timely filed by the applicant.

Comment 3: One comment also opposed the proposed changes in the PCT fees set forth in §§ 1.445 and 1.482. First, the comment indicated that the transmittal, search, and preliminary examination fees proposed in §§ 1.445 and 1.482 would be sixty percent higher than the filing fee, search fee, and examination fee proposed in the 21st Century Strategic Plan. Second, the comment indicated that an applicant must also pay the preliminary examination fee to amend the claims in an international application and obtain a written opinion reflecting the amended claims. Nevertheless, it is the Office’s experience that PCT applicants who file a Demand for international preliminary examination rarely include an amendment under PCT Article 34 with the Demand. Therefore, the enhanced international search and preliminary examination system will reduce costs for most PCT applicants by providing them with the benefits they seek from PCT Chapter II, namely, an extension (from twenty to thirty months) of the time limit for entering the national stage and a written opinion indicating whether the claims are in compliance with PCT Article 33(2)-(4), without requiring them to file a timely Demand for international preliminary examination and pay the international publication fee. When making an item-by-item comparison of the existing transmittal, search, and international preliminary examination fees with the revised transmittal, search, and international preliminary examination fees, one would readily appreciate the following: The enhanced international search and preliminary examination system reduces costs for most PCT applicants by providing them with the benefits they seek from PCT Chapter II without requiring them to pay the international preliminary examination fee. The Office’s costs for searching international applications are higher under the enhanced international search and preliminary examination system because international applications must be searched (and examined) under the PCT unity of invention standard and the search fee must also cover the preparation of a written opinion. The Office’s costs for international preliminary examination will be higher in certain situations under the enhanced international search and preliminary examination system because the Office will be required to provide an international preliminary examination on the basis of one or more amendments under PCT Article 34 since applicants filing a Demand under the revised system will likely be doing so to obtain a positive “International Preliminary Report on Patentability (Chapter II of the Patent Cooperation Treaty)” and thus will file one or more amendments under PCT Article 34 in the international application (under the former system, the majority of Demands were filed for the sole purpose of extending the national stage entry period and thus were filed without any substantial amendments to the claims). Finally, the fees set forth in former §§ 1.445 and 1.482 for search and examination of additional inventions were far too low to recover the Office’s actual average cost for search and examination of additional inventions.

Rule Making Considerations: Regulatory Flexibility Act: The USPTO published a proposed rule and certified that an initial Regulatory Analysis was not required. Only one comment was received which objected, in general, to the fee increases and made no reference to any impact of the fee increases on small entities. The Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that changes in this final rule will not have a significant economic impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)).

The changes in this final rule primarily implement corresponding changes required to conform United States rules for international applications to the amendments to the PCT Regulations, which become effective on January 1, 2004. The amendments to the PCT Regulations will simplify the PCT application process and fee structure. The changes to the PCT international stage fees are to adjust these fees to be in alignment with the actual average costs of conducting a PCT search and international
preliminary examination under the new process.

Executive Order 13132: This rule making does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

Executive Order 12866: This rule making has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

Paperwork Reduction Act: This final rule involves information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The collections of information involved in this final rule have been reviewed and previously approved by OMB under the following control numbers: 0651–0021 and 0651–0031. The United States Patent and Trademark Office is not resubmitting any information collection package to OMB for its review and approval because the changes in this notice do not affect the information collection requirements associated with the information collection under these OMB control numbers.

The title, description and respondent description of the information collection is shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Number: 0651–0021.

Title: Patent Processing (Updating).


Type of Review: Approved through July of 2006.

Affected Public: Individuals or households, business or other for-profit institutions, not-for-profit institutions, farms, Federal Government and State, Local and Tribal Governments.

Estimated Number of Respondents: 2,208,339.

Estimated Time Per Response: 1 minute 48 seconds to 8 hours.

Estimated Total Annual Burden Hours: 830,629 hours.

Needs and Uses: During the processing of an application for a patent, the applicant/agent may be required or desire to submit additional information to the Office concerning the examination of a specific application. The specific information required or which may be submitted includes: Information Disclosure Statements; Terminal Disclaimers; Petitions to Revive; Express Abandonments; Appeal Notices; Petitions for Access; Powers to Inspect; Certificates of Mailing or Transmission; Statements under § 3.73(b); Amendments, Petitions and their Transmittal Letters; and Deposit Account Order Forms. Comments are invited on: (1) Whether the collection of information is necessary for proper performance of the functions of the agency; (2) the accuracy of the agency’s estimate of the burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information to respondents.

Interested persons are requested to send comments regarding these information collections, including suggestions for reducing this burden, to Robert J. Spar, Director, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, Virginia, 22313–1450, or to the Office of Information and Regulatory Affairs of OMB, New Executive Office Building, 725 17th Street, NW., Room 10235, Washington, DC 20503, Attention: Desk Officer for the United States Patent and Trademark Office.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons set forth in the preamble, 37 CFR Part 1 is amended as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR Part 1 continues to read as follows:


2. Section 1.14 is amended by revising paragraphs (g)(1)(ii) and (g)(3) to read as follows:

§ 1.14 Patent applications preserved in confidence.

* * * * *

(g) * * * (i) (1) * * *

(ii) With respect to the Search Copy (the copy of an international application kept by the Office in its capacity as the International Searching Authority, see PCT Article 12(1)), the U.S. acted as the International Searching Authority, except for the written opinion of the International Search Authority which shall not be available until the expiration of thirty months from the priority date; or

* * * * *

(3) Access to international application files for international applications which designate the U.S. and which have been published in accordance with PCT Article 21(2), or copies of a document in such application files, will be permitted in accordance with PCT Articles 30 and 38 and PCT Rules 44 ter. 1, 94.2 and 94.3, upon written request including a showing that the publication of the application has occurred and that the U.S. was designated.

* * * * *

3. Section 1.413 is amended by revising paragraphs (a) and (c) to read as follows:

§ 1.413 The United States International Searching Authority.

(a) Pursuant to appointment by the Assembly, the United States Patent and Trademark Office will act as an International Searching Authority for international applications filed in the United States Receiving Office and in other Receiving Offices as may be agreed upon by the Director, in
accordance with the agreement between the Patent and Trademark Office and the International Bureau (PCT Art. 16(3)(b)).

(c) The major functions of the International Searching Authority include:
(1) Approving or establishing the title and abstract;
(2) Considering the matter of unity of invention;
(3) Conducting international and international-type searches and preparing international and international-type search reports (PCT Art. 15, 17 and 18, and PCT Rules 25, 33 to 45 and 47), and issuing declarations that no international search report will be established (PCT Article 17(2)(a));
(4) Preparing written opinions of the International Searching Authority in accordance with PCT Rule 43bis (when necessary); and
(5) Transmitting the international search report and the written opinion of the International Searching Authority to the applicant and the International Bureau.

4. Section 1.421 is amended by revising paragraphs (b) through (g) as follows:

§ 1.421 Applicant for international application.

(b) Although the United States Receiving Office will accept international applications filed by any resident or national of the United States of America for international processing, for the purposes of the designation of the United States, an international application must be filed, and will be accepted by the Patent and Trademark Office for the national stage only if filed, by the inventor or as provided in §§ 1.422 or 1.423. Joint inventors must jointly apply for an international application.

(c) For the purposes of designations other than the United States, international applications may be filed by the assignee or owner.

(d) A registered attorney or agent of the applicant may sign the international application Request and file the international application for the applicant. A separate power of attorney from each applicant may be required.

(e) Any indication of different applicants for the purpose of different Designated Offices must be shown on the Request portion of the international application.

(f) Requests for changes in the indicia concerning the applicant, agent, or common representative of an international application shall be made in accordance with PCT Rule 92bis and may be required to be signed by all applicants.

(g) Requests for withdrawals of the international application, designations, priority claims, the Demand, or elections shall be made in accordance with PCT Rule 90bis and must be signed by all applicants. A separate power of attorney from the applicants will be required for the purposes of any request for a withdrawal in accordance with PCT Rule 90bis which is not signed by all applicants. The submission of a separate power of attorney may be excused upon the request of another applicant where one or more inventors cannot be found or reached after diligent effort. Such a request must be accompanied by a statement explaining to the satisfaction of the Director the lack of the signature concerned.

§ 1.424 [Removed]

5. Section 1.424 is removed.

§ 1.425 [Removed]

6. Section 1.425 is removed.

7. Section 1.431 is amended by revising paragraphs (b)(3), (c) and (d) to read as follows:

§ 1.431 International application requirements.

(b) * * * * *

(3) The international application contains at least the following elements (PCT Art. 11(1)(iii)):

(i) An indication that it is intended as an international application (PCT Rule 4.2);

(ii) The designation of at least one Contracting State of the International Patent Cooperation Union (§ 1.432);

(iii) The name of the applicant, as prescribed (note §§ 1.421–1.423);

(iv) A part which on the face of it appears to be a description; and

(v) A part which on the face of it appears to be a claim.

(c) Payment of the international filing fee (PCT Rule 15.2) and the transmittal and search fees (§ 1.445) may be made in full at the time the international application papers required by paragraph (b) of this section are deposited or within one month thereafter. The international filing, transmittal, and search fee payable is the international filing, transmittal, and search fee in effect on the receipt date of the international application.

(1) If the international filing, transmittal and search fees are not paid within one month from the date of receipt of the international application and prior to the sending of a notice of deficiency which imposes a late payment fee, applicant will be notified and given one month within which to pay the deficient fees plus the late payment fee. Subject to paragraph (c)(2) of this section, the late payment fee will be equal to the greater of:

(i) Fifty percent of the amount of the deficient fees; or

(ii) An amount equal to the transmittal fee.

(2) The late payment fee shall not exceed an amount equal to the 25% of the international filing fee not taking into account any fee for each sheet of the international application in excess of thirty sheets (PCT Rule 16bis).

(3) The one-month time limit set pursuant to paragraph (c) of this section to pay deficient fees may not be extended.

(d) If the payment needed to cover the transmittal fee, the international filing fee, the search fee, and the late payment fee pursuant to paragraph (c) of this section is not timely made in accordance with PCT Rule 16bis.1(e), the Receiving Office will declare the international application withdrawn under PCT Article 14(5)(a).

8. Section 1.432 is revised to read as follows:

§ 1.432 Designation of States by filing an international application.

The filing of an international application request shall constitute:

(a) The designation of all Contracting States that are bound by the Treaty on the international filing date;

(b) An indication that the international application is, in respect of each designated State to which PCT Article 43 or 44 applies, for the grant of every kind of protection which is available by way of the designation of that State; and

(c) An indication that the international application is, in respect of each designated State to which PCT Article 45(1) applies, for the grant of a regional patent and also, unless PCT Article 45(2) applies, a national patent.

9. Section 1.434 is amended by revising paragraph (d) and adding paragraph (e) to read as follows:

§ 1.434 The request.

(d) For the purposes of the designation of the United States of America, an international application shall include:

(1) The name of the inventor; and

(2) A reference to any prior-filed national application or international application designating the United States of America, if the benefit of the filing date for the prior-filed application is to be claimed.
(e) An international application may also include in the Request a declaration of the inventors as provided for in PCT Rule 4.17(iv).

§ 1.445 International application filing, processing and search fees.

(a) The following fees and charges for international applications are established by the Director under the authority of 35 U.S.C. 376:

(1) A transmittal fee (see 35 U.S.C. 361(d) and PCT Rule 14)—$300.00

(2) A search fee (see 35 U.S.C. 361(d) and PCT Rule 16):

   (i) If a corresponding prior United States National application filed under 35 U.S.C. 111(a) with the filing fee under § 1.16(a) has been filed and the corresponding prior United States National application is identified by application number, if known, or if the application number is not known by the filing date, title, and name of applicant (and preferably the application docket number), in the international application or accompanying papers at the time of filing the international application—$300.00

   (ii) For all situations not provided for in paragraph (a)(2)(i) of this section—$1,000.00

(3) A supplemental search fee when required, per additional invention—$1,000.00

(4) A fee equivalent to the transmittal fee in paragraph (a)(1) of this section for transmittal of an international application to the International Bureau for processing in its capacity as a Receiving Office (PCT Rule 19.4).

(b) The international filing fee shall be as prescribed in PCT Rule 15.

§ 1.455 Representation in international applications.

* * * * *

(b) Appointment of an agent, attorney or common representative (PCT Rule 4.8) must be effected either in the Request form, signed by applicant, in the Demand form, signed by applicant, or in a separate power of attorney submitted either to the United States Receiving Office or to the International Bureau.

* * * * *

§ 1.480 Demand for international preliminary examination.

(a) On the filing of a proper Demand in an application for which the United States International Preliminary Examination Authority is competent and for which the fees have been paid, the international application shall be the subject of an international preliminary examination. The preliminary examination fee (§ 1.482(a)(1)) and the handling fee (§ 1.482(b)) shall be due within the applicable time limit set forth in PCT Rule 57.3.

* * * * *

(d) The filing of a Demand shall constitute the election of all Contracting States which are designated and are bound by Chapter II of the Treaty on the international filing date (PCT Rule 53.7).

(e) Any Demand filed after the expiration of the applicable time limit set forth in PCT Rule 54bis.1(a) shall be considered as if it had not been submitted (PCT Rule 54bis.1(b)).

§ 1.481 Payment of international preliminary examination fees.

(a) The handling and preliminary examination fees shall be paid within the time period set in PCT Rule 57.3. The handling fee or preliminary examination fee is payable on the date of payment.

(1) If the handling and preliminary examination fees are not paid within the time period set in PCT Rule 57.3, the applicant will be notified and given one month within which to pay the deficient fees plus a late payment fee equal to the greater of:

   (i) Fifty percent of the amount of the deficient fees, but not exceeding an amount equal to double the handling fee;

   (ii) An amount equal to the handling fee (PCT Rule 56bis.2).

(2) The one-month time limit set in this paragraph to pay deficient fees may not be extended.

* * * * *

§ 1.482 International preliminary examination fees.

(a) The following fees and charges for international preliminary examination are established by the Director under the authority of 35 U.S.C. 376:

(1) The preliminary examination fee is due on filing the Demand:

   (i) If an international search fee as set forth in § 1.445(a)(2) has been paid on the international application to the United States Patent and Trademark Office as an International Searching Authority—$600.00

   (ii) If the International Searching Authority for the international application was an authority other than the United States Patent and Trademark Office—$750.00

(ii) An additional preliminary examination fee when required, per additional invention—$600.00

(b) The handling fee is due on filing the Demand and shall be as prescribed in PCT Rule 57.

§ 1.484 Conduct of international preliminary examination.

* * * * *

(b) International preliminary examination will begin in accordance with PCT Rule 69.1.

* * * * *

(e) The written opinion established by the International Searching Authority under PCT Rule 43bis.1 shall be considered to be a written opinion of the United States International Preliminary Examining Authority for the purposes of paragraph (d) of this section.

(f) The International Preliminary Examining Authority may establish further written opinions under paragraph (d) of this section.

§ 1.481 Payment of international preliminary examination fees.

* * * * *

(b) An applicant will be permitted a personal or telephone interview with the examiner, which may be requested after the filing of a Demand, and must be conducted during the period between the establishment of the written opinion and the establishment of the international preliminary examination report. Additional interviews may be conducted where the examiner determines that such additional interviews may be helpful to advancing the international preliminary examination procedure. A summary of any such personal or telephone interview must be filed by the applicant or, if not filed by applicant be made of record in the file by the examiner.

(i) If the application whose priority is claimed in the international application
is in a language other than English, the United States International Preliminary Examining Authority may, where the validity of the priority claim is relevant for the formulation of the opinion referred to in Article 33(1), invite the applicant to furnish an English translation of the priority document within two months from the date of the invitation. If the translation is not furnished within that time limit, the international preliminary report may be established as if the priority had not been claimed.

Jon W. Dudas,
Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office.

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DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

50 CFR Part 679
[Docket No. 021122286–3036–02; I.D. 101403B]

Fisheries of the Economic Exclusive Zone Off Alaska; Trawl Gear in the Gulf of Alaska

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

ACTION: Closure.

SUMMARY: NMFS is closing directed fishing for groundfish by vessels using trawl gear in the Gulf of Alaska (GOA), except for directed fishing for pollock by vessels using pelagic trawl gear in those portions of the GOA open to directed fishing for pollock. This action is necessary because the 2003 Pacific halibut PSC limit for vessels using trawl was established as 2,600 metric tons (mt) by the final 2003 harvest specifications for groundfish of the GOA (68 FR 9924, March 3, 2003).

The Administrator, Alaska Region, has determined, in accordance with §679.21(d)(7)(i), that vessels engaged in directed fishing for groundfish with trawl gear in the GOA have caught the 2003 Pacific halibut PSC limit. Therefore, NMFS is closing the directed fishery for groundfish by vessels using trawl gear in the GOA, except for directed fishing for pollock by vessels using pelagic trawl gear in those portions of the GOA that remain open to directed fishing for pollock.

Classification
This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is contrary to the public interest. This requirement is contrary to the public interest as it would delay the closure of the fishery, lead to exceeding the 2003 Pacific halibut PSC limit and therefore reduce the public’s ability to use and enjoy the fishery resource.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by §679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 et seq.
Bruce C. Morehead,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

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DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

50 CFR Part 679
[Docket No. 021213310–3251–03; I.D. 100203C]

RIN 0648–AP92

Individual Fishing Quota (IFQ) Program for Pacific Halibut and Sablefish; Technical Amendment

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

ACTION: Final rule; technical amendment.

SUMMARY: This document reinstates recordkeeping and reporting regulations implementing the IFQ Cost Recovery Program which were inadvertently removed from regulations in a final rule published in the Federal Register on July 29, 2003. That final rule implemented Amendment 72 to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (Amendment 72) and Amendment 64 to the Fishery Management Plan for the Groundfish Fishery of the Gulf of Alaska (Amendment 64) (collectively, Amendments 72/64) and revised recordkeeping and reporting requirements for the IFQ and CDQ halibut programs. This action is necessary to correct the error and restore the regulations implementing the IFQ Cost Recovery Program.


FOR FURTHER INFORMATION CONTACT: Patsy A. Bearden, 907–586–7228 or patsy.bearden@noaa.gov.

SUPPLEMENTARY INFORMATION: The IFQ Cost Recovery Program is managed by the NMFS, Alaska Region, Restricted Access Management (RAM). Regulations implementing the IFQ Cost Recovery Program were published in the Federal Register on March 20, 2000 (65 FR 14919) and amended by publication in the Federal Register on January 28, 2002 (67 FR 4100). Under the regulations, an IFQ permit holder incurs a cost recovery fee liability for each pound of IFQ halibut or sablefish landed on his/her permit(s). The regulations included recordkeeping and reporting requirements at §679.5(l)(7) necessary to implement the IFQ Cost Recovery Program. See 65 FR 14923 (March 20, 2000), amended at 67 FR 4130 (January 28, 2002). A final rule published in the Federal Register on