Construing Patentability of Chemical Technology Inventions, with Focus on their Patent Eligibility and Industrial Applicability: *A Comparison on the Patent Examination Approach in the Philippines and in Japan*

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Abstract

The Intellectual Property Office of the Philippines (IPOPHL) must cope up with the emerging challenges in the patent examination of various fields of technology. The Chemical Technology field at IPOPHL covers a wide array of chemical-related subject-matters which in turn has resulted in handling concerns to the examiners assigned to perform substantive examination on such diverse technologies. Japan Patent Office (JPO) has provided comprehensive guidelines addressing various patentability issues, especially that of patent eligibility and industrial applicability of subject matters in the chemical field. By introducing conceptual aspects of the Japanese patent system as a model, this study allowed the investigation of the similarities and differences in JPO's and IPOPHL's examination procedure and assessment of patentability requirements, with focus on patent eligibility and industrial applicability of chemical technology inventions. Japan's practices, policies, and experience on handling such matters has provided a new perspective in different aspects of patent examination. Based on the best practices of examination standards and system of Japan, a series of recommendations on how we can handle the same matters in the Philippines was made. These findings may then help in developing clear patent examination guiding principles and implementation system regarding patent examination in the chemical technology field at IPOPHL. Ultimately, this study may prove to be helpful in understanding each Intellectual Property Office's examination standards and may aid in improving the work sharing between the two offices.

Keywords: patent examination, chemical technology, patentability requirements, patent eligibility, industrial applicability

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List of Abbreviations

ASEAN	Association of Southeast Asian Nations
BOP	Bureau of Patents
CII	Computer Implemented Inventions
CNIPA	China National Intellectual Property Administration
EPO	European Patent Office
ICT	Information and Communications Technology
ID	Industrial Design
IP	Intellectual Property
IP Code	Intellectual Property Code of the Philippines (R.A. 8293)
IPC	International Patent Classification
IPEA	International Preliminary Examining Authority
IPO	Intellectual Property Office
IPOPHL	Intellectual Property Office of the Philippines
IRR	Implementing Rules and Regulations
ISA	International Searching Authority
IT	Information Technology
JEGPE	Joint Expert Group for Patent Examination
JPO	Japan Patent Office
MPEP	The Manual for Patent Examination Procedure in IPOPHL
PPH	Patent Prosecution Highway
QUAMA	Cheaper and Quality Medicines Act or Republic Act 9502
SIPO	State Intellectual Property Office
UM	Utility Model
UPOV	International Union for the Protection of New Varieties of Plants
USPTO	United States Patent and Trademark Office

1. Introduction

Data indicating a growing activity in the patent market may partially be associated with the increasing role of patents in industries. However, this aspect may be more likely true for developed countries. The role of patent systems in developing countries is not as visible since in most developing countries, domestic application accounts for only a small percentage of total applications due to several factors. (Caviggioli, Scellato, & Ughetto, 2013; Ginarte & Park, 1997; Ivus, 2010; Kirim, 1985; Park & Ginarte, 1997)

In any jurisdiction with a patent office, there are usually very similar patentability criteria that should be met by an invention in order to be granted a patent. First off, inventions must fall within a patentable subject matter in order to qualify for a patent protection. Also, in addition to sufficient disclosure of the invention, the patentability of the inventions is usually evaluated based on three basic criteria: 1) it must be new, 2) it must involve an inventive step or is not obvious, and 3) it must be industrially applicable. Notably, there are several other requirements that must be met prior to the granting of patent depending on the jurisdiction. Throughout the patent prosecution, the patent application usually undergoes activities such as, a formality examination, a substantive examination, and the grant and publication of the successful patent application. It is important to note that the patent application process of several jurisdictions may differ from each other, thus some aspects of the patent application process may not be applicable.

Every year, the Intellectual Property Office of the Philippines (IPOPHL) receives thousands of patent applications (inventions) in various fields of technology. Despite advances in the Information technology (IT) field, the Chemical and chemical-related fields continue to contribute to the greatest number of filings of patent applications in the Philippines. At IPOPHL, chemical-related inventions are generally examined according to their sub technical fields broadly covering chemical technology, pharmaceutical, and biotechnology. IPOPHL patent examiners assess the patentability of chemical inventions based on the existing Intellectual Property Code (IP Code), Revised Implementing Rules and Regulations for Patents, Utility Models and Industrial Designs (IRR), and Manual for Patent Examination Procedure (MPEP). In addition to this, the pharmaceutical field and the biotechnology field each has a set of detailed guidelines in the examination of applications on their respective fields. The chemical technology field, however, does not have such detailed supplementary guidelines. Also, in general, the entire chemical field (chemical technology, pharmaceutical, and biotechnology),

does not have very clear and specific guidelines in assessing patent eligibility (patentable subject-matter) and/or industrial applicability.

In IPOPHL, the Chemical Technology field covers a wide array of chemical-related subject-matters which includes, but is not limited to, macromolecular chemistry, inorganic chemistry, surface technology, metallurgy, environmental technology, foodstuffs, and chemical compositions. As such, this diversity makes it difficult to assess the patentability (novelty, inventive step, industrial applicability, etc), of inventions involving these subject-matters at times. At present, substantive examination is mainly guided by the IP Code, the IRR, and the MPEP. However, the provisions provided in these references are becoming too general to address these highly diverse and/or specific topics and as such, these provisions are subject to interpretation of patent examiners. This is especially true when it comes to assessing patent eligibility and/or industrial applicability. As a result, the prosecution of chemical technology applications has become lengthy and subjective at times.

For those reasons, there is a need for IPOPHL to amend its present examination references and to address issues involving patentability (novelty, inventive step, industrial applicability, etc.), with emphasis on the patent eligibility and industrial applicability of patents relating to chemical technology inventions. The present IPOPHL examination resources appear to no longer be appropriate in addressing issues and challenges happening in the IP System.

Also, while there is an acceptable number of guiding principles and in depth discussions related to novelty and inventive steps in the Philippines, the same could not be said for patent eligibility and industrial applicability. Hence, examples and case studies related to patent eligibility and industrial applicability will indeed lead to a better and clearer understanding of these concepts, and thus will ultimately aid in their appropriate assessment. This study will also provide an opportunity to help provide more information which may be useful in developing clear patent examination guiding principles. Ultimately, it would help patent examiners from IPOPHL to examine these kinds of technologies using standardized procedures and with confidence.

IPOPHL has maintained its International Organization for Standardization (ISO) 9001:2008 certification since 2013 and is now in its transition to a 9001:2015 certification. To support IPOPHL’s goal, the Bureau of Patents is committed to deliver search and examination products with high and consistent quality and to continuously improve its processes through regular review and assessment of its performance and process flow to effectively address gaps and adopt a new approach or reinforce established standards. In light of this, the bureau is

currently undergoing research analysis based on findings from various sources in order to standardize the examination procedures and practices across all divisions in all fields of technology, especially in the chemical field.

Japan Patent Office (JPO) is an established International Searching and Preliminary Examining Authority (ISA/IPEA). Its long history of patent protection ensures that the quality of patents granted in Japan are high, wherein their patents have lower probability of being opposed nor revoked than patents granted in the United States of America or in Europe (Caviggioli et al., 2013). In Japan, Japan Patent Office has provided very detailed guidelines specifically addressing such issues, especially that of patent eligibility and industrial applicability of various subject matters, as provided in their Examination Guidelines for Patent and Utility Model. In addition to this, the Examination Handbook for Patent and Utility Model in Japan has also provided very informative Case examples (Annex A) and Court precedents (Annex D) on patentability matters, with detailed sections on eligibility for patent and industrial applicability.

It is expected that the findings from this study will allow us to see the similarities and differences in the patent prosecution procedure of another IP office and from this; it may help IPOPHL to formulate the appropriate guiding principles in examining patents in the chemical technology field, with focus on their patent eligibility and industrial applicability. An enhanced knowledge and specific understanding (with possible case studies and examples) on the different patent examination practices and perspective of other countries, particularly of JPO, in context with the existing Philippine laws on patents, will be beneficial. Likewise, the opportunity to discuss and obtain a new perspective from foreign IP offices, colleagues, and mentors, on certain issues regarding the patentability of several topics is expected.

The specific objectives of this study are as follows:

- To recognize the scope of the chemical field technologies and specifically, the chemical technology field in JPO and in IPOPHL.
- To understand the practice in assessing patent eligibility and industrial applicability for the chemical field inventions in JPO.
- To understand the practice in assessing Novelty, Inventive Step, and Industrial Applicability for chemical technology inventions in JPO.

- To determine the similarities and differences in the patent prosecution procedure in the chemical field, specifically in the chemical technology field in JPO and in IPOPHL.
- To analyze the limitations of the current examination practice in IPOPHL.
- To recommend examination principles based on the best practices of examination standards of JPO.

2. Basic information and previous studies

2.1 Background on the Patent Office and the Patent System in IPOPHL

2.1.1 *Overview of the Organizational Structure and Functions*

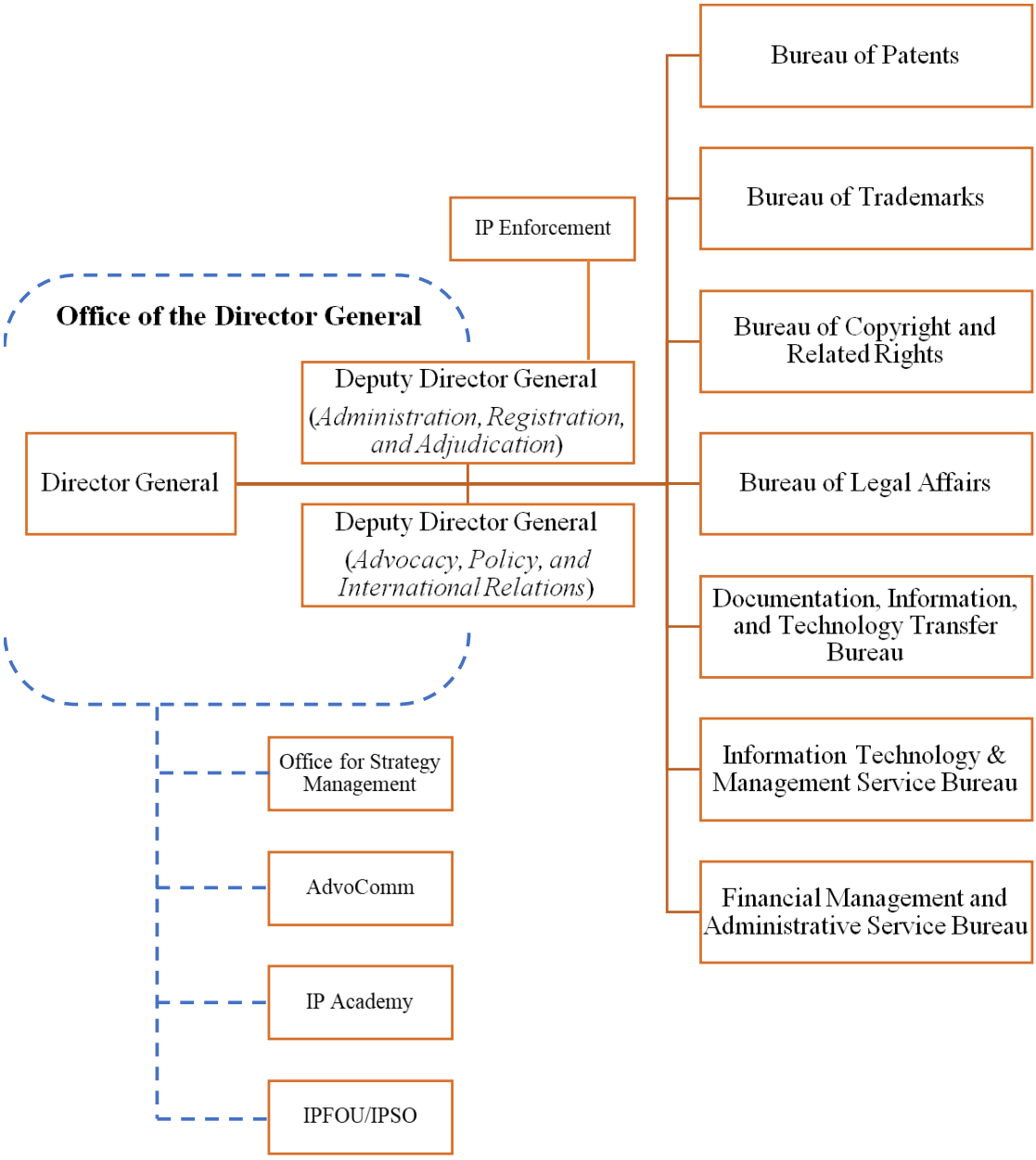

Figure 1. Organizational Chart of IPOPHL.

Figure 1 shows the Organizational Chart of IPOPHL. The Bureau of Patents (BOP) is one of the seven bureaus of the Intellectual Property Office of the Philippines. The bureau is responsible for receiving and examining all local, foreign and PCT applications for Inventions, Utility Models (UM), and Industrial Designs (ID). The Bureau is also responsible for

determining which of the said invention applications may be granted a patent, and which of said UM and ID applications may be granted registration. Figure 2 shows the organizational chart of the BOP. The Bureau is composed of ten (10) examining divisions directly under the supervision of the Director and the Assistant Director. Of the ten, eight (8) examining divisions handle Invention applications, one (1) examining division handles UM applications and one (1) examining division handles ID applications.

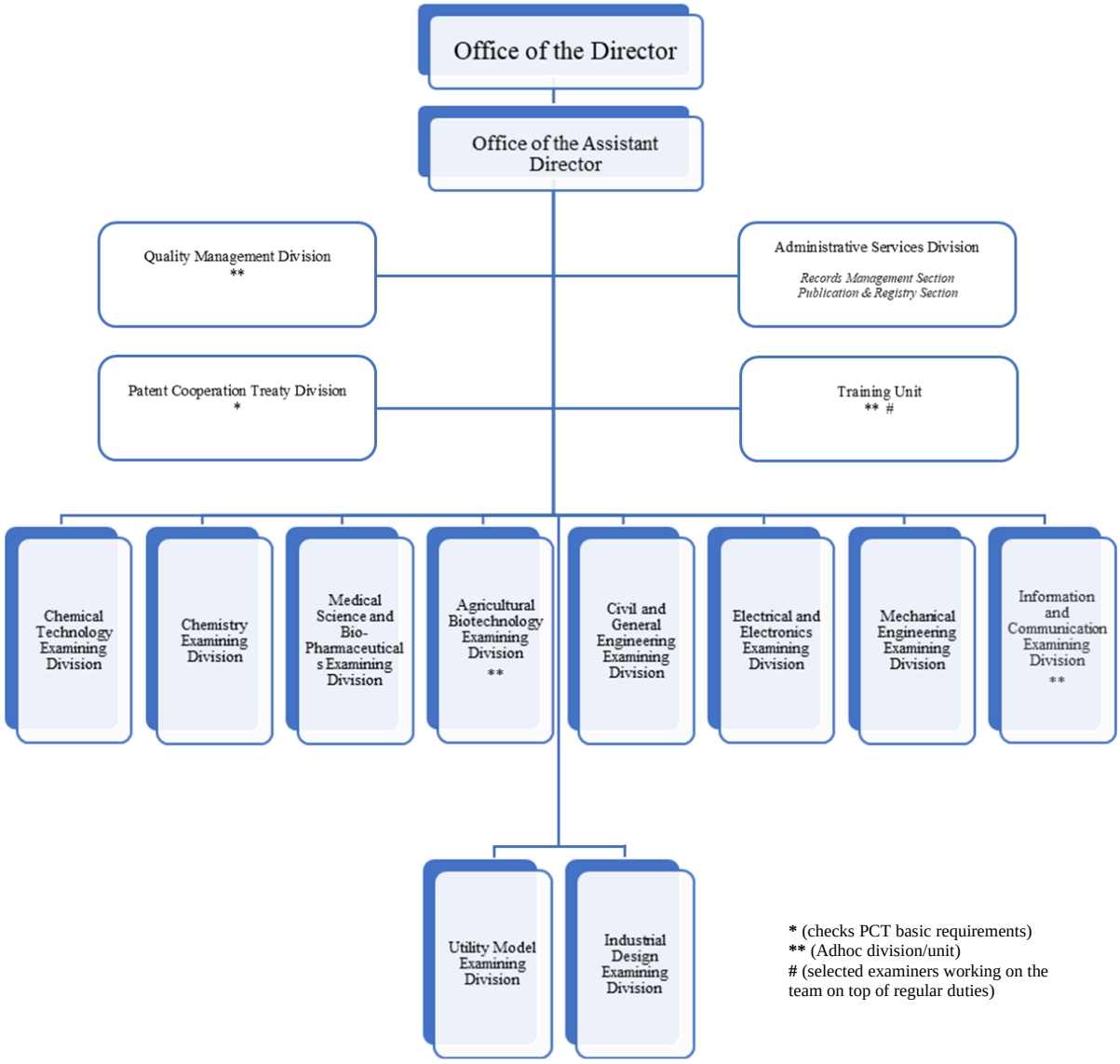

Figure 2. Organizational Chart of the Bureau of Patents in IPOPHL.

The eight (8) examining divisions handling Invention applications are responsible for conducting prior art searches and the preparation of office actions (formality, search and substantive examination). The examining divisions are divided according to specific fields of inventions classified using the International Patent Classification (IPCs). The examining divisions of the Mechanical group are the Civil and General Engineering Examining Division (CGEED), Electrical and Electronics Examining Division (EEED), Information and Communications Examining Division (ICED) and Mechanical Engineering Examining Division (MEED), while the examining divisions of the Chemical group are the Chemistry Examining Division (CED), Agricultural Biotechnology Examining Division (ABED), Medical Sciences and Bio-Pharmaceuticals Examining Division (MSBED), and Chemical Technology Examining Division (CTED). Presently, there are 108 examiners in the bureau with 50 examiners handling chemical invention applications. The examiners belonging to the Chemical Group have undergraduate degrees of BS Chemical Engineering, BS Chemistry, BS Biology, BS Respiratory Therapy, BS Biochemistry, BS Pharmacy, BS Medical Technology, and BS Agricultural Engineering.

New examiners undergo an intensive training course to equip them with the necessary competencies, skills and proper perspective before working on their respective examining division. The training is an in-depth study of Philippine statutes and rules covering various coursework and practical exercises focused on patent examination practices and procedures.

There are also continuous trainings and capacity-building activities provided for patent examiners in order to maintain and update their skills and knowledge at a competent level such as regular Lectures, Seminars, Workshops or Plant Visits conducted by University Professors or returning Filipino Scientists. Patent examiners also attend seminars and workshops conducted by other IP Offices (Local or Overseas) related to their technical fields. They are also encouraged to participate in distance learning courses offered by the World Intellectual Property Organization, the European Patent Academy, and other foreign IP offices.

The Quality Management Division (QMD) regularly monitors and ensures that quality examination work is being done by examiners. IPOPHL strives to promote IP creation and protection as well as supporting a competent workforce aimed at delivering high quality service to the stakeholders. To support IPOPHL’s goal, the Bureau of Patents is committed to deliver search and examination products with high and consistent quality and to continuously improve its processes through regular review and assessment of its performance and process flow to effectively address gaps and adopt a new approach or reinforce established standards.

2.1.2. *Managing Patent Examination in the Chemical Group*

Despite advances in the Information technology (IT) field and electronics field, the Chemical and chemical-related fields continue to contribute to the greatest number of filings of patent applications in the Philippines as shown in Figure 3. The chemical field encompasses a diverse number of subject-matters such as organic fine chemistry, biotechnology, pharmaceuticals, macromolecular chemistry/polymers, food chemistry, basic materials chemistry, materials/metallurgy, surface technology/coating, micro-structural and nano-technology, chemical engineering, and environmental technology.

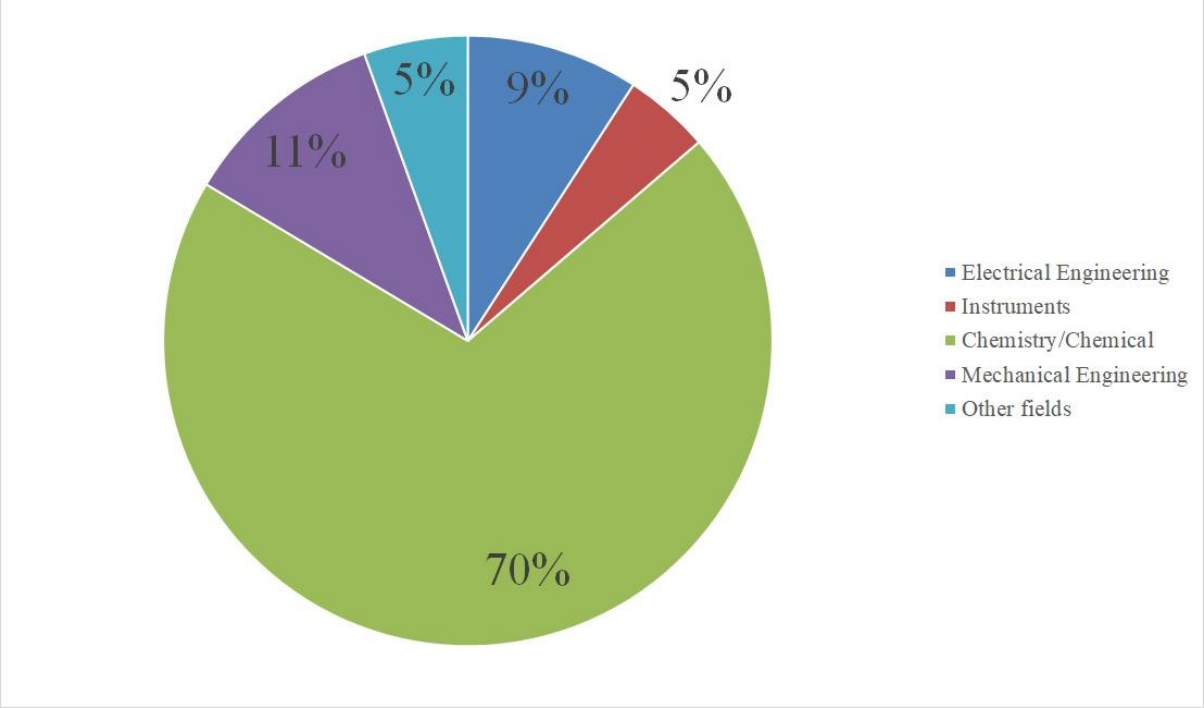

Figure 3. Total Patent Applications filed in IPOPHL by Field of Technology from 2014 to 2018.

Chemical invention applications are assigned to the different chemical group divisions based on the main field of technology covered by the application. Applications pertaining to the pharmaceutical field, particularly on drugs and medicines for humans in the form of chemical compounds and preparations, are examined by the Chemistry Examining Division. It should be noted that in this context, “drugs and medicines” are defined as any chemical compound or biological substance, other than food, intended for use in the alleviation of symptoms and the treatment, prevention or diagnoses of diseases in humans or animals. Biotechnology inventions relating to humans such as proteins, nucleic acid, antibodies, and

microorganisms, including their application in pharmaceuticals are handled by the Medical Sciences and Bio-Pharmaceuticals Examining Division. Applications relating to agriculture (e.g. pesticides, fungicides, etc.) and biotechnology inventions relating to plants, animals, and microorganisms are assigned to the Agricultural Biotechnology Examining Division. Those applications in the chemical field which do not belong to any of the aforementioned categories are broadly referred to as chemical technology applications and are managed by the Chemical Technology Examining Division. The technologies which are considered to belong to the chemical technology field include but are not limited to: macromolecular chemistry, inorganic chemistry, surface technology, metallurgy, environmental technology, foodstuffs, fuels, and other chemical compositions. Table 1 below summarizes the common International Patent Classifications (IPCs) symbols dealt by each chemical examining division.

Table 1. Summary of the IPCs corresponding to the chemical group examining divisions in IPOPHL.

Examining Division	Main or Common IPC handled
Chemistry Examining Division (CED)	A61K 9/00, A61K 31/00, A61K 33/00, A61K 35/00, A61K 36/00, A61K 38/00, A61P, C07B, C07C, C07D, C07F
Medical Sciences and Bio-Pharmaceuticals Examining Division (MSBED)	A61K, A61L (method only), C12N-C12S, C07+A61K, C07D
Agricultural Biotechnology Examining Division (ABED)	A01N/101P+C12N and/or C12P and/or C12Q, A23K/1P+C12N and/or C12P and/or C12Q, A01G, A01K, A01H, A01G
Chemical Technology Examining Division (CTED)	A21D, A23, A24, A61K 8/00, B01D, B01F, B01J, B03B, B05D, B32B 9/00, C01, C02, C03, C04, C06, C08G, C09, C10M, C11D, C22

It should be noted, however, that aside from the IPCs, specific keywords or subject-matters are also used to determine which division is the most appropriate to handle a certain invention. The more common subject-matters considered to belong to the Chemical Technology field in IPOPHL are as follows: chemical engineering processes, detergents, shampoos, cosmetics, dentifrices, deodorants, spray compositions, photobleaches and related products, whitening compositions, nail polish, binders, adhesives, coating materials, dyes,

paints, paper, textiles and fabrics, lubricants, oils, animal/vegetable oils, plastics, fuels, fertilizers, food technology, feeds, fermentation process, building products (cement, concrete), wastewater and water treatment, glass, metallurgy, polymers and polymerization (plastics, rubber, etc), synthetic resins, and alcohols.

2.1.3. *Patent Prosecution Practice in IPOPHL*

In the Philippines, there are three possible routes for filing a patent application. A resident applicant can file directly at IPOPHL while the non-resident has two routes: The Paris Route and the PCT Route. Figure 4 shows the Patent Prosecution Procedure in IPOPHL for directly filed applications (including the Paris Route). These applications will generally undergo formality examination, search, and substantive examination. For applications filed through the PCT route, they will generally be subjected to formality examination and substantive examination. A search will no longer be performed for the PCT application unless a divisional application is filed.

The formality examination for PCT and directly filed applications is different. Formality examination for PCT constitutes checking for PCT-related formality requirements, formality defects, and payments only. The formality examination for directly filed applications constitute checking for formality defects, clarity and unity issues, and payments.

The substantive examination will be performed once the corresponding fee is paid. The examination at this stage is as follows: The claim is first assessed whether or not it relates to a patent-eligible subject matter (Sec 21 and 22, IP Code). It is only once it is established that the claim relates to a patent eligible subject matter, will the claim be assessed with regards to Novelty, Inventive Step, and Industrial Applicability including Clarity/Support/Enablement,. However, if the claim does not relate to a patent-eligible subject matter, then there is no need to proceed to the assessment of other patentability requirements. Whether or not there is any Clarity/Support/Enablement issue, the claim may be assessed for Novelty, Inventive Step, and Industrial Applicability. A claim which is deemed as lacking novelty will no longer be assessed with regards to Inventive Step. A claim containing a novel subject-matter will be assessed for the presence of Inventive Step. Industrial Applicability will be assessed concurrently with the assessment on Novelty and Inventive Step. That is, whether or not the claim is Novel and/or Inventive, the claim will still be examined for its Industrial Applicability.

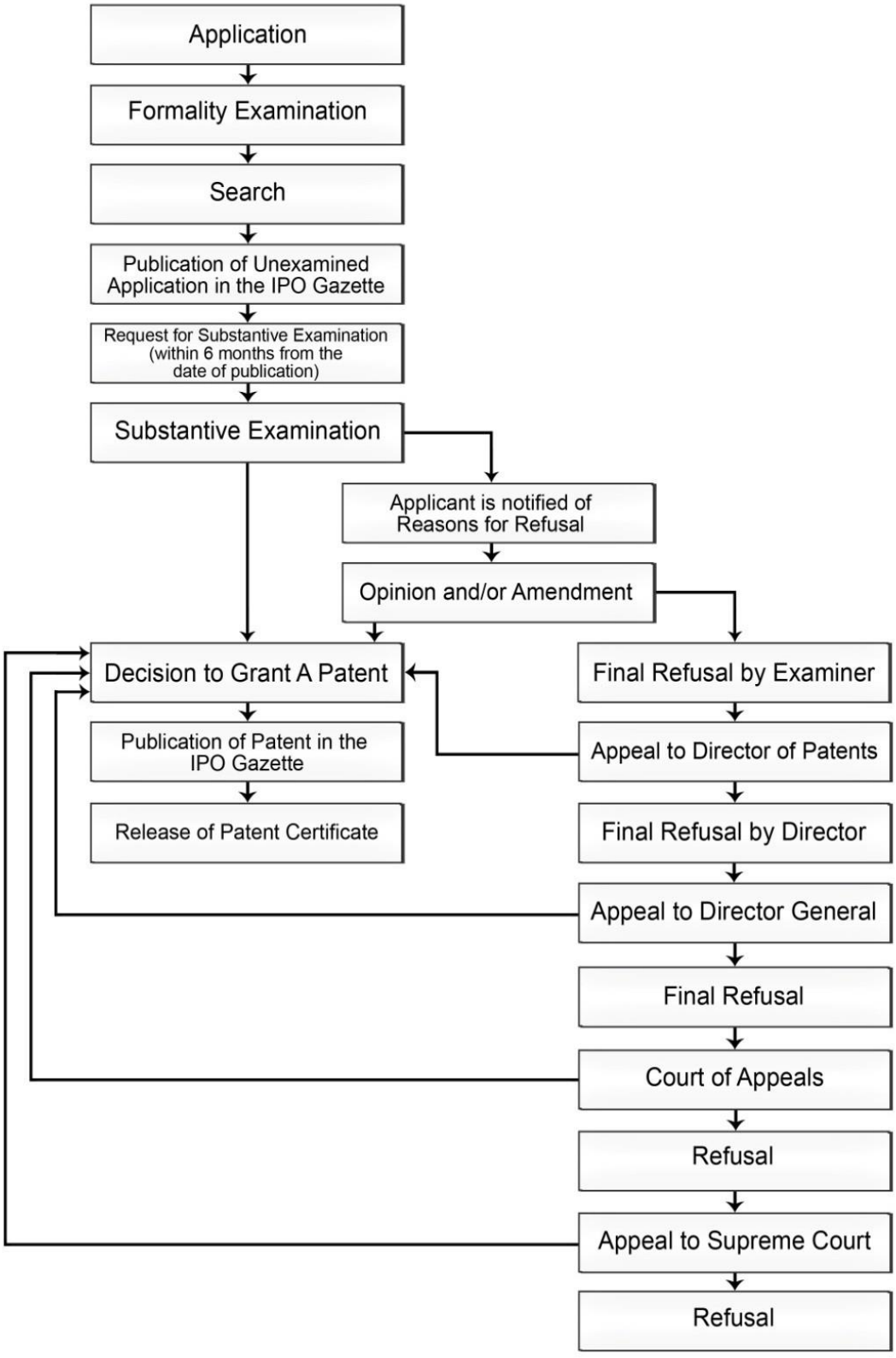

Figure 4 Flowchart of the Patent Prosecution Procedure in IPOPHL for Directly Filed (non-PCT) Applications.

The general flow of formality and substantive examination is the same in the mechanical field and the chemical field. It should be noted however, that there are significant differences in the specific assessment on matters concerning Clarity/Support/Enablement, Novelty, Inventive Step, and Industrial Applicability in some technologies in the chemical field. Based on the above figure, it is shown that prior art search is conducted prior to the publication of the application and before a request for examination is made.

2.2 Background on the Patent Office and the Patent System in JPO

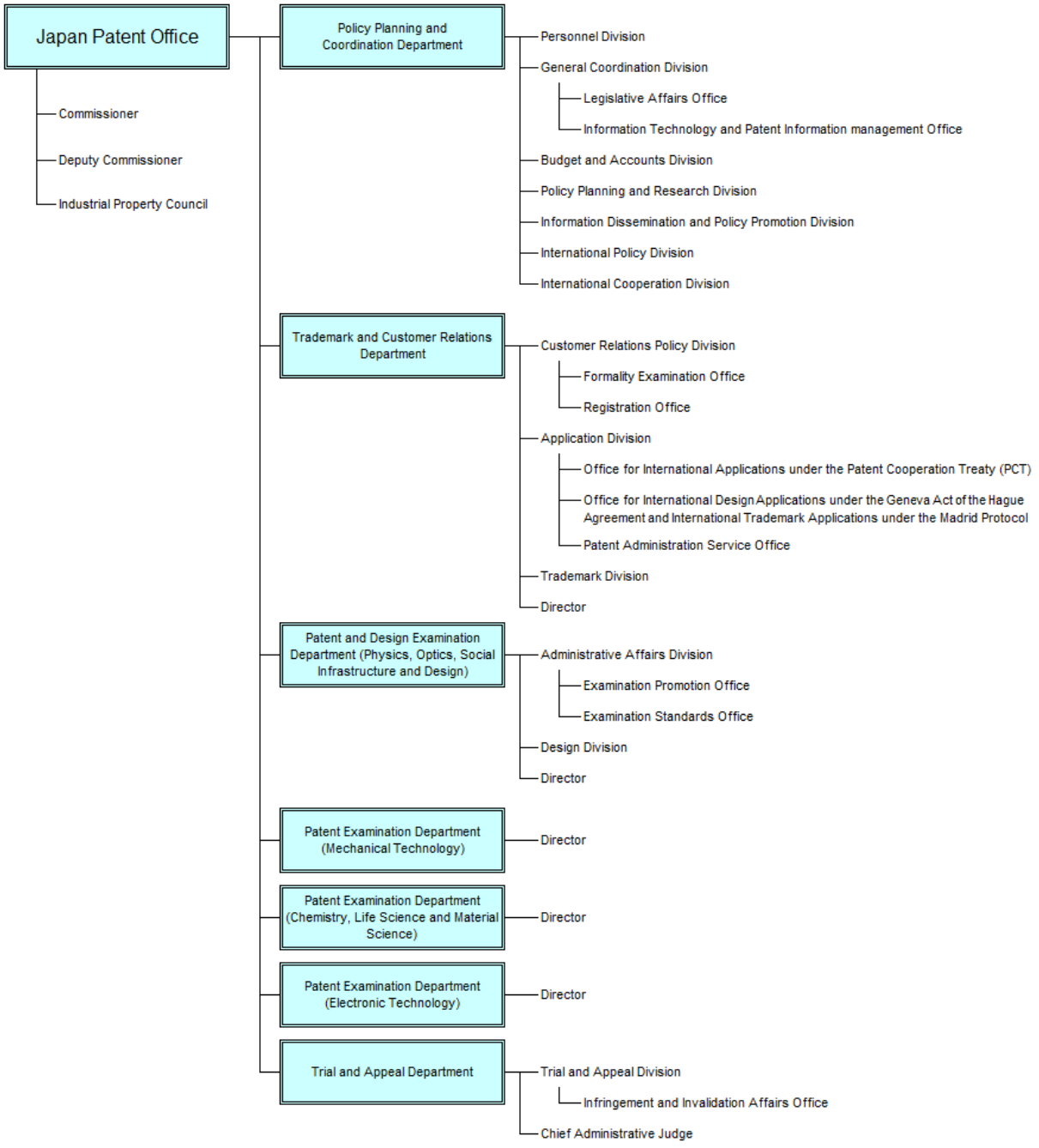

Figure 5. Organizational Chart of JPO.

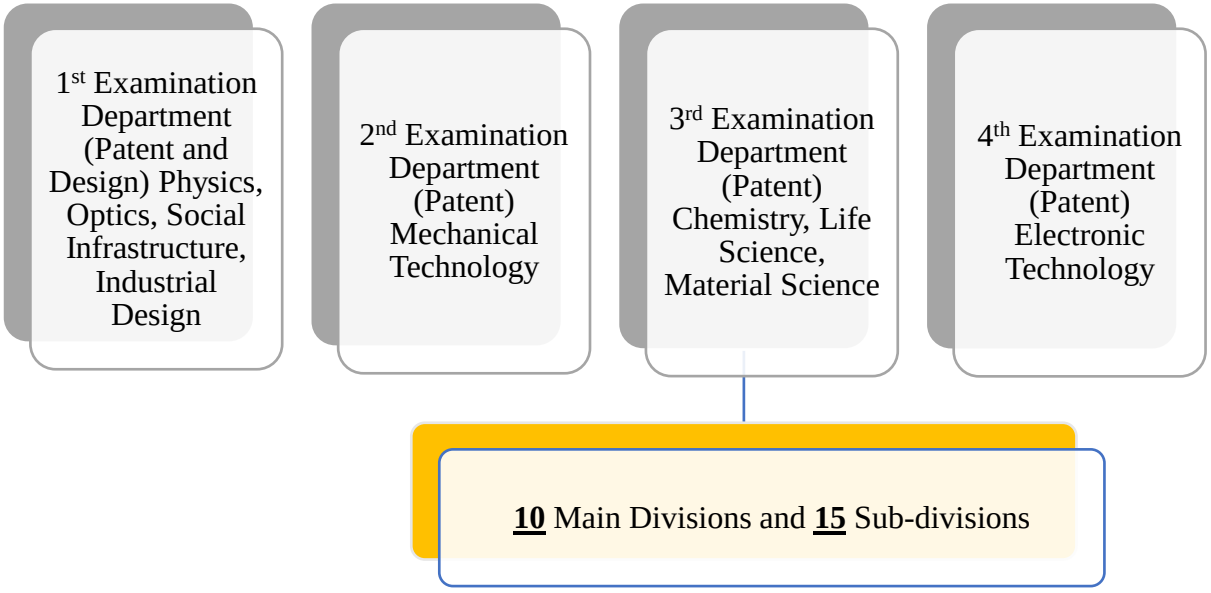

Figure 6. The Patent Examination Departments of JPO.

The Organizational chart of Japan Patent Office is shown in Figure 5. There are four patent examination departments specializing in different groups of technology (see Figure 6). Each of these departments is further composed of divisions handling specific fields. Chemical patent applications are handled by the 3rd Examination Department on Patents. The Patent Examination Department in Chemistry, Life Science and Material Science is composed of ten divisions: (1) Inorganic Chemistry and Environmental Chemistry Division, (2) Material Processing, Metals and Electrochemistry Division, (3) Metals and Electrochemistry Division, (4) Medical Science Division, (5) Organic Chemistry and Biotechnology Division, (6) Biotechnology Division, (7) Environmental Chemistry Division, (8) Applied Organic Chemicals Division, (9) Polymer Division, (10) Plastic Engineering Division.

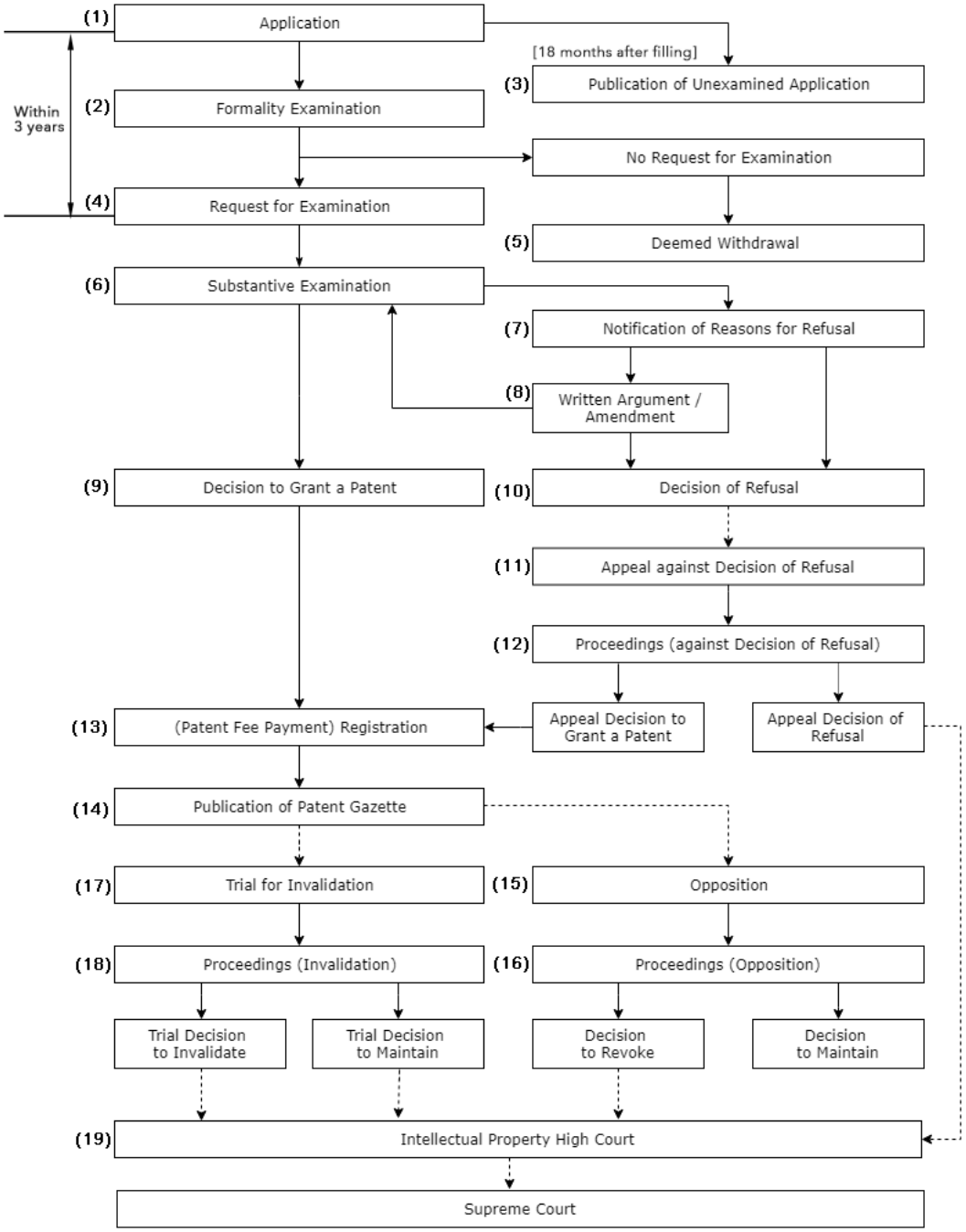

Figure 7. Flowchart of the Patent Prosecution Procedure in JPO.

Figure 7 shows the Patent Prosecution Procedure and Patent Examination Flow in JPO that is used for all types of technology. It should be noted that the search of prior art documents in JPO is usually conducted only once a request for examination is made.

The focus of this study is mainly on the substantive examination stage of JPO and IPOPHL, particularly on selected patentability requirements.

2.3 Overview of the Statutory Basis of Patentability Requirements

Table 2. Comparison of Statutory Basis on Patentability of JPO and the IPOPHIL.

Description	JPO (Japan Patent Act)	IPOPHIL (Intellectual Property Code of the Philippines)
Written Description - Enablement / Enabling Disclosure	Article 36 (4)(i)	Section 35
Definiteness / Clarity	Article 36 (6)(i-iv)	Section 36
Unity of Invention / Restriction	Article 37	Section 38
Filing of Patent Application	Article 39	Section 29
Patentable Inventions	Article 29(1)	Section 21
Non-patentable Subject Matter	Article 32	Section 22
Novelty	Article 29(1)	Section 23
Inventive Step	Article 29(2)	Section 26
Industrial Applicability	Article 29(1)	Section 27

Table 2 shows the Comparison of the Statutory Basis of JPO and IPOPHL, with the Japan Patent Act (*Act No . 121 of 1959*, n.d.) and the Intellectual Property Code of the Philippines (Republic Act No. 8293, as Amended, 2015) as references, respectively. The main focus of this study is on the comparison of the patentability requirements, namely, patent eligibility, novelty, inventive step, and industrial applicability. Figure 8 summarizes the IP Laws, Rules, Procedure, and Guidelines used in Patent Examination at IPOPHL.

2.4 Intellectual Property Laws, Rules, Procedure, and Guidelines of Japan and the Philippines

In the Philippines, it is very difficult to use the IP Code solely for examination since the content is worded very broadly and it is very difficult to apply it to an actual application. In practice, the Implementing Rules and Regulations (IRR) for Patents, Utility Models and Industrial Designs (IPOPHL, 2017b) and the Manual for Patent Examination Procedure (MPEP) (IPOPHL, 2017a) are the main references in examining all types of inventions and they are the ones employed in examining chemical technology inventions. In particular, the

Manual gives instructions as to the practice and procedure to be followed in the various aspects of the substantive examination of Philippine patent applications in accordance with the IP Code and the Revised Implementing Rules and Regulations (Revised "IRR"). They are addressed primarily to the staff in IPOPHL. In other technical fields, such as the pharmaceutical field, there are additional references that are available which are consulted during examination. The references employed by IPOPHL examiners in different fields are shown in Figure 8. Some of these materials have been amended and some have been created in order to help improve the examination practice of IPOPHL. The recent initiatives are as follows:

- Intellectual Property Code of the Philippines has been amended in 2015. (Republic Act No. 8293, as Amended, 2015)
- The Revised Implementing Rules and Regulations on Patents, Utility models, and Industrial Designs has been amended on July 10, 2017. (IPOPHL, 2017b)
- The Manual of Patent Examination Practice or MPEP has been revised in 2017. (IPOPHL, 2017a)
- The Guidelines on the Examination of ICT and CII was released in January 2018.
- The Guidelines on Examination of Biotechnological Applications was released in January 2018.
- The Guidelines on the Examination of Pharmaceutical Applications involving known Substances was revised in January 2018.

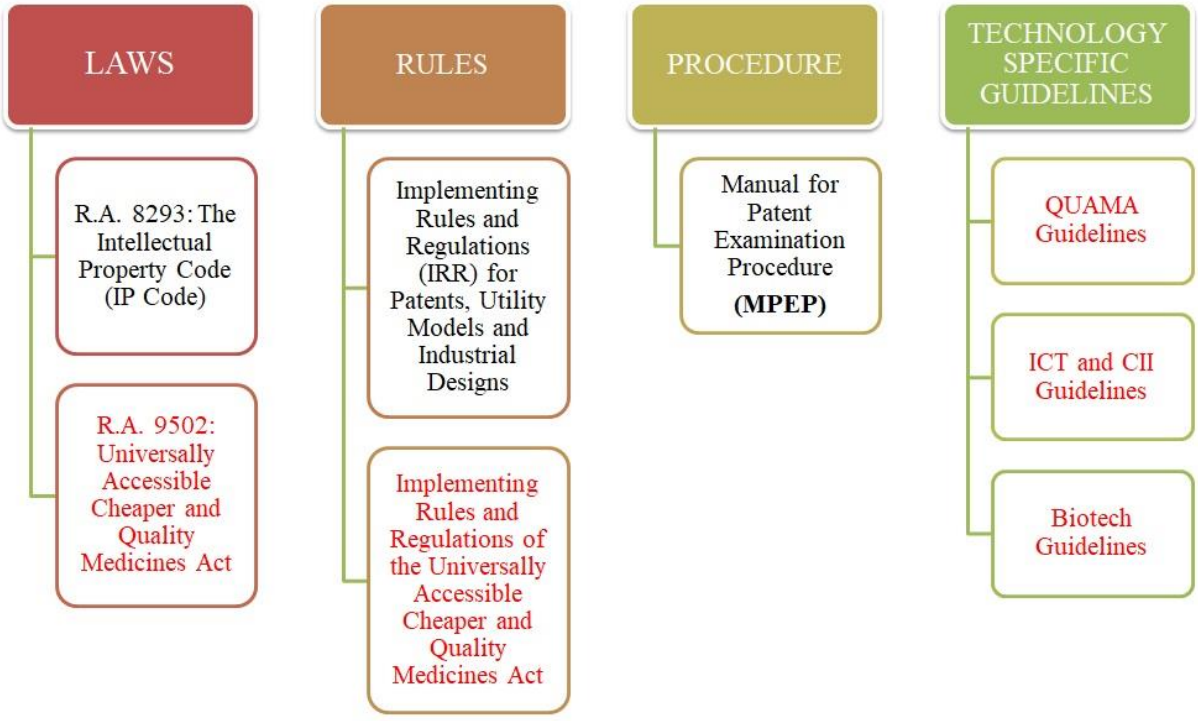

Figure 8. Intellectual Property Laws, Rules, Procedure, and Guidelines for Patent Examination at IPOPHL.

In Japan, JPO examiners have the following references in patent examination: (1) Japan Patent Act, (2) Examination Guidelines for Patent and Utility Model, and (3) Examination Handbook for Patent and Utility Model. The Japan Patent Act prescribes the basic rules for patent. The Examination Guidelines for Patent and Utility Model and The Examination Handbook for Patent and Utility Model provide the basic ideas of application of the relevant laws such as Patent Act. The Guidelines summarizes the best practices in applying Patent Act to examination. The Handbook summarizes practice and points to be noted when conducting examination, providing procedural aspects as examiners conduct examination. Case examples, court precedents, and application examples useful in understanding of the basic ideas of Examination Guidelines are also provided in the Handbook. The Guidelines have been revised five times: October 2015, March 2016, March 2018, June 2018, and most recently in March 2019.

2.5. Overview of Selected Previous Comparative Studies on Patent Examination

A number of comparative studies in patent examination have already been conducted worldwide. Most of these studies are among the biggest IP offices in the world such as JPO, the European Patent Office (EPO), the United States Patent and Trademark office (USPTO), the Korean Intellectual Patent Office (KIPO), and the China National Intellectual Property Administration (CNIPA). CNIPA was previously known as the State Intellectual Property Office (SIPO) (European Patent Office, 2018).

The Trilateral Co-operation was set up in 1983 among JPO, USPTO, and EPO. Comparative studies on laws and examination guidelines concerning patentability requirements such as Inventive step, Novelty, Requirements for Disclosure and Claims, to name a few, have been conducted and have been published. (Trilateral Co-operation, n.d., 2007, 2008, 2009)

JPO, KIPO and SIPO formed the Joint Expert Group for Patent Examination (JEGPE) in 2009 and have conducted comparative studies on laws and examination guidelines concerning “Inventive step”, “Novelty”, “Requirements for Disclosure and Claims”, and “Amendments”, as well as comparative case studies and published reports on those studies. The main purpose of this is to enhance mutual understanding of each of the three office’s examination standards and to improve the work sharing among the three offices. The

findings are summarized in the report titled, “Summary of Comparative Studies and Case Studies” published in 2016. (Japan Patent Office, 2017; JEGPE, 2016)

The abovementioned comparative studies on patent examination were conducted on selected topics using real and hypothetical cases for the enhancement of the examination quality so that that the users can have a better understanding of the examination standards on the practices of each jurisdiction and thus they will be able to prepare high quality patent applications. (Japan Patent Office, 2017; Trilateral Co-operation, n.d.)

3. Methodology of the study

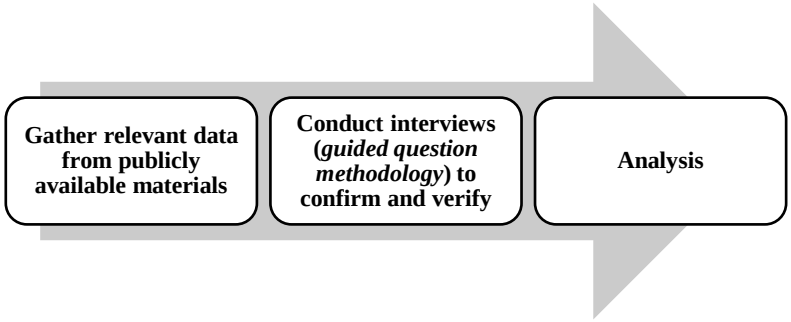

Figure 9. Flow diagram of the methods employed in the study.

Figure 9 shows the general flow diagram of the methods employed in the present study. The methodology mainly involves the following:

(1) Gather relevant data from the specific documents, observations, and interpretation of information from different publicly available materials such as patent laws and examination guidelines from the Philippines and in Japan, including technical and opinion papers from patent experts, the academe, and from various government and non-government organizations, relevant secondary literature, case studies, trainings, news articles, and court decisions.

(2) Conduct interviews employing a guided question methodology with patent law and examination experts, in order to confirm and verify the reliability and accuracy of information gathered from the publicly available materials.

(3) Analyze and study the overall patenting system and examination approach in the field of Chemical Technology in the Philippines and Japan, with specific focus on Patent Eligibility and Industrial Applicability. Results will be analyzed by organizing them into categories based on concepts or similar features. The similarities and differences of existing patent search/examination approaches and procedures will then be assessed and cross-examined.

The primary data on Japan's side are obtained from the interviews with different groups of interviewees, namely, authorities from JPO, Japanese stakeholders and patent experts. The questions list for each group has been designed and tailored corresponding to the main areas of the research study. One of my advisers, Ms. Mizuochi, who was an official of JPO, also gave me a lot of suggestions on the questions based on her experience in JPO.

The list of questions for the authorities from JPO mainly focuses on its substantive examination approach on inventions containing chemical technology subject-matters. This includes questions to establish the profile of chemical invention applications and chemical

group divisions in JPO, the examination procedure and flow, assessment point of view, and overall patent system and prosecution experience. The interviewees from JPO are as follows:

Mr. Toru Matsuoka

Deputy Director, Examination Standards Office, Japan Patent Office

Ms. Ayako Chinone

Assistant Director, Examination Standards Office, Japan Patent Office

On the stakeholders' side, the questions are aimed to determine the profile of chemical innovation in Japan according to their perspective, the handling of protection of chemical innovations in the company, factors affecting or specific issues encountered in the prosecution of chemical patent applications, and the companies' experience with the prosecution of chemical innovations in Japan and also in the Philippines (when applicable). Interviews were conducted with two big companies based in Japan whose products are considered as belonging to the Chemical Technology field in the Philippines. The first interview was with the person in charge of Intellectual Property in a multi-faceted food and beverage company and another interview was with those in a chemical company which produces a wide range of technologies and products centered on "chemistry".

It is also important to get some perspective from the patent expert who took part in the process of creating and amending the present patent examination guidelines of Japan. The questions are aimed to determine their experience on setting the examination guidelines for Patent and Utility Model in Japan as well as their experience with more recent patent system. The details of the patent expert interviewee are as follows:

Professor Setsuko Asami

Patent Attorney, Graduate School of Management, Tokyo University of Science

4. Results and Analysis

4.1 Profile of chemical technology inventions in Japan

There is only one department handling technologies in the chemical field at JPO which is the 3rd Examination Department or the Chemistry, Life Science and Material Science Examination Department. The range of technologies examined by each Division is determined mainly by taking into consideration relationships between technologies and workloads of the respective divisions. JPO regularly check the workloads of respective Divisions, and when their workloads become unbalanced, they review a range of technologies examined by each Division.

Table 3 shows the common International Patent Classifications (IPCs) symbols dealt by each examining division.

Based on the IPCs and technology-specific keywords, it was recognized that in JPO, the technologies handled by seven (7) out of the ten (10) main divisions and eleven (11) out of the fifteen (15) sub-divisions of the 3rd Examination Department (Chemistry, Life Science and Material Science Examination Department) correspond to those considered as chemical technology subject-matters in IPOPHL. The 7 main divisions and 11 sub-divisions are summarized in Table 4. It should be noted that in the case of the foods and microorganism's sub-division, it is only the food inventions which are considered to be chemical technology subject-matters.

4.2 Flow of Substantive Examination

JPO does not have specific guidelines solely for the chemical field. Patent examiners use Examination Guidelines that generalize across all industries. Thus, patent examiners conduct examinations in accordance with the Examination Guidelines for Patent and Utility Model regardless of the technical field. This means that all the inventions assigned to the different divisions and sub-divisions, collectively identified as chemical technology inventions, will have the same examination approach. It should be noted, however, that there are some types of inventions (e.g. *biology* or *medicines*), which merits further or more specific examination standards. For example, in the case of biology or medicines, examinations are conducted in accordance with the Appendix to the Examination Handbook for Patent and

Utility Model which explains applicable examination standards. In IPOPHL, there is no apparent specialized

Table 3. Summary of the IPCs corresponding to the chemical examining divisions of JPO

Examining Division	Main or Common IPC handled
1. Inorganic Chemistry Division	C01BCDFG C40B(40/18) B01J(21/-38/)
Ceramics Sub-Division	*C04B* *B28BC* *C03BC*
Vapor Deposition and Single Crystal Growth Technology Sub-Division	*C23C(14/-16/)* *C30B*
2. Material Processing Division	B21B B21C B22CD B22F C23C(exclude 14/-16/)DFG C25BCDF C21BC C22B C22C(1/,3/,26/,29/,33/,47/-49/)
Resin Processing Sub-Division	*B29B(7/-11/14,13/-15/06)* *B29C(31/-43/,45/-67/08,67/24,69/-71/02,73/)* *B29D(1/-29/,33/,99/)* *B33Y*
3. Metals and Electrochemistry Division	B23K(35/) C21D C22C(5/-25/,27/-28/,30/,35/-45)F F27BD
Electrochemistry Sub-Division	*H01M(2/)*
Batteries Sub-Division	*H01M(exclude 2/,8/04-8/06,10/42-10/667),H01G(9/20)*
4. Medical Science Division	A61K(31/-33/)P
Pharmaceutical Preparations Sub-Division	*A61K(6/,9/,47/),A61L(15/-33/)*

Biopharmaceutical Sub-Division	*A61K(35/-45/,48/-51/)*
5. Biotechnology Division	C12N(15/) C40B(10/,40/02,40/06-40/10,50/06)
Foods and Microorganisms Sub-Division	*C12MN(exclude 15/)PQ* *A01HK(67/02-67/027,67/033.501)* *A01J* *A21D* *A23BCDFGJL* *C12CFGHJL* *C13BK*
Protein Engineering Sub-Division	*C07GK*
6. Environmental Chemistry Division	C02F(1/00-1/42,1/46-11/20) B01D(21/) B01J(39/-49/) B01D(53/22,61/-71/) C02F(1/44) B02C A61K(8/)Q
Separation Sub-Division	*B01D(9/-19/,23/-51/,57/-59/)B03BCD* *B04BCB07B* *B01F(1/-15/)* *A62D* *A61L(9/)* *B01D(53/00-53/18,53/24-53/96)* *B01B* *B01D(1/-8/)* *B01J(2/-12/,14/-20/)* *F25J* *B01L*
7. Organic Chemistry Division	C07BCF C40B(40/00,40/04,40/16,50/00, 50/04,50/08-60/02,60/06- 60/08,60/14-99/00)
Heterocyclic Compounds Sub-Division	*C07D(201/-421/)* *C07D(451/-521/)* *C07HJ* *C08B* *C40B(40/12)*

Agrochemicals and Dyes Sub-Division	*A01NP* *C09B* *D06P*
8. Applied Organic Chemicals Division	A61L(2/,11/-12/) B01F(17/)B01J(13/) B09BC B29B(17/) C08J(11/) C10BCFGHJKL C06BCDF C05BCDFG C09FG C10M C11BCD C09K
Coatings and Adhesives Sub-Division	*C09D(exclude 11/-17/)* *C09J* *C09CD(11/-17/)*
9. Polymer Division	C08F C08G C08C C08H C09H C40B(40/14)
Polymer Composition Sub-Division	*C08KL*
10. Plastic Engineering Division	B29B(11/16,15/08-15/14)C(71/04), C08J(3/-9/,99/) B29C44/00-44/60, B29C67/20 B29D30/00-30/72,B60C(1/-19/)
Textiles and layered Products Sub-division	*B05BCD* *B32B* *B68F* *C14BC* *D03D(1/-27/)* *D04B(1/,21/)CDGH* *D06N* *D01DF* *D02GJ* *D06BCGHJLMQ* *D07B* *D21BCDFGHJ*

Table 4. Examining divisions of the Chemistry, Life Science and Material Science Examination Department handling technologies considered as chemical technology subject-matters in IPOPHL.

Main Division	Sub-Division
Inorganic Chemistry Division	• *Ceramics Sub-Division* • *Vapor Deposition and Single Crystal Growth Technology Sub-Division*
Material Processing Division	• *Resin Processing Sub-Division*
Metals and Electrochemistry Division	• *Electrochemistry Sub-Division* • *Batteries Sub-Division*
Not included	• *Foods and Microorganisms Sub-Division*
Environmental Chemistry Division	• *Separation Sub-Division* • *Agrochemicals and Dyes Sub-Division*
Applied Organic Chemicals Division	• *Coatings and Adhesives Sub-Division*
Polymer Division	• *Polymer Composition Sub-Division*
Plastic Engineering Division	• *Textiles and layered Products Sub-division*

examination procedure/flow for chemical technology invention. However, there are other technologies, such as pharmaceuticals, which employs more specific guidelines and a specialized flow during their examination.

At JPO, there is a recommended sequence during examination, however, it is not a required sequence. The assessment of Patent Eligibility, Industrial Applicability, and Clarity are normally performed prior to the assessment on Novelty and Inventive Step. It should be noted however, that the examiner determines that the claimed invention lacks novelty where there is no difference between the claimed invention and the prior art. It is only where there is a difference that the examiner determines whether there is an inventive step. It is only when the examiner finds an exactly the same prior art that the examiner stops the examination for other matters since that's enough for refusing the application. But normally, there's a difference between the prior art and the application. Patent Eligibility, Industrial Applicability, and Clarity

are usually judged first primarily because an examiner doesn't need prior art documents to decide upon the abovementioned requirements. Thus, the examiner can easily decide whether the invention satisfies Patent Eligibility, Industrial Applicability, and Clarity requirements right away. Patent Eligibility and Industrial Applicability are usually examined at the same time since there are only a few cases for refusing the application on these grounds, especially in the chemical field. At JPO, the search of prior art documents is done during the substantive examination stage once a request for examination has been made by the applicant. During search, issues on support/enablement compared to the prior art may be found by the examiner. This is the case when the search is done by the examiner. In the case where the search is outsourced, the examiner can already read the claim and result of the prior art search, so they may be able to judge clarity, support, enablement, novelty, inventive step, patent eligibility, and industrial applicability at the same time or simultaneously.

In IPOPHL, prior art search is performed prior to the substantive examination stage. The results of the search are already included in the first publication of the patent application - 18 months from the effective filing date. Thus, prior to the substantive examination stage, search results are already available. Recently, a sequence in the examination of the claims has been introduced. Assessment of Patent Eligibility is done first, followed by Clarity/Support/Enablement, Novelty, and then Inventive Step. In practice, the assessment of Industrial Applicability is performed last, but this step may be done at any time. Normally, the preliminary requirement must be satisfied as a prerequisite before continuing to the next step, with notable exceptions. The claim is first assessed whether it relates to a patent-eligible subject matter (Sec 21 and 22, IP Code). If this requirement is satisfied, then it shall proceed to the next step, which is the assessment on Clarity/Support/Enablement. Otherwise, the examination will be stopped at that step and the applicant must resolve the issue first before continuing with the evaluation on Clarity/Support/Enablement. If this next requirement is satisfied, then it shall proceed to the assessment of novelty. If this requirement is not satisfied, the question on whether the examination continues depends on the degree of significance of the Clarity/Support/Enablement issue. A significant one on such case will merit discontinuation to the next step and a minor concern will usually be allowed to proceed to the next step, which is the assessment on novelty. The assessment on inventive step shall only be considered if the novelty requirement is satisfied. A claim which is deemed as lacking novelty will no longer be assessed with regards to Inventive Step. Industrial Applicability will be assessed concurrently with the other requirements, but in practice, this step is usually performed last.

Based on the information above, the flow of examination at JPO and IPOPHL differs from each other. At JPO, all the patentability requirements may be assessed concurrent to each other, wherein the sequence of assessment for each part is of no consequence, though some parts are normally assessed first (e.g. Patent Eligibility and Industrial Applicability) prior to another (e.g. Novelty and Inventive Step). It is also important to note that even if the invention fails to satisfy a prior requirement, the examination for the rest of the requirements will still be continued. For example, even if the invention fails to satisfy Patent Eligibility and Industrial Applicability requirements, JPO examiners will still continue with the examination for the rest of the requirements. There are two reasons for this. The first one is that JPO does not have many cases on this in the chemical field. Second reason is that applicant can easily amend the claims to satisfy this requirement. It is not difficult for them to change the claims, so that examiners can continue with the examination. Examiners do not rely on the contents of the claims only but try to understand what the invention is based on the description, usually through the working examples. The same happens when it is not industrially applicable. The short pendency period from request for examination to grant of a patent may then be attributed to the abovementioned strategy in patent examination at JPO.

This is not the case for IPOPHL, wherein a tiered system is employed in evaluating each patentability requirement. Thus, the prosecution period can be lengthy at times specially for applications with eligibility issues. In the case wherein the claimed invention has issues related to any one of lacking clarity, lacking enabling disclosure, and lacking support, the degree of significance of the Clarity/Support/Enablement issue is used to decide whether to proceed with the next level of requirement. This means that there is a chance to proceed with the next assessment if the issue is relatively minor. In the case of JPO, it is only when the clarity issue is essential that the examiner does not proceed with the next requirement. That is, if the examiner can’t really understand what the invention is, then that is the only time that the examiner stops the examination and then issues an office action to the applicant.

In practice, a final rejection of a patent application to issues on clarity only is not commonly done in IPOPHL. In JPO, a final refusal can be issued for such case although it depends on the degree of clarity problem. But normally, the clarity problem is rectified easily. The examiner usually suggests amendments to the applicant. Normally, reasons for refusal are given 2-3 times. But there is no official limit to the number of office actions that can be issued. If there are still minor problems after the third time, then additional actions may be sent. JPO examiners would usually call the applicant and communicate with them before the next step.

4.3 Patentable Subject-matter and Industrial Applicability

4.3.1 *Overview of the differences in eligibility and industrial applicability assessment in JPO and IPOPHL*

Patentable subject-matter

The determination of patentable subject matter or patent eligibility is the first to be checked during substantive examination at IPOPHL. Assessment on "patent eligibility" comprises checking whether the invention relates to a statutory invention and whether the subject-matter of the claim is not an excluded subject-matter. Accordingly, it means that this part involves determining whether the invention belongs to the Statutory Classes of Patentable Inventions and whether the invention belongs to any of the Non-patentable Inventions.

The Statutory Classes of Patentable Inventions detailed in Rule 201 of the Revised IRR are product, such as a machine, a device, an article of manufacture, a composition of matter, a microorganism; a process, such as a method of use, a method of manufacturing, a non-biological process, a microbiological process; computer-related inventions; and an improvement of any of the foregoing. If the invention does not relate to any of the classes, then it will be rejected for containing patent-ineligible subject-matter.

The list of Non-patentable inventions, as stated in Rule 202 of the Revised IRR in accordance with Section 22 of the IP Code, excluded from patentability are generalized as follows:

(a) Discoveries, scientific theories, and mathematical methods, a law of nature, a scientific truth, or knowledge as such;

(b) Abstract ideas or theories, fundamental concepts apart from the means or processes for carrying the concept to produce a technical effect;

(c) Schemes, rules, and methods of performing mental acts and playing games;

(d) Method of doing business, such as a method or system for transacting business without the technical means for carrying out the method or system;

(e) Programs for computers;

(f) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply to products and compositions for use in any of these methods;

(g) Plant varieties or animal breeds or essentially biological process for the production of plants and animals. This provision shall not apply to microorganisms and non-biological and microbiological processes;

(h) Aesthetic creations; and

(i) Anything which is contrary to public order, health, welfare, or morality, or process for cloning or modifying the germ line genetic identity of humans or animals or uses of the human embryo.

If the invention relates to any of the above cases, then it is excluded from patent protection and will be rejected for being directed to a patent-ineligible subject-matter.

At JPO, the determination of an invention's patent eligibility is done through checking whether the invention belongs to the List of Subject Matters Not Corresponding to Statutory "Inventions" containing Patent Eligibility as stated in Part 3, Chapter 1, of the Examination Guidelines for Patent and Utility Model in Japan. The List of Subject Matters Not Corresponding to Statutory "Inventions" are as follows:

(i) The laws of nature as such;

(ii) Mere discoveries and not creations;

(iii) Those contrary to the laws of nature;

(iv) Those in which the laws of nature are not utilized;

(v) Those not regarded as technical ideas;

(vi) Those for which it is clearly impossible to solve the problem to be solved by any means presented in a claim.

When a claimed invention is considered as any of (i) to (vi) above, an examiner shall determine that the claimed invention does not comply with the requirements of eligibility for a patent.

Industrial Applicability

In the Philippines, Sec.27 of the IP Code states that: "An invention that can be produced and used in any industry shall be industrially applicable". Most invention in the chemical technology filed satisfies this requirement. However, methods for treatment of the human or

animal are regarded as inventions which are not industrially applicable. Additionally, it is required that the description should indicate explicitly the way in which the invention is "industrially applicable".

In JPO, the determination of an invention's industrial applicability is done through checking whether the invention belongs to the List of industrially inapplicable Inventions as stated in Part 3, Chapter 1, of the Examination Guidelines for Patent and Utility Model in Japan. The List of industrially inapplicable Inventions are as follows:

(i) Inventions of methods of surgery, therapy or diagnosis of humans;

(ii) Commercially inapplicable inventions;

(iii) Obviously impracticable inventions.

Unpatentable Invention

As previously stated, this issue is discussed in determining for patentable subject matter or patent eligibility at IPOPHL. The determination is done through checking whether the invention belongs to any of the Non-patentable Inventions. At JPO, the inventions liable to contravene public order, morality or public health shall not be patented even if it is industrially applicable, as provided in Article 32 of the Japan Patent Act.

To provide a clearer picture of the details on eligibility and industrial applicability as mentioned above, Table 5 summarizes the comparison of basis of refusal on inventions containing the subject-matters discussed. Additionally, the abovementioned comparisons will be illustrated in detail through some notable case examples in the next section.

4.3.2 *Notable case examples emphasizing the differences in eligibility and industrial applicability assessment in JPO and IPOPHL*

Method of Treatment of the Human Body

Inventions related to contraceptive devices (e.g. condoms) made from innovative materials are chemical technology subject-matters. Contraceptive devices per se are patentable subject-matters in both the Philippines and Japan. Issues usually arise when methods of using such devices in the human body are also claimed. Thus, a "Method of Contraception" which is to be applied in the private and personal sphere of a human being is a subject-matter considered as a method of treatment of the human body and will be refused under Industrial Applicability (thus unpatentable) in JPO in accordance with 3.1.1, Part 3, Chapter 1, of the

Examination Guidelines for Patent and Utility Model in Japan. At IPOPHL, this case will not also be considered as industrially applicable since in general, "Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human

Table 5. Comparison of Basis of Refusal on Patent Eligibility and Industrial Applicability in IPOPHL and JPO.

	IPOPHL	JPO
Public order or morality	Non-Patentable Subject-Matter	Unpatenable invention
Scientific theories, etc.	Non-Patentable Subject-Matter	Patent Eligibility
Rules, mental acts, business methods	Non-Patentable Subject-Matter	Patent Eligibility
Methods for treatment and diagnostic Methods	Non-Patentable Subject-Matter Industrial Applicability	Industrial Applicability
Plants and animals, etc.	Non-Patentable Subject-Matter	
Clearly impossible to solve the problem to be solved		Patent Eligibility
Commercially inapplicable inventions		Industrial Applicability
Obviously impracticable inventions		Industrial Applicability

or animal body", are not regarded as inventions which are industrially applicable as stated in section 4, Part 2 relating to Substantive Examination, Chapter IV of the MPEP. Additionally, this kind of subject-matter will also be rejected for being directed to a non-patentable invention under section 22 of the IP Code and thus excluded from patent protection in the Philippines. It should also be noted that unlike the provisions in the Philippines, the terms in Japan regarding

"method of treatment" excludes those practiced on animals provided that the methods practiced on humans are explicitly excluded.

Plant related inventions

In the Philippines, patent eligibility issues occur in inventions pertaining to plant and plant related invention. Plant breeds and animal breeds or essentially biological processes for the production of plants and animals are not patentable in accordance with Sec. 22 IP Code, as Amended. One reason for this exclusion is that, at least for plant varieties, other means of obtaining legal protection are available in most countries. Accordingly, the Plant Variety Protection Act of 2001, based on the UPOV Convention (1991 Act), provides *sui generis* protection for plant varieties (Republic Act No. 9168, 2002) in the Philippines. Consequently, a claim drafted as, "*Seed/Plant treated with a certain composition*…", though the invention lies with the composition (*chemical technology subject-matter*) itself, will generally be rejected as unpatentable in the Philippines. As drafted above, the gist of such claim is to be interpreted as to reside mainly on the seed/plant itself, though treated with the composition, and not on the composition used to protect the seed/plant. Plant or any generative parts of the plant is excluded from patentability. In Japan, the claim above will not be refused due to patent eligibility. Plants, specifically plant varieties, are not excluded subject-matters, provided that the requirements for patentability are complied with, and they may also be protected under the Plant Variety Protection and Seed Act (Llantos, 2016).

The assessment on patent eligibility of plant derived inventions, such as those focused on substances obtained from the plant, are somewhat problematic in the Philippines, since the guiding principles related to isolated products of nature are subject to interpretation at times. To find a substance freely occurring in nature is also mere discovery and therefore not patentable as stated in section 2, Part 2 relating to Substantive Examination, Chapter IV of the MPEP in the Philippines. Thus, in relation to this, a claim drafted as "Sap/resin obtainable from plant…", *may be* refused as unpatentable subject-matter if the degree of isolation is very minimal which may be perceived as discovery. Section 2, Part 2 relating to Substantive Examination, Chapter IV of the MPEP further states, however, that, "xxx *if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. Moreover, if the substance can be properly characterized either by its structure, by the process by which it is obtained or by other parameters and it is "new" in the absolute sense of having no previously recognized existence, then the substance*

per se may be patentable xxx". In the case of Japan, we refer to 2.1.2, Part 3, Chapter 1, of the Examination Guidelines for Patent and Utility Model in Japan), which states that things in nature such as chemical substances which have been "isolated" artificially from their "surroundings", are considered as creations and considered as a statutory "invention", thus patent eligible. In Japan's Patent Act (Article 2), invention is defined as the creation of technical idea utilizing the law of nature. It is to be understood that "artificially" is the technical idea so that isolating some compounds from nature is considered as an artificial method and not natural. Compounds or genes, or some chemical compounds isolated from natural things can be patent eligible subject-matter and can be an invention in Japan Patent Act so it can be protected in the Japan Patent Law. The degree or extent of artificial isolation is not so high in Japan. If the inventor collects this substance from nature, then it's understood as artificial isolation. The Japan Patent Law does not require a high degree of isolation for some kind of manufacture for material. The patent eligibility requirement is not so high in Japan, so these kinds of invention usually pass.

Public order or morality concerns

In the Philippines, any invention, the publication or exploitation of which would be contrary to "public order or morality" is considered as a non-patentable invention, and thus excluded from patentability. The reason for this is to exclude from protection inventions which may provoke riot or public disorder, or to lead to criminal or other generally offensive behavior such as in the case of a letter-bomb. This provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable. If this is the case, it should be raised under Sec.22 of the IP Code; otherwise not. In Japan, Chapter 5 Category of Unpatentable Invention (Patent Act Article 32) provides some examples of inventions which do not fall under the category of unpatentable invention including poisons, explosives, and anticancer drugs with side effects. There is almost no case for rejecting these kinds of inventions under the category of unpatentable invention. If the claim describes poisons for killing people, that is the only case where they may be refused under unpatentable invention. But there are also not so many cases such as these in Japan. If claims describe explosives for killing people then may also be rejected under unpatentable invention, but there have been no cases of these kinds of invention for killing people in Japan. Thus, for

such inventions, there will be no refusal in Patent Eligibility, unless the claim describes killing people and contrary to "public health order, or morality".

Other Cases

In the chemical technology field, most invention satisfies the industrial applicability requirement, except for those inventions related to method of treatment of human and animals. In the Philippines, an invention shall be considered “industrially applicable” if it can be produced and used in any kind of industry, wherein "Industry" is broadly defined as including any physical activity of "technical character", i.e. an activity which belongs to the useful or practical arts as distinct from the aesthetic arts. It should be noted however, that "susceptibility of industrial application" is not a requirement that overrides the restriction of Sec.22 of the IP Code, as Amended. There are no specific examples on how this is strictly applied since there are not so many issues on industrial applicability in chemical technology subject-matters. This, however, may be interpreted in the sense that the invention must have a useful or practical application in order to be industrially applicable. There are some special cases which caused differing opinions when it comes to assessment of industrial applicability in IPOPHL. Processes of producing materials or products wherein an extremely large amount of raw materials are to be used to produce a very small amount of product have sometimes been rejected in Industrial Applicability due to efficiency issues. It may be argued that the “usefulness” of the claimed invention was fully taken into consideration for the determination of industrial applicability and that such inefficient process is not susceptible of industrial application since it is not useful. However, it can also be argued that Sec.21 of the IP Code does not require that an invention to be patentable must entail some technical progress or even any useful effect. In JPO, no refusal under Industrial Applicability will be made for the abovementioned process, regardless of efficiency, provided that the producing method is clearly written. The focus would usually be on the quality and usefulness of the product compared with the prior art concerned.

In IPOPHL, examiners would sometimes encounter inventions wherein it cast doubt as to the workability of the invention based from the description and from common technical knowledge. Let us refer to the example below:

Claim 1:

A plant-based composition for use in protection from harmful UV rays comprising plant extract XAX, sap, carrier, and excipients.

Claim 2:

A method of protecting the body against harmful UV rays comprising contacting a part of the body with a container containing the composition of claim 1 to generate a UV field or barrier around the body.

(Note: 1-the composition is NOT to be applied in the skin but is to be placed in a container and worn as a necklace and touched so that a UV field/barrier materializes; 2-extract XAX is a component derivable only from plant XAX)

In the Philippines, both claims would be patent-eligible subject-matters. However, based from the description and from common technical knowledge, it can be deduced that it will not work. In such case, they will pass patent eligibility, but they will be rejected in the enablement requirement only. In Japan, both claims 1 and 2, may be deemed as not patent eligible as “Those for which it is clearly impossible to solve the problem to be solved by any means presented in a claim.” (2.1.6 in Part 3, Chapter 1, of the Examination Guidelines for Patent and Utility Model in Japan). JPO examiners normally interpret “clearly impossible” by examining from the viewpoint of common technical knowledge of this kind of technical field. Experimentations, tests, and visits to the applicant are not performed to verify. Examiners understand based from the description and from common technical knowledge. However, even though they are clearly not patent eligible, they would usually only be refused in the enablement requirement. This is because claims, despite their actual drafting, will be construed in the broadest possible interpretation, based on description to facilitate the examination of the application.

4.4 Novelty

Sec.21 of the IP Code requires an invention to be new in order to be patentable. Sec.23 gives a negative definition of novelty, i.e. that “an invention shall not be considered new if it forms part of a prior art”. The "prior art" is defined in Sec.24.1 as consisting of "everything which has been made available to the public anywhere in the world, before the filing date or the priority date of the Philippine application claiming the invention”. IPOPHL examiners are guided by section 7 mainly, including sections 5-6, Part 2 relating to Substantive Examination, Chapter IV of the MPEP, for novelty assessment.

In accordance with Sec.29(1) of the Japan patent Act, an invention is novel, except when, prior to the filing, it was: (i) publicly known; (ii) publicly worked; or (iii) described in a distributed publication or made publicly available through an electric telecommunications in Japan or foreign countries. JPO examiners determine the novelty on the basis of Part III Chapter 2 Section 1 (Novelty) of the Examination Guidelines for Patent and Utility Model in Japan.

The assessment of novelty in IPOPHL and JPO are generally similar. The examiner compares the claimed invention with the prior art to identify the differences. If there is a difference, then the claimed invention is novel, otherwise, the claimed invention lacks novelty. In considering novelty, it is not permissible to combine separate items of prior art together.

4.4.1 *Number of Prior Art*

As of this writing, there are some efforts from the quality management unit of IPOPHL to implement the use of only one prior art in the assessment of novelty per claim, even if each document, taken independently, is relevant for the novelty refusal. At JPO, there is no strict rule, but it depends on the invention. However, if the examiner feels that one document is enough, then examiner will only use one document. But if the examiner feels it is better for using two documents at the same time, then examiner will use two documents and send reasons for refusal using two documents at the same time. For Markush claims, JPO examiners use about five or six documents at the same time for refusing novelty.

4.4.2 *Use Invention for food/beverage*

The Examination Guidelines for Patent and Utility Model in Japan has been revised on April 1, 2016, which has a large effect in the field of food and beverage inventions. In the revision, the novel use or application of a known ingredient in food and beverages can be a novel technical feature in a claim provided that (i) the claimed use application is based on a newly discovered property of the active ingredient and (ii) the claimed use application is novel clearly distinguishable from the conventional use applications of the active ingredient (Nakajima, 2017). Generally, IPOPHL considers non-distinctive characteristics of a particular intended use of claims directed to a physical entity to be disregarded, unless the use referred to implies a particular form of the substance (e.g. the presence of certain additives) which distinguishes it from the known form of the substance. In practice, the concept of a "use invention" is not applied in the field of food and beverage products. Thus, use-limited food and

beverage inventions are generally regarded the same as to a food/beverage having the same composition. "Use invention", however, is commonly accepted in the pharmaceutical field.

4.4.3 *Product-by-process claims*

In the Philippines, claims for products defined in terms of a process of manufacture are admissible only if the products as such fulfil the requirements for patentability, i.e. inter alia that they are new and inventive. A product is not rendered novel merely by the fact that it is produced by means of a new process. A claim defining a product in terms of a process is to be construed as a claim to the product as such. In practice, product-by-process claims may be deemed novel if the resulting product is distinguishable from a similar product.

Product-by-process claims are generally not allowable in Japan, unless the product cannot be characterized in any other way, that is the invention involves "impossible or impractical circumstances". As stated in the Handling Procedures for Examinations involving Product-by-process Claims (Japan Patent Office, 2016), the term "impossible or impractical circumstances" means any circumstances in which it is impossible or utterly impractical to define the product directly based on its structure or characteristics at the time of the filing of the application. Usually, in cases of plant-based components wherein the extracts can't be described from the viewpoint of a compound because it's a mixture of many compounds, a product-by-process claim may then be used by the applicant. Additionally, if the structure of a chemical compound is different from the known forms of the compound, in terms of structure or other similar characteristics, then the invention is novel.

4.5 Inventive Step

Among the five criteria of patentability, inventive step is considered to be the most difficult hurdle that must be overcome for a patent to be granted. The claimed invention should not be a straightforward modification of anything which is already in the public domain. An exclusive right should not be rewarded for an invention made within the job routine of a skilled person. Determination of inventive step is usually very difficult in IPOPHL. Sec.26 of the IP Code regulates that an invention shall be considered to involve an inventive step if, having regard to the prior art, it is not obvious to a person skilled in the art. Section 9, Part 2 relating to Substantive Examination, Chapter IV of the MPEP provides the methodology to be performed by examiners in order to assess obviousness. When assessing inventive step, the

examiner will normally apply the following “problem and solution approach” comprising of three mainstages:

1. determining the closest prior art;
2. establishing the technical problem to be solved; and
3. considering whether or not the claimed invention, starting from the closest prior art and the technical problem.

Article 29(2) of the Japan Patent Act provides that a patent shall not be granted for an invention (an invention lacking an inventive step) where a person ordinarily skilled in the art of the invention (hereinafter referred to as "a person skilled in the art" in this Part) would have been easily able to make the invention based on the prior art. JPO examiners determine the inventive step on the basis of Part III Chapter 2 Section 2 (Inventive Step) of the Examination Guidelines for Patent and Utility Model in Japan. JPO does not use the “problem and solution approach”. Accordingly, the general concept of inventive step JPO is in determining whether a person skilled in the art would easily arrive at the claimed invention based on the prior art.

In deciding obviousness, JPO and IPOPHL examiners would consider subtests, which are usually grouped as positive and negative subtests. Positive subtests indicate presence of inventive step, while negative pointers indicate otherwise. There are subtests applicable in the chemical technology field that are common to JPO and IPOPHL. Positive subtests present in both jurisdictions include advantageous technical effect and existence of technical prejudice, while negative subtests common to both include arbitrary selections from the prior art and non-synergistic aggregations of known features.

4.6 Trends and Other Findings

4.6.1 *Profile of chemical innovations in Japan*

In terms of the overall number of patent applications filed with JPO, the general trend is that it continues to slightly decline (Japan Patent Office, 2019). This trend is also the same of the applications filed with IPOPHL, although the filing in the chemical field continue to contribute the most filings every year as shown in Figure 10.

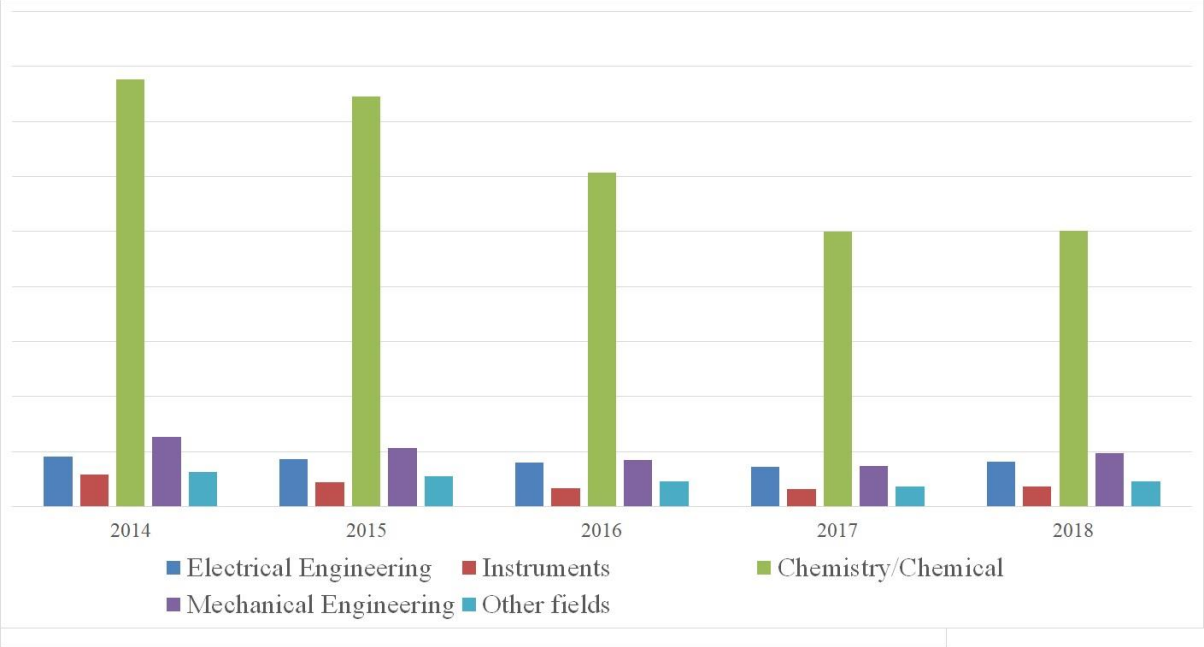

Figure 10. Patent applications filed with IPOPHL by field of technology FROM 2014 TO 2018.

According to the chemical company, the theme for innovation in the chemical field right now is on "contributing to the sustainable development goals (SDGs)" as set by the United Nations in 2014. Each chemical company is discussing how to achieve the SDGs and developing products related to its realization. Thus, chemical companies and industries in Japan, including the chemical company, are focused on sustainable issues.

In April of 2016, there was a major revision and change concerning invention or usage claim system in the Japanese patent field for food and that was a major shift which affected patent. This change in the guidelines is in response to the requests from companies. Prime Minister Shinzo Abe's Abenomics is behind the regulation change. Since the revision of the use invention for food and beverage recently in 2016, the number of applications for this invention for food and beverage is increasing. Japanese companies whose technologies and products are centered on food and beverage may have benefited from this recent change in improving their IP prospect.

In an interview with the food and beverage company, it was reported that there has been an increased filing of innovations related to food and beverage for those under the following IPCs - A23F:A23L2, C12C-C12G, in particular, those pertaining to alcoholic drinks. In recent years, some of the alcoholic drinks have unique functional features and companies have started launching alcoholic drinks in entirely new chance. This major change in the guidelines, and the

deregulation concerning food with health benefits or Food for Specified Health Uses (FOSHU) in 2015, have been credited with the significant impacts on the Japanese food industry in recent years (Yamamoto, 2016). It is expected that these changes would continue to drive the expansion of markets for functional foods and FOSHU in Japan for years. As of 2018, the total market for functional foods is estimated to be at 8 billion dollars (Iwatani & Yamamoto, 2019).

In an interview with the chemical company, it was determined however, that the changes in the examination guidelines in 2016 did not affect their business too much since this change was not very related to their business. The chemical company's products are not just food, since they are a chemical company. However, they are also considering taking advantage of this change and reflect it to their application strategy for inventions. The chemical company is most interested in getting patent protection in these four sectors: Health care, reducing environmental impact, Food, and ICT are the main sectors. The most common inventions that the chemical company files with JPO are those relating to IT related chemicals mainly due to the large number of competitors in this field. Innovations related to Health & Crop Sciences is more commonly filed as patent applications globally and such number has been increasing.

4.6.2 *Protection of chemical innovations in the company*

In Japan, applicants also make use of the accelerated examination system to expedite the granting of their patents. However, this depends on the technology field. It should be noted that the accelerated examination option is not available to inventions in all fields. Green innovations such as innovations relating to energy-saving or CO_2 reduction are eligible for Accelerated Examination in Japan. Fast moving markets such as the food and beverage industry, the IT-related chemical sector, and other fields where there are many competitors, are often the consideration in requesting for accelerated examination in order to quickly get patent rights and start the business. Depending on the products, sometimes the product is launched within one year. Companies are actively working to develop inventions in a short period of time. In the case of FOSHU, however, it may take years due to requirements of the clinical tests, as well as various regulations, in addition to obtaining license from the government.

Understandably, applicants would ideally desire protection for the same innovation by patent and utility model, also design patent, and trademark. They want to protect their innovation through Intellectual Property. There's also trade secret. In the chemical and chemistry field, applicants usually try to extend patent period to apply many patent applications for changing very small things.

In the Philippines, it is generally not allowable to have protection under more than one IP for exactly the same innovation. In Japan, also, it is not allowed to have protection under more than one IP for the same innovation according to Art 39 of the Japan Patent Act. If an invention can be described in another aspect (or differently) but not exactly the same, then it is possible to protect their innovation under different IP. Protection through Utility Model are sometimes attractive to applicants in the Philippines due to its speedy prosecution. However, in Japan, stakeholders are concerned on the reliability of utility model since no actual examination happens and the longevity is shorter than a patent. Establishing consumer reliability is of utmost importance and so major companies choose patent based on its reliability, longevity, and credibility. It is important to note that chemical inventions such as innovations related to food and beverage may be protected as a Utility Model under the Philippine law. Unlike in the Philippines, however, the Utility Model law in Japan only protects the shape or structure of an article. Thus, for chemical companies whose inventions are mainly related to materials, utility model is unsuitable protecting our invention. For at least the abovementioned reasons, patent protection continues to be the choice of protection of innovations in the chemical field in Japan.

4.6.3 *Experience with the prosecution of chemical innovations in Japan*

Most cases of refusal of chemical technology inventions in Japan are with regards to as follows: Inventive step > Novelty > Inappropriate description > other issues (including eligibility and industrial applicability). This is consistent for both JPO's and the stakeholders' point of view. Accordingly, there are not so many issues concerning eligibility and industrial applicability in Japan. Even if there were such cases, the norm would be not to refuse it under eligibility and industrial applicability since the claims, despite the actual drafting, are usually construed in the broadest possible way so that the invention can still be assessed in a different requirement. In the chemical company's experience, refusals have been increasing in the IT-related chemicals for energy and functional materials area. This may be due to the fact that since patent application relating to these products have been filed for a long time, there are already many prior arts in these fields. Thus, it tends to be difficult to overcome the refusals based on the many prior art.

According to JPO, there are also issues for inventions in the chemical field regarding claims defined by parameters and the product-by-process claims. For product-by process claims, of which there was a major court case in previous years, the extent to which product-

by-process claims can be accepted is of major concern. As for claims specified by some kind of parameter or characteristic, there have been cases when the compound itself is not new but the inventors measure the characteristic of this compound by new equipment or new measurement method and specify the compound as if it is new and it becomes problematic during examination. IPOPHL should be prepared in handling these inventions.

Based on the interviews conducted, it can be discerned that the stakeholders are satisfied with the overall strategy and actions of JPO when it comes to the patent prosecution and overall patent system. Every year, JPO tries to accelerate the period from filing to approval and is continuously working on improving the examination guidelines in line with the movement of the Japanese industry.

4.6.4 *Experience with the prosecution of chemical innovations in the Philippines*

The chemical company has a business related to only agrochemicals in the Philippines. They develop and sell fungicide for bananas in the Philippines. Therefore, the company seeks patent protection focused on this business. Based on their experience during the patent prosecution of their patent applications, they found no aspect in the patent examination approach that are significantly different between Japan and the Philippines. It is of their opinion that the examination of IPOPHL is brighter, clearer, and faster than that of other ASEAN countries. Many similarities in the description of the Philippines' and Japan's examination guidelines were also observed. It was noticed however, that there are differing approach with the interpretation of product by manufacture invention in Japan and in the Philippine, thus the examination of such inventions are noticeably different between the two jurisdictions.

4.6.5 *Experience on setting the examination guidelines for Patent and Utility Model in Japan and on the recent patent system*

Prior to setting the present Examination Guidelines for patent and Utility Model, there were separate guidelines per technology field and/or industry. For example, in the chemical field, there were individual examination guidelines for each of textile, organic chemistry, high molecular area, glass, among several others. These existing guidelines were then combined to create a unified, clearer, and easier to understand new guidelines which is applicable across all fields of technology. Decisions of the IP High Court as well as the Supreme Court of Japan were also taken into consideration in the creation of new guidelines and its subsequent amendments. As discussed in the previous sections, sometimes the changes in the examination

guidelines were motivated by strong requests from Japan. Amending the patent examination guidelines in Japan requires a process that necessitates the cooperation of not only JPO (Examination Standards Office and Examination Departments), but also the involvements of external groups comprising experts from the private/public sectors, and the public. It is important to note that the experience in Japan teaches that the creation and amendment of the examination guidelines required appropriate consultations and efforts for smoother transition.

The overview of the updating process of the Examination Guidelines involves the following procedure: Internal consultations by the Examination Standards Office of JPO is conducted, taking into account the amendments of laws, court decisions, inputs from industries, study reports on foreign practices, and etc. At this stage, revision policies are established, and the Guidelines are drafted. After drafting the Guidelines, the next step will involve discussion at sessions of external working group (WG) on the Examination Guidelines. The external working group usually consists of legal professionals, patent attorneys, jurists, economists, scientists, and heads of institutions and companies so as to present views from different perspectives. Once the basic policies and the gist of the revision are approved by the WG, JPO then invites public comments on the revision draft of the Guidelines. The final step is the publication and enforcement of the revised Guidelines.

5. Implications and the recommendations to IPOPHL

The Chemical Technology field of IPOPHL covers a wide array of chemical-related subject-matters which in turn has resulted in handling concerns to the division assigned to perform examination on such diverse technologies. The provisions provided in the references employed by IPOPHL patent examiners have become too general to address these highly diverse and/or specific topics. As such, it becomes difficult to apply them to actual application since these provisions are subject to various interpretation of patent examiners. This is especially true for issues on eligibility and industrial applicability.

This study allowed us to compare selected aspects of the patent prosecution of chemical technology inventions of JPO and IPOPHL. It was determined that there are indeed similarities and differences in JPO's and IPOPHL's examination procedure and assessment of patent eligibility, novelty, inventive step, and industrial applicability. Mainly, the differences are worth investigating, especially on the flow and procedure of patent examination and the evaluation of eligibility and industrial applicability.

It is beneficial for IPOPHL to revisit problematic cases on inventions containing issues on patent eligibility and industrial applicability. The detailed explanation and very clear case examples as provided in the Guidelines and Handbook of JPO has proven to be helpful in understanding the appropriate approach in the determination of patent eligibility and industrial applicability of chemical technology inventions. The requirement on patent eligibility and industrial applicability in Japan is not so high nor strict, and there are not so many cases of refusal on these in the chemical technology field at JPO. The same could be said in the Philippines. It may be beneficial to further explore the possibility of adopting some of the substantive examination perspective of JPO in addressing eligibility and industrial applicability issues.

Formulating a new flow or procedure of examination in IPOPHL solely for chemical technology subject-matters is not strictly necessary. Ultimately, a standardized flow and a standardized procedure for all fields of technology is ideal in the long run for consistency and clarity. However, it would be in IPOPHL's best interest to revisit the present flow in assessing inventions since they affect the length of prosecution of those applications with issues.

There is also a need to clarify and broaden some aspects of the examination references, especially in the MPEP, in order to address issues mainly regarding how statements in the MPEP should be properly interpreted. Case examples would provide a meaningful addition to

this. As previously stated, JPO has provided very detailed guidelines specifically addressing such issues, in their Examination Guidelines and Handbook with very informative Case examples and Court precedents on patentability matters. They merit a closer look on which parts can be incorporated in our references taking into consideration our own national laws.

It is further recommended for IPOPHL to encourage continuous research on patent eligibility and industrial applicability not only in the chemical technology filed but also in other chemical fields. Application of use invention for food and beverage should also be explored. Undergoing research analysis based on findings from various sources in order to standardize the examination procedures and practices across all divisions in all fields of technology, especially in the chemical field, will be beneficial in amending the patent examination references.

It is challenging to perform substantive examination when there are many technologies that are examined in the Chemical Technology Examining Division. As previously shown, the technologies handled by the Chemical Technology Examining Division of IPOPHL are examined by 7 main divisions and 11 sub-divisions at JPO. It may be ideal for IPOPHL to further review the range of technologies examined by the Chemical Technology Examining Division and consider creating new divisions to handle some of these technologies. Specializing on examining in a small and closely related fields may help improve the quality of examination.

Based on IPOPHL’s data, Japan continues to be among the top two filers of Patent in the Philippines. Accelerated examination through the Patent Prosecution Highway (PPH) is being utilized by Japanese filers leading to faster prosecution of their important inventions. Though the differences in assessment between JPO and IPOPHL is not generally felt too much by the Japanese filers in the Philippines, it would be beneficial to still take a closer look on these aspects of the examination in order to resolve confusing provisions to the applicants. With that in mind, applicants will have a better understanding of the examination practices of each jurisdiction and thus they will be able to prepare high quality patent applications.

Ultimately, Japan's practices, policies and experience on chemical technology invention applications examinations has provided a new perspective on how we can handle the same matters in the Philippines, taking into consideration the existing national laws. IPOPHL must cope up with the emerging challenges in the patent examination of various fields of technology. In future amendments of IPOPHL patent examination references, it should feature the best practices of examination standards from leading IP offices so that examiners will have

confidence in drafting Examination Reports with findings that could withstand even the meanest scrutiny and eventually produce patents that can withstand any patent prosecution. It is appropriate to provide case examples and similar guiding principles to aid in the proper interpretation of the provisions in the references employed by IPOPHL examiners during patent examination. This may then lead to clearer and better understanding and proper application of said provisions. Perhaps if this could be done, the provisions will no longer be subject to interpretation of patent examiners. This is especially true when it comes to assessing patent eligibility and/or industrial applicability, wherein it was determined in the previous section the differing perspective when it comes to these requirements. It is important to note that the experience in Japan teaches that the creation and amendment of the examination guidelines requires appropriate consultations and efforts for smoother transition.

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To God be the glory!

Anthea Kristine Y. Paculan

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Appendix: Minutes of the interview to Prof. Asami

Date:

30 September 2019

Time:

3:30 PM to 5:30 PM

Venue:

Tokyo University of Science, Tokyo

Interviewees:

Professor Setsuko Asami

Patent Attorney, Graduate School of Management, Tokyo University of Science

QUESTIONS FOR THE INTERVIEW

1. What was your experience on setting the *first* examination guidelines for Patent and Utility Model in Japan?

1.1 Prior to the setting of the Examination Guidelines for Patent and Utility Model in Japan, what source materials did the patent examiners use as the basis for patent examination?

1.2 What was the primary motivation towards the establishment of the (*amended*) JPO Examination Guidelines for Patent and Utility Model in Japan? When was the first/original Examination Guidelines for Patent and Utility Model in Japan established?

Answer to questions 1.1 and 1.2
In 1993, the examination guidelines were compiled but even prior to that, guidelines did exist. The old examination guidelines prior to 1993 were classified according to technology per technical field. For the chemical field, the technical field that this was divided into was for example: alloy, textiles, organic chemistry, glass matters, high molecular area focus and so on. There are many. These were compiled in 1964. This was just for the chemistry field. And in addition to that, there are other guidelines in other areas such as mechanical, electricity, and so. The old examination guidelines were divided into so many different types and therefore you had to study so many different things from different guidelines. Plus, for inventions which involves multiple technical field, in the case like that, there is the question of which particular examination guidelines they had to refer to. And because of that, in order to make all the different guidelines easier to understand, it unified and integrated these guidelines. And in the year 1993, the new examination guidelines was compiled and this new one was not classified into different technical fields but in order to present an overall

unified concept and philosophy as examination guidelines so that it can cover all the different technology fields. And in the new examination guidelines, the contents were divided according to patentability requirements per item and not per technology field. SO for example, patent eligibility, industrial applicability, novelty, inventive step, and so forth, all those patentability requirements. The concept behind that was for example, if we're talking about Inventive Step, the philosophy behind Inventive Step needs to be common across all technology fields. It shouldn't differ according to technical field. And I understand that the concept is the same as the one adapted by USPTO, EPO.
See attachment after this.
The examination guidelines is used not only for examiners but for applicants as well in order to deepen their understanding of the examination guidelines. In 1993, the first integrated version of the examination guidelines was issued and since then, revisions and amendments have been conducted on the basis of international harmonization as well as to provide sufficient protection of the results and outcomes of technological development and also in response to all the legal revisions and amendments of the Japanese Act.

1.3 Could you explain the general process involved in the setting of the patent examination guidelines in Japan? Who were tasked to take part in this procedure? How long did it take to do this (*start to completion*)?

Please see attachment.
I'm sure you've already visited the JPO examination guidelines office, they come up with the draft plan for the contents of the guidelines first. After the draft is compiled by the members of the JPO Examination guidelines office, externals are commissioned consisting of external members, they are experts in this particular field and they have discussions concerning the contents of the draft. At the METI, the Japanese Ministry of Economy, Trade, and Industry, they have various councils, and one of them is the Industrial Structure Council, and they have a subcommittee on the patent system and within the subcommittee they have a working group specializing on examination guidelines. And the working group consists of approximately ten members, I'm one of them, I am among the panel and we discuss the draft. And after we come up with a draft proposal, a public hearing session will be held where the general public present their comments, and based on the comments, the JPO will have another discussion and review the contents, and based on that, the examination guidelines are compiled.
A major revision was conducted in 2015 to the examination guidelines. This revision was not aimed to change, for example the interpretation of Inventive Step. The purpose was to make the examination guidelines easier to understand. We also incorporated new aspect based on the trend of the International harmonization. Also, revisions were made based on the jurisprudence of the IP High Court as well as the Supreme Court of Japan. And since then, we already embark of making case studies on technology fields such as AI or Internet of Things with the advent of such technologies.

1.4 What were the scopes of the 2015 Examination Guidelines for Patent and Utility Model in Japan? Which areas/aspects did you handle or assist?

Same as 1.1. Patentability Requirements such as Novelty, Inventive Step, etc.
When we compile the guidelines, we do not do it by technical field. When we make the guidelines, it's according to each patentability requirement such as novelty, inventive step, etc.

1.5 Which areas of the examination guidelines have been the most difficult to work with? Which section(s) has(have) been problematic to work with? (e.g. *Patent Eligibility, Industrial Applicability, Novelty, Inventive Step, others…*) **Why?** What was your experience in working on the areas related to Unpatentable Invention, Patent Eligibility, and Industrial Applicability?

In the working group that I belong to, of course, we have discussions when the examination guidelines are revised, but we do not have discussions for each different technical field. We look at the common overall concept for each different requirement, for example Inventive Step or Industrial Applicability. So the draft revision proposal is compiled by the JPO Examination Guidelines Office and based on that, we have discussions.
For Inventive Step, we have the biggest number of jurisprudence and therefore how to compile the new examination guidelines for Inventive step? It was the most difficult aspect.
In terms of Patent Eligibility, the definition of an invention here in Japan is an invention needs to be a creation utilizing technical ideas of the law of nature. For example, it is an invention utilizing economic rules, that is against patent eligibility. As for Industrial Applicability, in the case of Japan, medical treatments are the only category that is considered not to have industrial applicability. So regarding issues on other patentability requirements, we do not have any in the field of Chemistry. So personally, it is not a good idea to make examination guidelines per technology field and it's not a common practice here in Japan. However, if you have to do so in the field of chemistry, I don't think you need examination guidelines for patent eligibility and industrial applicability for chemistry related inventions.

1.6 What were the main challenges you encountered in the process of setting the examination guidelines? What were the problems encountered in implementing (*putting into practice*) the patent examination guidelines? How did you solve them?

Since there are so many jurisprudences, I'm sure it was very difficult for JPO Examination Guidelines office how to select the wording and it's difficult for them to express them in sentences and I'm sure it's hard to compile it. But based on that, we have discussions. And the question of which particular jurisprudence we select and incorporate. Because depending on the particular case we choose, that may change the method of determination. So the difficult part was to strike the right balance and to make sure that it's not too arbitrary or intentional. Also, we take into consideration the basic trend of international harmonization. We have to make sure that the decisions made by the JPO are not too different from decisions made by other offices, specially the USPTO, EPO, SIPO, and KIPO. So we do study the trend of decisions made by these offices. They are prepared by the JPO Examination guidelines office. Based on the information, we have discussions and make sure that the Japanese decisions are not too different from theirs.
As I explained earlier, whenever we make examination guidelines, first the JPO comes up with a draft, but then there will be a public hearing where the public is given the opportunity to present their comments. Therefore, from a very early stage, applicants are given the opportunity to know about the contents of the guidelines. First, the JPO examiners get to see the content of the new examination guidelines from an early stage. And the JPO examination guidelines office will explain all the details of the new

standard to all the examiners of the JPO. And training programs are provided to all the examiners of the JPO. At the JPO, they have the section called the quality management office. And if the guideline is amended or if new parts or rules are added, the quality management division make sure that they check to see whether adequate examination are conducted by examiners based on the newly incorporated rules and regulations.

1.7 In general, how did the examination guidelines affect the patent examination and the overall patent situation in Japan?

In 1993, we came up with examination guidelines which were not divided per technical field, the unified version in 1993, and since then it has been amended several times. And that's partly because of new jurisprudence. And also, naturally whenever the Japan law and act are divided and amended, based on that, the examination guidelines has to be revised and amended. And of course, Inventive Step and Novelty, they remain unchanged but those legal amendments concerning "amendments" and therefore based on the new rule, the examination guidelines were also revised.
Yes it improved the patent situation in Japan.

2. What is your experience with the more recent patent system in Japan?

2.1 Are there any specific changes in the examination guidelines in Japan which affected (*either helped improve or worsened*) the examination/prosecution of chemical innovations?

Yes there was a revision in the field of food but that was not because of jurisprudence but that was based on the very strong request submitted by the food industry. And when it was revised in 2016, I was one of the members in charge of it. And before the revision, usage invention in the field of food was not accepted in Japan but as a result of the amendment came to be accepted. Therefore, Japanese companies involved in R&D activities in the field of food were very pleased with the revision and so far, we had not heard of any negative effects as a result of this issue.
As for the JPO examiners, if the standards have changed, they conduct examination based on the new standards. So as far as the examiners are concerned, no problem. As for the applicant's side, if we are to amend the examination guidelines, first we announce it, and we spend at least 6 months for preparation and they're given the opportunity to fully understand the content of the new standard specially the applicant who are interested in that particular field had sufficient time to study the content. So no big issues on the applicant's side.
Specially in the field of food, a lot of people are interested in health food and therefore we conducted the revision in order to promote R&D activities in the field where the people are very much interested in. And this applies not just for food-related industries. If there is a possibility to further develop certain industries in Japan and if examination guidelines are revised based on the trend, I think it's a verification that patent act is appropriately implemented to practice here in Japan.

2.2 According to the Revision History of Examination Guidelines for Patent and Utility Model in Japan, the guidelines have been revised on October 2015, March 2016, March 2018, June 2018, and March 2019. To your knowledge, could you explain the steps/processes/procedures involved in revising the examination guidelines? Is it

generally the same as that of the original setting of guidelines? What are the primary reasons/motivations for the revisions in the patent examination guidelines in Japan?

Answered already in previous items.

2.3 What are the usual problems encountered in implementing the changes in the patent examination guidelines/practice/Patent law (*if there is any*)? Please describe. How do you resolve them?

Answered already in previous items.

2.4 Are there any specific part/area in the patent examination guidelines/practice/Patent law in Japan which you think still needs to be changed or improved (*especially those related to the chemical field*)? What are the major problems right now in the examination of technologies in the chemical field?

We don't use the idea of changing according to technical field. So for example, on recent years, inventions in the field of IOT or AI continue to increase and the JPO is aware of such trend and they think it's necessary to encourage and promote inventions in these fields. So in the case like that, they make new case studies and case examples so that the general public can see the content and deepen their understanding concerning the new fields. But these case studies are not examination guidelines, these are just virtual examples to provide ideas to the people. Examination guidelines themselves remain the same. But examples are given to these new fields so people can actually see and these examples need to be easy to understand so that the people can actually foresee what kind of invention can be patentable. I think it's a good idea for the Philippines to compile such examples which are easy to understand so that people can see and understand.

2.5 In 2007, the JPO has set-up its Quality Management Office, to especially focus on quality management. How did this affect the JPO (*especially the examiners*) and the applicants?

The basic aspect of quality management is to make sure that the PPC cycle runs in the most appropriate manner. Example, they randomly select notifications of refusal written by JPO Examiners and these random samples are checked. And the people who conduct the checks are people with a lot of experience and expertise. They have an experience working as substantive examiner for at least 20 years, experience working as appeal board examiners at the JPO, so that kind of experience of the veteran people of the quality management office. First, as I explained earlier, if the examination guidelines were revised or if new practice and operation were introduced, these people who conduct the check will focus on those areas and conduct the checks.