Improving Patent Examination Guidelines for the Biotechnological Field: *A Comparative study on the examination practice between JPO and MyIPO*

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Abstract

The Intellectual Property Corporation of Malaysia (MyIPO) has been offered to participate in the Long-term Research Fellowship in Japan from November to December 2022 on the improvement of the examination guidelines in the biotechnology field in Malaysia. This topic was chosen due to the advancement of the research in biotechnology in recent years that needs to be addressed especially the one that is related to genetic engineering such as gene editing, the use of human embryogenic stem cells and many more. The focus of this study would be a comparison of the examination practices between both offices JPO and MyIPO. It will further look into the practice of handling the biotechnology/biology-related invention with specific attention to the patentability requirements. The methodology of the research consisting of three (3) components: 1) Gather information from available documents such as JPO Examination Guideline and JPO Examination Handbook; 2) Conduct interviews based on guided questions with Prof. Sumikura from GRIPS and JPAA Bio Life Science Committee; and 3) Analyzed and discussed the data gathered from the available documents and from the interviews conducted. The recommendations will then be made to MyIPO based on the findings from the study. It is hoped that through this study, the understanding of JPO examination practice especially on the biotechnology-related invention will be much understood and the knowledge can be brought back to Malaysia.

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List of Abbreviations

ASEAN	Association of Southeast Asian Nations
CNIPA	China National Intellectual Property Administration
EPO	European Patent Office
ID	Industrial Design
IP	Intellectual Property
IPC	International Patent Classification
IPEA	International Preliminary Examining Authority
IPO	Intellectual Property Office
ISA	International Searching Authority
JPO	Japan Patent Office
MyIPO	Intellectual Property Corporation of Malaysia
PPH	Patent Prosecution Highway
SIPO	State Intellectual Property Office
UPOV	International Union for the Protection of New Varieties of Plants
USPTO	United States Patent and Trademark Office

1. Introduction

Patent is one of many other components of intellectual property. The definition of patent maybe slightly different throughout different countries but the essence and the function of the patent system itself is basically the same. Patent according to the World Intellectual Property Organization (WIPO) is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application.

Hence, in order to get a patent rights, an invention should meet certain requirements such as enabling requirement, clarity of claims, novelty, inventive step and industrial applicability. These are the basic requirements to be met by an invention of any technical fields including biotechnology related invention. These requirements usually be the based for the national patent law/act. Besides that, patent examination guidelines also usually will be established and published to clearly described various format and situations of the patent applications received and how to handle them. Many examples usually stated in the guidelines to help the patent examiner make decision on the patentability of an invention and also to let the public know on how the patent office do the examination so that they will be able to prepare a better specification that meet all those requirements.

In Malaysia, biotechnology started to gained serious attention in the early 2000 when the Malaysian Government introduces National Biotechnology Policy in 2005 to induce the technology in the country. The main purpose of the policy is to further develop three economic sectors namely agriculture, healthcare and industrial manufacturing, as

well as to support the growth of an enabling eco-system throughout the scientific, academic and business communities in the country. Since then, biotechnology related invention is growing and thus the patent application related to the technology is also increasing throughout the year. While this is a good indicator in terms of the economic point of view, but the policy and practice in Malaysia with regards to the substantive examination on biotechnology invention is still unclear.

The consequences of not having the clear policy and examination practice is immense in which it creates problem such as longer time needed to process an application related to the technology. Currently, the examiners have to compare the practices in other countries when dealing with the biotechnology related invention and make the decision based on the research that they have done. This is not a practical solution as the examiner have to do this back and forth each time and it is also time consuming. The long prosecution of biotechnology invention as stated above will cause build-ups in backlogs.

Realize on the problems that will rise if no stand on policy as well as procedures to handle the bio related invention, Intellectual Property Corporation of Malaysia (MyIPO) initiated an effort to establish a biotechnology guideline with the help of a consultant from the European Patent Office (EPO). The draft biotechnology guideline that was drafted by the consultant is in line with the EPO practice. Through the cooperation, MyIPO managed to have the draft biotechnology guidelines that consist of a very comprehensive guide in dealing with the patent application related to biotechnology covering all possible fields including microorganism, genetic engineering as well as the application of biotechnology in agriculture. The draft is aimed to be the backbone of MyIPO biotechnology guidelines back then but due to an unknown reason, the draft is not adopted and published.

MyIPO however planned to establish the new biotechnology guideline together with other technology guideline to be in line with the recent amendments made to the patent act and regulations. There are four main objectives of the patent acts amendment 2022:

1) Malaysia's commitment in an Agreement/International Treaty (Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Patent Cooperation Treaty (PCT))
2) To enable Malaysia to accede Agreement/International Treaty (Regional Comprehensive Economic Partnership (RCEP) and Budapest Treaty)
3) To update Act 291 to be in line with the international update.
4) To enhance the patent administration procedure.

In order to address the effect of the amendment of the patents act and regulations with regards to the patent examination and procedures accordingly together with the long-awaited demand for a clear policy on biotechnology related invention, it is the right time for MyIPO to established the biotechnology guideline along with other specific technical fields guidelines.

As of now, MyIPO is still working on the general guidelines for patent examination as well as other specific technology guidelines. The general guideline has been posted on the MyIPO official website for public consultation from 1st November until 14th November 2022, while the rest of the guidelines are still undergoing. For the establishment of these guidelines, MyIPO formed a standing committee for each and every guideline. The job scope of the committee is basically to do a comparative study on

the practices of other countries and make recommendations that are best suited to the national interest based on the findings.

The same working plan also applies to the biotechnology guideline committee. The committee has decided to study the examination practices from JPO and EPO while using the draft biotechnology guidelines prepared years before as a working draft. The committee also has submitted the working draft to both JPO and EPO for comments and feedback and we have received very constructive feedback from both offices for consideration. A series of meetings have been conducted and some amendments were made to the working draft to reflect the suggestions and feedback received. The draft guideline now is ready to be adopted by the end of the year 2022. However, it should be noted that guidelines are live documents where it can be amended from time to time to reflect on the dynamic examination practice that might differ after some time. Due to that, continuous study should be done to keep up with the latest development in examination practices around the world.

The main objective of this research is to do a comparative study on the policy and practices in Japan Patent Office (JPO) regarding the patentability of an invention related to biotechnology. The specific objectives for this study are as follows:

i) To understand the practice in assessing patent eligibility and industrial applicability for the biotechnological inventions in JPO.

ii) To understand the practice in assessing Novelty, Inventive Step, and Industrial Applicability for biotechnological inventions in JPO.

iii) To identify the similarities and differences on the examination practices for biotechnological inventions between JPO and MyIPO.

iv) 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 MyIPO

2.1.1 Overview of the Organizational Structure and Functions

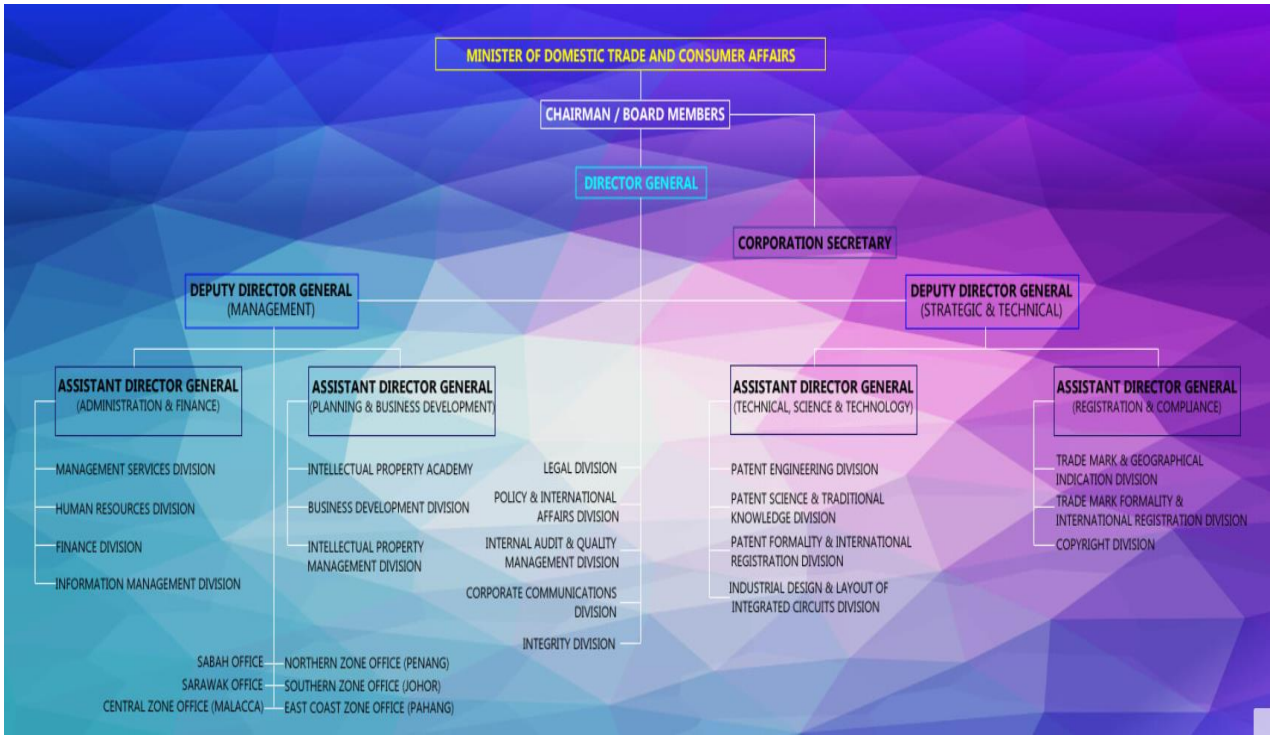

Figure 1. Organizational Chart of MyIPO.

Figure 1 shows the Organizational Chart of MyIPO. MyIPO is an agency under the Ministry of Domestic Trade dan Consumer Affairs. As a corporate body of the federal government, MyIPO has a board responsible for oversight and planning of the organization. At the same time, the management headed by a Director General (DG) is responsible for MyIPO daily operations. The DG is assisted by a Deputy Director General (Management) and Deputy Director General (Strategic & Technical). The Patent Division

is under the purview of the Assistant Director General (Technical, Science & Technology). It consists of two patent examination divisions: Patent Engineering Division and Patent Science & Traditional Knowledge Division. Besides that, the Patent Formality & International Registration Division responsible for receiving all local, foreign and PCT applications is also under the same department together with the Industrial Design & Layout of Integrated Circuit Division. Figure 2 shows the organizational chart of the Patent Science & Traditional Knowledge Division. The Division is composed of seven (7) examining units directly under the supervision of the Senior Director.

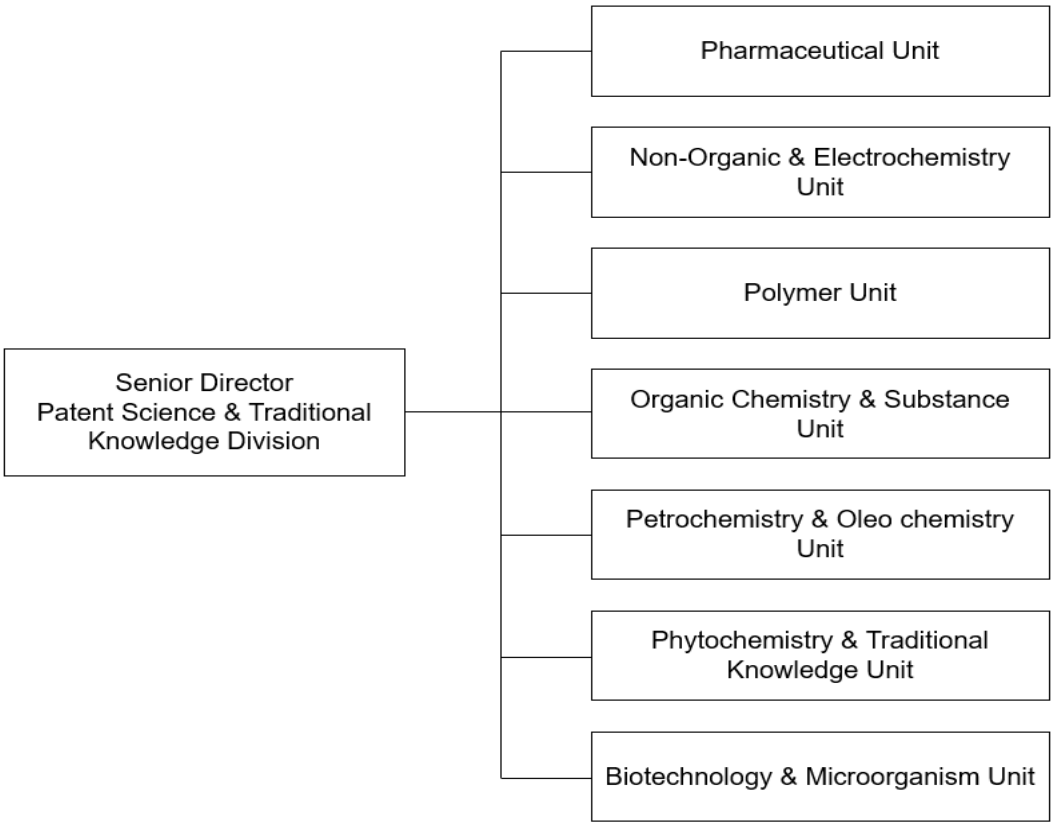

Figure 2. Organizational Chart of the Patent Science & Traditional Knowledge Division in MyIPO.

Currently, there are seven (7) examining units under the Patent Science & Traditional Knowledge Division with 35 examiners altogether. All the units handling

patent applications and are responsible for conducting prior art searches and performing substantive examination including some formality requirements check and the preparation of office actions. The examining units are divided according to specific fields of inventions but it is not specifically according to the IPC class. Even if that is the case for the division, the specific technical field as named has a different class of IPCs. This is unique from other IP offices as they usually divide the examination units or divisions according to the IPC class. Presently, there are 77 examiners in total for both examination division with only 10 examiners handling biology related invention applications that are coming from two units: Phytochemistry & Traditional Knowledge Unit and Biotechnology & Microorganism Unit. The examiners under these units possess a Bachelor's Degree in Biology, Biochemistry, Biotechnology (Engineering) and Biotechnology.

Although this division does not have a special unit for training, but we have a training committee made up of senior patent examiners with more than five (5) years of experience. Most of these trainers used to participate in the Regional Patent Examination Training (RPET) which is a program of ASEAN and Australia cooperation with the support from WIPO. The RPET program module has become the basis for our current training module for the new and existing examiners. New patent examiners have to undergo intensive training for a maximum period of two years before they can conduct examinations on their own without the need for observation from a trainer or supervisor. This training is a competency-based training called Malaysia Patent Examination Training (MyPEXT). The training consists of four phases where the first three phases are an introduction to the patent system, skills and knowledge to interpret patent specifications by applying rules of construction (interpretation), searching and so on.

While the last phase is On the Job Training where the examiner has to perform a patent examination with the observation from the supervisor, who is usually the Head of Unit and trainer.

Apart from that, there is also another training for existing examiners. Among the training that will usually be carried out is training for a specific technology. The objective of the training is to enable patent examiners to keep up with the latest technological developments. This is very important to ensure that the patent examiner will be able to conduct the examination more efficiently. For this training, each division will get lecturers from local universities to share the latest technologies in their field of expertise. In addition, MyIPO also provides an opportunity for any officer, especially a patent examiner, to continue their studies to a higher level such as a Master's Degree and Doctor of Philosophy.

There is another important committee but does not appear as a unit in the organization chart which is the Patent Quality Management (PQM) Team. This committee consists of the Head of Unit for each unit from both examining divisions. The objective of the PQM is to determine the quality of patent examination works carried out by the patent examiners. With the existence of this PQM, it is hoped to ensure that the quality of examination by patent examiners at MyIPO always reaches the standards that have been set.

2.1.2. *Managing Patent Examination in the Biotechnology Group*

In general, the number of patent applications for two main technology groups, science and engineering field is almost the same according to the statistics for the years 2019 - 2021. Referring to Figure 3, the percentage of applications for the field of science consisting of chemistry, pharmaceuticals, biotechnology, chemical engineering and human necessity is 52%. On the other hand, the percentage of applications for engineering technology, which consists of electrical engineering, mechanical engineering, civil engineering, computer and optics, is 48%.

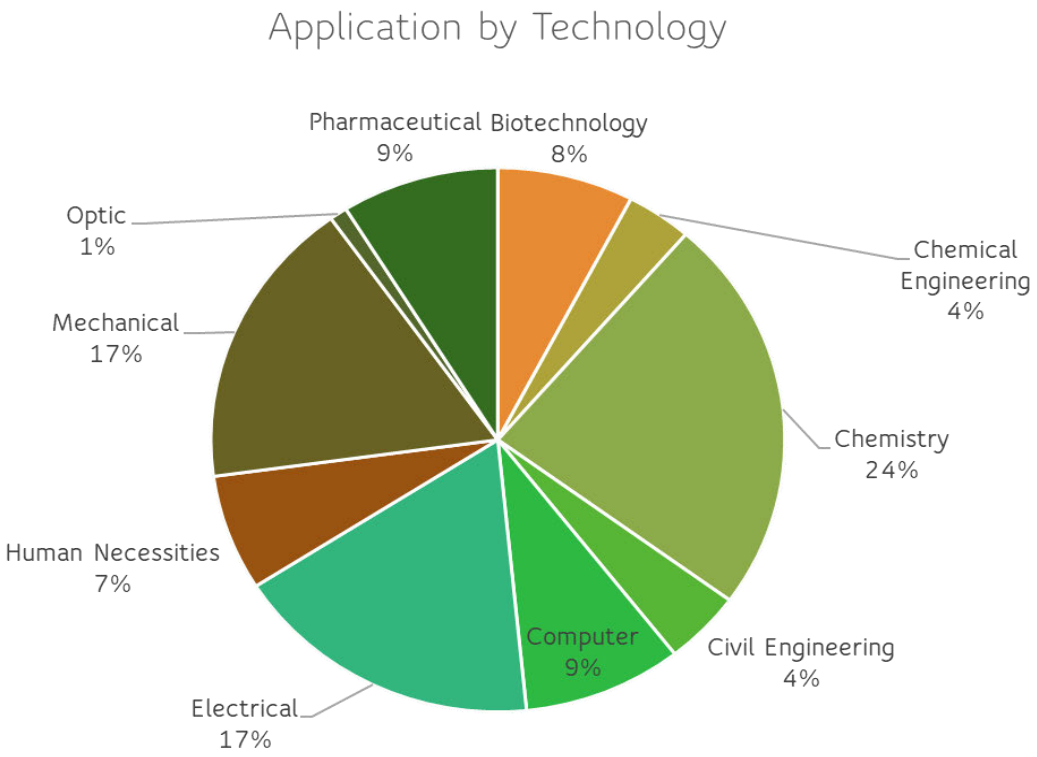

Figure 3. Total Patent Applications filed in MyIPO by Field of Technology from 2019 to 2021.

As for the breakdown of the biotechnology group, the percentage of the number of patent applications is as much as 8%, with a total of 1,720 applications. The fraction of the

application number according to their subgroups can be seen in figure 4. As shown from the figure, the biotechnology group is further divided into several sub-technology groups, including antibody/antibiotic technology, enzyme technology, genetic engineering, microorganisms, plants, protein, sequences, vaccines and others. Inventions related to antibodies/antibiotics are the technology with the highest applications received at 513 application, followed by inventions related to nucleotide/protein sequence and protein-related inventions with 375 and 285 applications received respectively. On the other hand, the least received applications come from vaccine technology with only 27 applications.

SUBBIOTECHNOLOGY	TOTAL	% of Total P..
Antibody/Antibiotic	513	29.8%
Enzyme	42	2.4%
Genetic Engineering	116	6.7%
Microorganism	265	15.4%
Plant	42	2.4%
Protein	285	16.6%
Sequence	375	21.8%
Vaccine	27	1.6%
Others	55	3.2%
Grand Total	1,720	100.0%

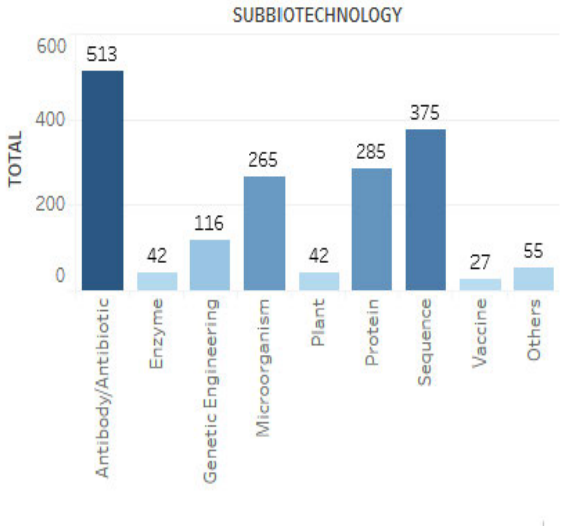

Figure 4. Total Patent Applications filed in MyIPO in the field of Biotechnology from 2019 to 2021.

Patent applications on biotechnology inventions will be assigned to the patent examiner handling the biotechnology inventions. Two units consisting of ten examiners will carry out examinations in the field of biotechnology in MyIPO, namely Biotechnology & Microorganism Unit and Phytochemistry & Traditional Knowledge Unit. Any applications related to innovation for all sub-technologies mentioned before

will be allocated to patent examiners from these two units. There is no specific classification assigned for each patent examiner. Therefore, applications for any innovation related to biotechnology can be distributed to anyone from the units, regardless of whether it is related to genetic engineering, antibodies, microorganism, plant or any other sub-technologies.

In addition to handling patent applications for biotechnology-related innovations, these units also receive applications from other technology groups if the patent applications for biotechnology are not enough to be distributed to patent examiners for that particular month. For cases like this, patent examiners from these two units will usually receive applications from the pharmaceutical field and human necessities categorized as miscellaneous, as well as from another technology group like chemistry. However, this kind of patent applications must be provided with a granted patent from other IP offices or at least be provided with the search report from ISA (ISR, IPRP I/IPRP II and Written Opinion) or any other IP offices. The patent application provided with these documents is categorized as an enhanced application which can be assigned to any patent examiners in the division.

2.1.3. *Patent Prosecution Practice in MyIPO*

In Malaysia, there are three methods to apply for a patent. For local applicants, they can file the application directly at the head office counter or any MyIPO branch office. For applicants from abroad, they can make the application via two routes, the PCT route or the Paris route. This application must be made through an appointed patent agent. All applications received whether direct, Paris or PCT will go through a formality review process before they are submitted to the examination section for substantive examination.

Figure 5 shows the flowchart of the patent application process.

In the Examination Division, the list of patent applications that are ready to be examined will be pre-searched by several selected patent examiners. This pre-search process is to identify the patent application field of invention and to search whether the patent application has a corresponding application from any other country and if the corresponding application has a Search Report (SR) from ISA or has been granted a patent. For patent applications that have an SR or Granted Patent, they are categorized as 'Enhanced' as previously stated. While patent applications that do not have any corresponding application will be categorized as 'Full'.

Once the preliminary search process is complete, these patent applications will then be distributed to patent examiners based on the field and category of the patent application. Generally, most patent examiners will accept both the Full and Enhanced categories. For patent applications in the Full category, it is necessary to carry out a prior art search, as well as a substantive examination. Enhanced category patent applications will usually only be conducted through substantive examination based on available SR and Granted Patent, but no prior art search will be conducted.

In terms of examination rules, patent examiners are not bound by any particular method, but sufficient disclosure (Regulation 12), clarity of claims (Regulation 13), novelty (Section 14), inventive step (Section 15), and industrial applicability (Section 16) are typically among the important requirements that must be examined. However, special care should be taken with patent applications involving biological inventions to ensure compliance with public order or morality (Section 31(1)). Apart from that, the biological invention also needs to be ensured whether it uses prohibited substances such as an active compound from *Mitragyna speciosa* and *Cannabis sativa* locally known as Ketum and

Ganja respectively. The active compounds from these plants are listed as psychotropic substances under the Poisons Act administered by the Malaysian Ministry of Health. If the patent application is found to use the material as a basis for the invention, then the patent application will be brought to the Security, Ethics and Public Order Committee that was just established this year for further action. This committee is an internal task force to address the issues related to ethical and safety issues. If the committee found that the disclosure of the patent application may threaten public safety, then its publication may be prohibited in accordance with Section 30A of the Patent Act. However, since the establishment of this committee, no patent application falls under this provision, thus, no prohibition of publication has ever been made.

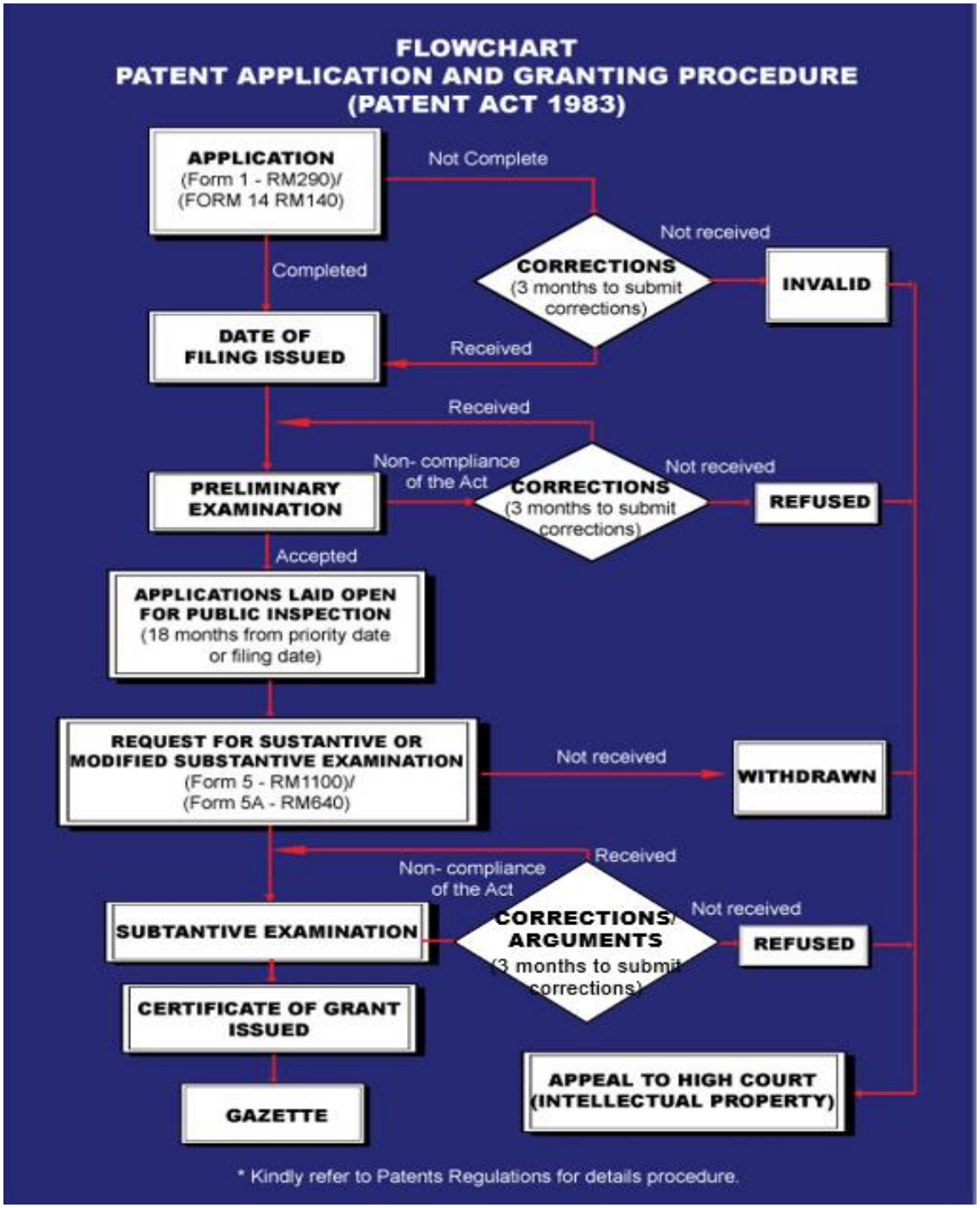

Figure 5. Flowchart for the patent application process in MyIPO.

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

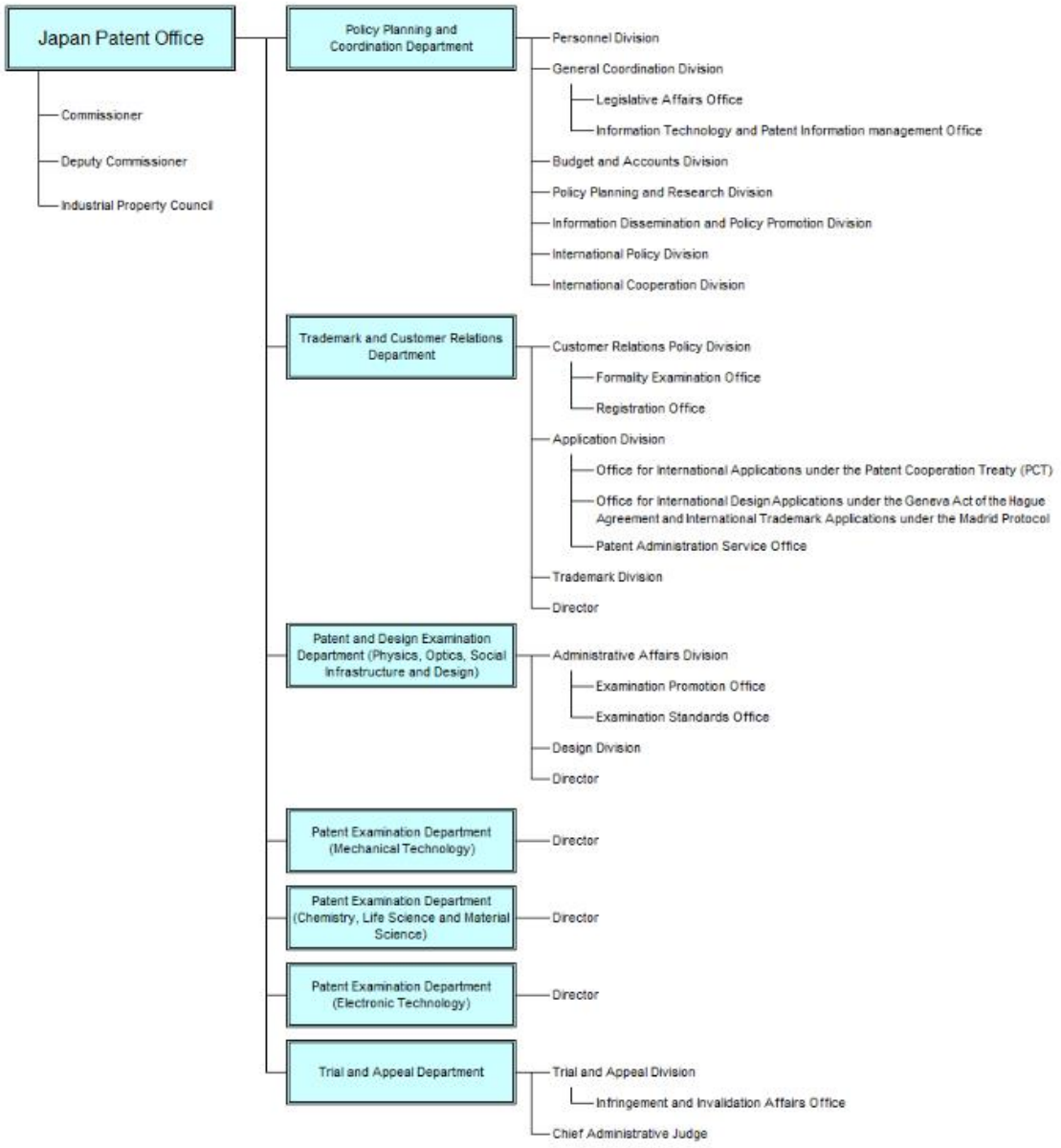

Figure 6. Organizational chart of JPO.

Figure 6 shows the JPO organizational chart that has seven departments as below:

1) Policy Planning and Coordination Department,

2) Trademark and Customer Relations Department,

3) 1st Examination Department (Patent and Design) - Physics, Optics, Social Infrastructure, Industrial Design),

4) 2nd Examination Department (Patent), - Mechanical Technology,

5) 3rd Examination Department (Patent) - Chemistry, Life Science, Material Science,

6) 4th Examination Dept. (Patent) - Electronic Technology, and

7) Trial and Appeal Department.

In 2021 JPO has 1,883 examiners with 1,665 are from Patents/Utility model, 50 are from Designs and 168 are from Trademarks. There are four (4) examination departments, with nine to ten (9) examination divisions in each department. Examinations for inventions in the fields of physics, optics, social infrastructure, and industrial design are often conducted by the first examination department (patent and design) while inventions relating to mechanical technology shall be handled by the 2nd Examination Department (Patent). Electronic technology related invention will be examined by the 4th Examination Department (Patent), whereas technology linked to chemistry, life science, and material science will be handled by the 3rd Examination Department (Patent) and the final department.

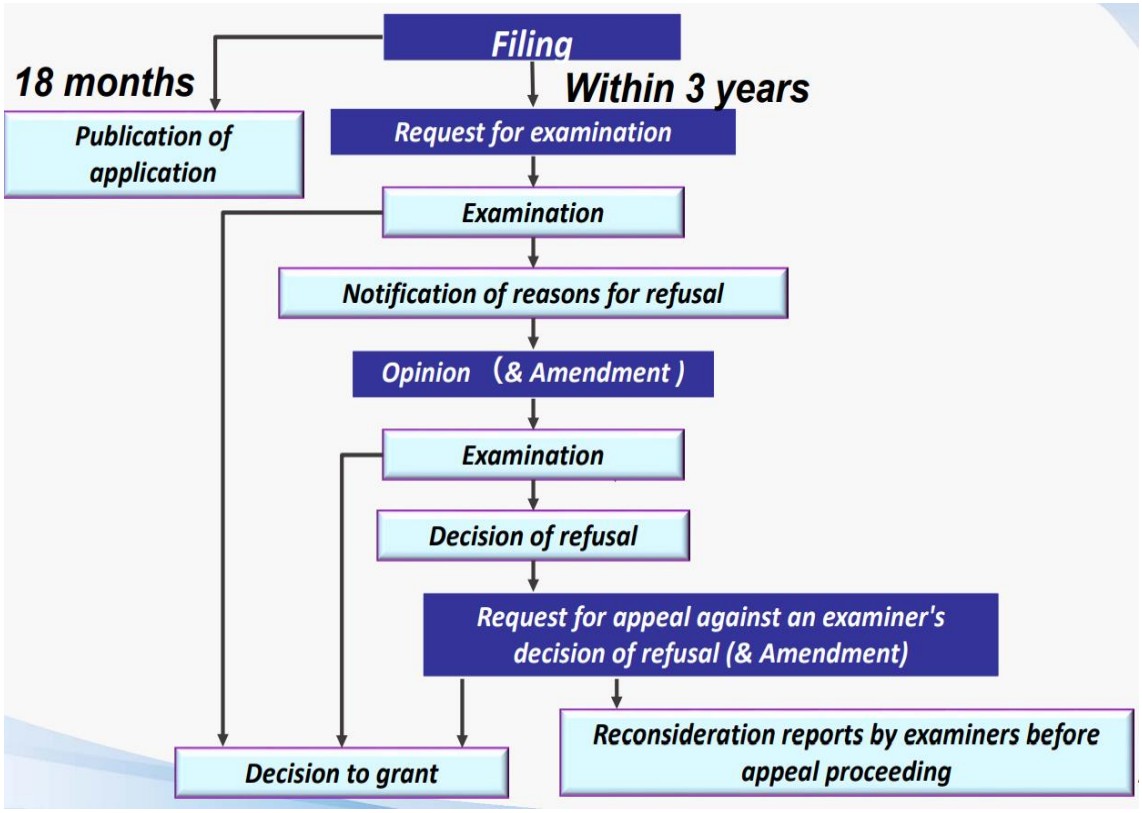

Figure 7. Patent Examination Procedure of JPO.

Figure 7 depicts the JPO's patent examination procedure, which is used in all technological fields.

It should be noted that this study focuses primarily on the substantive examination stage of the JPO and MyIPO, specifically on selected patentability requirements.

2.3 Overview of the Statutory Basis of Patentability Requirements

Table 1. Comparison of Statutory Basis on Patentability of JPO and the MyIPO.

Description	JPO (Japan Patent Act)	MyIPO (Patent Acts and Regulations 1983)
Written Description - Enablement / Sufficient Disclosure	Article 36 (4)(i)	Regulation 12
Definiteness / Clarity of claims	Article 36 (6)(i-iv)	Regulation 13
Unity of Invention	Article 37	Section 26
Filing of Patent Application	Article 39	Regulation 5
Patentable Inventions	Article 29(1)	Section 11
Non-patentable Subject Matter / Non-patentable inventions	Article 32	Section 13
Novelty	Article 29(1)	Section 14
Inventive Step	Article 29(2)	Section 15
Industrial Applicability	Article 29(1)	Section 16

Table 1 compares the Japan Patent Act and the Malaysia Patent Act in some key areas of patent examination. It should be noted that, aside from differences in patent act provisions, there are also differences in the use of names for the topic. One of them is enablement, which is known as sufficient disclosure in Malaysia, and definiteness, which refers to the clarity of claims in Malaysia. Although they are named differently, they refer to the same thing. It should be noted, however, that the focus of this study is a comparison of the following criteria: patent eligibility, novelty, inventive step, and industrial applicability.

2.4 Intellectual Property Laws, Rules, Procedure, and Guidelines of Japan and Malaysia

The Patents Act and Regulations 1983 (Amended 2022) is the primary reference source in Malaysia for patent examiners as well as those in the intellectual property industry. In general, it outlines the fundamentals of patent application and granting in Malaysia. The definition of the invention, non-patentable invention, novelty, inventive step, and industrial applicability are among essential elements set out in the patent act and regulations. Malaysia has patent examination guidelines in addition to the patent act and its regulations. There are several examination guidelines available on the website, including general examination guidelines and examination guidelines for specific technologies such as chemistry, biotechnology, pharmaceutical and computers. However, at the time this report was prepared, the examination standards for particular technologies were still being developed.

The primary reference for patent examiners at the JPO is the Japan Patent Act, the Examination Guidelines for Patent and Utility Model, and the Examination Handbook for Patent and Utility Model. The Japan Patent Act outlines key issues concerning the patentability of an invention. The Examination Guidelines describe how to conduct a patent examination. The Examination Handbook should be consulted for a more detailed explanation, as well as various examples, of how a patent examination is carried out for a specific field. The main references for the examination of patents in the field of biology are Chapter 2 and 3 of the Examination Handbook.

2.5. Overview of Selected Previous Comparative Studies on Patent Examination

A comparative study report on patent examination is made up of a comparison outline, which includes the laws and examination policies at each Office under several headings on a table, and a Comparative Analysis, which examines and contrasts the laws and examination policies at each Office item by item. In order to foster patent collaboration between the JPO, KIPO, and SIPO, the Joint Expert Group for Patent Examination (JEGPE) was founded in 2009. Every year, the trilateral offices undertake comparative studies on patent laws and examination guidelines, as well as comparative case studies on selected themes, so that users can thoroughly comprehend the examination standards applicable to their practices and create high-quality patent applications. The JPO, KIPO, and SIPO conducted comparative studies on laws and examination guidelines pertaining to "Inventive step," "Novelty," "Requirements for Disclosure and Claims," and "Amendments," as well as comparative case studies and published reports on those studies. Those reports can be found on the JPO website.

Apart from that, there is also comparative research on the patent systems of Japan, the United States and Europe which was published in March 2017. The research focuses on patent application procedures in the three countries, including topics related to patentability, the definition of inventions, inventive steps and many more. In addition to that, there is also a comparative study that has been conducted regarding examination practice in the field of biology that also involves the same three countries, namely JPO, USPTO and EPO. The results of the study were published under the title of “Bio Patent’ in 2010 where some of the specific examples from the study were used in Chapter 2 of Examination Handbook JPO. Patents claiming a general plant, animal protection, microorganism protection, and gene-related invention protection are just a few of the

topics covered in the comparative study.

3. Methodology of the study

Figure 8. Flow diagram of the methodology applied for this study.

The approach taken for this study is shown in Figure 8. There are three stages in total, with the first stage focusing on gathering available data on examination procedures for biotechnological inventions. The second stage involves consulting with experts in the field to confirm the understanding gained from the information that has been gathered and the third stage involves analyzing the information gleaned from the two previously mentioned methods. The methods will be explained in greater detail below:

i) Gather information about examination practice in the biotechnological field from existing documents.

The Japanese patent book, Malaysia Patents Act and Regulations, JPO Bio Patent (which contains information related to a comparative study regarding examination practice in the field of biology between JPO, EPO, and USPTO), JPO Examination Guidelines, JPO Examination Handbook, JPO comparative study report, related articles, and court decisions were among the documents used in this study.

ii) An interview based on predetermined inquiries

There were two interview sessions, as previously noted. The first interview session was with Professor Koichi Sumikura from the National Graduate Institute for Policy Studies. His specialty is biotechnology invention-related intellectual property policy. One of the inquiries made to him concerned Japan's stance on the development of human-embryogenic stem cells, which sparked an international debate. He was also asked about the policy for cutting-edge technology, such as gene editing with the CRISPR-Cas9 protein. The second interview was with the Biotechnology Committee of the Japan Patent Attorneys Association (JPAA). The purpose of the second interview session is to obtain confirmation on several issues concerning patent applications for biotechnology inventions. Among the questions presented are those concerning the main issues encountered for patent applications in this field, which sub-fields received the most patent applications in recent years, and the main cause of patent application refusal in the biotechnological field.

The data obtained from the two methods must then be analyzed and discussed in the form of a comparison with current practice in Malaysia. The discussion is limited to biotechnology inventions and focuses on patentability requirements as well as industrial application.

4. Results and Analysis

4.1 Profile of biotechnology inventions in Japan and Malaysia

As previously stated, the 3rd Examination Department in JPO is in charge of examining patent applications in the field of chemistry. There are ten main divisions and a number of sub-divisions under it. The Medical Science Division and the Biotechnology Division are the two main divisions that handle patent applications for biotechnology inventions. The International Patent Classification (IPC) is used to classify each division and subdivision at the JPO. Table 2 shows the relevant IPC for main divisions and sub-divisions for biotechnology inventions.

Table 2. The examining division handling Biotechnology invention in JPO with the corresponding IPC

Examining Division	Main or common IPC handled
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/)*
Biotechnology division	C12N(15/) C40B(10/,40/02,40/06-40/10,50/06)
Cells 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*

Chemical-related inventions in Malaysia are managed by one of the two main divisions which is the Patent Science and Traditional Knowledge Division. This division contains seven units in total, as mentioned in the previous chapter. Only two units, the Biotechnology and Microorganism Unit and the Phytochemistry and Traditional Knowledge Unit, are responsible for conducting examinations for patent applications for biotechnology-related inventions. In MyIPO, a patent application is always referred to as a "file," which is also commonly referred to as a "case" in many other countries, including Japan. Despite the fact that each unit in this division is not split up in accordance with the pertinent IPC, the distribution of files to each unit is still done in accordance with the IPC, in addition to looking at the general information of the innovation for file classification.

4.2 Flow of Substantive Examination

In Japan, the Examination Guideline for Patent and Utility Model is used as a general reference across all technologies. However, specific guidelines exist for fields such as biotechnology and medicine. This specific examination guideline is known as Examination Handbook for Patent and Utility Model that can be find in Annex B of the examination guideline, with Chapter II focusing on patent examination for biological inventions and Chapter III providing a more in-depth look at medicinal inventions. However, it should be noted that for the purpose of this study, Chapter II of the examination handbook will be used as a reference for a comparison with the examination practice that Malaysia has. In the past, the Guidelines for Patent Examination were the only examination guidelines that became a reference for patent examiners in Malaysia. It is a general guideline that can be applied in any fields. However, as stated in the previous chapter, Malaysia is currently working to amend the examination guidelines and establish

new examination guidelines specific to biotechnology, chemistry, pharmaceuticals, and computers.

At JPO, there is a sequence to conduct an examination efficiently, but it is not a requirement to be followed by the examiner. Prior to the assessment of novelty and inventive step, it is customary to do the assessments of patent eligibility, industrial applicability, and clarity. However, it should be emphasized that where there is no distinction between the claimed invention and the prior art, the invention lacks novelty over the prior art. But, if the invention can be distinguished from each other, the invention is considered novel. The examiner only considers on assessing an inventive step when the invention is novel. The approach of assessing the patent eligibility, industrial applicability and clarity is applied mainly because it is the fastest and most logical way to do it as it does not involve prior art searching and substantive examination beforehand. The examiner will therefore be able to assess those requirements right away after looking over the patent application's specification. After examining patent eligibility, industrial applicability and clarity, the next step that follows is prior art searching. Prior art searches at the JPO can be outsourced to registered search organizations or else can be carried out by the patent examiner himself. By outsourcing prior art searches to registered search organizations, the JPO manage to expedite the examination process. In 2021, the number of outsourced searches was approximately 134,000 cases which is almost half of the total applications received that year. Through prior art searching, it is expected to obtain the relevant documents that will then be used for assessing the novelty, inventive step, and in some cases, the unity of invention.

The examination procedure in MyIPO is nearly identical to that of the JPO. Although it is not required to follow any of the suggested sequences in assessing the

patentability requirements of a patent application in general, it is preferable to conduct the assessment of patent eligibility, industrial applicability, and clarity prior to the actual substantive examination. To assess the patent eligibility, a provision of the non-patentable inventions (*Section 13*) should be cross-examined.

With regards to clarity requirement, it is advisable for the examiner to read through the claims first before reading the description. The reason is, our ability to find out any clarity issues is higher because we will not be obscured by the information from the invention too much. However, this is just a tip among examiners and not really a guide for the examiner to asses clarity of the claim and therefore it is not stated anywhere in the examination guidelines. However, these tips will be taught in the course for new patent examiners.

Prior art search in MyIPO is carried out after the patent eligibility, industrial applicability and clarity of the claims have been assessed by the examiner. If the invention is not considered as an invention under non-patentable inventions and it is identified that the invention also is industrially applicable, the prior art search can be started. It should be noted, however, in the case of claims with methods for the treatment of human or animal body by surgery or, and diagnostic methods practised on the human or animal body therapy, the applicant will be advised to amend the claims into Swiss-type format in the first office action together with other substantive and non-substantive (e.g. clarity, unit measurement, etc.) objections. Swiss-type claims are interpreted as defining the manufacture of a medicament, where the medicament is intended for a specified medical treatment. This is different to the method of treatment claims which concern the administration of the medicament for treatment of a disease. The Swiss-type claim format generally is in the form of ‘The use of (substance X) for the manufacture of a medicament

for the therapeutic and/or prophylactic treatment of (medical condition Y)'. For prior art searches in MyIPO, there are several databases generally used by the examiners. Among them are the free available databases such as Espacenet, Google Patents, The Lens, Patentscope and NCBI for nucleotide and amino acid sequence search. MyIPO also subscribed to paid databases such as STN mainly used for sequence searching, IEEE, Epoquenet and ScienceDirect. For inventions related to genetic resources (GR) and associated traditional knowledge (TK), TKDL India and Malaysia Traditional Knowledge Digital Library (MyTKDL) should also be used to search for prior art documents. MyTKDL is a database that MyIPO developed in-house as a defensive protection for TK and GR. From the prior art search, relevant documents might be retrieved and the assessment for the novelty and inventive step will be conducted. The determination for novelty is done by comparing the invention with the relevant prior art and if all the features of the claimed invention are disclosed in the prior art, the invention is considered not novel but if any features from the invention found to be different from that of the prior art, thus the novelty of the invention can be recognized. If the invention is not novel, it is inherently not inventive and therefore no assessment on inventive step is needed. Inventive step evaluation should only be conduct if the claim of the invention is novel.

4.3 Patentable Subject-matter and Industrial Applicability

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

Patentable subject-matter

In general, any invention is patentable as long as it satisfies the patentability

requirements of novelty, inventive step and industrially applicable under sections 14, 15 and 16 respectively. As previously stated, to evaluate the eligibility of the invention, a provision of a non-patentable invention should be examined. The invention that falls under the non-patentable inventions in Malaysia as quoted from Section 13(1) of the Patent Acts and Regulations 1983 are as follows:

(a) discoveries, scientific theories and mathematical methods;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, micro-biological processes and the products of such micro-organism processes;

(c) schemes, rules or methods for doing business, performing purely mental acts or playing games;

(d) methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body: Provided that this paragraph shall not apply to products used in any such methods.

If the invention falls under this provision, the patent application will not be examined further because it is excluded subject matter. However, as stated before, some cases like method for the treatment of the human/animal body still have the chance to proceed with the substantive examination if the claims amended to Swiss-type claim format. For the inventions related to biology, discovery is also another important element to look into because it could be that the application is just a mere discovery of something for instance a microorganism that was found in a specific area. A mere discovery of microorganism is not patentable; however, the situation is different if the microorganism

is isolated from the environment and that the microorganism is identified to be useful in something that was not known before. The isolated microorganism and the use of the microorganism is eligible for patent.

Besides the provision of non-patentable invention, there are also other cases that cannot be patented in Malaysia. For example, the invention that relates to a human embryogenic stem cell which is objected under Section 31(1) as it is considered to be contrary to public order or morality. Other example of biotechnology case that is be objected under Section 31(1) is process of cloning or modifying the germline of human/animal. The break-through technology like gene editing of human or animal genome using CRISPR-Cas9 could be objected under the same provision for the same reason. Plant variety is not patentable in Malaysia, but it can be protected under the Plant Variety Act under the administration of the Ministry of Agriculture.

The JPO on the other hand, determines an invention's patent eligibility by examining whether it is on 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 following are the subjects that do not correspond to statutory "inventions":

(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.

If a claimed invention is found to be on any of the above-mentioned lists, the examiner will object to the patent application because it does not meet the patent eligibility requirement.

Industrial Applicability

In Malaysia, an invention shall be considered industrially applicable if it can be made or used in any kind of industry (Section 16). Usually, biotechnological inventions in Malaysia meet the requirement of industrial applicability. But special attention should be paid to the invention that claiming method for the treatment of human/animal body as this is also considered not industrially applicable. However, the examiner only objected this under non-patentable invention and not industrial applicability (Section 16).

In Japan, the evaluation of whether an invention is industrially applicable or not needs to refer 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.

Table 3 shows the comparison between MyIPO and JPO with regards to the patent eligibility and industrial applicability.

Table 3. Comparison of Basis of Refusal on Patent Eligibility and Industrial Applicability in MyIPO and JPO.

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

4.4 Novelty

In Malaysia, Section 14 defines novelty as "*an invention is new if it is not anticipated by prior art*". In practice, novelty determination can be done by comparing between the claimed invention with the cited prior art and try to establish any differences between them. If there are any differences, the claimed invention is considered novel. But, if all the features of the claimed invention are the same with the cited prior art, thus the claimed invention lacks novelty. The manner on how to assess the novelty of an invention can be found in The Patent Examination Guideline, Chapter IV (Only applicable for applications before the enforcement of Patents (Amendment) Act 2022 and Patents (Amendment) Regulations 2022).

In Japan, an invention is not considered novel according to Section 29(1) of the Japan Patent Act if any of the following occurred before the filing: (i) the invention was publicly known; (ii) the invention was publicly worked; or (iii) the invention was described in a distributed publication or made publicly accessible through an electric telecommunication in Japan or other countries. Part III Chapter 2 Section 1 (Novelty) of the Examination Guidelines for Patent and Utility Model in Japan is used by JPO examiners to determine novelty.

From the comparison, the novelty assessment for both offices is generally the same. However, JPO has examination handbook that detailing out the novelty evaluation for biology invention with very useful examples to guide the JPO examiner. As Malaysia is yet to established our own biotechnology guideline, therefore it is important that this study look into some of the examples presented in the Annex B Chapter 2 of the handbook. In the handbook, novelty topic is elaborated through a specific sequence of the main categories of invention as follows: 1) Inventions related to Nucleic acids and Polypeptides; and 2) Invention relating to Microorganisms, Animals and Plants. For the

first category, it is then further divided into sub-topics of protein and antibodies, while for the latter category is not divided further.

Among notable examples are on the novelty status of an invention claiming a recombinant protein that is specified by a process of production, where it is considered lacks of novelty when the isolated and purified protein is publicly known. However, a recombinant protein that is specified by a process of production is novel if it can be distinguished from the known recombinant protein by having different glycan as a result of obtaining them from different microorganism, plants or animals even though the recombinant protein has the same amino acid sequence as the publicly known protein. With regards to the invention of a differentiated cells, the novelty of the stem cells that was obtained through a differentiation induction cannot be acknowledge if the cells cannot be distinguished from the publicly known differentiated cells as a product (for example, in a case where the obtained cell expresses only a publicly known differentiation marker), even if the stem cells and a process of inducing differentiation are novel.

4.5 Inventive Step

In Malaysia, the determination of inventive step consists of several steps. As previously stated, an invention that is considered to be novel over the prior art will be assessed for their inventiveness but not for the claimed invention that is not novel because it is inherently not inventive. In general, where the claimed invention has novel features over the prior art, the examiner will then compare the differences between both the claimed invention and the prior art and eventually determine whether the novel features of the claim is obvious or not to the person skilled in the art (PSA). There are three (3) elements to consider in order to arrive at the decision on the obviousness of the claimed

invention: 1) Obvious due to common general knowledge (CGK); 2) obvious because it is something already thought by the prior art; and 3) obvious because it can be achieved by routine experimentation. If the difference is obvious to the person skilled in the art, then the invention is considered to lack an inventive step and vice versa if the claimed invention is not obvious. Basically, the steps to determine inventive step are as follows:

(i) Determine the PSA and closest prior art.

(ii) Determine the differences between the claimed invention and the closest prior art.

(iii) Establish the objective technical problem to be solved.

(iv) Determine what would constitute CGK.

(v) Determine if the claimed solution is obvious.

Article 29(2) of Japanese Patent Law 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. In JPO, the determination of inventive step consists of these steps:

(i) Identifying claimed inventions

(ii) Choosing the prior art that is most suitable for the reasoning

(iii) Comparing claimed and cited inventions

(iv) Whether or not a person skilled in the art easily arrives at the claimed invention should be determined by comprehensively assessing various facts in support of the existence or non-existence of an inventive step.

In order to identify if the inventive step exists or not, these factors should be considered:

i) Motivation for applying other prior arts to primary prior art

ii) If it is just a kind of design variation of primary prior art

iii) Or if it is just a mere aggregation of prior arts

If the claimed invention does have one of these factors, it is considered that the claimed invention is not inventive. However, if the invention has advantageous effect over the prior art and common general knowledge at the time of filing, the inventiveness of the claimed invention can be acknowledged. Besides that, obstructive factors also can be used to determine the inventive step of an invention.

The assessment of inventive step for both offices from the comparison above are generally the same. The advantageous effect or sometimes also known as surprising effect or synergistic effect over the prior art is something that the patent examiner always considers when evaluating the inventiveness of the claimed invention. This effect is commonly found in the chemistry and biology invention. To better understand how the determination of an inventive step is done in JPO for the biological invention, it is worth noting some of the examples from Chapter 2 of the examination handbook under the inventive step topic. It should be noted that the example listed below are just a few examples among others that were selected based on the invention commonly received at MyIPO. Complete information on the inventive step assessment should be referred to the Annex B Chapter 2 of the examination handbook.

The flow of the guideline according to the topics on inventive step is basically the same as the previous topic of novelty. However, it is slightly different where the inventions of the first category (invention related to nucleic acid and protein) are divided with the addition of another sub-topic which is “a Nucleic acid such as genes”. The determination of inventive steps according to the examination handbook of a few selected

examples are as follows:

i) Invention relating to Nucleic acids and Polypeptides

Nucleic acid and genes

a) If protein A is novel and inventive, the gene encoding the protein A is also novel and involves inventive step.

b) In a case where protein A is publicly known but the amino acid sequence is not known, the gene encoding protein A is considered to not involves an inventive step because the person skilled in the art will be able to determine the amino acid sequence easily at the time of filing. However, if the gene encoding protein A is specified by a specific nucleotide sequence and has advantageous effect that a person skilled in the art did not expect compared to a known gene having different nucleotide sequence, thus the inventive step of the claimed invention can be acknowledge.

c) If an amino acid of protein A is publicly known, an invention of a gene encoding protein A does not involve an inventive step. However, if an invention of a gene encoding protein A is specified by a specific nucleic acid and has advantageous effect that the person skilled in the art cannot expect in comparison to a gene encoding the same protein A with different nucleotide sequence, the invention of said gene involves an inventive step.

d) If a structural gene is publicly known, an invention of a structural gene which has high sequence identity to the publicly known structural gene and has the same property and function as that of the publicly known structural gene, does not involves inventive step. However, if the claimed structural gene has an advantageous effect that a person skilled in the art cannot expect in comparison to the publicly known structural

gene, the invention of the said structural gene involves an inventive step.

e) If an invention of a gene A does not have novelty or involve an inventive step, an invention of a primer or a probe for detecting gene A does not involve an inventive step. However, if an invention of the primer or probe specified by a nucleotide sequence, and the specified primer or probe has advantageous effects that a person skilled in the art cannot expect, the invention of said primer or probe involves an inventive step.

Proteins

If a protein is publicly known, an invention of a mutant of the protein which has the same property and function as that of the protein, does not involve an inventive step. However, if the claimed mutant protein has advantageous effects that a person skilled in the art cannot expect in comparison with the publicly known protein, the invention of the said mutant of the protein involves an inventive step.

Antibodies

If an antigen A is publicly known and it is evident that the antigen A has immunogenicity (for example, the antigen A is a polypeptide with a large molecular weight), an invention of "an antibody to the antigen A" does not involve an inventive step. However, if the invention is further specified by other characteristics and has advantageous effects that a person skilled in the art cannot expect, the invention of said antibody involves an inventive step.

ii) Invention relating to Microorganisms, Animals and Plants

Fused Cells

If both of parent cells are publicly known, an invention of a fused cell obtained by fusing parent cells using a means which a person skilled in the art commonly uses does

not involve an inventive step. However, if the fused cell obtained by a specific combination of them has advantageous effects that a person skilled in the art cannot expect, the invention of said fused cell involves an inventive step.

Microorganisms (obtained by means other than genetic engineering)

(a) An invention of a microorganism obtained by performing mutating treatment of a publicly known species, which a person skilled in the art commonly uses, does not involve an inventive step. However, if the microorganism has advantageous effects that a person skilled in the art cannot expect, the invention of said microorganism involves an inventive step.

(b) In a case of fungi or bacteria, a person skilled in the art usually and easily ascertains the applicability (for example, material productivity) and effects of publicly known species within classification hierarchy (for example, "genus") for which it is known that they have the same property, by culturing each microorganism. Therefore, an invention relating to the use of a fungus or bacterium does not involve an inventive step in general, if the fungus or bacterium used in the invention is a taxonomically known species and belongs to the same classification hierarchy (for example, "genus") as another fungus or bacterium for which the same mode of use as the invention is known, and it is publicly known that the fungus or bacterium belonging to the same classification hierarchy has the same property. However, the invention relating to the use of the fungus or bacterium has advantageous effects that a person skilled in the art cannot expect, the invention involves an inventive step.

Animals and Plants (obtained by means other than genetic engineering)

An invention of an animal or a plant obtained by using a means which a person skilled in the art commonly uses does not involve an inventive step. However, if the animal or plant has advantageous effects that a person skilled in the art cannot expect, the invention of said animal or plant involves an inventive step.

4.6 Requirement for description

In Malaysia, the statutory basis for the requirement of a description is stated in Regulation 12. Under this regulation, one of the requirements for a description is that a patent application should discloses an invention in a manner sufficiently clear and complete for the invention to be evaluated and to be carried out by a person having ordinary skilled in the art. In applications which either claim microorganisms or use microorganisms to carry out the invention, it is essential that the microorganism is adequately defined if the requirements of sufficiency of the description (Regulation 12(1)(c)) are to be met. However, it is difficult to describe the characteristics of a microorganism in a written description and therefore, there is a need to deposit the microorganism to the recognized depository institute to meet the requirement of clear and complete disclosure under this regulation. Malaysia has just acceded Budapest Treaty and the regulation for it was just enforced earlier this year on 18th March 2022 where any application received after the enforcement of the regulation should follow the rules outlined which is to deposit the microorganism to any one of the recognized International Depository Institution (IDA) under the Budapest Treaty. This single deposit will be recognized by every country that is a member to the treaty. The patent application received before the enforcement of the regulation that relates to a microorganism is actually to be treated the same, however as Malaysia was not a signatory of the Budapest

Treaty before, the deposit made in any depository institution needs to be accompanied by a Statutory Declaration that allows the public to have access to the samples and to be furnished of the samples of the microorganism deposited. In addition to the recognition of the deposit made to IDA under the Budapest Treaty, Malaysia also recognized a deposit made to a National Depository Authority (NDA). This decision was actually made after a demand from the local research institution to gives alternative to the local patent applicant that has limitation to make the deposit to the IDA. The proposal was taken into consideration and eventually a regulation on the NDA was enforced on 30th June 2022. Under the new regulation amendments, there is a regulation that specifies the requirement to be an NDA. However, at the point this report was written, no local culture collection centre had applied to be recognized as the NDA as the regulation was just enforced and no engagement has been made yet with all the potential culture collection centres to explain the new regulation as well as the requirement to become NDA.

As JPO is also a signatory of the Budapest Treaty, the same principle of the deposit of a microorganism also applies here where any applications relating to a microorganism shall be deposited to the IDA or a depositary institution designated by the JPO Commissioner. It is basically the same concept as the NDA in Malaysia and Japan is actually the model country that was the subject of the study by the MyIPO Patent Law Review Committee (PLRC) in implementing the NDA. Apart from the requirement to deposit a microorganism to an IDA or a designated institution for an invention relating to microorganisms, there are exceptions to certain cases listed under the

Microorganisms Excluded from Obligation to be Deposited of the Annex B Chapter 2 as follows:

(a) Microorganisms which cannot be deposited by a depositary institution

designated by the JPO Commissioner for technical reasons or the like. In such a case furnishing of the microorganisms provided in Article 27ter of Regulations under the Patent Act should be guaranteed by the applicant. (Such microorganisms should preferably be deposited with a reliable culture collection.)

(b) Microorganisms easily available for a person skilled in the art stated in "Article 27bis of Regulations under the Patent Act". More specifically, the following microorganisms are included for example:

(i) Commercially available microorganisms, such as baker's yeast, koji (Aspergillus oryzae), Bacillus natto, etc.

(ii) Microorganisms in a case where it has been evident, prior to filing, that the microorganisms have been stored at a reliable culture collection and are freely furnished from a catalog or the like issued by the culture collection. In this case, the storage number of the microorganism should be stated in the originally attached description.

(iii) Microorganisms which can be produced by a person skilled in the art on the basis of the description.

For the purpose of having a better insight in regards to the enablement requirement in the JPO, this report will quote some of the examples stated in the Annex B Chapter 2 of the examination handbook that outline the assessment on the enablement requirement of an invention relating to a biological material. In addition to that, simplified explanation also provided in my own words based on my understanding from the detailed explanation given in the examination handbook, as follows:

Example 1

A polynucleotide selected from the group consisting of:

(i) a polynucleotide whose sequence is represented by ATGTATCGG.....TGCCT

(ii) a polynucleotide whose DNA sequence has more than X% of sequence identity to that of (i) and which encodes the protein having the activity of enzyme B.

(Note) A protein encoded by the polynucleotide of (i) has the activity of enzyme B.

X% represents extremely low identity.

(Explanation)

The description of this example discloses about the polypeptide (i) that encodes the protein having the activity of enzyme B. In a case of polypeptide (ii), it has X% identity to that of (i) and which encodes the protein having the activity of enzyme B and X% is extremely low identity. Even though polynucleotide (ii) is specified by the protein that has the activity of enzyme B, it is construed to include the protein that does not have the activity of enzyme B and therefore trial and errors and a sophisticated experimentation needed that is beyond the extent the person skilled in the art should be reasonably expected. Thus, the description is not clearly and sufficiently discloses the invention to enable the person skilled in the art carry out the invention. However, if the claimed invention is only limited to that of polynucleotide (i), then the description is considered to meet the description requirement. Through this example also, we can see that the enabling requirement also usually related to a claim support requirement where the objection can be raised for both requirements at the same time if the case of this example occur.

Example 2

A polynucleotide selected from the group consisting of:

(i) a polynucleotide whose DNA sequence is represented by ATGTATCGG.....TGCCT

(ii) a polynucleotide whose DNA sequence identity has more than X% of identity to that of (i)

(Note) A protein encoded by the polynucleotide of (i) has the activity of enzyme B.

(Explanation)

As for this example, polynucleotide (ii) is not specified by its function and thus includes a poylnucleotide encodes for a protein that does not have the activity of enzyme B. Referring to page 3 of the Annex B Chapter 2 of the examination handbook, "*In order to show how an invention relating to a gene can be used, it may be described that the gene has a specific function*". If X% identity is a high percent identity such as 90% and above, the person skilled in art would be able to expect that polynucleotide (ii) encodes a protein that has the activity of enzyme B. But if the X% identity is of a low identity, it requires trials and errors and sophisticated experimentation that beyond the extent that the person skilled in the art should be reasonably expected and therefore in this case, the description is not enabling/clearly described as it is not disclosed in a clear and sufficient manner that allows the person skilled in the art to carry out the invention.

4.7 Policies on the patentability of an invention related to human embryonic stem cells

In Malaysia, there is no clear guidelines on how to treat an invention related to human embryonic stem cells. However, in principle, an invention that relates to the use of human or animal body or part of the body are not patentable under the provision of Section 31(1) because it is considered as contrary to public order or morality. This includes the invention on human embryonic stem cells where it is considered morally unacceptable because to obtain the human embryonic stem cell, the destruction of a human embryo usually takes place. In the case that the patent application discloses the

destruction of human embryo in the invention or if it is not explicitly disclosed whether that steps taken, the examining division will object the invention under this provision. Depending on the claims were drafted, if it is claiming a method of treatment or therapy for a disease using the human embryonic stem cell, the examining division will also object the invention under the non-patentable subject matter as stated previously. However, if the applicant proves that the process of obtaining the human embryonic stem cells does not require the destruction of a human embryo, the invention may be patentable provided that other patentability requirements are met.

In Japan, it is clear that the patentability of human embryonic stem cell is not allowed if the invention disclosed the destruction of human embryo in the patent specification. However, there is an exception to the invention of human embryonic stem cells if the embryo is derived from an excess human embryo. Excess embryo is actually an unused embryo obtained from in vitro fertilization treatment with the consent from the donor. In the in vitro fertilization treatment, many embryos produced in vitro and the embryo obtained will then froze for further use. After the donor successfully having a baby or if they did not want to pursue the process, the excess frozen embryo will be discarded if it is not used anymore. That is where the excess embryo is actually coming from. In this case, the human embryonic stem cells derived from excess embryos is patentable. The invention in a higher category of ethical issues treated differently case by case. This is shown in figure 9 as below.

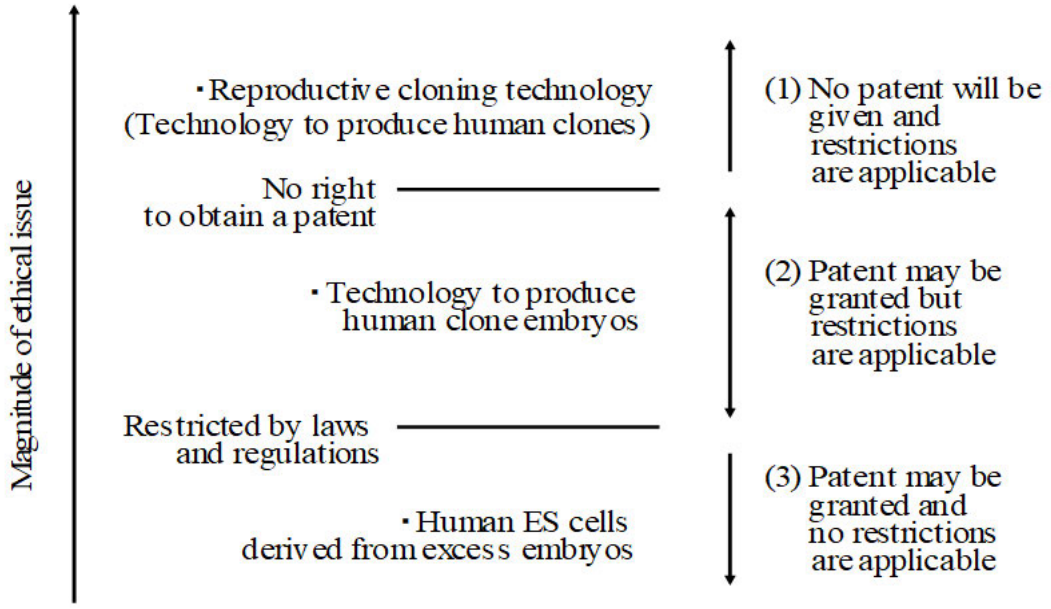

Figure 9. Flow diagram of patentability of an invention having a different degree of ethical issues in Japan (Credit to Prof. Sumikura).

In a case of technology to produce human clone embryos, it is considered to be in the middle of a hierarchy of a magnitude of ethical issue. Invention on human clone embryos only patentable with some restrictions, for examples it is used for a treatment of disease. Human clone embryos actually derived from an egg of a donor which is enucleated and further fused with another nucleus from other cell. This same method is applied to produce “Dolly” sheep but in a case of cloning human or animal it is clearly impossible to be patented as we can see at the top of the hierarchy of Figure 9. But if the same method applies only to produce human embryo stem cell lines for a treatment of a disease, the patentability of that invention is possible but with some restrictions applicable.

4.8 Flow procedure of establishing and reviewing examination guidelines.

As previously mentioned, currently Malaysia has only one examination guideline called Guidelines for Patent Examination (General Provision). Due to the recent amendment made to the Patent Acts and Regulations, the revision of the guideline needs to be done and several specific technology examination guidelines are going to be established. In order to facilitate the process of the revision and the establishment of the new guidelines, several committees were formed according to the specified guideline consisting of the General Provision Committee, Pharmaceutical Examination Guideline Committee, Biotechnology Examination Guideline Committee, Chemistry Examination Guideline Committee and Computer Examination Guideline Committee. Also, as previously stated, the committee member is selected among the patent examiners. Each committee are assigned to do a comparative study on several examination guidelines from well-established patent office's such as JPO, EPO, KIPO and USPTO. The study then becomes a basis for the amendment or an outline for the newly established guideline. After the draft guidelines are completed, the guideline will then be posted on our website to seek for public consultation for a few weeks. This is quite different from the public consultation for patent law review where we usually explain the proposed amendments and have a discussion on the subject matter with the patent attorney association, universities, research institutes and other stakeholders on a specific occasion. Besides that, we also encourage public engagement by giving their opinions about the proposed amendments through written feedback for a specific period of time after it is published on our website just like the way we did for public consultation for the proposed guidelines.

In the past, JPO established and revised the examination guidelines in the same way as what MyIPO is actually doing now where it is work done by a dedicated patent

examiner. However, currently, a special council consisting of an expert on patent laws and specific technology fields in Japan for example a representative from the Japan Patent Attorney Association (JPAA), professors, etc. being appointed by the JPO for reviewing the existing guidelines. This council will meet several times when JPO finds it necessary to review the guidelines and the minutes of the meeting will be published on the JPO website for public reference. The appointment of the member of the council will be able to ensure that the examination guideline in JPO takes into account the opinion of the experts outside from the organization and thus will be able to make it a comprehensive guideline.

According to the JPAA Bio Life Science Committee Member, the demand for a revision of a patent examination guideline is not coming from stakeholders but rather an initiative by the JPO itself when certain issues arise. The patent examiner is considered as a front liner of an invention in the country and therefore they usually be the first to notice or realize the needs to revised a guideline to react to those issues. In Japan, the examination guideline is not only important for patent examiners but it is also intended to educate the applicant and inventor on how to come out with a clear and complete specification as required by the law.

The comparison above shows that the JPO is moving towards better engagement with stakeholders and experts outside of the JPO by bringing them on board to improve the examination guidelines. MyIPO, on the other hand, encourages stakeholders to participate in improving the examination guidelines through public consultation, but the effort could be strengthened in some way to ensure that any public concerns are heard.

5. Conclusion and the recommendations to MyIPO

Malaysia always tries to put intellectual property (IP) as an important agenda for the nation. Many national and international programs that relate to innovation and IP were made in order to cultivate an innovation culture in the country to move forward from a user country to an innovator country. To achieve this, Malaysia needs to learn from developed countries such as Japan in various aspects of IP starting from the organizational structure, manpower, academic qualifications, laws and many more. The recent amendments made to the Malaysian Patent Law are actually to be in line with the international IP practice so that the nation can attract more inventors to protect their inventions in our country as it is much more convenient to them when most of the IP laws are harmonized. As previously stated, among the amendments made are in relation to the biotechnology invention. The requirements to deposit microorganisms and the regulation of the National Depository Authority (NDA) are among the main amendments made to the Malaysian patent law. In accordance with the amendments, the revision of the patent examination guideline as well as the establishment of the examination guidelines in the biotechnology field and other specific technologies should be followed next.

The opportunity to participated in the long-term research in Japan is offered at the right time as Malaysia will be able to study on the Japan examination practice especially with regards to the biotechnology invention. Through this study, it is found that there are similarities and also some differences between the JPO and MyIPO examination practice. The JPO examination guidelines and also examination handbook is really comprehensive and covers all relevant technologies including biotechnology that can be find on Annex B Chapter II of the examination handbook. Various examples were

provided in a greater detail in an easy to understand flow that covers each topics of biotechnology for example nucleotide sequence such as genes, primer and probe, protein and antibody.

It is recommended that MyIPO will be able to adopt the examples provided in the JPO examination handbook into Malaysia's biotechnology examination guideline. In addition to that, MyIPO also needs to consider tailoring some new examples when there is a need, to address a new issue that maybe arise in the biotechnology research in the future. As previously stated, this is something that our guidelines committee has considered as we also have asked for feedback from the JPO on our guideline working draft and in return, we have received very constructive feedback. In fact, the JPO Examination Guidelines on Patent and Utility Model and JPO Examination Handbook on Patent and Utility Model have become the primary source of input in our effort to establish the guideline. In addition to that, it is suggested that we revisit and study the differences discovered in JPO examination practice for further consideration in applying that into our practice if it is well suited and beneficial to MyIPO.

The establishment of our examination guideline for biotechnology invention seems to be in the right direction and it is expected to be ready by 2023. The next challenge to MyIPO after the establishment of the guideline will be to further study the necessity to react to the progressive biotechnology research in the industry as it is expected that more advanced technology will emerge and requires attention, especially in terms of the patentability of the subject as biotechnology involves living organisms and tends to contribute a debate of an issue related to public order or morality.

On top of that, the cooperation between the MyIPO and JPO should continue and strengthen as this will benefit both countries in many ways, especially in promoting

innovation and the protection of IP. Dialogues between the JPO and MyIPO as well as with the Japanese companies in Malaysia could be part of the effort that can be initiated in the near future.

Acknowledgements

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Special thanks to my employer, **Intellectual Property Corporation of Malaysia (MyIPO)** for selecting me to participate in this program. I hope that the study that I have been doing in Japan will be beneficial to my organization.

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Last but not least, my deepest gratitude to my wife, **Maszlin Mohd Yusof** my son **Muhammad Fathurrahman**, **Muhammad Lutfirrahman** and **Muhammad Amar Rahman** for their continued support.

Mohd Sukri bin Mohd Nor

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Appendix A: Minutes of the interview to Prof. Sumikura

Date:

14 December 2022

Time:

3:00 PM to 4:30 PM

Venue:

National Graduate Institute for Policy Studies (GRIPS), Tokyo

Interviewees:

Professor Koichi Sumikura

Professor, Intellectual Property Policy, Science and Technology Policy

QUESTIONS FOR THE INTERVIEW

1.0 What is the policy about an invention that relates to human-embryonic stem cells in Japan?

1.1 Is it morally acceptable and can be patentable in Japan?

1.2 What about an invention in that the inventor claims the stem cells are not directly derived from any treatment to the embryo but are actually from the cell lines?

1.3 What about the statutory basis used by the patent examiner to limit the scope of the claims or to refuse the application based on Japan Patent Law (e.g. Public order/morality provision)?

Answer to questions 1.1 to 1.3

Article 27.2 of the TRIPS Agreement stated that "[M]embers may exclude from patentability inventions, the prevention within their territory of commercial exploitation which is necessary to protect the public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation

is prohibited by their law." In many countries, there is a regulation in research work especially with regards to ethics. On the other hands, patent is different system as patent is protected for a very long time which is 20 years from the filing date, so it is advised not to judge patentability concerning public order or morality by judging the current regulation only as the guidelines or rules on the morality aspects might be changing over time. If we simply object on morality without carefully foresee the benefits to mankind, the applicant might lose many years of protection on their invention. EU directive under article 6 also stated that an invention shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

Wisconsin Alumni Research Foundation (WARF) filing a patent on human embryonic stem cell in 1996 to the EPO but it is partly rejected. The claim of the patent application is about culture of human embryonic stem cell because it using human embryo for commercial purposes so this is against Article 6, 2(c) that states the uses of human embryos for industrial or commercial purposes shall not be patentable. However, WARF argued that their invention does not falls under that provision, as the culture of human embryonic stem cell is not embryo as it is, so it should be allowed to be patented. EPO in their prosecution, viewing that the claim does not mentioned anything about the destruction of human embryo but somehow it is described in the description of the patent application. In conclusion for this case, the EPO decided that any invention which requires the destruction of human embryo corresponding to the technological standard of the application date, is not patentable. But the question is, if the invention does not require destruction of human embryo, is it patentable? But after that, iPS cells was invented by Prof. Yamanaka and his team from Kyoto University whereby the production of the iPS does not require the destruction of human embryo and therefore the invention is patented.

In Japan however, no cases reported on an invention refused in terms of bioethics. Article 32 of Japanese Patent Law is there to prohibit the invention of a very high standard of ethical issue.

Referring to Figure 9, the diagram shows a different kind of invention related to humans and the patentability of the invention according to the magnitude of an ethical issue. Prof Sumikura explains how the excess embryo is actually could be obtained. Usually,

a partner with some difficulties having a baby will try out in vitro fertilization or IVF. For that, a lot of embryos are produced in vitro and once the partner successfully conceived a baby, the remaining frozen embryo will usually be discarded. For the purpose of stem cell research, the excess frozen embryo can be used after getting approval from the donor. So, in the case of an invention that uses the excess embryo from the explanation above, a patent may be granted provided that all other patentability requirements are met. In 2009, there were changes made to the research regulation in Japan and among that production of human clone embryos for regenerative medicine was approved. Before that, patents for that technology may be granted but restrictions were applicable. However, technology to produce human clones other than regenerative medicine research is not patentable because it is morally not acceptable and unethical. If a patent application claiming an invention within the allowable current research guidelines, then the invention will not raise any morality issue.

2.0 What is the policy on transgenic animals in Japan?

2.1 Is it morally acceptable and can be patentable in Japan?

2.2 How Japan views this type of invention, as evidenced by the most well-known case involving a transgenic animal known as "Oncomouse," leads to different perspectives within different jurisdictions?

2.3 Is there a specific court case on transgenic animals that served as the foundation for Japan's policy on the subject?

Answer to questions 2.0 to 2.3

Harvard University produced a genetically modified mouse that was highly susceptible to cancer, by introducing an oncogene that can trigger the growth of tumors. In EPO the patent application on oncomouse was initially rejected because it falls under EPC Article 53 on exceptions to patentability where animal varieties are not patentable. In 1991, the Examining Divison granted a patent by judging the transgenic non-human mammalian animal written in the claim is patentable because it is a higher concept than animal variety. Since then, many religious and environmental groups have filed objections to the granting of patents on genetically engineered plants and animals. One of the main contributors to a complexity of the determination of the definition of an animal variety is because in EPC there are three common languages used English, French and Germany. At the time animal variety described, the meaning of animal variety is slightly different according to the language used. In French the definition of

animal variety is a sub-unit of a species. However, mammalian animal is higher concept than animal variety, so rejection on animal variety is not applicable. Eventually, in 2001 it is patented after it is limited to the transgenic rodents containing an additional cancer gene. The decision on this patent is varied country by country. Canada supreme court decision ruled that highly evolved living organism including plant is not regarded an invention (except bacteria). In Japan, transgenic animal is morally acceptable. The debate on morality and bioethics is not common compared to the USA and Europe.

3.0 What is your opinion regarding the invention of gene editing on human using CRISPR-Cas9?

3.1 Do you think that the current IP policy is sufficient to address any cutting-edge technology particularly in biotechnology?

Answer to questions 3.0-3.1

Human genome editing using CRISPR-Cas9. A few years ago, in IP high court there are two cases about patentability of CRISPR-Cas9 applied from the Broad Institute. One patent is denied and another one is granted. For example, designer baby. In future if it is used for healing diseases, for example a new born baby having a disease, genome editing could be very beneficial. But if it is used for human enhancement, it is not good for evolution of human being because the genome is going to change and eventually mankind will be vanished. But there is a very thin line between the treatment of disease and enhancement. If a person whose expression level of human growth hormone is normal but he wants to be treated to be bigger, it is considered as enhancement.

4.0 What is the policy on access to genetic resources and the benefit sharing in Japan?

4.1 Is there any specific regulation in Japan to regulate the access to genetic resources?

4.2 Do Japan's local communities' traditional knowledge have any protections (such as positive or defensive measures)?

Answer to questions 4.0 to 4.2

Policy of the genetic resources and access and benefit sharing. Japan ratified Nagoya Protocol, so Japan just following the Nagoya Protocol. In Japan the debate on CBD is usually from the pharmaceutical company from Japan because they want to have access

to some genetic resources and developed some products and the profit from the commercialization will be able to be given back to the community. But it is most frequently discussed that Japan is only the user of the genetic resources. But in Japan, many traditional Japanese food is usually made from genetic resources such as yeast and certain bacteria. So maybe these are more examples of the genetic resources in Japan. Mainly the Japanese traditional medicine came from China. Japanese beef is very tasty, Matsuzaka beef is very high quality. Several years ago, there is issue where the sperm of Japanese bull is transported to USA and Canada where they have a very large farm. Some of produced beef was exported back to Japan. So, Japan made some regulation on that, where if the cattle is not grown in Japan it is not considered a Japanese beef. Japanese amended and established the rules to protect Japanese beef to be unofficially exported, in order to protect the genetic resource of the country.

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Appendix B: Minutes of the interview to Bio Life Science Committee, Japan Patent Attorneys Association (JPAA)

Date:

16 December 2022

Time:

1:30 PM to 2:30 PM

Venue:

Video conference, Zoom

Interviewees:

1) Mr. Keiji Nakano
Vice President, Japan Patent Attorneys Association

2) Mr. Yosuke Kawasaki
Chairperson, Biotechnology and Life Science Committee,
Japan Patent Attorneys Association

QUESTIONS FOR THE INTERVIEW

1.0 How modern biotechnology gives impact to the existing JPO biology guideline?

1.1 Did the existing guidelines is sufficient to address the new biotechnology applications?

1.2 How usually are the demands for updating the guidelines being made?

1.3 Demand from the public or through the discovery from the patent application filed or any other method?

Answer to questions 1.1 to 1.3
In principle, the JPO examination guideline and the examination handbook is sufficient to cater the newly developed technologies. When it comes to Examination Handbook, it is frequently revised.

The demand for a revision of Examination Guideline and Examination Handbook are not from Bio Life Science Committee, JPAA. The JPO will make the revision when they think it is necessary to amend the particular guidelines or handbook through a council consists of experts in intellectual property and specific technology. In fact, JPAA representative also invited to be in the council. The reports of the council meeting are published in the JPO website for public reference. The examination guidelines or handbook will be revised under this committee which organized by the JPO and the draft guideline will be published to get feedback from the interested parties including JPAA. Three years ago the examination handbook was revised to include the AI technology for the diagnosis of a disease.

2.0 How the discussions were made in the guidelines committee in chronological order to address any new matter in the guidelines?

2.1 Is it usually will be discussed on the enabling requirement first, and then the clarity of the claims and further on the other patentability criteria? Or there is no specific order in the discussion?

2.2 How does the guideline committee keep the content of the guidelines up to date?

2.3 How many times do the committee meets to discuss on certain matters when there is a need to amend the guideline.

Answer to question 2.1

This is not something that the Bio Life Science Committee of JPAA will be able to tell because they are not directly involve in the council formed by the JPO for the examination guideline and handbook revision. But, to answer that in the view of JPAA that has the representative in the council, no specific flow or chronological order in the discussion but rather it depends on the JPO as the organizer.

Answer to question 2.2 and 2.3 unanswered, because the JPO handle the revision of the Examination Guideline and Handbook.

3.0 How can you describe the bonds that exist between the JPO and the industry player?

3.1 Did the good relationship between the JPO with the industry player help in many ways especially in improving the practices that JPO has?

3.2 Did the industry player usually being the demander for the change of policy or

practices in the JPO office?

3.3 How does the JPO office try to initiate the strong bonding with the industry player and how do they keep the bonds strong?

Answer to questions 3.1 to 3.3

It really helps because the JPO will be able to know from the side of the industry player and therefore try their best to serve them better, and it is also good to the industry player as they will be able to share their concern on certain matters, suggestions and etc. to the JPO for consideration. The JPO usually conduct a meeting once a year to meet the industry player including the JPAA and this is how the good relationship between the JPO and the industry player is done. In addition to that, JPO also invite public to give their feedback anytime (information from the JPO's website).

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