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: **15 January 2010**

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 Patents (DCP) and the Associate Commissioner for Patent Examination Policy (ACPEP). The DCP and the ACPEP are 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. The DCP and ACPEP are therefore, collectively involved in the operation and/or implementation of an overall Quality Management System designed to ensure compliance with Chapter 21 of the Guidelines.

Additionally, the Director of the USPTO has recently established a PCT Task Force which has been tasked with reviewing all aspects of PCT processing at the USPTO, including the Quality Management System, in an effort to identify areas where improvements can be made. In addition to reviewing USPTO PCT processing, the Task Force will also be considering what changes, if any, should be made to the PCT system as a whole. The Task Force is comprised of staff from all areas of the USPTO that are involved, either directly or indirectly, with the processing of PCT applications. The Task Force will also be soliciting advice from our users on areas where improvements can be made in USPTO PCT processing and to the PCT system as a whole.

Resources - infrastructure (Paragraph 21.05)

The office of the DCP continuously monitors staff resources in an attempt to ensure that search and examination of international applications can be accomplished in a timely manner. Additionally, the DCP currently maintains systems to train 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 ACPEP, 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 DCP, 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 DCP, 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 patentspecific 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 DCP 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 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 ACPEP, 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 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 greatly expanded the sampling of applications and implemented an expanded and more-defined evaluation instrument. OPQA employs a sampling design that ensures 95% confidence in review findings. The evaluation instrument covers 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 ACPEP, DCP, and OPCTLA for use in the identification of areas in need of quality improvement. 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 (FY09) the PCT Help Desk handled more than 33,000 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 improve areas of weakness.

[End of report]

PCT QR Form

Serial No.	Reviewer	Date o	f Review				
Examiner	Sea	arch conducted by Reviewer	Yes	No			
Contractor							
<u>Prior Art</u>							
inventive ste	prior art that supports the hold ep of a claim that was shown in ovelty and inventive step or had ventive step.	the ISR/Written Opinion to	Υe	es No			
	vly found reference used (E.2.1) y art of record used (E2.2.1)	1.1)					
(2) An impro raised. (E.2.:	pper opinion regarding lack of no 2.2)	ovelty or inventive step was	Ye	es No	NA		
	(3) An opinion was not clearly explained using language appropriate to examination under the Patent Cooperation Treaty? (E.2.3.7)						
they apply to	r art on the From 210 was impro b each claim (e.g., designated a of the references on the Form	as X, Y or A in accordance	Ye	es No			
(5) Clearly b ISR/Written	Ye	es No	NA				
	Industrial Applica	ability					
(6) An opini	on regarding a lack of industria	l applicability was missed.	Ye	es No)		
The claim was shown to have both novelty and inventive step. (E.2.1.2) The claim was shown to lack of novelty or inventive step. (E.2.2.4)							
(7) An impro raised. (E.2.:	pper opinion regarding lack of in 2.3)	dustrial applicability was	Ye	es No	•		
	Unsearchablility o	f Claims					
(8) A claim	was searched that should be he	eld as unsearchable.	Ye	es No			
by th inter requ	claim relate to subject matter reference uspect of because the clair relational application that do not uirements to such an extent that relational search can be carried	n relate to parts of the comply with the prescribed to meaningful					
	claim is a dependent claim and the second and third sentence						
(9) A search	able claim was held to be unse	archable. (E.2.2.5)	Ye	es No			

Unity of Invention

(10) At least one holding of lack of unity was improper, i.e. improper grouping of claims or supporting rational. (E.2.2.6)	Yes	No	NA
<u>Observations</u>			
(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. (E.2.3.6)	Yes	No	
<u>Formalities</u>			
(12) The application was improperly classified or failed to use the latest version of the IPC or USPC. (E.2.3.2)	Yes	No	
(13) The search recordation was incomplete or in improper form. (E.2.3.4)	Yes	No	
(14) A U.S. priority claim was treated improperly. (E.2.3.5)	Yes	No	NA
(15) Any PCT form was not filled out properly. (E.2.3.9)	Yes	No	
(16) Bibliographic data errors including: (E.2.3.10) Mailing address International filing date International application number Applicant's name Priority date	Yes	No	
(17) Other formality errors, such as: (E.2.3.11) Figure to be published with abstract; and Abstract missing.	Yes	No	

Comment/Explanations

Comments/Explanations continued

Summary:

Level 1 - 211	212	213								
Level 2 - 221	222	223	224	225	226					
Level 3 - 231	232	233	234	235	236	237	238	239	2310	2311