Dated: October 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–26866 Filed 11–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2004–P–0205 (formerly Docket No. 2004P–0464)]

Food Labeling: Health Claims; Calcium and Osteoporosis, and Calcium, Vitamin D, and Osteoporosis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of Monday, September 29, 2008 (73 FR 56477). The final rule was published with an inadvertent error in the ''Analysis of Economic Impacts'' section. This document corrects that error.

DATES: This correction is effective: November 12, 2008.

FOR FURTHER INFORMATION CONTACT: Jillonne Kevala, Office of Nutrition, Labeling, and Dietary Supplements (HFS–830), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1450.

SUPPLEMENTARY INFORMATION: In FR Doc. E8–22730, appearing on page 56477 in the **Federal Register** of September 29, 2008, the following correction is made:

1. On page 56481, in the second column, starting in the forth line, the sentence ''Therefore, because of the limited use of the current calcium and osteoporosis health claim, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.'' is corrected to read ''Therefore, because of the limited use of the current calcium and osteoporosis health claim, the agency believes that the final rule will not have a significant economic impact on a substantial number of small entities.''

Dated: November 5, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–26868 Filed 11–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 578

Decorations, Medals, Ribbons, and Similar Devices

AGENCY: Department of the Army, DOD.

ACTION: Final rule; removal.

SUMMARY: This action removes 32 CFR Part 578, Decorations, Medals, Ribbons, and Similar Devices. The Department of the Army has determined that the rules prescribing policy and criteria for military awards and the administrative instructions for processing military awards are not required to be published in the Code of Federal Regulations (CFR) because they are not generally applicable and have no legal effect per 44 U.S.C. 1505.

DATES: Effective date November 12, 2008.

ADDRESSES: U.S. Army Human Resources Command, *ATTN:* AHRC–PDP–A, 200 Stovall Street, Alexandria, VA 22332–0471.

FOR FURTHER INFORMATION CONTACT: Mr. Les Plooster, Policy Section, Military Awards Branch, 703–325–4761.

SUPPLEMENTARY INFORMATION: The Deputy Chief of Staff, G–1, is the proponent for the regulation represented in 32 CFR Part 578. The objective of the Department of the Army Military Awards Program is to provide tangible recognition for acts of valor, exceptional service or achievement, special skills or qualifications, and acts of heroism not involving actual combat. Implementation of the program is a command responsibility, with the goal of fostering mission accomplishment by recognizing excellence of both military and civilian members of the force and motivating them to high levels of performance and service. As such, the program does not have the general applicability and legal effect required to publish rules pertaining to this program in the Code of Federal Regulations.

List of Subjects in 32 CFR Part 578

Decorations, Medals, Awards, Military Personnel.

PART 578—[REMOVED]

■ Accordingly, for reasons stated in the preamble, under the authority of Sec. 3012, Public Law 84–1028, 70A Stat. 157, and 10 U.S.C. 3013, 32 CFR Part 578, Decorations, Medals, Ribbons, and Similar Devices, is removed in its entirety.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. E8–26699 Filed 11–10–08; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

RIN 0651–AC28

[Docket No.: PTO–P–2008–0023]

Fiscal Year 2009 Changes to Patent Cooperation Treaty Transmittal and Search Fees

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The United States Patent and Trademark Office (Office) is amending the rules of practice to adjust the transmittal and search fees for international applications filed under the Patent Cooperation Treaty (PCT). The Office is adjusting the PCT transmittal and search fees to recover the estimated average cost to the Office of processing PCT international applications and preparing international search reports and written opinions for PCT international applications.

DATES: *Effective Date:* The changes to 37 CFR 1.445 are effective on January 12, 2009 and are applicable to any international application having a receipt date that is on or after January 12, 2009.

FOR FURTHER INFORMATION CONTACT: Boris Milef, Legal Examiner, Office of PCT Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, by telephone at (571) 272–3288; or by mail addressed to: Box Comments Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313–1450.

SUPPLEMENTARY INFORMATION: The PCT enables United States applicants to file one application (a PCT international application) in a standardized format in English in a Receiving Office (either the United States Patent and Trademark Office or the International Bureau of the World Intellectual Property

Organization (WIPO)) and have that application acknowledged as a regular national or regional filing by PCT member countries. *See* Manual of Patent Examining Procedure (MPEP) § 1801 (8th ed. 2001) (Rev. 7, July 2008). The primary benefit of the PCT system is the ability to delay the expense of submitting papers and fees to the PCT national offices. *See* MPEP § 1893.

The Office acts as a Receiving Office for United States residents and nationals. *See* 35 U.S.C. 361(a), 37 CFR 1.412(a), and MPEP § 1801. A Receiving Office functions as the filing and formalities review organization for PCT international applications. *See* MPEP § 1801. The Office, in its capacity as a Receiving Office, received over 50,000 PCT international applications in each of fiscal years 2006 and 2007. The Office also acts as an International Searching Authority (ISA). *See* 35 U.S.C. 362(a), 37 CFR 1.413(a), and MPEP § 1840. The primary functions of an ISA are to establish: (1) International search reports, and (2) written opinions of the ISA. *See* MPEP § 1840.

The transmittal and search fees for a PCT international application are provided for in 35 U.S.C. 376. *See* 35 U.S.C. 376 (the Office ''may also charge'' a ''transmittal fee,'' ''search fee,'' ''supplemental search fee,'' and ''any additional fees'' (35 U.S.C. 376(a)), and the ''amounts of [these] fees * * * shall be prescribed by the Director'' (35 U.S.C. 376(b)). In addition, 35 U.S.C. 41(d) provides that fee amounts set by the Office ''recover the estimated average cost to the Office of such processing, services, or materials.'' *See* 35 U.S.C. 41(d). The current PCT transmittal, search, and supplemental search fees are set at amounts that do not recover the estimated average cost to the Office of performing these functions for PCT international applications. Therefore, the Office is adjusting the PCT transmittal fee, search fee, and supplemental search fee to recover the estimated average cost to the Office of processing PCT international applications and preparing international search reports and written opinions for PCT international applications.

The Office uses an Activity Based Information (ABI) methodology to determine the estimated average costs on a per process, service, or material basis. The ABI analysis includes compiling the Office costs for a specified activity, including the direct costs (*e.g.*, direct personnel compensation, contract services, maintenance and repairs, communications, utilities, equipment, supplies, materials, and training), an appropriate allocation of direct allocated costs (*e.g.*, rent, program-related automation, and personnel compensation benefits such as medical insurance and retirement), and an appropriate allocation of indirect allocated costs (*e.g.*, general financial and human resource management, non-program specific automation, and general Office expenses). The direct cost for an activity plus its direct allocated costs and indirect allocated costs is the ''fully burdened'' cost for that activity. The ''fully burdened'' cost for an activity is then divided by production measures (number of that activity completed) to arrive at the fully burdened per-unit cost for that activity. The cost for a particular process is then determined by ascertaining which activities occur for the process, and how often each such activity occurs for the process.

The ABI analysis in this final rule is based upon fiscal year 2007 costs, as fiscal year 2007 is the most recent fiscal year for which complete cost and production measure information is available. The Office is adjusting the fiscal year 2007 cost by the change in the Consumer Price Index for All Urban Consumers (CPI–U) between fiscal year 2007 and fiscal year 2009 as the CPI–U is a reasonable basis for determining the changes in Office costs between fiscal year 2007 and fiscal year 2009. Thus, the Office will adjust the fiscal year 2007 costs by five percent to account for the increase in Office costs between fiscal year 2007 and fiscal year 2009 to determine the estimated fiscal year 2009 costs. The Office plans to revalidate these costs every three to five years, and use the CPI–U as the basis for adjustment of these fees in the intervening years as the changes in the CPI–U is a reasonable basis for determining the year-to-year changes in Office costs.

Finally, the fiscal year 2009 cost amounts are rounded by applying standard arithmetic rules to the nearest five dollars for fee setting purposes so that the resulting fee amounts will be convenient to patent users.

The processing of PCT international applications involves the following activities, with the fiscal year 2007 costs of the activity per PCT international application indicated in parentheses: (1) Application capture and initial processing ($20); (2) application scanning ($96); (3) application formalities review ($107); and (4) classification and security review ($7). Thus, the Office estimates that the average fiscal year 2007 cost to the Office of processing a PCT international application was $230. Therefore, the estimated average fiscal year 2009 cost to the Office of processing a PCT international application is $241 ($230 multiplied by 1.05). Accordingly, this final rule sets the transmittal fee at $240.00.

The Office currently prepares an international search report and written opinion for a PCT international application by one of three methods: (1) Transcribing an Office action for a prior-filed application under 35 U.S.C. 111(a), if possible; (2) having an Office examiner prepare the international search report and written opinion; and (3) acquiring the international search report and written opinion from a competitive source.

Obtaining an international search report and written opinion for a PCT international application by transcribing an Office action for a prior-filed application under 35 U.S.C. 111(a) involves having Office personnel transcribe the Office action for the prior-filed application into an international search report and written opinion. The Office estimates that the average fiscal year 2007 cost to the Office of this activity per international search report and written opinion was $218.

Acquiring the international search report and written opinion by having an Office examiner prepare the international search report and written opinion involves at least the following activities, with the fiscal year 2007 costs of the activity per international search report and written opinion indicated in parentheses: (1) Fee processing and classification of the application by technology center art unit ($108); and (2) analysis, search of prior art, and preparation of an international search report and written opinion by an Office examiner ($2,284). Thus, the Office estimates that the average fiscal year 2007 cost to the Office of acquiring an international search report and written opinion by having an Office examiner prepare the international search report and written opinion was $2,392.

Acquiring the international search report and written opinion from a competitive source involves the following activities, with the fiscal year 2007 costs of the activity per international search report and written opinion indicated in parentheses: (1) Contract for an international search report and written opinion ($1,837) (direct allocated costs are excluded from this cost amount because the use of Office space is not involved); and (2) contract oversight and quality review of international search report and written opinion ($237). Thus, the Office estimates that the average fiscal year 2007 cost to the Office of acquiring the international search report and written

opinion by acquiring the international search report and written opinion from a competitive source was $2,074.

Preparing an international search report and written opinion for a PCT international application by transcribing an Office action for a prior-filed application under 35 U.S.C. 111(a) is a viable option for only an incidental number (five percent) of PCT international applications due to the current pendency to first Office action. Therefore, to meet the time frames established in the PCT, the Office must rely upon having an Office examiner prepare the international search report and written opinion, or acquiring the international search report and written opinion from a competitive source, in the vast majority (ninety-five percent) of PCT international applications. The Office is migrating towards obtaining international search reports and written opinion for a PCT international application from a competitive source in the ninety-five percent of applications for which transcribing an Office action for a prior-filed application under 35 U.S.C. 111(a) is not a viable option. Therefore, the fiscal year 2009 average cost of obtaining an international search report and written opinion for a PCT international application is estimated on the basis of the Office transcribing an Office action for a prior-filed application under 35 U.S.C. 111(a) in five percent of applications and acquiring the international search report and written opinion from a competitive source in ninety-five percent of applications, resulting in a composite fiscal year 2007 cost of $1,981 ($2,074 multiplied by 0.95 plus $218 multiplied by 0.05). Therefore, the estimated average fiscal year 2009 cost of preparing an international search report and written opinion for a PCT international application is $2,080 ($1,981 multiplied by 1.05). Accordingly, this final rule sets the search fee and supplemental search fee at $2,080.

Discussion of Specific Rules

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

Section 1.445: Section 1.445(a)(1) is amended to change the transmittal fee from $300.00 to $240.00. Section 1.445(a)(2) is amended to change the search fee from $1,800.00 to $2,080.00. Section 1.445(a)(3) is amended to change the supplemental search fee from $1,800.00 to $2,080.00.

Response to Comments: The Office published a notice proposing to adjust the transmittal and search fees for international applications filed under the PCT to recover the estimated average cost to the Office of processing PCT international applications and preparing international search reports and written opinions for PCT international applications. *See Fiscal Year 2009 Changes to Patent Cooperation Treaty Transmittal and Search Fees,* 73 FR 34672 (June 18, 2008), 1332 *Off. Gaz. Pat. Office* 295 (July 15, 2008) (proposed rule), and *Fiscal Year 2009 Changes to Patent Cooperation Treaty Transmittal and Search Fees,* 73 FR 38027 (July 2, 2008), 1332 *Off. Gaz. Pat. Office* 421 (July 29, 2008) (correction).

Comment: The Office received one comment (from the American Intellectual Property Law Association (AIPLA)) in response to the proposed rule making notice. The comment supported the principle that patent users should pay the average costs incurred by the Office in providing services but raised a number of concerns with respect to the proposed changes to the transmittal and search fees. The comment first requested information on how the transmittal and international search fees under § 1.445 were calculated so that the patent user community can determine whether the proposed increases in fees are necessary or reasonable. The comment also stated that the international search fee under § 1.445 overcharges and discriminates against U.S. nationals using the PCT because the costs for search and examination of national applications are subsidized by issue and maintenance fees, and PCT applications from U.S. nationals generally result in national stage applications which will generate issue and maintenance fees to the same extent as other national applications. The comment also stated that the international search fee under § 1.445 overcharges and discriminates against U.S. applicants who file PCT applications claiming priority of an earlier-filed U.S. national application, as such applicants will pay both the full national search fee and the full international search fee thus effectively paying twice for the same search. The comment also questioned why the transmittal fee set forth in § 1.445(a)(1) is higher than transmittal fees charged by other PCT Receiving Offices and suggested that instead of increasing the transmittal fee, the Office should determine how it can perform its Receiving Office functions at costs in line with the rest of the world.

Response: The basis for the estimated average costs to the Office of processing PCT international applications and preparing international search reports and written opinions for PCT international applications has been discussed previously. The patent fee structure set forth in 35 U.S.C. 41 is a combination of specified patent fees (35 U.S.C. 41(a), (b), (d)(1), and (d)(2)(A) through (C)) that cover enumerated processing, services, and materials, and a provision (35 U.S.C. 41(d)(2)) directing the Office to establish fees for all other processing, services, or materials relating to patents that are not otherwise specified in 35 U.S.C. 41. The provisions of 35 U.S.C. 41(d)(2) apply to the PCT fees by the Office under the authority provided in 35 U.S.C. 376. *See* H. Rep. 97–542, at 8 (1982) (noting that the ''other processing'' and ''services'' covered by 35 U.S.C. 41(d)(2) (then 35 U.S.C. 41(d)) include *inter alia* the processing of PCT international applications). The transmittal and international search fees under § 1.445 are not fees specified under 35 U.S.C. 41, but rather are processing or services pertaining to PCT international applications. Thus, 35 U.S.C. 41(d)(2) provides for the Office to set the transmittal and international search fees to recover their estimated average costs to the Office.

The application filing fees (filing, search, and examination fees) for an application under 35 U.S.C. 111(a), which currently total $1090.00 ($545.00 small entity) for an original nonprovisional patent application (other than plant or design), do not recover the Office's costs of initial processing and examination of an application, but rather this cost is subsidized by patent issue and maintenance fees. *See* H.R. Rep. 108–241, at 15 (2003) (noting that the Office's costs of examining applications are subsidized by issue and maintenance fees). 35 U.S.C. 41(a) and (b) provide a fee structure under which the application filing fees for an application under 35 U.S.C. 111(a) are lower than the Office's costs of initial processing and the examination provided for in 35 U.S.C. 132(a) and are subsidized by patent issue and maintenance fees. 35 U.S.C. 41 and 376 do not provide for the Office to establish PCT international stage fees lower than the Office's costs and to subsidize the costs by revenue generated from patent issue and maintenance fees. Rather, 35 U.S.C. 41(d)(2) provides for fees that recover the estimated average cost to the Office of the processing, services, or materials, which is incongruous with setting a fee lower than the cost of the processing, service, or material and to be subsidized by revenue generated from other fees. In any event, since international applications under the PCT do not themselves mature into patents, it is appropriate that the fees

paid in PCT international applications accurately reflect the costs to the Office of the processing, search, and examination of these applications.

The Office provides a reduced search fee for applications entering the national stage under 35 U.S.C. 371 where the search fee has been paid on the PCT international application to the Office as an International Searching Authority. *See* § 1.492(b)(2).

The Office does not provide a reduced search fee for PCT international applications where there has been a prior-filed application under 35 U.S.C. 111(a). As discussed previously, the Office's current pendency to first Office action does not allow for the use of the search in the prior-filed application under 35 U.S.C. 111(a) for the preparation of an international search report and written opinion for a PCT international application for the vast majority of applications, if the Office is to meet the time frames established in the PCT. Thus, the Office generally incurs the cost of conducting separate searches for the PCT international application and the prior-filed application under 35 U.S.C. 111(a) in this situation.

The PCT transmittal fee being adopted in this final rule is lower than what some Receiving Offices charge and higher than what other Receiving Offices charge. What transmittal and search fees other Receiving Offices and International Searching Authorities charge are immaterial. The Office encounters different costs than do other Receiving Offices and International Searching Authorities for a number of reasons beyond the control of the Office. In addition, it is not clear that other Receiving Offices and International Searching Authorities set their transmittal or search fees on a cost-recovery basis as provided for in 35 U.S.C. 41(d)(2).

Rule Making Considerations

A. Final Regulatory Flexibility Analysis

1. Description of the Reasons That Action by the Agency Is Being Considered

The Office is revising the rules of practice to adjust the transmittal and search fees for international applications filed under the PCT. The Office is adjusting the PCT transmittal and search fees to recover the estimated average cost to the Office of processing PCT international applications and preparing international search reports and written opinions for PCT international applications.

2. Succinct Statement of the Objectives of, and Legal Basis for, the Rules

The Office is adjusting the PCT transmittal and search fees to recover the estimated average cost to the Office of processing PCT international applications and preparing international search reports and written opinions for PCT international applications. The changes in this final rule are authorized by 35 U.S.C. 41(d) and 376.

3. Description and Estimate of the Number of Affected Small Entities

The Small Business Administration (SBA) small business size standards applicable to most analyses conducted to comply with the Regulatory Flexibility Act are set forth in 13 CFR 121.201. These regulations generally define small businesses as those with fewer than a maximum number of employees or less than a specified level of annual receipts for the entity's industrial sector or North American Industry Classification System code. The Office, however, has formally adopted an alternate size standard for the purpose of conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations. *See Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations*, 71 FR 67109 (Nov. 20, 2006), 1313 *Off. Gaz. Pat. Office* 60 (Dec. 12, 2006). This alternate small business size standard is the previously established size standard that identifies the criteria entities must meet to be entitled to pay reduced patent fees. *See* 13 CFR 121.802. If patent applicants identify themselves on a patent application as qualifying for reduced patent fees, the Office captures this data in the Patent Application Location and Monitoring (PALM) database system, which tracks information on each patent application submitted to the Office.

Unlike the SBA small business size standards set forth in 13 CFR 121.201, this size standard is not industry-specific. Specifically, the Office's definition of small business concern for Regulatory Flexibility Act purposes is a business or other concern that: (1) Meets the SBA's definition of a ''business concern or concern'' set forth in 13 CFR 121.105; and (2) meets the size standards set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees, namely an entity: (a) Whose number of employees, including affiliates, does not exceed 500 persons; and (b) which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under this definition. *See Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations*, 71 FR at 67112, 1313 *Off. Gaz. Pat. Office* at 63.

The changes in this final rule will apply to any small entity who files a PCT international application in the United States Receiving Office and to any small entity who requests a search by the United States International Searching Authority. The Office received between 52,000 and 53,000 PCT international applications in each of fiscal years 2006 and 2007. There is no provision in 35 U.S.C. 376 (or elsewhere) for a small entity reduction for the transmittal or search fees for a PCT international application. Thus, PCT applicants do not indicate and the Office does not record whether a PCT international application is filed by a small entity or a non-small entity. The Office's PALM and Revenue Accounting and Management (RAM) systems indicate that 12,043 of the PCT international applications in fiscal year 2006 claim priority to a prior application (nonprovisional or provisional) that has small entity status, and that 2,559 of the PCT international applications in fiscal year 2006 do not claim priority to any prior nonprovisional application or provisional application. The Office's PALM and RAM systems indicate that 12,716 of the PCT international applications in fiscal year 2007 claim priority to a prior application (nonprovisional or provisional) that has small entity status, and that 4,016 of the PCT international applications in fiscal year 2007 do not claim priority to any prior nonprovisional application or provisional application.

4. Description of the Projected Reporting, Recordkeeping and Other Compliance Requirements of the Rules, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Requirement and the Type of Professional Skills Necessary for Preparation of the Report or Record

This final rule does not involve any reporting, recordkeeping and other compliance requirements. This final rule only adjusts the PCT transmittal and search fees. As discussed previously, there is no provision in 35 U.S.C. 376 (or elsewhere) for a small entity reduction for the transmittal or search fees for a PCT international

application. The following table (Table 1) indicates the PCT international stage fee, the number of payments of the fee received by the Office in fiscal year 2007 (number of entities who paid the applicable fee in fiscal year 2007), the former fee amount, the revised fee amount, and the net amount of the fee adjustment.

TABLE 1

Fee	Fiscal Year 2007 payments	Former fee amount	Revised fee amount	Fee adjustment
Transmittal fee	54,335	300.00	240.00	(60.00)
Search Fee	30,965	1800.00	2080.00	280.00
Supplemental Search Fee	941	1800.00	2080.00	280.00

The PCT international search fee and supplemental search fee were adjusted from $1,000.00 to $1,800.00 in November of 2007. *See April 2007 Revision of Patent Cooperation Treaty Procedures*, 72 FR 51559 (Sept. 10, 2007), 1323 *Off. Gaz. Pat. Office* 26 (Oct. 2, 2007) (final rule). Thus, the change to the search fee and supplemental search fee in this final rule is a $280.00 increase over the current search fee and supplemental search fee set in November of 2007, and a $1,080.00 increase over the search fee and supplemental search fee that was in effect prior to November of 2007.

The PCT does not preclude United States applicants from filing patent applications directly in the patent offices of those countries which are Contracting States of the PCT (with or without previously having filed a regular national application under 35 U.S.C. 111(a) or 111(b) in the United States) and taking advantage of the priority rights and other advantages provided under the Paris Convention and the World Trade Organization (WTO) administered Agreement on Trade-Related Aspects of Intellectual Property (TRIPs Agreement). *See* MPEP § 1801. That is, the PCT is not the exclusive mechanism for seeking patent protection in foreign countries, but is instead simply an optional alternative route available to United States patent applicants for seeking patent protection in those countries that are Contracting States of the PCT. *See id.*

In addition, an applicant filing an international application under the PCT in the United States Receiving Office (the United States Patent and Trademark Office) is not required to use the United States Patent and Trademark Office as the International Searching Authority. The European Patent Office (except for applications containing business method claims) or the Korean Intellectual Property Office may be selected as the International Searching Authority for PCT international applications filed in the United States Receiving Office. The applicable search fee if the European Patent Office is selected as the International Searching Authority European is currently $2665.00 (set by the European Patent Office), and the applicable search fee if the Korean Intellectual Property Office is selected as the International Searching Authority is currently $244.00 (set by the Korean Intellectual Property Office). The Office also recently entered into an agreement with IP Australia under which IP Australia may be selected as the International Searching Authority for certain PCT international applications filed in the United States Receiving Office.

5. Description of Any Significant Alternatives Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact on Small Entities

The alternative of not adjusting the PCT transmittal and search fees would have a lesser economic impact on small entities, but would not accomplish the stated objectives of applicable statutes. *See* 35 U.S.C. 41(d) (provides that fees set by the Office recover the estimated average cost to the Office of the processing, services, or materials).

6. Identification, to the Extent Practicable, of All Relevant Federal Rules Which May Duplicate, Overlap or Conflict With the Rules

The Office is the sole agency of the United States Government responsible for administering the provisions of title 35, United States Code, pertaining to the examination of patent applications and granting of patents. Therefore, no other federal, state, or local entity shares jurisdiction over the examination and granting of patents.

The Office previously adjusted the patent fees set by statute to reflect fluctuations in the Consumer Price Index (CPI). *See Revision of Patent Fees for Fiscal Year 2009*, 73 FR 47534 (Aug. 14, 2008), 1334 *Off. Gaz. Pat. Office* 45 (Sept. 2, 2008) (final rule). The Office is also in the process of studying the cost of a number of processes and services covered by the cost-recovery provisions of 35 U.S.C. 41(d)(2) (*e.g.*, reexamination proceeding costs), and the Office will propose adjustments to the fees for these processes and services if appropriate. The changes that would be proposed in any rule makings resulting from this study would also not duplicate, overlap, or conflict with the changes proposed in this notice.

Other countries, however, have their own patent laws, and an entity desiring a patent in a particular country must make an application for patent in that country, in accordance with the applicable law. Although the potential for overlap exists internationally, such overlap cannot be avoided except by treaty harmonizing the patent laws for all countries (such as the Paris Convention for the Protection of Industrial Property, or the PCT).

Nevertheless, the Office believes that there are no other duplicative or overlapping rules.

B. Executive Order 13132 (Federalism)

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

C. Executive Order 12866 (Regulatory Planning and Review)

This rulemaking has been determined to be significant for purposes of Executive Order 12866 (Sept. 30, 1993), as amended by Executive Order 13258 (Feb. 26, 2002) and Executive Order 13422 (Jan. 18, 2007).

D. Executive Order 13175 (Tribal Consultation)

This rulemaking will not: (1) Have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

E. Executive Order 13211 (Energy Effects)

This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

F. Executive Order 12988 (Civil Justice Reform)

This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

G. Executive Order 13045 (Protection of Children)

This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

H. Executive Order 12630 (Taking of Private Property)

This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

I. Congressional Review Act

Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the United States Patent and Trademark Office will submit a report containing this final rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the Government Accountability Office. The changes in this final rule are not expected to result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this final rule is not a ''major rule'' as defined in 5 U.S.C. 804(2).

J. Unfunded Mandates Reform Act of 1995

The changes in this final rule do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 *et seq.*

K. National Environmental Policy Act

This rulemaking will not have any effect on the quality of environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 *et seq.*

L. National Technology Transfer and Advancement Act

The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are inapplicable because this rulemaking does not contain provisions which involve the use of technical standards.

M. Paperwork Reduction Act

The changes in this final rule involve information collection requirements which 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 collection of information involved in this notice has been reviewed and approved by OMB under OMB control number 0651–0021. The Office did not resubmit an information collection package to OMB for its review and approval because the changes in this final rule concern revised fees for existing information collection requirements associated with the information collection under OMB control number 0651–0021. The Office will submit fee revision changes to the inventory of the information collection under OMB control number 0651–0021.

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

37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of Information, Inventions and patents, Reporting and record keeping requirements, Small Businesses.

PART 1—RULES OF PRACTICE IN PATENT CASES

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

Authority: 35 U.S.C. 2(b)(2).

■ 2. The authority citation for subpart is revised to read as follows:

Authority: Secs. 1.401 to 1.499 also issued under 35 U.S.C. 41 and 351 through 376.

■ 3. Section 1.445 is amended by revising paragraphs (a)(1), (a)(2) and (a)(3) to read as follows:

§ 1.445 International application filing, processing and search fees.

(a) * * *

(1) A transmittal fee (see 35 U.S.C. 361(d) and PCT Rule 14)	$240.00
(2) A search fee (see 35 U.S.C. 361(d) and PCT Rule 16)	$2,080.00
(3) A supplemental search fee when required, per additional invention	$2,080.00

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Dated: October 21, 2008.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. E8–26711 Filed 11–10–08; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R09–OAR–2008–0306; FRL–8724–7]

Approval and Promulgation of Implementation Plans; Designation of Areas for Air Quality Planning Purposes; State of California; PM–10; Revision of Designation; Redesignation of the San Joaquin Valley Air Basin PM–10 Nonattainment Area to Attainment; Approval of PM–10 Maintenance Plan for the San Joaquin Valley Air Basin; Approval of Commitments for the East Kern PM–10 Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving the State of California's request under the Clean Air Act (CAA or the Act) to revise the designation for the San Joaquin Valley (SJV) serious nonattainment area for particulate matter of ten microns or less (PM–10) (SJV nonattainment area) by splitting the area into two separate nonattainment areas: The San Joaquin