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: Brazilian National Institute of Industrial Property

(INPI-BR)

on: 14/03/2008

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:

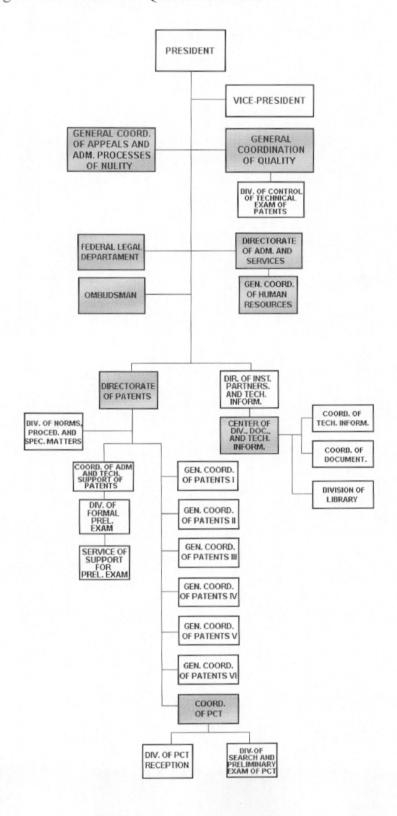
- Recognised normative reference or basis for quality management system besides
 Chapter 21, e.g. ISO 9000.
- An organigram showing at least the organizational units responsible for implementation of the Authority's QMS. It could be referred to in the rest of the report, as necessary.

The National Institute of Industrial Property (INPI-Br) is a Federal Autonomous Entity within the Brazilian Federal Government. Created in 1970, INPI-Br is linked to the Ministry of Development, Industry, and Foreign Trade with the purpose of executing the norms that regulate the industrial property, considering its social, economic, legal, and technical functions.

In its almost four decades of existence, INPI-Br staff has constructed a high level of consciousness and responsibility regarding the service rendered to its users. Under these circumstances, the demand for better examination and management procedures increased significantly. First attempts to establish a pro—quality culture took place between 1993 and 1994 with the creation of a Total Quality Management Program. INPI-Br's Administration has long recognized the ISO 9001:2000 standard as an internationally recognized and accepted set of guidelines and requirements. Apart from being adopted as a normative

reference by many other Offices, it has been revealed as the most appropriate model to be followed indeed.

To all intents and purposes, it shall be clarified that the establishment of an INPI-Br QMS is still in progress in this reporting year. Furthermore, the new proposed organigram, which was sent to the Ministry of Development, Industry and Foreign Trade for evaluation, contemplating the areas related the QMS follows below.



General-Coordination of Quality:

Plans, coordinates and executes the quality policies of administrative services and activities of INPI-Br's technical fields. Its *Division of Control of Technical Exam of Patents* is responsible for giving opinions about the directives and operational procedures that orient these activities, promoting and coordinating the certification for patents of all INPI-Br activities according to the norms and standards. It also accomplishes controls to verify the quality policies application, of elaborating reports which contains proposals of measures to sanitize detected dysfunctions, divulging norms and procedures, and giving technical orientation to the involved unities.

General-Coordination of Appeals and Administrative Processes of Nullity:

Gives technical instructions concerning appeals and nullity processes administratively invoked. This is the area in charge of processing the appeals and nullity requests, of controlling the deadlines related to appeals and nullity and of proposing the improvement of directives of examination procedures related to these matters.

Federal Legal Department:

Exercises the legal and paralegal representation of INPI-Br, acting in the processes of which the Autarchy is invoked.

Directorate of Administration and Services:

Plans, coordinates, directs, supervises, promotes, accompanies and evaluates execution of human resources activities, including supplying and allocation of employees of general services, informatics, information and financial administration. Responsible for administrative modernization and organization, among others.

General Coordination of Human Resources:

Plans, coordinates and supervises the execution of activities related to personal administration and INPI-Br human resources development, including training and capacity building.

Ombudsman:

Analyses and treats the requests, information, praises, complaints and suggestions that arrive from our users; creates reports with indicative and qualitative analysis, identifying critical points and contributing on the search of solutions.

Directorate of Patents:

Coordinates, supervises, accompanies and promotes the application of projects, agreements and treaties that concern patents; analyses, decides and grants patentary privileges according to the present legislation; and proposes the practical improvement and develops operational standards for patent analysis and concessions.

Coordination of PCT:

Exercises the inherent activities, in Brazil, as the receiver office of international requests. It is also responsible for activities related to Search and Preliminary Exam of PCT.

Center of Divulgation, Documentation and Technological Information:

Manages and updates patent information and other national or foreign publications; and promotes technological information divulgation and diffusion, generated and managed by INPI-Br, focusing on national development.

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.

Challenges most recently faced in the international economic scenario especially in the last decade pushed intangible assets to occupy a central role in the global economy, dependent of increasingly efficient systems for its effectiveness and competitiveness.

Due to that, INPI-Br is currently planning the establishment and implementation of a QMS based on the most appropriate patterns available. Taking into consideration the commitments assumed by the administration, several meetings concerning the focused subject have been held.

The Administration understands as extremely beneficial the creation of a *Division of Norms*, *Procedures and Special Matters*, directly linked to the Directorate of Patents, designated to be officially in charge of harmonizing and updating all technical procedures, in accordance to PCT/GL/ISPE rules and related PCT documents.

Based on those contents, the criteria and parameters to be followed by internal audits will be carried out by the *Division of Control of Technical Exam of Patents* within the *General Coordination of Quality* (hereinafter referred to as GCQ). This is an independent body linked directly to the President (see organigram) with the responsibility of leading the quality internal process in the specific field of patents.

It is worth to mention that the involved staff will most certainly be composed by patent examiners, rotated from time to time, in views of guaranteeing that as many examiners as

possible will learn the importance of quality standards and will take it to their daily examination practices.

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.

In respect of academic qualifications, all patent examiners must possess, as a minimum requirement of public selection, a Master's Degree. Furthermore, around 30 percent of examiners already possess a PhD level.

INPI-Br's current training program for patent examiners consists of a two-year formal training with an on-the-job approach in a great variety of patent law and examination subjects, such as the main national and international legislation, jurisprudence, advanced patent prosecution and patentable subject matter.

Training efforts are not restricted to the education of new examiners. Experienced examiners, as well as the administrative staff, are also engaged in a continuous training and are encouraged to keep abreast of the most recent technology developments related to their field of specialty by several possible means: reviewing technical periodicals; evaluating electronic tools (for example: EPOQUE, DIALOG¹); attending conferences; taking part in technical events; designing training programs; and exchanging best practice information with other Patent Offices. By the way, INPI-Br has established institutional agreements with many others offices and institutions to construct a positive scenario of international partnerships. Put simply, INPI-Br understands as necessary to provide its technical staff with the best knowledge available and necessary capabilities.

Likewise, INPI-Br has a large number of examiners that are able to adequately perform their work in both English and Spanish. Besides, English knowledge is a minimum requirement of

DIALOG is the world's online information retrieval system that provides online-based information services about Industrial Property in our case.

the public selection. Many of them have practical skills in additional foreign languages. Also, INPI-Br established a continuous program for capacity building for its employees on foreign languages.

INPI-Br's Human Resources Department maintains a capacity-building program to all the careers by means of permanent education and continuous formation in and outside the country. Besides, this program aims to motivate employees and make good use of their abilities and acquaintances. From January/2007 to June/2007, around 500 employees had participated in a considerable number of activities regarding capacity building.

INPI-Br patent examiners use high standard databases in search and examination activities. There are both national databases (PORTAL CAPES²) as well as external ones (EPOQUE, DIALOG and others). All examiners have a permanent online access to the most current information through their own workstation.

Its facilities have personnel workstations with one PENTIUM computer per person, with a CD/DVD-ROM drive and Internet access through a high-speed connection. This permits access to the EPOQUE Database system, and provides patent examiners with the necessary facilities to conduct their search and examination functions.

INPI-Br is conducting projects in international level to build new on-line tools that will enable the involved offices to share information and to facilitate the access to patent documents. For instance, we may point out the project for construction of a Portuguese Speaking Countries Intellectual Property Portal, resultant from a bilateral cooperation with INPI-Portugal. This project enables both institutions to share Portuguese patent documents, which exists not only in both countries, but also includes all the other Portuguese Speaking Countries all over the world, mainly African ones. Moreover, INPI-Br is committed with the maintenance of the translation of the IPC 8th edition to Portuguese.

Another on-line tool, called South American Intellectual Property Portal, is being built jointly with other nine countries³ in South America. The first draft of this new Portal is prospected for 2007, enabling those Offices to share information in real time about exams and final decisions regarding patent applications.

These plans cited above, as well as other ones in national level show serious commitment of INPI-Br with the quality of its patent searches and exams. INPI-Br has made a great effort in order to increase the number of digitized Brazilian language patent documentation up to the oldest documents in our archive. Also, these records have been sent to EPO to be integrated and shared in the EPOQUE system.

All patent examiners have been provided with detailed information on PCT procedures through training. They are provided with up-to-date legal texts, Manual of Procedures for the Preliminary Formal Examination, Search and Examination Guidelines and work instructions and have access to the WIPO site, which also contains all PCT information. INPI-Br is always

CAPES Portal is a famous database of documents, article and scientific texts related to non-patent literature. It is administered by the Coordination of Improving Actions for the University Degree (CAPES) .For more information and details, see www.capes.gov.br and www.periodicos.capes.gov.br.

³ Argentina, Bolivia, Chile, Colombia, Ecuador, Paraguay, Perú, Surinam and Uruguay.

reviewing these procedures and work instructions and new instructions are continuously transmitted to all patent examiners.

Besides, INPI-Br is now in the process of developing practical and detailed work manuals for patent examiners, which will contain work procedures and guidelines as to how to elaborate technical reports, and how to search and exam under certain quality criteria and standards. *A Division of Norms, Procedures and Specific Matters* will be the area responsible for compiling, updating and disseminating work instructions for all staff. Also, it will keep work manuals for examining staff up-to-date and ensure their effective distribution. Moreover, all staff is instructed to adhere to the work procedures described in internal instructions.

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.

All Heads and Managers make use of an INPI-Br Electronic Device System (SINPI) for Follow-up of Applications and for Monitoring purposes.

Fluctuations in demand and backlog management are addressed during Manager Meetings. If necessary, Working Groups are created in order to discuss on strategies and/or possible solutions.

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.

All activities related to verification, validation and monitoring in regards to INPI-Br's quality standards are issued in due accordance to those terms as specified in the PCT/GL/ISPE, in particular Chapter 21.

In general terms, each Directorate is responsible for quality concerning its own area. This process starts with the Head of the Examining Division responsible for carrying out Search and Examination, who distributes the applications to Examiners in accordance to their

technical qualifications and attributes. At this stage, it is equally important for the Head to take into consideration whether or not an Examiner has competence of approval or denial for the concession of a patent.

This information is mainly relevant when considering new examiners. In Brazil, all public employees must go under a period of experience, which takes exact three years. As a rule, no Patent Examiner is considered experienced enough before an average of five years of sufficient training, tutoring and demonstration of necessary technical skills. Up to this point, non-experienced examiners may only issue reports outlining opinions or requesting for corrections. In doing so, the production of New Examiners is constantly monitored so as to correct deficiencies regarding S&E work and to guarantee its conformity with the various directives and regulations in force.

Other than that, Heads of Divisions may make use of sample-based studies to evaluate whether a considerable amount of Applications analyzed by a certain Examiner is object of appeals or nullities. At the same time, a periodical analysis shall be ordered for measuring purposes. And the methodology for comparing the number of applications with no history of objections and the total amount that either go under a process of appeal or nullity will be further refined. Nevertheless, all information collected will provide an efficient picture of INPI-Br's framework.

At this point, it is worth to mention that GCQ is conceived to play a strategic role in all INPI-Br's policies concerning quality practices. Once established, it will function as the formal area with the necessary expertise to spread a quality culture within INPI-Br.

By doing that, INPI-Br intends to guarantee that best practices concerning each area are disseminated. Also, GCQ will provide the necessary tools to better orient Heads and Managers in their continuous search for quality.

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;
- (ii) corrective action, i.e. action necessary to prevent recurrence, is identified and implemented;
- (ii) best practice is identified, disseminated and adopted.
- (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.

All patent examiners whose work has been subject to verification are informed about the outcome and are asked to perform any necessary corrections. Director, Coordinator and Head of Divisions conduct the verification of Search and Examination work. Corrective and preventive actions will be taken after a problem is identified. Best practice, when identified, will be disseminated and adopted.

INPI-Br's PCT Coordination under Directorate of Patents is committed with maintaining prompt feedback from WIPO, designated and elected Offices to all divisions of Directorate of Patents.

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.

There are several communication channels available for a direct contact between examiners and applicants or their respective representatives, through telephone, personal interview, mail, fax, e-mail and/or Ombudsman.

Applicants and/or Legal Representatives may also apply for an interview or meeting with the Examiner, as long as it is requested with sufficient prior notice. All examiners are well trained and prepared to provide applicants/legal representatives the necessary consultancy regarding their queries.

In addition, Guidance to applicants on Intellectual Property, including information on the search and examination process is provided by various means, such as the INPI-Br website (www.inpi.gov.br) and some training seminars organized in cooperation with WIPO. It is being developed by INPI-Br a User's Guideline to explain how to file patent applications through PCT system.

INPI-Br website is frequently upgraded to give information concerning notices, announcements, events, as well as courses and activities related to Intellectual Property. Also, all the important information related to the Institute is made available, including a session about most frequently asked questions (FAQ) related to different areas of INPI-Br, as well as all Brazilian laws and normative acts referred to Industrial Property.

Last year, INPI-Br created a modern electronic system, called "e-marcas", that made the Institute capable to receive and to speed up the internal application's flow. A link to "e-marcas" is available to INPI-Br website users. It is in development a similar system to the patent area in order to facilitate patent application filing.

Within the Center of Divulgation, Documentation and Technological information, a Section of Searches makes use of an evaluation handed out to our clients, as an important instrument of services improvement. Each received evaluation is treated individually and, in case of dissatisfaction, the problem is identified and fixed. Along with that, a further contact with the client is established by either e-mail or telephone for any necessary elucidations.

In 2004, INPI-Br's new internal structure included an Ombudsman *persona*, responsible for receiving questions, complaints and suggestions from our clients, both through the online electronic "System of the Ombudsman" and the "Contact Us" area, as a form of raising opinions from our clients, to improve INPI-Br's attendance and the content of exchanged information. Nonetheless, the Ombudsman department will most certainly undergo significant changes after the GCQ starts its activity so as to become increasingly aligned with internal QMS policies.

Meanwhile, an INPI-Br Academy of Intellectual Property and Innovation has turned out to be a very relevant instrument of dialogue with our external clients, mainly society and users of the Brazilian IP System as a whole. The production of papers and articles helps the Institution to better understand external demands and expectations and to use the knowledge debated for managerial intents.

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.

Although INPI-Br has not yet implemented a formal QMS, internal review activities are carried out in distinct levels for quite some time within the Board of Directors and with the President. In the course of the first semester of 2007, several meetings along with administrative and technical areas have taken place in order to discuss on the ISA/IPEA requirements for an internal QMS and to demonstrate in what extent the PCT/GL/ISPE are being applied consistently and effectively.

Nevertheless, appropriate correction and/or preventive measures will be adopted after the first official report by the GCQ identifying gaps is issued. Thus, internal reviews will be promoted once the QMS as presently envisioned is fully established. In a first phase, it is intended to take place every six months and at least once a year.

The Internal Review shall make use of reports prepared by the GCQ based on the results obtained from Internal Audit's work concerning S&E activities. Furthermore, the full range of

parameters of the PCT Search and Examination Guidelines, in particular Chapter 21, will be focus of analysis to guarantee conformity with the previous requirements or, whenever necessary, measures for improvement.

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