

Dated: June 19, 2009.

P.B. Trapp,

*Captain, U.S. Coast Guard Acting
Commander, Fifth Coast Guard District.*

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DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

[Docket No.: PTO-P-2009-0025]

RIN 0651-AC34

July 2009 Revision of Patent Cooperation Treaty Procedures

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The United States Patent and Trademark Office (USPTO) is revising the rules of practice in title 37 of the Code of Federal Regulations (CFR) to conform them to certain amendments made to the Regulations under the Patent Cooperation Treaty (PCT) that take effect on July 1, 2009. These amendments result in a change to the procedure under the PCT whereby applicants may make amendments to the claims in an international application.

DATES: *Effective Date:* The changes to 37 CFR 1.485 are effective on July 1, 2009.

FOR FURTHER INFORMATION CONTACT: Richard R. Cole, Senior Legal Examiner, Office of PCT Legal Administration (OPCTLA) directly by telephone at (571) 272-3281, or by facsimile at (571) 273-0459.

SUPPLEMENTARY INFORMATION: During the September 2008 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 July 1, 2009. The amended PCT Regulations were published in the PCT Gazette of December 11, 2008 (38/2008), at pages 166-167. The amendments include provisions which modify the procedures for making amendments to the claims in an international application.

The Patent Cooperation Treaty (PCT) enables an applicant to file one application, "an international application" or a "PCT application," in a standardized format in a PCT Receiving Office and have that application acknowledged as a regular

national or regional filing in as many Contracting States to the PCT as the applicant desires. The requirements for PCT applications are specified in the PCT Treaty Articles and the Regulations issued under the PCT Treaty (the PCT Regulations). Certain requirements of the PCT Treaty and PCT Regulations are reiterated in the USPTO's rules of practice in 37 CFR for the convenience of patent applicants. Changes to the PCT Regulations (PCT Rules 46.5 and 66.8) that govern the manner of making amendments to the claims in international applications will become effective on July 1, 2009. Under the current PCT Regulations, applicants are required to submit replacement pages for only those pages which contain changes, where under the revised PCT Regulations applicants will be required to submit a complete set of the claims when amending any of the claims. The USPTO's rules of practice in 37 CFR (37 CFR 1.485) set forth the current practice for amending claims and must be changed to be consistent with the changes to the PCT Regulations.

The changes to 37 CFR 1.485 are effective on July 1, 2009, and apply to any amendment filed in an international application on or after that date regardless of the filing date of the international application.

Discussion of Specific Rules

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

Section 1.485: Section 1.485 is amended to require that amendments to the claims in a PCT international application must be made in accordance with PCT Rule 66.8.

Rulemaking Considerations

A. Administrative Procedure Act: The change in this final rule merely revises the USPTO's rules of practice to conform to the requirements of the PCT Regulations that become effective on July 1, 2009. 35 U.S.C. 364(a) provides that international applications shall be processed by the USPTO in accordance with the applicable provisions of the PCT, the Regulations under the PCT and Title 35 of the United States Code. Therefore, these rule changes involve interpretive rules or rules of agency practice and procedure under 5 U.S.C. 553(b)(A). Accordingly, the changes in this final rule may be adopted without prior notice and opportunity for public comment under 5 U.S.C. 553(b) and (c), or thirty-day advance publication under 5 U.S.C. 553(d). *See Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336-37, 87 U.S.P.Q.2d 1705, 1710 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35

U.S.C. 2(b)(2)(B), does not require notice and comment on rulemaking for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." (quoting 5 U.S.C. 553(b)(A))).

B. Regulatory Flexibility Act: As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 (or any other law), neither a regulatory flexibility analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) is required. *See* 5 U.S.C. 603.

C. 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).

D. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be significant for purposes of Executive Order 12866 (Sept. 30, 1993).

E. 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).

F. 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).

G. 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).

H. 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).

I. 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).

J. 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 USPTO will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office.

K. *Unfunded Mandates Reform Act of 1995*: The changes proposed in this notice 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.*

L. *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.*

M. *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 not applicable because this rulemaking does not contain provisions which involve the use of technical standards.

N. *Paperwork Reduction Act*: This notice involves 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 USPTO is not resubmitting an 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 OMB control number 0651-0021.

Interested persons are requested to send comments regarding these information collections, including suggestions for reducing this burden, to: (1) The Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10202, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the

Patent and Trademark Office; and (2) Robert A. Clarke, Director, Office of Patent Legal Administration, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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.

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. Section 1.485 is revised to read as follows:

§ 1.485 Amendments by applicant during international preliminary examination.

The applicant may make amendments at the time of filing the Demand. The applicant may also make amendments within the time limit set by the International Preliminary Examining Authority for reply to any notification under § 1.484(b) or to any written opinion. Any such amendments must be made in accordance with PCT Rule 66.8.

Dated: June 24, 2009.

John J. Doll,

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

[FR Doc. E9-15303 Filed 6-30-09; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR PART 17

RIN 2900-AM99

Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA): Preauthorization of Durable Medical Equipment

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA)

medical regulations for the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) preauthorization section by increasing the dollar ceiling for purchase or rental of durable medical equipment (DME) from \$300 to \$2,000.

DATES: *Effective Date:* The final rule is effective July 31, 2009.

FOR FURTHER INFORMATION CONTACT: Lisa Brown, Chief, Policy Management Division, VA Health Administration Center, P.O. Box 460948, Denver, Colorado 80246; (303) 331-7882. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** on October 28, 2008 (73 FR 63914), VA proposed to amend its medical regulations at 38 CFR Part 17 concerning CHAMPVA benefits. Specifically, it proposed to amend § 17.273(e) regarding durable medical equipment (DME) by increasing the dollar ceiling for purchase or rental of durable medical equipment (DME) from the \$300 to \$2,000.

CHAMPVA is a VA medical benefits program for (1) spouses and children of veterans who have a permanent and total service-connected disability and (2) surviving spouses and children of veterans who died as a result of a service-connected disability or while rated permanently and totally disabled from a service-connected disability, or who died in the active military, naval, or air service in the line of duty and there is not otherwise entitlement to Department of Defense TRICARE benefits. DME is included among the health care items that are available to CHAMPVA beneficiaries. To ensure that DME purchases and rental are medically necessary, appropriate and within the Department's budgetary constraints, VA requires non-VA providers to obtain preauthorization before the purchase or rental of DME for a CHAMPVA beneficiary when the cost of the DME exceeds \$300. DME purchases greater than \$300 are currently reviewed twice, *i.e.*, first when a request is submitted for preauthorization and again when the claim is officially submitted for payment.

The current rate was put in place in 1973. Since the cost of common DME items has steadily increased, this ceiling no longer reflects current costs. Raising the dollar amount to \$2,000 would make the administrative processing of DME claims easier for CHAMPVA beneficiaries and providers as well as for VA, since claims under that amount will only be reviewed once.

VA provided a 60-day comment period that ended December 29, 2008.