JPO LONG-TERM STUDY CUM RESEARCH FELLOWSHIP PROGRAM

IMPACTS OF NATIONAL PATENT STRATEGIES AND POLICES TOWARD CORPORATE ATTITUDE AND INVESTMENT IN PATENT ACTIVITES OF PHARMACEUTICAL INDUSTRY – EXPERIENCE FROM JAPAN

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The views and findings in this report are those of the author and do not necessarily reflect the views and policy of the organization or sponsor of this study.

Abstract

The objective of the study is “to understand the significant strategy and policies of Japan in promoting R&D and patent activities and the implementation practices by relevant Japan authorities, organization, institutions and business operators and the implication on the overall development of pharmaceutical industry then putting forward suggestions for Vietnam.

The study focuses mainly on the importance of patent in pharmaceutical industry and the national intellectual property strategies and policies of Japan with specific connection to IP-related policies that support and promote innovation and patent activities of pharmaceutical companies in Japan.

For the time being, desktop study by accessing into various previous studies and in-depth interviews to specific interviewers who are knowledgeable and experienced in policy making and practice on the innovation and patent in pharmaceutical industry in Japan.

The outcome of the study is “grasping the comprehensive intellectual property strategy, patent policy and IP-related policies of Japan that support and promote innovation & patent activities of pharmaceutical companies” and “recommendations for IP strategy in general and the policies for encouraging innovation and patent activities of Vietnam pharmaceutical companies”.

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CHAPTER 1- OVERVIEW

Vietnam has transformed itself to the group of a lower middle-income country and is now one of the most dynamic emerging countries in East Asia region. The country was ranked 45th in 2018 Global Innovation Index (GII) Rankings and top up to 42th in 2019. The GII 2019 looks at the medical innovation landscape, exploring the role and dynamics of medical innovation as it shapes the future of healthcare, and analyzing the potential influence this may have on economic growth.

In the healthcare sector, pharmaceutical industry plays a critical role that exert critical impact to the economy and life of people in the country of nearly 100 million population. Vietnam pharmaceutical market has been increasing significantly recently with market size of U$4.6 billion in 2017, US$5.2 billion in 2018 and is projected to reach $6.6 billion by 2020 [Angelino et al., 2017].

However, in reviewing the patent data in pharmaceutical industry, it is worth noting that 90% of pharmaceutical patents being filed and granted by the Intellectual Property Office of Vietnam so far are of foreign applicants and just about 10% are of Vietnamese applicants [IP VIETNAM, 2019]. Domestic pharmaceutical factories are now capable of producing almost all types of formulations but most of them are are generics and not the first or high-value drugs. It is due to the very low investment in R&D activities, especially in patent activities. It is also the fact that Vietnam pharmaceutical companies seem not to be interested much and confident enough in R&D, the corporate IP management, and especially in investment into patents.

Japan is always in the top three largest pharmaceutical industries in the world. According to the CPhIPharma Insights report 2018, Japan has been enjoying its longest sustained period of growth over decade as a bastion of patented drug consumption. It is also noted that 14.4% of the new drugs (New Chemical and Biological Entities) launched worldwide between 1998 and 2012 were developed by Japanese companies as announced by the European Federation of Pharmaceutical Industries and Associations [EFPIA, 2013]. National intellectual property strategy and

policy is one of the important factors resulting to such achievement in pharmaceutical industry.

With this approach, the research theme “Impact of national patent strategy and policy toward corporate attitude and investment in patent of pharmaceutical industry – experience from Japan” is picked up with an expectation of attaining informative, knowledgeable and useful experience from Japan.

CHAPTER 2- BASIC INFORMATION AND PREVIOUS STUDIES

2-1. The Vietnam Status Quo

2.1.1. Legislation and Polices

In January 1981, 06 year after the reunification of the country, Vietnam Government promulgated Decree No. 31-CP on innovation to effect technical improvement and rationalization in production and inventions setting up the basic ground for promotion and protection of innovation and invention. Under this Decree, innovation is a technical solution, or solution in relation to the organization of the production, which is new, applicable and practically useful to the collective organization, unit establishment, while invention is defined as technical solution which might be *device, a process, a substance or the use of known device, process substance for performing a new function*. To be eligible to protection, invention must present a technical solution which, in comparison with the available world technology, is new, involves an inventive step and is applicable to economic-social fields.

Since then, the development of the legislation and policies of Vietnam Government on promotion of innovation and protection of intellectual property rights, particularly patent rights, can be divided into three (03) important periods from 1981 to 1989, from 1989 to 2005 and from 2005 to present.

Period 1981 - 1989: this period marked a turning point in Vietnam's intellectual property legal system, that the very first above-mentioned legal document i.e. Decree 31-CP on industrial property in general and on patent protection in particular had been issued. Accordingly, all efforts to create techniques, to rationalize production and to bring practical benefits to the State, society and agencies are rewarded spiritually and materially. Yet, at this point of time, under this legal document, patent protection is established in the form of an *inventor certificate*, whereby the inventor has only the moral rights of the invention, and the patent belongs to the State.

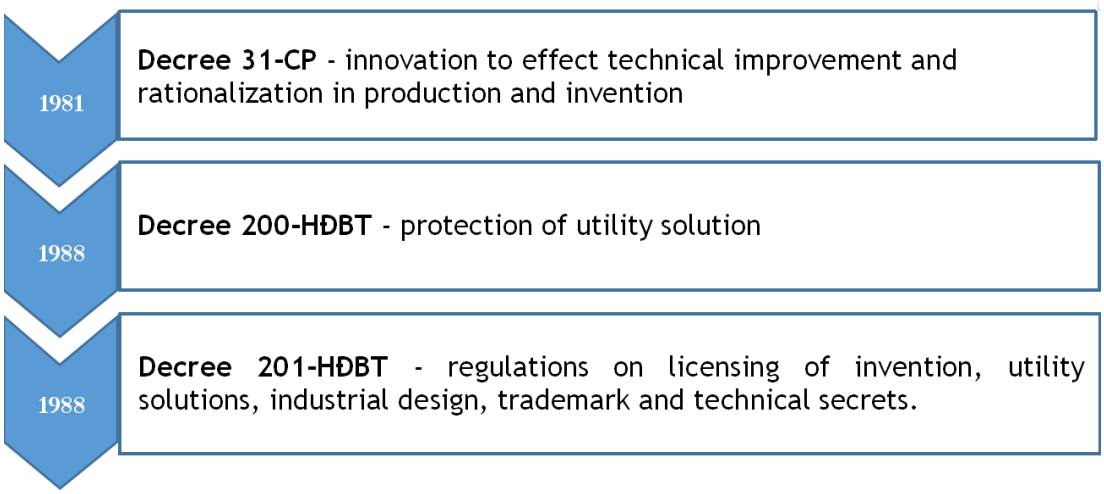

Figure 1. History of Vietnamese legislation on intellectual property from 1981 to 1998

The issuance of Decree 200-HĐBT protecting utility solution is considered as further effort of Vietnam Government to encourage innovation taking into account the protection conditions are novelty and practically applicable. In addition, Decree 201-HĐBT was also good approach of the country's polices to commercialize the results of research and innovation.

In consideration of the economic situation of the country at the period, it could be seen that from the early of 80s, Vietnam Government already recognized the importance of innovation, research and development with protection of industrial property rights, especially invention and utility solution.

Period of 1989 - 2005: this period triggered important historical landmarks in 1989, 1995, 2000 in legislation systems of Vietnam with regard to innovation, science & technology, intellectual property rights and pharmaceutical industry.

Firstly, the Ordinance 13-LCT/HDNN8 re-affirmed that State recognizes and protects industrial property rights of organizations and individuals in connection with invention, utility solution, industrial design, trademark and appellation of origin. State also realizes the importance and encourages efforts in creation of invention, utility solution, industrial design.

Secondly, under the Civil Code 1995, industrial property right is recognized for the first time as a civil right, followed by Governmental decrees and circulars providing detailed guidelines for implementation of the law.

Then, in 2000, Vietnam determined that science and technology constitute a top national policy, play the key role in the cause of national construction and defense and serve as foundation and driving forces for industrialization, modernization, fast and sustainable development of the country. Accordingly, law on science and technology was enacted for realization of the said approach.

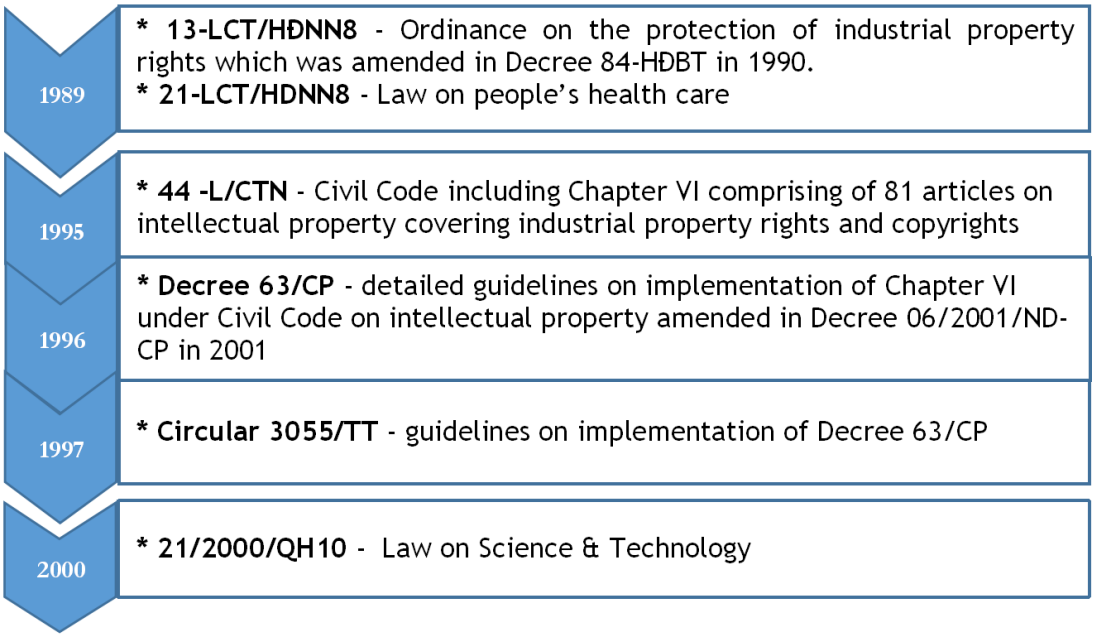

Figure 2. History of Vietnamese legislation on intellectual property from 1989 to 2000

Also in this period, especially after the embargo was lifted and relationship between Vietnam and the U.S was normalized, Vietnam actively negotiated and signed bilateral agreement with Switzerland (1999), and particularly the bilateral trademark agreement with the U.S in which intellectual property is one of the most important parts.

From 2005 to present, the legislation systems and policies of Vietnam on science and technology, intellectual property and pharmaceutical have been transformed and developed rapidly to cope up with the growth and integration of the country into the world.

By the time Vietnam applied for accession to the World Trade Organization (WTO), to meet the requirements of "adequacy" and "effectiveness" of TRIPS Agreement and other bilateral and multilateral international treaties on intellectual property, in 2005 Vietnam promulgated the Intellectual Property Law, changing the entire structure of the intellectual property legislation system, shifting from a system of single legal documents comprising of inconsistent provisions and regulations, into the unified specialized law. Up to date, the intellectual property legislation comprising of intellectual property law 2005 and amended in 2009 and 2019 together with 17 decrees, 19 circulars and joint circulars providing detailed guidelines on implementation of the law, not only meets the standards of international treaties but also getting closer to the intellectual property system of many advanced countries in the world.

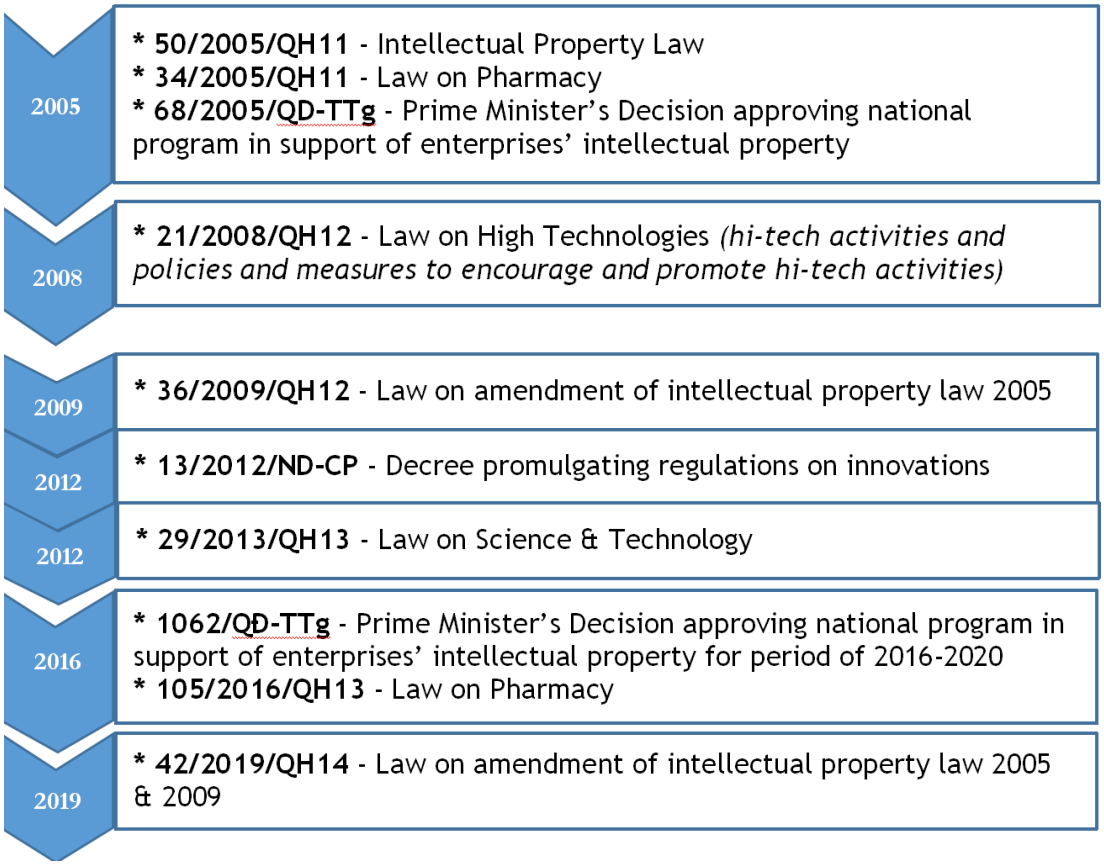

Figure 3. History of Vietnamese legislation and policies on intellectual property from 2005

Following the inaction of law, amended law on intellectual property, law on high technologies, new law on science & technology, and law on pharmacy 2005

and 2016, Vietnam also released a comprehensive range of decrees, circulars, directives and various regulations to provide guidelines for implementation of the laws. It is obvious that Vietnam Government pay more and more attention to innovation, scientific and research activities, and of course better regime for protection of patent and utility solution. Consistently, since 1981, both product patent and process patent are eligible to protection in Vietnam. Yet, up to date, use claim or new use claim is not subject to patent protection in Vietnam.

It is worth noting that Vietnam also has a series of policies to support and promote the creation, transfer and dissemination of intellectual property, many of which are legalized as well as supporting programs have been developed including the policy of empowerment *(giving autonomy to scientific research organizations and science and technology enterprises; empowerment of patent registration, management and patent exploitation to the host organization research projects)*; policies and mechanisms to divide rights and interests in public-private research cooperation; policies to encourage the exploitation of inventions created from the State's funding sources; policies to support intellectual property development at enterprises through the program of supporting intellectual property development, etc. Particularly, Program 68, (Prime Minister's Decision No. 68/2005/QD-TTg) brought opportunities to enterprises to get technical support and financial funding in creation and establishment of intellectual property rights of inventions and utility solution. This program, led and managed by Intellectual Property Office of Vietnam, provided wide range of support and assistance to inventors, creators nationwide. In the period of 2011 - 2015, 213 projects have received technical support and funding from this program. In 2016, Prime Minister approves the 2nd phase of this program with focus on application and commercialization of inventions and utility solutions, from which 23 projects are undergoing up to present.

Currently, Vietnam is a member of almost international treaties of the international intellectual property system, such as the Paris Convention on Industrial Property Protection; The Berne Convention on the Protection of Literary and Artistic Works; Rome (Rome) Convention on Protection of Performers, Producers of Phonograms and Broadcasting Organizations; International Convention for the Protection of New Plant Varieties (UPOV Convention); The Stockholm Convention

(Stockholm) on the Establishment of the World Intellectual Property Organization (WIPO) ...; international treaties on facilitating international registration of intellectual property rights, such as the Patent Cooperation Treaty (PCT Treaty); The Madrid Agreement and Protocol (Madrid System) on the International Registration of Marks. On 30 September 2019, Vietnam submitted the ratification for joining the Hague System for international registration of industrial designs, which will come into effect in 03 months.

The transformation and improvement of intellectual property legislation of Vietnam should take into account the international commitments of the country under bilateral and multilateral free trade agreement. Up to present, Vietnam has concluded FTAs with Japan, South Korea, Eurasian Economic Union, Chile, and recently the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) and Europe - Vietnam Free Trade Agreement (EVFTA), apart from the FTA under the frame work of ASEAN. Commitments to intellectual property and pharmaceutical sectors are always the most important parts of the FTAs followed by the new law on pharmacy in 2016 with new regulations on pharmaceutical business being issued in 2019 and the approval of the amended intellectual property law in June 2019.

In pharmaceutical field, Circular 22/2009/TT-BYT in 2009 provides that organization and individual are responsible for intellectual property rights and in the event the approved drug, medicine is concluded by competent authorities as infringement of intellectual property, Drug Administration of Vietnam might revoke the corresponding marketing authorization. It is also specified that within 02 years prior to the expiry of patent protection term, application for registration of generic product can be submitted for evaluation provided that sufficient patent documents proving the expiration of the concerned patent should be attached.

In 2012 and 2013, Vietnam issued the regulations on the requirement for a drug, medicine to be listed as original proprietary medicines that apart from other technical documents, the corresponding patent as granted by any of 16 patent offices (Austria, Australia, Brazil, Canada, EU, Spain, Finland, Israel, Japan, Korea, Russia, Sweden, US, Germany and United Kingdom) must be submitted. Drug, medicine once listed as original proprietary medicine will enjoy priority to be

classified in a separate group when participating into tender for supply of drugs, medicines under insurance coverage.

In summary, Vietnam Government recognizes the important role of science and technology covering innovation and intellectual property that it constitutes the top national policies, plays the role in the cause of national construction and defense and serve as foundation and driving forces for industrialization, modernization, fast and sustainable development of the country.

Besides the positive development, it cannot be denied the existence of many restriction in the intellectual property system of Vietnam. Firstly, the management structure is not centralized, discrete non-systematic resulting to ineffective coordination mechanism. Though having a lot of improvements and transformation, the legislative system is still quite cumbersome and complicated comprising of multi-level and inconsistent provisions, rules and regulations that allows different interpretation in practice.

Secondly, the process of examination and granting protection at various offices is not really transparent, making it difficult for applicants and the public to access to necessary information. While the number of applications for plant varieties and copyrights protections is limited, the volume that of industrial property increases sharply from year to year resulting to the serious backlog at IPVN. Accordingly, time line for getting a patent protection in Vietnam has been prolonged that negatively deter the applicants.

Thirdly, the enforcement of intellectual property rights is practically complicated with many administrative agencies and each of them is in charge of a specialized or a scope of competence leading to the overlapping of authorities and responsibilities and less coordination. Data system is not updated and linked causing much difficulties to holders of intellectual property rights as well as enforcement actions. Meanwhile, the court system does not have enough trained and experienced personnel to quickly and effectively resolve complicated intellectual property cases. The mechanism to resolve disputes through mediation and arbitration has not been promoted.

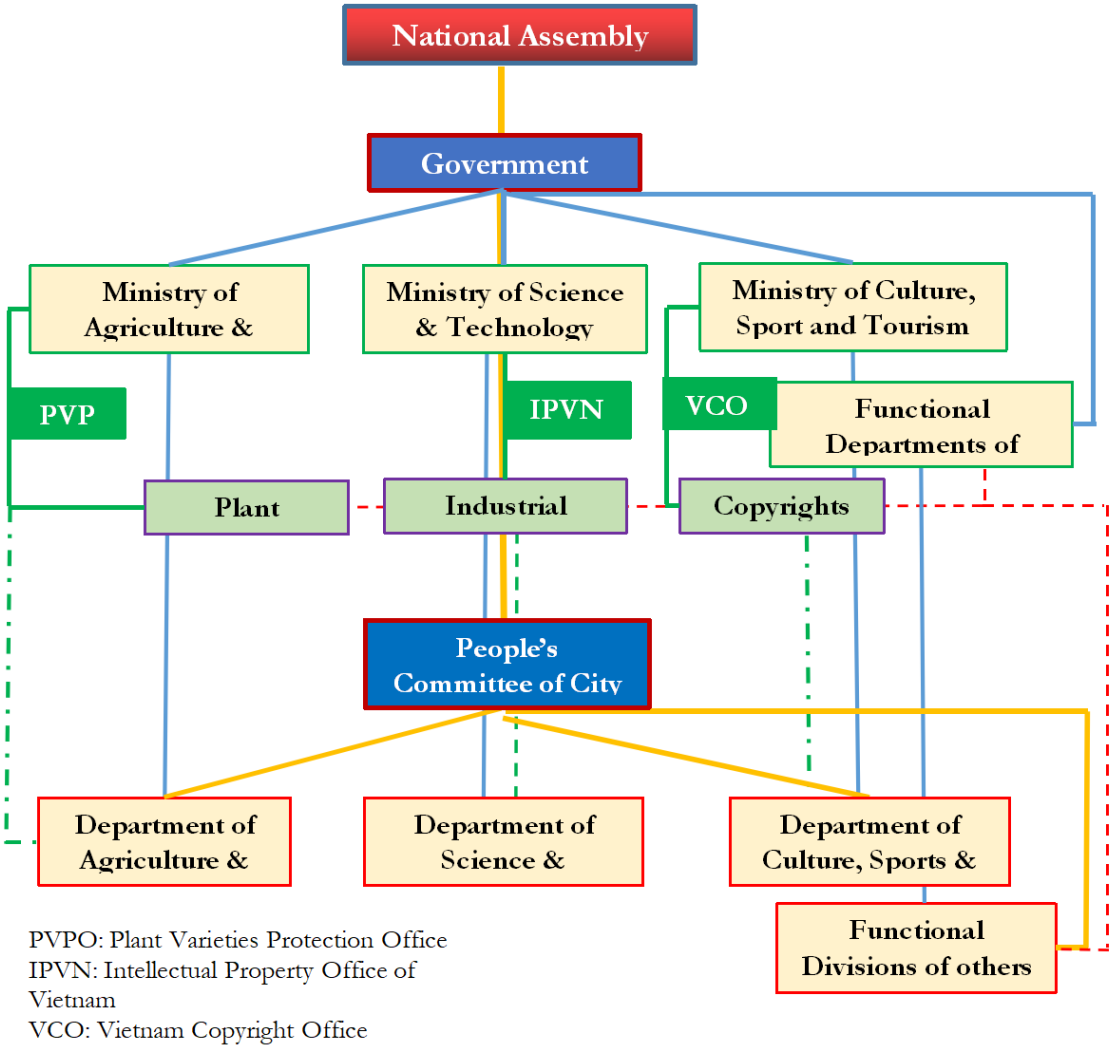

Figure 4. Legislative system of IP policy and management in Vietnam (IP VIETNAM, 2019)

Lastly and the most important factor is the awareness of people, organizations and corporate entrepreneurs on protection of intellectual property rights is not high. There is low level of initiative to protect their own intellectual property rights as well as respect the rights of others. Additionally, rights holders seems to have not yet passed the psychology of fear of touching the court case and still prefer to choose administrative measures for settlement of the disputes.

2.1.2. Research & development and patent activities of Vietnam companies

2-1-2-1. Country overview

Research and development (R&D) activities increasingly play an important role for businesses, can create breakthroughs in production, creating new products and new technologies to meet market demand. However, at present, Vietnamese enterprises have not paid much attention to R&D activities, making it difficult for them to take the initiative in the competition of foreign enterprises.

Refusing to spend money on research and development (R&D), the production capacity to create new products of Vietnamese enterprises is now even lower than enterprises from neighboring Cambodia. It is reported that the level of payment for R&D activities of Vietnamese enterprises is inferior to that of Cambodia and in the bottom of the Southeast Asian countries. Vietnamese enterprises only spend about 1.6% of annual revenue for R&D, while this rate in Malaysia is 2.6% and Laos is 14.5%.

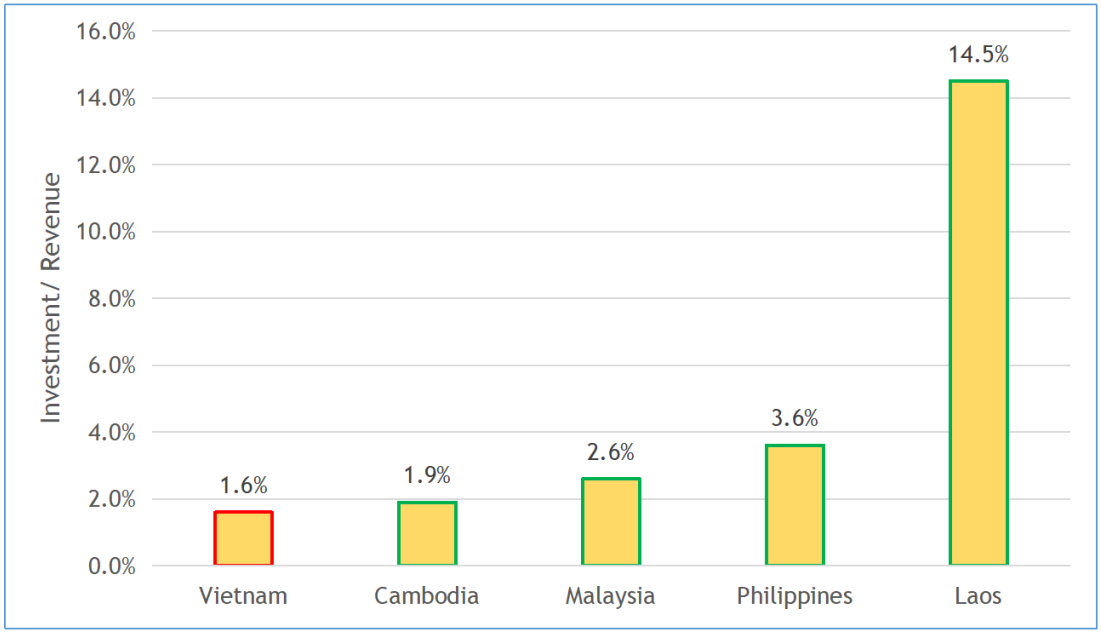

Figure 5. R&D investment per revenue from 2014-2017 (The World Bank Group, 2017)

Vietnamese enterprises possess knowledge, expertise and invention but rarely apply new research into the operation process leading to no innovation [NISTPASS, 2014]. Yet, for those enterprises who are paying attention and investment to R&D, the characteristics of R&D activities are as follows:

a. Research and improvement of existing production processes

The improvement of production processes includes technological improvements, machine improvements, production methods, replacement of materials, etc. that occupies highest percentage of research activities. This can be explained by the fact that investment in production process improvement research is less expensive than new investment in machinery and technology while being active in improving product quality, improving productivity, producing innovative products or new products.

b. Research on product improvement and design for new products

The type of activity with high rate of enterprises followed by product improvement research and new product design. The regular implementation of product improvement and new product offering is an objective requirement for businesses, especially those producing consumer goods such as garments, cosmetics, paints, footwear, etc., to diversify products, to meet the needs of customers according to the changes of external factors such as weather, environment, fashion, tastes.

c. Research on the application of new production processes

For some businesses, research on the application of new production processes is often done with the nature of expanding production and business rather than technological innovation. This means that the new investment of technological lines in the enterprise or to increase the output of existing products, or the development of new products that can be of the same type as the current products and may also be a completely different item. There is less application of new production processes in the way of completely replacing the existing equipment, machinery, and technology lines as this requires the enterprise to have a huge investment.

d. Research and development

Research and development are the few activities that most enterprises in Vietnam have done to innovate production technology. This reflects the limited research and development capacity of enterprises. In theory, research and development activities are carried out by enterprises including research to innovate products or production processes; or research to create technology to produce products or upgrade technology and imported production processes to suit specific conditions. However, in practice today, businesses conduct research and deployment for the majority of technology application and operation purposes rather than technological innovation.

A survey under Vietnam Science and Technology Potential Assessment Project in 2014 unveiled the similar models that investment into research & development (new products, new technologies, new production processes) accounts for smallest portion.

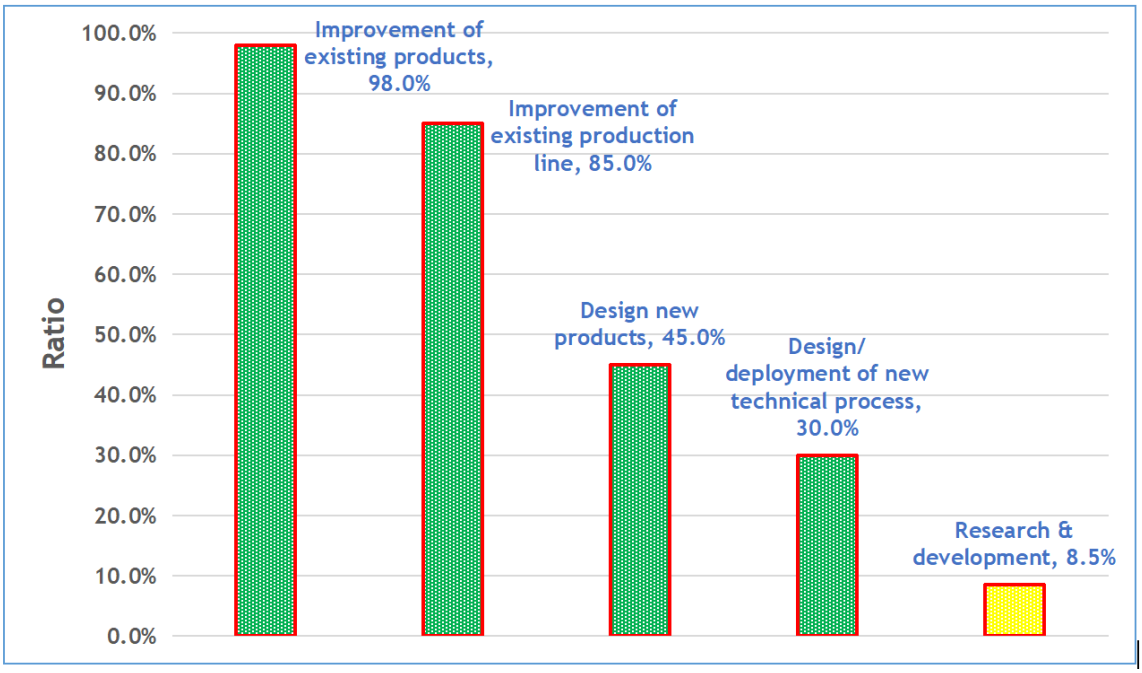

Figure 6. Content of research activities of Vietnam enterprises from 2004-2014 (NISTPASS, 2014)

This could be an answer for the question of small number of patent application for invention and utility solution of Vietnamese applicants so far.

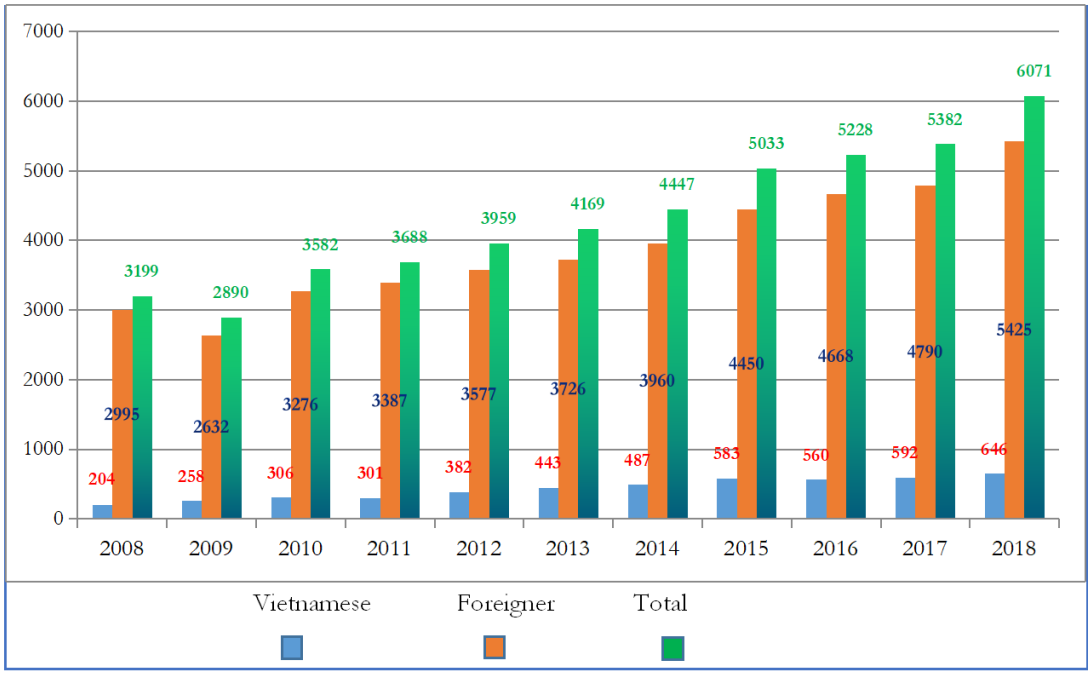

Figure 7. Filed patent applications in Vietnam from 2008 to 2018 (IP VIETNAM, 2019)

Vietnam patent applications account for only about 10-15% of total filed patent applications into the country and this rate is even much lower for granted patents at ~ 5%. This rate increases to 10% for the last 02 years.

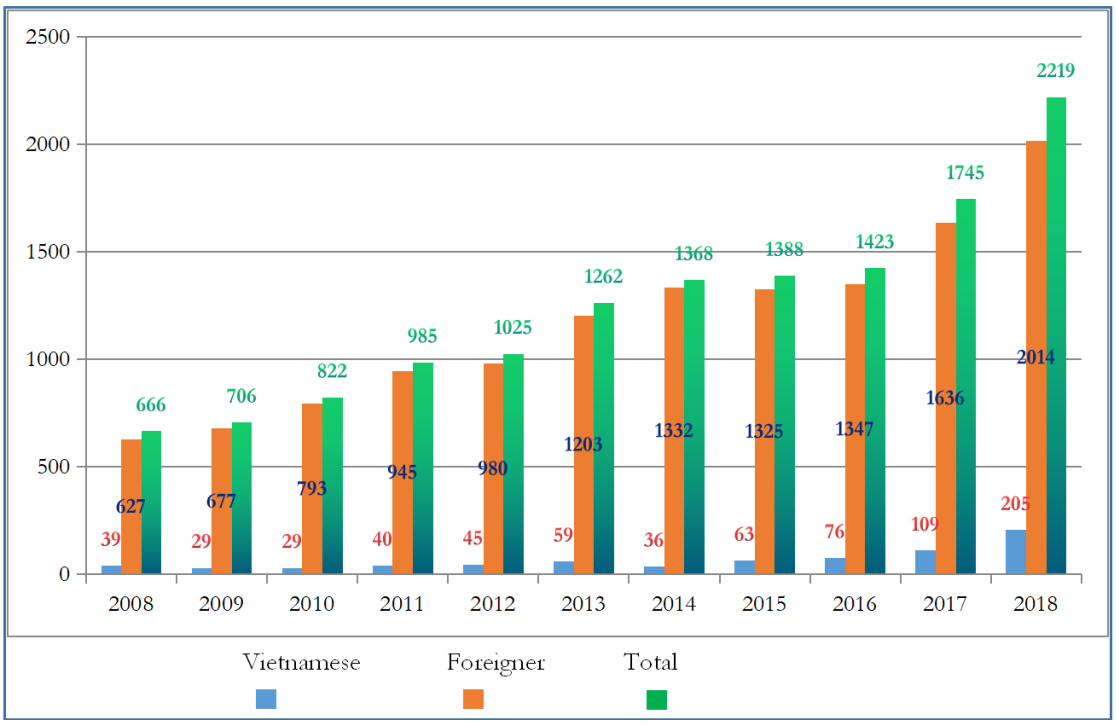

Figure 8. Granted patents in Vietnam from 2008 to 2018 (IP VIETNAM, 2019)

Inventors as well as enterprises, even universities and research institutes in Vietnam, are still weak in patent creation skills. In developed countries, inventions are formulated professionally, with a clear strategy, orientation, and roadmap. Before embarking on the creation of inventions, people always learn the technical situation, conduct the research on prior art and perform various analysis on previous studies to be able to avoid infringement inadvertently due to lack of understanding or in necessary cases, may require the transfer of prior patent rights to support the creation.

Technically, Vietnamese inventors generally lack of skills, especially in search and creation skills. Thus, the scope of protection of Vietnamese inventions is often narrow. The narrow scope of protection will make it difficult for owners to enforce a patent, and competitors can base on published patent information to create inventions of similar nature, even better.

Production technology is largely backward. Currently, most of Vietnam enterprises are using outdated technologies which are behind the world from 2 to 3 generations. Machinery and equipment being used in Vietnamese enterprises are only 10% modern, 38% average, 52% obsolete and very backward. The rate of high-tech use is only 2% meanwhile this rate in Thailand is 31%, Malaysia is 51% and Singapore is 73% [NISTPASS, 2014].

2-1-2-2. Vietnam pharmaceutical industry

Currently, Vietnam has about 180 pharmaceutical manufacturing enterprises both inland and FDI having approximately 200 manufacturing plant. This data does not include traditional medicine workshops and clinics which is presumably very large.

Local pharmaceutical enterprises mainly produce the simple preparation forms, generic drugs (patent expired drugs) of which most are common drugs having simple formulation. The manufacture business includes domestic market production and contract manufacturing (outsourcing) for foreign pharmaceutical MNCs. Capacity of producing new and advanced product is very limited. Investment in research & development of new drug is very low at less than 5% of revenue while this rate is 15% for foreign firms [Chi L.T.K., 2018].

According to some reports, the pharmaceutical industry in Vietnam has reached an intermediate level of international integration resulting in the development of a domestic pharmaceutical industry that is specialized in manufacturing generics and exporting non sophisticated pharmaceutical products to other countries. However, it should be noted that so far the domestic industry mainly produces drugs out of imported raw materials while the value-added of exports is very small in comparison to the inputs imported for production.

Product registration is under the responsibility of the Drug Administration of Vietnam and requires long local trials as it is conducted case by case, with the regulator retaining considerable discretion. Under these conditions, genuinely private and foreign firms are disadvantaged in market access, enabling small producers of generic drugs to survive in what on the surface looks like a highly competitive market.

Newly developed drugs may take around 5 years to be approved for circulation Vietnam. In principle, existing drug registration takes maximum 6 months, and is valid for 3–5 years. In practice, it can be anything between 18 and 30 months.

With the Pharmacy Law passed in 2005, the Government set out a master plan for the long-term development of the pharmaceutical industry. The ultimate goal was to transform the pharmaceutical industry into a "spearhead techno-economic branch", by building a network of circulation, distribution and supply of pharmaceutical products, thus "ensuring sufficient pharmaceutical products to meet the people's demands".

In this context, Vietnam Government encourages organizations and individuals to "conduct scientific research into preparation technologies and bio-technologies for manufacturing new pharmaceutical products; to invest in production of pharmaceutical products". The government also commits to "protect lawful rights and interests of organizations and individuals in pharmacy research, trading and use of pharmaceutical products in Vietnam".

The government aimed to reach 60% of pharmaceutical needs met by local manufacturers by 2015. However, by 2015, the target was not achieved due to lack of capacity of the local industry in supplying key raw materials and lack of adequate

human resources while the investment in R&D of private sector is very low [Angelino et al., 2017].

In June 2016, the National Assembly promulgated the new Law on Pharmacy, which came into force since 1 January 2017, replacing the old version passed in 2005. This reform is combined to the promotion of a "Masterplan of Medicinal Ingredient Development to 2020" and the "National Strategy for Development of the Vietnamese Pharmaceutical Industry to 2020". These policies are likely to mark a consistent shift in the government industrial policy approach towards the pharmaceutical sector which appears to have been targeted as a strategic sector, given its potential in terms of market expansion and knowledge spillovers.

The new Law introduces new supports to the investments in drug production, drug materials, essential drugs, social diseases drugs, and vaccines. The Government provides new incentives to R&D in production technology and biotechnology to manufacture new drugs. In detail, the Law establishes the prioritized fields of development in the pharmaceutical industry, including:

(1) Research and production of drug materials from medicinal material sources available in Vietnam to serve the preparation and production of medicinal material drugs and traditional drugs;

(2) Manufacturing of drugs upon the expiration of patents and relevant protection titles, and of vaccines, biological products, medicinal materials, drugs from medicinal materials, traditional drugs and rare drugs; and

(3) Development of medicinal material sources and medicinal material culture and cultivation zones; conservation of gene sources and development of precious, rare and endemic medicinal material species and varieties.

With a series of policies to support R&D in pharmaceutical industry, the research and development of new drug, new technology are growing followed by the increase in patent invention. However, it practically seems to be not yet as expected.

Pharmaceutical is one of the industries that has largest number of patent applications filed in Vietnam. From 2006 to 2017, average number of pharmaceutical

patent application being filed in Vietnam is about 700 applications and Vietnamese applications only occupies for approximately 2.3% which is extremely low.

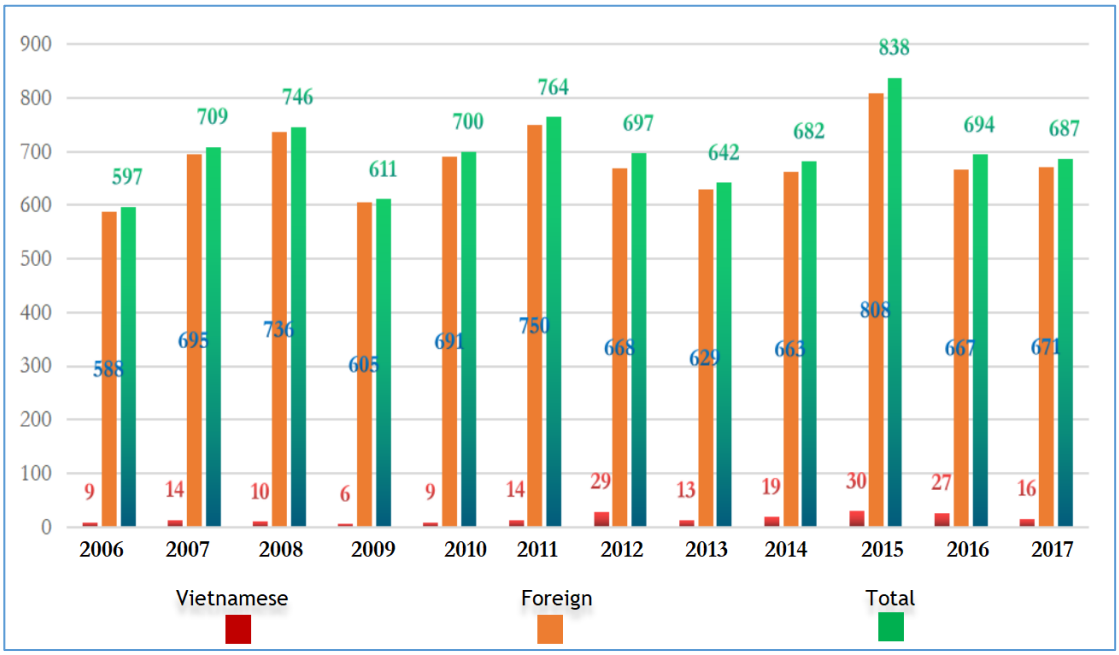

Figure 9. Pharmaceutical patent applications in Vietnam from 2006-2017 (IP VIETNAM, 2019)

The granting rate for foreign pharmaceutical patent is about 28.3% in compared with 14.3% for domestic pharmaceutical patent. Yet, there are only 28 domestic granted patents for the period of 2006-2017 in pharmaceutical industry.

On December 26, 2018, Vietnam Report in collaboration with Vietnamnet Newspaper, announced the Top 10 prestigious pharmaceutical companies in 2018. Top 10 prestigious pharmaceutical companies are built based on scientific and objective principles. Companies are assessed and ranked based on three main criteria:

(1) Financial capacity shown in the latest financial statements: total assets, total revenue, profits, capital use efficiency;

(2) Media reputation is assessed by Media Coding - coding articles about the company on influential media channels; and

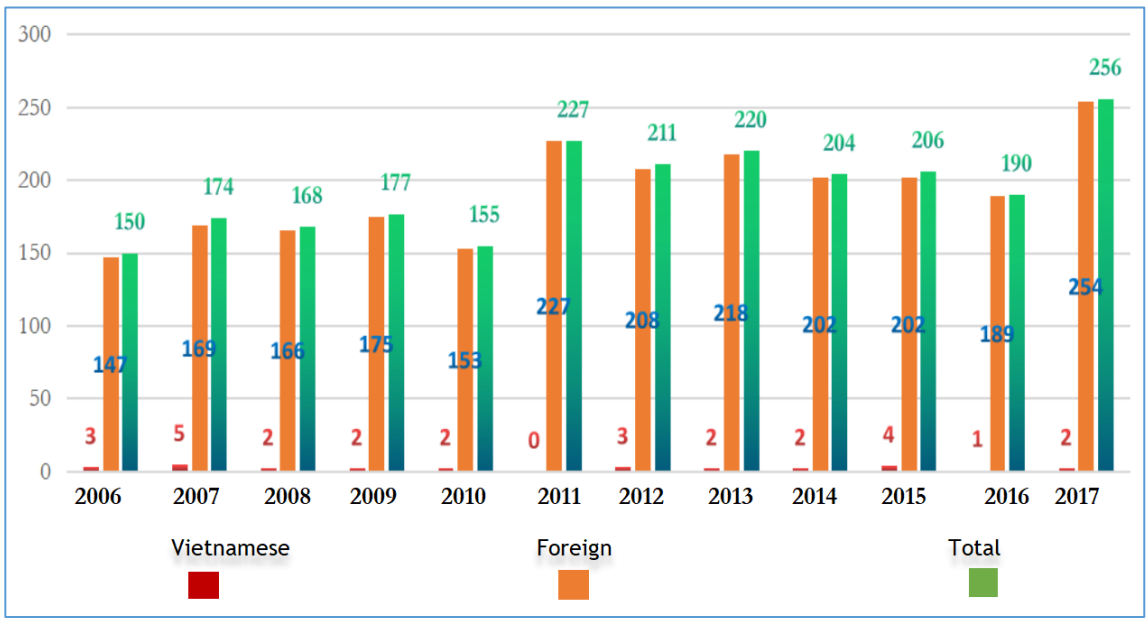

Figure 10. Pharmaceutical granted patents in Vietnam from 2006-2017 (IP VIETNAM, 2019)

(3) Direct survey of pharmacists working in pharmacies, industry experts and Enterprise Survey conducted in December 2018 on capital size, market, labor, revenue growth rate, profit, operation plan in 2019.

It is worth noting that the 1st company amongst top 10 prestigious pharmaceutical manufacturing company of the year 2018, DHG PHARMA with total asset value of ~ USD 190 million and net sale revenue of 2018 is ~ USD 175 million, has no record of patent in the industry.

Together with announcement of Top 10 pharmaceutical manufacturing companies of Vietnam in 2018, Vietnam Report also disclosed the survey on 06 emerging concerns of Vietnamese pharmaceutical companies including:

(1) Dependence on the imported materials, mostly from China & India;

(2) Complicated tender (supply bidding) procedures;

(3) Very limited investment in research & development;

(4) Lack of qualified personnel & hi-tech facilities/equipment;

(5) Quality of local products is lower than imported products; and

(6) Problem of patent and intellectual property protection.

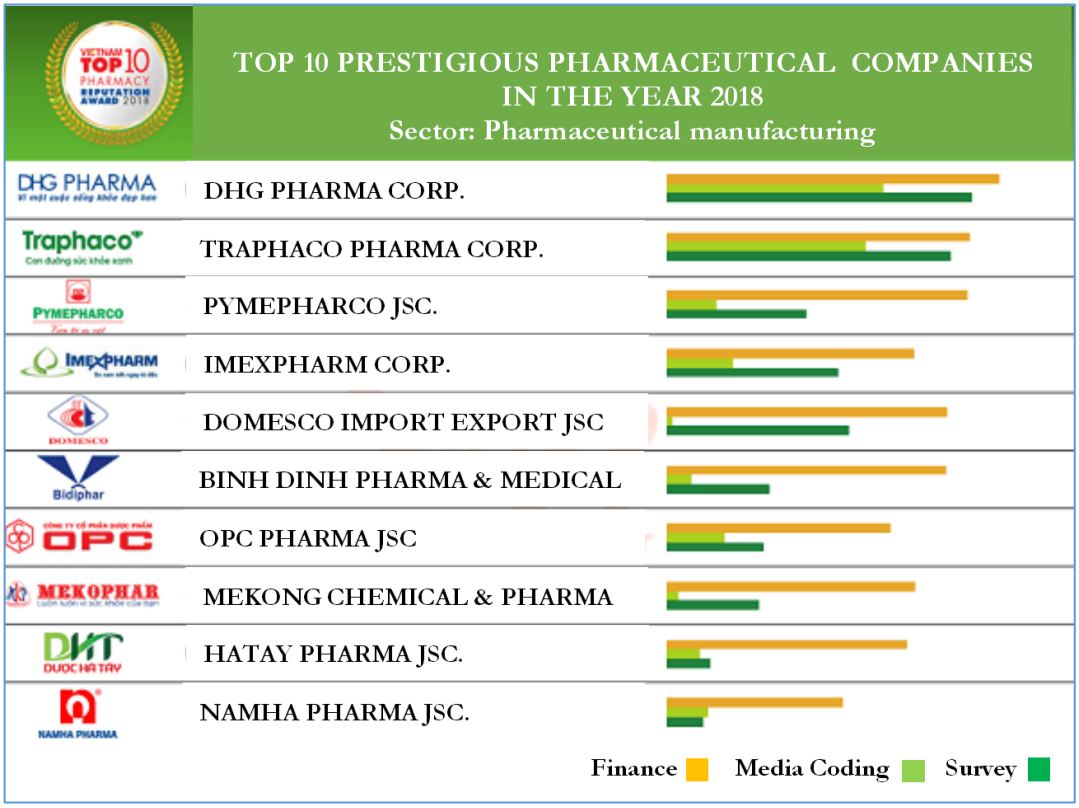

Figure 11. Top 10 pharmaceutical companies in Vietnam in 2018 (VietnamReport, 2018)

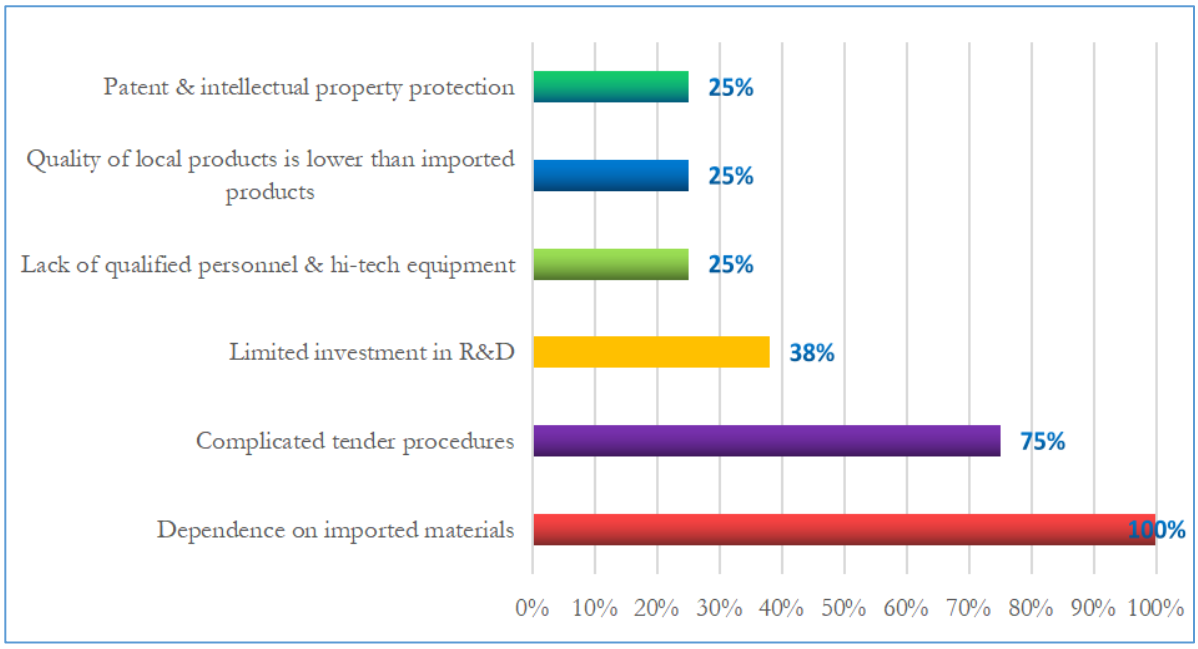

Figure 12. Top concerns of Vietnam pharmaceutical companies (VietnamReport, 2018)

From the above information and analysis, it is obvious that national patent strategies and policies has significant impact on the development of pharmaceutical industry. A proper strategies and supportive patent policies, on the one hand, will be one of sufficient tools for the Government to promote patent activities in the industry, and on the other hand, the motivation for pharmaceutical companies to pay attention and due investment into innovation and patent activities.

2-2. The importance of patent in pharmaceutical industry

2-2-1. Patent and Pharmaceutical Patent

A patent is a property right granted by a sovereign state to the inventor of a novel, inventive (non-obvious) and industrially-applicable (useful) invention. Patent rights are territorial in nature and exist only in the national jurisdictions in which the patentee has applied for and received recognition of his intellectual property rights. The benefit of granting an inventor the exclusive intellectual property right of a patent for the limited period of 20 years is to give a powerful incentive to create. The inventor is assured that investors will be given the incentive to commit the financial resources necessary to support the inventor's research and to develop it to the point where it can be manufactured and made available to the market [Lehman, 2003].

Patents in the pharmaceutical industry are somewhat different and possibly more important than in other industries because of the laboratory research and clinical trials that must be done beforehand. This research costs the pharmaceutical company and is usually accomplished through capital investment on the basis that the result will lead to profit for the company [Lehman, 2003].

In an ideal world, medicine would be accessible to all. However, to continually create new and better medications, somebody has to invest in research for them, and unfortunately, the amount of financial capital required is no small figure. The process for researching and developing new medicines is growing in difficulty and length. On average, it takes at least ten years for a new medicine to complete the journey from initial discovery to the marketplace, with clinical trials alone taking six to seven years on average. In a release by Tufts Center for the Study of Drug Development (CSDD) briefing on "cost for developing a new drug", in 2014,

the average cost to research and develop each successful drug is estimated to be $2.6 billion [Tufts, 2014]. This number incorporates the cost of failures – of the thousands and sometimes millions of compounds that may be screened and assessed early in the R&D process, only a few of which will ultimately receive approval. The overall probability of clinical success (the likelihood that a drug entering clinical testing will eventually be approved) is estimated to be less than 12% [PhRMA, 2015].

Practically, most pharmaceutical patents are filed in phases from “early discovery” patent that includes screening, identification of a target, and data involved, to “lead development” patent that covers chemical synthesis activity against targets and compound development leading to clinical trials, then patents for finished products [Bodem, 2008].

The patent system allows drug companies to profit from patents by prohibiting any other company from marketing and selling an identical prescription drug. This system seems to be the best way to provide drug companies with the reward of potential profit for the research and development spending that in necessary to develop new and innovative prescription drugs. This means that pharmaceutical companies must be concerned with the protection of their works at several stages of the development process and illustrates how important patents are to ensuring pharmaceutical companies will have profit potential [Kumazawa, 2017].

2-2-2. Pharmaceutical patent & right balancing issue

Pharmaceutical patent is a way to prevent market failure and allow for greater investment in research. However, patent-protected drugs face no price caps nor competitors for about twenty years, giving patent holders market exclusivity.

Markets are morally neutral. They operate on the principal of scarcity. Scarce products cost more than widely available products. The market exclusivity and higher prices made possible by the patent rights function as a reward for the risk undertaken by those who financed the research and development leading to the new drugs and technologies to save lives. Corporations wouldn’t want to invest their time and money in something they wouldn’t be able to profit from due to competition. Thus, the amount of pharmaceutical innovations in society would be less than the socially optimal quantity. Similarly, corporations wouldn’t want to

invest in research for drugs that treat only a small group of people such as people with “orphan diseases”. Patents provide motivation for such investment into research and development [Bodem, 2008].

In general, businesses will try to maximize their profits, and these attempts typically result in an overall benefit to society in terms of cheaper prices and greater innovations. In the case of pharmaceutical companies with unregulated market exclusivity, however, these attempts to profit can end up hurting society, as unreasonable prices can restrict access to health care [Mahdavi, 2017].

2-2-3. Patent and R&D in pharmaceutical industry of the developing countries.

In the developing countries, economies are based on agricultural commodities, extraction of minerals or low-tech, low wage manufacturing and the scientists and engineers most likely to invent are employed in the public sector, either in state-owned laboratories or universities [Lehman, 2003].

Developing countries lack the institutions and policies that encourage and make possible the patenting and commercialization of inventions of public sector employees. The patent incentive neither not available nor not practically effective because of weak patent protection for health-related technologies. Further, the national patent offices of many developing countries are under-funded and under-staffed, making it difficult for them to provide services to local inventors.

The problem of weak patent protection for pharmaceutical products in many developing countries also is a product of import substitution policies leading the national pharmaceutical markets being dominated entirely by local companies producing the copied drugs and therefore precluding the development of a local research-based commercial pharmaceutical industry. Most of the research and development in developing countries is financed by the public sector rather than private pharmaceutical companies, which in these countries overwhelmingly manufacture generic versions of drugs developed elsewhere.

It is a fact that the world of the poor live without making use of the vast majority of inventions available in developed countries. While this has significant implications for the economic gap between wealthy and poor countries, in most cases the lack of access to the most innovative technologies is not a necessity. In

health care sector, it is not to dismiss the fact that many patients in the world cannot pay for patented drugs and do not have access to them. Ultimately, this is not the result of the patent system but the lack of a source of funding for the purchase of drugs for those currently too poor to buy them themselves.

Practically, in every countries all over the world, especially in the developing countries, governments normally bear the cost of providing their citizens with patented drugs or purchasing inventions that relate directly to public health care. To such an extent, the market of the inventions and patented drugs is primarily a market of governments, not individuals.

In summary, patents play critical role in pharmaceutical industry that creates the readiness and consideration to make huge investment investment in research and development of new drugs. Proper approaches by the Government for issuance of good strategies and proper policies in patent, I.e pro-patent policies, would navigate and stipulate the development of the pharmaceutical industry. In parallel, the necessary intervention of should be made by the Government to regulate the exclusivity enabling more access to medicines for a better life.

CHAPTER 3- METHODOLOGY OF THE STUDY

3-1. Desktop Study

Desktop study is performed to gather various types of input relating to the situation of innovation and patent in pharmaceutical industry both in Vietnam and Japan with more focus on Japan's side. Input is collected and compiled from the previous studies, legislative documents, governmental documents, published literature, audiovisual materials, reports, case studies, seminars, and workshop documents.

For Vietnam, reviewing the previous studies is to grasp up the consciousness and problem that the research targets.

Desktop study emphasizes on consolidating the information on the national strategy and policy system that could promote the innovation and patent activities in pharmaceutical industry in Japan. This study helps to understand the history of development, changes, and causes of changes of Japan strategy and policy on patent in general and patent in pharmaceutical industry in particular.

3-2. In-depth interview

This study is mainly dependent on the expert opinion obtained through the in-depth interviews to the representatives from various institutions and organizations and individuals who are in or relating to pharmaceutical industry and involve in making and implementing the national strategy and policy to promote innovation and patent activities in pharmaceutical industry. The interviewees were divided into three categories as below.

3-2-1. The person in charge of the most related organizations

- *Intellectual Property High Court*
  Judge Makiko TAKABE, Chief Judge, IP High Court
  Judge Takafumi KOKUBU, IP High Court
- *Japan Agency for Medical Research and Development (AMED)*
  Ms. Mina ASANO, Director of IP Department, Japan Agency for Medical Research & Development (AMED). Ms. ASANO is the former patent examiner at JPO.

- *Japan Generic Medicine Association*

  Representatives from IP Committee and International Affairs Committee of who are also people in charge of intellectual property or patent or R&D in the pharmaceutical companies.

3-2-2. The experts who have careers for the issues in this study

- *Professor Mr. Takao YAGI*

  Prof. YAGI is from Kyoto Prefectural University of Medicine. He used to work in IP department of Otsuka Pharmaceutical then IP department of Japan Agency for Medical Research & Development (AMED).

- *Ms. Emiko YANO - Patent Attorney*

  Ms. YANO is the partner of Kubota Law Firm. She used to be Executive Director of First Group at IP Department of Astellas Pharma. She is vice chairperson of Tokyo Pharmaceutical Manufacturers' Association.

- *Professor Mayumi SHIKANO*

  Prof. SHIKANO is from Faculty of Pharmaceutical Science at Tokyo University of Science. She is a former senior official at Pharmaceutical & Medical Device Agency (PMDA)

3-2-3. Officials in the International Cooperation Division of JPO

- Mr. Minoru NITTA, Deputy Director
- Mr. Tomohiro HAKAMADA, Deputy Director, Regional Cooperation Office
- Ms. Megumi IZEKI, Assistant Director, Regional Cooperation Office
- Ms. Junko WATANABE, Assistant Director, Developing Country Cooperation Section

Questions for the interviews are designed based on the focuses and objectives with specific target to different expert interviewees. The questions lists for the persons in charge of the most related organizations were attached as Appendix of this report.

3-3. Output and report

The output uses qualitative parameter based on very limited focus for better understanding new things and drawing useful lessons.

Study report is drafted and reviewed, commented and advised by supervisor & advisors before completing the final version.

CHAPTER 4- SUMMARY OF FINDINGS

4-1. History of patent laws in Japan

Late in the 19th century, roughly 100 years after the Industrial Revolution, Japan began its own industrial modernization based on technologies introduced from the United States and European countries, which led to its economic development [JPO, 2005].

The patent system, playing an important role in developing Japanese economy and industry, serves even today as a basis for supporting industrialized society.

Over a period of roughly two centuries from 1603 to 1867, the seclusion policy completely isolated Japan, as well as its economy and technology from the outside world. Japan was left without any gains in technological development via the Industrial Revolution started in the late-18th century in England. Furthermore, the Government had gone so far as to prohibit the manufacture of new products based on new technologies in Japan. As a result, Japan was forced to lag behind the United States and Europe in technical fields over the 17th and 18th centuries.

The political system in Japan had remarkably renovated itself under the Meiji government (1868 to 1912) which well recognized the important role which the patent system could play in achieving industrial development.

In 1871, the “Exclusive Rights Law” based on the examination and first-to-file principles were adopted. However, this rapid attempt at establishing a patent system ended in failure due to the lack of sufficient preparation. It was not possible that the mere adoption of a law could make an entire patent system work in the absence of a basis for its operation. Although the employment of the examination principles and the granting of patent rights were regulated, there was no government office to accept patent applications. Nor were there any officials meant to handle patent applications. The invention-promotion system adopted by the Meiji government was hardly accepted among the Japanese people.

In the absence of a patent system, technology transfers from advanced countries were extremely difficult and so was the development of domestic industry.

Lack of a patent system, a variety of inconveniences lead to situations where inventions were widely imitated and misappropriated without any apparent sense of guilt.

Establishment of the First Patent System in Japan under the Patent Ordinance in 1885. The patent ordinance is regarded as the first Japanese patent law which was revised in 1888 to incorporate the first-to-invent principle.

From 1885 to 1911, the foundation for the Japanese patent system was completed within the framework of Japanese patent law following the start of numerous patent systems overseas. Japan became party to the Paris Convention in 1899 and incorporated a patent law revision allowing the grant of patents to foreigners. Against this, the number of patent applications filed by foreigners increased indicating the reliability of the Japanese patent system served to promote technology transfers from overseas. In this respect, the patent system is one basic national system.

In 1899, the revised Patent Law recognized rights of non-residents, incorporated priority claim provisions and set forth provisions for the protection of inventions exhibited at an international exposition, etc. In addition, the adoption of utility model law applicable to “useful and new devices” was also happened.

Patent law was again revised in 1909 including newly incorporated provisions for an employee inventions, express definitions of public knowledge and public use at home and abroad as criteria for the judgement of novelty and corrected problematic aspects of the first-to-invent principle to grant a patent.

The Patent Law of 1921 adopted the first-to-file principle, incorporated a provision for compulsory licensing, adopted a system for the notification of reasons for refusal, adopted a publication system and an opposition system, and provided various rights to an employee invention.

In 1950, the Ministry of International Trade and Industry installed a “Council for Study of Industrial Property System Revision” (presently, the Industrial Property System Study Council) which studied legal revisions so as to cope with needs arising in light of overseas patent systems.

In 1956, the council adopted a recommended revision which was submitted to the Minister of International Trade and Industry. A bill for revising Patent Law and other industrial property-related laws was worked out and presented to the Diet in session, which passed it into law in 1959.

Under the Patent Law in 1959, a patentable invention was changed from an "industrial invention" to an "industrially-applicable invention, and a provision concerning inventive step was included. It was possible to file a patent application covering more than one single invention. Overseas publications were included in the criteria for the judgement of novelty. A substance manufactured through nuclear transformation was included in non-patentable items. And, publications and disclosures at academic meetings were included in cases where exceptions to the loss of novelty are applicable.

The Patent Law was revised in 1970, incorporating the adoption of the disclosure system for applications, the examination demand system, the pre-trial examination system, limitations on time limits for correction, divided applications and conversion of applications, and reinforcement of rights under provisional protection

A major point in the revised Patent Law 1975 was the adoption of systems for substance patents and multi-claim applications. Accordingly, "an invention relating to foodstuffs or table luxuries," "an invention for manufacturing drugs with the use of a single medicine or a combination of more than one single medicine" and "an invention for manufacturing a substance through chemical processing" were deleted from non-patentable items. Thus, inventions falling into these categories were made patentable. This is significantly important to innovation and patent in pharmaceutical industry [JPO, 2005].

The Patent Cooperation Treaty (PCT) was signed in 1970 in Washington by 20 countries, including Japan, and went into force on January 24, 1978. In order for Japan to join the PCT, it was necessary to introduce a multi-claim patent application system. Therefore, Patent Law was revised, incorporating a multi-claim application system as the first of a number of measures to make various domestic laws and regulations comply with the PCT. In addition, in order to match the Law Concerning

the International Application of the Patent Cooperation Treaty, the 1978 revision of Patent Law incorporated provisions to link international applications to domestic procedures.

The revisions to Patent Law in 1985 introduced an internal priority system for use with patent applications in order to more effectively handle rapidly-progressing technological developments and abolished the system for filing a new application after an amendment is declined and filing an additional patent application.

In specific fields, and the pharmaceutical field in particular, adequate measures were needed to resolve the problem that the long period of time required for experiments and examination to obtain a permission or approval as required by the government, profits ought to be gained during a certain period of time, the very basis for the protection of an invention under Patent Law. The Patent Law was revised in 1987 incorporated improvement of the multi-claim system & the requirements for descriptions in claims, and restoration of patent right not exercised with respect to pharmaceutical products. It was stipulated that patent rights concerning pharmaceutical products subject to approval under Pharmaceutical Law can be restored for a period of two years to five years, depending on the scope and term under which that right may not be exercised due to the provisions of law.

The revision of the Patent Law in 1994 was designed to actively cope with international harmonization of individual industrial property systems varying from one country to another and to improve industrial environments for creative business activities. The term of a patent was revised to be 20 years from the date of an application. An invention for a substance manufactured through a nuclear transformation was deleted from non-patentable items. The phrase “offering for assignment or lease” was added as an act of working a product or process invention as well as for manufacturing a product. It was also stipulated that the owner of a patent right invalidated due to a failure to pay the annual patent fee within the designated time limit for reasons beyond control can demand the restoration of the invalidated patent right by paying the due sum within 14 days (two months in the case of a non-resident) after the expiration of the time limit for the prescribed

delayed payment. The effects of the restored patent right are defined as not being applicable to acts taken before the restoration of the original patent right.

As a re-evaluation of criminal charges and civil relief in regard to patent infringement, Patent Law was revised in 1998 so as to: (i) facilitate verification of lost earnings, (ii) authorize appropriate sums for exploitation fees in consideration of definite circumstances, (iii) make patent infringement a crime no longer requiring the filing of a complaint for prosecution, and (iv) impose greater corporate criminal infringement liability.

At the same time, additional revisions were carried out in regard to: (i) the elimination of the name for a patent from entries in the application form, (ii) the re-evaluation of procedures for determining rejection of an application based on subsequent or prior submissions, (iii) data exchange with other national patent offices regarding priority claims, (iv) a reduction in patent fees and a system allowing for fees and handling costs to be shared by both public and private entities, (v) the acceleration of invalidation trial deliberations (vi) re-stating guidelines to acceptable validation requirements, etc.

In 1999 Japanese Patent Law was revised so as to guarantee prompt accession to patent rights while effecting wide, strong, and fast means to relief along with a more suitable environment for accelerating intellectual creativity. Revisions to the law included (i) curtailment of the period for examination requests, (ii) re-statement of demands for corrections, (iii) establishment of a clerk system for trial deliberations, (iv) expansion of means for relief in the case of patent infringement, (v) facilitation of confirmation of patent infringement (vi) re-statement of extension procedures for the continuation of a patent, (vii) system for early publication of a filed application, (viii) the exchange of information relating to patent infringement cases between courts and the Patent Office, (ix) an expansion of defined causes for the destruction of novelty, (x) expansion of applicable subjects to exceptional conditions to loss of novelty, (xi) simplification of procedures for division or converted applications, and (xii) the reduction of patent fees.

In 2002 Japanese Patent Law was revised so as to build a patent system capable of reflecting a more networked society by establishing codes incorporating the characteristics of cyber space and promoting means to speedier and more precise examination as well as international harmony. Revisions incorporated (i) clarification of what patent exploitation consists of, (ii) expansion of the terms of indirect infringement, (iii) separation of the domains of written description and claims, (iv) an extension of the term applied for domestic application of the Patent Cooperation Treaty, (v) insertion of a system for the disclosure of prior art documentation, and (vi) a recall of the reservations to Patent Cooperation Treaty regulations.

In 2003 Japanese Patent Law was revised so as to account for the growing need to fortify international cooperation by meeting demands for the establishment of speedier and more appropriate protection for patents and other intellectual properties. The revised law included (i) revisions to patent-related charges, (ii) an insertion of a refund system for examination request fees, (iii) re-evaluations of reduced rates and exemptions to shared patent rights, (iv) re-evaluations of related statutes for reduced rates and exemptions to patent fees, (v) integration of the systems for filing an opposition and invalidation through trial, (vi) re-evaluation of requirements for the filing of invalidation trial requests, (vii) exceptional allowances for admitting corrections to invalidation trial requests that change the substance of the original reason, (viii) limitations to the term for requesting a corrections trial while the ruling for an invalidation suit is pending, (ix) insertion of a system for requesting corrections upon/after the reversal of a ruling following an appeals suit, (x) insertion of a system for pursuing and constructing a statement of opinion within an appeal suit against an invalidation ruling, (xi) re-evaluation of provisions determining unity of invention, and (xii) simplification of international application procedures.

In 2004 Japanese Patent Law was revised so as to handle the demand for speedier, more efficient patent protection given the growing need to rise towards fortifying international competitive power in the industrial field. The revised law included (i) re-evaluation of the system for designated evaluation authorities, (ii) insertion of a system for particular terms given for registration examination, (iii) the

distribution of disclosed information through the internet, (iv) reimbursement of patent fees for those using the prepayment system, and (v) the insertion of a patent application system based on utility model registration, as well as a re-evaluation of employee invention provisions.

It is obviously seen that all the change, revision of the patent law in Japan from the beginning is on the recognition of the important of the protection of creativity, innovation then promotion of patent activities, increasing patent applications in all industries including pharmaceutical industry.

4-2. Japan Intellectual Property Basic Act

After the bubble burst in 1980s, Japan fell into an unprecedented, extended economic depression due to a complicated mixture of various factors. The Government of Japan and Japanese companies have switched to the offensive, but changes have occurred in the source of competitiveness from that time up to date [JPO, 2005].

The first change is that technology innovation plays a more important role in promoting global economic growth. As implied in the term “knowledge-based economy,” the value added by knowledge is becoming much more important than ever before in current economic activities. The competition is becoming more dynamic in that companies are being required to provide innovative products and services differentiated from those of their competitors.

The second change is that intellectual property in a broad sense, including not only scientific technology but also contents and brands, makes a country more attractive. Furthermore, the “Japan Brand,” which consists of Japan’s originality and tradition in food, fashion, and local culture, has attracted the attention of the world.

In the age of the knowledge-based economy and competition for attractiveness among countries, in order to utilize innovation, contents, and brands as the driving force of economic growth and emphasize the attractiveness of Japan, it is necessary to stimulate and revitalize intellectual creation as well as properly protect and effectively utilize the results of such creation as intellectual property.

Based on such awareness, Prime Minister Junichiro KOIZUMI, in February 2002, stated that the Government of Japan should promote an intellectual property policy as a national policy. In the same year, the Strategic Council on Intellectual Property established the Intellectual Property Policy Outline, setting the goal of making Japan an **"intellectual property-based nation."**

The basic goal is to encourage Japanese people to fully utilize their capabilities to make inventions and create works. From an economic perspective, in the 21st century, competition will be focused on technical capabilities, so only such countries that have survived technology competition will be able to enjoy economic prosperity. Therefore, the Government aims to develop a Japanese economy and society focusing on intellectual property [JPO, 2005].

Based on the Intellectual Property Policy Outline, the Basic Law on Intellectual Property passed the Diet with approval of all political parties in November 2002, and the Intellectual Property Policy Headquarters was established in the Cabinet Secretariat in March 2003.

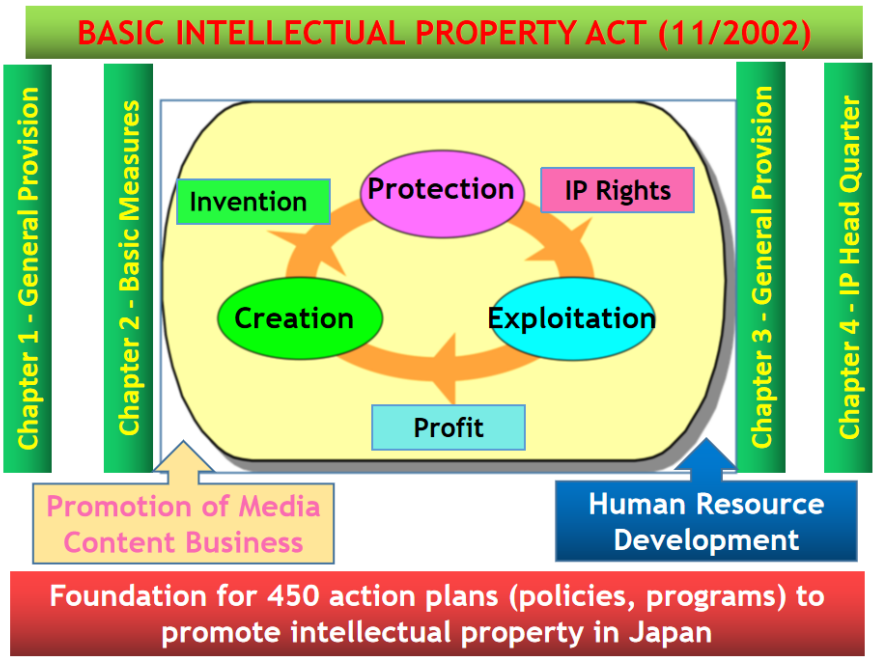

Figure 13. Basic Intellectual Property Act, November 2002 (Arai, 2016)

In order to increase national wealth through the effective use of intellectual property, it is necessary to promote the creation of high-quality intellectual property in the R&D sector and the content businesses, promptly protect such IP legally, and commercialize the results of such creation as economic activities. It is important to establish this flow more firmly, thereby enhancing reproduction of intellectual property and establish a virtuous cycle of creation, protection, and exploitation of intellectual property, an intellectual creation cycle.

To make Japan an intellectual property-based nation in which the international competitiveness of industry is strengthened by focusing on intellectual property, thereby increasing national wealth, the Policy Headquarters, in July 2003, developed the Strategic Program 2003 consisting of about 270 measures. Prior to the development of this program, in June 2003, the Task Force on Intellectual Property Policy in the Council for Science and Technology Policy developed an intellectual property policy focusing on the promotion of intellectual property-related activities at universities and other institutes, which was reflected in the Strategic Program developed by the Policy Headquarters.

While taking into account the progress made for the Strategic Program 2003 and adding necessary measures, in May 2004, the Policy Headquarters developed the Strategic Program 2004 consisting of about 400 measures.

In order to make steady progress every year while quickly responding to the changing circumstances, the Strategic Program has been developed by the rolling plan method that is widely adopted in the private sector.

Three task forces including Task Force on Strengthening of the Foundation for Right Protection, Task Force on Contents, and, especially **Task Force on the Protection of Patents of Medical-Related Acts,** were established to discuss important issues in intellectual property policy, which had been considered to require further study and discussion in order to complete the Strategic Program. These three task forces started their functions in the fall of 2003.

4-3. Important national strategic policies that have impact on patent activities in pharmaceutical industry

Innovation, research and development, and patent activities in pharmaceutical industry enjoyed the benefits from national strategic policies of Japan on intellectual property including creation of intellectual property, protection of Intellectual property, exploitation of intellectual property, and developing human resources and improving public awareness.

4.3.1. Creation of Intellectual Property

The goal of making Japan an “intellectual property-based nation” cannot be achieved without a mechanism for producing creative and innovative R&D assets and for supplying those assets to society. It is therefore necessary to establish a mechanism by which universities and public research institutes create outstanding intellectual property, including inventions, software, and databases and for such property to be utilized to the maximum extent in society. It is also necessary to increase the motivation of remarkably talented researchers to create intellectual property.

Then, It is also necessary to encourage companies to shift the emphasis in their intellectual property strategy from quantity to quality and reinforce the foundation for intellectual creation as well as intensify their efforts for industry-academic-government cooperation.

Under this approach, the policies of the Government of Japan aim at (I) promoting the creation of intellectual property at universities and other Institutes; (ii) promoting industry-academic-government cooperation based on intellectual property; (iii) improving the creation environment for researchers; (v) promoting the creation of high-quality intellectual property at companies; and (vi) promoting the creation of a new Japan Brand [JPO, 2005].

Pharmaceutical industry benefits from this policy because research and development of healthcare product is not any easy task and very costly. Universities and research agencies having a lot of resource on research activity should play an extremely important role in IP creation and should arrange system to ensure the creation, obtainment, management and exploitation of IP.

In 1998, Law on Technology Licensing Organization was enacted. In 1999, Japan introduced Japanese version of Bayh-Dole Act giving the university the right to obtain a patent and making it possible to commercialize it by themselves through licensing activities. In 2000, Industrial Technology Enhancement Act was adopted allowing the faculty members to serve as company officers that facilitate the working conditions as well as creating the motivation to the innovation and patent. Furthermore, in 2004, Law on national university corporation paved broader way for the research and patent activities in general and in pharmaceutical industry particularly through the industry-academia cooperation.

On May 28, 2004, a bill for amendment of Article 35 of the Patent Law was passed which strengthen the employees: influence on deciding the amount of compensation, and, during the course of dispute resolution or litigation, to make courts consider not only the company's related profits but also the inventor's working conditions and the company's efforts in its production and sales, when defining the reasonable pricing of certain invention [Arai, 2005].

One of the benchmark that has impact on the innovation and patent activities in the healthcare sector generally and pharmaceutical industry particularly is the establishment of Japan Agency for Medical Research and Development. In February 2013, the Office of Healthcare Policy was established. In May 2014, Act on Promotion of Healthcare Policy and Act on the Independent Administrative Agency of Japan Agency for Medical Research and Development passed, giving the birth of Japan Agency for Medical Research and Development (AMED) in April 2015 [AMED, 2019].

AMED is the special agency with the consolidated functions, resources, power and authority from The Prime Minister Cabinet, The Ministry of Education, Culture, Sports, Science and Technology, The Ministry of Health, Labour and Welfare and The Ministry of Economy, Trade and Industry. It aims to act as a "control tower" that directs integrated research, from basic research to practical application, to deal with problems of lacking a system that provides the seamless funding, and lacking a system that adequately implement clinical studies / trials, causing discovery of new drugs to take too long.

Accordingly, AMED's functions include (I) Management of medical Research and Development, (ii) Data management in clinical research and trials; (iii) Support for practical applications; (iv) Support for the development of R&D infrastructure; and (v) Promoting international strategies.

AMED has organized and implemented 10 main projects [AMED, 2019] including:

(1) Project for Drug Discovery and Development Promotes *(development of innovative drugs, and strengthens support functions aimed at new drug discovery)*;

(2) Project for Medical Device Development *(Develops medical devices that meet medical needs, and establishes / maintains support system therefore)*;

(3) Project of Translational and Clinical Research Core Centers *(Works to strengthen / enhance centers that can achieve seamless implementation, from basic research to practical application and promotes practical application of innovative medical technology)*;

(4) Japan Regenerative Medicine Project promotes the development of regenerative medicine products;

(5) Japan Genomic Medicine Project Promotes *(aimed at clinical application)*;

(6) Japan Cancer Research Project;

(7) Project for Psychiatric and Neurological Disorders Accelerate;

(8) Emerging / Re-emerging Infectious Disease Project of Japan Provides;

(9) Rare/Intractable Disease Project of Japan; and

(10) R&D projects required to promote the Healthcare Policy *(the elucidation of disease pathologies as well as the development and standardization of new methods for prevention, diagnosis, treatment and health guidance in consideration of medical settings and wide-ranging social needs)*.

AMED formulated the Intellectual Property Policy in the interest of pursuing medical research and development and facilitating efforts to put the

outcomes of research and development to practical use. Under this Intellectual Property Policy, AMED establishes a regime enabling personnel at AMED and research institutions to manage intellectual property in the most suitable manner at every stage from planning to concluding research and development projects, and undertake to promote the practical application of the outcomes.

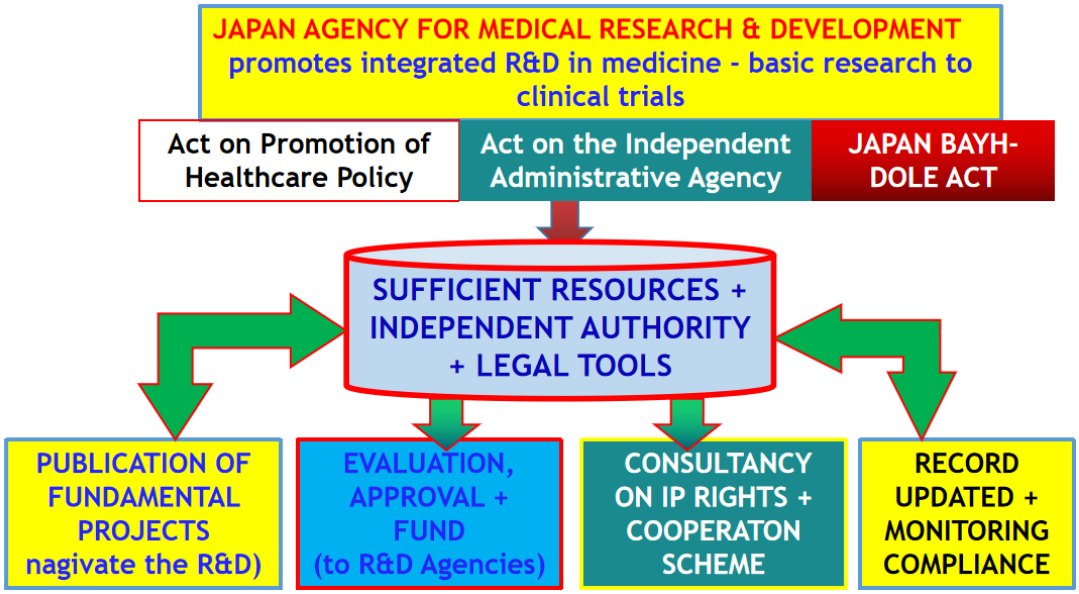

Figure 14. Functions of Japan Agency for Medical Research Development (AMED)

Policy on developing university intellectual property headquarters and TLOs plus the exploitation of Japanese Bayh-Dole Act while amending patent law to improve the researcher working conditions has benefited the pharmaceutical industry in term of promoting innovation, research and patent activities.

The strategic approach and appropriate policy is deployed to feasible and workable measures exerted great positive impact on patenting the outcome of research and development in pharmaceutical industry. It creates the circle collaboration between government, agencies, universities and private companies to organize and perform the research and innovation followed by the increase in patent application, new products and high return.

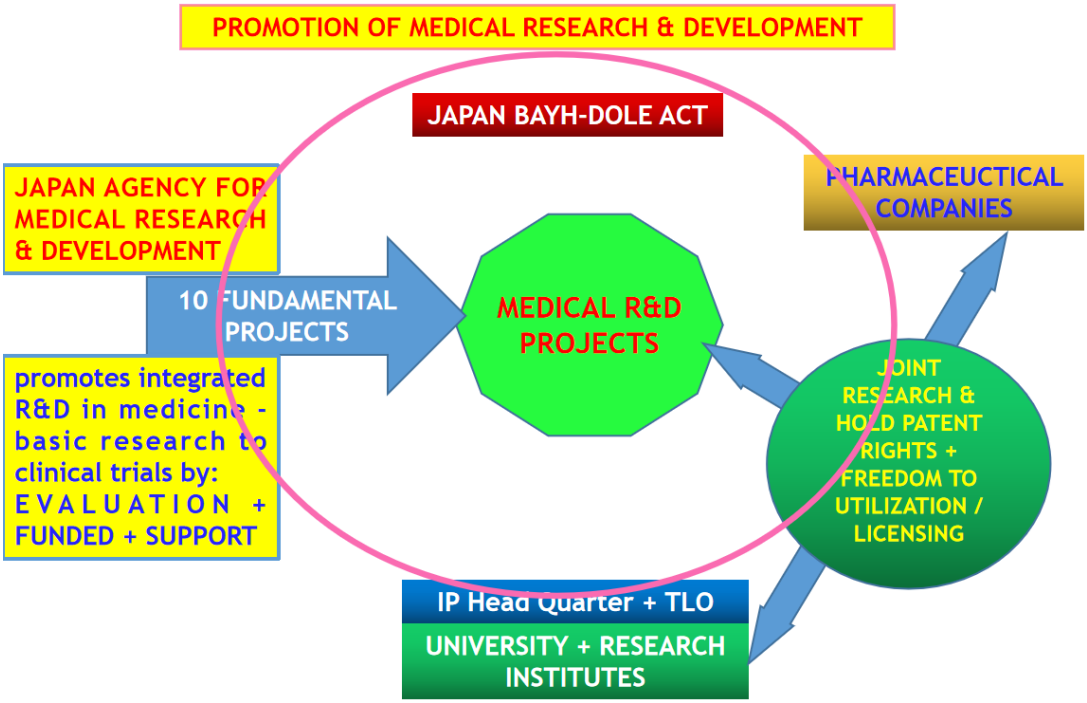

Figure 15. Promotion of Medical Research & Development (created by the author based on the information from the interviews)

4.3.2. Protection of intellectual property

For more incentive to create and effectively utilize intellectual property, Japan Government reinforce the relative system and organizations, i.e. strengthening the intellectual property protection.

Firstly, Japan expedites the patent examination process by revising the Patent Law and related laws to enable the JPO to recruit more fixed-term examiners with ten-year tenures. JPO then step by step clears the backlogs and reduces the waiting time for patent examination followed by shortening the examination process. Significantly, the first action period in a patent examination reduces from about 30 months to less than 12 months [Arai, 2005].

Secondly, Japan upgrades the dispute resolution mechanism. In February 1998, via the ball spline bearing case, the Supreme Court redefined the doctrine of equivalents. Accordingly, even if there exists a portion in the patent claim that is different from the alleged infringing product, an infringement may be found provided *(1) the differing portion is not an essential part of the patented invention;*

(2) the same function and results are still obtained serving the same purpose as that of the patented invention even if that portion is replaced by the corresponding element found in the allegedly infringing product; (3) the above replacement would have been easily conceived by a person skilled in the art with reference to the time of manufacture of the infringing product; (4) the infringing product is not the same as the art publicly known at the time of filing for the disputed patent and it could not have been easily conceived by a person skilled in the art at the time of filing for the patent based on such publicly known art; and (5) no special circumstances exist such as the intentional exclusion of the infringing product from the scope of the patented claim during the prosecution of the patent application for the patented invention.

In January 1998, the new Code of Civil Procedure took effect. This is essentially the first overhaul of the civil procedure in Japan since 1926. The entire code was rewritten to make the civil procedure easier to use and more understandable for the people. IP lawsuits are processed with higher speed and improved efficiency. Furthermore, in June 2004, the bill on the amendment of Law on Court Organization is passed allowing the plaintiff to impose documentary submission obligations to the adverse or third party to verify the infringement or the amount of damage incurred.

In 2003, the revised Code of Civil Procedures gives jurisdiction over the civil lawsuits relating to patents, utility models, IC layout integrated circuit, or computer program copyrights at the first instance to Tokyo and Osaka District Courts. Four (04) special divisions at the Tokyo High Court functioning as patent courts which were deemed to be the most advanced court in the world for intellectual property matters, are integrated resulting to the establishment of Intellectual Property High Court in April 2005 [Okuyama, 2016].

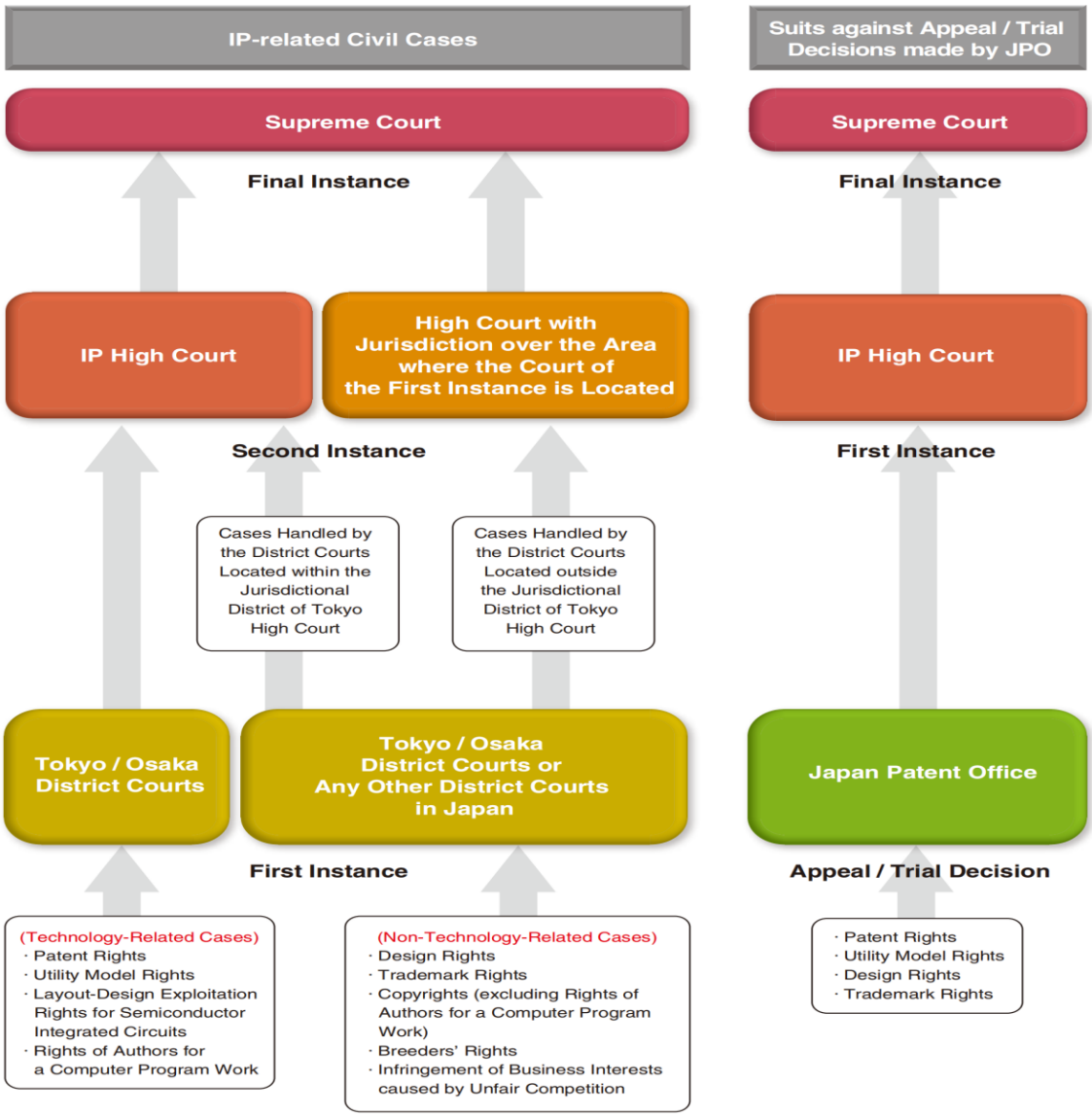

Figure 16. Organization of Intellectual Property Courts (The IP High Court, 2016)

Thirdly, in order to reduce the burden that are endured by patent applicant and the patent office when a patent application is filed in several countries, Japan Government organized examiner exchange programs between Japan (JPO), the United States (USPTO) and Europe Union (EPO) that enables the mutual usage of prior art investigation [Arai, 2005].

Particularly, in pharmaceutical industry, one of the important policy is the protection of the patent right for an original drug of the innovator pharmaceutical companies. In principle, Pharmaceutical and Medical Device Agency

(PMDA) will not approve any generic drugs as long as the patent right that covers the active ingredients of the original drug is valid. This is to avoid a situation where the patent holder of the original drug makes a claim for an injunction against the generic drug manufacturer to cease the sale of the generic drugs, and the stable supply of the generic drugs cannot be maintained due to such dispute. The duration of a patent is 20 years from the filing date of the patent application; however, a patent holder in the field of pharmaceuticals must commonly wait for a considerable period of time to use its patented invention for business purposes, due to the requirement that pharmaceutical products must be approved by the governmental health authority, i.e. the issuance of a Marketing Authorization.

In light of this erosion of the patent term, the Patent Law of Japan has established the patent term extension system to compensate the patent holder, normally the innovator pharmaceutical companies, for the time lost while awaiting an Marketing Authorization. If there is a period during which a patent holder cannot use its patented invention for a drug product because it is waiting for the Marketing Authorization for the drug product, the duration of the patent right can be extended. The extended term is based on the period in which the patent holder was unable to use the patented invention, after the patent was granted, due to obtaining an Marketing Authorization.

In Japan, multiple patent term extensions can be granted under the Patent Law for one patent if two or more Marketing Authorizations have been granted for different indications of the drug covered by the patent. The maximum duration of each extended term is five years. The effect of a patent term extension does not cover all of the patent rights. Only the use of the patented invention for the specific drug product that was the subject of the Marketing Authorization triggering the patent term extension is covered. That is, if the Marketing Authorization covers a specific usage of the drug product the patent term extension is limited to that specific usage. When a patent holder holds a patent right on a new chemical substance, and when a Marketing Authorization has been granted for a new drug that contains that substance as an active ingredient for a specific indication, a patent term extension can be registered for the patent. This extension covers only the use of this substance for this specific indication. Therefore, after the original

expiration date, that is, 20 years after the filing date of the patent application, anyone can use the patented substance except for the use to this specific indication.

If, however, another Marketing Authorization is granted for a second indication, a second patent term extension can also be registered for the patent right for the substance. The duration of the extension is based on the period for obtaining the additional Marketing Authorization. Therefore, the duration of the second extension can be longer than that of the first. For example, if the duration of the first extension is two years and that of the second is four years, between the expiration date of the first (two years after the original expiration date) and the second (four years after the original expiration date), third parties can use the drug in relation to the first indication but not the second indication [Koizumi, et al., 2011].

4.3.3. Exploitation of Intellectual Property

The intellectual creation cycle starts from creating the intellectual property and the go on to registering the rights but will finish with its exploitation, which produces earning that will used for further technology development. For the companies in the selection and concentration stages, especially in pharmaceutical industry, it is vital to strategically exploit their patents and other intellectual properties.

To that end, Japan Government implemented the measures to support the strategic exploitation of intellectual properties. Accordingly, the Trust Business Act was passed to enable trust business to handle intellectual property and to admit the TLOs and other general businesses to enter into trust market. Additionally, for stabilizing and reinforcing the license agreements of intellectual property, the amended Bankruptcy Act was pass in May 2004 allowing more diverse agreements and limit the trustee's rights and give more protection to the licensee. In March 2004, new Japan-US Tax Treaty came into force waiving tax on royalty for intangible assets including intellectual property at a source country [Arai, 2005].

4.3.4. Developing human resources and enhancing the public awareness on intellectual property

It is important to improve the various systems in each field, industry by promoting the creation, protection and exploitation of the intellectual property, but whether or not the system could be used effectively and obtain significant results, eventually depends on human factor. Therefore, Japan Government implemented policies and measures to enhance the quantity and quality of lawyers and patent attorneys who play vital role in matters such as acquisition, utilization and dispute resolutions. In parallel, Government of Japan promoted intellectual property education at law schools, professional schools specialized at intellectual property. And last but not least, raising the public awareness of intellectual property is essential to make the people understand and be respect of intellectual property, especially in pharmaceutical industry [JPO, 2005].

4.3.5. Drug Re-examination

In pharmaceutical industry, patent rights are a fundamental legal protection for the innovator pharmaceutical companies. Europe and the US have developed data exclusivity and marketing exclusivity systems, respectively, to provide certain protections for innovator pharmaceutical companies. These systems aim to ensure that innovator pharmaceutical companies have the exclusive right to market the original drugs for a certain period of time by preventing health authorities from relying on the innovator's clinical data to approve applications for generic drugs.

In Japan, though no system similar to either the data exclusivity or marketing exclusivity systems, the Pharmaceutical Affairs Act of Japan does provide a re-examination system and, although its primary purpose is to ensure the efficacy and safety of newly approved drugs, in practice it functions in a manner similar to the data exclusivity or marketing exclusivity systems.

Drug re-examination is the special policy under the Pharmaceutical Affairs Act of Japan which is independent without any relevance to the Patent Law. However, in pharmaceutical industry, it could be regarded as a special policy to promote innovation and patent activity.

When an MA is granted, the new drug is designated by the PMDA as a drug for which the active ingredients, quantities, dosage, administration, and indications are clearly different from those of drugs which have already been approved for marketing. Although an applicant for the Marketing Authorization of a new drug must submit to the PMDA the clinical data supporting the safety and efficacy of the drug, the scope and the number of clinical cases examined in the Marketing Authorization approval process are limited. Accordingly, an additional review concerning the safety and efficacy of the newly approved drug is necessary even after the marketing of the drug has begun. The purpose of this re-examination system is to ensure the safety and efficacy of a newly approved drug by imposing on the Marketing Authorization holder the obligation to gather clinical data during a certain period after the Marketing Authorization is granted so that the PMDA has the opportunity to re-examine the safety and efficacy of the drug.

A Marketing Authorization holder for a new drug must apply for a re-examination by the PMDA within three months after the expiration of a certain period of time, i.e. the study period, based on the category of the drug. The study period for each new drug is determined by the category of the drug in accordance with Notification No. 725 of the Director-General of the Pharmaceutical Affairs Bureau, 25 August 1993 and Notification No. 0401001 of the Pharmaceutical and Food Safety Bureau, 1 April 2007. In accordance with the said Notifications, study period for orphan drugs is up to ten years from the date the Marketing Authorization was granted. This period is 08 years from the granting date of the Marketing Authorization for drugs with a new active ingredient, excluding orphan drugs. Drugs for which only the indications clearly differ from those of drugs which have already been approved for marketing enjoys from four to six years from the granting date of the Marketing Authorization [APEC Harmonization Center, 2015].

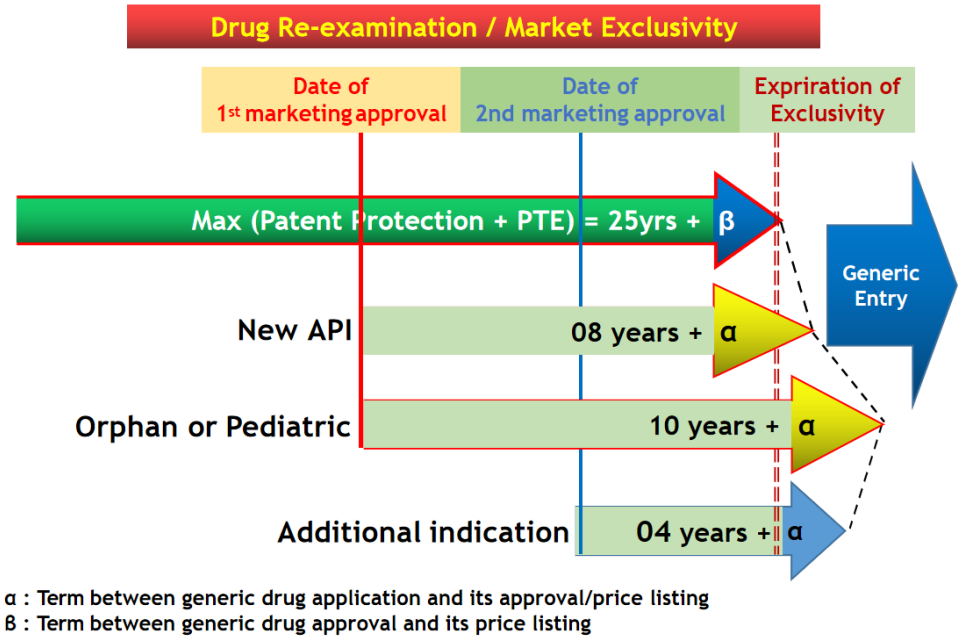

Figure 17. Drug re-examination/Market Exclusivity (Okumura, 2016)

4-4. Achievement of Japan pharmaceutical industry

For many decades up to date, Japan pharmaceutical industry is always ranked in the world's top three largest industry, with total annual pharmaceutical spend of about $93 billion. Japan is enjoying its longest sustained period of growth in over a decade, as a bastion of patented drug consumption, with a strong innovative pharmaceutical industry. According to a GlobalData survey, the pharmaceutical sector is forecast to reach $72 billion by 2021, representing 17% growth between 2011–2020. An aging population and broad access to healthcare are the driving factors. With over 100 domestic pharmaceutical companies, such a fragmented market is likely to develop into an acquisitional environment, particularly with internationals looking to enter [CPhI Japan, 2019].

During the period from 1998 to 2012, Japan pharmaceutical industry introduced 14.4% of the new drugs including New Chemical Entities (NCE) and New Biological Entities launched worldwide [EFPIA, 2013]. In 2016, Japan pharmaceutical industry is ranked 2nd in the world for the number of new drugs develop, and as world-class drug research country [CPhI Japan, 2019].

Global sales volume of pharmaceutical drugs of Japan in 2016 is also ranked 2nd occupied 13% of the world sale volume.

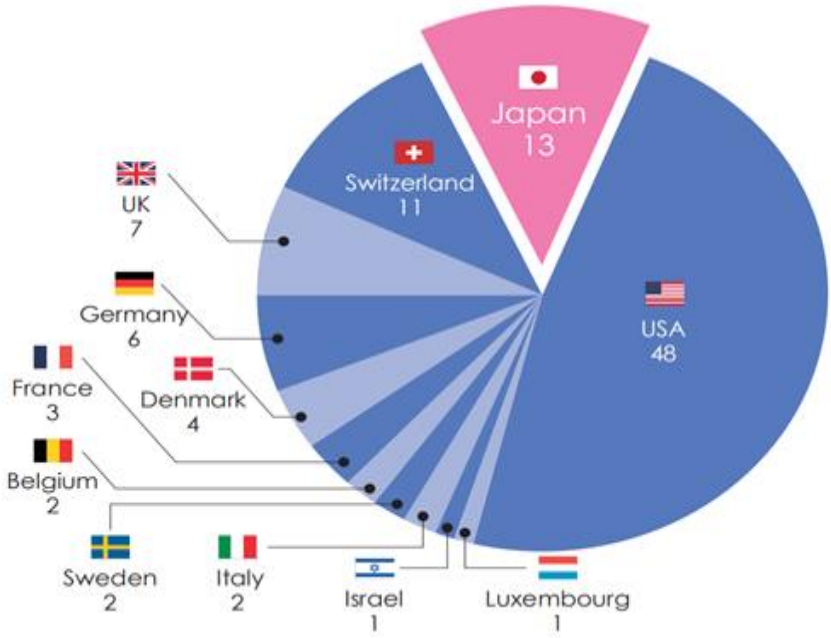

Figure 18. Global Sales of Pharmaceutical Drugs: A Comparison of Origins by Country for the Top 100 Drugs, 2014 (JPMA, 2019)

In parallel, it is seen obviously that the investment and expense of Japan pharmaceutical industry for research and development has increased from year to year and decade by decade.

During the period from 1995 - 2000, investment into to research & development ranked 7th amongst other industries including electronic industry (37%), transportation and communications (15%), transport equipment (13%), general machinery (12%), precision machinery (9%) [Motohashi, 2004].

The investment into research and development in pharmaceutical industry increased and ranked 1st amongst others. Ratio of expenditure for R&D to Net Sales in pharmaceutical industry is 10.04%. This ratio is up to 17.5% counted for top 10 pharmaceutical companies [JPMA, 2018].

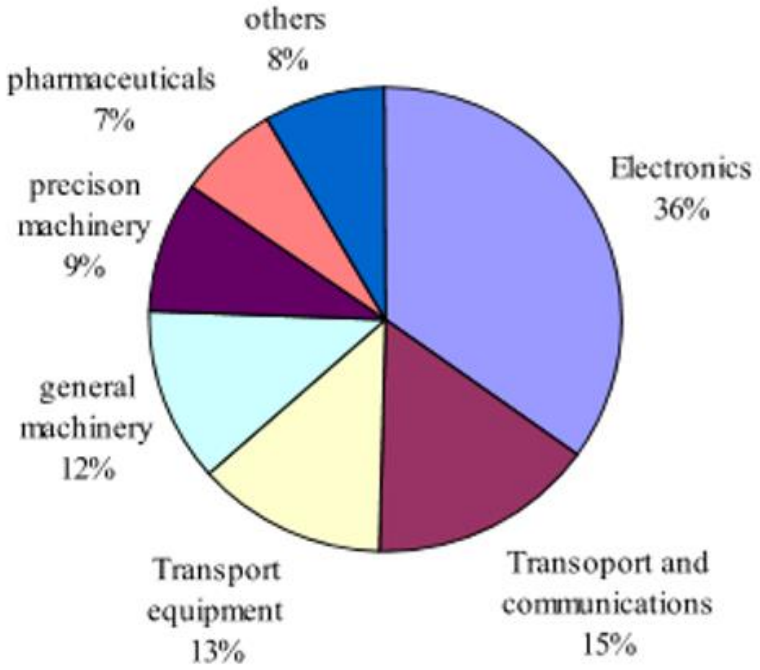

Figure 19. Incremental Amount of R&D from 1995-2000 (Motohashi, 2004)

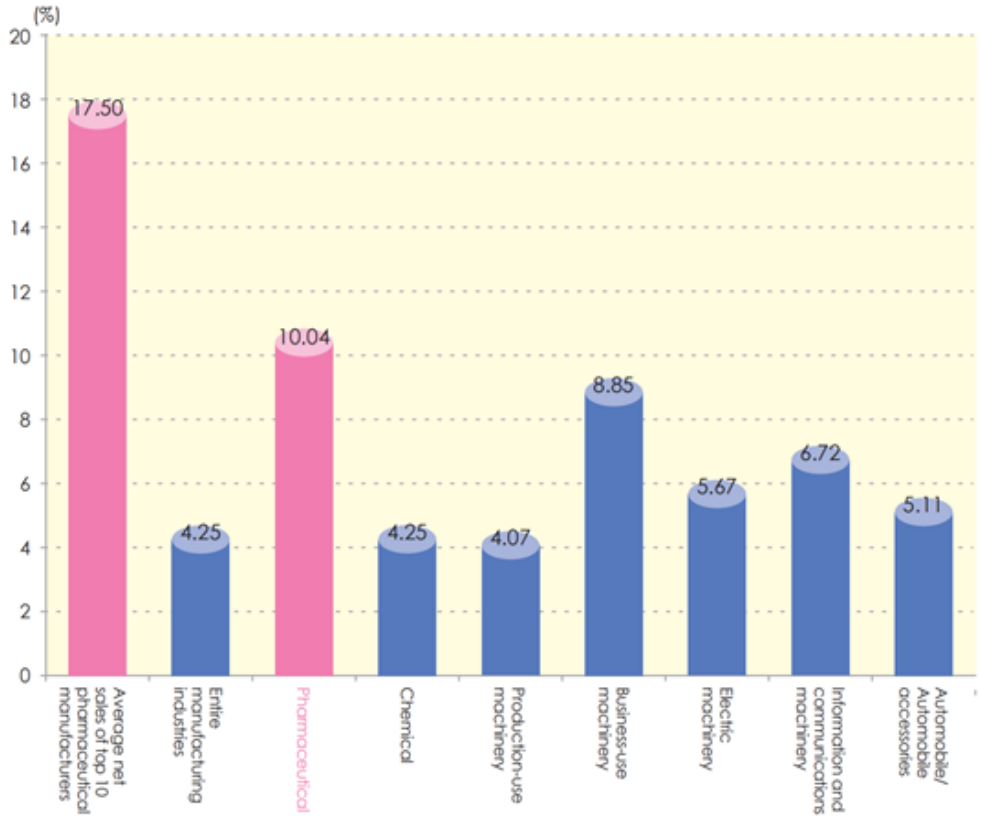

Figure 20. R&D Expenditure/Ratio of Net Sales by Main Manufacturing Industries in Japan (JPMA, 2018)

Specifically, in terms of spending on biomedical research & development, Japan is the 3rd largest worldwide behind the US and Europe, for approximately 10% of total expenditure [CPhI Japan, 2019].

CHAPTER 5- IMPLICATIONS AND RECOMMENDATIONS

5.1. Implications

Intellectual property plays the critical roles in the whole economy and in any particular industry. Witnessing the fact that the world is changing, the national resources is exhausting, the readiness of the labor force is decreasing, the only way to enhance the competitiveness of the economy, of each industry, of each company and each product, is to increase the value of intangible of which the most important part is intellectual property.

National strategy and policies on intellectual property are critical for the development of intellectual property in general and for the innovation, research & development as well as patent activity in the industry, in particular.

Proper approach by the Government for issuance of the comprehensive set of measures to realize the national strategies and policies on intellectual property would navigate and stipulate the development of the economy and industries including pharmaceutical industry.

Due investment plus the feasible and workable programs from the Government agencies, institutions, in collaboration with organization, associations and especially business operators shall drive the patent activity then develop the industry.

In parallel, the necessary intervention of should be made by the Government to regulate the exclusivity enabling more access to medicines for a better life.

5.2. Recommendations

According to Article 59, subject matters which are not patentable include (I) scientific discoveries, theories and mathematical methods; (ii) schemes, plans, rules and methods for mental activities, domestic animal training, game playing and business practice; computer programs; (iii) Information display method; (iv) solutions that are of aesthetic characteristics only; (v) plant varieties, animal breeds; (vi) processes of plant or animal production which is mainly of a biological

nature, other than microbiological processes; and (vii) human and animal disease prevention, diagnostic and treatment methods.

Under the current law, new use or advance formulation is not eligible to patent protection. In addition, the criteria for determining if a process is the human and/or animal disease prevention, diagnostic or treatment method are not clear and seems to be behind the development of technology under 4th industrial revolution.

From the experience of Japan, and taking into account the level of research & development as well as the average base of knowledge of Vietnam pharmaceutical industry, the revision of Law on Intellectual Property to include new use, advance formulation, and certain therapies into the list of patentable subject matters.

Currently, time schedule for examining patent application is too long. Although the current Law on Intellectual Property regulates the period of first office action for patent application is 18 months but this period in reality is over 36 months. Learning the lesson from Japan, it is recommended that Vietnam Government should consider a comprehensive measures to expedite the examination process including (i) reforming the organization of IP VIETNAM by giving more independent authority in recruiting more long-term examiners; and (ii) socializing certain scope of works which could save time of examiners such as formality examination services and prior art search.

In Japan, and particularly at the JPO, the guidelines for patent examination is made pubic and updated from time to time. Any individual or organization is able to access into the examination criteria and procedures enabling the creation invention and preparation of patent application in more appropriate and proper manner.

Patent term extension is applicable in the US, Europe and Japan in different manners in accordance with the practical situation and the strategy of the country. Pharmaceutical industry of Vietnam is currently generic-driven wherein most pharmaceutical companies are generic companies. Vietnam pharmaceutical companies has step by step realize the importance of intellectual property, or in more details patent in the course of increasing the value of products. More and more

companies start paying attention as well as making investment into research and development with a vision to possess a patent to be able to launch an original drug. In this circumstance, Government is advisable to consider the policy on patent term extension with a view to the year 2030.

In strengthening the protection of intellectual property, it is emerging and vital to revise the law to make clear on patent infringement, settlement of patent dispute and especially to provide the details on damage claim against the patent infringement.

Witnessing the emerging and increase in intellectual property dispute as well as difficulty, less efficiency in handling patent infringement cases, Vietnam is strongly recommended to start the process of preparation and establishment of specialized intellectual property courts. At the early stage, such court could be established in the form of a special division under High Courts in Hanoi, Ho Chi Minh City and Da Nang. The establishment of special intellectual property courts, as per experience of Japan, will definitely improve the efficiency of dispute settlement in intellectual property matter then enhancing the confidence of inventors, investors, companies in enforcement. Thus, they will be more open and confident to make investment in research and development leading to potential patent and original product in pharmaceutical industry particularly and in all other industries generally.

Experiencing from Japan, Government should create useful tools and access to informative database of intellectual property. Currently, the system is very week and less update causing difficulty for inventor, investor, practitioner and people to search and gather necessary information about prior art and/or relevant information.

Research activities in universities and research institutes are not practical and applicable. Pharmaceutical companies are not able and not willing to invest into the cooperation with universities and research institutes to form up any project for innovation. It is the issue of current regulation on the ownership and exploitation of patents acquired from the research projects funded by State budget. Vietnam Government should consider the sets of polices made by Government of Japan giving more room for researchers, universities and private companies to own and exploit

the patents regardless it is the result of project funded by State budget or other sources. Learning experience from Law of Technology Licensing Organization, Japanese Bayh-Dole Act and National University Corporation Act could be a good reference.

Lacking the policy regarding the intellectual property in the National strategy on development of Vietnam pharmaceutical industry up to 2020 with the vision toward 2030 as well as in the “Plan for deployment of National Strategy for Development of the Vietnam’s pharmacy industry" by 2020 and orientation towards 2030 under the Prime Minister’s Decision No. 68/QD-TTG dated January 10, 2014” could be seen as the problem of no specific organization functioning to study and propose the pro-patent policies. Then, it is recommended to assign the Health Strategy and Policy Institute to be in charge of study and make proposal for intellectual property strategy in healthcare sector including pharmaceutical industry.

Lastly, and in macro vision, it is proposed that Government of Vietnam should change the approach of the country toward intellectual property. The IP-based nation strategy of Japan is the practical reference. Government should be more decisive and pro-active in making intellectual property strategy while allocating sufficient resources for the development of intellectual property. By doing that, Government could restructure and add new function, authorities, and responsibilities of the National Council for Science & Technology enabling it to be the headquarter of intellectual property.

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Appendixes

A. Questions for the Interview to Judge Makiko TAKABE, Chief Judge, IP High Court

1. How do you divide the development period of law & policies in IP enforcement and litigation of Japan? What are the changes, development of the judiciary system in IP field that have significant impact on innovation and patent activities of Japan pharmaceutical company?

2. How does the Judge understand the technical contents of the case, especially in the patent dispute case?

3. How is the damage from the act of infringement determined, especially in pharmaceutical patent cases?

4. Are the penalties, sanctions and compensation against the infringers, particularly pharmaceutical patent infringers, strong enough for the preventive purpose?

5. From the judiciary perspective, what are core factors that should be taken into consideration when designing IP strategies and policies in general and patent policies in particular that could promote the investment in research and patent activities of companies in pharmaceutical industry?

6. In your opinion, is there practical impact of national healthcare policy on reducing healthcare expenses to the investment of pharmaceutical companies in the R&D and patent activities? Is there the conflict between Plan for Promotion of Medical Research & Development and Plan for Promoting the use of generic medicines?

7. What is the role of JPO and PMDA in settlement of pharmaceutical patent dispute at the court?

8. As per your extensive experience, what are the important issues that should be taken into account for the preparation and establishment of specialized IP court? What are the difficulties in the establishment and operation of such court?

B. Questions for the interview to Ms. Mina ASANO of AMED

1. How independent AMED is, as an Independent Administrative Agency, in terms of influence and power to push other agencies in collaborating and implementing the policies, plans, measures?

2. How strong AMED is in term of the financial power/ support? Where are the funding come from? And, is there specific policies and regulations for AMED to use, utilize such funds and spending?

3. Who are main partners of AMED in implementing main projects that cover almost important fields in healthcare sector? Are pharmaceutical companies the important partner?

4. What are the policies, mechanisms and action plans to attract and involve Japan pharmaceutical companies to invest into R&D projects initiated by AMED?

5. Projects being implemented by AMED are macro and fundamental. How does AMED navigate and direct the local pharmaceutical companies to invest into R&D focuses that are in line with main objectives of AMED's projects?

6. What are the policies about the proprietorship of the R&D's results, about funding, and about incentives, priority given to local pharmaceutical companies who invests into the R&D projects *(within the scope of AMED's projects and specific projects that are in line with objectives of AMED's projects)?*

7. What is the police that *"AMED will not accept transfer of IP rights from contractors"*? Is it possible for local companies to conduct its own project then offering to transfer IP rights to AMED, assuming that such project is in line with objectives of AMED's main projects?

8. How is AMED's IP department established and organized? What are the roles of IP Department in implementing policies and projects of AMED?

9. Is IP Policy under AMED applicable to projects initiated and implemented by AMED only? Is there any interaction or intervention by AMED to local pharmaceutical companies with regard to making patent strategy?

10. Does AMED provide technical support and financial support to register and establish the patent rights attached to the R&D results conducted achieved from R&D projects conducted by Japan pharmaceutical companies? If yes, what are the policies and mechanism?

11. What is the relation and link between AMED and JPO? Is there any special mechanism of cooperation or joint-taskforce between AMED & JPO to promote and support the patent activities in pharmaceutical industry?

12. How effective (what are the main outcomes) of the AMED's policies on promotion of medical research & development for the time being?

13. How do the AMED's polices and plan for promotion of medical research & development influence (impact) the investment in R&D and patent activities of Japan pharmaceutical companies?

14. Do you think the policies/regulations on patentability, scope of protection, exemption on use of patented inventions, examination process has important impact on the decision of pharmaceutical companies on investment in patent activities (patent filing, patent litigation, etc.)?

15. What are the important rules/ issues that country should take into consideration when making national healthcare policies that can promote local companies to invest into R&D and patent activities in medical (pharmaceutical) industry?

16. AMED promote basic research and development emphasizing into new drugs, new therapy while the country is promoting the use of generic medicines. What do you think about the "right balancing" issue in patent protection?

17. What are the major directions/focuses in research & innovation of Japanese pharmaceutical companies in the last 10 years? How are they different from innovation company to generic company?

18. How do Japanese pharmaceutical companies decide the strategic investment in research & innovation? And, what are the major considerations when determining patent activities in the companies?

C. Questions for the interview to the member companies of Japan Generic Medicines Association (JGA)

1. How do you divide the development period of law & policies in IP, especially patent law of Japan? What are the important changes of IP/patent policies and strategies that have significant impact on innovation and patent activities of Japan pharmaceutical company?

2. What are main factors that affect research investment in pharmaceutical industry:

a. Finance
b. Level of technology and R&D
c. Manpower in R&D
d. Patent policies (patent laws, regulations)
e. Market access and healthcare policy
f. Clinical trial length
g. Country's policies to promote upstream and/or downstream innovation?
h. Other

3. How patent policies affect investment in research and innovation in pharmaceutical industry?

a. Disclosure function
b. Stronger protection *(longer term & broader scope of protection)*
c. Possible patent on existing technology *(subsequent research)*
d. Examination
e. Enforceability/ Litigation
f. Licensing possibility
g. Incentives system
h. Others

4. How easy that incentive system and/or support mechanism is created that companies/innovators can access to support their research & innovation?

5. What is the impact of national healthcare policy on reducing healthcare expenses to the investment of pharmaceutical companies in the R&D and patent activities? Are the practical conflict between Plan for Promotion of Medical Research & Development and Plan for Promoting the use of generic medicines?

6. How many percentages that patent activities contribute to the company's business revenue in Japan pharmaceutical industry? And in turn, how much is the investment of companies on R&D? for IP? and for patent activities particularly? (percentage on revenue)

7. Do the Japanese pharmaceutical companies consider policies, plan and projects that initiated and implemented by Japan Agency for Medical Research and Development is one of the direction and navigation of the R&D focus and well as investment in patent activities?

8. Do Japanese companies consider academia-industry collaboration as important strategy for innovation? Does the Japan policy on this sector have impact on the patent activities as well as corporate's decision on investment in patent activities?

9. How IP/Patent department/division/group is organized in the company?

10. What are the main focuses of R&D activities?

NCE, New drug, New Process/Method, Off-patent product, Product improvement, Others

11. How does the company decide the strategic investment in research & innovation? And, what are the major considerations when determining patent activities in the company?

12. What are the factors that affect the investment in patent activities of the company?

13. For determining the company's patent filing, what are factors that affect the decision?

a. Patent disclosure

b. Patentability (subject-matter eligible to protection)

c. Requirements (documents/ data)

d. Examination time & process

e. Protection term

f. Fee and expenditure (filing, granting, annuities)

g. Others

14. What are main challenges of pharmaceutical company in research & patent activities?