

PATENT COOPERATION TREATY

Common Quality Framework for
International Search and Preliminary Examination

Report Under Paragraph 21.17 of the PCT International Search and Preliminary Examination Guidelines

by: **United States Patent and Trademark Office (USPTO)**

on: **21 December 2006**

Documents referred to in this report:

Attached to this report is a copy of the evaluation instrument used by the USPTO's Office of Patent Quality Assurance personnel in evaluating International Applications.

INTRODUCTION (PARAGRAPHS 21.01–21.02)

Chapter 21 of the PCT International Search and Examination Guidelines (the Guidelines) sets forth an overview of the Quality Management System each International Authority is expected to implement with respect to its processing of International Applications. The Guidelines set forth criteria with respect to resources, administration, quality assurance, feedback arrangements, communication and guidance to users, and internal review procedures. The overall implementation of the Quality Initiative for International Applications within the USPTO is discussed below with reference to specific sections of Chapter 21 of the Guidelines.

QUALITY MANAGEMENT SYSTEM (PARAGRAPHS 21.03–21.09)

Establishment and maintenance of QMS (Paragraph 21.03)

The Quality Management System for international applications at the USPTO operates under the overall administrative and policy direction of the Commissioner for Patents. Under the Commissioner for Patents, management of overall PCT operations is divided between the Deputy Commissioner for Patent Resources and Planning (DCPRP), the Deputy Commissioner for Patent Operations (DCPO), and the Deputy Commissioner for Patent Examination Policy (DCPEP). Each of the Deputy Commissioners is responsible for specific aspects of the USPTO activities as Receiving Office, International Searching Authority (ISA) and International Preliminary Examining Authority (IPEA) under the Patent Cooperation Treaty. Each Deputy Commissioner is, therefore, involved in the operation and/or implementation of an overall Quality Management System designed to ensure compliance with Chapter 21 of the Guidelines.

Resources - infrastructure (Paragraph 21.05)

The office of the DCPO continuously monitors staff resources in an attempt to ensure that search and examination of international applications can be accomplished in a timely manner. Additionally, each Technology Center under the DCPO currently maintains systems to train paralegal and technical support staff on the processing of ISA and IPEA reports. The Office of Patent Cooperation Treaty Legal Administration (OPCTLA), which operates under the office of the DCPEP, is responsible for developing and providing training to the Patent Examining Corps professional and technical support staffs. OPCTLA is also responsible for updating the USPTO's Manual of Patent Examining Procedure (MPEP) with respect to PCT matters, and regularly reviews and revises the MPEP to reflect the ongoing PCT rule changes related to the PCT Reform efforts. The Office of Patent Classification and Documentation Standards, also under the DCPEP, provides support, representation, advice and direction on technical matters relating to the International Patent Classification (IPC) System, and other international documentation-related standards. Finally, under the DCPRP, is the Office of Patent Cooperation Treaty Operations (PCT Operations), the Search and Information Resources Administration (SIRA), and the Office of Patent Resources Administration (OPRA). PCT Operations checks applications for compliance with the Treaty, Regulations, and Administrative Instructions, assigns international filing dates, and assures payment of appropriate fees. SIRA maintains search systems, technical information sources and ensures that PCT minimum documentation requirements are met and also manages the provision of information technology and automation equipment and facilities to ensure effective handling of PCT applications at all stages of search and examination. OPRA is responsible for managing and overseeing patent-specific resources as allocated at the corporate level, and establishing patent program activity targets and continually evaluating performance against patent program objectives. These responsibilities include continually evaluating the level of resources required to carry out PCT operations at all levels.

Administration - procedures (Paragraphs 21.06(a) and (b))

The majority of PCT administration responsibilities are handled by PCT Operations. These responsibilities include processing all International Applications for which the USPTO serves as the ISA, processing Demands for International Preliminary Examination, mailing of notices and reports, and other administrative duties. PCT Operations contributes to the ability of the USPTO to monitor timeliness and pendency of PCT search and examination by

maintaining systems for tracking application movement and workflow. In addition to the work performed by PCT Operations, the office of the DCPO continuously monitors workload fluctuations and makes adjustments in an attempt to ensure that search and examination of international applications can be accomplished in a timely manner, and each Technology Center maintains systems to monitor the timely issuance of search and examination reports. Finally, OPCTLA operates the PCT Help Desk, which handles customer complaints and provides customers with assistance on a wide variety of PCT matters.

Quality Assurance Procedures (Paragraph 21.07)

The Office of Patent Quality Assurance (OPQA), under the DCPO, has primary responsibility for the development and implementation of an effective internal quality assurance program. Preliminary development of the framework for the PCT Quality Review Program began in the 4th quarter of FY04. In the initial study, OPQA selected a random sample of International Applications and reviewed them against ten search report and written opinion criteria as noted below:

1. The application is properly classified using the current version of the IPC.
2. Field of search and search strategy are appropriate to claimed subject matter and encompass the inventive concept and claimed features.
3. Relevant documents are properly identified and characterized with respect to each claim subjected to search (e.g., “X”, “Y”, “A”, etc. with respect to claims...).
4. Where the international application was not considered as complying with the requirement of unity of invention, determination of lack of unity was appropriate.
5. Where the international application was not considered as complying with the requirement of unity of invention, groupings of claims set forth by the examiner were proper.
6. All claims (excluding claims that are not subjected to search) are addressed with regard to novelty, inventive step (unobviousness), and industrial applicability.
7. All appropriate opinions are set forth.
8. No inappropriate opinions are set forth.
9. Observations raised in Box No. VIII are appropriate.
10. Opinions and observations are explained clearly using language appropriate to examination under the Patent Cooperation Treaty.

This preliminary stage of review was intended to solidify the framework for a more intensive review process, namely to:

- Evaluate the resource requirements needed per reviewed application;
- Evaluate the reliability and effectiveness of the evaluation instrument;
- Establish sufficient sampling parameters; and
- Identify sources of potential bias and misinterpretation.

Based on the results of the initial study, the USPTO's current quality assurance program commenced in FY05 with a greatly expanded sampling of applications as well as with an expanded and more-defined evaluation instrument. OPQA employs a sampling designed to ensure 95% confidence in review findings. The evaluation instrument now covers 21 items in the areas of overall search, the search report, and the written opinion. The review instrument was expanded largely to be able to identify specific improvement strategies. Reviewers assess the applicability and appropriateness of each item as well as provide comments specific to each area of review (see attached evaluation instrument).

Feedback arrangements (Paragraph 21.08)

Reports setting forth the quality review findings are distributed on a regular basis to the DCPO, OPCTLA and Patents Technology Centers for use in the development of training and quality programs. These reports help to aid in the identification of systemic errors which may need correction on an office-wide basis. Additionally, personnel from OPCTLA are in regular contact with officials from PCT Operations at WIPO, and are available to officials from the designated/elected offices, for the purposes of receiving feedback on quality matters.

Communication, Guidance and Responses to Users (Paragraphs 21.06(c), 21.09)

OPCTLA develops and provides training on a regular basis to users of the PCT system, including patent attorneys and agents, legal administrators, legal secretaries and other members of the patent community. Additionally, OPCTLA, as discussed above, operates the PCT Help desk, which provides customers with assistance on a wide variety of PCT matters. In the most recent fiscal year (FY06) the PCT Help Desk handled more than 32,500 calls from PCT users. Finally, OPCTLA provides information, forms, and updates on the PCT home page of the USPTO Internet site.

INTERNAL REVIEW (PARAGRAPHS 21.10–21.15)

Required Arrangements for Internal Review (Paragraph 21.10)

Review instrument reliability is continuously monitored to ensure that conclusions made from the data gathered through the PCT Quality Review Program are accurate and valid. A final report is prepared at the end of the Fiscal Year that provides the information necessary to evaluate and adjust training and quality improvement programs so as to ensure attainment and maintenance of high quality levels. Finally, as information is gathered and analyzed from the search and examination report review program, OPCTLA will develop and provide supplemental training to the Technology Centers to improve areas of weakness.

[End of report]

DO NOT SCAN - DO NOT PLACE IN FILE

| | | |
|----------------------------|-------------------|-------------------------|
| PCT QR Form | | Review Date: |
| Application Number: | P237 Date: | Review Type: PCT |
| Examiner: | Reviewer: | Tech Center: |

PRIOR ART

1. There is prior art that supports the holding of lack of novelty or inventive step of a claim that was shown in the ISR/Written Opinion to have both novelty and inventive step or had no proper opinion under novelty or inventive step. Yes No

1A. Newly found reference used Only art of record used

2. An improper opinion regarding lack of novelty or inventive step was raised. Yes No N/A

3. An opinion was not clearly explained using language appropriate to examination under the Patent Cooperation Treaty? Yes No

4. The prior art on the Form 210 was improperly designated as to how they apply to each claim (e.g., designated as X, Y or A in accordance with the use of the references on the Form 237) Yes No

5. Clearly better prior art was found that was not cited in the ISR/Written Opinion. Yes No N/A

INDUSTRIAL APPLICABILITY

6. An opinion regarding a lack of industrial applicability was missed. Yes No

6A. The claim was shown to have
 both novelty and inventive step. lack of novelty or inventive step.

7. An improper opinion regarding lack of industrial applicability was raised. Yes No

UNSEARCHABILITY OF CLAIMS

8. A claim was searched that should be held as unsearchable. Yes No

8A.
 The claim relates to subject matter not required to be searched by the USPTO or because the claim relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out.
 The claim is a dependent claim and is not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

9. A searchable claim was held to be unsearchable. Yes No

UNITY OF INVENTION

10. At least one holding of lack of unity was improper, i.e. improper grouping of claims or supporting rational. Yes No N/A

OBSERVATIONS

11. An inappropriate observation was raised or an observation was missed relating to the clarity of claims, the description, the drawings, and whether the claims are fully supported by the description. Yes No

FORMALITIES

12. The application was improperly classified or failed to use the latest version of the IPC or USPC. Yes No

13. The search recordation was incomplete or in improper form. Yes No

14. A U.S. priority claim was treated improperly. Yes No N/A

15. Any PCT form was not filled out properly. Yes No

16. Bibliographic data errors including: Mailing address; International filing date; International application number; Applicant's name; Priority date. Yes No

17. Other formality errors, such as: Figure to be published with abstract; and Abstract missing. Yes No

TIMELINESS

21. Were the search report and written opinion established within the Rule 42 time limit (i.e., the later of 3 months from the date the case was forwarded to the TC from PCT Ops or 9 months from the priority date)? Yes No

Comments: