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: The Israel Patent Office (ILPO) on: *21 December 2009*

Documents referred to in this report:

[list any documents which appended to the report for information or publicly available documents which are referred to]

Each Authority must provide information with respect to its Quality Management System (QMS) arranged under the main headings as set forth in this template. The descriptions in this template below each main heading should be considered examples of the type and arrangement of information that should be included under each heading. Each Authority may provide additional information beyond that set forth in this template as desired. This template is to be used for a main report under paragraph 21.17 of the PCT International Search and Preliminary Examination Guidelines. Updating reports may thereafter usually be presented in abbreviated format using template T21-18.

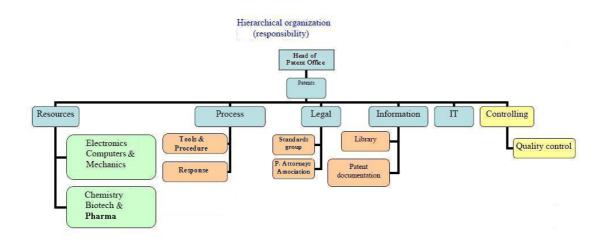
INTRODUCTION (PARAGRAPHS 21.01–21.02)

The Authority should provide general background information relevant to the quality management system (QMS). The following may be included, if applicable:
Recognized normative reference or basis for quality management system besides Chapter 21, e.g. ISO 9000.

In accordance with the agreement reached by the Meeting of International Authorities under the PCT (PCT/MIA) during its 13th session and in accordance with paragraph 21.17, the Israel Patent Office (ILPO) respectively submits its first report on a Common Quality Framework for International Search and Preliminary Examination. The ILPO is expected to commence offering its services as an International Searching Authority and International Preliminary Examining Authority on the 1st of January 2012.

The ILPO has been implementing various components to establish a Quality Management System (QMS) which will operate according to ISO 9001 standards. The ILPO has applied for certification of its QMS under the ISO 9001 system. This system covers all services offered by ILPO.

• An organigram showing at least the organizational units responsible for implementation of the Authority's QMS. It could be referred to in the rest of the report, as necessary.



QUALITY MANAGEMENT SYSTEM (PARAGRAPHS 21.03–21.09)

Establishment and maintenance of QMS (Paragraph 21.03)

The Authority should show that it has established and is maintaining, or is establishing, a QMS which:

(a) sets out basic requirements regarding resources, administrative procedures, feedback and communication channels required to underpin search and examination (S&E);
(b) incorporates a quality assurance scheme for monitoring compliance with these basic requirements and with PCT/GL/ISPE.

Quality is of paramount importance to the ILPO. Over the course of the past two years, we have taken measures towards instituting a quality control framework for the processing of national applications. At present, quality control mechanisms at the ILPO already cover most of the requirements of the Quality Framework set out in Chapter 21 of the PCT International Search and Preliminary Examination Guidelines; work to cover all requirements of that Quality Framework is under way. Control mechanisms presently in place are indicated below:

This process starts with the Head of each technical group responsible for carrying out S&E, who distributes the applications to examiners in accordance with their technical qualifications and attributes. Furthermore, each technical group Head is also responsible for performing a secondary examination on at least 20% of all group applications. Final approval, as well as final rejection, is decided by the group Head together with each examiner. Additionally, Division Heads randomly review examiner reports on a daily basis. Finally, during the publication process prior to acceptance, a group of designated examiners reviews all applications once again.

Division Heads are also responsible for the control of resources, guiding of work and the uniformity of practices among technical groups in his or her division. The objective is to ensure that S&E of any application should lead to the same result irrespective of which technical group performed the task. One of the resulting measures taken was to upgrade both S&E reports so as to conform with International S&E report formats.

The ILPO also has a quality dedicated Control Group that verifies all objections are supported by articles, rules and Commissioner's circulars. In ensuring the quality of examination work, a central role is played by the continually updated Patent directives, which contain instructions in respect to the work.

A special work group has been appointed to develop and support search methods based on the databases at the disposal of the ILPO. Members of this group consist of our most competent examiners, all of who are well acquainted with the use of databases

Resources - infrastructure (Paragraph 21.05)

Provide information about the infrastructure in place which ensures the following:

(a) Adequate quantity of search and examination (S&E) staff, including:

(i) means for matching the quantity of S&E staff to the inflow of work;

(ii) means for ensuring that recruited S&E staff have the necessary technical qualifications; (iii) means for ensuring that S&E staff have language skills, or have access to supporting

translation

arrangements, as necessary to meet Rule 34.

(b) Adequate quantity and skills of administrative staff to support S&E.

(c) Provision of appropriate equipment and facilities to support S&E.

(d) Provision of the minimum documentation supporting S&E, as referred to in Rule 34.

(e) Provision of up-to-date work manuals. These must include explanations of:

(i) quality criteria and standards;

(ii) descriptions of work procedures;

(iii) instructions ensuring that the work procedures are adhered to.

(f) Provision of an effective training and development program for all staff involved in S&E, including means to ensure the acquisition and maintenance of the necessary experience, skills and

familiarity with work manuals.

(g) Continuously monitoring and identifying resources, other than staff, required to deal with demand and comply with quality standards for S&E.

(a)

The ILPO currently has 92 examiners, 17 of whom were just recruited and by mid 2010 the ILPO will have over 100 examiners. 30 of the existing examiners have more than 10 years experience in their respective fields of science. The ILPO examiners have the language skills to comprehend at least those languages in which a minimum documentation is referred to in Rule 34, as well as several others.

Israel is known for its advanced technology and large number of high-tech companies in many diverse fields. The ILPO patent examiners are all experts in their fields. Previous to employment by the ILPO, many of the patent examiners were employed in their industrial field and are therefore well versed in the related technology. This diversity in examiner competencies is warranted by the multi-faceted structure of our national industry. Additionally, the examiners hold advanced academic degrees in their respective branches of science or technology. Specifically, the Biotechnology, chemistry and Pharma division has 42 examiners, 18 of whom hold PhD degrees

All examiners are fluent in English and Hebrew. Some examiners also have excellent knowledge of German, French, Russian, Spanish, Arabic, Italian, Romanian and Portuguese. A large number of examiners are able to work in two foreign languages.

New examiners undergo two years of intensive training by a senior examiner, along with lectures from experts. This training program provides the examiner with a better

understanding of procedure and legal aspects of patent law. This training also enhances the capability of examiners to perform novelty searches in particular and their examination competence in general.

A large number of patent examiners are graduates of prestigious universities such as the Technion, Weizmann Institute and the Hebrew university. Examiners are further encouraged to participate in seminars and courses in their respective technological fields in order to maintain and update their competencies at a high level.

In ensuring the quality of examination work, a central role is played by the continually updated, previously mentioned Patent directives, which contain instructions in respect to the work. This facilitates staff comprehension and adherence to quality criteria and high standards

(b)

The ILPO has a well trained, competent administrative staff comprised of 18 employees well versed in not only supporting the technical staff, but in dealing with applicants as well.

All procedures, from examination until grant or rejection, including all quality related measures, are documented and maintained in our automated system for administration of patent applications, PARSIL. This allows for tracking and monitoring the quality process in its entirety, utilizing Business Intelligence Reports ("BI Reports"). These reports are utilized by senior managers within the ILPO to facilitate their decision making processes and to monitor fluctuations in demand and backlog. This is the main tool used to track changes and trends in national application submissions.

The administrative tasks of this International Authority will be performed by the highly skilled staff of the Receiving Office who has a wealth of previous experience in a wide variety of PCT- related matters.

(c)

In 2002, the ILPO began its efforts to modernize operations by developing information technology solutions for the processing of patent applications. This was done with the express purpose of improving access to patent data and to achieve greater efficiency gains in the delivery of patent products and services.

These early efforts have led to the deployment of "PARSIL" (Patent Administration and Registration System for the [Israel] Patent Department) an automated system for administration of patent applications, alluded to earlier, a joint venture of the ILPO and WIPO created in 2004. This automated system incorporates the entire process of patent administration from filing to grant, including S&E functions, and includes an extensive set of controls, checks and mechanisms to facilitate the processing and maintenance of patent applications and patents.

The capability of simultaneous access to a single document by a multiplicity of users has allowed the ILPO to process a greater number of applications, correspondence and fee payments, without a subsequent increase in support staff.

Currently, all patent applications received in paper form are immediately scanned into the PARSIL system, while images of applications entering the national phase under

the PCT are loaded directly from WIPO's Patent Scope System.

As of the onset of 2009, the ILPO offers a website granting the public access to our patent registry. Public access is available to all patent documents, including bibliographic details, annual fee payments and legal status information of patents. It is now possible to conduct searches within the ILPO database based on the following criteria: name of applicant, name of inventors, key words from the title of the invention, international classification, etc. The website is both English and Hebrew supported. The ILPO has been undergoing an intensive process of OCR in cooperation with WIPO, to be completed by the end of 2009. This will allow for a full search service.

At present, the ILPO is involved in creating a paperless intellectual property environment and a public website for correspondence and information. In addition, the ILPO is now in the process of upgrading, expanding and enhancing its current Patent System and its existing website, enabling online submission of intellectual property applications, online search of the Patent Registry, and online submission and receipt of applicant's correspondence.

A new RO/ISA/IPEA system planned to replace the current PCT RO system is now in the final stages of design and about to commence development. It too will lead to paperless international application files and will support all correspondence with the applicants, payments and the entire file's life cycle.

Technology and Environment employed by the ILPO

The current ILPO system was developed in the Microsoft .Net environment with Client/Server architecture using a Microsoft SQL Server database.

The ILPO patent examiners are equipped with Pentium IV workstations with XP Operating System and Windows 2003 Server. Each workstation has a CD-ROM drive and Internet access through a high-speed connection. This provides patent examiners with the necessary facilities to conduct their S&E functions.

The ILPO implemented many international standards for improving the efficiency, availability, flexibility, scalability and manageability of the systems.

The ILPO's Service Management implements the ITIL Standard (Information Technology Infrastructure Library) the most widely accepted approach to IT service management in the world. The ILPO adopted a disaster recovery policy and is in the process of implementing GeoCluster which protects the organization from equipment failures, power outages and natural disasters.

The ILPO's Server farm contains HP Blade servers that are managed under VMware which provides a completely virtualized set of hardware. Its website operates on a very high data security level, using several firewalls and strict security policy.

(d) Patent Literature The ILPO has full access to PCT-minimum documentation as referred in Rule 34. Searches are mainly conducted electronically online through STN. Thomson Innovation databases accessible through the Internet are naturally available. IT tools, including work stations used by the examiners are of a high and modern standard. Our collection of patent documents and other publications in paper form is very comprehensive and is used whenever deemed appropriate.

Patent literature searches utilize WPI, along with certain full text databases.

Non Patent Literature

Non-patent literature searches utilize INSPEC, COMPENDEX, MEDLINE, ELSEVIER and IEEE among others, via STN. Additionally Chemical abstract and BIOSIS, along with EMBASE, accessed via STN, are used for searches in chemistry, pharmaceuticals and biotech. STN and Thomson Innovation are also used for accessing other databases as needed. Various useful internet sites pertaining to additional documentation and the classification system are available via intranet. Currently, the ILPO has access to almost all of the non patent literature via STN and Thomson Innovation or via dedicated websites.

The ILPO is in the process of making arrangements for access to the remaining few journals and will have these available for searching prior to commencing operation as an International Searching Authority and International Preliminary Examining Authority

(e)

All examiners have on line access to PCT Guidelines and PCT Regulations. In addition, the ILPO has manuals for all parts of the patent process. A group specifically dedicated to improvement of tools and procedures, quality control, and initiation of corrective action in response to feedback from the quality control process has been established.

(f)

The ILPO maintains a rigorous training regime, with the express purpose of ensuring the acquisition and continued high level of necessary experience and skills of the personnel.

The ILPO training system has been developed so as to allow for the rapid recruitment and training of as many new examiners as possible new demand requires.

New examiners are trained and supervised by a senior examiner for a period of 24 months,. The senior examiner has the role of a personal tutor and is responsible for all decisions made by the new examiner in the processing of an application. During this apprenticeship, new examiners participate in in-house training programs comprising a basic course of 80 hours that imparts deep insight into the patent processing procedure including knowledge of various legal aspects of patent law and performing searches. These training programs also confer upon new examiners a broader perspective of the patent, such as the role of patents as an economical tool for enhancing innovation and as a strategic business tool for companies.

All patent examiners are kept updated as to relevant changes in patent related legislation, practice and procedures. There are also regular training activities on improved search tools.

After concluding the apprentice period, examiners participate in an "extended patent course" of 100 hours organized by the ILPO in conjunction with the patent attorney offices and support of Israeli Universities. There are also ongoing in-house language courses. The overall idea in this training is continuing the examiners education.

Examiners are authorized to make their own decisions after thorough verification of their competencies and skills. There is an examination at the end of each year during the training period. Upon successful completion of a final exam they are awarded a patent examiner certificate, approved and signed by the Commissioner.

Examiners are encouraged to participate in seminars and courses in their respective technological fields in order to maintain and update their competencies at a high level.

An examiner who has been authorized to work independently carries out searches and examinations of applications without strict supervision. However, decisions on refusal of grant or grant must always be discussed with and approved by a senior examiner.

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

Provide information on those administrative procedures and control mechanisms which ensure the following:

(a) Timeliness of S&E and related functions, to quality standards in accordance with PCT/GL/ISPE.

(b) Coping with fluctuations in demand and backlog management.

(a) With respect to the handling of S&E requests and performing related functions, in the new computerized processing ISA/IPEA system a control mechanism will be implemented to ensure the timely issuance of ISRs/WOs. Each stage of the task will be color coded to enable users to quickly determine when a time limit will expire.

(b) All Heads and Managers use BI system for follow-up of applications and for monitoring purposes.

Management continuously monitors both fluctuations in demand and possible backlogs to ensure there are enough resources available at all times.

Information mentioned in (a) and (b) can be extracted from an IT system, and reports concerning this information are generated for management.

Quality Assurance Procedures (Paragraph 21.07)

Provide information on procedures which ensure that S&E reports of a quality standard in accordance

with PCT/GL/ISPE are issued. In particular, provide information on:

(a) Activities related to verification, validation and monitoring; as carried out in order to assess compliance of S&E work with PCT/GL/ISPE.

(b) Processes for measuring, recording, monitoring and analysing performance of the QMS to assess its conformity with the requirements of Chapter 21 and, if applicable, any other normative reference for the QMS.

(c) Activities related to verifying the effectiveness of actions taken to deal with deficiencies, including:

(i) those actions taken to eliminate, correct or authorise release of deficient S&E work which does not comply with the quality standards;

(ii) those actions taken to eliminate the causes of deficient S&E work and prevent the deficiencies from recurring.

(d) Activities ensuring the continuous improvement of established processes underpinning the issue of S&E reports.

(a) PCT quality checks are composed of the following procedures:

1. Every examiner is checked by a second examiner from the same technical group who carries out a quality review in accordance with quality Assurance guidelines.

2. Technical group heads and senior examiners check decisions, to grant or refuse patents, as well as review S&E report quality on a regular basis.

3. Quality Control personnel carry out spot checks.

(b) The performance of the QMS itself is scrutinized separately by internal as well as external audits and monitored..

(c) The following activities are carried out to verify the effectiveness of actions taken to deal with deficiencies in accordance with ISO 9001 practices :

- (i) Deficiencies in S&E work are corrected immediately upon detection.
- (ii) All deficiencies are reported and a specialized Tools & Procedures group asses possible causes, as well as solutions to insure prevention of future recurrences.

(d) The Tools & Procedures group and the Response group are assigned to continuously improve the S&E process in order to achieve product compliance with regulations, standards and customer needs. The quality assurance procedures discussed above, along with customer feedback and other measurements taken by both groups serve as sources of input towards continuous improvement of the S&E process. Furthermore, contact with other S&E authorities will provide us with additional crucial information that will expedite improvement

Feedback arrangements (Paragraph 21.08)

Give information on arrangements to:

(a) Provide feedback to staff informing them of results of verification, validation and monitoring carried out in order to assess compliance of S&E work, so that: (i) deficient S&E work is corrected:

(iii) best practice is identified, disseminated and adopted.

⁽i) deficient S&E work is corrected;

⁽ii) corrective action, i.e. action necessary to prevent recurrence, is identified and implemented;

(b) Accommodate prompt feedback from WIPO, designated and elected offices; so that potential systemic issues, e.g. recurring deficiencies of S&E work, as identified by these bodies, are evaluated and addressed.

(a) The ILPO has a client feedback mechanism in place for filed patent applications. Client feedback is always checked thoroughly and any action that may be warranted is taken, be it corrective or preventive. Corrective actions are communicated to all relevant staff.

In addition we have put in place a mechanism that includes meeting with representatives from both local industry and patent attorney firms periodically to discuss quality related issues, as well as circulating customer satisfaction questionnaires.

Teams of patent experts discuss and conclude best practices. Best practice is implemented in training and by drawing up guidelines.

(b) Feedback from WIPO is handled by the director of the PCT division

Communication, Guidance and Responses to Users (Paragraphs 21.06(c), 21.09) *Give information on arrangements to:*

(a) Provide communication channels for dealing promptly with enquiries and enabling appropriate two-way communication between applicants and examiners.

(b) Provide concise and comprehensive guidance and information to users (particularly unrepresented applicants) on the S&E process using the website of your Authority, guidance literature, and other means.

(c) Monitor and react to user needs and feedback, including:

(i) measuring user satisfaction and perception;

(ii) handling complaints;

(iii) correcting deficiencies identified by users;

(iv) taking corrective action, i.e. action to eliminate the cause of deficiencies, in response to recurring or systematic deficiencies identified by users.

(v) taking preventive action, i.e. action to eliminate the cause of potential deficiencies, in response to potential deficiencies or problems identified by users;

(vi) ensuring needs and legitimate expectations of users are met.

(a)

Examiners and supporting staff are available to applicants by e-mail and phone. Meetings are held at the request of the applicant. The ILPO has an excellent rapport with our applicants. We are committed to reply to all applicant requests within 24 hours.

The PCT division provides detailed guidance for applicants.

(b)

The ILPO website contains a comprehensive and complete guide to the S&E process. Moreover, the ILPO web pages are continuously improved for better information and guidance for customers. Information is posted on the ILPO's website to help users better understand the examination process. The ILPO's website informs applicants about new developments in the Office and changes to Office practice. A "PCT International Phase" page is a part of the ILPO's website and used to inform applicants about updates in the PCT.

(c)

Client feedback is always checked thoroughly and any action that may be warranted is taken, be it corrective or preventive. We have put in place a mechanism that includes meeting with representatives from both local industry and patent attorney firms periodically to discuss quality related issues, as well as circulating customer satisfaction questionnaires.

INTERNAL REVIEW (PARAGRAPHS 21.10-21.15)

Paragraph 21.10 specifies that, in addition to a "quality assurance system for checking and ensuring compliance with the requirements set out in its QMS" [c.f. Paragraphs 21.03, 21.07], "each Authority should establish its own internal review arrangements to determine the extent to which it has established a QMS based on the above model". This model is set out by Chapter 21 as a whole [c.f. Paragraph 21.02]. Since a QMS which does not contain this provision for internal review would not meet the requirements of Chapter 21, the report under 21.17 should contain at least the information on the extent to which arrangements for internal review required by 21.10 are in place. These are as below.

Required Arrangements for Internal Review (Paragraph 21.10)

The Authority should show that arrangements are in place to ensure that:
(a) An internal review is carried out to determine:
(i) the extent to which a QMS complying with the model of Chapter 21 has been established;
(ii) the extent to which the Authority complies with the requirements of its QMS;
(iii) the extent to which the Authority complies with PCT/GL/ISPE.
(b) The internal review demonstrates whether or not the requirements of the QMS and PCT/GL/ISPE are being applied consistently and effectively.
(c) The internal review takes place at least once a year.

The ILPO is currently investigating utilizing an external resource for scrutinizing and ensuring compliance with the requirements set out in our quality measures.

Internal Review

The ILPO has yet to fully implement all parts of our QMS and therefore carried out a partial internal review at this time.

Internal reviews, such as the one undergone this year (2009), will take place at least once a year, as well as external audits that will take place annually as well, in order to achieve and maintain ISO 9001 certification.

OPTIONAL INFORMATION UNDER PARAGRAPH 21.17

Guide to Internal Review Arrangements (Paragraphs 21.11–21.15)

Paragraph 21.11 states that 21.12 - 21.15 are "proposed as a guide to the basic components of an internal review mechanism and reporting system", and are thus optional. Authorities may respond to the following points to indicate the provisions they have in place for Internal Review.

The Authority may show that the following arrangements are in place and will be used for the purpose of internal review:

(a) Arrangements providing information on conformity of S&E work; i.e. information from activities related to verification, validation and monitoring, as carried out in order to assess compliance of S&E work with PCT/GL/ISPE [c.f. point (a) under "Quality Assurance" above].
(b) Arrangements providing information on the effectiveness, and the extent of

implementation, of the QMS and its processes; whereby it can be established to which extent the QMS complies with the requirements of Chapter 21 and, if applicable, any other normative reference for the QMS.